DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401 and 405

[CMS–4064–IFC]

RIN 0938–AM73

Medicare Program: Changes to the Medicare Claims Appeal Procedures

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: Medicare beneficiaries and, under certain circumstances, providers and suppliers of health care services, can appeal adverse determinations regarding claims for benefits under Medicare Part A and Part B under sections 1869 and 1879 of the Social Security Act (the Act). Section 521 of the Medicare, Medicaid, and SCHIP Benefits Act of 2000 (BIPA) amended section 1869 of the Act to provide for significant changes to the Medicare claims appeal procedures. This interim final rule responds to comments on the November 15, 2002 proposed rule regarding changes to these appeal procedures, establishes the implementing regulations, and explains how the new procedures will be implemented. It also sets forth provisions that are needed to implement the new statutory requirements enacted in Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

DATES: *Effective date:* These regulations are effective on May 1, 2005. However, in view of the wide span of applicability of these rules and the complex, intertwined nature of the affected appeal procedures, not all of these provisions can be implemented simultaneously. Please see section I.E. of the preamble for a full description of the implementation approach.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 9, 2005.

ADDRESSES: In commenting, please refer to file code CMS–4064–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments*. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4064–IFC, P.O. Box 8011, Baltimore, MD 21244–8011.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier*. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: Michele Edmondson-Parrott, (410) 786–6478 (for issues relating to general appeal rights). Janet Miller, (410) 786–1588 (for issues relating to assignment or authorized representatives). Jennifer Eichhorn Frantz, (410) 786–9531 (for issues relating to initial determinations and redeterminations). Arrah Tabe-Bedward, (410) 786–7129 or Jennifer Eichhorn Frantz, (410) 786–9531 (for issues relating to Qualified Independent Contractor (QIC) reconsiderations). Arrah Tabe-Bedward, (410) 786–7129 or John Scott (410) 786–3636 (for issues relating to expedited access to judicial review, Administrative Law Judge (ALJ) hearings and Medicare Appeals Council (MAC) reviews). Jennifer Collins, (410) 786–1404 or Rosalind Little, (410) 786–6972 (for issues relating to reopenings).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–4064–IFC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7197.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. The web site address is: *http://www.access.gpo.gov/nara/index.html*.

To assist readers in referencing sections contained in this preamble, we are providing the following table of contents.

Table of Contents

I. Background

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

A. Overview of Existing Medicare Program

The original Medicare program consists of two parts (Part A and Part B). Part A, known as the hospital insurance program, covers certain care provided to inpatients in hospitals, critical access hospitals, and skilled nursing facilities, as well as hospice care and some home health care. Part B, the supplementary medical insurance program, covers certain physicians' services, outpatient hospital care, and other medical services that are not covered under Part A.

In addition to the original Medicare program, beneficiaries may elect to receive health care coverage under Part C of Medicare, the Medicare Advantage (MA) program. Under the MA program, an individual is entitled to those items and services (other than hospice care) for which benefits are available under Part A and Part B. An MA plan can provide additional health care items and services that are not covered under the original Medicare program. Beginning in January 2006, beneficiaries also can elect to receive prescription drug coverage under Part D of Medicare through the Medicare prescription drug benefit.

Under the original Medicare program, a beneficiary can generally obtain health services from any institution, agency, or person qualified to participate in the Medicare program that undertakes to provide the service to the individual. After the care is provided, the provider or supplier (or, in some cases, a beneficiary) can submit a claim for benefits under the Medicare program to the appropriate government contractor, either a fiscal intermediary (FI) (for all Part A claims and certain Part B claims) or a carrier (for most claims under Part B). If the claim is for an item or service that falls within a Medicare benefit category, is reasonable and necessary for the individual, and is not otherwise excluded by statute or rule, then the contractor pays the claim. However, the Medicare program does not cover all health care expenses. Therefore, if the Medicare contractor determines that the medical care is not covered under the Medicare program, then it denies the claim.

Generally, when a contractor denies a claim, it notifies the provider, supplier, or beneficiary of the denial and offers the opportunity to appeal the denial. The existing appeal procedures for original Medicare are set forth in regulations at 42 CFR part 405, subparts G and H. Separate procedures for appealing determinations made under the Part C program are set forth at subpart M of part 422. There is a similar, separate appeals process for Part D claim determinations set forth at subpart M of Part 423. After an appellant has exhausted the administrative appeal procedures offered under the Medicare program, the Medicare statute provides the opportunity for a dissatisfied individual to seek review in Federal court.

Consistent with section 1852(g)(5) of the Act, the MA regulations provide that enrollees in MA plans who are dissatisfied with determinations regarding their Part C benefits have the right to a hearing before an Administrative Law Judge (ALJ), review by the Departmental Appeals Board (DAB), and judicial review at the Federal district court level in much the same manner as beneficiaries have under the fee-for-service Medicare program. These regulations are codified at §§ 422.600 through 422.612. Section 1860D–4(h) of the Act establishes similar rights for enrollees in Medicare prescription drug plans. To the extent that there are any differences in the appeal procedures for these enrollees, we will address those differences in future Part C and Part D rulemaking documents.

The regulations in part 405 subpart G beginning at § 405.701 describe reconsiderations and appeals under Medicare Part A. When a Medicare contractor makes a determination for a Part A claim, the beneficiary or, in some circumstances, the provider, can appeal the determination. (Consistent with sections 1861(u) and 1866(e) of the Act and § 400.202, the term ''provider'' generally includes hospitals, skilled nursing facilities (SNFs), home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), and hospices, as well as certain clinics, rehabilitation agencies, and public health agencies.) If the determination is appealed, then the contractor reconsiders the initial determination. If the contractor upholds the original determination, a party can request a hearing before an ALJ, provided that the amount in controversy is at least $100. If a party is dissatisfied with the ALJ's decision, a party can request review by the DAB. The component within the DAB that is responsible for Medicare claim appeals is the Medicare Appeals Council (MAC). (Although the Medicare appeals regulations in part 405 contain some limited provisions regarding ALJ and MAC proceedings, these proceedings are generally governed by the Social Security Administration (SSA) regulations at 20 CFR part 404, subpart J.) MAC decisions constitute the final decision of the Secretary and can be appealed to a Federal court. Generally, the lower level of appeal must be exhausted before the appeal can be elevated to the next level.

Medicare Part B appeal procedures are set forth in part 405 subpart H (§ 405.801 *et seq.*). Under these

regulations, beneficiaries and suppliers that accept assignment for Medicare claims can appeal to a Medicare contractor for a review of the contractor's initial determination that a claim cannot be paid, either in full or in part. (The term ''supplier'' is defined under section 1861(d) of the Act, as amended by section 901(b) of the MMA, and means a physician or other practitioner, a facility, or other entity (other than a provider of services that furnishes items or services) under Medicare. This regulation will use the term ''supplier'' to include physicians.) Suppliers that do not take assignment and providers, in some circumstances, also have appeal rights.

If the contractor's review results in a continued denial of the claim, and the amount in controversy is at least $100, the appellant can request a second level appeal known as a ''fair hearing.'' If the hearing officer upholds the denial, the appellant can request a hearing before an ALJ, provided that the appellant meets the amount-in-controversy requirement. (We published a ruling, CMS Ruling No. 02–1, which implemented the $100 amount-in-controversy requirement for Part B ALJ hearings specified in section 521 of BIPA for initial determinations made on or after October 1, 2002. *See* 67 FR 62478, 62480 (Oct. 7, 2002). For initial determinations prior to October 1, 2002, the amount in controversy threshold was $500 for all services other than home health ($100).) Subsequent aspects of the appeals process for Part B claims are identical to those described above for a Part A claim.

B. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

Section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, (Pub. L. 106–554) (BIPA), amended section 1869 of the Act to require revisions to the Medicare fee-for-service appeals process. Among the major changes required by the BIPA amendments are—

- Establishing a uniform process for handling Medicare Part A and Part B appeals, including the introduction of a new level of appeal for Part A claims;
- Revising the time frames for filing a request for Part A and Part B appeals;
- Imposing a 30-day time frame for certain ''redeterminations'' made by the contractors;
- Requiring the establishment of a new appeals entity, the qualified independent contractor (QIC), to conduct ''reconsiderations'' of contractors' initial determinations (including redeterminations) and allowing appellants to escalate cases to an ALJ hearing, if reconsiderations are not completed within 30 days;
- Establishing a uniform amount in controversy threshold of $100 for Part B appeals at the ALJ level;
- Imposing 90-day time limits for conducting ALJ and DAB appeals and allowing appellants to escalate cases to the next level of appeal if ALJs or the MAC do not meet the 90-day deadline; and
- Imposing ''de novo'' review when the MAC reviews an ALJ decision made after a hearing.

On November 15, 2002, we published in the **Federal Register** a comprehensive proposed rule (67 FR 69312) to implement the provisions of section 521 of the BIPA, as well as other complementary changes needed to improve the Medicare claim appeal procedures.

Revised section 1869 of the Act also requires that the Secretary establish a process by which a beneficiary can obtain an expedited determination if the beneficiary receives a notice from a provider of services that the provider plans to terminate all services or discharge the beneficiary from the provider. Previously, this right to an expedited review existed under statute only for hospital discharges (under sections 1154 and 1155 of the Act). On November 26, 2004, we published a separate final rule, Expedited Determination Procedures for Provider Service Terminations (69 FR 69252), to respond to comments on that aspect of the November 15, 2002 proposed rule and to set forth the regulations needed to establish new expedited review procedures for provider service terminations.

C. Related Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted. The MMA includes a number of provisions that affect the Medicare claim appeals process, each of which is summarized below. To the extent that the new statutory language has necessitated revisions or additions to our proposed regulations to ensure that they conform to the MMA, we have incorporated the needed changes into this interim final rule. A brief summary of these provisions follows. To the extent that the MMA provisions entail regulatory changes, a discussion of those changes is set forth in the appropriate section of this preamble.

1. Requirement To Transfer the Administrative Law Judge Function to the Department of Health and Human Services (Section 931 of the MMA)

Section 931 of the MMA requires transfer of the functions of administrative law judges (ALJs) responsible for hearing appeals under title XVIII of the Act (and related provisions of title XI of the Act) from the Commissioner of SSA to the Secretary of the Department of Health and Human Services (DHHS). These ALJs are required to be organizationally and functionally independent from CMS and must report to and fall under the general supervision of the Secretary of DHHS. The DHHS and SSA were required to jointly develop a plan to facilitate this transfer not later than April 1, 2004, and the transfer will take place no earlier than July 1, 2005, but not later than October 1, 2005. On March 25, 2004, DHHS and SSA submitted a report to the Congress that describes the process through which DHHS and SSA will accomplish the transfer of responsibility for the ALJ function. A copy of that report is available online at *http://www.hhs.gov/medicare/appealsrpt.pdf*.

2. Process for Expedited Access to Judicial Review (Section 932 of the MMA)

Section 1869(b) of the Act provides for expedited access to judicial review in situations involving Medicare claims appeals. Section 932 of the MMA amends section 1869(b) of the Act by requiring a review entity to respond to a request for expedited access to judicial review in writing within 60 days after receiving the request. The term ''review entity'' means up to three reviewers who are ALJs or members of the Departmental Appeals Board as determined by the Secretary. If the review entity does not act within the 60-day deadline, then the party can request judicial review. Expedited access to judicial review can be granted when the MAC does not have authority to decide questions of law or regulation relevant to matters in controversy and there is no material issue of fact in dispute. *See* § 405.990.

3. Revisions to the Medicare Fee-for-Service Appeals Process (Section 933 of the MMA)

a. Requirement for Full and Early Presentation of Evidence (Section 933(a))

Section 933(a) of the MMA amends section 1869(b) of the Act to require providers and suppliers to present any evidence for an appeal no later than the

QIC reconsideration level, unless there is good cause that prevented the timely introduction of the evidence. In this interim final rule with comment, we are adopting regulations to specify that in the absence of good cause, a provider, supplier, or beneficiary represented by a provider or supplier must present evidence at the QIC level. Evidence not presented by the parties at the QIC level cannot be introduced at a higher level of appeal. *See* § 405.956(b)(8), § 405.966(a), § 405.1018, and § 405.1122(c).

b. Use of Patients' Medical Records (Section 933(b))

Section 933(b) of the MMA amends section 1869(c)(3)(B)(i) of the Act to require QICs to review an individual's medical records when conducting a reconsideration involving medical necessity. *See* § 405.968(a).

c. Notice Requirements for Medicare Appeals (Section 933(c))

Section 933(c) of the MMA amends sections 1869(a), 1869(c), and 1869(d) of the Act to require appeal notices issued at the initial determination, redetermination, reconsideration, and ALJ levels to include certain information. As amended, section 1869(a)(4) of the Act requires that a notice of an initial determination include the reasons for the determination, including whether a local medical review policy (LMRP) or local coverage determination (LCD) was used. The notice of initial determination must also include procedures for obtaining additional data concerning the determination and notification of any applicable appeal rights, including instructions on how to request a redetermination. *See* § 405.921(a).

Section 1869(a)(5) of the Act specifies that a notice of redetermination must include the specific reasons for the redetermination, a summary of the clinical or scientific evidence used to make the redetermination, if applicable, information on how to obtain additional information concerning the redetermination, and notification of any applicable appeal rights. *See* § 405.956.

Reconsideration notices, under the amended section 1869(c)(3)(E) of the Act, are required to include information about applicable appeal rights. *See* § 405.976. Section 1869(d) of the Act is also amended to require that notices of ALJ decisions give the specific reasons for the decision, including, if applicable, a summary of the clinical or scientific evidence used in making the decision, the procedures for obtaining additional information about the decision, and any applicable appeal rights. *See* § 405.1046(b). Additionally, section 933 of the MMA amends sections 1869(a), 1869(c), and 1869(d) of the Act to require all appeal notices to be written in a manner calculated to be understood by a beneficiary.

d. Qualified Independent Contractors (QICs) (Section 933(d))

Prior to the MMA, section 1869(c) of the Act, as amended by section 521 of BIPA, required the Secretary to enter into contracts with at least 12 entities called qualified independent contractors (QICs) to conduct reconsiderations of contested claim determinations. Section 1869(c) sets forth certain requirements for the QICs and their reviews and panels. Section 933(d) of the MMA makes a number of revisions to section 1869(c) of the Act, including providing additional detail regarding the eligibility requirements for QICs (section 933(d)(1) of the MMA) and the eligibility requirements for QIC reviewers (section 933(d)(2) of the MMA). We have added § 405.968(c)(3) to reflect the requirement of section 1869(g)(1)(C) that 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. In addition, section 933(d)(3) of the MMA amended section 1869(c)(4) of the Act to reduce from 12 to 4 the minimum number of QICs with whom the Secretary must contract.

4. Process for the Correction of Minor Errors or Omissions Without Pursuing an Appeal (Section 937 of the MMA)

Section 937 of the MMA requires that the Secretary develop a means of allowing providers and suppliers to correct minor errors or omissions to claims submitted under the programs under title XVIII without initiating an appeal. The statute specifies that this process be available no later than December 8, 2004. We have revised § 405.980 to allow providers and suppliers to make these corrections through the reopenings process. *See* § 405.927 and § 405.980.

This process was developed in consultation with Medicare contractors and representatives of providers and suppliers, as required by section 937 of the MMA. We published an article on April 30, 2004 that is available online at *http://www.cms.hhs.gov/medlearn/matters/mmarticles/2004/SE0420.pdf* to address the implementation of section 937 and consulted with providers and suppliers about this implementation during open door forums held between August 3 and August 31, 2004. We also created an e-mailbox, *PBG937@cms.hhs.gov,* for providers and suppliers to comment on our proposed implementation. The comment period closed September 10, 2004.

5. Appeals by Providers When There Is No Other Party Available (Section 939 of the MMA)

In situations where a beneficiary dies and there is no other party available to appeal an unfavorable determination, section 939 of the MMA amends section 1870 of the Act to permit a provider or supplier to file an appeal. *See* § 405.906(c).

6. Revisions to the Appeals Time Frames and Amounts in Controversy (Section 940 of the MMA)

Sections 1869(a)(3)(C)(ii) and 1869(c)(3)(C)(i) of the Act as added by section 521 of BIPA established 30-day decision making time frames at both the redetermination and reconsideration levels. Additionally, section 1869 (b)(1)(E) of the Act established the amount in controversy (AIC) requirement for ALJ hearing requests and judicial review as $100 and $1000, respectively. Section 940 of the MMA amended these provisions so that the decision-making time frame for redeterminations and reconsiderations is 60 days and the AICs for ALJ hearings and judicial review will now be adjusted annually, beginning on January 1, 2005, by the percentage increase in the medical care component of the consumer price index (CPI) for all urban consumers and rounded to the nearest multiple of $10. *See* § 405.950(a), § 405.970(a), and § 405.1006. A conforming amendment applies these AICs to the Part C MA program as well, and we have proposed that they apply to Part D when the new prescription drug benefit becomes available in January 2006. *See* 69 Fed. Reg. 46,866, 46,910, and 46,911, 46,722 for the MA proposed rule and 69 Fed. Reg. 46,632 for the Part D proposed rule. (The medical care component of the CPI increased by 4.5 percent in 2004. Consequently, the AIC in 2005 for ALJ hearings will remain $100, and the AIC for judicial review will be $1,050.)

7. Determinations of Sustained or High Levels of Payment Errors (Section 935(a) of the MMA)

Consistent with section 1893(f)(3) of the Act, as amended by section 935(a) of the MMA, determinations by the Secretary of sustained or high levels of payment errors are precluded from administrative or judicial review. *See* § 405.926(p).

8. Limitations on Further Review of Prior Determinations (Section 938(a) of the MMA)

Section 1869(h)(6) of the Act, as amended by section 938(a) of the MMA, requires that there must be no administrative or judicial review of ''prior determinations'' on coverage of physicians'' services, a new aspect of the Medicare program that the MMA specifies must begin by June 2005. See § 405.926(q).

D. Codification of Regulations

The current regulations governing Medicare administrative appeals are set forth in 42 CFR part 405, subparts G and H. These regulations will continue to be necessary for an indefinite transition period until the completion of all appeals that result from initial determinations made before the implementation of the new procedures set forth in this interim final rule. However, the new BIPA and MMA provisions make possible a largely uniform set of appeals procedures that can be applied for claims under both Parts A and B of Medicare. Therefore, this interim final rule establishes a new subpart I of part 405 that sets forth in one location the administrative appeals requirements for Medicare carriers, fiscal intermediaries (FIs), QICs, ALJs, and the MAC. The major subjects covered in subpart I of part 405 are as follows:

- *General Rules (§ 405.900 through § 405.912)*—Definitions and requirements concerning initial determinations, parties to appeals, appointing a representative, and assigning appeal rights.
- *Initial Determinations (§ 405.920 through § 405.928)*—Requirements concerning the processing time frames for initial claim determinations, descriptions of actions that are initial determinations, and the effect of an initial determination.
- *Redeterminations (§ 405.940 through § 405.958)*—Requirements concerning requesting a redetermination, the redetermination process, applicable notice requirements, and the effect of a redetermination.
- QIC Reconsiderations (§ 405.960 through § 405.978)—Requirements concerning requesting a reconsideration, the reconsideration process, applicable notice requirements, and the effect of a reconsideration.
- *Reopenings (§ 405.980 through § 405.986)*—Requirements concerning reopening of determinations and decisions, including the good cause standard, content requirements for notices of revised determinations or decisions, and the effect of a revised determination or decision.
- *Expedited Access to Judicial Review (§ 405.990)*—Requirements concerning obtaining expedited access to judicial review.
- *ALJ Hearings (§ 405.1000 through § 405.1064)*—Requirements concerning requesting a hearing, the hearing process, applicable notice requirements, the effect of an ALJ's decision, and the applicability of national and local coverage determinations.
- *MAC Review (§ 405.1100 through § 405.1140)*—Requirements concerning requesting a review, the review process, applicable notice requirements, the effect of a review decision, and the requirements for requesting judicial review.

E. Implementation of the New Appeal Requirements

We believe that the changes set forth in this interim final rule, in conjunction with the introduction of a new case-specific appeal data system that we are now developing, will produce substantial improvements in the efficiency of the Medicare claims appeal process. We expect that the implementation of these new appeal procedures, along with the transfer of the ALJ function from SSA to DHHS, will reduce appellants' concerns over the fairness and timeliness of Medicare appeal decisions. The introduction of QICs, in particular, will not only reassure appellants of the independence of the reconsideration process, but also offer them for the first time routine reconsideration, by a panel of physicians or other health care professionals, of all medical necessity issues. As a result, we believe these new procedures will lead, over time, to significant reductions in the need to pursue appeals at the later stages of the appeals system, such as ALJ hearings and MAC reviews.

In the short term, however, we recognize that implementing the changes set forth in this interim final rule may prove challenging both for the entities responsible for conducting appeals and for appellants themselves. For example, there may be an initial increase in requests for second level appeals (that is, reconsiderations by QICs), given the availability of these new independent appeal entities and the introduction of physician review panels, as well as the fact that the time frame for a QIC decision is only half of the current time frame for a contractor fair hearing. Similarly, increases in requests for ALJ hearings or MAC reviews are also possible, in view of the establishment of relatively short decision-making time frames for these entities.

Another challenge involves the need for appeal entities to process appeals that were filed before and after the implementation of these new appeal procedures. For example, the DHHS ALJs and the MAC will need to continue processing appeals received before the implementation of QICs at the same time that they begin to receive appeals of QIC reconsiderations. Thus, until all appeals that were filed under the rules in effect before full implementation of these regulations are completed, different administrative deadlines and procedures may apply, depending on the timing and source of the previous, lower-level appeal decision. Based on previous experience, the need for parallel procedures could extend over a year, as all cases currently in the appeals pipeline are resolved.

In addressing these challenges and implementing the new procedures, we need to balance the goal of implementing the new procedures as quickly as possible with our responsibility to facilitate a clear and well-organized transition to the new procedures for appellants and appeals entities alike. We also need to ensure that existing appeals continue to be carried out as expeditiously as possible as we transition fully to the new appeals procedures. These goals drive the implementation approach described below.

The appeal procedures set forth in section 521 of BIPA were to take effect for initial determinations made on or after October 1, 2002. As discussed in the proposed rule, we were unable to fully implement the BIPA provisions by that date without disrupting other fundamental functions of the Medicare program (for example, the processing and payment of claims). We were also aware of the possibility of additional statutory changes, as were subsequently enacted in the MMA. Additionally, we recognize that the MMA has, in some cases, established specific deadlines for implementation of certain appeals provisions. For example, section 933(a)(2) of the MMA establishes an effective date of October 1, 2004 for the prohibition on submission of new evidence, absent good cause, by providers or suppliers in any ALJ or MAC appeal if that evidence was not presented at the QIC reconsideration. For other provisions, the MMA either makes no explicit reference to an effective date, or specifies (under section 933(d)(4)) that certain MMA amendments will be effective as if included in the BIPA legislation; that is, as of October 1, 2002. In the absence of

a specific effective date, the provisions became effective on the date of enactment of the MMA.

Given the unavoidable delays in full implementation of the BIPA changes, it will not be possible to meet all of the MMA deadlines. As a practical matter, full, effective implementation of both the MMA and BIPA provisions can be achieved only in concert with the availability of QICs in the Medicare appeals process. Thus, we believe that full implementation of these regulations must be premised on, and linked to, QIC implementation.

As noted above, another important related MMA provision is the transfer of the ALJ hearing function for Medicare claims appeals from SSA to DHHS. Section 931(b) of the MMA mandates that this transition take place not earlier than July 1, 2005, and not later than October 1, 2005. We have also taken this impending change into account in establishing the implementation schedule for the new appeals provisions set forth in this interim final rule.

Based on all of these considerations, the table below illustrates the implementation approach that we are following for the provisions of this interim final rule:

IMPLEMENTATION APPROACH

Section(s)	Effective
§ 401.108	Effective date of interim final rule.
§ 405.900–§ 405.928	Effective date of interim final rule.
§ 405.940, § 944(a), and § 944(b)	FI initial determinations issued on or after May 1, 2005. Carrier initial determinations issued on or after January 1, 2006.
§ 942(a)	Effective date of interim final rule.
§ 405.942(b), § 405.944(c), § 405.946 through § 405.958	All requests for redeterminations received by FIs on and or after May 1, 2005. All requests for redeterminations received by Carriers on or after January 1, 2006.
§ 405.960–§ 405.978	May 1, 2005 for redeterminations issued by FIs January 1, 2006 for redeterminations issued by Carriers.
§ 405.980–§ 405.990	Effective date of interim final rule.
§ 405.1000–§ 405.1018	Effective for all appeal requests stemming from a QIC reconsideration.
§ 405.1020	July 1, 2005 for all ALJ hearing requests.
§ 405.1022–§ 405.1140	Effective for all appeal requests stemming from a QIC reconsideration.

As the table reflects, we have concluded that the best approach to implement the new appeal procedures is to phase in the new procedures beginning in FY 2005. QIC reconsiderations will become available in two stages depending on if an FI or carrier carries out the redetermination. For all FI redeterminations issued on or after May 1, 2005, appellants will have a right to reconsideration by a QIC within 60 days of their request for reconsideration, as well as escalation to an ALJ if the reconsideration is not completed timely. Similarly, the new reconsideration and escalation procedures will take effect for all carrier redeterminations issued on or after January 1, 2006. Thus, in 2006, all new appeals will be carried out under the regulations set forth in this interim final rule, including provisions on—

- Reconsiderations by QICs;
- The new statutory time frames for reconsiderations, ALJ hearings, and MAC reviews;
- The possibility of escalation of cases where the time frames are not met;
- The new notice and evidence rules; and
- Medicare-specific ALJ procedures.

The phased-in approach enables at least two QICs to begin carrying out reconsiderations of appealed FI redeterminations beginning in May 2005, and thus to provide the second level reconsideration envisioned by the statute for Part A claims as soon as possible. In January 2006, at least four QICs will begin carrying out reconsiderations of appealed carrier redeterminations. We believe that this phased-in approach to QIC implementation constitutes the only viable approach for an undertaking of this magnitude and is critical to ensuring that we: (1) Minimize disruption among the current Medicare contractors and current appellants; and (2) have adequate opportunity to educate providers, suppliers, and beneficiaries about the new procedures. Phasing in the transition from the current process serves to eliminate any unnecessary risk in terms of our ability to manage major appeal transitions at all of our FIs and carriers simultaneously. In addition, these contractors are dealing at the same time with numerous statutorily mandated changes (such as the contracting reform changes required under Title IX of the MMA).

We have chosen to implement the changes initially for redeterminations conducted by fiscal intermediaries for several reasons. Fiscal intermediaries are responsible for all appeals involving Part A claims, as well a limited number of Part B claims. The Part A process currently does not include a second level of contractor appeal prior to an ALJ hearing, unlike the Part B fair hearing procedure. Thus, introducing the QIC reconsideration step first for these claims ensures that Part A appellants have access to a second pre-ALJ appeal process as soon as possible. Implementing the new procedures for appeals resulting from FI determinations also gives us an opportunity over several months to identify and address any process problems or other technical difficulties involved in the first stages of QIC reconsiderations before transitioning the much larger Part B appeals workload that is now performed by carriers.

One unavoidable consequence of this change will be that some employees of current contractors will need to be either reassigned or discharged since the FIs and carriers will no longer be conducting fair hearings. However, we believe that the slightly longer transition for the much larger carrier workforce will help to ameliorate the potential human costs of this change.

Finally, we note that wherever it was feasible (that is, where the BIPA and MMA appeals provisions are not fundamentally premised on the introduction of QIC reconsiderations into the appeals process), we have already taken a series of steps to implement the new appeal provisions mandated by the statute, including most notably the transition to a uniform redetermination process by our FIs and carriers. We issued instructions (CR 2620) to effect this change beginning on October 1, 2004. The instructions incorporate both the redetermination decision-making time frames and notice requirements required by the statute

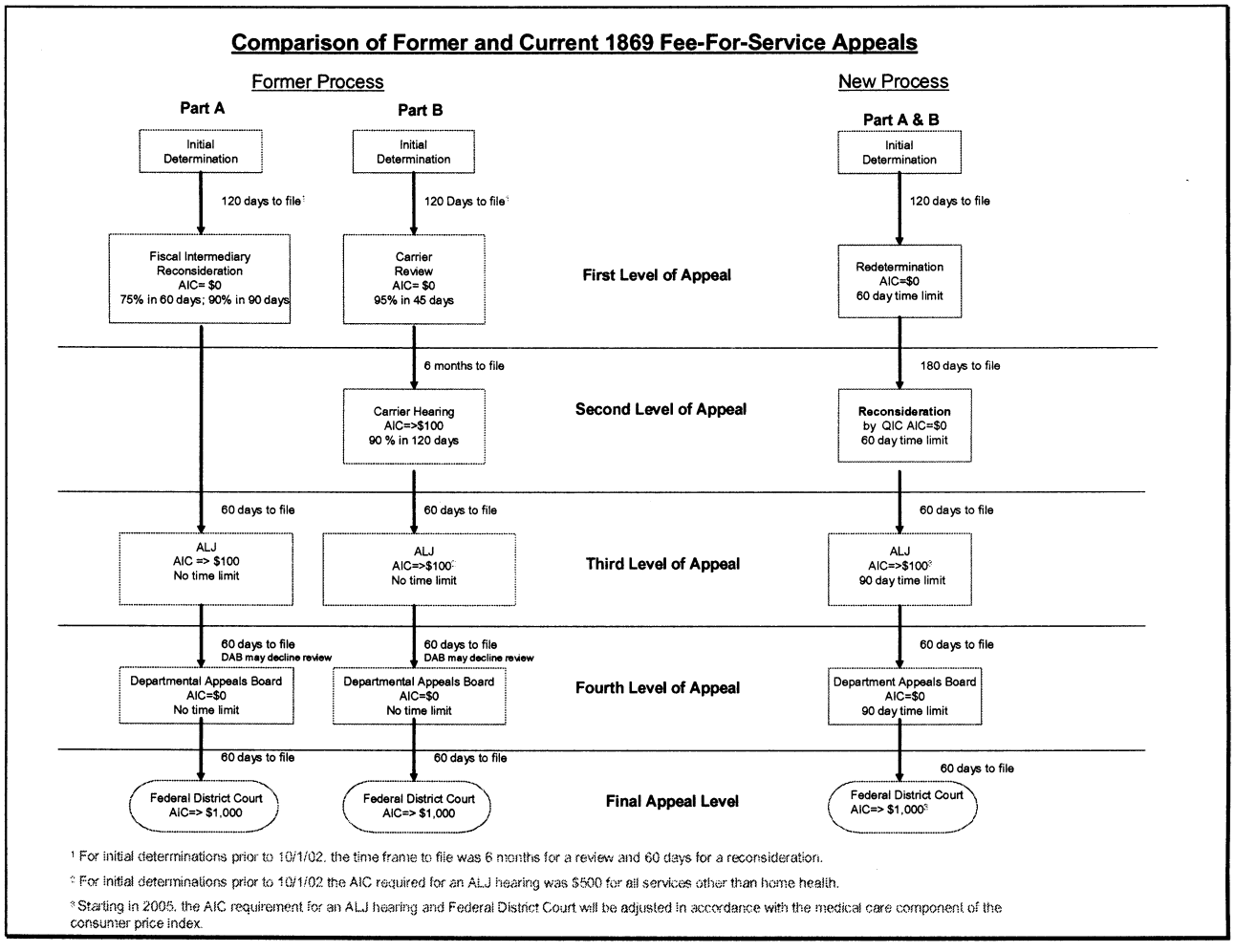
(under sections 1869(a)(2), 1869(a)(3) and 1869(a)(5) of the Act, as amended by section 521 of BIPA and sections 933 and 940 of the MMA). We have also issued instructions to the contractors regarding the implementation of section 939 of the MMA (which took effect upon enactment of the MMA) concerning appeals by providers when there is no other party available because of the death of the beneficiary appellant. These regulations codify those changes.

II. Analysis of and Responses to Public Comments

A. Overview of Comments on November 15, 2002 Proposed Rule

We received 37 timely comments from organizations representing providers and suppliers, beneficiary advocacy groups, administrative law judges, law offices, health plans, and others. The issues most frequently raised by commenters include: Beneficiary protections, particularly for unrepresented beneficiaries; deadlines for filing appeals and time frames for decision-making; notices; differences between an assignee and an appointed representative of a beneficiary; authority of representatives of parties; time frames for the escalation of cases from one level to the next when adjudicators fail to meet their deadlines; the role of the new entities, qualified independent contractors (QICs), that will perform reconsiderations; evidentiary requirements; the perceived formality of administrative law judge (ALJ) procedures, especially adversarial proceedings whereby we enter the process in general, and the impact on beneficiaries in particular; whether an ALJ's role changes and how much deference the ALJ gives to our policies; dismissals and remands of appeals; and distinctions between reopenings and appeals.

These comments and our responses are discussed below, in order of the new regulations text. (For the convenience of the reader, we are presenting below a chart offering a sequential overview of the available procedures and related time frames associated with the former and current appeals process. This chart is for illustrative purposes only, and certain details (such as when escalation of a case is permissible) have been omitted for ease of presentation. For a full description of the applicable requirements, please consult the preamble material that follows and the regulations text.)



B. Appeal Rights (§ 405.900 Through § 405.912)

1. Basis and Scope, Definitions, General Rules, and Parties to Initial Determinations, Redeterminations, Reconsiderations, Hearings and Reviews (§ 405.900 Through § 405.906)

[If you choose to comment on issues in this section, please include the caption ''Appeal Rights—Basis and Scope, etc.'' at the beginning of your comments.]

In the proposed rule, we proposed that providers would be allowed to file an administrative appeal of Medicare initial determinations to the same extent as beneficiaries. Currently, providers have limited rights to appeal Medicare initial determinations: providers can appeal Medicare determinations only when the determination involves a finding that: (1) The item or service is not covered because it constitutes custodial care, is not reasonable and necessary, or for certain other reasons; and (2) the provider knows, or reasonably could have been expected to know, that the item or service in question is not covered under Medicare (that is, there is a finding with respect to the limitation of liability provision under section 1879 of the Act). Regarding non-participating providers and suppliers, however, we proposed maintaining the current appeal policies.

Consistent with section 940 of the MMA, in this interim final rule, we are making a change to § 405.904(a)(2) concerning the amounts in controversy for ALJ hearings and judicial review. Section 940 of the MMA requires the amount in controversy to be adjusted annually based on the medical care component of the consumer price index for all urban consumers. Accordingly, we have deleted specific references to the previous $100 and $1,000 threshold requirements.

We have made two revisions to proposed § 405.906. In the proposed rule, we inadvertently omitted certain nonparticipating suppliers as potential parties to an initial determination. The interim final rule corrects that error by specifying under § 405.906(a)(2) that a nonparticipating supplier who has accepted assignment can be a party to an initial determination.

Also, consistent with section 1870(h) of the Act, as amended by section 939(a) of the MMA, we have added a conforming provision to § 405.906(c) concerning parties to appeals. Where a provider or supplier is not already a party, revised § 405.906(c) permits the provider or supplier to appeal an initial determination relating to services it rendered to a beneficiary who subsequently dies. This provision is intended to give appeal rights to nonparticipating suppliers who are not considered parties to the initial determination and who may not have secured an assignment of appeal rights from the beneficiary.

Comment: Several commenters sought clarification on whether the intent of the proposed rule was to give party status to providers on the basis of a ''technical denial.'' (A technical denial is a denial based on an item or service failing to meet all of the requirements of a Medicare-covered benefit, rather than on a determination that an item or service is not reasonable and necessary under section 1862(a)(1)(A) of the Act, or on a determination that an item or service constitutes custodial care.) Many interpreted the proposed rule as maintaining the current policy that providers do not have appeal rights for these types of denials. Other commenters believed that our intent was to allow providers to appeal to the same extent as beneficiaries and agreed with the proposal. Still other commenters questioned whether the change in policy to expand appeal rights for providers would mean that contractors would no longer deny claims because the claims failed to meet the requirements of the Medicare benefit.

Response: A provider or supplier can appeal a properly submitted claim only after the contractor has issued an initial determination on that claim. Thus, if a contractor rejects a claim because the claim was improperly submitted (for example, the claim was missing the basic information needed to process it), that rejection does not constitute an initial determination.

Currently, § 405.710(b) allows a provider to appeal an initial determination on Part A coverage only when a contractor determines: (1) That an item or service is not covered because it constitutes custodial care; (2) that an item or service is not covered because it 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; (3) that an item or service is not covered because it was a hospice service provided to a non-terminally ill individual; (4) that the item or service is not covered because it is not reasonable and necessary; and (5) either the beneficiary or provider of services, or both, knew, or could reasonably have been expected to know, that the item or service is excluded from Medicare coverage. Historically, only beneficiaries were afforded the right to appeal claims that were denied because the items or services failed to meet the requirements of the Medicare covered benefit (for example, a denial of home health services due to the lack of a physician certification). Despite this restriction, however, providers routinely accessed the appeals process by acting as the beneficiary's appointed representative in situations where they would otherwise not have had appeal rights.

As discussed in the proposed rule, a clear goal of the BIPA legislation was to establish a uniform appeals process for Part A and Part B claims, and thus for all beneficiaries, providers, and participating suppliers. In keeping with this goal, we believe that the interests of the appeals process would be best served by ensuring that providers are afforded an equal opportunity to be heard with regard to all Medicare initial determinations. Therefore, as proposed, we are specifying that Medicare providers may file administrative appeals of initial determinations to the same extent as beneficiaries. With this change, we achieve consistency in our approach to which individuals or entities can bring an appeal under Part A and Part B.

This interim final rule does not change the available bases for claim denials. Contractors may continue to deny claims on the basis that the item or service is not a Medicare benefit, or more precisely, that the item or service in question does not adhere to all the requirements set forth in the definition of the Medicare benefit. Rather, this interim final rule changes the appeals status of providers and participating suppliers, allowing them to appeal all denials on their own accord.

Comment: One commenter requested clarification on whether a beneficiary can appeal even if the beneficiary has appointed a representative or initiated a valid assignment of appeal rights. The commenter expressed concern that under proposed § 405.906, any party to the initial determination can request a redetermination. A literal reading of this section would permit a beneficiary to pursue an appeal even if the beneficiary has an appointed representative or has assigned appeal rights to a provider or supplier. In addition, the commenter asked if beneficiaries could pursue an appeal at the same time as the provider.

Response: The commenter raises two sets of issues: (1) The appeal rights of a beneficiary who has appointed a representative; and (2) the appeal rights of a beneficiary who has assigned these rights to a provider or supplier.

Beneficiaries can either exercise their appeal rights themselves or through an appointed representative, or they can assign their appeal rights to the provider

or supplier that delivered the service or item. (We note that appointment of a representative and assignment of appeal rights are two different and unrelated actions.) Unlike assignment, appointment of a representative does not entail transferring one's appeal rights, nor does it make the appointed representative a separate party to the appeal. An appointed representative is chosen by a party to assist a beneficiary in exercising appeal rights with respect to one or more initial determinations. The beneficiary retains party status during the appeals process, and therefore, never loses the right to appeal to subsequent levels of the appeals process. To avoid confusion regarding representation, either the beneficiary or the appointed representative (but not both the beneficiary and the appointed representative) should request the appeal.

On the other hand, when a beneficiary completes a valid assignment of appeal rights, the beneficiary assigns appeal rights for the particular claim or claims to a provider or supplier who is not otherwise a party to the initial determination. If the beneficiary assigns appeal rights in accordance with § 405.912(f), then the beneficiary transfers any right to request a redetermination, reconsideration, hearing, or MAC review with respect to the item or services at issue, unless the assignment is revoked in accordance with § 405.912(g). While it is not permissible for a beneficiary to file an appeal when a valid assignment of appeal rights is in force, it is possible for more than one party to file a request for an appeal on the same claim when no assignment of appeal rights has been made (for example, a beneficiary and a supplier that has accepted assignment of a claim). We are providing under §§ 405.944(c) and 405.964(c) that if more than one party timely files a request for redetermination or reconsideration on the same claim before a redetermination or reconsideration is made on the first timely filed request, the contractor or the QIC will consolidate the separate requests into one proceeding and issue one determination. These provisions are consistent with the longstanding policy that multiple parties have t he right to appeal the same claim. We note, however, that has been very rare for more than one party to exercise this right.

Comment: One commenter pointed out that § 405.906(a)(1) lists a beneficiary who has filed a claim for payment or has had a claim for payment filed as a party to the initial determination. The commenter suggested that we revise this provision since beneficiaries in most instances do not file claims.

Response: As a general rule, we require providers and suppliers to submit claims to seek reimbursement for items or services that they have delivered to beneficiaries. Thus, beneficiaries generally do not need to file claims, but they continue to have the right to do so. (In some situations, however, beneficiaries are prohibited from filing claims on their own, such as for glucose test strips.) Accordingly, we believe that it is necessary to maintain this language in the interim final rule to accommodate those rare instances where beneficiaries may submit claims (for example, because a supplier improperly refuses or fails to submit a timely claim with Medicare for reimbursement). For clarity, we have added § 405.926(n) and § 405.926(o) to reflect that a provider or supplier's failure to request an initial determination or submit a timely claim does not constitute an initial determination, and that determinations with respect to whether an entity qualifies for an exception to the electronic claims submission requirement under 42 CFR, part 424, are not considered initial determinations.

2. Medicaid State Agencies (§ 405.908)

[If you choose to comment on issues in this section, please include the caption ''Medicaid State Agencies'' at the beginning of your comments.]

In the proposed rule, we drafted a separate provision acknowledging the right of a Medicaid State Agency to pursue an appeal on behalf of a beneficiary who is entitled to benefits under both Medicare and Medicaid. We proposed that a Medicaid State Agency would not be considered a party, unless the agency actually pursued a redetermination on behalf of a dually eligible beneficiary. A contractor would not automatically send a Medicaid State Agency notice of determinations made during the administrative appeals process, nor would the agency be permitted to request QIC reconsiderations, ALJ hearings or MAC reviews, unless the agency actually filed a request for redetermination for a beneficiary. If a Medicaid State Agency filed a request for a redetermination, it would retain party status for the claim throughout the rest of the appeals process.

Comment: With regard to a Medicaid State Agency filing an appeal on behalf of an individual that is entitled to both Medicare and Medicaid benefits, one commenter recommended that we clarify the definition of a dual eligible.

Response: A dual eligible beneficiary is one who is eligible for and enrolled to receive benefits under both the Medicare and Medicaid programs. To clarify this concept, we have replaced the proposed text ''dually eligible for Medicare and Medicaid'' in § 405.908. Instead, the text now states that ''[w]hen 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 dual eligible beneficiary.'' We note that we further clarified in this provision that the Medicaid State Agency's appeal is only with respect to services for which has made payment or for which it may be liable.

Comment: A commenter recommended that we clarify what qualifies as a timely filed redetermination request under § 405.908.

Response: A request for a redetermination by a Medicaid State Agency will be considered timely if it meets the requirements at § 405.942. Section 405.942(a) specifies that a request for a redetermination must be filed within 120 calendar days from the date the party receives the notice of the initial determination. Although the Medicaid State Agency is not a party to the initial determination, it is filing a redetermination request with respect to a claim for items and services furnished to a beneficiary. Therefore, the timeliness of the request will be determined by the date that the beneficiary receives the initial determination notice, otherwise known as the Medicare Summary Notice (MSN). For purposes of calculating the date of receipt of the MSN under § 405.942(a)(1), it is presumed that the beneficiary received the MSN 5 days after the date on the MSN, unless there is evidence to the contrary.

3. Appointed Representatives (§ 405.910)

[If you would like to comment on issues in this section, please include the caption ''Appointed Representatives'' at the beginning of your comments.]

Under proposed § 405.910, we incorporated and modified several of the provisions in 20 CFR part 404, subpart R, and 42 CFR part 405, subparts G and H, as they relate to the representation of parties. These provisions eliminated the need for incorporation of the existing SSA regulations regarding appointment of representatives.

Proposed § 405.910(a) sets forth the definition of appointed representative as an individual authorized by a party, or

under State law, to act on the party's behalf in dealing with any of the levels of the appeals process. Appointed representatives do not have independent party status and take action only on behalf of the individual or entity they represent.

Under proposed § 405.910(d), we set forth that in order to be valid, an appointment both needs to be in writing, and signed by the party making the appointment and the individual agreeing to accept the appointment (even when the individual being appointed is an attorney). Proposed section § 405.910(e) establishes the time frame governing the duration of representation as: (1) The life of an individual appeal, and (2) for purposes of appeals of other initial determinations, one year from its original effectuation.

New section 1869(b)(1)(B)(iv) of the Act makes clear that section 206(a)(4) does not apply in the case of Medicare appeals. This section permits the award of attorney's fees (not to exceed 25 percent) from a claimant's entitlement to past-due disability benefits. Therefore, in proposed § 405.910(f), we are explicit that no award of attorney fees can be made against the Medicare trust funds. However, we requested comments on petitions to ALJs to review and approve attorney fees.

In proposed § 405.910(g) through § 405.910(k), we delineated the responsibilities and rights of an appointed representative. In proposed § 405.910(l), we established the rules regarding delegation. (Delegation is the act of empowering another to act as a representative.) In order for an appointed representative to designate another person to act as a representative (the designee), the appointed representative must: (1) Give the designee's name to the party; (2) secure the designee's acceptance of both the representation and the requirements of that representation; and (3) secure the represented party's acceptance of the new arrangement with a signed, written document. We note that the decision on whether to have an appointed representative belongs to the party, and we neither encourage nor discourage representation. Therefore, under proposed § 405.910(m), a party would have the ability to revoke an appointment for any reason, at any time.

Comment: A commenter suggested amending the regulation to require that appointed representatives for providers be members of the bar. However, this commenter also recommended permitting non-attorneys to act as representatives for beneficiaries, but only if these representatives waived receipt of a fee for their services.

Response: Section 1869(b)(1)(B)(iv) of the Act establishes that the requirements set out in sections 205(j) and 206 of the Act govern who may serve as a representative for a Medicare beneficiary. Section 405.910 of the regulations permits anyone who satisfies the requirements outlined in section 205(j)(2) to act as a representative. The provisions of § 405.910(b) discuss persons not qualified to act as an appointed representative. Nothing in section 205(j)(2) requires appointed representatives to be members of the bar. Therefore, we do not agree that it is appropriate or necessary to limit providers' access to the administrative appeals process by requiring them to retain attorneys if they wish to appoint a representative.

Similarly, there is nothing in section 205(j)(2) that requires non-attorneys who represent beneficiaries to waive their fees. However, we agree with the commenter that certain precautions be taken to prevent a conflict of interest when the party that provides an item or service is the same party representing the beneficiary in a claim appeal. Therefore, in accordance with section 1869(b)(1)(B)(iii) of the Act, new § 405.910(f)(3) requires that a provider or supplier who both furnished the service being appealed and represents the beneficiary in the Medicare claim appeal, must waive the right to collect a fee for acting as the appointed representative. Additionally, if the appeal involves a question of liability under section 1879 of the Act, the provider or supplier may not represent the beneficiary unless the provider or supplier also waives the right to collect payment for the item or service at issue.

Comment: We solicited comments on our proposal to require attorneys to petition ALJs for review and approval of fees. A few commenters suggested that appointed representatives who are members of the bar of one of the fifty States, the District of Columbia, or Puerto Rico, not be required to petition an ALJ in order to collect a fee. Instead, one commenter suggested that oversight should be left to the bar of which the attorney is a member.

There were also a number of comments regarding the ability of appointed representatives to charge fees. The commenters noted that the proposed rule addressed only fees charged by attorney representatives, and recommended that we address fees for non-attorneys in this interim final rule. One commenter recommended that the final rule include explicit language requiring non-attorney representatives to waive any right to charge and receive a fee. Finally, other commenters inquired about the applicability of the Equal Access to Justice Act (EAJA) to the new appeals process and recommended that the final rule reference the availability of attorney's fees.

Response: Section 1869(b)(1)(B)(iv) of the Act establishes that the provisions of sections 205(j) and 206 (other than subsection (a)(4)) of the Act apply to representation for Medicare claim appeals in the same manner as they apply to representation for Social Security claims. By incorporating these sections, the Congress maintained that for appeals before the Secretary, appointed representatives, including attorneys, must obtain approval of fees before charging a party.

Consistent with the current practice of fee petitions before ALJs, and sections 205(j) and 206 (other than subsection (a)(4)) of the Act, as applied by section 1869(b)(1)(B)(iv) of the Act, we are requiring in new § 405.910(f)(1) that an attorney or other person who represents a beneficiary, and who wishes to charge a fee for services rendered in connection with an appeal before the Secretary, must seek approval of the fee from the Secretary. Although it would be up to the Secretary to determine the reasonableness of the fee, we do not believe the provisions in sections 206(a)(2) and 206(a)(3) of the Act will be relevant in determining whether a fee is reasonable. In Social Security appeals, those provisions limit a representative's fee, in certain instances, to the lesser of 25 percent of past due benefits or $4,000 (with the $4,000 cap subject to an update factor determined by the Commissioner of Social Security). Unlike Social Security appeals, Medicare appeals do not involve past-due cash benefits; moreover, the benefits at issue can vary from as little as $100 (the minimum amount in controversy for an ALJ appeal) to $100,000 or more, and we do not believe that applying a 25 percent test to these divergent figures is reasonable. Therefore, the test in sections 206(a)(2) and 206(a)(3) of the Act is irrelevant in determining the reasonableness of representatives' fees. Also, section 206(a)(4) does not apply, because the Medicare program does not involve past-due cash benefits. The process for obtaining fee approval will be further described either in future rulemaking or in ALJ and MAC level procedural manuals or other issuances, as appropriate.

We do not consider services below the ALJ hearing level in connection with

claims in proceedings before Medicare contractors (such as intermediaries, carriers, QICs, QIOs and other independent review entities) to be services provided in connection with proceedings before the Secretary. Section 206(a) authorizes the Commissioner of Social Security to prescribe rules and regulations to govern the representation of claimants in proceedings before the Commissioner. This provision has been interpreted to include proceedings at the ALJ level and above. Thus, appeals before the Secretary of HHS have long been interpreted to include only the ALJ level and above. Therefore, the fee petition provisions do not apply to services rendered below the ALJ hearing level, nor do they apply to representatives of non-beneficiary appellants.

We also agree that fee limitations are appropriate for certain non-attorneys who represent beneficiaries. Accordingly, § 405.910(f)(3) requires providers and suppliers who furnished the items or services in question to waive the right to charge and collect any fee for representing a beneficiary in a claim appeal. This is required by section 1869(b)(1)(B)(iii) of the Act. To ensure that this policy is followed consistently, we will revise the Appointment of Representative form, CMS–1696–U4, to reflect this policy. In § 405.910(f)(4), we also added that the Secretary does not review fee arrangements made by a beneficiary for the purposes of making a claim for third party payment (as defined in 42 CFR § 411.21) even though that representation may ultimately include representation for a Medicare Secondary Payer recovery claim.

Guidelines for the application of Equal Access to Justice Act (EAJA) to claims before the Department may be found at 45 CFR part 13. (The final rule was published in the **Federal Register** at 69 FR 2843 (January 21, 2004)). The final rule governs the applicability of EAJA to the Medicare claim appeals process. The Department intends to review the EAJA provisions to determine what, if any, amendments may be necessary to reflect the changes being implemented in this regulation.

Comment: A commenter asked what, if anything, are the consequences of failing to satisfy all seven of the requirements set out in proposed § 405.910(d) for making out a valid appointment.

Response: All of the requirements in new § 405.910(c) are necessary to complete a valid appointment of representation. To clarify this matter, we are specifying under new § 405.910(d) that if any of the required elements are missing or defective, adjudicators must contact the party with a description of the missing documentation or information. 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. An individual may also use a CMS–1696 form to appoint a representative. That form contains all of the required elements to complete a valid appointment of representation.

Comment: We received several responses to our request for comments regarding alternative time frames for the duration of an appointment of representative. Some commenters simply wanted clarification of the policy in the proposed rule. Others understood our proposal to make appointments valid for one year, but wondered if the one-year period began on the date-of-service for the appealed claim, or on the date that the beneficiary, provider or supplier authorized another individual to appeal on their behalf. One commenter argued that because we offered no indication that representatives were initiating appeals without the consent of the appellants, limiting the duration of appointments would serve only to create unnecessary hardships for appellants. Providers, and suppliers would be prevented or delayed from entering the claim appeals process, and beneficiaries with chronic conditions would be required to renew the appointment every year.

Response: A number of the comments that we received indicate some confusion between the appointed representative provisions at § 405.910 and the assignment provisions at § 405.912. Appointing a representative and assigning appeal rights are two different and unrelated actions under the new appeals process. Beneficiaries have the option of either assigning their appeal rights to a provider or supplier, or appointing a representative to exercise their appeal rights for them.

Under the assignment provision, a beneficiary transfers his or her right to appeal a specific claim or claims to a provider or supplier who is not already a party to the initial determination. In doing so, the beneficiary completely relinquishes any right to appeal the claim or claims at issue and the provider or supplier becomes a party and may appeal.

Appointing a representative, however, does not transfer a party's appeal rights, nor does it make the appointed representative a party to the appeal. An appointed representative is chosen by a party for the duration of one year to assist the party in exercising appeal rights for one or more initial determinations. We believe that once an appeal of an initial determination has been filed, the appointed representative retains the right to manage that appeal through the entire appeals process, regardless of how long it takes to reach a final decision. In § 405.910(e)(3), we state that unless revoked, an appointment is valid for the life of the appeal.

In § 405.910(e)(4), we made an exception for appointments signed in connection with Medicare Secondary Payer recovery claims, because liability, no-fault, and worker's compensation claims often take more than one year to resolve. Where an appointment of representative is related to these recovery claims, the appointment is valid from the date that it is signed through the duration of any subsequent appeal.

We do not agree that either an appointment or the representative's ability to file appeals of future claims continues indefinitely. Appointed representatives have unlimited access to protected health care information, and as we stated in the proposed rule, we have an affirmative duty to ensure that our adjudicators only disclose protected health information to authorized third parties. Taking this into consideration, we believe that it is both necessary and appropriate to limit the duration of an appointment and a representative's ability to file additional appeals to a period of one year, beginning on the day that the appointment becomes effective.

In § 405.910(i)(4), we specifiy that for initial determinations involving MSP recovery issues, the notice of initial determination must be sent to the beneficiary and appointed representative. This differs from non-MSP determinations where only the beneficiary receives the notice of initial determination to prevent more than the minimum amount of personally identifiable health information from being disclosed. Unlike other notices of initial determination, which may include information on claims not at issue, MSP notices of initial determination are limited to include only the minimum necessary amount of information related to the claims at issue.

Section 405.910(e)(1) clarifies that the effective date of the appointment is the day that the Appointment of Representative (AOR) form or other written instrument contains the signatures of both the party and appointed representative. Also, we are

requiring under § 405.910(e)(2) that during this one-year period, representatives must submit a copy of the signed and dated original appointment with each additional appeal that they file on behalf of the party.

Finally, we made one other significant change to § 405.910. Although we proposed provisions in the context of appeals, we solicited comments on whether the appointment of representative procedures should apply for initial determination purposes as well. We did not receive comments on this issue, but we believe there is no reason to imply that different procedures or rules apply to initial determinations. Therefore, we have provided under § 405.910(a) of this interim final rule that the appointment of representative provisions apply for initial determinations, as well as for appeals. Also, under § 405.910(e)(3), an appointment signed in connection with the party's efforts to request payment of a claim is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked. When a contractor issues an initial determination, it sends a notice of that action only to the party, and not to the party's appointed representative.

Comment: One commenter was concerned about the inability of an appointed representative to delegate an appointment to another person without first obtaining the party's signature. The commenter opined that requiring a beneficiary's signature in order to delegate an appointment would greatly impede a beneficiary's ability to receive timely representation. By way of example, the commenter noted that a signature requirement would prevent a family member acting as a representative for an incapacitated beneficiary from retaining an attorney or paralegal to represent the beneficiary in a Medicare claim appeal. Additionally, the commenter stated that the signature requirement would prevent appointed representatives who are members of a law firm or a legal services organization from designating a new representative within the firm or organization when program turnover or workload necessitated a change.

Response: Although we appreciate the administrative benefits to be gained from allowing an appointed representative to delegate an appointment to another individual, the privacy concerns that we noted previously seriously impact our ability to permit delegation in most instances. We believe that the benefits that are gained by ensuring that a beneficiary is made aware when an appointment has been delegated outweigh the burden of obtaining the beneficiary's consent. We also do not believe that this requirement will greatly impede the beneficiary's ability to receive timely representation.

In the case where a beneficiary is no longer mentally capable of giving consent or signing the appointment of representative form, the family member or friend should refer to State law. As defined in § 405.902, an authorized representative is an individual authorized under State or other applicable law to act on behalf of a beneficiary or other party involved in the appeal. Unlike an appointed representative, an authorized representative ''stands in the shoes'' of the beneficiary. State requirements differ with respect to what is required to legally represent an incompetent beneficiary. Individuals appointed or designated under State statutes may act as authorized representatives. For example, some States have health care consent statutes providing for health care decision-making by surrogates on behalf of patients who lack advance directives and guardians. Other States have laws that grant authority to individuals with durable powers of attorney. In an emergency, a disinterested third party, such as a public guardianship agency, may be an authorized representative, for example, in a situation where the beneficiary's inability to act has arisen suddenly (for example, a medical emergency, a traumatic accident, an emotionally traumatic incident, disabling drug interaction, or stroke), and there is no one who can be genuinely considered to be the beneficiary's choice as his or her authorized representative. Thus, an individual who has legal authority under State law is able to make decisions on behalf of a beneficiary, including the ability to delegate the appointment to another person, without first obtaining the beneficiary's signature.

Attorneys in law firms and legal service organizations present a unique situation. As a general rule, attorneys within the same law firm already are obligated to observe strict confidentiality rules with respect to client information, and therefore, the common practice of delegating cases to other attorneys within the firm does not warrant privacy concerns. Thus, we believe it is appropriate to permit attorneys to delegate another attorney within the same firm or organization as a substitute representative. Section 405.910(l)(2) is amended to reflect this policy.

Comment: A commenter asked that we provide information on how to change an appointed representative during the appeals process.

Response: As indicated in the proposed rule, we believe that the decision of whether to retain an appointed representative be left entirely to the party bringing the appeal. Section 405.910(m) permits a party to revoke an appointment at any time and for any reason by submitting a signed, written statement to the entity processing the appeal. The revocation is effective once it is received by the entity hearing the appeal. The party can then appoint a new representative.

4. Assignment of Appeal Rights (§ 405.912)

[If you choose to comment on issues in this section, please include the caption ''Assignment of Appeal Rights'' at the beginning of your comments.]

Under proposed § 405.912, we created new regulatory procedures for the assignment of appeal rights by a beneficiary to a supplier or provider of services. We proposed that a provider or supplier that furnished the item or service at issue and that wanted to take assignment of a beneficiary's appeal rights for a particular claim must waive any right to payment from the beneficiary in order to fully protect beneficiaries when their appeal rights are assigned. This does not prohibit the provider or supplier from recovery of any coinsurance or deductible or claiming payment in full where the beneficiary has signed an Advance Beneficiary Notice (ABN) accepting responsibility for payment. We proposed that the assignment be valid for the duration of the appeals process, but only for the items or services listed on the assignment form.

Comment: One commenter requested clarification on whether an assignment applies to an individual item or service, or to all items or services within an entire claim. The commenter believed that assigning different providers or suppliers for multiple items or services within a claim would be too confusing.

Response: We do not believe that it is appropriate or necessary to require beneficiaries to relinquish their rights to appeal individual items or services. Consistent with our longstanding policy where we allow beneficiaries to appeal individual items or services within a single claim, § 405.912 permits beneficiaries to assign their appeal rights for individual items or services to providers and suppliers. We believe that this will not cause confusion since each claim originates from a single provider or supplier. The provider or supplier

needs to ensure that the assignment form includes the full range of items or services furnished on the date of service.

Comment: One commenter expressed concern that obtaining assignment after services were provided would adversely affect providers with transient populations because their beneficiary contact information is usually for temporary residences. The commenter suggested that the assignment form be available to be signed at admission.

Response: We understand the concerns of the commenter, and agree that the assignment form may be completed at admission. Section 405.912(c) does not prevent a provider and beneficiary from being able to complete and execute the assignment at the time that the beneficiary receives services. When a provider needs to appeal an initial determination that denies payment for the services rendered, the provider can submit the previously signed assignment form with the request for redetermination.

Comment: One commenter suggested that the regulation be clarified to ensure that the waiver of collection from the beneficiary applies even if the appeal is unsuccessful.

Response: We agree that the regulation should be clarified to specify that the waiver of the right to collect payment by the assignee remains valid in the event of an unfavorable determination or decision. We have amended our proposed § 405.912(d)(1) to specify that the waiver remains in effect regardless of the outcome of the appeal decision. We have also taken the opportunity to correct an omission in § 405.912(d)(1). The waiver of payment also remains in effect if the assignment is revoked under § 405.912(g)(2) or § 405.912(g)(3). That is, if the assignee fails to file an appeal of an unfavorable decision or if an act or omission by the assignee is determined to be contrary to the financial interests of the beneficiary, the assignee will not be able to collect payment from the beneficiary.

Comment: One commenter recommended that the waiver of the right to collect from the beneficiary apply regardless of whether there is an ABN in effect. The commenter expressed concern that a provider or supplier might be inclined to require a beneficiary to sign an ABN for any item or service in order to protect any future collection of payment.

Response: We prohibit providers and suppliers from routinely issuing ABNs for all services. ABNs generally are issued only when the provider or supplier has reason to believe that Medicare is not likely to cover the furnished services. Thus, we are maintaining the provision at § 405.912(d)(2) that an assignee that furnished the item or service is not prohibited from recovering payment when an ABN has been properly executed. We believe an alternative policy would create disincentives for providers and suppliers to bring appeals on behalf of beneficiaries when they believe Medicare is denying coverage improperly. If providers and suppliers are faced with the choice of appealing what they believe to be an erroneous denial or collecting from the beneficiary in the event of an unfavorable decision, they may simply decide to place the burden of appeal on the beneficiary.

Comment: Some commenters raised concerns about our proposal to permit beneficiaries to revoke an assignment. One commenter recommended that assignment be irrevocable until the appeal is filed or the deadline for filing has expired in order to prevent a provider or supplier from wasting resources pursuing an appeal. The commenter suggested that we establish a time frame for a beneficiary to revoke an assignment. Another commenter requested that we define the specific circumstances that constitute abandonment.

Response: We believe that it is unnecessary to establish a time frame to limit a beneficiary's right to revoke an assignment. The inherent nature of an assignment protects the interests of a beneficiary since transferring the appeal rights to a provider or supplier precludes the provider or supplier from collecting payment from the beneficiary in the event of an unfavorable determination. We believe that beneficiaries will rarely revoke an assignment; therefore, the possibility of providers and suppliers unnecessarily pursuing appeals is remote. A somewhat more likely scenario involves abandonment, that is, inaction on the part of the assignee to undertake or proceed in the appeals process. Section 405.912(g)(2) addresses this situation by specifying that an assignment may be revoked ''[b]y abandonment if the assignee does not file an appeal of an unfavorable decision.''

Comment: One commenter supported the use of a standardized form for assignment. The commenter suggested that the form include an explanation of assignment and what an assignee does for a beneficiary. The commenter also suggested that proposed § 405.912(d)(2) should be revised to reflect that the assignment may be executed by the beneficiary or his or her representative.

Response: We agree with the commenter and are developing a standardized form for assignment, as required by section 1869(b)(1)(C) of the Act. This form, which has been consumer-tested with the beneficiary population, contains extensive information to assist beneficiaries in understanding the assignment and execution of their appeal rights.

As mentioned in an earlier response, we added a definition of an ''authorized representative'' at § 405.902. Authorized representatives (for example, a legal guardian or someone with a power of attorney) possess all the rights associated with the appeals process to the same extent as beneficiaries. Therefore, we do not believe that it is necessary for new § 405.912(c)(2) to reflect that an authorized representative may execute an assignment of appeal rights on behalf of a beneficiary. Appointed representatives under § 405.910, including attorneys, may assist the beneficiary or another party with Medicare appeals, but they do not have any other rights or responsibilities with respect to the beneficiary or another party, and may not sign documents as the beneficiary or party. Thus, an appointed representative may not assign appeal rights under § 405.912 without the beneficiary's or other party's consent.

5. Initial Determinations (§ 405.920 Through § 405.928)

[If you choose to comment on issues in this section, please include the caption ''Initial Determinations'' at the beginning of your comments.]

Section 1869(a)(2)(A) of the Act establishes that for all claims other than clean claims (a clean claim is a claim that has no defect or impropriety), an initial determination must be concluded, and a notice of that determination must be mailed, by no later than 45 days after the carrier or fiscal intermediary receives the claim. We proposed that interest would not accrue on non-clean claims that were not adjudicated within 45 days. By definition, non-clean claims are often claims that require additional documentation, and therefore take additional time to process.

With respect to clean claims, section 1869(a)(2)(B) of the Act requires that interest accrues if clean claims are not processed within 30 days. This standard remains the same as specified in sections 1816(c)(2) and 1842(c)(2) of the Act.

We proposed to continue to notify parties of the initial determination in writing. The proposed content of the notices included the basis for the determination and notification to the parties of their right to a

redetermination if they were dissatisfied with the outcome of the initial determination. Consistent with existing policy, the Remittance Advice (RA) and Medicare Summary Notice (MSN) would be used as a notice of initial determination.

We also proposed the types of actions that constitute initial determinations, as well as those that do not constitute initial determinations. We generally proposed to maintain the existing policies concerning initial determinations, while at the same time unifying the Part A and Part B rules. We have also included examples specific to Medicare Secondary Payer situations in listing the type of actions that constitute initial determinations. We specified our longstanding policy that SSA will continue to make Part A and Part B entitlement and enrollment determinations. As noted previously in section I.C.1 of this interim final rule, section 931 of the MMA requires the transfer of ALJ hearing functions from SSA to HHS. Although SSA will continue to make Part A and Part B entitlement and enrollment determinations and reconsiderations subject to the requirements set out at 20 CFR Part 404, Subpart J, HHS will be responsible for reviewing entitlement and enrollment decisions at the ALJ and MAC levels. We note, however, that this regulation does not provide the specific procedural requirements that will apply to the adjudication of entitlement appeals. These instructions will instead be provided separately once this interim final rule is published. We believe that this approach will ensure that beneficiaries, providers, suppliers, and other interested parties receive clear guidance regarding the procedures for appealing an entitlement determination at each level of the appeals process.

We addressed the circumstances under which an appeal can be filed when a beneficiary disputes the computation of coinsurance amounts. Previously, our rules stated that beneficiaries could appeal Medicare determinations regarding the ''application of the coinsurance feature.'' We clarified this provision to state that the contractor's ''computation of coinsurance'' was considered an initial determination, and therefore, could be appealed. In making this proposal, we considered that for most Part B services, beneficiaries were responsible for a 20 percent coinsurance payment and, since the contractor calculated the percentage, a beneficiary should be able to appeal the contractor's computation. In instances where the coinsurance amount was not computed by the contractor, but rather, was an amount prescribed by regulation (for example, outpatient services), the issue of the appropriateness of the coinsurance amount was not appealable since it was an automatically calculated amount based directly on a fee schedule exempt from review.

We also specified that there be no administrative appeal rights available for certain aspects of initial determinations. For example, under section 1833(t) of the Social Security Act (the Act), administrative appeals are prohibited for issues involving the calculation of coinsurance amounts for outpatient services subject to prospective payment rules, and under section 1848(i) of the Act, the values used to calculate allowable amounts under the physician fee schedule may not be the subject of an administrative appeal. Additionally, we proposed some further examples of actions that are not initial determinations, such as waiver of interest determinations and certain Medicare Secondary Payer actions.

Comment: One commenter suggested that the initial determination notice contain more details about requesting a redetermination, such as the documentation needed to pursue an appeal. The commenter recommended that the notice give exact citations for the rules and policies upon which the determination is based and explain how to obtain them. The commenter also suggested that the notice include a toll free number that appellants can call to receive copies of coverage rules and policies.

Response: We agree with the commenter that initial determination notices contain information necessary for beneficiaries to initiate appeals. However, we believe that existing notice requirements are fully compatible with this objective, and we do not believe that additional detail is appropriate.

Currently, beneficiaries receive initial determination notices through the Medicare Summary Notice (MSN), and providers and suppliers receive notices on the Remittance Advice (RA). The MSN is a consumer-tested, customer-friendly monthly statement that lists all of the services or supplies billed to Medicare during a 30-day period. It contains information about requesting an appeal on the bottom of the last page and at the back of each page. The MSN indicates the date that an appeal must be filed in order for it to be considered timely. The MSN also allows beneficiaries to appeal by circling an item, explaining why they disagree, and signing and sending the notice, or a copy of the notice, to a specified address.

We also agree with the commenter that MSNs indicate when the basis for a claim denial involves a local or national coverage determination. Effective during 2003, CMS now requires fiscal intermediaries and carriers to provide references to coverage policies when they describe the basis for claim denials. However, based on nationwide testing of Medicare beneficiary focus groups, CMS does not include regulatory citations in MSNs because they are confusing to beneficiaries. We believe that referring to a local or national coverage determination is more meaningful to beneficiaries in helping them understand the reason their claim has been denied.

The MSN contains the Medicare toll-free number so that beneficiaries can obtain information about various aspects of the Medicare program, including individual claim determinations. Beneficiaries can also use the toll-free number to request a copy of the coverage rule or policy used as the basis to deny a claim, or they may access the policies via the Internet.

Thus, in light of the information already contained in MSNs, we do not believe that it is necessary to modify the initial determination notices sent to beneficiaries. However, we believe it is appropriate to include in the regulations the explicit notice requirements that are set forth under section 933(c)(1) of the MMA. Therefore, § 405.921(a)(1) specifies that contractors must write the MSNs in a manner calculated to be understood by the beneficiary. We have also set forth the statutory content requirements as to the contents of the notice in § 405.921(a)(2). That is, the notice must contain the reasons for the determination, including whether a local medical review policy, local coverage determination, or national coverage determination was applied, the procedures for obtaining additional information concerning the determination, such as the specific provision of the policy, manual, law, or regulation used in making the determination, and notification to the parties of their right to a redetermination if they are dissatisfied with the outcome of the initial determination. The notice also must include instructions on how to request a redetermination. Again, we believe that the existing MSNs meet all the new MMA requirements and have codified these beneficiary notice requirements in § 405.921(a). Furthermore, although the statutory requirements apply only with respect to beneficiary notices, we have adopted very similar requirements for notices to providers and suppliers under

§ 405.921(b). The format and content requirements adopted as the national standard for remittance advice transactions under HIPAA and the corresponding CMS requirements for electronic and paper remittance advice notices already require use of messages or codes to explain initial determinations, and the reasons for any full or partial denial decisions that apply to services on a claim, as well as the appeal rights in relation to the decision. Thus, the MMA requirements for beneficiary notices are generally already in use in the remittance advice notices to providers and suppliers.

Finally, we note that contractors will issue MSNs to beneficiaries only, and not to appointed representatives or assignees. Throughout § 405.910, we have reinforced the concept that appointed representatives have the same right as beneficiaries to receive information on claims only after an appeal has been filed. Consistent with HIPAA, a contractor may not disclose protected health information without a valid appointment. MSNs encompass a range of health services and supplies that were billed to Medicare within a 30-day period. Because an appointed representative may not have authority to receive information on all such services or supplies, we believe that it is appropriate for contractors to disseminate MSNs only to beneficiaries. Furthermore, we believe that it is unnecessary to incur the substantial costs to modify the standard systems to generate MSNs to appointed representatives.

Comment: We received several comments regarding procedures that should be established when contractors do not meet the statutory deadlines for making initial determinations. Section 521 of BIPA maintains the existing 30-day time frame for 95 percent of clean claims under sections 1816(c)(2) and 1842(c)(2) of the Act, and establishes a 45-day time frame for claims that are defective or require special treatment or substantiating documentation. Some commenters believe that we should create an escalation provision for initial determinations similar to the escalation provisions required by statute for QIC reconsiderations, ALJ hearings and MAC reviews. This would enable parties to proceed to the redetermination level of the appeals process when contractors fail to meet the 45-day statutory time frame. One commenter recommended that when the contractor fails to make an initial determination within 45 days, the claim bypasses the redetermination level and advances to the reconsideration level.

Some commenters argued for contractor penalties such as strict contractor evaluations, sanctions, or non-renewal of contracts based on noncompliance beyond a reasonable threshold. These commenters believed that any exceptions to the 45-day rule should be narrow. Other commenters urged us to assess interest penalties for non-clean claims that would mirror the provision for clean claims. Still other commenters thought that the 45-day time frame for non-clean claims might be too stringent and that we should set up specific, achievable time frames with appropriate penalties to ensure compliance.

Response: We understand the commenters' concerns regarding the need for contractors to process claims timely and pay them promptly. It is also important that contractors employ appropriate medical review strategies to ensure the appropriate payment of billed claims. When a contractor undertakes medical review on a claim, it is not always possible to pay within 45 days, particularly if a provider or supplier does not submit the additional documentation requested in a timely manner. We believe that protecting the Medicare Trust Funds through medical review of certain questionable claims that are flagged by our system edits is preferable to making inappropriate payments, absent proper evidence. We retain reputable independent third-party auditing firms to ensure that contractors are following all Medicare laws, rules, and regulations.

In addition, we strongly believe that providers and suppliers play a vital role in the FIs' and carriers' ability to meet their decision-making time frames. If providers and suppliers submit clean claims, they can avoid the delays that are associated with processing non-clean claims. The more complete the claim is upon initial submission, the greater the ability of the Medicare contractor to process the claim quickly. Until a determination can be made, however, we continue to believe that no interest should accrue on non-clean claims. In addition, the Congress has authorized interest only in the case of clean, complete claims.

We also believe that it would be inefficient and result in unnecessary costs to escalate undeveloped claims to the redetermination or reconsideration levels. These claims could not be reviewed or reconsidered because there would be no initial determination to review. Furthermore, the Congress weighed the merits of escalation and chose to implement that option only at the QIC level and above.

Comment: A few commenters suggested that we define the terms ''non-clean'' and ''clean'' in the context of claims.

Response: As defined in sections 1816(c)(2)(B)(i) and 1842(c)(2)(B)(i) of the Act, ''[t]he term ''clean'' claim means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim.'' Claims that do not meet this definition are considered ''non-clean'' claims. Since the term ''clean claim'' is clearly defined in statute, we are maintaining this definition as proposed in § 405.902.

We have also included in § 405.902 other statutory and regulatory definitions, such as, beneficiary, provider, supplier, carrier and fiscal intermediary. We did not define these terms in the proposed rule because they are defined in 42 CFR part 400. However, for the convenience of Medicare appellants, we have decided to provide definitions in this section as well.

Comment: One commenter believed that we should clearly state whether a beneficiary who has paid for an item or service up front is entitled to any interest that would accrue if the contractor does not pay the clean claim within the statutory time frame, regardless of whether the claim was submitted by the beneficiary or on the beneficiary's behalf. The commenter argued that in this situation, the beneficiary would suffer irreparable harm by the delay in processing the claim, as opposed to the provider or supplier, and paying interest to them would result in their unjust enrichment.

Response: In the agreement and attestation statement signed by a provider, the provider agrees not to charge beneficiaries for services for which beneficiaries are entitled to have payment made on their behalf by the Medicare program. In accordance with the provider participation agreement, the provider may only bill the beneficiary upfront for any unmet deductible and the applicable coinsurance. Therefore, institutional providers are always paid directly by the FI, including any applicable interest.

Likewise, participating suppliers and suppliers who accept assignment are also precluded from charging the beneficiary more than the unmet deductible and the applicable coinsurance. If the supplier collects any additional payment from the beneficiary before submitting the claim, the supplier must show on the claim form

the amount collected. The carrier then will refund directly to the beneficiary the additional payment along with any applicable interest on the over collected amount. In situations where the supplier does not accept assignment on a claim, the carrier makes payment directly to the beneficiary and includes any applicable interest regardless of whether he or she paid the supplier up-front for the item or service.

Comment: One commenter asserted that the proposed rule's reference to SSA making initial determinations with regard to entitlement issues was incorrect.

Response: We disagree with the commenter and maintain our longstanding policy that SSA makes initial determinations concerning applications for enrollment, as well as determinations regarding Part A and Part B entitlement. Consistent with our current regulations at 42 CFR § 405.704(a)(3) and § 405.704(a)(4), we have also added language to § 405.924(a)(3) to specify that an initial determination includes 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 of an application for hospital or supplementary medical insurance. Section 405.904(a)(1) clarifies the jurisdictional authority of SSA and DHHS with respect to initial determinations and appeals for applications and entitlement issues. That is, SSA will continue to perform initial determinations and reconsiderations, and DHHS'' ALJs and MAC will conduct hearings and reviews. As noted above, we intend to provide further guidance on how ALJs and the MAC will process entitlement appeals in separate instructions.

Comment: We received a comment on whether proposed § 405.924(b)(13), which defines an initial determination as a determination having a current or potential effect on the amount of benefits to be paid, includes Resource Utilization Group (RUG) categories. The commenter asked that we clarify in the final rule that the appeal rights for RUG reclassifications established in CMS Transmittal A–00–08 are continued in the final rule. The commenter also believes that proposed § 405.906(a)(3) and § 405.940 appeared to grant providers the right to seek redeterminations when a RUG is down coded to another category. However, the commenter noted that this conflicted with the reopening provisions at § 405.980, which seemed to suggest that all adjustments to claims must be handled through the reopenings process.

Response: As the commenter points out, CMS Transmittal A–00–08, which is now in the Program Integrity Manual at Chapter 6, allows skilled nursing facilities (SNFs) to appeal denials based on section 1862(a)(1)(A) of the Act. Nothing in this interim final rule limits the right of appeal created by CMS Transmittal A–00–08.

Although down coding a RUG category may be considered an initial determination under new § 405.924(b)(12), if the down coding was alleged to be the result of a clerical error as defined in § 405.980(a)(3), then the request for appeal likely can be processed as a request for reopening. This approach is consistent with section 937(a) of the MMA and the reopening provisions at § 405.980, whereby errors or omissions may be corrected without pursuing appeal. We note that, in this interim final rule, we have added a new section at § 405.927 regarding initial determinations that may be subject to the reopenings.

We also note that we have added specific language to new § 405.924(b)(13) to make it clear that the issue of whether a waiver of adjustment or recovery under sections 1870(b) and 1870(c) of the Act is appropriate is an initial determination with respect to a provider, supplier, or beneficiary in the context of both non-Medicare Secondary Payer overpayments and Medicare Secondary Payer recovery claims.

Comment: One commenter questioned whether the amount of coinsurance owed under the outpatient prospective payment system (OPPS) would be considered an initial determination, given that § 405.924(b)(5) indicates that the computation of coinsurance amounts constitutes an initial determination. The commenter pointed out that § 405.926(b) states that ''coinsurance amounts prescribed by regulation for outpatient services under the prospective payment system'' are not initial determinations. The commenter believed that section 1833(t)(12) of the Act does not preclude administrative and judicial review of the computation of OPPS coinsurance amounts.

Response: Section 4523(a) of the Balanced Budget Act of 1997 (BBA) amended section 1833 of the Act by adding subsection (t) which provides for the implementation of a prospective payment system (PPS) for outpatient services. Section 1833(t)(12) of the Act precludes administrative or judicial review of the calculation of the unadjusted coinsurance amount, as well as administrative or judicial review of coinsurance amounts directly premised on base amounts calculated pursuant to section 1833(t)(3) of the Act. Therefore, the unadjusted coinsurance amount under 1833(t)(3) of the Act is not an initial determination subject to any type of review. On the other hand, if a party believes that an item or service was incorrectly coded, leading to a higher coinsurance amount for that service, the party can challenge that determination in an appeal.

Comment: One commenter argued that inherent reasonableness is an initial determination under proposed § 405.924(b)(13) because it is an issue that has a present or potential effect on the amount of benefits to be paid under Part A or Part B. Another commenter believed that a party who is dissatisfied with an initial determination should be able to appeal a claim where the amount of payment was determined based on the application of an inherent reasonableness policy.

Response: Sections 1842(b)(8) and 1842(b)(9) of the Act authorize the Secretary to deviate from the payment methodologies prescribed in the Act if the application of those methodologies would result in a payment amount for a particular service or group of services that is determined to be grossly excessive or deficient, and therefore, is not inherently reasonable. Section 1842(b)(8)(A)(i) of the Act requires the Secretary to describe in regulations the factors to be considered in determining an amount that is realistic and equitable.

Furthermore, pursuant to section 1842(b)(9) of the Act, before making any adjustment for inherent reasonableness, the Secretary is required to publish a notice of proposed determination in the **Federal Register** and allow no less than 60 days for public comment on the proposed determination. The public comment period on proposed inherent reasonableness adjustments gives the public an opportunity to raise issues and concerns regarding these adjustments. All issues and concerns that the public raises are given full consideration, and a final determination is published before the actual adjustments in payments are made. Any adjustment would be broadly applicable to a given service or group of services, rather than just to an individual claim determination. Thus, we do not believe that the Congress intended for inherent reasonableness adjustments to payment amounts to constitute initial determinations that are subject to the appeals process. We have modified § 405.926(c) to clarify this issue.

We agree with the commenter that where the amount of payment on a

claim was determined based on an inherent reasonableness policy, this would result in an initial determination that is appealable. It is important to note the difference between an initial determination made on a specific claim, and the payment policy or methodology used to make that initial determination. The latter is not considered an appealable initial determination under this subpart.

We have added six items that also do not constitute initial determinations under § 405.926. Under § 405.926(n), we incorporated CMS'' longstanding policy that a finding that a provider or supplier failed to submit a claim, or failed to submit a timely claim, despite being requested to do so by the beneficiary or the beneficiary's subrogee, does not constitute an initial determination, and would preclude the claim from being subject to the appeals process. Second, consistent with section 1893(f)(3)(A) of the Act, as amended by section 935(a) of the MMA, we have added a conforming provision at § 405.926(p) that determinations by the Secretary of sustained or high levels of payment errors are precluded from administrative or judicial review. Also, consistent with section 938(a) of the MMA, § 405.926(q) provides that a contractor's prior determination related to coverage of physicians' services is not subject to the administrative appeals process or judicial review. However, a negative determination would not prevent an individual from obtaining a service, seeking reimbursement and, in the event of a denied claim, appealing the denial under section 1869(b) of the Act. Finally, consistent with established policies, we have added three items at § 405.926(o), § 405.926(r), and § 405.926(s). Under § 405.926(o), determinations with respect to whether an entity qualifies for an exception to the electronic claims submission requirement under part 424 of this chapter are not initial determinations. Section 405.926'' provides that requests for anticipated payment under the home health prospective payment system under § 409.43(c)(ii)(2) are not initial determinations. Lastly, claim submissions on forms or formats that are incomplete, invalid, or do not meet the requirements for a Medicare claim and are returned or rejected to the provider or supplier also do not constitute initial determinations. We welcome comments on these additions.

6. Redeterminations (§ 405.940 through § 405.958)

[If you choose to comment on issues in this section, please include the caption ''Redeterminations'' at the beginning of your comments.]

a. Requesting and Filing a Redetermination Request

In the proposed rule, we proposed to continue the policy of permitting parties to file their requests for a redetermination not only with the appropriate CMS contractor, as indicated on the notice of initial determination, but also at a local SSA or CMS office. In maintaining this policy for filing requests, we proposed that the date the redetermination request would be considered to be *filed* meant the date the contractor, SSA, or CMS received the request. Additionally, we specified that for purposes of issuing a redetermination, the date of timely filing would be considered as the date that the contractor responsible for the redetermination received the redetermination request. We proposed to allow extensions to the time frames for redetermination requests if a party showed good cause for missing the 120-day deadline. In order to determine whether a party had shown good cause for missing the deadline, the contractor would consider: the circumstances that kept the party from making the request on time; whether the contractor's actions misled the party; and whether the party had any physical, mental, educational, or language limitations that prevented the party from filing a timely request, or from understanding or knowing the need to file a timely request for redetermination.

We also indicated that redetermination requests would need to be made in writing. Previously, Part B requests for review could be made by telephone; however, we proposed to eliminate telephone requests in order to provide a reliable record of the request, and to encourage the submission of evidence to support the request. We proposed that requests would need to be made using a standard CMS form. Alternatively, when not made on a CMS form, the request would need to contain all the elements listed in § 405.944(b), that is, the beneficiary's name, Medicare health insurance claim (HIC) number, specific date of service, and identification of the item or service for which the party was requesting the redetermination, and the name and signature of the party or appointed representative.

We solicited comments on alternative approaches that would be convenient and easy for appellants. We also proposed that a beneficiary or beneficiary's appointed representative could continue to file a request for an appeal using the instructions on the MSN, that is, he or she could satisfy the requirements by circling an item on the MSN, signing the bottom of the MSN, and returning the MSN to the contractor. In situations where more than one party requested a redetermination on the same claim, we proposed that the contractor would consolidate the requests into one proceeding in order to avoid duplication.

Comment: Several commenters suggested that we clarify the procedures for how fiscal intermediaries and carriers calculate and record the receipt date for redetermination requests. One commenter recommended that we establish that the receipt date is the date the request first arrives at the appropriate address. Another commenter objected to presuming that the receipt of the initial determination, which is used to calculate the time frame for a redetermination request, will be 5 days after the date of the initial determination notice. The commenter argued that often appellants receive initial determinations much later than the date on the notice. In some cases, the provider does not receive the initial determination until a month later. The commenter believed that 10 days would be a more realistic time frame for contractors to assume receipt and begin calculating whether a party met the 120-day time frame for requesting a redetermination.

A few commenters requested that we define ''evidence to the contrary'' of the presumed 5-day receipt date in order to prevent discrepancies in how different contractors handle requests for redeterminations. One commenter suggested that ''evidence to the contrary'' should be a receipt from a mail delivery service containing the date of delivery to the appropriate address. Another commenter asked whether a date stamp by the provider would be an acceptable way to verify the date of receipt of an initial determination.

Response: We appreciate the concerns about calculating and recording the receipt date for appeal requests based on the delivery time for the initial determination notice. We agree that a uniform process needs to be used for calculating and recording the date of receipt of an appeal request. Thus, we proposed to incorporate into the regulations CMS's clear, longstanding policy that the date of receipt is presumed to be 5 days after the date of the initial determination notice. We will carefully monitor our contractors to ensure that they calculate the time frames appropriately. If we determine that any additional instructions are

needed, we will provide them in manual instructions.

We understand that in some cases the initial determination notice will be received later than 5 days from the date of the notice, which is why the regulations allow more than 5 days where there is evidence to the contrary. An example of evidence to the contrary would include a postmark date or a receipt from a mail service containing the date of delivery to the party. We do not believe it would be appropriate to attempt to include in regulations all the possible ways for a party to demonstrate when the party received an initial determination notice. Instead, we will allow adjudicators to exercise their discretion as to whether a party's evidence demonstrates that the party received the initial determination beyond 5 days from the date on the notice. Finally, we note that 120 days is a significant amount of time for a party to file an appeal and that appellants also have an opportunity to request an extension of this deadline; thus, we believe that the calculation of the receipt date for appeal requests based on the prevailing 5-day standard will not pose an undue hardship for most appellants.

Comment: One commenter requested clarification on whether adjudicators could request appellants to provide proof to support good cause for failing to file an appeal within the allotted time frame.

Response: Adjudicators may request appellants to provide supporting documentation that demonstrates that they have good cause for filing an appeal beyond the deadline. We strongly encourage appellants to provide supporting documentation when requesting a contractor, QIC, ALJ, or the MAC to consider good cause for filing an appeal late. In fact, an adjudicator can summarily dismiss a request made on the basis of good cause when there is no evidence to support the request.

Comment: Some commenters raised objections to beginning the decision-making time frame on the date that the contractor received the redetermination request if an appellant filed an appeal at an alternative location. One commenter agreed with this approach, but indicated it would be difficult for appellants to know when the time frame for making a decision started. The commenter suggested that we add a requirement that the contractor notify the appellant when the request has been received and the date the time frame began. Another commenter suggested that we establish a definitive deadline by which an appeal would be presumed received by the appropriate contractor for purposes of tracking the adjudication time frame. The commenter thought that an appellant should be able to presume that a contractor received a request within 60 days; and therefore, the appellant should expect a decision within 90 days. Another commenter suggested that CMS develop a web-based system for local SSA, CMS or contractor staff to enter and immediately transmit the request to the appropriate adjudicator. A few commenters believed that the delayed decision-making time frame penalized beneficiaries for something that was beyond their control. They argued that the policy would be unfair to beneficiaries because they would not receive a timely decision when they used an alternative filing location.

Response: We recognize the commenters' concerns about the confusion and potential delays involved in transmitting requests filed at alternative locations to the appropriate contractor. Further, as noted above, under section 931 of the MMA, SSA's role in the Medicare claims appeal process will end with the impending transfer of the ALJ function from SSA to DHHS no later than October 1, 2005. In view of the reduced role of SSA in the processing of Medicare appeals, we do not believe it is appropriate to specify in the regulations that appeals may be filed at SSA offices. We have revised § 405.942(a) to eliminate the reference to alternative filing locations. We believe that directing appellants to only one filing location will reduce confusion and eliminate the potential delay in transmitting the request. We will also allow an extension to the filing deadline when a party, in good faith, sends a request to a government agency within the time period to file and the request does not reach the appropriate contractor until after the time period to file expires.

The elimination of alternative locations will obviate any routine need for notices informing appellants of the date of receipt at the adjudicating contractor. Given the elimination of alternative filing locations, we think it would be unnecessarily burdensome on contractors to notify all appellants of the receipt date, given that it could be easily calculated to within a few days. In addition, we are actively exploring the development of a web-based system that would permit appellants to access real-time information about the status of their appeals.

Comment: We received several comments on whether redetermination requests should be accepted orally or in writing. One commenter disagreed with the elimination of accepting requests over the telephone. The commenter believed that taking requests by telephone is a convenient and simple method for filing an appeal. Another commenter pointed out that telephone requests facilitated meeting the decision-making time frame. The commenter also indicated that telephone appeals are advantageous because additional documentation can be requested while the appellant is on the phone. Other commenters agreed that requests for redeterminations be made in writing only. They stated that when the request and the response are given on the telephone, it leaves room for interpretation on what occurred during the telephone call. Also, it could be difficult for the QIC to construct the case file if the redetermination was handled over the telephone. The commenter suggested alternative methods such as the use of a secure system for fax or electronic mail requests. Another commenter agreed with our discussion in the preamble to the proposed rule that the changes to the reopening process could resolve the types of issues addressed in the current telephone appeals process, and encouraged our efforts to clarify the reopening rules.

Response: We recognize that initiating a redetermination over the telephone can under some circumstances provide a faster process for appellants than a written appeal. In the past, providers and suppliers generally initiated reviews by phone for routine, uncomplicated matters. However, section 937(a) of the MMA requires CMS to develop a process whereby, in the case of minor errors or omissions that are detected in the submission of claims, a provider or supplier can be given an opportunity to correct these minor errors or omissions without the need to initiate an appeal. Contractors would also continue to handle these types of issues over the telephone through procedures other than appeals, such as reopenings, including any associated adjustments. The reopening process is discussed in more detail later in this preamble under its own heading.

Written requests offer other advantages of efficiency and accuracy. An appellant submitting a written request can submit evidence at the same time as the request. The early submission of evidence leads to resolving appeals at lower levels and promotes more accurate decision-making. Furthermore, many appeals involve judgment calls that require thought, research and analysis, much of which cannot be addressed in a phone call. Also, as noted by a commenter,

written appeals aid contractors in developing case files for use at later appeal stages.

Thus, as proposed, we will require that appellants request redeterminations in writing. We will work on identifying simple and convenient methods for appellants to request redeterminations in writing, such as via facsimile or electronic mail request. Finally, we note that contractors are by no means prevented from communicating with appellants by phone in situations where contact by telephone can provide information needed to resolve an appeal.

Comment: Some commenters raised questions about requests for redetermination made by more than one party. A few commenters objected to our proposal that where two or more parties requested an appeal on the same initial determination, the contractor's deadline for processing the appeal would be based on the latest filed request. One commenter disagreed with the consolidation of multiple requests into one proceeding, and argued that this would result in unwarranted delays. The commenter suggested that we stipulate in this final regulation that the decision-making time frame starts with the first request for redetermination. The commenter also thought that contractors should be required to act on beneficiary appeals when they are received, rather than waiting to see if another party appeals. Another commenter was concerned whether the contactor would wait until the end of the full 120-day filing deadline to see if another party would request an appeal.

Response: Instances when more than one party files a request for an appeal of the same claim have always been rare, and we do not expect any change in this regard under the new appeals procedures. Although we appreciate the concern that contractors might wait 120 days to see if another party appeals, contractors could not do so even if they wanted to, given the requirement that they process a redetermination within 60 days of a timely filed request. A delay will occur only if another request is received before the contractor issues a decision. Therefore, we do not believe that consolidating the decision-making time frame for appeals with multiple parties will create an impediment to the efficient resolution of appeals. To the contrary, we believe that when another party subsequently requests an appeal before a decision has been made on the original request, fairness demands that the two requests be combined into one case. We have amended § 405.944(c) to clarify this point.

Comment: Several commenters made recommendations about the place and method of filing redetermination requests. One commenter suggested that all review organizations have an address for delivery services other than the U.S. Postal Service. The commenter stated that appellants sometimes wish to use private services to deliver their appeals, particularly to ensure that contractors receive the appeals timely. A few commenters suggested that CMS provide appellants an opportunity to submit a redetermination request via facsimile or via e-mail. The commenter believed that these alternatives would create better efficiencies for appellants.

Response: We encourage appellants to use delivery services that will ensure the timely receipt by contractors of appeal requests. We will explore with contractors ways to achieve efficiencies in the appeals process, including establishing addresses for private delivery services. We also will look into the extent to which contractors can set up a process to accept facsimile and electronic requests in compliance with applicable security and privacy policies and procedures. Should these changes prove feasible, we will implement them through manual instructions.

Comment: Several commenters urged us to make the standard form for requesting a redetermination widely available to ensure accessibility by beneficiaries. They suggested including the form for requesting a redetermination with the initial determination notice. Alternatively, the initial determination should provide information about where to obtain the standard form. Commenters recommended that the standard form be available upon request by telephone, on the Internet, and at all SSA and CMS contractor offices.

Response: We agree that standardized forms should be readily accessible to beneficiaries. As mentioned earlier in our discussion about initial determinations, beneficiaries now routinely receive Medicare Summary Notices (MSNs). The MSN contains information on the appeals process and instructions for requesting an appeal. Beneficiaries can use the MSN to request an appeal by circling the item or service with which they disagree, explaining why they disagree, signing the MSN, and returning it or a copy to the specified address. Consumer testing has shown that the information on the MSN is complete and easy for beneficiaries to understand. In most cases, we believe that allowing beneficiaries to use the MSN to request an appeal is a more effective practice than referring them to a required form.

We will ensure that customer service representatives at our 1–800–MEDICARE number provide beneficiaries with accurate information on how they may obtain standardized appeal forms. Updated appeal forms will continue to be available on the Internet at *http://www.cms.hhs.gov/forms* and *http://www.Medicare.gov/Basics/forms,* as well as at CMS contractor offices.

b. Evidence Submitted With the Redetermination Request

In the proposed rule, we specified that a party should explain why he or she disagrees with the contractor's initial determination and include any evidence that the party believes should be considered by the contractor in making its redetermination. We wanted to encourage appellants to make their case at the earliest possible level. To facilitate this goal, we proposed that if appellants could not submit relevant documentation along with their redetermination requests, then they could provide later submissions. However, since it would be difficult to process the redetermination within the appropriate time frame, we proposed to permit contractors to extend the decision-making time frame by up to 14 days based on the later submission of evidence.

Comment: One commenter suggested that prior to issuing a redetermination, the contractor should request the necessary documentation from the appellant and allow the appellant 14 days to either submit the documentation requested or to certify that there are no additional records to submit. The commenter also indicated that if the appellant failed to provide the documentation, an unfavorable decision should be rendered based on failure to provide the necessary documentation. The commenter also questioned whether it was our intent to preclude the QIC from accepting documentation other than what is requested in the redetermination letter.

Response: We believe that the efficiency and accuracy of the appeals process is enhanced when appellants submit all necessary documentation with their redetermination requests. Although appellants have the opportunity to submit evidence related to the claim at issue at any time during the redetermination process, we strongly encourage appellants to submit, at the time of their request, all evidence that they want to be considered. If supporting documentation is not submitted with the request, the contractor may contact the appellant to try to obtain the missing information.

The contractor will not necessarily uphold an unfavorable initial determination based solely on the lack of documentation submission. The contractor must make a decision based on the information in the case file.

If the contractor believes that the appellant is missing specific information or documentation necessary for processing the redetermination, but cannot obtain the information before its deadline, the contractor will uphold the claim denial and then list the specific missing information in the redetermination letter. If the appellant requests a QIC reconsideration, the appellant should submit the documentation specified in the redetermination notice with the request for reconsideration. The QIC may accept any additional documentation, even if it is not specified in the redetermination notice. If the appellant fails to submit this evidence before the QIC issues its reconsideration, the appellant may be precluded from introducing the evidence at higher levels of the appeals process, absent a showing of good cause. (See the discussion below regarding the regulatory and statutory requirements for full and early presentation of evidence.)

c. Conducting a Redetermination and Time Frame for Making a Decision

Section 1869 of the Act provides little or no guidance with respect to the conduct of redeterminations, with the exception of establishing the filing and decision-making time frames. Thus, with few exceptions, we did not propose major changes to the existing procedures for first level appeals of claim determinations. To assist appellants who might be unable to submit relevant documentation along with the request for redetermination, and to promote the resolution of appeals at the earliest possible level, we proposed to allow later submission of documentation. If the appellant submitted evidence after the request, an automatic 14-day extension would be added to the decision-making time frame. *See* § 405.946(b).

Comment: One commenter contended that CMS exceeded its statutory authority by changing the standard with respect to the established time frame for a decision on a request for redetermination. The commenter disagreed with the proposal of an automatic 14-day extension to the time frame when an appellant submits evidence after the request. Another commenter agreed that additional time might be necessary to issue a decision when a party submits additional evidence. The commenter noted that we did not specify whether a party could submit additional evidence more than once, and if so, what the impact would be on the decision-making deadline. For example, would a 14-day extension apply each time a party submitted additional evidence, or would there by only one extension, regardless of how many times a party submitted additional evidence? The commenter suggested that we specify that there are no limits on evidence submission at the redetermination level and that a party can submit additional evidence as many times as it deems appropriate until a specific point near the time to issue a decision. The commenter recommended that evidence should be permitted until 5 days prior to the decision-making deadline (for example, additional evidence could be submitted until 55 days after the contractor received the redetermination request).

Response: We believe allowing extensions of decision-making time frames under some circumstances is consistent with the statute. We believe that an appeal request should include the pertinent evidence for an adjudicator to make an appropriate determination, as indicated in § 405.946(a). If the evidence is not submitted with the request, the 14-day extension allows time for an adjudicator to carefully review and consider additional evidence. It is unreasonable first to expect an adjudicator to prepare a decision based on incomplete information submitted with the appeal request, and then in as little as a few days, potentially rewrite a decision based on new evidence.

While a party, by regulation, may submit additional evidence as many times as it deems appropriate until the contractor issues a decision, the impact is that the contractor may extend its decision-making deadline by up to 14 days each time. The only way to avoid the need for extended decision-making time frames would be to preclude the submission of additional evidence by appellants after they file their redetermination requests. Note that although the contractor may extend the deadline, this does not mean that we expect the contractor to take the maximum time to issue the decision in all cases. As mentioned in the comment above, we urge appellants to submit all necessary documentation with their requests in order to avoid delays. We note that from the outset, appellants have twice the amount of time to request an appeal as adjudicators do to conduct the appeal.

Comment: Some commenters argued that we should impose penalties on fiscal intermediaries and carriers that fail to meet the 60-day deadline for issuing a redetermination. In addition, the commenters recommended that we establish specific remedies for appellants, such as the ability to escalate cases to QICs, when contractors fail to meet their time frames. One commenter argued that non-enforcement of the time frame would have a negative impact on beneficiaries, since they cannot proceed to the QIC until the contractor issues a redetermination.

Response: We do not believe that it is appropriate to permit escalation of redeterminations when contractors do not meet their deadlines. We believe this is consistent with the statute in that the Congress seems to have weighed the merits of escalation and chose to implement that option only at the QIC level and above. The statute also already directs that the Secretary monitor the timeliness of all contractors' redeterminations. Sections 1816(f) and 1842(b)(2) of the Act require us to develop criteria, standards and procedures to evaluate a fiscal intermediary's or carrier's performance of its functions. Measuring the timeliness of redeterminations is a critical part of this process, and a contractor's inability to process redeterminations within the required 60-day time frame will be enforced through corrective action plans and other tools that CMS has available to ensure that carriers and fiscal intermediaries fulfill their statutory and contractual obligations. Under our ongoing Contractor Performance Evaluation (CPE) process, CMS devotes extensive resources to onsite surveys of contractors to ensure that they meet these obligations.

Comment: One commenter recommended that we prohibit Medicare contractors and QICs from raising new issues during an appeal. Any issues that are different from those in dispute should be raised through the reopening process. The commenter stated that bringing up new issues creates great confusion for appellants.

Response: A redetermination consists of a fresh examination of all the issues involved in a claim to determine whether it is payable. Therefore, the redetermination is not limited to validating the original reason for the denial of the claim at issue in the appeal. All applicable statutory and regulatory provisions, as well as CMS-issued policies and procedures, bind contractors making redeterminations (for example, CMS Rulings, Medicare manual instructions, program memoranda, national coverage determinations, local coverage

determinations, and regional medical review determinations). As a result, all these authorities must be considered as part of the redetermination.

d. Withdrawals and Dismissals

In the proposed rule, we proposed to allow parties to withdraw redetermination requests within 14 days of the original request in order to avoid situations where the request for withdrawal and the decision crossed in the mail. We also proposed several reasons a contractor might dismiss a request (for example, where a request for redetermination did not contain the minimum elements for a redetermination request set forth in proposed § 405.944). We also proposed to dismiss a request if the party filing the request died and there was no information in the record to determine whether another party might be prejudiced by the redetermination.

We also proposed that when a contractor dismissed a request, a written notice would be sent to the parties. Also, a dismissal could be vacated at any time within 6 months from the date of the dismissal notice for good and sufficient cause. Finally, an appellant could request a QIC reconsideration of the dismissal within 60 days of the dismissal notice. See proposed § 405.974(b).

Comment: A commenter recommended that the dismissal notice under § 405.952(c) should inform the appellant of the right to request that the contractor vacate the dismissal within 6 months.

Response: We agree that the dismissal notice should include information about vacating the dismissal. We have revised § 405.952(c) to require that the dismissal notice state that there is a right to request that the contractor vacate the dismissal action.

Comment: Proposed § 405.952(a) permits a party to withdraw its appeal request by filing a written and signed request for withdrawal within 14 calendar days of the filing of the redetermination request. A commenter questioned whether a contractor would disregard a request for withdrawal made after the 14th day. The commenter argued that there was no legitimate reason to issue a redetermination if someone wanted to withdraw an appeal request. The commenter recommended that as long as the withdrawal request was received before the contractor issued a redetermination, then the request for redetermination should be dismissed.

Response: We agree with the commenter and will not limit requests for withdrawal to within 14 days of filing the request for redetermination. Under this interim final rule, a request for withdrawal must be received before a redetermination has been issued. We encourage appellants to submit written requests early to avoid having the notice of a redetermination and a request to withdraw cross in the mail.

Comment: Proposed § 405.952(b)(2) requires a contractor to dismiss a request for a redetermination if the contractor determines that a party has failed to make out a valid request for redetermination that substantially complies with § 405.944. Proposed § 405.944(b) requires an appellant to either use a standard CMS form or submit a written request containing four elements: (1) The beneficiary's name; (2) the beneficiary's health insurance claim number; (3) the specific services(s) and item(s) for which the redetermination has been requested, as well as the specific date(s) of service; and (4) the name and signature of the party or appointed representative of the party. Two commenters pointed out that these elements do not mirror the requirements contained on the current standard CMS form to request a review.

The commenters requested us to clarify if the current review form would comply with § 405.944. They also inquired as to whether we would develop a new form. If CMS developed a new form, the commenters suggested providing space on the form for all of the required elements listed in the proposed rule. Additionally, one commenter requested that CMS develop and disseminate a standard form as quickly as possible so that parties can become familiar with the information required in the form.

Response: We realize that the current standard forms for requesting a review and reconsideration, CMS forms 1964 and 2649 respectively, do not contain all of the elements required under § 405.944. However, we are in the process of revising all of our current appeal forms. The standard CMS form will contain all of the elements specified in § 405.944. Once we complete the new forms, they will be released and made available to appellants at contractor offices, CMS offices, on the Internet, and by calling 1–800–MEDICARE. We intend to release the new forms in conjunction with the implementation of these interim final regulations.

Comment: One commenter contended that allowing contractors to dismiss redeterminations when appellants fail to make out valid requests effectively denies appellants the ability to pursue appeals. Other commenters maintained that requiring specific elements in order to make a request would penalize unrepresented beneficiaries or those that have limited English-speaking abilities or mental capacity. One commenter argued that unrepresented beneficiaries should be given notice of any deficiencies and an opportunity to correct and file an amended redetermination request within a reasonable time period (for example, 10 business days after receipt of the notice). The commenter also recommended that the notice of an incomplete request should inform the party of the information necessary to request a redetermination; otherwise, the party would not know what information was missing.

Response: We do not agree that contractors should be required to inform appellants of the defects in their redetermination requests instead of being able to issue dismissals. Section 405.944(b) requires only four elements for making out a valid redetermination request: (1) The beneficiary's name; (2) the Medicare health insurance claim number; (3) the specific services(s) and item(s) for which the redetermination is requested and the specific date(s) of service; and (4) the name and signature of the party or representative of the party. This constitutes the minimum information needed to process an appeal, and we believe that it is entirely appropriate to require the party appealing to provide this basic information. Absent this information, it would be difficult, if not impossible, to ascertain whether the individual requesting the appeal is in fact a party or representing a party, or to identify the claim at issue. We believe that accepting appeal requests with insufficient basic information about the claim and requiring contractors to inform appellants of the defects in their appeal requests would make for an inefficient appeals process. Note that identification of the specific items or services for which a redetermination is being requested can be accomplished in a variety of relatively simple ways. For example, a beneficiary may simply circle the denied service in question on the MSN. Alternatively, for revised initial determinations (for example, overpayment cases or Medicare Secondary Payer recovery cases), appellants can meet this criterion by including a copy of the ''demand letter'' used to initiate these cases. Thus, meeting these minimum requirements is not onerous.

In arriving at the decision to allow contractors to dismiss invalid redetermination requests under § 405.952(b)(2), we considered the fact that a dismissal does not necessarily

terminate a party's right to file an appeal. If the 120-day time frame for filing a redetermination has not expired at the time a contractor issues a dismissal, then a party may correct the defect and resubmit the appeal. Also, a contractor may vacate a dismissal at any time within 6 months from the date of the dismissal notice, if good and sufficient cause is shown. Alternatively, if a party believes that the contractor inappropriately dismissed a request, the party can request a reconsideration by the QIC within 60 days of the dismissal.

Therefore, we are adopting our proposed policy in this interim final rule of dismissing requests that do not meet the requirements of § 405.944. A contractor may, but is not required to, contact appellants to give them an opportunity to cure a defect in their redetermination request before dismissing it. We believe that this policy is reasonable given that it is clear how a party must make out a valid redetermination request. As under the former appeals process, we will continue to allow a beneficiary to file an appeal by following the requirements detailed on the MSN. We will instruct our contractors to take into consideration any special needs of unrepresented beneficiaries, or those with limited capacities or abilities. Also, we are in the process of creating a redetermination form that will assist appellants who are unfamiliar with the process (for example, unrepresented beneficiaries) with their requests.

Comment: One commenter requested clarification on the circumstances under which a request for redetermination would be dismissed when a beneficiary dies. The commenter requested clarification about any potential liability of the deceased beneficiary's estate, including recovery by a State. The commenter believed that § 405.952(b)(4) also should clarify the situations an adjudicator must consider to determine whether dismissing the redetermination request may prejudice another party. The commenter indicated that in almost every situation, the beneficiary's estate would be prejudiced by the determination and argued that a dismissal would preclude the beneficiary's family or estate from protecting its right to seek reimbursement.

Response: We have revised the proposed language in § 405.952(b)(4) to make the needed clarifications. A contractor will dismiss a redetermination request when the beneficiary whose claim is being appealed dies while the request is pending, under the following circumstances: (1) The beneficiary's surviving spouse or estate has no remaining financial interest in the case based on whether either remains liable for the services or subsequent similar services; (2) no other individual or entity with a financial interest in the case wishes to pursue the appeal; and (3) no other party filed a valid and timely redetermination request. For example, the contractor will dismiss the request if the beneficiary or the beneficiary's representative filed the request for redetermination but the beneficiary was not held liable for the services at issue. The contractor will inquire whether another party wishes to continue the appeal. However, the contractor will not be required to inquire whether any other party wishes to continue the appeal unless a valid and timely request for redetermination is filed. We wish to note that when a beneficiary dies and the request for redetermination is subsequently dismissed, a party, including the beneficiary's estate, may request the contractor to vacate the dismissal under § 405.932(c) for good and sufficient cause. Examples of good and sufficient cause include when there is the possibility of Medicaid liability or when there is a possibility the State (which pays Medicaid funds) will attempt recovery of its payment from the estate.

As mentioned in our discussion above on parties to initial determinations and appeals, § 405.906(c) now establishes that in the event of the death of a beneficiary, a provider or supplier may appeal if there is no other party available to appeal an initial determination. Thus, the provider or supplier of the item or service may request a redetermination in these situations, consistent with the clear direction of section 939 of the MMA.

Comment: A commenter requested that we clarify the meaning of ''otherwise transmit'' in proposed § 405.952(d) in terms of a contractor providing a dismissal notice to the parties at their last known addresses. The commenter pointed out that the type of transmission is particularly important for beneficiaries who do not have access to facsimile and electronic mail.

Response: The dismissal notice, like a redetermination notice, will be delivered through first class U.S. mail. Although contractors do not currently transmit notices by facsimile or electronic mail, we want to ensure that the regulations allow them the flexibility to do so in the future should CMS believe that other notification methods are appropriate. Nevertheless, even if contractors use alternate means to provide dismissal notices, we will instruct contractors to allow parties to elect their preferred method of delivery.

7. Redetermination, Notification, and Subsequent Limitations on Evidence'' (§ 405.954, § 405.956, and § 405.966)

[If you choose to comment on issues in this section, please include the caption ''Redetermination, Notification, and Subsequent Limitations on Evidence'' at the beginning of your comments.]

When a contractor's redetermination fully reverses the initial determination, we proposed to maintain the current policy that proper notification would be achieved through the MSN or the RA, which contractors send to beneficiaries, and providers and suppliers, respectively. If a redetermination affirmed the initial determination, either in whole or in part, we proposed that a redetermination notice contain: (1) A clear statement indicating the extent to which the redetermination is favorable or unfavorable; (2) a summary of the facts; (3) an explanation of how the pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case; (4) a summary of the rationale for the redetermination; (5) notification to the parties of their right to a reconsideration, the procedures that a party would follow in order to request a reconsideration, and the time limit for requesting a reconsideration; (6) a statement of the specific missing documentation that would need to be submitted with a request for a reconsideration; (7) an explanation that if the specific supporting documentation specified in the notice is not submitted with the request for a reconsideration, the evidence will not be considered at an ALJ hearing, unless the appellant demonstrates good cause as to why the evidence was not provided previously; and (8) any other requirements specified by CMS. When a redetermination notice is sent to a provider or supplier announcing a full or partial reversal of the initial determination, the Medicare contractor must also issue an electronic or paper remittance notice to the provider or supplier to explain the payment.

In general, the proposed requirements for the redetermination notice were similar to existing instructions concerning the content of contractor appeal determinations. However, our proposal that contractors also specify supporting documentation that would need to accompany a reconsideration request was a new requirement.

Comment: We received many comments on the requirement for the redetermination notice to include a statement of the specific missing

documentation that must be submitted with the reconsideration request. In general, the commenters agreed with the requirement to identify additional supporting documentation in the redetermination notice. They also agreed that this change would improve the efficiency of the appeals process by assisting appellants in knowing the type of documentation to submit.

Several other commenters objected to this provision. Two commenters argued that the statute and Medicare regulations require filing certain documentation with particular types of claims (for example, claims for power wheel chairs require submission of a power wheelchair Certificate of Medical Necessity (CMN)). They argued that if the statute and regulations do not require the submission of a particular piece of documentation, but a contractor needs that documentation before it will pay a claim, then the contractor should be required to explain why it needs the documentation and consider the impact of requiring compliance with the a request (consistent with the Paperwork Reduction Act of 1995 (PRA)). They proposed that the carrier or fiscal intermediary explain in detail the rationale for collecting any additional documentation not required for submitting a particular claim. The commenter argued that the rationale should include the legal and medical necessity reason for such collection.

Response: We believe that the appeals time frames and procedures mandated by section 521 of BIPA and Title IX of the MMA clearly require greater efficiency in the Medicare appeals process. This belief is reinforced by section 933(a) of the MMA, which requires that a provider or supplier may not, in any subsequent level of appeal, introduce evidence that was not presented at the reconsideration conducted by the QIC, unless there is good cause that precluded the introduction of that evidence at or before that reconsideration. However, absent advance notice of what documents are needed to support a claim, appellants may have difficulty determining what constitutes relevant evidence for their claim appeals. Thus, although not required by the statute, we believe that requiring contractor redetermination notices to identify necessary missing documentation will provide very valuable information for appellants to present their cases to QICs. Therefore, we believe this provision is advantageous to appellants since it should result in a better understanding of the basis for the unfavorable redetermination and lead to more accurate reconsiderations.

Comment: One commenter recommended revising the new evidence provisions to preclude the subsequent submission of information only to the extent that it involves objective medical information (for example, a specific blood gas percentage or patient height and weight). Another commenter suggested that we distinguish between the submission of new evidence that involves readily available clinical documentation directly implicated in the claim dispute and other evidence (for example, expert opinions, clarifying treating physicians' opinions, or evidence from providers not directly involved in the dispute). The commenter recommended only precluding clinical documentation.

Other commenters argued that this provision was too burdensome for providers, suppliers, and beneficiaries, particularly when they do not have easy access to supporting documentation that may be required. Some of the commenters suggested that we exempt beneficiaries from these rules because they do not have ready access to medical records and other documentation.

One commenter believed that the proposed rule was too lenient and recommended that we limit the rules on submission of evidence at the redetermination and reconsideration levels. The commenter suggested that we require appellants to sign a form certifying that they do not have any more records to submit.

Response: We do not believe that it is either practical or consistent with the statute to limit the requirement on full and early presentation of evidence by attempting to distinguish between evidence that is readily available to the provider and that which is obtained from providers not directly involved in the claim dispute. Similarly, we cannot limit this provision to objective medical information. Given the vast amount of medical services and items that could be involved in a claim dispute, it would be extremely difficult to draw clear distinctions among the numerous types of documentation that might be needed. Nevertheless, where it is not feasible to obtain this documentation, as indicated in § 405.1028, an ALJ will make a determination on whether good cause for failure to submit the evidence to the QIC exists. This applies to all documentation, including the items listed in the notice of redetermination.

Finally, we note that, consistent with section 933(a) of the MMA, we have specified in the interim final rule that the limitation on the presentation of new evidence, absent good cause, applies only to providers and suppliers, and not to beneficiary appellants. The limitation on the presentation of new evidence will also apply to beneficiaries represented by providers or suppliers to ensure that providers or suppliers do not attempt to circumvent these rules by offering to represent beneficiaries. Further, to the extent that beneficiaries may not be as sophisticated as providers or suppliers regarding the administrative appeals process this consideration would not apply in the case of a beneficiary represented by a provider or supplier. Thus, although contractor redetermination notices will uniformly identify any necessary missing documentation, beneficiaries, except those represented by providers or suppliers, will still be permitted to introduce evidence after the QIC reconsideration level (although for efficiency reasons, they would be better served by doing so as soon as possible). We believe it would be unnecessarily burdensome to require appellants to certify that they have no further evidence to submit. (See section II.D.3 below for a further discussion of rules related to evidence at QIC reconsiderations.)

Comment: Several commenters made additional suggestions for improving the notices that inform parties of the decision on an appeal. Some commenters suggested including a form to request a reconsideration on the back of the redetermination notice. Other commenters suggested that CMS make available upon request the laws, regulations, policy manuals, national coverage determinations (NCDs), local coverage determinations (LCDs), and local medical review policies (LMRPs) that were used to make the decision. They recommended that notices should include the correct citations to the appropriate provisions. One commenter recommended that if the MSN is used to inform a beneficiary of a redetermination that is wholly favorable, the MSN should be sent within the proper time frame. This commenter also suggested that the appointed representative receive a copy of the decision.

Response: We agree that including a form to request a reconsideration with the redetermination notice would assist appellants and help them to provide the information QICs need to process reconsiderations. At one time, we had considered including a reconsideration request form on the reverse side of the redetermination notice, but consumer-testing results indicated that appellants found this confusing. We intend to continue exploring how best to make available a reconsideration request form with the redetermination. Consistent

with section 1869(a)(5) of the Act, as amended by section 933(c)(1) of the MMA, we require in § 405.956(b)(9) that contractors make available upon request correct information on the laws, regulations, policy manuals, national coverage determinations (NCDs), local coverage determinations (LCDs), and local medical review policies (LMRPs) that were used to make the decision.

We appreciate the commenter's concern about receiving MSNs within a reasonable amount of time from the date of a fully favorable redetermination. However, it is more efficient and cost-effective for beneficiaries to receive MSNs on a monthly basis, as opposed to each time a claim or appeal is processed. Thus, if an adjustment is made to a claim as the result of an appeal decision, the beneficiary will not receive the MSN until the next scheduled monthly release. We believe that this is an acceptable amount of time, and it continues a longstanding Medicare practice. CMS will monitor contractor performance in this regard.

To ensure that appellants are made aware of the outcome of a fully favorable redetermination in a timely manner, we added § 405.956(a) and § 405.956(c) to reflect that contractors must send a written notice to the appellant within 60 calendar days of receipt of the request for a redetermination. The written notice must contain a clear statement indicating that the redetermination is wholly favorable to the appellant.

Additionally, we wish to clarify that all parties to the appeal are required to receive a copy of an unfavorable or partially favorable redetermination notice, with the sole exception of overpayment cases involving multiple beneficiaries. Our experience has been that beneficiaries often are confused by the copies of notices that they receive in conjunction with overpayment and recovery letters to providers and suppliers. To minimize confusion, under § 405.956(a)(2), we specify that in these situations, contractors are permitted to issue written notices only to appellants.

Although we agree that an appointed representative must receive a copy of the redetermination, we do not agree, for privacy reasons, that the appointed representative also should receive a copy of the MSN. MSNs contain information about other claims filed during the previous month, with which the appointed representative may have no authorized involvement.

Comment: A commenter pointed out that we did not impose a deadline for a contractor to make payment on a claim after a favorable decision. The commenter recommended that we require payment to be made within 60 days of the date of the favorable decision.

Response: We agree that payment should be made within a reasonable time from the date of a favorable determination. We will continue to evaluate contractors' performance in effectuating favorable decisions.

8. Reconsiderations (§ 405.960 Through § 405.978)

[If you choose to comment on issues in this section, please include the caption ''Reconsiderations'' at the beginning of your comments.]

a. Time Frame for Filing a Reconsideration Request

Proposed § 405.962(a) specified that appellants who wished to file a request for reconsideration would be required to do so within 180 days of receipt of the redetermination notice, or within additional time as the QIC might allow for good cause. In proposed § 405.964, we set forth the place and method for filing a request for reconsideration. We would permit parties to file requests with the QIC, CMS, or SSA offices. For purposes of establishing whether an appellant had timely filed a request for reconsideration, a request would be considered filed on the date it was received by the QIC, SSA, or CMS. However, for reconsideration requests submitted to CMS or SSA offices, the QIC's decision-making period would not begin until the QIC received the request.

We also specified that reconsideration requests could either be made using a standard CMS form, or some other written document, as long as it contained the key elements captured by the form; that is, the beneficiary's name, HIC number, date(s) of service and service(s) at issue, and the name and signature of the party or representative of the party. If the reconsideration request did not contain any one of the essential elements referenced above, we proposed that the QIC would dismiss the reconsideration on the basis that the party failed to make out a valid request.

We also proposed in §§ 405.964(c) and 405.970(b)(3) that QICs would consolidate multiple requests for reconsideration into a single proceeding, and would issue one reconsideration determination to all parties within 30 days of the latest reconsideration request.

Proposed § 405.970 set forth the general requirement that QICs would complete their reconsiderations within 30 days of receiving a timely filed request. By no later than the close of the 30-day decision-making period, a QIC would either issue its reconsideration, notify all parties that it would not be able to complete its review by the decision-making deadline, or dismiss the request for reconsideration. Pursuant to section 1869(c) of the Act, the notice that the QIC is unable to complete its reconsideration within the decision-making period would advise the appellant of the right to request escalation of the appeal to an ALJ. Under § 405.970(d), appellants would be able to submit a written request directing the QIC to escalate the appeal. We proposed that whenever a QIC received an escalation request, the QIC would take one of two actions within 5 days: (1) Complete its reconsideration and notify the parties of its decision; or (2) acknowledge the escalation request in writing and forward the case file to the ALJ.

Comment: A few commenters expressed concern about how appellants that filed appeals at alternative sites would know whether or when the proper adjudicator received their reconsideration request. To address this situation, the commenters recommended requiring adjudicators to send acknowledgement letters to appellants that file at alternative locations. Other commenters suggested requiring all adjudicators to use addresses that are accessible by delivery other than the U.S. postal service to enable appellants to file directly with the proper adjudicator.

Response: As discussed above in the context of requests for redeterminations, we agree with the commenter that appellants who use alternate filing locations would have difficulty determining if and when the proper adjudicator received their request. Our experience has been that very few appellants use alternative filing locations (for example, SSA field offices). However, when they do so, requests often do not arrive timely at the proper adjudicating entity. Moreover, as noted previously, consistent with section 931 of the MMA, SSA will no longer play a role in Medicare claims appeals. For these reasons, and consistent with the policy for redetermination requests, we have revised § 405.964(a) to specify that all requests for a reconsideration must be filed with the QIC indicated on the notice of redetermination. Just as we plan to do with intermediaries and carriers, we also will explore with QICs ways that we can create efficiencies in the appeals process, including establishing addresses for private delivery services.

Comment: Many commenters disagreed with the proposal of ''tolling

the decision-making clock'' for a QIC reconsideration when an appeal is filed at an alternative location (for example, at an SSA office rather than with the QIC). Commenters perceived this provision as unfairly penalizing appellants that used alternative filing locations. Rather than beginning the decision-making time frame only when a QIC receives an appeal request, commenters suggested that CMS develop an electronic filing system. An electronic filing system would allow appellants to continue filing their appeals at alternative filing locations and permit adjudicators to receive the appeals almost immediately, thereby eliminating the need to toll the decision-making clock. (Note that the issue of tolling the decision-making deadline also applies to other levels of the appeals process.)

Response: As discussed above, we believe the best way to facilitate a QIC's ability to adjudicate a reconsideration timely is to require that all reconsideration requests be filed at the QIC. Thus, the comments on the ''tolling of the clock'' issue are no longer pertinent. Note that redetermination notices will clearly specify the proper entity to whom to direct a reconsideration request. We do recognize that the development of an electronic filing system would make the appeals process more efficient; therefore, we intend to pursue this goal both with QICs and the new Medicare administrative contractors that are mandated by the MMA.

Comment: Some commenters inquired whether carriers and intermediaries would be required to create case files, or to forward redetermination letters and documentation to the QIC for reconsiderations. One commenter argued that the QIC's success in meeting its decision-making time frame would depend upon the contractors' compliance with a time frame to forward cases to the QICs. If contractors are responsible for forwarding case files to QICs, the commenters suggested that CMS establish a time frame in the regulation for performing this activity. One commenter recommended a 15-day time frame to complete both the preparation and forwarding of the case file.

Response: In order to achieve the statutory time frame for QIC decisions, efficient processing and forwarding of case files to the QICs is essential. From an appellant's perspective, however, this will be a seamless process, and we believe that the proper vehicle to address the mechanics of case file transmission is through our contractor evaluation process and manual instructions, rather than through regulations.

Comment: Some commenters pointed out that currently, some contractors define the date of receipt as the day that the contractor logs in the request, while others define it as the day the request is received in the contractor's mailroom. To eliminate confusion, one commenter asked that CMS clarify in the final rule that the date of receipt of a reconsideration request would be the date that the request arrived in the QIC's mailroom.

Response: We recognize the need for consistency in this regard and agree that inefficiencies in logging in an appeal request should not adversely affect an appellant. We intend to address the issue through the QIC contracts and instructions.

b. Withdrawal or Dismissal of a Request for Reconsideration

Proposed § 405.972 established provisions for withdrawing and dismissing requests for reconsideration. We proposed that appellants should be able to withdraw their reconsideration requests by filing a written request for withdrawal to the QIC within 14 calendar days of filing the reconsideration request. Under proposed § 405.972(b), we set forth the reasons why a QIC would dismiss a request for reconsideration (for example, if the party failed to make out a valid request consistent with the requirements identified in § 405.964). We also proposed under § 405.972(e) to allow appellants to request an ALJ review of a QIC dismissal of a reconsideration request if the request was filed within 60 days of the QIC's dismissal notice.

Comment: Some commenters asked us to give a rationale for allowing appeals of dismissals and remanding reversed dismissals. Other commenters argued that a reconsideration regarding the dismissal of a redetermination request should be final and not appealable. In addition, the same commenters asked that we include a provision that a subsequent reversal of a dismissal have no effect on a party's appeal rights.

Response: Although we recognize that permitting appeals of dismissals can be inefficient at times, we believe our approach of providing for review of dismissals at the next adjudicative level balances the need for review with the need for finality. Because dismissals will only be based on the circumstances involving the appeal request (for example, whether the party included the proper elements in its appeal request, (or whether it is a proper party to request an appeal) rather than the merits on whether the claim is payable, we do not believe further review is necessary. Accordingly we are adding § 405.1004(c) to specify that an ALJ's decision with respect to a QIC's dismissal of a reconsideration request is final and not subject to further review. Finally, we are not adopting the commenter's suggestion that a subsequent reversal of a dismissal have no effect on a party's appeal rights. On the contrary, a subsequent reversal by an ALJ of a dismissal would restore the party's reconsideration rights. Thus, it is necessary for the case to be remanded for the QIC to render a decision on the substantive issue of whether a claim must be paid.

Comment: We received many comments and questions on the procedural aspects of the dismissal provision in the reconsideration section of the proposed rule. Commenters asked us to specify the circumstances in which a dismissal would be appropriate and to identify what an appellant would need to show in order to successfully appeal the dismissal of a reconsideration request. The commenters also asked us to clarify the circumstances under which an adjudicator can dismiss a reconsideration request when a beneficiary dies.

Response: Section 405.972(b) describes the circumstances that warrant dismissal of a reconsideration request, either entirely or as to any stated issue. A dismissal is appropriate when the person or entity requesting a reconsideration is not a proper party under § 405.906 or does not otherwise have a right to a reconsideration under section 1869(b) of the Act. A dismissal also is warranted where a party fails to make out a valid request for reconsideration under § 405.964(a) and § 405.964(b) or fails to file a request within the proper time frame under § 405.962.

On appeal, the party contesting the dismissal must provide evidence sufficient to refute the basis for the dismissal. For example, if a reconsideration request were dismissed because the person filing the appeal is not a proper party, then the appellant would have to show that they are in fact a proper party.

We have amended § 405.972(b)(4) to identify, in the event of a beneficiary-appellant's death, the circumstances an adjudicator must consider to determine whether dismissing the reconsideration request prejudices another party. The adjudicator will look to determine whether all three circumstances are present: (1) The beneficiary's surviving spouse or estate has no remaining

financial interest in the case, based on whether either remains liable for the services, or 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 the appeal; and (3) no other party to the redetermination filed a valid and timely reconsideration request. For example, the QIC will dismiss the request if the beneficiary or the beneficiary's appointed representative filed the request for reconsideration, but the beneficiary was not held liable for the services at issue. The QIC will inquire whether the provider or supplier of the item or service wishes to continue the appeal. However, the QIC will not be required to inquire whether any other party wishes to continue the appeal unless a valid and timely request for reconsideration is filed by another party. We wish to note that when a beneficiary dies and the request is subsequently dismissed, a party, including the beneficiary's estate, may request the contractor to vacate the dismissal under § 405.972(d) for good and sufficient cause. Examples of good and sufficient cause include the possibility of Medicaid liability or the possibility that the State (which pays Medicaid funds) will attempt recovery of its payment from the estate.

As mentioned in our discussion above on parties to initial determinations and appeals, § 405.906(c) reflects that in the event of the death of a beneficiary, a provider or supplier will be able to appeal if no other party is available to appeal the redetermination. Thus, the provider or supplier of the item or service is able to request reconsideration in these circumstances.

Comment: Some commenters criticized the policy regarding dismissals of incomplete reconsideration requests. Rather than dismissing incomplete reconsideration requests, commenters thought that a better policy would be to inform appellants of the defect and afford them an opportunity to cure the defect. At a minimum, the commenters suggested an exception for beneficiaries.

Response: Consistent with the previous discussion of dismissals of redetermination requests, we do not agree with the commenters that QICs must be required to inform appellants of the defects in their reconsideration requests instead of being able to issue dismissals. We believe that this policy is reasonable given the new redetermination notice requirements and the simplicity of the elements of a valid reconsideration request.

Section 405.964(b) requires only five elements for making out a valid reconsideration request: (1) The beneficiary's name; (2) the beneficiary's Medicare health insurance claim number; (3) the 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 representative of the party; and (5) the name of the contractor that made the redetermination. We added the requirement that the party specify the contractor that made the redetermination to facilitate the QIC obtaining the case file from the appropriate contractor. Since QICs need this basic information in order to process an appeal, we believe that it is appropriate to require the party appealing to provide adequate information to identify the specific claim at issue. Further, the name and signature of the appellant is necessary to ascertain whether the individual requesting the appeal is in fact a party. This basic information is all that is required under § 405.964(b), and it essentially mirrors the information that would have already been provided by an appellant at the redetermination level. Thus, we believe that requiring QICs to accept appeal requests with insufficient information about the claim and to inform appellants of the defects in their appeal requests makes for an inefficient appeals process.

As under the former appeals process, CMS will create a standardized reconsideration form that will assist appellants, particularly unrepresented beneficiaries, with their requests. Furthermore, a dismissal of a request for reconsideration does not necessarily terminate a party's right to file an appeal. If the 180-day time frame for filing a request for reconsideration has not expired at the time a QIC issues a dismissal, then a party may correct the defect and resubmit the appeal. Additionally, if a party believes its reconsideration was inappropriately dismissed, it can either ask the QIC to vacate its dismissal, or appeal the dismissal to an ALJ.

Comment: A few commenters asked how the dismissal of a consolidated appeal or a remand resulting from a reversed dismissal affects a party's appeal rights.

Response: Under § 405.964(c), QICs are required to consolidate multiple requests for reconsideration of the same claim into one proceeding. The dismissal of a party's individual appeal request within a consolidated appeal does not affect any remaining party's appeal. When a dismissal is appealed to the next level, the adjudicator will determine if the dismissal is correct. If the adjudicator reverses the dismissal, the dismissal is vacated and remanded to the previous level of appeal. The remand of a vacated dismissal is meant to ensure that appeals are resolved at the lowest level possible. If one party's appeal is remanded on a consolidated appeal, all other parties' appeals on the same claim are remanded. The previous adjudicator will reopen the dismissal and issue a new determination. This new determination will provide appeal rights.

Comment: A few commenters opined that appellants should be able to withdraw a reconsideration request any time after filing the appeal request, but before a decision is rendered.

Response: Consistent with our policy for redetermination requests, we agree with the commenters that an appellant should be allowed to withdraw an appeal request any time after a request is filed, but before the QIC issues a decision. Thus, we have removed the proposed provision that a withdrawal request must be filed with the QIC within 14 calendar days of the filing of the reconsideration request. Section 405.972(a) now reads ''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 be received in the QIC's mailroom before the reconsideration is issued.''

c. Evidence Submitted With the Reconsideration Request

Proposed § 405.966(a) describes the type of evidence that accompanies reconsideration requests and specifies that the failure to submit documentation listed in the redetermination notice at the reconsideration level generally prevents the introduction of that evidence at subsequent appeal levels. Under proposed § 405.966(b), if appellants submit additional documentation after their request for reconsideration has been filed, including documentation listed in the redetermination notice, the late submission results in an automatic 14-day extension of the QIC's decision-making time frame. Section 933(a) of the MMA subsequently added a similar, new statutory requirement with respect to the full and early presentation of evidence.

Comment: When filing a request for reconsideration, proposed § 405.966(a) requires a party to present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the redetermination. In addition, the evidence would need to include any missing documentation

identified in the redetermination notice. Absent good cause, the failure to submit evidence generally prevents its introduction at subsequent levels of the appeals process. Many commenters perceived this ''penalty'' for failing to comply with the requirement for early presentation of evidence as too harsh.

Some argued that requiring beneficiaries to submit evidence and make allegations of fact and law at the reconsideration level changes the nature of the appeal from an informal review to an adversarial proceeding. These commenters believe that beneficiaries generally lack the resources and sophistication to make a showing at the time a reconsideration request is filed and are better able to present evidence and explain their case in a hearing. Other commenters indicated that requiring early presentation of evidence is unfair to all appellants, not just beneficiaries, especially since the proposed rule would allow CMS to enter an appeal as a party at the ALJ level and to submit evidence and position papers. To address this issue, commenters recommended either eliminating this provision entirely, or creating an exception to this requirement for unrepresented beneficiaries.

Response: Section 1869(b)(3) of the Act, as amended by section 933(a)(1) of the MMA, now specifies that providers and suppliers may not introduce evidence in any appeal that was not presented at the reconsideration conducted by the QIC, unless there is good cause that prevented the introduction of that evidence at or before that reconsideration. This statutory change is largely consistent with the policy identified in the proposed rule; therefore, we are adopting this provision as proposed for provider and supplier appellants.

However, we are establishing an exception to the ''full and early presentation of evidence'' requirement for beneficiaries. Specifically, we have added § 405.966(c) to allow beneficiary-appellants to submit documentation that was specified as missing in the notice of redetermination at any time during a pending appeal without the need for good cause. Note that § 405.966(c)(2) clarifies that this exception does not apply to beneficiaries who are represented by providers or suppliers. See the discussion above at Section II, B&, ''Redetermination, Notification, and Subsequent Limitations on Evidence'', for a complete discussion of this issue.

We will develop manual instructions requiring QICs to help beneficiary-appellants to obtain documentation requested in the notice of redetermination.

Any case involving the late submission of evidence, including appeals by beneficiaries, will continue to result in a 14-day extension of the decision-making time frame. We believe this policy is necessary to encourage all appellants to submit evidence with their appeal requests and to ensure that adjudicators have adequate time to thoroughly review all evidence prior to issuing a decision. A 14-day extension does not apply when the submission of evidence is in response to a request by a QIC, unless the QIC's request pertains to documentation specified in the redetermination notice.

Any evidence submitted after the reconsideration level by providers, suppliers, or beneficiaries who are represented by a provider or supplier, will be evaluated against a good cause standard for late filing described at § 405.1028. Note that the full and early presentation of evidence requirement established under section 933 of the MMA and § 405.966 does not apply to CMS, and therefore, it does not limit CMS' ability to introduce evidence at the ALJ level. CMS still must submit any evidence within the time frame designated by the ALJ. An extension of this deadline is permissible for good cause at the discretion of the ALJ.

Comment: Proposed § 405.966(b) allows the QIC to automatically extend its time frame by 14 additional days when a party submits additional evidence after filing its reconsideration request. One commenter recommended that the automatic 14-day extension apply only once, even if an appellant makes more than one late submission.

Response: Consistent with our policy for redeterminations, a party may submit additional evidence as many times as it deems appropriate until the QIC issues a decision, but the QIC may extend its decision-making deadline by up to 14 days each time. Thus, we have clarified in § 405.966(b) that the 14-day extension applies each time a party submits additional evidence. We note that this provision also applies to late submissions of evidence by other parties to the appeal. The 14-day extension allows time for the QIC to carefully review and consider the additional evidence. Again, although the QIC may extend the deadline, by no means do we anticipate that QICs will use the maximum time to issue decisions in all cases. The only time that the submission of evidence will not trigger the automatic 14-day extension is when the QIC requests documentation not previously requested in the redetermination notice.

9. Conduct of a Reconsideration (§ 405.968 and § 405.976)

[If you choose to comment on issues in this section, please include the caption ''Conduct of a Reconsideration'' at the beginning of your comments.]

In proposed § 405.968, we defined a QIC reconsideration as ''an independent, on-the-record review of an initial determination, including the redetermination.'' If an initial determination involved a finding on whether an item or service was 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 be based on clinical experience and medical, technical, and scientific evidence, to the extent applicable. Under proposed § 405.968(b), QICs would be bound by NCDs. QICs would be required to follow LCDs, LMRPs and CMS program guidance unless the appellant questioned the policy and provided a persuasive reason why the policy should not be followed.

Under proposed § 405.976, we specify that reconsiderations be in writing and contain several substantive elements, including: (1) A clear statement as to whether the reconsideration is favorable or unfavorable; (2) a summary of the facts; (3) an explanation of how the pertinent laws, regulations, coverage rules, and CMS policies apply to the facts; (4) an explanation of the medical and scientific rationale for the reconsideration when the case involved determining whether an item or service was reasonable or necessary for the diagnosis or treatment of an illness or injury; and (5) a clear statement of the QIC's rationale for its decision. Consistent with proposed § 405.968(b)(3), if the QIC's decision conflicts with an LCD, LMRP, or with program guidance (for example, a CMS manual instruction), the notice needs to include the QIC's rationale for not following the policy in question. Similarly, consistent with proposed § 405.976(b)(5), the reconsideration notice needs to address how any missing documentation affects the reconsideration and the limitations on the presentation of evidence at the ALJ hearing level.

Comment: We received many comments on the provision requiring QICs to give deference to a local coverage determination (LCD) or local medical review policy (LMRP) unless an appellant questions the policy and provides a reason why the policy should not be followed that the QIC finds persuasive. Some commenters thought that CMS had exceeded its statutory

authority by binding QICs to LCDs and LMRPs and questioned the propriety of requiring QICs to give deference to policies that they allege sometimes contradict statutes and regulations, and that are not promulgated through notice-and-comment rulemaking. They also expressed concern over whether unrepresented beneficiaries would be able to effectively challenge CMS policies and noted that requiring QICs to give deference to LCDs and LMRPs would prevent QICs from reviewing these policies.

Response: We continue to believe that it is both appropriate and consistent with the statutory intent of BIPA to require QICs to consider LCDs and LMRPs and other CMS program guidance and to apply these policies appropriately in a particular case. A QIC is not required to follow a given policy in an individual case if it believes that the policy is not legally persuasive under specific circumstances. However, this does not mean a QIC may ignore or invalidate an LCD for all subsequent appeals. The Congress created a new and entirely separate process for reviewing the validity of LCDs in section 1869(f) of the Act, as added by section 522 of BIPA. Section 1869(f) of the Act permits beneficiaries who are seeking coverage from an item or service to challenge the reasonableness of an LCD. A challenge to an LCD under section 522 of BIPA is reviewed by an ALJ.

As the commenter suggests, however, we have reevaluated the proposed requirement that a QIC could choose not to follow LCDs, LMRPs, and CMS program guidance only if the appellant questioned the policy and provided a persuasive reason why the policy should not be followed. As a result, we have revised § 405.968 to provide that a QIC may decline to follow a policy in a particular case either at the request of a party or at its own discretion.

Thus, as revised, § 405.968 states that a QIC is not bound by LCDs, LMRPs, or CMS program guidance, but will give substantial deference to these policies if they are applicable to a particular case. Moreover, 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. Thus, QICs will not review LCDs, LMRPs, or other CMS guidance. Rather, they will evaluate the applicability of the LCD, LMRP, or CMS guidance to a particular claim denial. Their decisions will not affect subsequent cases and are not precedential. A QIC does not have the authority to require CMS or a contractor to withdraw or revise its LCDs, LMRPs, or other guidance. This amended provision eliminates the burden imposed on appellants, including beneficiaries, to challenge CMS policies in the claim appeals process. (See section II.G.5 of this preamble for a related discussion of ALJ and MAC consideration of local coverage policies.)

We also note that section 522 of BIPA created a new review process that enables certain beneficiaries to challenge LCDs at the ALJ hearing and MAC review levels and NCDs at the MAC review level. Thus, we believe that it is important to note how the coverage appeals process could affect QICs in processing claim appeals.

If a party appeals a denial that is based on an LCD or NCD by filing only a claim appeal, then adjudicators will apply the coverage policy that was in place on the date the item or service was received, regardless of whether some other beneficiary has filed a coverage appeal based on the same LCD or NCD. This policy is consistent with original Medicare policy that requires LCD or NCD changes to only be applied prospectively to requests for payment.

If an appellant files both a claim and a coverage appeal based on the same initial determination, both appeals will go forward. The claim appeal adjudication time frames will not be impacted because the appeals will be conducted simultaneously. In adjudicating the claim appeal, adjudicators will apply the coverage policy that was in place on the date the item or service was provided, unless the appellant receives a favorable coverage appeal decision. If the appellant receives the favorable coverage decision prior to a decision being issued for the claim appeal, then pursuant to 42 CFR § 426.488 and § 426.560, the claim appeal will be adjudicated without consideration of the invalidated LCD or NCD provision(s). If an appellant receives a favorable decision in the coverage appeal after receiving an unfavorable claim appeal decision, then the appellant is entitled to have the claim appeal reopened and revised for good cause, subject to the provisions in § 405.980 and § 405.986, without consideration of the invalid LCD or NCD provision(s). As a result of these clarifications, we have added § 405.1034(c) to permit ALJs to remand an appeal to a QIC in this situation.

Comment: Although a few commenters agreed with the proposal that all QIC proceedings would be ''on-the-record,'' most commenters opposed this proposed policy and recommended that QICs be required to offer appellants an opportunity for a hearing, as has been the case under the existing Part B fair hearing process. Commenters stated that requiring all QIC proceedings to be held on-the-record was contrary to congressional intent and would limit an appellant's ability to interact with the adjudicator. The commenters believed that appellants would be deprived of an important opportunity to provide adjudicators with clarifications and additional information not contained in the record, and that adjudicators would not have an opportunity to personally assess a beneficiary's physical/mental condition. Commenters suggested that beneficiary appellants in particular would be adversely affected by this policy. Other commenters agreed that QICs should not be required to conduct in-person or telephone reconsiderations within the statutory decision-making time frame, but expressed concern over the accuracy of the QICs' on-the-record decisions.

Response: As the commenters point out, under the existing appeals process, appellants have had an opportunity to request a ''fair hearing'' with respect to Part B determinations. This process, which has involved on-the-record, telephone, or in-person proceedings, has served as the second level of appeals for Part B claims, consistent with section 1842(b)(3)(C) of the Act, which specifies that an individual will be granted an opportunity for a fair hearing by the carrier in any case where the amount in controversy is at least $100. Section 1842(b)(2)(B)(ii) of the Act establishes a 120-day deadline for the fair hearing decision. The existing regulations governing appeals under Medicare Part B, in Subpart H of Part 405, describe the available hearing procedures.

However, the right to a fair hearing has never been part of the appeals process for Part A claims. For these claims, § 405.710 establishes a right to a ''reconsideration.'' Neither the statute nor the implementing regulations under Subpart G of Part 405 provide for any type of hearing before the ALJ level for Part A claims. Neither the statute nor the regulations establish a minimum amount in controversy for Part A reconsiderations.

In contrast to the pre-BIPA statute, revised section 1869 of the Act establishes a uniform set of appeals requirements for all Part A and Part B claim determinations. The required procedures now available under the statute consist of a ''redetermination'' by an intermediary or carrier, a ''reconsideration'' by a QIC, a ''hearing'' before an ALJ, and then a ''review'' by the DAB. As under the existing Part A process, the statute does not establish any minimum amount in controversy

for reconsiderations and sets this amount at only $100 for ALJ hearings.

Section 1869 of the Act, as amended by BIPA and the MMA, does not require, or even mention, a hearing at the QIC level. Instead, section 1869(c)(3)(B)(i) of the Act specifies that in conducting a reconsideration, the QIC ''* * * shall review initial determinations'' and that when the determination involves whether an item or service is reasonable and necessary under section 1862(a)(1)(A) of the Act, ''* * * such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and [decisions] shall be based on applicable information, including clinical experience (including the medical records of the individual involved) and medical, technical, and scientific evidence.'' The statute then specifically provides for ''hearings'' at the ALJ level under section 1869(d)(1). Finally, the Congress established rigorous decision-making time frames at all levels of the appeals process that will significantly reduce the amount of time in which an appellant who chooses to use the ALJ process will obtain a decision.

Taking into consideration all of the above information, we believe our proposal is consistent with the substantially revised appeals methodology, including faster decision-making time frames, physician reviewers, and lower amount in controversy thresholds. We believe that the Congress was fully aware of the historical meaning of the terms ''reconsideration'' and ''hearing'' and did not use them lightly in the new statute. Appellants retain the right to a hearing at the ALJ level, and this hearing will take place generally within the same time frame as a ''fair hearing'' under the previous Part B appeals process. Thus, we continue to believe that the statute does not intend or require that the QIC reconsideration process include an opportunity for a hearing. Finally, we note that QICs are not precluded from contacting appellants and obtaining necessary information from them by phone or other means.

Comment: A few commenters inquired about the QICs' ability to hear or raise new issues. One commenter recommended that QICs be prohibited from raising new issues. Most commenters, however, agreed that QICs should be able to hear or raise new issues not raised at the initial determination or redetermination levels. In a related question, another commenter asked whether a QIC panel would adjudicate an appeal if a section 1862(a)(1)(A) issue (that is, a medical necessity issue) was raised for the first time at the reconsideration level.

Response: A reconsideration is a new and independent review of an initial determination and we believe adjudicators at the reconsideration level should be permitted to raise and develop any issues that they believe are relevant to the claims in the case at hand. Accordingly, we have added § 405.968(b)(5) to clarify this policy. Section 1869(c)(3)(B)(i) of the Act requires that a reconsidered determination involve consideration by a panel of physicians or other health care professionals when the initial determination is based on section 1862(a)(1)(A) of the Act. Thus, if a medical necessity issue was raised for the first time at the reconsideration level, we believe that review by a panel of health professionals would be required. Although the panel may consider new issues involving the claims in dispute, it must not adjudicate new claims for which the contractor has not issued a redetermination.

Comment: One commenter thought that the redetermination and reconsideration levels were redundant and suggested eliminating one in order to make the appeals process more efficient.

Response: Section 1869(a)(3)(A) of the Act gives appellants who are dissatisfied with their initial determination the right to request a redetermination. If an appellant is dissatisfied with the redetermination, then section 1869(b)(1)(A) of the Act grants the appellant the right to request a reconsideration. Thus, both the redetermination and reconsideration levels are unambiguously required by statute. It is not within CMS' discretion to eliminate either the redetermination or reconsideration levels of appeal.

a. Time Frame for Making a Reconsideration

Comment: Proposed section 405.970(c) specified that, by no later than the close of the 30-day decision-making time frame, a QIC must issue to the parties either a reconsideration, a dismissal, or a notice stating that the QIC will not be able to complete its review by the deadline. The notice would also advise the appellant of the right to request escalation of the appeal to an ALJ. CMS further specified that, whenever a QIC receives an escalation request, the QIC, within 5 days, would either complete its reconsideration and notify the parties of the decision, or acknowledge the escalation request and forward the case file to an ALJ.

A number of commenters felt that BIPA unequivocally requires QICs to issue reconsiderations within 30 days of their receipt of a request for reconsideration. Thus, they were critical of the proposed policy to allow a QIC to issue a notice to an appellant indicating that it is unable to complete a reconsideration within the prescribed decision-making time frame. The commenters complained that allowing QICs to issue these notices, rather than an actual reconsideration, contradicts the statutory intent and creates a loophole for QICs to avoid compliance with the decision-making time frames established by BIPA.

Response: We realize that the Congress intends for QICs to issue reconsiderations in response to timely filed reconsideration requests within 60 days as stated in section 1869(c)(3)(C)(i) of the Act (as amended by section 940(a)(2) of the MMA). We disagree, however, with the assertion that the drafters envisioned that QICs would be able to issue timely decisions for every reconsideration request no matter what the circumstances involved. To the contrary, the Congress clearly expected that there would be situations in which QICs would not be able to comply with the statutory decision-making time frames, as evidenced by the inclusion of the escalation provisions of section 1869(c)(3)(C)(ii) of the Act, ''Consequences of Failure to Meet Deadline.'' Here, the Congress created a new right for appellants to escalate appeals to the ALJ level in the event that the QIC failed to mail the notice of reconsideration within the decision-making time frame. In order to accommodate appellants' ability to exercise this right, it is essential that QICs provide appellants with a notice when a reconsideration cannot be issued timely.

Sections 405.970(a)(2) and 405.970(c)(2), therefore, do not conflict with the statutory intent or create a loophole for avoiding compliance with the statutory decision-making time frames. Rather, these provisions help guarantee that appellants will be able to exercise their right to escalate an appeal by ensuring that appellants receive timely notice of the QIC's inability to issue a reconsideration within the statutory time frame. We believe this process is highly preferable to not informing an appellant of this fact. We also wish to point out that if an escalation request is received prior to the end of the 60-day adjudication period, the QIC will proceed with its review of the reconsideration request

and either (1) issue its reconsideration by the end of 65 days (the 60-day period plus 5 days from receipt of the request to escalate) or (2) send notification to the party on the 60-day deadline that the QIC cannot complete its review by the 60-day deadline and escalate the request at that time.

Comment: Two commenters expressed concern over applying the 30-day decision-making time frame to reconsiderations of post-pay audit cases involving statistical sampling. The commenters stated that the large volume of claims to be reviewed for these types of cases would prevent QICs from ever meeting the 30-day time frame or would force the QICs to simply rubberstamp the redetermination in order to meet the 30-day deadline. The commenters further surmised that ALJs would regularly overturn QIC reconsiderations on these ''big box'' cases for lack of development. The commenters recommended that CMS either provide a longer decision-making time frame for these types of cases, or bypass the reconsideration level for these cases and allow appellants to go to the ALJ hearing level if they are dissatisfied with the audit determination.

Response: We appreciate the commenters' observation that it will be difficult for the QICs to process ''big box'' cases resulting from complex post-payment audits that involve individual consideration of multiple claims in a timely manner, even under the new 60-day time frame established by section 940(a)(2) of the MMA. At this point, we do not have a basis for direct evaluation of this issue since the QICs are not yet conducting reconsiderations. However, we know that in the former appeals process when a fair hearing officer receives a ''big-box'' case, it generally has taken 60 days to review the extensive medical records and other documentation associated with these cases. As mentioned in the previous response, we believe that the Congress expected that there would be situations in which QICs would not be able to comply with the decision-making time frame, as evidenced by the inclusion of the escalation provision of section 1869(c)(3)(C)(ii) of the Act. Thus, if an adjudicator fails to complete a reconsideration of a ''big-box'' case within 60 days, an appellant has the option of either waiting for the QIC's reconsideration, or requesting escalation of the case to the ALJ hearing level. We intend to work very closely with carriers, FIs, and QICs to identify ways to streamline the redetermination case file transmission and reconsideration procedures in order to facilitate the achievement of this deadline.

b. Notice of a Reconsideration

Comment: Because the proposed rule gives providers and participating suppliers the same appeal rights as beneficiaries, some commenters wondered who would receive the reconsideration notice if both the beneficiary and the provider or supplier filed timely appeals.

Response: Section 405.964(c) establishes that ''[i]f 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.'' Thus, pursuant to §§ 405.970(c)(1) and 405.976(a)(1), all of the parties will receive a copy of the reconsideration. This applies to all reconsiderations, including consolidated cases. To minimize confusion for beneficiaries who have no financial liability in overpayment cases involving multiple beneficiaries, we added an exception at § 405.976(a)(2) that QICs need to issue written notices only to the appellants in these cases. Therefore, the beneficiary will only receive a written notice of the reconsideration in such an overpayment case when he or she files an appeal request or it is a consolidated case.

We also note that we have added a requirement at § 405.976(b)(7) that the QIC must also indicate whether the amount in controversy meets the threshold requirement for an ALJ hearing if the reconsideration is partially or fully unfavorable. We believe this addition will be beneficial to appellants as well as to adjudicators at those levels where AICs apply.

c. Publication of Reconsiderations

Comment: Citing the statutory requirement to make reconsiderations available, two commenters suggested that the final rule include information about publication of QIC reconsiderations. Specifically, the commenters thought that CMS should establish a time frame for publication of QIC decisions and identify how the public would be able to view and obtain copies of reconsiderations, in order to ensure that appellants have access to prior reconsiderations as they make their own reconsideration requests.

Response: Section 1869(c)(3)(G) of the Act requires QICs to make reconsiderations available, but does not require CMS or the QICs to ''publish'' all reconsiderations. However, we do not believe that this interim final regulation is the appropriate vehicle to provide information regarding the availability of reconsiderations. CMS is working with the QICs to determine how best to provide the public with specific information regarding prior QIC reconsiderations.

Although we expect QICs to issue consistent reconsiderations, and appellants will have access to those prior reconsiderations, it is worth noting that reconsiderations, like all other Medicare administrative appeal decisions, have no precedential value. Moreover, based on current workload, there may be as many as one million QIC reconsiderations a year; given the large volume of anticipated reconsiderations, we do not intend to ''publish'' them, but we will ensure they are made available.

d. QIC Qualifications

Comment: Many commenters asked that the final rule include more explicit information about the QICs. In particular, commenters wanted the final rule to identify the minimum qualifications for the QIC panel members and reviewers, clearly define the role of the QIC panel in the reconsideration process, and describe the on-going training that would be made available to the panel members and reviewers. Most of these commenters strongly believe that QIC panelists should be licensed, practicing health care professionals with sufficient expertise in the relevant area of medicine involved in the appeal, and also possess some legal experience. One commenter suggested that the requirements currently used for Quality Improvement Organization (QIO) reviewers might be a good model for developing the QIC reviewers' qualifications. Commenters also asked that the final rule spell out the provisions that would be put in place to ensure the QICs' independence.

Response: We agree with commenters that details regarding the qualifications of the QICs' panel members and reviewers, the structure of the QICs, and their operational policies need to be established before implementation of the new appeals process. Both BIPA and the MMA have provided extensive direction in regard to QIC independence requirements and the eligibility requirements for QIC reviewers, and we intend to ensure through the QIC contracting process that QICs are fully compliant with these requirements. We have also established QIC training requirements through the procurement process. However, we do not believe it is necessary or appropriate to address these types of issues in regulations, and instead will follow the normal business

practice of including this information in the contracts with the QICs.

Comment: Although commenters overwhelmingly agreed that using panels of health care professionals at the QIC level would be an improvement over the current appeals process, at least one commenter questioned the cost-effectiveness of using these panels for appeals involving low dollar claims and recommended that we develop alternative ways of reviewing these kinds of appeals.

Response: We appreciate the commenter's concern and recognize that using panels of physicians and other health care professionals to review appeals of section 1862(a)(1)(A) denials will not always be cost-effective. However, based on the unambiguous language in section 1869(c)(3)(B)(i) of the Act, the Congress clearly intended that panels of physicians or other health care professionals review all appeals involving determinations on whether an item or service is reasonable or necessary, regardless of the dollar value of the claim(s) involved. We intend to work with QIC's to determine the most cost-effective means of fulfilling this statutory requirement.

10. Reopenings of Initial Determinations, Redeterminations, Reconsiderations, Hearings and Reviews (§ 405.980 through § 405.986)

[If you choose to comment on issues in this section, please include the caption ''Reopenings of Initial Determinations, Reconsiderations, Hearings, and Reviews'' at the beginning of your comments.]

Section 1869(b)(1)(G) of the Act, as added by BIPA, provides for the reopening and revision of any initial determination or reconsidered determination according to guidelines prescribed by the Secretary. As we pointed out in the proposed rule, clear reopening provisions are needed not only to comply with BIPA, but also to address longstanding confusion over the reopening rules for Medicare claim determinations. Thus, we proposed to establish a unified set of reopening regulations that consolidate and clarify the existing reopening provisions of subparts G and H of part 405. (*See* 67 FR 69327.)

First, proposed § 405.980(a) establishes the general rule that a reopening is a remedial action taken by a carrier, intermediary, QIC, ALJ, the MAC, or any other entity designated by CMS to change a final determination or decision made with respect to an initial determination, redetermination, reconsideration, hearing, or review, even though the determination or decision may have been correct based upon the evidence of record. (For purposes of reopenings, the term ''contractors'' includes carriers, intermediaries, and program safeguard contractors.) Under proposed § 405.980(a)(4), we define a clerical error as human and mechanical mistakes (for example, mathematical or computational mistakes, or inaccurate data entry).

Proposed § 405.980(b) through § 405.980(e) specify the time frames and requirements for reopening initial determinations, redeterminations, reconsiderations, hearing decisions, and reviews, both for reopenings initiated by contractors, QICs, ALJs, or the MAC, as well as those requested by parties. Either a party can request a reopening, or a contractor can reopen on its own motion, for any reason, within one year from the date of the notice of the initial determination or redetermination. A party or a contractor has a 4-year time frame for requesting or initiating reopenings for good cause. However, although a party can request a reopening, the contractor can nevertheless determine that there is not good cause to reopen the case. (An example of good cause to reopen based on a clerical error is when payment for a claim is denied because an erroneous code, which is not covered by Medicare, was used and it is later determined that the procedure was miscoded.) We also proposed that a contractor can reopen within 5 years from the date of the initial determination or redetermination if the contractor discovers a pattern of billing errors or identifies an overpayment extrapolated from a statistical sample.

Finally, we proposed to maintain the longstanding policy that reopenings are permitted at any time on claim determinations that have been procured through fraud or similar fault. Proposed § 405.980(b)(4)(ii) defines similar fault as ''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 it filed a proper claim as defined in part 411 of this chapter.'' Similar fault is intended to cover instances where Medicare payment is obtained by those with no legal rights to the funds, but where law enforcement is not proceeding with a recovery based on fraud. This includes instances where a provider has been paid twice for the same claim where the contractor erroneously pays for codes that should not have been paid, but there is no evidence that the provider intentionally failed to refund the money; or where there is the manipulation of legitimate codes to obtain a higher reimbursement. While this last example might appear to be an example of fraud, it is also an example of an instance when the similar fault provision might be used. The similar fault provision is appropriately used where fraudulent behavior is suspected but law enforcement is not proceeding with recovery on the basis of fraud.

Proposed § 405.980(d)(1) and § 405.980(e)(3) provide 180 days from the date of a reconsideration for either a party to request, or a QIC to initiate, a reopening. Similarly, both the parties and the adjudicators at the ALJ and MAC levels also have 180 days from the date of a hearing or review decision to request or initiate a reopening. The party, QIC, ALJ, or the MAC have to establish good cause for a reopening.

Proposed § 405.982 through § 405.984 require contractors, QICs, ALJs, or the MAC to mail notices of revised determinations or decisions based on reopened determinations, reconsiderations, or decisions to the appropriate parties at their last known addresses. In the case of a reopening that results in a favorable decision and issuance of additional payment to a provider or supplier, a revised remittance advice (RA) must be issued to the provider or supplier that explains the payment and reports the appeal rights; this RA will serve as the notice of the reopening determination. In the case of a reconsideration that results in additional payment to a provider or supplier, both a reconsideration determination notice and an electronic or paper remittance advice notice must be issued. Proposed § 405.986 specifies how a party, contractor, QIC, ALJ, or the MAC would establish good cause for a reopening. In this interim final rule, we have revised proposed § 405.986(b), to clarify that although a change in substantive law or interpretative policy is not good cause for reopening, the provision does not preclude contractors from reopening claims to effectuate a decision issued under section 1869(f) of the Act, as amended by section 522 of BIPA. The final regulation implementing the coverage appeals process was published after the notice of proposed rulemaking for this regulation was issued. Thus, we have now added language at § 405.980(b)(5) to enable contractors to reopen claim determinations at any time in order to effectuate favorable coverage appeals decisions issued to a beneficiary. We

wish to make clear that this provision does not allow retroactive application of coverage decisions to payment denials.

a. Reasons and Conditions for Reopenings

Comment: Several commenters mentioned that the proposed definition for a reopening does not acknowledge that the purpose of a reopening is to ensure correct payment amounts; and therefore, a reopening may result from either an overpayment or an underpayment. They believed that CMS should clarify in the regulations that a reopening can be initiated for either an overpayment or an underpayment.

Response: We agree with the commenter that the underlying goal of the reopening process is to pay claims appropriately, subject to considerations of administrative finality. In the proposed rule (67 FR 69327), we state that, ''the purpose for conducting a reopening should be to change the determinations or decisions that result in either overpayments or underpayments.'' To accommodate this concept in the regulations, we have added text at § 405.980(a)(1) that makes clear that a reopening is an action to change a final determination or decision that results in either an overpayment or an underpayment.

Comment: One commenter requests clarification on the conditions for reopening. The commenter seeks further clarification on whether good cause is required for reopenings that occur within 1 year from the date of the initial determination or redetermination, or whether a contractor would grant a request for reopening for any reason within the one-year time frame.

Response: The authority for a contractor to reopen a claim or appeal within one year from the date of the initial determination or redetermination for any reason exists under § 405.750(b)(1) and § 405.841(a). Therefore, we have removed proposed text formerly in § 405.980(a)(2)(i) in order to avoid the implication that contractor reopenings within one year are premised on good cause. This is consistent with § 405.980(b)(1) and § 405.980(c)(1), which maintain the authority for contractors to reopen claims or appeals within 1 year for any reason. Thus, contractors do not need to establish good cause under § 405.986(a) to reopen within 1 year.

We also note that under § 405.980(b)(3), contractors may reopen at any time if there exists reliable evidence that an initial determination was procured by fraud or similar fault. In addition, we have added § 405.986(c) to provide that if a third party payer changes its assessment of whether it has primary payment responsibility more than 1 year after the date of Medicare's initial determination, the contractor is without authority to find good cause to reopen a claim.

b. Distinguishing Between Reopenings and Appeals

Comment: Two commenters express uncertainty over whether CMS intends for contractors to process corrections of clerical errors as reopenings or appeals. One commenter contends that CMS provides conflicting information by suggesting in one section of the preamble that adjustments resulting from clerical errors are handled through the reopenings process, while stating in another section of the preamble, that either a party would need to exhaust all appeal rights, or the time limit to file an appeal would need to expire, in order for the contractor to conduct a reopening to correct these errors. Another commenter maintains that the proposed rule requires human or mechanical errors to go through the appeals process instead.

Response: As we stated in the proposed rule, ''requests for adjustments to claims resulting from clerical errors must be handled through the reopenings process. Therefore, when a contractor makes an adjustment to a claim, the contractor is not processing an appeal, but instead, conducting a reopening'' (67 FR 69327). Moreover, section 937 of the MMA subsequently amended the Act to specify that in the case of minor errors or omissions that are detected in the submission of claims, CMS must give a provider or supplier an opportunity to correct that error or omission without the need to initiate an appeal. We equate the MMA's minor errors or omissions to fall under our definition of clerical errors, located in § 405.980(a)(3). We believe that it is neither cost efficient nor necessary for contractors to correct clerical errors through the appeals process. Thus, § 405.927 and § 405.980(a)(3) require that clerical errors be processed as reopenings rather than appeals. Consistent with the process that we developed in consultation with Medicare contractors, and representations of providers and suppliers as required under section 937 of the MMA, we have made a conforming change at § 405.980(a)(3) to specify that contractors must grant reopenings for clerical errors or omissions. Section 405.980(a)(4) of this interim final rule states that a contractor may reopen and revise its initial determination or redetermination on its own motion 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. In the event that a contractor does not believe that a clerical error exists, the contractor must dismiss the reopening request and advise the party of its ability to pursue to the appeals process on the claim denial, provided the timeframe to request an appeal has not expired. It should be noted that the party would be requesting an appeal of the original denial, not the dismissal of the reopening request. Reopenings continue to be discretionary actions on the part of the contractors; therefore, their decision not to reopen is not subject to appeal.

Similarly, we believe that improper denials based on duplicate claims essentially involve clerical errors that can be best resolved through the reopenings process. When a provider or supplier receives a denial based on the contractor's determination that the claim is a duplicate and the provider or supplier believes the denial is incorrect, and the contractor agrees that the denial was incorrect, the contractor should reopen the denial. Thus, we added text at § 405.980(a)(3)(iii) to specify that if a provider or supplier wishes to resolve a denial based on a claim being erroneously identified as a duplicate, the contractor should process the request as a reopening rather than as an appeal. In the event the contractor does not believe the denial was improper, 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.

Comment: One commenter was concerned that the proposed rule would limit opportunities for reopenings, because proposed § 405.980(a)(5) would preclude a reopening when a party has filed an appeal request. The commenter asked whether one can assume that a reopening will not be granted when a provider requests an appeal of a denial or partial payment such as that resulting from a provider submitting an incorrect CPT code, diagnosis code, or modifier.

Response: Under normal circumstances, a valid request for an appeal must be processed as an appeal, and once an adjudicator receives a valid appeal request, the entity that made the previous determination generally no longer has jurisdictional authority to reopen that determination. We have revised § 405.980(a)(4) to clarify this point.

Section 405.980(a)(4) ensures that the reopening and appeal processes are not engaged at the same time. We recognize,

however, that in certain situations, it will be apparent that the provider that is requesting an appeal is actually bringing a clerical error to the attention of the contractor. Under this interim final rule, irrespective of the provider's or supplier's request for an appeal, a contractor will treat the request for appeal of a clerical error as a request for a reopening. Therefore, as a practical matter, under § 405.980(a)(4), the contractor must transfer the provider's or supplier's appeal request to the reopenings unit for processing. On the other hand, if a contractor receives a request for a reopening, but disagrees that the issue is a clerical error, then the contractor must dismiss the reopening request and advise the party of any appeal rights, provided that the timeframe to request an appeal on the original denial has not expired.

CMS understands that educational efforts must be undertaken in conjunction with this regulation to make the provider and supplier communities aware of their ability, and the contractor's obligation to resolve clerical errors through the reopenings process. Until that education occurs, many providers and suppliers may continue to believe that their only, or best, recourse is to request an appeal.

c. Similar Fault and Reopenings Within 5 Years

Comment: As noted above, proposed § 405.980(b)(4)(ii) defines similar fault as ''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 it filed a proper claim as defined in part 411 of this chapter.'' Several commenters believe that this definition is too broad and allows contractors to reopen almost any claim, for any reason.

Response: The definition of similar fault covers situations where a contractor identifies an inappropriate billing that does not rise to the level of fraud. It is necessary to define similar fault as those situations when a contractor has identified inappropriate billing by a provider or supplier that knows or could have been reasonably expected to know that the claim should not have been paid for items or services, but the situation is not one where a law enforcement agency has made a determination that the billing is fraudulent. The similar fault provision is appropriately used where fraudulent behavior is suspected but law enforcement is not proceeding with recovery on the basis of fraud. We do not believe this definition is overly broad, given the implicit requirement that the fault be ''similar'' to fraud.

Comment: Several commenters express concern over the provision in the proposed rule at § 405.980(b)(3), which allows a contractor to reopen initial determinations and redeterminations within 5 years of discovering a pattern of billing errors, or identifying an overpayment extrapolated from a statistical sample. The commenters point out the difficulty and burden in locating documentation on older claims. The commenters also argue that CMS does not provide a rationale for the proposed 5-year time frame.

Response: CMS proposed this provision in an effort to accommodate overpayments identified by external auditors and law enforcement agencies. There were instances where auditors utilized a 5-year sampling methodology, identified an overpayment, and instructed the Medicare contractor to recoup the overpayment. Since the audit results were usually amounts extrapolated from a statistical sample based on 5 years of records, carriers and intermediaries experienced difficulty collecting the overpayments because § 405.750(b)(2) and § 405.841(b) bound carriers and intermediaries to a 4-year limit for the identification and collection of overpayments where a law enforcement agency did not make a fraud determination.

However, we recognize providers' concerns with this proposal and consequently have decided to remove it from the final regulation. To the extent that law enforcement findings suggest a need for reopenings in situations that involve inappropriate billing patterns, but fall short of outright fraud, contractors may rely on the similar fault provision at § 405.980(b)(3) to reopen claims.

Comment: One commenter asks whether proposed § 405.980(b)(4), which allows contractors to reopen initial determinations procured by fraud or similar fault, is limited to initial determinations that have not been appealed or reopened.

Response: Section § 405.980(a)(4) of this interim final rule requires that when a party files a valid request for an appeal, the adjudicator no longer has jurisdiction to reopen the pending claim or appeal at issue. However, in cases of fraud or similar fault, the government may be pursuing legal action for claims it suspects are fraudulent, an activity which falls outside of the administrative appeals process. In the event legal action results in a favorable decision for CMS, CMS has the ability to reopen the claims in question and recoup any overpayment. Additionally, if a claim has gone through the appeals process on a completely separate issue, CMS may reopen the claim, but only to address an issue not previously decided on appeal. For example, if a claim is denied as not medically necessary and that denial on medical necessity is the issue being brought before the adjudicator on appeal, yet an issue of fraud is discovered on the same claim, the claim may be reopened to address the issue of fraud not previously considered on appeal. The reopening action on the fraud issue would occur only after the claim had proceeded through the appeals process on the medical necessity issue. Any unfavorable decision that was issued based on the subsequent reopening would generate appeal rights and any party to that determination would be able to contest any new denial through the appeals process. A previously appealed claim could also be reopened by the adjudicator to correct a later discovered clerical error.

Comment: One commenter asks if it is CMS' intent to revise § 405.355(b), which allows a reopening for the collection of an overpayment within 3 years from the date of the initial determination.

Response: Section 405.355(b) pertains to the waiver of an adjustment or recovery from a provider or other individual who is deemed to be without fault. The provision does not address a contractor's ability to reopen an initial determination or redetermination, and is not affected by this interim final rule.

d. Authority To Reopen

Comment: One commenter recommends that CMS require in the regulation text that a determination or decision can be reopened only by the entity that rendered the decision. For example, only a QIC can reopen a QIC's decision.

Response: As originally proposed, §§ 405.980(a)(1)(i) through 405.980(a)(1)(iv) specify that only the entity that issues a determination, reconsideration or other decision can initiate a reopening of that decision. Although this remains true in most instances, we note that this interim final rule contains an exception to this general principle at § 405.980(a)(1)(iv), whereby the MAC can reopen an ALJ's hearing decision. It should be noted that this is a continuation of CMS' current practice and does not constitute a change in policy. We also note that § 405.986(b) specifies that a change in

legal interpretation, regulations, or program instructions (or a declaration of what the law means or meant), whether by the judiciary or otherwise, does not form a basis for reopening.

e. Time Frames and Notice Requirements

Comment: One commenter recommends that CMS establish a time frame for processing and completing reopenings.

Response: We agree that, wherever possible, a party must have a reasonable expectation as to the administrative finality of a decision on a claim or claims in question. However, since an adjudicator can reopen at any time for fraud or similar fault, we do not believe that CMS can establish meaningful time frames for processing and completing reopenings. Instead, CMS will monitor the processing of reopenings by contractors during performance reviews and desk audits.

Comment: One commenter states that an adjudicator must be required to send both a reopening notice and a decision notice resulting from the reopening. The commenter contends that a reopening notice helps the party determine the adjudicator's time frame for issuing a decision. Also, the decision notice must provide the basis and evidence supporting the reopening.

Response: We are not requiring adjudicators to provide a notice to a party when they reopen claims and appeals, since any action that might result from the reopening will result in a party receiving a notice of the revision. Section 405.982 provides that adjudicators must issue notices of revised determinations or decisions which, in the event of an adverse revised determination or decision, must state the rationale and basis for the revision, and information about appeal rights. In the case of an adverse determination, a party would need this information should the party decide to appeal. In addition, if a contractor's reopening of an initial determination results in an overpayment determination, then the contractor must issue a demand letter to the affected party. If the reopening results in a favorable determination, then a revised MSN and RA will be generated.

f. Establishing an Evidentiary Burden of Proof To Reopen

Comment: One commenter recommends that CMS add to the regulation text that a contractor has an evidentiary burden of proof, particularly with respect to those reopening actions that occur after the 1-year limit on reopenings for any reason.

Response: Our policy that, within 1 year, for any reason, contractors may reopen claims and parties may request reopenings, is fair and equitable; moreover, no evidentiary standard is needed in the those situations. For reopenings after that time, the rules we proposed are sufficient; that is, contractors must have good cause for reopening claims within 4 years and must have obtained reliable evidence for reopening at any time for fraud or similar fault. No matter what the outcome of a reopened and revised determination, parties retain the right to challenge the new determination at the appropriate appeal level.

g. Inability To Appeal a Decision on Whether To Reopen

Comment: One commenter expresses concern that a party cannot seek review of a determination not to grant a request for reopening. The commenter argues that not allowing an appeal violates a party's due process rights.

Response: It is our longstanding rule that failure to grant a request for reopening is not reviewable. The Supreme Court has upheld this concept. *See Your Home Visiting Nurses Services, Inc.* v. *Shalala*, 525 U.S. 449 (1999); *Califano* v. *Sanders*, 430 U.S. 99 (1977). This does not violate the party's due process rights, because the administrative appeals process for Medicare claims already affords ample due process to the party. The reopenings process simply offers, but does not guarantee, an additional process if a party misses the time frame for filing an appeal or if the party has exhausted his or her appeal rights. For purposes of administrative finality and efficiency, CMS cannot sanction an endless cycle of reopening requests and appeals.

h. Enforcement of the Good Cause Standard

Comment: One commenter recommends that CMS create enforcement provisions for the good cause standard when contractors reopen claims. The commenter says that contractors often ignore the guidelines set out in regulations and manuals and cite a request for medical records as good cause for a reopening, even though the medical records existed at the time the contractor initially reviewed the claim.

Response: The regulations require that contractors abide by the good cause standard for reopening actions after one year from the date of the initial or revised determination. CMS assesses a contractor's compliance with Federal laws, regulations and manual instructions during audits and evaluations of the contractors' performance. Thus, the necessary monitoring and enforcement mechanisms are already in place.

i. Applying Similar Reopening Standards to Adjudicators and Parties

Comment: One commenter recommends that CMS apply the same reopening standards to adjudicators and parties and that a party be able to challenge an adjudicator's reopening action.

Response: As discussed above, an adjudicator's decision on whether to reopen a claim or an appeal is discretionary and not subject to an appeal. However, the reopening standards that apply to parties and adjudicators are very similar in this interim final rule. The only provisions that necessitate a difference are those provisions, which allow adjudicators to reopen at any time if reliable evidence exists that a determination or decision was procured by fraud or similar fault, and § 405.980(b)(5), which allows contractors to reopen at any time to effectuate a decision issued under the coverage appeals process. Clearly, a party that obtains payment through fraudulent or other similar means has no use for this provision. Again, if a contractor issues a revised determination or decision that is unfavorable, the affected party has the right to appeal.

11. Expedited Access to Judicial Review (EAJR) (§ 405.990)

[If you choose to comment on issues in this section, please include the caption ''Expedited Access to Judicial Review'' at the beginning of your comments.]

In proposed § 405.990, we incorporate the current regulations governing the expedited appeals process (EAP) at § 405.718 and § 405.853 with only two changes. First, since under BIPA the appeals process is the same for both Part A and B claims, we consolidated the Part A and B regulations governing expedited review of cases involving those claims. Second, under BIPA, ALJs are bound by all NCDs rather than only by NCDs based on section 1862(a)(1)(A) of the Act. Therefore, the regulations no longer limit expedited review to cases involving NCDs based on section 1862(a)(1)(A) of the Act.

In addition, we establish under proposed § 405.992 the standards that apply to ALJs and the MAC for policies that are not subject to the expedited appeals process. These standards have been moved to § 405.1060 in this interim final rule and are discussed in detail in the ALJ section. (*See* section II.G.5 of this preamble).

Comment: One commenter questions the requirement in § 405.990 for a $1,000 amount in controversy and the requirement for unanimous, written concurrence from all parties in order to request use of the EAP. The same commenter also requests that we make a number of clarifications in § 405.990, including stating explicitly that use of the EAP is not automatic, the decision by the review entity is not reviewable, and certification from the review entity does not trigger an action in Federal district court; the appellant must file a suit.

Response: As noted above, proposed § 405.990 includes no significant changes to the existing EAP process. The policies cited by the commenter (decisions to certify a case are not reviewable, a certification does not automatically trigger a Federal suit and written concurrence from all parties) are longstanding elements of the EAP process. Since publication of the proposed rule, however, the MMA has revised the applicable statutory requirements. In this interim final rule, we intend to maintain the proposed policies, as well as the changes necessitated by section 932 of the MMA. Therefore, we are revising § 405.990 so that it is consistent with the MMA requirements.

Section 932 of the MMA states that the Secretary must establish a process under which a provider or supplier or a beneficiary may obtain access to judicial review when a review entity determines that the Departmental Appeals Board (DAB) does not have the authority to decide the question or law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. As a result, we are modifying proposed § 405.990(f)(1) and § 405.990(f)(2) to require that requests for expedited access to judicial review (EAJR) be evaluated by a review entity. (Note that in this interim final rule we have replaced references to the EAP with EAJR in order to avoid confusion with the expedited appeals process under § 405.1200 through § 405.1206, which permits beneficiaries to request an expedited appeal of provider service terminations.) Also, in § 405.990(a), we define a review entity as a decision-making body composed of up to three reviewers who are ALJs or members of the DAB, as determined by the Secretary. The MMA also establishes a 60-day decision-making time frame for EAJR requests. Therefore, we have amended § 405.990(f)(2) to implement this change.

Section 932 of the MMA provides that a review entity's determination ''shall be considered a final decision and not subject to review by the Secretary.'' This language plainly has two effects—(1) a review entity's determination that is favorable to the party requesting EAJR is the final agency decision for purposes of judicial review, and (2) an ALJ or the MAC may not alter an unfavorable determination in the regular appeals process. Therefore, in § 405.990(f)(3), we are prohibiting an ALJ or the MAC from reviewing a decision by the review entity that either certifies that the requirements for EAJR are met, or denies the request. In § 405.990(h)(3), we cross reference to § 405.1136 since requests for EAJR certified by the review entity must also meet the requirements under that section for filing a civil action in a Federal district court.

Finally, as required under the MMA, if a provider, supplier, or beneficiary is granted judicial review, § 405.990(j) requires the application of interest to the AIC.

12. ALJ Hearings (§ 405.1000 Through § 405.1064

[If you choose to comment on issues in this section, please include the caption ''ALJ Hearings'' at the beginning of your comments.]

a. Introduction

In the proposed rule, we included new procedures to both implement section 1869 of the Act, as amended by BIPA, and codify in the Medicare regulations at 42 CFR, part 405, subpart I, all of the requirements that apply to ALJ and MAC proceedings. Most of the previous regulations used by the ALJs and the MAC were set forth in 20 CFR, part 404 of SSA's regulations, which focuses on SSA's disability appeals procedures. We note that we are generally carrying over relevant provisions of these rules applicable to Medicare proceedings, but will discuss in the preamble any new regulations that make substantive changes to the ALJ and MAC processes.

In addition to receiving comments on the proposed new provisions, we received some comments on the carry over of regulations that are already in effect for Medicare ALJ hearings and MAC review. Since most of these comments were associated with general concerns about changes to the ALJ process, we note them, where applicable, in the sections below.

Finally, as noted above, this interim final rule includes some straightforward changes to the ALJ and MAC process required by the MMA.

b. Escalation

(1) General Application

One of the most significant changes required under section 521 of BIPA is the introduction of an appellant's right to escalate a case to an ALJ if a QIC fails to make a timely reconsideration, or to the MAC if an ALJ hearing does not produce a timely decision on an appeal of a QIC reconsideration. As we noted in the proposed rule, the statute does not allow an appellant to proceed beyond the initial contractor level until he or she has received a redetermination from that contractor, even if the contractor does not issue the initial determination or redetermination within the statutory time frames. This is consistent with the pre-BIPA regulations, which require an appellant to complete all steps of the appeals process in sequence, except when an appellant invokes the expedited appeals process described in §§ 405.718 [Part A appeals] and 405.853 [Part B appeals].

BIPA, however, adds the option to advance a case to the next level of appeal when, in certain circumstances, an adjudicator does not act on the appeal within the statutory deadline. In the proposed rule, we use the term ''escalation'' to describe this movement of a case to the next level of appeal.

Section 1869(c)(3)(C)(i) of the Act, as amended by section 940(a)(2) of the MMA, requires the QICs to decide appeals within 60 days. Sections 1869(c) and 1869(d) of the Act, as amended by the MMA, now provide that an appellant may escalate an appeal as follows: (1) By requesting an ALJ hearing if the QIC does not decide the appeal within 60 days; (2) by requesting a review by the MAC if the ALJ does not decide the appeal of a QIC reconsideration within 90 days; and (3) by requesting judicial review if the MAC does not complete its review of an ALJ decision within 90 days. (At the ALJ and MAC levels, the statutory time period for completing the action begins on the date the appeal is timely filed.) When an appellant does not request escalation to the next level, the case remains with the current adjudicator until a final action is issued. We have revised proposed §§ 405.990 and 405.1136(c) to conform to these requirements.

We emphasized in the proposed rule that appellants must consider carefully the type of review that is best to resolve their case before deciding to escalate an appeal, because the type of proceedings and adjudicator varies with each step. For example, appellants who escalate a case from the ALJ level to the MAC will ordinarily not have the opportunity to

present their case during an oral hearing, unless they received an oral hearing at the ALJ level before escalating their case to the MAC. We also indicated that the statutory decision making deadlines apply only where there is a decision issued at the prior level. We did not propose any alternate deadlines for escalated cases, but encouraged comments on whether the final rule must include time frames and, if so, what time frames are be appropriate.

Comment: Most commenters on this point argue that allowing unlimited time for escalated cases is contrary to statutory intent; they recommended that cases that are escalated to the ALJ and MAC levels be subject to a time limit. Commenters varied, however, on how to establish appropriate time frames. Recommendations included: (1) Requiring escalated cases to be decided within the ''normal'' 90 days; (2) adding an additional 30 days to the ''normal'' 90-day time frame; and (3) adding the adjudication time frame from the previous level to the current level. Under the third recommendation, which preceded the enactment of the MMA, a case escalated from the QIC level to the ALJ would have a 120-day time frame (the pre-MMA 30-day QIC time frame plus the 90-day ALJ time frame) and a case escalated from the ALJ level to the MAC would have a 180-day time frame (90-day ALJ time frame plus the 90-day MAC time frame.) Adjusting this suggestion to reflect the new MMA adjudication period for the QICs, the time frame for the ALJ level would be 150 days.

Response: We hold that our original proposal is consistent with the language of the statute. Moreover, as we noted in the proposed rule, when ALJs and the MAC receive cases that have not completed the process below, they will require more time to determine what issues are properly before them and how to resolve those issues. As indicated in the proposed rule, however, we see value in establishing time limits for escalated cases to ensure that appellants do not wait indefinitely for a decision. After considering the commenters' suggestions, we have decided to establish a 180-day decision deadline for cases escalated to the ALJ and MAC levels. (For purposes of this discussion, we call these requirements the ''escalated time frames.'') These new time frames are, in essence, a modification of the third recommendation described above. Given the nature of ALJ proceedings, which includes scheduling and conducting a hearing, we do not believe that adding the QIC's adjudication time is sufficient.

As a corollary to the above decision, we are revising the regulations to provide that, in certain circumstances, an appellant has a right to escalate a case to the next level when the ALJ or MAC does not decide that case within its escalated time frame. Thus, § 405.1016(c) now specifies that for a case escalated to an ALJ, the ALJ must issue a decision no later than 180 days after the date that the request for escalation is received by the ALJ hearing office. We also revised sections 405.1100 and 405.1106(b) to establish a parallel deadline for a case that is escalated from the ALJ to the MAC.

(2) Specific Provisions Affected by Escalation

In the proposed rule, we note that the statute does not provide a specific mechanism for appellants to request escalation, nor does it indicate the effect of an escalation request on case development or other adjudication efforts the QIC, ALJ or MAC may be conducting when the escalation request is received. We are particularly concerned about the adverse impact on appellants and adjudicators if cases that are close to completion are deemed automatically escalated at the end of the statutory adjudication period. To alleviate this problem, we proposed that, when a QIC, ALJ, or the MAC receives a request for escalation after the adjudication period has expired, it will defer sending the case to the next level for 5 days after the request is received. If possible, the QIC or ALJ will issue its action within the 5-day period. If fully favorable to all parties, the determination or decision will be sent to the appropriate CMS contractor for effectuation. If the action is not fully favorable, any party to the appeal can file a request for an ALJ hearing or MAC review, as applicable, within the 60-day appeals period. If the QIC or ALJ is not able to decide the case within the 5-day period, the appellant will be notified and the case will be forwarded to the next level of appeal. We provide in proposed § 405.1104(b) the procedures an ALJ must follow when the ALJ is not able to issue a final action or remand within 5 days of receipt of the request for escalation.

We also proposed similar rules for cases in which an appellant requests escalation from the MAC level to Federal district court when the amount in controversy is $1,000 or more. We proposed that the MAC can, if feasible, issue a final action within 5 days of the request for escalation. We also provided in proposed § 405.1132(b), that when the MAC is not able to issue a final action within 5 days of receipt of the request for escalation, it will send a notice to the appellant acknowledging receipt of the request for escalation. A party can then file an action in Federal district court within 60 days after it receives notice of the MAC's decision.

Comment: One commenter expresses concern that the procedures outlined in § 405.1132(b) are not parallel to the procedures governing escalation from the QIC and ALJ levels, and are too burdensome. The commenter suggests that if the MAC does not issue an action within 5 days of the receipt of the request for escalation, the appellant must be able to proceed directly to court without issuance of a MAC ''decision.''

Response: Our use of the word ''decision'' in proposed § 405.1132(b) was an error and did not convey clearly the intention of the provision. We are revising the regulation to clarify that when the MAC issues its ''notice'' acknowledging that the MAC has not been able to complete its action within the statutory period, the appellant can file a civil action with the district court within 60 days of receipt of the MAC's acknowledgment notice. We recognize that the commenter may view the notice as an unnecessary step, since an appellant escalating to the ALJ or MAC level need only file the request for escalation and wait for a response (either an action from the QIC or ALJ or a notice that the case has been forwarded to the next level). However, we believe that the notice described in § 405.1132(a)(2) of this final rule will benefit appellants in several ways. We anticipate that some appellants may file a request for escalation before the MAC's 90-day period has expired; prompt notification of when the time period will expire and an indication, if possible, of when the MAC anticipates issuing its decision, will save appellants unnecessary court costs. We also note that BIPA has not changed the mechanism whereby appellants who are dissatisfied with the final decision of the Secretary may bring a civil action in Federal district court. Section 1869(b)(1)(A) of the Act provides that judicial review of the Secretary's final decision continues to be governed by section 205(g) of the Act. Under that provision, appellants seeking judicial review of the Secretary's action must file a civil action within 60 days of the Secretary's decision, or within any additional time allowed by the Secretary. We believe that the notice we intend to provide under § 405.1132(b) is within our authority under section 205(g), and will provide a useful benchmark for both appellants and the

courts to determine when a civil action in an escalated case is timely filed. We have revised the regulation text of § 405.1132(b) to make the effect of the notice clearer.

Similarly, we have retained, at § 405.1134, the provision carried over from SSA's appeals regulations that allows the MAC to extend the time to file a civil action for good cause. This regulation is also consistent with the language in section 205(g) quoted above, and provides protection for beneficiaries and other appellants who may need additional time to file a civil action or who wish to protect their right to commence a civil action while a request to the MAC to reopen its action is pending. In our experience, the above provisions are particularly helpful to beneficiaries proceeding pro se and in no way diminish their access to the Federal courts.

c. Conduct of ALJ Hearing—General Rules

In our November 15, 2002 proposed rule, we discussed how ALJ hearings in Medicare cases are currently conducted and how we proposed to conduct those hearings in the future. Section 1869(b)(1)(A) of the Act, as amended by BIPA, provides that any individual who is dissatisfied with an initial determination can request a reconsideration, as well as a hearing, provided that the request for the hearing is timely filed and that the amount in controversy requirements are met, as provided by section 205(b) of the Act. Traditionally, the Secretary has granted individuals entitled to a 205(b) hearing an in-person hearing. Regulations at 20 CFR § 404.948, which are incorporated into the current regulations governing Part A and Part B appeals, allow an appellant to waive an in-person hearing and request a decision based on the written record. We stated in the proposed rule that we would continue that policy and we did not receive any comments on this proposal.

We also indicated in the proposed rule that we intend to offer appellants an opportunity for hearings by telephone or videoteleconferencing (VTC), as available. We note at the time the proposed rule was published, VTC was available only at selected hearing sites throughout the country. We also explained the advantages of offering telephone and VTC hearings as alternatives to in-person hearings. These advantages include: (1) Providing a hearing in a convenient setting for beneficiaries who have trouble traveling even short distances; and (2) providing a more convenient site for providers and suppliers who may not wish to travel to a more distant hearing site. Finally, we stated that we were proposing the above alternatives to an in-person hearing because we believed they would enable ALJs to complete more cases within the 90-day adjudication period and give some appellants, who currently waive their right to a hearing and request an on-the-record decision because of traveling or scheduling difficulties, an opportunity to present their case orally.

On January 5, 2001, SSA issued a proposed rule in which it proposed to authorize use of VTC in conducting hearings before ALJs. *See* 66 FR 1059. SSA's final rule with comment (68 FR 5211), published February 3, 2003, addressed the public comments on the proposed rule and invited comment on the one significant change in the final rule, which provides that appellants may object to VTC only with respect to their own appearance. Because SSA's ALJs have been conducting Medicare hearings, the reasons articulated in the final rule with comment for adopting VTC as a alternative to an in-person hearing reflect SSA's experience with conducting Medicare hearings, as well as retirement and disability hearings. In responding to public comments, the final rule with comment identifies the factors that supported including VTC as a means of providing a 205(b) hearing. In summary, SSA found that:

- Use of VTC, where available, has decreased the necessity of sending ALJs to remote sites to hold in-person hearings. This, in turn, has decreased processing times, since to make travel to remote hearing sites as effective as possible, ALJ hearing offices ordinarily wait until they have a sufficient number of hearing requests to schedule a full day of hearings.
- Use of VTC decreases the difficulty of obtaining expert witnesses for a hearing, since it can be difficult to find medical experts who are available to travel to remote sites.
- The time ALJs have spent traveling to remote sites can be used to perform their adjudicatory responsibilities.
- Surveys of appellants, including beneficiaries, rated VTC procedures positively. A large percentage has rated the procedures as ''convenient'' or ''very convenient.'' Test data showed that processing time for these hearings was substantially less than for hearings conducted at remote sites, and that the ratio of hearings held to hearings scheduled was significantly higher for hearings using VTC procedures than for hearings scheduled in person.

Because SSA's regulations at 20 CFR, part 404 subpart J governing procedures for ALJ hearings are incorporated by reference in the former regulations governing Part A and Part B appeals, SSA's VTC rules, codified at 20 CFR §§ 404.929, 404.936, 404.938 and 404.950, have been effective for Part A and Part B ALJ hearings since March 5, 2003. Like other relevant SSA rules, we have incorporated certain policies regarding the use of VTC into this interim final rule. (On December 11, 2003, SSA issued a final rule on VTC, which responded to comments on the February 3, 2003, rulemaking, but did not change any of the regulation text. *See* 68 FR 69003). Thus, where available, ALJs have been conducting hearings via VTC in Medicare cases for over a year. Our knowledge of this new process, as well as our experience with telephone and in-person hearings and on-the-record decisions, forms the basis of our responses to the comments described below.

Comment: One commenter states that the proposed rule does not indicate whether a party may object to the type of hearing (in-person, by VTC, or by telephone) scheduled by the ALJ. The commenter also notes that a proposal for Medicare ALJ hearings conducted by telephone was rejected after criticism from claimant organizations, legal groups and other organizations was received. One of the main concerns at that time was a fact finder's potential difficulty in assessing witness credibility and demeanor in a telephone hearing.

Response: This interim final rule makes clear that an appellant can object to the type of hearing scheduled by the ALJ, including proceedings by telephone or VTC. As noted in our discussion in the proposed rule, some appellants waive any type of oral hearing on the grounds that they believe that written submissions to the ALJ will adequately present their case. In the past, others have waived the right to an oral hearing, stating that they are unable to leave their homes or cannot travel as far as the ALJ hearing office or other designated site. In our experience, telephone and VTC hearings offer an opportunity for individuals to present their case orally without the burden of extensive travel and, thus, provide an alternative to presenting their case solely in writing. Given these advantages and benefits, we are convinced of the advantages of incorporating VTC procedures into the Medicare hearings process, particularly in view of the BIPA time frames. Therefore, we have revised § 405.1020 to require ALJ hearings to be conducted by VTC if the VTC technology is available, but allow the appellant to request an in-person hearing, which will be granted upon a finding of good cause,

with the understanding that the request constitutes a waiver of the 90-day time frame for holding a hearing and rendering an opinion.

ALJs may determine that an in-person hearing should be conducted if VTC technology is not available or special or extraordinary circumstances exist. For example, an ALJ could find special and extraordinary circumstances for holding an in-person hearing when the case presents complex, challenging or novel presentation issues that necessitate an in-person hearing. Similarly, an appellant's proximity to and ability to go to the local hearing office for the hearing may constitute special and extraordinary circumstances that warrant the scheduling of an in-person hearing.

Additionally, § 405.1020(e)(4) of this interim final rule specifies that a party who objects to either a VTC or telephone hearing has a right to request an in-person hearing, which will be granted upon a finding of good cause. An ALJ could find good cause to grant a request for an in-person hearing when a party demonstrates that the case presents complex, challenging or novel presentation issues that necessitate an in-person hearing. Similarly, an ALJ may find good cause to schedule a hearing based on a party's proximity to and ability to go to the local hearing office. Consistent with SSA's current policy, § 405.1020(i)(5) provides that a party may object to the use of a VTC or telephone hearing only with respect to his or her own testimony, but not with respect to the entire hearing.

We anticipate that providers and suppliers will be particularly interested in VTC hearings, because they reduce the amount of nonproductive travel time previously associated with in-person hearings.

We believe that VTC and telephone hearings are convenient not only for providers and suppliers, but also for beneficiaries and their representatives. In particular, we note that many beneficiaries are represented by an adult child whose ability to take time off from work to attend an in-person hearing is often limited. Use of telephone hearings and VTC enables these individuals to pursue their parents' appeals without undue disruption of their daily routine. Moreover, because the interim final rule makes clear that an in-person hearing may be requested by all appellants, appellants who believe that their appeal can be presented effectively only in person, will have the right to request an in-person hearing, which will be granted upon a finding of good cause. In light of the new policy on the use of VTC and telephones for ALJ hearings, § 405.1020, § 405.1022, and § 405.1036 require ALJs to conduct VTC hearings whenever the technology is available and allow ALJs to offer to conduct telephone hearings if the hearing request or administrative record suggests that a telephone hearing may be more convenient for one or more of the parties.

d. Actions That Are Reviewable by an ALJ

Current regulations governing the Part A and Part B appeals process do not provide ALJs jurisdiction to overturn dismissals issued by a contractor or a carrier hearing officer. In the proposed rule, we proposed giving ALJs the authority to decide or review all final actions issued by a QIC, including dismissals for untimely filing, failure to exhaust administrative remedies, or *res judicata*. The proposed rule also specifies that if an ALJ decides that the QIC's dismissal is improper, the ALJ will remand the case to the QIC for a substantive decision.

Comment: One commenter questions the propriety of allowing an ALJ to review a contractor's dismissal order and whether that review constitutes a reopening of the contractor's action.

Response: Under the pre-BIPA appeals process, ALJs have sometimes identified contractor dismissals that were inappropriate. Because the regulations did not provide appellants a direct right of appeal of dismissals, referring those cases to CMS or the contractor was cumbersome and delayed the resolution of the appellant's appeal. We believe that providing a direct right of appeal will provide both a simpler and more cost-effective method to challenge a dismissal the party believes is inappropriate. Because we are providing a direct appeal right, the ALJ's remand to the contractor is not a reopening of the contractor's dismissal order. To clarify the effect of the remand order, we have revised § 405.1004(b) to provide that when the ALJ determines that the QIC's dismissal was in error, the ALJ will vacate the QIC's dismissal and remand the case to the QIC for a reconsideration. Consistent with the discussion above regarding appeals to QICs of contractor dismissals, appeals of dismissals will be permitted only at the next adjudicative level, and we have added § 405.1004(c) to clarify that an ALJ's decision regarding a QIC's dismissal of a reconsideration request is final and there is no subsequent appeal right.

e. Authorities That Are Binding on an ALJ

In the proposed rule, we explain that the Medicare statute, CMS regulations, and CMS Rulings bind ALJs. Prior to BIPA, ALJs and the MAC were also bound by NCDs, based on section 1862(a)(1) of the Act, but not NCDs, based on other statutory provisions. Under BIPA, all NCDs, whether based on section 1862(a)(1) of the Act or on other grounds, are binding on ALJs and the MAC. This change is reflected in §§ 405.732 and 405.860, as amended at 68 FR 63692, 63715, 63716 (November 7, 2003), and is also reflected in § 405.1060 of this interim final rule.

We also note a change in this interim final rule to § 401.108, which pertains to the binding nature of CMS Rulings on CMS components, and SSA to the extent that it adjudicates matters under the jurisdiction of CMS. In light of the transfer of responsibility for the ALJ hearing function from SSA to HHS, we are amending § 401.108(c) and creating a new § 405.1063 to specify that CMS Rulings bind HHS components that adjudicate matters under CMS' jurisdiction. We recognize that this is an expansion of the current policy, but believe this new requirement will help ensure consistency among appeals decisions.

In the proposed rule, we also address the degree to which ALJs and the MAC must defer to non-binding CMS and contractor policies such as LCDs, LMRPs, manual instructions and program memoranda. As reflected in proposed § 405.992, ALJs and the MAC are expected to give deference to these policies. The proposed regulations also provide, however, that a party can request that an ALJ or MAC disregard a policy, but the request must provide a rationale for why the policy should not be followed in the particular case.

Comment: Several commenters disagreed with the proposed regulation, because they believed that it placed an undue burden on appellants, particularly unrepresented beneficiaries, to identify policies applicable to their case and to explain why the policy should not be followed.

Response: New § 405.1060 through § 405.1062 alter the regulation text proposed under § 405.992 to clarify the applicability of NCDs, LCDs, LMRPS, and CMS program guidance to ALJs and the MAC. Section 405.1062 gives ALJs and the MAC the authority to consider whether guidance documents (for example, LCDs, LMRPs, and manuals) should apply to a specific claim for benefits on their own motion, rather than doing so only at the appellant's

request. This eliminates barriers for those beneficiaries who are not able to raise these issues on their own. We note, however, that particularly with the advent of the Internet, an increasing number of beneficiary appeals contain challenges to medical policies citing medical research and other grounds. These appeals will be easier to pursue because notices of redetermination under § 405.956 will now include more detailed explanations concerning the basis for a claim denial, including the application of a LMRP or LCD.

Comment: Requiring ALJs to defer to CMS and contractor policy alters the ALJ's role as an independent fact finder and, thus, changes the character of a 205(b) hearing.

Response: We disagree with the commenter's characterization of the proposed hearing process. Under this regulation, ALJs will continue their traditional role as independent evaluators of the facts presented in an individual case. Requiring an ALJ to consider CMS policy and give substantial deference to it, if applicable to a particular case, does not alter the ALJ's role as fact finder. Indeed, ALJs have always been bound by Medicare policies included in CMS regulations, CMS rulings, and NCDs based on section 1862(a)(1) of the Act.

The Federal courts have considered and applied deference standards in considering the validity of various Medicare policies, and have also recognized that ALJs and the MAC properly consider issues relating to deference as well. For example, in *Abiona* v. *Thompson*, 237 F. Supp. 2d 258 (E.D.N.Y. 2002), the court upheld a decision in which the MAC denied anesthesiologists' requests for payment of post-surgical administration of patient-controlled analgesia (PCA). In its decision, the MAC relied, inter alia, on the preamble to the Medicare physician fee schedule and a CMS program memorandum, both of which provided that payment for physician services related to PCA was included in the global fee paid to the surgeon and, therefore, was not routinely payable to anesthesiologists.

In response to the above comments and to provide a clearer standard of review, we have revised the regulation to provide that: (1) ALJs and the MAC must give substantial deference to LCDs, LMRPs, CMS manuals or other program guidance; (2) the applicability of a CMS manual instruction or other non-binding issuance may be raised by either the appellant or the MAC or ALJ on their own motion; and (3) the ALJ or MAC may decline to follow a policy in a particular case, but must explain the reason why the policy was not followed. These decisions apply only for purposes of the appeal in question, and do not have precedential effect.

The ALJ or MAC will review the facts of the particular case to determine whether and how the policy in question applies to the specific claim for benefits. If an ALJ or MAC decision concludes that a policy should not be followed, the decision will explain why the policy was not followed in light of the facts of the particular case. We believe this will provide a useful framework for deciding cases in which a particular, non-binding policy is the focus of the appeal.

Section 522 of BIPA created a new coverage appeals process that enables certain beneficiaries to challenge LCDs and NCDs. Because a beneficiary can conceivably bring an appeal under both the section 522 coverage appeals process and the section 521 claims appeal process, we are clarifying in this interim final rule how adjudicators will handle simultaneous appeals. These clarifications are consistent with CMS' final rule that created the new process to allow LCD and NCD challenges. *See* 68 FR 63692 (November 7, 2003). If a party appeals a denial that is based on an LCD or NCD by filing only a claim appeal, then adjudicators will apply the coverage policy that was in place on the date the item or service was received, regardless of whether some other beneficiary has filed a coverage appeal based on the same LCD or NCD. This policy is consistent with original Medicare policy that requires changes to LCD or NCDs to be applied prospectively to requests for payment.

If an appellant files both a claim and a coverage appeal based on the same initial determination, both appeals will go forward. The claim appeal adjudication time frames will not be impacted because the appeals will be conducted simultaneously. In adjudicating the claim appeal, adjudicators will apply the coverage policy that was in place on the date the item or service was provided, unless the appellant receives a favorable coverage appeal decision. If the appellant receives the favorable coverage decision prior to a decision being issued for the claim appeal, then pursuant to 42 CFR § 426.488 and § 426.560, the claim appeal will be adjudicated without consideration of the invalidated LCD or NCD provision(s). If an appellant receives a favorable decision in the coverage appeal after receiving an unfavorable claim appeal decision, then the appellant is entitled to have the claim appeal reopened and revised for good cause, subject to the provisions in § 405.980 and § 405.986, without consideration of the invalid LCD or NCD provision(s). As a result of these clarifications, we have added § 405.1034(c) to permit ALJs to remand an appeal to a QIC in this situation.

f. Aggregating Claims To Meet the Amount in Controversy

Prior to the enactment of section 521 of BIPA, the statute and regulations provided different amounts in controversy for Part A and Part B appeals. Under Part A, an appellant received a reconsideration of the initial determination regardless of the monetary value of the claim, but had to meet a $100 threshold to receive a hearing before an ALJ. Similarly, an appellant contesting an initial determination issued on a Part B claim received a review determination regardless of the amount in controversy. However, there was a $100 amount in controversy requirement for a Part B carrier hearing and a $500 threshold for an ALJ hearing with respect to a Part B claim determination (except for home health where the threshold for ALJ appeals was $100).

The pre-BIPA aggregation provisions found at former section 1869(b)(2) of the Act directed the Secretary to devise a system for allowing appellants to combine claims to meet the amount in controversy as follows:

> In determining the amount in controversy, the Secretary, under regulations, shall allow two or more claims to be aggregated if the claims involve the delivery of similar or related services to the same individual or involve common issues of law and fact arising from services furnished to two or more individuals.

The Secretary implemented the above provisions in a final regulation published March 16, 1994 (the existing regulations can be found in § 405.740 and § 405.817). The regulation established two methods of aggregation: one for individual appellants and one for multiple appellants. Individual appellants appealing either Part A or Part B claims were allowed to aggregate two or more claims within a specified period, regardless of issue, to meet the jurisdictional minimums for a carrier hearing and ALJ hearing. Multiple appellants, however, were allowed to aggregate their claims only under the statutory requirements; that is, if the claims involved the delivery of similar or related services to the same individual or common issues of law and fact arising from services furnished to two or more individuals.

BIPA 521 changed the amount in controversy requirements. Section 1869(b)(1)(E) of the Act provides that the amount in controversy for an ALJ

hearing will be $100 for appeals of both Part A and Part B claims. In addition, the aggregation provisions were revised: Two or more appeals are allowed to be aggregated when the appeals either involve the delivery of similar or related services to the same individual by one or more providers and suppliers, or there are common issues of law and fact arising from services furnished to two or more individuals by one or more providers or suppliers.

In the proposed rule, we proposed to limit aggregation of claims under BIPA to those that meet the statutory requirements for aggregation, that is, those that involve the delivery of similar or related services to the same individual, or common issues of law and fact arising from services furnished to two or more individuals. Individual appellants will no longer be allowed to aggregate all timely filed claims, regardless of issue. We explained that this change was appropriate because under BIPA, unlike the previous appeals system, appellants will have a right to appeal to an independent contractor (a QIC) regardless of a claim's monetary value. We also proposed the following related policies:

- To continue our pre-BIPA policy of restricting claims that may be aggregated to those that are appealed within 60 days after receipt of all reconsiderations being appealed, because to do otherwise would in essence extend the time to file a request for hearing beyond the 60-day limit;
- To provide separate rules for claims that are escalated from the QIC to the ALJ level to ensure that only appeals that meet the amount in controversy requirements are escalated to the ALJ level; and
- To require appellants to explain in their request for aggregation why they believe the claims involve common issues of law and fact or the delivery of similar or related services.

Comment: Two commenters believe that the proposed limits on aggregation are too restrictive, because some claims with low dollar amounts, but involving important issues, will not reach the ALJ level. One commenter added that there are some claims, such as therapy evaluations, that usually fall below the $100 limit. Another commenter recommended that the 60-day deadline to file a request for ALJ hearing be tolled to enable an appellant to aggregate the appeal with another claim still pending with the QIC.

Response: The statute requires ALJs and the MAC to apply the applicable amount in controversy standard under § 405.1006 for an ALJ hearing. Moreover, as we noted in the preamble to the proposed rule, with the creation of the QICs, appellants will have access to a review by an independent contractor regardless of a claim's monetary value. Our experience suggests that the large majority of Part A and Part B appeals decided by the QICs will equal or exceed the threshold amount in controversy. We also believe that the QIC review will provide sufficient due process for claims below the threshold amount in controversy. (In addition, as noted below, the Congress has recently provided that the amount in controversy be increased annually beginning in 2005.) Moreover, as explained in the proposed rule, extending or tolling the time for an appellant to aggregate a claim with another would in essence extend the statutory deadline to file a request for hearing beyond the 60-day deadline and would also prevent ALJs and the MAC from completing appeals within the statutory deadlines.

Comment: Several commenters asked for specific guidance in calculating the amount in controversy for services where reimbursement is governed by a specific formula or fee schedule.

Response: The interim final rule does not alter the pre-BIPA regulation's instructions for calculating the amount remaining in controversy. Regardless of the type of service or payment methodology, the amount remaining in controversy for an ALJ hearing is computed as the actual amount charged the individual for the items and services in question, less any amount for which payment has been made by the initial contractor or ordered by the QIC, and less any deductible and applicable coinsurance amounts. (Section 405.1006(d)(1)).

Finally, section 940(b)(1) of the MMA provides that, for requests for an ALJ hearing or judicial review made after 2004, the amount in controversy thresholds will be increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Amounts determined under this formula that are not a multiple of $10 will be rounded to the nearest multiple of $10. We have proposed to revise § 405.1002, § 405.1006, and § 405.1136(a) to reflect this statutory change. When this formula results in revisions to the amount in controversy, CMS will alert the public through a **Federal Register** notice, or other appropriate vehicle.

g. The ALJ Hearing

(1) When CMS or Its Contractors May Participate in an ALJ Hearing

As we explained in the proposed rule, previous regulations have not addressed whether CMS or its contractors can participate in ALJ hearings. Occasions have arisen, however, in which an ALJ has determined that input from CMS or a contractor will help resolve an issue in a case. In some instances, ALJs have requested position papers, testimony, or other evidence from CMS or a contractor, but these proceedings have been cumbersome, because the regulations did not provide specific procedures for input. After reviewing the outcome of other cases, CMS, as well as the Department's Office of Inspector General (in its report issued in September 1999 (OEI–04–97–00160)), concluded that the cases might have been resolved more appropriately if CMS or the contractor had been party to the appeal.

In response to the above concerns, we included several provisions in the proposed rule that define the extent to which CMS and its contractors may participate in the hearing process. We were also mindful that section 1869(c)(3)(J) of the Act specifically provides that the new independent contractors, the QICs, will participate in hearings to the extent required by the Secretary. Consistent with this provision, we proposed to revise our regulations to allow a representative of CMS, or a CMS contractor, to participate in an ALJ hearing at the request of an ALJ, the QIC or CMS. Participation may include filing position papers (within the time frame specified by the ALJ) or providing testimony to clarify factual or policy issues in a case, but will not include those aspects of full party status (for example, the right to call witnesses or to cross-examine the witnesses of the appellant or another party to the hearing). Because the role of a participant will be non-adversarial, we proposed to allow participation of the QIC, CMS, or CMS' contractors in cases brought by all appellants, including beneficiaries. We also explained in the proposed rule that an ALJ will not have the authority to require CMS or a contractor to participate in a case, nor may the ALJ draw any inferences if CMS or a contractor decides not to participate. Consistent with the practice before an ALJ, we amended § 405.1120 and § 405.1124 by adding language to clarify that the MAC is prohibited from drawing any adverse inferences if CMS or a contractor decides not to participate in a MAC review.

In addition, we proposed allowing CMS or its contractor to enter an appeal at the ALJ level as a party, unless an unrepresented beneficiary brings the appeal. In this circumstance, CMS or its contractor will have all the rights of a party, including the right to call witnesses or cross-examine other witnesses, to submit additional evidence within the time frame specified by the ALJ, and to seek MAC review of a decision adverse to CMS. Similar to the participation rules, an ALJ will not have the authority to require CMS or a contractor to enter a case as a party or to draw any inferences if it does not participate in the case.

One reason for these proposals is to allow ALJs and the MAC to resolve issues of fact and law more quickly and reduce the need for remands for additional development. Another aim is to reduce the number of cases referred to the MAC for own motion review because factual issues have not been addressed during the ALJ proceedings. In that regard, we note that these new regulations link CMS' ability to refer certain types of cases to the MAC for own motion review to the extent to which CMS has been a party or has participated in the appeal below. For example, under § 405.1110(b), if CMS or its contractor does not participate as a party or otherwise in a case at the ALJ level, any subsequent referral to the MAC for own motion review is limited to ALJ decisions or dismissals containing errors of law or a broad policy or procedural issue that may affect the public interest. This provision affords appellants a measure of administrative finality when CMS chooses not to participate as a party or otherwise in a case at the ALJ level and the resolution of the case hinges on the weight of the evidence rather than the controlling law and policy.

Comment: Although we received some positive comments concerning expanding CMS' role in the appeals process, most of the commenters who addressed this aspect of the proposed regulations are opposed or suggested modifications to the process. Those opposed are concerned that allowing CMS or its contractors to be parties or participate will change the nature of the hearing from an informal process to an adversarial hearing process not contemplated by the Congress. Some of these commenters stated that the change will particularly disadvantage beneficiaries.

Response: We disagree to some extent with the commenters' characterization of the nature of the ALJ hearing process under the pre-BIPA statutory and regulatory scheme. While CMS or its contractors are not explicitly recognized as parties in fee-for service appeals under the pre-BIPA statute (former section 1869(b)(2) of the Act), appeals brought by enrollees of managed care organizations (MCOs) are, by statute and regulation, adversarial at the ALJ, MAC, and Federal district court levels. Notably, sections 1852(g)(5) and 1876(c)(5)(B) of the Act, which reference the right to a ''205(b) hearing,'' provide that the MCO, as well as the enrollee, is a party to the hearing. MCOs that receive adverse decisions at the ALJ and MAC levels may appeal those decisions to the MAC and Federal district court, as applicable.

Our experience with these managed care hearings and appeals suggests that most beneficiaries, including those who are not represented, are able to participate fully in the hearing process even when the MCO appears at the hearing. This is due, in part, to the control exercised by the ALJ, one of whose roles is to ensure that all parties receive a full and fair hearing. We expect that ALJs will continue to fulfill this role under these new rules for fee-for-service appeals. Neither the existing nor the proposed regulations contemplate that the ALJ will conduct a trial-like proceeding with formal rules of evidence. (Moreover, as noted above, CMS or its contractors may not invoke full party status when the appellant is an unrepresented beneficiary.)

In addition, fee-for-service appeals conducted under 42 CFR part 405, subparts G and H, are currently adversarial when liability under sections 1879 or 1842(l)(1)(C) of the Act is an issue. When a provider or supplier has concluded that the service it provided to a beneficiary is not covered and asserts that it has informed the beneficiary of potential non-coverage before providing the service, the interests of the provider or supplier and the beneficiary concerning liability are adverse and can be contested during the ALJ hearing.

We also disagree with the commenters' conclusion that the Congress did not envision that CMS or its contractors might, in some instances, be represented at a hearing and before the MAC. As noted in the proposed rule, section 1869(c)(3)(J) of the Act provides that the new independent contractors, the QICs, will participate in hearings to the extent required by the Secretary. This is a clear indication that the Congress recognized the benefit of agency participation in the appeals process. Thus, we continue to believe that limited expansion of CMS role in the ALJ hearing process is appropriate, necessary, and consistent with the statute.

Comment: As noted above, several commenters favored the provision allowing CMS' and its contractors to invoke party status or otherwise participate at the hearing level, stating that participation will create a full and fair record. These commenters suggested various changes to the regulations to clarify who may participate and how the various parties to the hearing would be notified.

Response: Consistent with the above comments, we expect that allowing CMS or a contractor party status or participation, combined with the new rules concerning the submission of evidence, will create a record that is more complete at an earlier stage in the appeals process. These commenters noted the benefit to the Medicare program of a fully developed record that clearly conveys the program's coverage and payment policies. We believe a fully developed record will benefit all participants to the hearing. For example, after the statute was amended in 1986 to provide for ALJ hearings for Part B claims, some beneficiaries appealed the amount of payment awarded to their physicians under the reasonable cost system because they did not understand how the amounts had been calculated. In those circumstances, the hearing and resulting decision essentially served an informational purpose. Similarly, CMS participation at a hearing may assist beneficiaries, as well as adjudicators, in understanding concepts (for example, the distinction between hospital inpatient and observation admissions) that may affect coverage for certain benefits. We also hope to alleviate the difficult position that many ALJs currently face in adjudicating a case completely and impartially when the appellant introduces expert evidence, in the form of testimony, for the first time during the ALJ proceedings, and the ALJ does not have a routine avenue of obtaining information on the same topic from the agency.

We also expect that a fully developed record at the ALJ level or below will lead to a reduction in MAC remands to the ALJ level, as well as CMS referrals to the MAC for own motion review. In order to encourage this development, § 405.1110(c)(2) provides that if CMS or its contractor does not participate at the ALJ level, the MAC will exercise own motion review only if the ALJ's action contains an error of law or abuse of discretion material to the outcome of the case, or if the case presents a broad policy or procedural issue that may affect the general public interest. In other words, cases in which CMS or its

contractor decide not to participate at the ALJ level as a party or otherwise will not be reviewed by the MAC on its own motion if the perceived error concerns the ALJ's evaluation of the facts of the case rather than an error of law or procedure.

Proposed section 405.1000 listed the types of contractors that may participate as parties in hearings before an ALJ, to include Quality Improvement Organizations (QIOs). Therefore, we have amended § 405.1000 to include this technical change.

Comment: Several commenters noted that the proposed regulations do not address sufficiently how the participation of CMS or its contractors will affect ALJ hearing procedures such as the issuance of the notice of hearing and the potential for discovery.

Response: We have modified several of the regulations to clarify how a hearing will be handled when CMS or its contractor invokes party status or decides to participate in a hearing. For example, in § 405.1020(c) we require the ALJ to send a copy of the notice of hearing to both the QIC and the contractor that issued the initial determination. (The QIC or the contractor will be responsible for advising CMS of any significant cases in which the agency may decide to participate.)

Comment: Several commenters raised concerns that the proposed regulations contain more formal procedures than the previous regulations and will, therefore, inhibit the ability of an unrepresented beneficiary to pursue an appeal.

Response: Many of the provisions cited by the commenters are identical to those that have been part of the current regulations since 1980 and, in our experience, have not been difficult for unrepresented beneficiaries to follow. For example, a few commenters suggested that the requirement that a beneficiary object to the issues in the notice of hearing will require the beneficiary to file formal objections or pleadings. This is not the intent of the regulation, nor in our experience has it inhibited beneficiaries from pursuing their requests for hearings. Section 405.1024 of the regulation is a carryover from 20 CFR § 404.939, which has applied to Social Security retirement, disability, and Medicare hearings since August 1980. *See* 45 FR 52078, 52081 (August 5, 1980). We decided to maintain this regulation not to formalize the proceedings, but rather to give beneficiaries and other parties the opportunity to make corrections in those instances, albeit rare, in which the ALJ hearing office does not correctly identify the issue to be decided or the parties to the hearing. It is in the interest of the parties and the adjudicator to correct these mistakes at the earliest opportunity so that hearings do not have to be postponed or supplemented because necessary parties were not sent the notice of hearing or appropriate expert witnesses were not obtained because the issues before the ALJ were not properly identified before the hearing. Parties may respond to the notice, as they do now, in an informal manner. The regulation does not require or anticipate formal written submissions.

Comment: Several commenters indicated that while the proposed rules include a provision for issuing subpoenas, they do not require CMS to respond to discovery requests or orders.

Response: BIPA does not explicitly provide for discovery during ALJ proceedings, and given the time frames for adjudications under BIPA, we do not envision that most hearings will include discovery. However, in light of these and other comments relating to discovery, we believe it is appropriate to permit discovery when an ALJ hearing is adversarial (that is, whenever CMS or its contractor is a party to an ALJ hearing). Therefore, we have added § 405.1037 to permit limited discovery when CMS participates in an ALJ hearing as a party. Our experience indicates that most information that is relevant to issues before an ALJ can be obtained by direct request by the ALJ or subpoena. Therefore, we anticipate that extensive discovery will not be necessary.

In general, we allow discovery for matters relevant to the specific subject matter of the ALJ hearing, but only if they are 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. We also limit discovery by permitting a party only to (1) request of another party the reasonable production of documents for inspection and copying, and (2) take the deposition of another party if 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. An ALJ will decide on a case-by-case basis the time frame within which a party that seeks discovery must submit its request and when all discovery must be concluded.

Section 405.1037(d) sets forth rules for motions to compel and protective orders. A party that files a motion to compel or a protective order must also include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute.

As a general rule, the MAC may review an ALJ discovery or disclosure ruling only during the course of its review as specified in § 405.1100, § 405.1102, § 405.1104, or § 405.1110. However, there may be immediate MAC review where an ALJ's 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 to the ALJ. An ALJ must stay all proceedings affected by a ruling for a minimum of 15 days when the ALJ receives notice that a party intends to seek MAC review of the ruling. If the MAC grants a request for review or takes own motion review of a ruling, the ALJ ruling will be stayed until the MAC issues a written decision that affirms, reverses, or modifies, the ALJ's ruling. When CMS requests review of an ALJ ruling, the MAC must grant the request, and the ruling is automatically stayed pending the MAC's order. With respect to requests 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, then the stay will be lifted and the ruling will stand.

If a party requests discovery against another party to the ALJ hearing, the ALJ adjudication time frame specified in § 405.1016 will be tolled. Tolling the ALJ's decision-making time frame pending resolution of the discovery dispute will ensure that ALJs have an appropriate opportunity to consider the merits of an appeal, while also maintaining an appellant's ability to escalate to the MAC if the ALJ is unable to issue a decision within the statutory time frame.

In developing the discovery procedures, we considered their potential effects on appellants and other parties to an appeal. We believe that reasonable discovery can enhance the fairness of proceedings and the accuracy of decisions. We also believe that discovery should be limited to hearings where CMS has joined as a party because it has not been previously available for ALJ hearings and these hearings will be adversarial because of CMS party status. Additionally, ALJs will not be able to schedule and hold hearings in an efficient manner if broad discovery is permitted. As previously mentioned, we expect the number of appeals in which CMS elects to participate as a party to be quite low. When CMS does participate as a party, we expect the need for discovery to be

minimal. Also, because we anticipate that the majority of appeals in which CMS elects to participate as a party will involve overpayments, CMS will not arbitrarily invoke party status, subject itself to possible discovery requests, and risk additional interest liability in an attempt to delay the proceedings. Therefore, we believe that it is unlikely that these procedures regarding discovery will negatively impact the appellant and other parties to an appeal.

When all other discovery efforts have failed, parties may also obtain evidence by requesting subpoenas. The Social Security Act provides for the use of subpoenas, and the proposed regulations, like the current SSA regulations applicable to ALJ hearings, allow an ALJ, through independent initiative or at the request of a party, to issue subpoenas concerning the attendance and testimony of witnesses and production of evidence. The ALJ will rule on whether and to what extent a party's requests for subpoenas will be granted, taking into account any objections that may be raised. We note that if a party fails to comply with a subpoena, neither the ALJ nor a party may seek judicial enforcement; instead, the ALJ must make application to the Secretary for such enforcement. Similarly, the Administrative Procedure Act and the current regulations applicable to Part A and Part B appeals allow the MAC to issue subpoenas. Therefore, we have amended § 405.1122 by adding paragraph (d), which largely mirrors § 405.1036(f) and describes the MAC's ability to issue subpoenas and the requirements for submitting a subpoena request.

We recognize that this interim final rule does not fully discuss how the discovery and subpoena provisions apply to CMS when it enters an ALJ hearing as a party. Therefore, following publication of this interim final rule containing the regulatory provisions on subpoena and discovery procedures, we will issue a CMS Ruling clarifying the application of these provisions to CMS.

(2) Issues Before an ALJ

In the proposed rule, we generally adopted the provisions from 20 CFR § 404.946 regarding issues before an ALJ. Section 405.1032(a) generally discusses the types of issues that an ALJ may consider at a hearing. ALJs may consider all of the issues brought out in the previous determinations that were not decided entirely in a party's favor. Under certain circumstances, ALJs may also consider issues decided favorably.

Comment: Some commenters objected to § 405.1032(a) allowing an ALJ to consider issues decided favorably to a party by a QIC or other contractor even if those issues are not raised on appeal. One commenter suggested that this regulation places the ALJ ''in an appellate position.''

Response: This regulation is a direct carryover from a currently applicable regulation at 20 CFR § 404.946(a). In our experience, it is rarely used in the Medicare context. We decided to retain it, however, to give the ALJ the authority to remedy clearly inconsistent outcomes that sometimes present themselves in a case before an ALJ. For example, an ALJ who has been asked to reverse a determination that the second week of skilled nursing facility services was not medically necessary may discover that the beneficiary did not have a 3-day qualifying inpatient hospital stay. Section 405.1032(a) allows the ALJ to take jurisdiction of an earlier, fully favorable determination with respect to the first week of care, which is also subject to the 3-day qualifying stay requirement, but only if: (1) That determination may be properly reopened under the reopening regulations; and (2) the ALJ gives proper notice to the parties that this issue will be addressed. Although we anticipate that this provision will be rarely invoked, we have included it in the regulation to address the type of situation described above.

Section 405.1032(c) discusses whether an ALJ can consider a claim that is not the subject of a hearing request. This paragraph was added to address CMS'' concerns that ALJs not consider claims that have not been previously adjudicated. Section 405.1032(c) prohibits an ALJ from taking jurisdiction of a claim that has not been adjudicated at the lower appeals levels through the QIC level. It is important to note the distinction between new claims versus new issues for purposes of applying § 405.1032. A new issue is one that is raised for the first time at the ALJ level, that is relevant to the dates of service that are before the ALJ, but was not previously considered in the appeal. For example, if a claim was previously denied for a reason other than medical necessity and the appellant raises a medical necessity issue at the ALJ hearing level, the medical necessity issue is new, since it is relevant to the claim but not the original dispute in the appeal. A new claim, however, is a claim that has not completed the appeals process at the through the QIC level. A claim can only be combined with an appeal at the ALJ level if it has already been reconsidered by a QIC.

(3) Parties to an ALJ Hearing

In proposed § 405.1020(a), we stated that the ALJ must send the notice of hearing to ''all parties and the QIC that issued the reconsideration determination.'' We received several comments concerning whether ALJs are always required to send notices of hearing to ''all parties.''

Comment: ALJs currently encounter significant difficulties in determining who receives the notice of hearing when the appeal concerns either a large number of initial claims filed by a single provider or supplier, or a postpayment audit involving statistical sampling and a resulting overpayment assessed against a provider or supplier. Although the beneficiaries who received the items or services technically may be parties to these appeals, in many instances they have not been involved in the proceedings below and, due to the application of the limitation of liability and overpayment provisions, may have no financial liability for the services at issue. Attempting to locate and send notices of hearing to these beneficiaries is extremely time-consuming and will hinder the ALJ's efforts to hold a hearing and issue a decision within the 90-day adjudication period.

Response: We have modified the notice of hearings requirements in § 405.1020(c) to clarify that an ALJ is not required to send a notice of hearing to a party who has not participated in the determinations below and whose liability status for the items or services in dispute has not been altered since the initial determination. We believe that this will ensure that all parties who have an interest in the appeal are given an opportunity to participate, while at the same time alleviating the ALJ hearing office's obligation to contact those individuals who have not pursued their appeals rights at the earlier levels, or have no financial interest in the outcome. However, the regulation does not prohibit the ALJ from notifying a party who has not previously participated in the appeal, if the ALJ's pre-hearing development suggests that the party's interests may be adversely affected by the outcome of the case.

h. Filing Requests for ALJ Hearing and MAC Review—Time and Place

Section 1869(b)(1)(D)(ii) of the Act provides that ''[t]he Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 205 and 206.'' In addition, section 1869(d)(1)(A) of the Act provides that ''[e]xcept as provided in subparagraph (B), an administrative

law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed.'' Similarly, section 1869(d)(2)(A) of the Act provides that the MAC ''shall conduct and conclude a review of [an ALJ decision] and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed.''

Section 205(b) of the Act gives an appellant 60 days to request a hearing. The current regulations governing appeals of Medicare claims provide for appealing from the contractor's determination or decision to an ALJ and, thereafter, from the ALJ level to the MAC. In the proposed rule, we stated that we will continue to require parties to file their appeals to the ALJ level and the MAC within 60 days. We also stated that ALJs and the MAC will continue to follow most of the general principles currently found in 20 CFR § 404.933 and 42 CFR § 405.722 when they decide whether an appeal has been timely filed for purposes of establishing the appellant's right to appeal. These regulations provide that an appeal is considered filed on the day it is received by a Social Security office, CMS, including its contractors, an ALJ, or, in the case of a request for MAC review, the MAC. We stated in the proposed rule that we will continue to calculate the 60-day filing period based on the date the appeal is actually received by one of the above offices, as reflected in proposed § 405.1014(b). However, for purposes of calculating the 90-day adjudication period that governs ALJ and MAC actions, we stated that if a request for ALJ hearing was not filed directly with the ALJ hearing office or a request for MAC review was not filed directly with the MAC, the 90-day adjudication period would not begin until the appeal is received by the ALJ or MAC, as applicable. Finally, we indicated that in those requests for hearing or MAC review in which an appellant does not file an appeal within the 60-day filing period but contends that there is good cause for filing late, the 90-day adjudication period will begin with the date the good-cause explanation is received by the ALJ or MAC, as applicable, assuming that the ALJ or MAC determines that the explanation provides good cause for filing the appeal late.

Comment: We did not receive any adverse comments concerning starting the calculation of the 90-day adjudication period from the date when an adjudicator receives an appellant's good cause explanation for filing an appeal late. However, we received several comments objecting to tolling the 90-day adjudication period for appeals not filed directly with the ALJ hearing office or MAC until the appeal reaches the appropriate adjudicator. Commenters objected for essentially two reasons: (1) They felt that tolling the adjudication period was contrary to the Congress' direction that the appeals be completed within 90 days and (2) that beneficiaries and other appellants must not be penalized for delays caused by the government and its contractors. Suggested solutions included increased coordination between SSA and CMS local offices with the appeals entities and establishing deemed or presumed dates of receipt for appeals whose actual receipt is delayed because the component that initially received the appeal does not forward it timely to the adjudicator.

Response: As noted in the proposed rule, and discussed in detail above in both the contractor and QIC context, directing appellants to only one filing location will reduce confusion and eliminate potential delays in transmitting the appeal request. Similarly, in the case of ALJ hearings or MAC reviews, requiring appellants to file their appeals with a single appeals entity will be the simplest and most efficient way of eliminating the delays that concern the commenters. In two sections of the proposed rule, SSA was listed as a filing location. As mentioned previously, given the reduced role of SSA in the processing of Medicare appeals, we believe that an explicit regulatory reference to SSA field offices is no longer appropriate. Therefore, we have revised § 405.1014(b) and § 405.1106(a) to eliminate the references to SSA as an alternative filing location. We intend to instruct the QICs to include in their reconsideration notices the appropriate entity to whom a subsequent appeal must be directed. We will also continue our efforts to make forms for requesting an ALJ hearing and MAC review accessible and easy to use. In that regard, we note that a specific form for requesting MAC review with directions for filing under the current regulations is available on the Departmental Appeals Board's Web site at *http://www.hhs.gov/dab.*

Consistent with our managed care regulations, §§ 405.1106(a) and 405.1106(b) require that an appellant send a copy of the request for review (or escalation) to the other parties involved in the appeal. Although the MAC will not dismiss an appeal on the grounds that the appellant failed to satisfy this requirement, the adjudication deadline will be tolled if the appellant fails to copy the other parties. This is one of several provisions we will monitor for effectiveness, and we will assess the need for changes as we gain experience with the new process.

Comment: One commenter suggested that the ALJ be required to notify the appellant when the request for review is received, so that the appellant will know when the 90-day adjudication period begins.

Response: We agree with the commenter. ALJ hearing offices and the MAC routinely send acknowledgment notices to the appellant when they receive a request for hearing or MAC review. However, this interim final rule requires ALJ hearing requests to be filed with the entity specified in the notice of reconsideration. Therefore, the decision-making time frame begins on the date an appeal is timely filed with this entity. Accordingly, § 405.1014(b) has been modified to require ALJ hearing offices to send appellants a notice of the date of receipt of an appeal request only when a hearing office receives a request that was initially filed with an entity other than the one specified in the notice of reconsideration. Similarly, § 405.1016(a) now requires notice of the date of receipt to be sent only when a request for MAC review is filed with an entity other than the MAC or ALJ hearing office.

i. Adjudication Deadlines

Section 1869(d)(1)(A) of the Act provides that, unless the appellant waives the statutory adjudication deadline, the ALJ ''shall conduct and conclude a hearing on a decision of a [QIC]'' and issue a decision within 90 days from the date a request for hearing is timely filed. As we discussed in the proposed rule, we interpret this provision as requiring an ALJ to decide a case within 90 days only when the QIC has issued a final action in a case. Therefore, we proposed that when an appellant escalates an appeal from the QIC to the ALJ level, the proceedings before the ALJ will not be subject to the 90-day limit.

Comment: As noted in our discussion of escalation, we received several comments objecting to the above proposal. Some commenters stated that cases escalated from the QIC level to the ALJ level be subject to the 90-day limit, and others suggested an extended, but still limited, time frame.

Response: As indicated in our discussion above, this interim final rule requires that ALJs complete their action in cases escalated from the QIC level to the ALJ level within 180 days of the date of receipt of the escalation request.

We also proposed that the 90-day adjudication period be tolled when delays in submitting evidence or requests for postponement of a hearing by an appellant, rather than the ALJ's actions, extend the length of the proceedings. We received no specific objections to this proposal. Because we have now limited cases escalated from the QIC level to the ALJ level to a 180-day adjudication period, we have included in the final regulation text that an appellant's actions that delay the proceedings will similarly toll the 180-day adjudication deadline.

Comment: One commenter asked us to clarify the effect of the statutory provision that allows an appellant to waive the 90-day adjudication period. The commenter asked if this provision allows an appellant to, in essence, agree to an extension of the adjudication period for a limited period.

Response: We agree with the commenter that in some instances the appellant may benefit by agreeing to a limited extension of the adjudication period in order to give the ALJ sufficient time to obtain additional testimony or evidence, or otherwise consider the appeal and issue a decision. Section 405.1036(d), consistent with section 1869(d)(1)(B) of the Act, allows an appellant to waive the adjudication period. We have modified that section to provide that the waiver may be for a specific period of time agreed upon by the ALJ and the appellant.

13. Remand Authority (§ 405.1034)

In the proposed rule, we noted that the current regulations governing Medicare appeals do not contain clear guidance concerning if and when an ALJ can remand a case to a contractor for further proceedings. We proposed giving ALJs remand authority for three specific reasons: (1) When the ALJ decides that the QIC's dismissal of a request for reconsideration was improper; (2) when the record provided to an ALJ lacks the technical information needed to resolve the case, which only the contractor can provide; and (3) when an appellant submits new evidence to the ALJ without providing a good reason for not providing it at the QIC level.

Comment: We did not receive any comments concerning the ALJ's authority to remand when the ALJ decides that the QIC's dismissal of a request for reconsideration was improper. However, several commenters expressed concern that the mandatory remand provisions altered the ALJ's role as the trier of fact, as well as the de novo aspect of an ALJ hearing. Others contend that it will be unfair to restrict a party's right to submit new evidence not considered by the QIC, and at the same time allow CMS to submit evidence and position papers if it participates in a case. Many others reference specific situations in which they said the prohibition concerning the introduction of new evidence should not be applied, or, alternatively, in which good cause to introduce the evidence should be found.

Response: As noted earlier in this rule, the MMA amended several of BIPA's appeal provisions. Effective October 1, 2004, section 1869(b)(3) of the Act, as amended by section 933(a) of the MMA, requires that a provider of services or supplier not introduce evidence in any appeal that was not presented at the reconsideration conducted by the QIC, unless there is good cause that prevented the introduction of that evidence at or before the reconsideration.

This new statutory provision is more restrictive than the proposed rule, in which we proposed only to require that evidence specifically identified in the notice of redetermination be produced no later than the reconsideration level. In accordance with section 933(a) of the MMA, we have amended § 405.1028 and § 405.1122(c) to require providers and suppliers to submit all evidence at the reconsideration level unless there is good cause for not submitting it at, or before, that level. Similarly, in § 405.1028, we require beneficiaries who are represented by a provider or supplier to submit all evidence at the reconsideration level unless there is good cause for not submitting it at, or before, that level. Although the statute does not require application of this standard to beneficiaries who are represented by providers or suppliers, we think it is appropriate to extend the requirements of section 933(a) to these beneficiaries. Doing so will likely prevent a provider or supplier from subverting the requirement for full and early presentation of evidence simply by offering to represent a beneficiary, rather than appealing on its own behalf. In light of these changes, we have eliminated the portions of proposed § 405.1030 and § 405.1034 that would have required an ALJ to remand a case to the QIC when an appellant introduced new evidence at the ALJ level without good cause. Although an ALJ or the MAC may not rely on evidence submitted untimely in deciding the substantive issue(s) in an appeal, unless good cause is found for the late submission of evidence, § 405.1042(a)(2) ensures that the excluded evidence will become a part of the record, and that the ALJ or MAC will explain in its action why the evidence has been excluded.

Comment: Several commenters noted that, while the appellant's right to submit new evidence beyond the QIC level is restrained by the good cause standard, the regulations do not appear to place similar restrictions on CMS or its contractors if they decide to submit evidence at the hearing.

Response: We disagree with the commenters' position that it is unfair to prevent providers and suppliers from submitting new evidence at the ALJ level, while allowing CMS or its contractors to submit evidence at the ALJ level if the agency elects to join the appeal as a party. We have also considered these comments in light of the statutory change described above that impose a good cause standard on providers and suppliers for purposes of submitting evidence beyond the QIC level. CMS and its contractors are not permitted to participate in the appeals process prior to the ALJ level. Consequently, they are also prohibited from submitting evidence in either the redetermination or the reconsideration. Therefore, if CMS elects to join an appeal as a party, the agency should be afforded an opportunity to present evidence and the ALJ level is the earliest opportunity for this to take place. We anticipate that there are several scenarios in which an ALJ will need to consider whether a provider or supplier appellant's request to introduce new evidence at the ALJ level must be granted for good cause.

While it is not possible to delineate in a regulation all of the situations that can constitute good cause, we note that the type of new evidence that may be introduced at various levels of appeal will also be affected by the number of issues that are considered during the course of an appeal. For example, if a QIC disagrees with a contractor's denial of a claim on technical grounds, it may still determine that the claim is not payable because the service was not medically reasonable and necessary. Since the issue of medical necessity may not have been addressed until the QIC's determination, the ALJ will need to take that into account when determining whether the appellant has good cause to produce additional evidence on the medical necessity issue at the ALJ level. Similarly, in instances in which CMS introduces evidence at the ALJ level that was not part of the

record below, the ALJ should consider whether the introduction of this evidence constitutes good cause for granting an appellant's request to introduce new evidence.

Comment: One commenter objects to the provision that allows an ALJ to remand to the QIC when the record provided to the ALJ lacks technical information that is material to resolving the case, and only the contractor can provide the information. The commenter suggests that the ALJ retain the appeal and ask the contractor to forward the information to the ALJ.

Response: We anticipate that most appeal files forwarded to the ALJ will have all of the documents necessary to decide the case. In the rare instance in which the file lacks necessary technical information, we believe that the most effective way of completing the record is to return the case, via remand, to the contractor. However, § 405.1034 will give an ALJ the option of either remanding the case to the contractor, or asking the contractor to forward the missing information to the ALJ hearing office. In the event that we move to an electronic file system, we will consider revising this provision further.

14. When an ALJ Can Consolidate a Hearing (§ 405.1044)

[If you choose to comment on issues in this section, please include the caption ''ALJ—Consolidation of Hearing'' at the beginning of your comments.]

We have continued the longstanding practice of allowing ALJs to consolidate requests for hearing where appropriate. We added in the proposed rule, however, a provision requiring an ALJ to notify CMS of the intent to consolidate hearings because we believe that the consolidation of hearings may affect CMS' decision on whether to participate or invoke party status.

Comment: We received one comment on this provision. The commenter recommends that a beneficiary have the right to object to a request for consolidation of the beneficiary's appeal with those of another party (for example, a provider or supplier appealing numerous appeals on the same issue). The commenter's concern is that consolidation of the appeal will eliminate the 90-day deadline for resolution of the case. The commenter also states that consolidation will complicate the hearing and make it more difficult for the beneficiary to assert rights in the appeal.

Response: We expect the situation described by the commenter to occur only rarely. In our experience, providers and suppliers make requests for consolidation of hearings in cases involving identical coverage and payment issues for the same item or service provided to multiple beneficiaries. In the majority of these cases, the liability of individual beneficiaries has been waived or, if not, the beneficiary has not filed an appeal or otherwise participated in the determinations below, and has not filed a separate request for ALJ hearing. However, if the beneficiary and the provider or supplier, as applicable, both file a request for hearing in response to the same QIC reconsideration, the provider or supplier may not, in essence, waive the beneficiary's right to an ALJ action within 90 days because it wants to consolidate that determination with other similar appeals. Beneficiaries who do not waive the 90-day adjudication period in order to participate in the consolidated proceedings must be mindful, however, that their case will be decided without the benefit of any of the testimony that can be given at the consolidated hearing, and that their decision may be revised if the evidence considered and resulting outcome of the consolidated hearing provides a basis for reopening the beneficiary's case.

15. When an ALJ Can Dismiss a Request for a Hearing (§ 405.1052)

[If you choose to comment on issues in this section, please include the caption ''When an ALJ Can Dismiss a Request for a Hearing'' at the beginning of your comments.]

We note that CMS' pre-BIPA regulations did not address this issue; rather, ALJs followed the regulations at 20 CFR § 404.957. Those regulations were designed to resolve appeals filed by applicants for Social Security retirement and disability benefits. Therefore we proposed new regulations that address the specific procedural issues that arise in Medicare claims appeals. We described an ALJ's authority to dismiss a request for hearing on several grounds, including: The death of the beneficiary when there is no substitute party with a remaining financial interest; dismissals in response to a request for withdrawal; dismissals based on a previous determination or decision about the appellant's rights on the same facts and on the same issue or issues, and dismissals based on abandonment. We received one comment concerning dismissals related to the survival of an appeal following the death of the beneficiary, and one concerning when, if ever, an ALJ may vacate a dismissal.

Comment: We received a general comment concerning whether ALJs can be given the authority to vacate their own dismissal orders.

Response: SSA's regulations include a provision allowing ALJs to vacate their own dismissals. However, in practice, this provision has not been an effective remedy in Medicare appeals because the claims folder is no longer in the ALJ hearing office and is unavailable to the ALJ by the time the request to vacate the order is received in the ALJ hearing office. Moreover, resolutions of these requests have been delayed or complicated when appellants have simultaneously asked the ALJ to vacate the dismissal order and asked the MAC to review the dismissal. In light of these problems, we believe that the better practice is to provide only for an appeal of the dismissal order to the MAC.

Comment: We proposed that either the ALJ or the MAC could dismiss a request for hearing or review, as applicable, when a beneficiary dies before an appeal is filed, or during the pendency of the appeal. We did not receive any comments concerning the ALJ's right to dismiss the request for hearing, but did receive a comment concerning a MAC's dismissal on the same grounds. The commenter states that the MAC must hold a hearing at the request of the beneficiary's estate on the issue of whether there is any remaining financial liability of the estate that establishes the estate as a substitute party that can continue the appeal.

Response: In our experience, it is not necessary to hold a hearing at either the ALJ or MAC level to resolve whether the beneficiary's estate has a right to a hearing or MAC review. The issue in these circumstances is whether there remains an interested, substitute party who has a remaining financial interest in the outcome of the appeal. As indicated in the proposed rule, this remaining financial interest can be established if the beneficiary either paid for the service (and, thus, the beneficiary's surviving spouse or estate is seeking reimbursement on behalf of the beneficiary) or the beneficiary's spouse or estate continues to be potentially financially liable to pay for the service. Conversely, if the beneficiary's liability for the service was waived and that determination was not used as a basis to establish the beneficiary's liability for subsequent services, the beneficiary's spouse or estate has no remaining financial interest in the appeal. Neither the statute nor existing regulations require a hearing before an appeal may be dismissed on the above issue, and, in our experience, a determination of the estate's remaining financial liability, if any, can be established without a

hearing. We wish to note that when a beneficiary dies and the appeal is subsequently dismissed, a party, including the beneficiary's estate, may ask the MAC to vacate the dismissal under § 405.1108(b). Examples of situations in which a dismissal should be vacated include when there is the possibility of Medicaid liability or when there is a possibility the State (which pays Medicaid funds) will attempt recovery of its payment from the estate.

We note, however, that section 939 of the MMA now provides that, if a beneficiary dies and there is no substitute party available to appeal a determination, the provider or supplier who furnished the item or service can pursue the appeal. We have amended § 405.1052(a)(5) to reflect this change. However, because a beneficiary's estate may have an interest in having Medicare cover a service so that a State (which pays Medicaid funds) will not attempt to recover its Medicaid payment from the estate, adjudicators may only dismiss requests involving dually eligible beneficiaries pursuant to the requirements set out in § 405.1052.

16. Content of ALJ's Decision (§ 405.1046)

[If you choose to comment on issues in this section, please include the caption ''Content of ALJ's Decision'' at the beginning of your comments.]

Section 405.1046 of the proposed rule sets forth general rules regarding the ALJ's decision notice. We received no comments on these provisions. Subsequently, section 933(c)(3) of the MMA amended section 1869(d) of the Act to provide that an ALJ decision must be written in a manner calculated to be understood by the beneficiary and must include:

- The specific reasons for the decision (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the decision);
- The procedures for obtaining additional information concerning the decision; and
- Notification of the right to appeal the decision and instructions on how to initiate such an appeal.

1. These provisions have now been incorporated in § 405.1046(b) of this interim final rule. The new provisions are basically verbatim restatements of the statute and are completely compatible with, although more detailed than, the proposed provisions.

2. In addition to changes needed to implement section 933(c)(3) of the MMA, we have added paragraph (c) to § 405.1046 to clarify CMS' long-standing position that ALJ decisions are not final for purposes of determining the actual amount of payment due. ALJ decisions involving underpayments often indicate that Medicare must make payment for a service, but do not calculate a specific underpayment amount to be made. These determinations are not final, because the contractor must still calculate the underpayment amount by determining the principal amount to be paid. In addition, 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. Therefore, the date of the final determination for purposes of determining when interest charges on underpayments begin accruing is the date that the contractor completes the calculation and makes the written determination of the principal amount that Medicare owes.

17. Appeals Involving Overpayments (§ 405.1064)

[If you choose to comment on issues in this section, please include the caption ''Appeals Involving Overpayments'' at the beginning of your comments.]

A decision that is based on only a portion of a statistical sample does not accurately reflect the entire record. Therefore, we have added § 405.1064 to set forth a general rule regarding ALJ decisions that are based on statistical samples. The effect of this technical change is that when an appeal from the QIC involves an overpayment issue and the QIC relies on a statistical sample in reaching a decision, the ALJ must base his or her decision on a review of all claims in the same statistical sample.

18. Review by the MAC and Judicial Review (§ 405.1100 Through § 405.1140)

[If you choose to comment on issues in this section, please include the caption ''Review by the MAC and Judicial Review'' at the beginning of your comments.]

a. Introduction

The component of the Departmental Appeals Board (DAB) that decides cases brought under section 521 of BIPA is called the Medicare Appeals Council (MAC). Prior to this interim final rule, the MAC considered requests for review of Medicare cases under the procedures used by SSA's Appeals Council. *See* 20 CFR §§ 404.966 through 404.985. In the proposed rule, we proposed that some of the regulations governing the SSA's Appeals Council be modified to meet the particular needs of the Medicare process and proposed adding other regulations to effectuate the BIPA provisions governing MAC review.

b. MAC Review of an ALJ's Action/De Novo Review

Under the regulations governing the pre-BIPA process, the MAC could deny or dismiss a request for review, or it could grant the request for review and either issue a decision or remand the case to an ALJ. The MAC could also review an ALJ's action in order to dismiss a request for hearing for any reason for which it could have been dismissed by the ALJ. The MAC also had the authority under the pre-BIPA process to review an ALJ's action on its own motion, provided that it took review of the case within 60 days after the date of the hearing decision or dismissal. In the proposed rule, we described the factors the MAC considered under the pre-BIPA regulations in deciding whether to grant review. We also noted that if the MAC denied review of an ALJ's decision under those regulations, the ALJ's action, not the denial of review, was the final decision of the Secretary and was reviewable in Federal district court on a substantial evidence standard.

BIPA establishes a new standard for MAC review of an ALJ's action. Section 1869(d)(2)(A) of the Act directs the MAC to conduct its review of an ALJ decision and make a decision or remand the case to the ALJ within 90 days of a request for review. Section 1869(d)(2)(B) of the Act specifies that the MAC reviews the case *de novo.* In addition, section 1869(d)(3)(A) of the Act allows parties to request a review by the MAC if within 90 days of timely filing a request for an ALJ hearing, the ALJ has not issued a decision, ''notwithstanding any requirements for a hearing for purposes of the party's right to such a review.''

We proposed under § 405.1100 that when a party requests a MAC review, the MAC reviews the ALJ's decision *de novo.* The party does not have the right to a hearing before the MAC, and the MAC considers all evidence in the administrative record. If a case requires additional evidence or proceedings at the ALJ level, the MAC remands the case to the ALJ for further action. Otherwise, the MAC communicates its final action on the case by issuing a final decision or order that adopts, modifies, or reverses the ALJ's action, as appropriate. We also proposed other changes to the MAC's current procedures to accommodate the statute's changes to the MAC's standard of review, as well as the adjudication deadlines. (Some of the changes concerning time and place of filing a review and other changes that affect both the ALJ and MAC process are

discussed earlier in this preamble.) Because an ALJ's decision is not final and binding on all parties if the MAC reverses the ALJ's decision, we have amended § 405.1048 to make that point clear.

Consistent with our managed care regulations, §§ 405.1106(a) and 405.1106(b) require that an appellant must send a copy of the request for MAC review or escalation to the MAC and to the other parties involved in the appeal. Although the MAC will not dismiss an appeal on the grounds that the appellant failed to satisfy this requirement, the deadline will be tolled if the appellant fails to copy the other parties.

Comment: Most of the comments we received concerning MAC review pertained to the MAC's procedures when a case is escalated from the ALJ level to the MAC. However, one commenter expressed the concern that the MAC's *de novo* review standard would diminish an ALJ's authority to make findings of fact.

Response: Section 1869(d)(2)(B) of the Act requires the MAC to conduct any review of an ALJ's decision under a *de novo* review standard. Therefore, when the MAC reviews an ALJ's decision, the MAC will not apply a substantial evidence standard when it considers an ALJ's findings of fact. However, an ALJ's findings and conclusions on factual issues will still carry weight, particularly with respect to the credibility of witnesses, and by no means do the BIPA changes diminish an ALJ's authority to make findings of fact.

As we indicated in the proposed rule, the MAC must carefully consider all evidence in the record in conducting its review. It must then adopt, modify, or reverse the ALJ's decision, or remand the case to an ALJ for further proceedings (the MAC can also dismiss a request for review). Note that under § 405.1112, an appellant's request for a review must identify the parts of the ALJ decision with which the appellant disagrees and explain why the ALJ's findings and conclusions are wrong. The MAC will limit its review to those exceptions, unless the appellant is an unrepresented beneficiary. Thus, the MAC will review an ALJ's findings of fact or conclusion only when specifically challenged by an appellant. Under those circumstances, or in the case of an unrepresented beneficiary appellant, the *de novo* review standard will apply. Note that the MAC can remand the case to an ALJ if the MAC determines that additional evidence is needed or additional action by the ALJ is required.

c. Escalation of an Appeal From the ALJ Level to the MAC

Section 1869(d)(3)(A) of the Act, as amended by section 521 of BIPA, provides that if an ALJ does not issue a decision within the 90-day adjudication period, ''the party requesting the hearing may request a review by [the MAC], notwithstanding any requirements for a hearing for purposes of the [appellant's] right to such a review.'' We originally proposed that cases escalated to the MAC from the ALJ level under this provision would not be subject to the 90-day adjudication deadline. As discussed earlier in this preamble, we have decided to require that the MAC complete its action in an escalated case within 180 days of the receipt of the request for escalation.

We also indicated in the proposed rule that we interpret section 1869(d)(3)(A) of the Act to mean that only the person or entity that requests the ALJ hearing can escalate the appeal to the MAC if the ALJ does not meet the 90-day adjudication deadline. For example, where CMS has entered a case as a party, it may not seek escalation. We did not receive any comments concerning this proposal. We also stated that we believed that the statute does not require the MAC to hold a hearing when a case is escalated from the ALJ to MAC level.

Comment: We received several comments that the MAC be required to hold a hearing when a case is escalated from the ALJ level. Some commenters note that proposed § 405.1108(d)(2) allows the MAC to hold a hearing.

Response: As we noted in the proposed rule, the statute describes different procedures and standards for adjudication or review for the various steps of appeal. Just as some appellants in the pre-BIPA process chose different processes at the carrier hearing level (in-person hearing, telephone hearing, or on-the-record decision) and made similar choices at the ALJ level, appellants who consider escalating their cases will have to determine how important it is in their case to receive the type of process provided at a particular level. As we explained in the proposed rule, the statute does not require that the MAC hold a hearing if a case is escalated to it; rather, the statute allows escalation ''notwithstanding any requirements for a hearing.'' Moreover, § 405.1108(d)(2) does not establish an appellant's right to a hearing before the MAC; rather, it gives the MAC the option to hold a hearing when the MAC concludes that it is necessary. Therefore, although an appellant who escalates a case to the MAC can request that the MAC hold a hearing, the MAC has the authority to deny the request and decide the case on the written record.

We also explained that when the MAC receives a case escalated from the ALJ level, the MAC might issue a decision, dismiss either the request for hearing or request for review on procedural grounds, or, if the administrative record is insufficient to take any of the above actions, remand the case to the ALJ for specific development and a decision.

Comment: Some commenters state that it is inappropriate for the MAC to remand a case to an ALJ that has been escalated to the MAC because the ALJ has not decided the case within the 90-day period. Instead, the MAC must correct any deficiencies in the record itself.

Response: We do not anticipate that the MAC will routinely remand an escalated case to the ALJ. However, we need to retain this option for those rare occasions in which the MAC cannot resolve the case at its level, or when the request for escalation and the other remedies requested by the appellant in the request for review are mutually exclusive. For example, where an ALJ fails to issue a decision after a hearing that the appellant does not believe was a fair hearing, the appellant might escalate at the end of the 90-day adjudication period for the purpose of requesting a hearing and decision by a different ALJ. Here, if the MAC concludes that the appellant did not receive a fair hearing before the first ALJ and determines that the appropriate remedy is a hearing before a different ALJ, then the MAC can remand that case accordingly.

C. Miscellaneous Comments

Comment: We received a number of questions about the prioritization of appeals once the new BIPA appeals process is implemented. In particular, commenters are concerned that at the post-redetermination levels of appeal, requests filed on or after the effective date of the BIPA changes will receive priority because of the new adjudication deadlines and the possibility of escalation. Commenters request that we clarify how adjudicators will be expected to prioritize appeal requests. They recommended that CMS require that appeal requests be adjudicated in the order in which they are received. In a related comment, we were asked to clarify what impact, if any, implementation of the new appeals process will have on appeals that are already in progress.

Response: As discussed in section I–E of this preamble, we are fully cognizant of these important issues and have taken them into consideration in developing an implementation approach for these new requirements. In general, we agree with commenters that adjudicators can be expected to continue to carry out appeals in the order in which appeal requests are received. Thus, CMS intends to work closely with the FIs and carriers to ensure that all appeal requests are completed on a timely basis. Similarly, CMS, SSA, and HHS are working together to reduce the backlog of cases at the ALJ and MAC levels, and thus, minimize this problem.

Comment: In the current appeals process, contractors are required to effectuate appeal decisions within 30 days. A commenter asked what effectuation time frame(s) FIs and carriers will be required to adhere to in the new appeals process.

Response: The current appeal regulations do not require carriers or fiscal intermediaries to effectuate ALJ or MAC decisions within a specific time frame. The effectuation time frames that our contractors follow in the current appeals process are based on manual requirements. Neither BIPA nor MMA impose any statutory requirements for effectuation of appeals decisions. Nonetheless, it is our intention to maintain the current manual requirements for effectuation of ALJ and MAC decisions in the new appeals process. The relevant manual provisions can be found in the Internet-only Manual (IOM)(Medicare Claims Processing Manual (Pub. 100–4) at Chapter 29 Sections 60.20.2, 60.22, and 60.24. In conjunction with implementation of the new appeals process, an additional section will be added to the IOM detailing the effectuation time frames for QIC decisions.

Comment: One commenter asks whether the changes implemented by BIPA also apply to the Medicare Cost Program.

Response: The changes to appeal procedures that are required under section 521 of BIPA, and Title IX, Subtitle D, of the MMA, apply only to claim determinations with respect to Part A and Part B of Medicare. However, section 1876(c)(5) of the Act and § 417.600 of the Medicare cost plan regulations establish that cost plan enrollees have a right to an ALJ hearing and a subsequent right to MAC and judicial review. Thus, the new ALJ and MAC regulations will generally apply to cost plans. We intend to address this issue in further detail in either a CMS Ruling or future rulemaking.

Comment: Under the proposed rule, CMS has the option of joining certain appeals at the ALJ level. A commenter recommends that if CMS elects to join an appeal, the agency must be required to hire an attorney to represent it.

Response: In the current claim appeals process, appellants and other parties retain almost complete discretion to elect or not to elect an appointed representative. With few exceptions, parties can choose any person to act as their appointed representative. In the new appeals process, as in the old, we believe that all decisions with respect to the selection of an appointed representative should be left up to the party, regardless of whether the party is a beneficiary or CMS. Accordingly, the Appointed Representative provisions found in section 405.910 of the interim final rule maintain our current policy of giving parties almost complete control over the selection of an appointed representative. As a party to an appeal, CMS enjoys the same rights and privileges as any other party, including control over its selection of an appointed representative.

Comment: One commenter asks us to clarify what, if any, continuing education will be available to QICs and ALJs.

Response: The new Administrative QIC (AdQIC) will have primary responsibility for fulfilling the educational and training needs of the QICs.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comments, we are not able to acknowledge or respond to them individually. We will consider all comments concerning the provisions of the interim final rule that we receive by the date and time specified in the **DATES** section of this preamble, and respond to those comments in the preamble to the final rule.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment when a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The PRA exempts most of the information collection activities referenced in this Interim Final Rule with Comment. In particular, 5 CFR 1320.4 excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment. There is, however, one requirement contained in this rule that is subject to the PRA because the burden is imposed prior to an administrative action or denial of payment. This requirement is discussed below.

Section 405.910 Appointed Representatives

In summary, section 405.910 states an individual or entity may appoint a representative to act on their behalf in exercising their rights to an initial determination or appeal. This appointment of representation must be in writing and must include all of the required elements specified in this section.

The burden associated with this requirement is the time and effort of the individual or entity to prepare an appointment of representation containing all of the required information of this section. In an effort to reduce some of the burden associated with this requirement, we have developed a standardized format that the individual/entity may opt to use.

We estimate that approximately 27,277 individuals and entities will elect to appoint a representative to act on their behalf each year. Because we have developed the optional standardized form, we estimate that it should only take approximately 15 minutes to supply the required information to comply with the requirements of this section. Therefore, we estimate the total burden to be 6,819 hours on an annual basis.

If you wish to view the proposed standardized notices and the supporting documentation, you can download a copy from the CMS Web site at *http://www.cms.hhs.gov/regulations/pra/.*

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Dawn Willinghan, CMS–4064–IFC Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer Comments submitted to OMB may also be e-mailed to the following address: e-mail: *Christopher_Martin@omb.eop.gov* or faxed to OMB at (202) 395–6974.

V. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption ''Regulatory Impact Analysis'' at the beginning of your comments.]

A. Introduction

We have examined the impact of this interim final rule with comment under the criteria of Executive Order 12866 (September 1993, Regulatory Planning and Review), section 1102(b) of the Social Security Act, the Regulatory Flexibility Act (RFA) (Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). Although we do not expect this interim final rule to have a substantial financial impact on beneficiaries, providers, or suppliers, we anticipate that Federal costs to implement this rule may exceed the $100 million threshold. Therefore, this is a major rule and in compliance with Executive Order 12866, we have prepared the RIA below. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The RFA requires agencies, in issuing certain rules, to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $25 million or less annually. For purposes of the RFA, all providers and suppliers affected by this regulation are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for a rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act. As discussed in further detail below, we are uncertain how many small entities will be affected by this rule. The purpose of this interim final rule is to improve the efficiency of the claims review and appeals process, and to the extent that these changes shorten the appeals process, these regulations should reduce the associated burden on small entities. Similarly, the impact on small rural hospitals is likely to be negligible or slightly positive. Therefore, we are certifying that the interim final rule will not have a significant impact on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that would include any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. This rule will not have this effect on State, local, or tribal governments, or on the private sector.

B. Scope of the Changes

We did not receive any comments regarding the impact analysis provided in the proposed rule. Therefore, this analysis largely repeats the proposed rule impact analysis and estimates. This interim final rule adopts most of the proposed provisions and adds changes required under the MMA. The impact of any changes is discussed below.

As discussed in detail above in section II of this preamble, this interim final rule establishes new regulations concerning appeals procedures for Medicare claims determinations, consistent with section 1869 of the Act as amended by section 521 of BIPA 2000 and sections 931, 932, 933, 935, 937, 939, and 940 of the MMA.

Among the significant changes required by the BIPA and MMA amendments are:

- Establishing a uniform process for handling Medicare Part A and Part B appeals, including the introduction of a new level of appeal for Part A claims.
- Revising the time frames for filing a request for a Part A and Part B appeal.
- Requiring appeals notices issued at the redetermination, reconsideration, and ALJ levels to include specific information.
- Imposing a 60-day time frame for redeterminations made by fiscal intermediaries and carriers.
- Requiring the establishment of a new appeals entity, the qualified independent contractor (QIC), to conduct ''reconsiderations'' of contractors' initial determinations including redeterminations, and allowing appellants to escalate the case to an ALJ hearing, if reconsiderations are not completed within 60 days.
- Requiring providers and suppliers to present all evidence for an appeal no later than the QIC reconsideration level, unless the appellant demonstrates good cause as to why that evidence was not provided previously.
- Establishing uniform amount in controversy thresholds for ALJ hearings and judicial review that will be adjusted annually by the medical care component of the Consumer Price Index for all urban consumers.
- Establishing a 90-day time limit for conducting ALJ and DAB appeals and allowing appellants to escalate a case to the next level of appeal if ALJs or the MAC do not meet their deadlines.
- Establishing a requirement for ''de novo'' review when the MAC reviews an ALJ decision made after a hearing.

This interim final rule does not establish new rules, or alter existing rules, with respect to the substantive standards for determining whether a Medicare claim is payable. Claims that enter the administrative appeals process represent an extremely small portion of the total number of claims that Medicare processes each year. In FY 2003, for

example, Medicare contractors processed 1.05 billion claims; of these only about 5.7 million were appealed. Thus, the number of Medicare claims that enter the administrative appeals system represents only about 0.5 percent of the total number of claims filed with Medicare. Moreover, the 5.7 million figure represents the total number of claims appealed, not the number of appellants. From our experience, the vast majority of appeal requests are filed by a relatively limited group of appellants. Therefore, the number of providers, physicians and other suppliers, as well as beneficiaries who enter the appeals process is far fewer than the 5.7 million claims that are appealed. Given the small percentage of claims and appellants involved in the administrative appeals process, we believe that this interim final rule will have little or no effect on most Medicare providers and suppliers. The changes set forth are even less likely to affect beneficiaries, whose appeals are estimated to constitute no more than 3 to 5 percent of total appeals. As discussed in detail below, however, for those providers, suppliers, and beneficiaries who do file appeals of Medicare claim determinations, the effects of this interim final rule should be positive.

C. Anticipated Effects on Providers, Physicians and Other Suppliers, and Beneficiaries

We expect that the changes set forth in this interim final rule will produce substantial improvements in the consistency and efficiency of the claims appeal process. For the most part, the anticipated positive impact of the interim final rule on providers, physicians and other suppliers will be similar to the anticipated effects on beneficiary appellants, although again the impact on the provider and supplier communities would be more pronounced due to the much greater volume of provider and supplier appeals. We include a brief discussion of the anticipated impact of major changes below.

In general, we do not anticipate that the introduction of these new appeals procedures will have a substantive impact on the final results of claims appeals; that is, there is no reason to believe that the use of QICs, or other changes required by BIPA and the MMA, will result in any change in the extent to which appeals eventually result in favorable decisions for providers, suppliers, or beneficiaries. Thus, we do not anticipate that these changes will have a quantifiable impact on Medicare claims payments. From an administrative perspective, however, the introduction of better notice requirements, new independent review entities, and mandatory physician review of medical necessity issues should increase appellants' confidence in the Medicare appeals process. Thus, we believe that the implementation of requirements that ensure appellants of both the fairness of the decision-making process and the accuracy and consistency of the decisions reached can eventually lead to measurable reductions in the need for the elevation of appeals to the slower, more costly levels of the appeals system (for example, ALJ hearings and MAC or Federal court review).

In the short term, it will not be surprising if there is an initial spike in requests for reconsiderations by QICs given the reduced time frame for these second level appeals, the availability of new appeal entities, and the introduction of physician review panels. Similarly, it is foreseeable that the number of requests for ALJ hearings or MAC reviews may increase given the establishment of relatively short decision-making time frames for these entities.

Most of the major changes set forth in this interim final rule (for example, as the new time frames for appeals decisions) are mandated by the statutes and thus, are not subject to the Secretary's discretion. To the extent that we have exercised discretion (for example, in establishing procedures for conducting appeals), we have attempted to balance the need for accurate, expeditious appeals decisions with our responsibilities to implement these changes in a cost-effective manner.

A discussion of the anticipated impacts of key provisions follows.

1. Decision Making Time Frames and Escalation

Perhaps the most significant changes set forth are the reductions in mandatory time frames for issuing decisions on appeals. In general, this means faster receipt of decisions and, for favorable decisions, faster payment. For example, under the interim final rule, the time frame for a reconsideration (formally called a carrier hearing) has been reduced from 120 days to 60 days. If the decision is favorable (that is, the appeal results in a reversal of an initial determination that a claim could not be paid), effectuation of the favorable decision will be initiated as soon as a decision is reached. Given the reduced decision-making time frames, payments will be received substantially sooner than under the current system. These benefits to appellants will extend to all levels of the Medicare administrative appeals process.

In addition to the new time frames for making decisions, the interim final rule will allow appellants the option of escalating an appeal to an ALJ if the QIC fails to make a decision timely. Escalation is also available at the appellants' option from the ALJ level to the MAC if an ALJ fails to issue a hearing decision on a QIC decision within 90 days of a request for an appeal of a QIC reconsideration (or similarly from the MAC to Federal court). Clearly, these options will be a positive change for appellants, who have greater control of their appeals and a viable recourse during the appeals process if, during one stage of the appeals process, their appeal is not decided timely.

Overall, these changes will reduce the amount of time that it takes for a claim to make its way through the administrative appeals process. In the past, it generally took 3 to 5 years for appealed claims to reach resolution at the MAC level. We anticipate that a claim will now take about 18 months to make its way through the entire administrative appeals process.

2. Transfer of ALJ Function

After the proposed rule was published in the **Federal Register,** a significant development occurred involving the transfer of the ALJ function. Section 931 of the MMA requires the responsibility for the functions of ALJs for hearing appeals under title XVIII of the Act (and related provisions on title XI of the Act) to be transferred from the Commissioner of SSA to the Secretary of the DHHS. For the most part, organizational responsibility for this function should not have a material impact on appellants. To the extent that there is an impact, it should be positive since ALJs will now be able to focus solely on Medicare issues instead of both SSA and Medicare issues. Note that although this rule reflects the transfer of the ALJ function from SSA to DHHS, the rule does not implement this change.

3. Review of Claims by a Panel of Health Care Professionals

Another important change implemented through this interim final rule is the requirement that a panel of physicians or other qualified health care professionals conduct QIC reconsiderations when the initial determination being appealed involves a medical necessity issue. BIPA mandates that when an initial determination involves a finding on whether an item or service is reasonable and necessary for the diagnosis or treatment of an

illness or injury, a QIC's reconsideration must be based on clinical experience and medical, technical, and scientific evidence to the extent applicable. MMA further provides that if a claim is for treatment, items, or services furnished by a physician, the reviewing professional must also be a physician. We believe that this change will give appellants more confidence that a fair decision has been reached, potentially reducing their need to pursue subsequent appeals. Thus, the introduction of routine involvement of physicians and other health care professionals into the appeals process should produce administrative finality at an earlier level of the process and benefit both appellants and the Medicare program.

4. Decision Letters and Documentation Requirements

An important aspect of the proposed rule concerns the content of the notices sent to parties when a contractor upholds its initial determination. These requirements include a written summary of the rationale for the redetermination decision and the identification of any specific missing documentation that contributed to the decision to deny the claim in question. Since publication of the proposed rule, section 933(c) of the MMA amended sections 1869(a), 1869(c), and 1869(d) of the Act and established statutory notice requirements that are very similar to those we proposed. Those statutory requirements have been incorporated into this interim final rule. We believe that these policies will provide appellants with the information they need to build their case early in the appeals process. We believe the impact of these requirements will be to produce more accurate decisions at the QIC reconsideration level, based on all the appropriate medical information, rather than appeals often needing to be raised to an ALJ before needed documentation is produced. This will give beneficiaries, providers, and suppliers more detail about why their claim was denied and allow them to fashion their appeal accordingly.

In addition, section 1869(b)(3) of the Act, as amended by section 933(a)(1) of the MMA, now specifies that providers and suppliers may not introduce evidence in any appeal that was not presented at the reconsideration conducted by the QIC. As a matter of policy, we also have extended this requirement to beneficiaries represented by providers and suppliers. This will ensure that providers and suppliers do not attempt to circumvent this evidence requirement by offering to represent beneficiaries. If the information is not submitted to the QIC, but instead is presented later in the appeals process, the evidence will not be considered unless the appellant demonstrates good cause why the information was not submitted to the QIC. We believe the end result of these provisions will be that appeals are resolved at the earliest possible administrative level, which is a positive result for all appellants.

5. Appeal Rights

In the past, providers could appeal in their own right only when the item or service was not covered because it constituted custodial care, was not reasonable and necessary, or in certain other limited situations when the determinations involved a finding with respect to the limitation of liability provision under section 1879 of the Act. In order to appeal in other circumstances, providers must have acted as representatives of beneficiaries.

In the interim final rule, we permit participating providers to appeal to the same extent as beneficiaries, or suppliers who take assignment. Also, consistent with section 1870(h) of the Act, as amended by section 939(a) of the MMA, we permit a provider or supplier to appeal a claim denial where that provider or supplier has rendered items or services to a beneficiary who subsequently dies and there is no other party available to appeal the denial. We believe these changes will have several positive impacts on appellants. For example, they should eliminate any confusion providers may have in determining whether they have standing to appeal an initial determination, and they remove the burden for the provider of obtaining an appointment of representative from a beneficiary. Thus, this interim final rule expands both provider and supplier appeal rights.

D. Effects on the Medicare Program

In the final analysis, the primary financial impact of implementing these changes falls upon the government agencies responsible for conducting appeals; that is, CMS and DHHS. Deciding appeals within shorter timeframes and establishing new independent review entities to conduct these appeals entail significant new costs, as does the development of an appeals-specific data system to track the results of these appeals. By establishing shorter decisionmaking timeframes and improved procedures in the Medicare appeals system, BIPA and the MMA created additional opportunities and incentives for providers, suppliers, and beneficiaries to request appeals. Also, the statute no longer provides for any minimum amount in controversy (AIC) for appeals below the ALJ level, and lowers the AIC from $500 to $100 (plus an annual increase based on the CPI) for Part B claim determinations that are appealed to an ALJ. The AIC for Part A claims remains at $100 (plus an annual increase based on the CPI).

Thus, although we anticipate that the impact of these changes will be positive for the provider, physician, supplier, and beneficiary communities, implementing these procedures has generated substantial costs to the Medicare program. CMS' FY 2004 operating plan included $10 million for QIC implementation start-up costs and $6 million for the Medicare Appeals System (MAS), which will be used to track appeals electronically. In addition, CMS plans to spend $6 million from the FY 2004–2005 Medicare Modernization Act appropriation for MAS. Higher spending is likely in FY 2006, as more of the appeals workload is transferred over to the QICs, not to mention the additional costs to implement necessary changes at the ALJ and MAC appeals levels.

E. Federalism

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

VI. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a document take effect. However, section 553(b) of the Administrative Procedure Act provides for waiver of this procedure, if an agency for good cause finds that the notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and the reasons for it into the notice issued.

Subsequent to the publication of the proposed rule on November 15, 2002, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108–173) was enacted on December 8, 2003. Title IX of the MMA includes a number of essentially nondiscretionary provisions that directly affect the Medicare claims appeals process. As discussed below, we find good cause to incorporate these

requirements into this interim final rule, rather than to issue a notice of proposed rulemaking to address statutory changes. Due to the close relationship between the provisions of the rule that address new MMA requirements and the policies that were included in the November 15, 2002 proposed rule, we are soliciting comments on all provisions contained in this interim final rule and, as required under section 902 of the MMA, will publish a subsequent final rule addressing any comments received in response to this interim final rule not later than 3 years after the publication date of this rule. The BIPA section 521 provisions have previously been subject to comment in the proposed rule of November 15, 2002. The comments received in response to that proposed rule are described in this interim final rule, and the policies included in this interim final rule reflect those comments.

As a rule, the MMA appeals provisions are straightforward and self-explanatory and do not involve significant agency discretion in how they should be implemented. For example, section 940 of the MMA establishes new decisionmaking timeframes for both redeterminations and reconsiderations, and it would be unnecessary and contrary to the public interest not to implement these deadlines as soon as possible. Similarly, section 939 of the MMA establishes new appeal rights for providers when a beneficiary dies and there is no other party available to appeal a determination; not implementing this provision as soon as practicable would again be contrary to the public interest.

Not only would proposed rulemaking be unnecessary and contrary to the public interest, it would also be impracticable. The BIPA provisions that were set forth in our proposed rule are in many cases inextricably linked with the subsequent MMA provisions, and it would be virtually impossible to finalize the proposed rule without incorporating the MMA provisions. Moreover, the MMA legislation mandated provisions that were nearly identical to those set forth in the proposed rule, such as the requirements concerning the full and early presentation of evidence under section 933(a) of the MMA and the new notice requirements for Medicare appeals under 933(c) of the MMA. Even absent the MMA provisions, the requirements set forth in this interim final rule would have constituted logical outgrowths of the proposed rule, and it would be both impracticable and illogical not to incorporate these requirements into this regulation.

Thus, we believe there is good cause to include the appeals provisions of the MMA along with the appeals provisions of BIPA (which were previously addressed in the proposed rule) in this interim final rule. Publishing these provisions in an interim final rule will give the public ample opportunity to submit comments. Note that given the close linkage between many of the proposed requirements and those set forth under the MMA, we believe it is appropriate to consider comments on all aspects of this rule, including those that have previously been subject to notice and comment. Publication of this interim final rule will serve the public interest by ensuring that Medicare beneficiaries, providers, and suppliers have access to the improved Medicare appeals system as expeditiously as possible, consistent with congressional intent.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 405

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

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

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

Subpart B—Confidentiality and Disclosure

■ 1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh). Subpart F is also issued under the authority of the Federal Claims Collection Act (31 U.S.C. 3711).

■ 2. Amend § 401.108 by revising paragraph (c) to read as follows:

§ 401.108 CMS rulings.

* * * * *

(c) CMS Rulings are published under the authority of the Administrator, CMS. They 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 pertaining to Medicare Part A and Medicare Part B under the jurisdiction of CMS.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 3. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a) 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a) 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and Sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 4. Add a new subpart I, § 405.900 through § 405.1140 to read as follows:

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

Sec.

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

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the provisions of sections 1869 (a) through (e) and (g) 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.

§ 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.

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.

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.

§ 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.

(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.

§ 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;

(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.

(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, the adjudicator sends notices and requests to both the beneficiary and the appointed 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.

§ 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 assignee. 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 assignor, 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.

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—

(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; and

(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. 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. 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:

(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; and

(vi) Any other requirements specified by CMS.

§ 405.922 Time frame for processing initial determinations.

The contractor issues initial determinations on clean claims within 30 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.

§ 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:

(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) The number of home health visits used;

(8) Periods of hospice care used;

(9) 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;

(10) 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;

(11) 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;

(12) 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;

(13) 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.

(14) 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.

(15) 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.

(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.

§ 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—

(a) Any determination for which CMS has sole responsibility, for example—

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

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

(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 in a particular case);

(k) 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 or contributes to 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 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; and

(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.

§ 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 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-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.

§ 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-day decision-making time frame is automatically extended for 14 calendar days for each submission.

§ 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-day filing deadline made in accordance with § 405.942(b), the 60-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 days of the latest filed request.

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

§ 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 final and binding, unless it is modified or reversed by a QIC under § 405.974(b) or vacated under paragraph (d) of this section.

§ 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 final and 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.

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, 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 days after the date of the notice of redetermination, unless there is evidence to the contrary.

(2) For purposes of meeting the 180-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-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).

§ 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-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-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.

§ 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 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-day filing deadline made in accordance with § 405.962(b), the QIC's 60-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 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-day decisionmaking timeframe is extended by up to 14 days for each submission, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* Within 60 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 appellant 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.

(3) Notify all parties that it has dismissed the request for reconsideration consistent with § 405.972.

(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 days of receipt of the notice or 5 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.

§ 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;

(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 final and binding, unless it is modified or reversed by an ALJ under § 405.1004 or vacated under paragraph (d) of this section.

§ 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 days after receipt of the contractor's 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 final and not subject to any further review.

§ 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 final and 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.

Reopenings

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

(a) *General rules.* (1) A reopening is a remedial action taken to change a final determination or decision that resulted in either an overpayment or underpayment, even though the determination or decision was correct 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 mirror errors and omissions) as reopenings, instead of 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 and 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 a claim at issue until all appeal rights are exhausted. Once the appeal rights 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 final and not subject to appeal.

(6) A Medicare secondary payer demand to recover a conditional payment, based upon a provider's or supplier's failure to demonstrate that it filed a proper claim with a plan, program, or insurer, as defined in § 411.21 of this chapter, because this action is a reopening.

(b) *Time frames and requirements for reopening initial determinations and redeterminations initiated by a contractor.* A contractor may reopen and revise its 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).

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

(3) The MAC may reopen its review decision on its own motion within 180 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 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 reopen his or her decision within 180 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 days from the date of the review decision for good cause in accordance with § 405.986.

§ 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.

(d) *MSP recovery claim.* 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.

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 final decision of the ALJ has been issued;

(B) MAC review in accordance with § 405.1102 and a final decision 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 final action within the time frame 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 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 final and 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 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 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-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-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.

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, including the QIC, QIO, fiscal intermediary or carrier, may participate in or join the hearing as a party. (*see* § 405.1010 and § 405.1012).

(d) The ALJ 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.

§ 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 days after receipt of the notice of the QIC's reconsideration; and

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

(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 final action within 5 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.

§ 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 days after receipt of the notice of the QIC's dismissal; and

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

(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 final and not subject to further review.

§ 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 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.

§ 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, including a QIC, 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 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.

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

(a) CMS and/or one or more of its contractors, including a QIC, 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 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.

§ 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 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-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-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 hearing office grants the request to extend the filing deadline.

§ 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-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-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 hearing office 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-day period beginning on the date that the request for escalation is received by the ALJ hearing office, unless the 180-day period is extended as provided in this subpart.

(d) When CMS 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 paragraph (a) and (c) of this section is tolled.

§ 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 days of receiving the notice of hearing).

(b) If a party submits written evidence later than 10 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 is 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.

§ 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 will send a notice of hearing to all parties that filed an appeal or otherwise participated in any of the determinations in paragraphs (c) through (i) of this section, any party who was found liable for the services at issue subsequent to the initial determination, the contractor that issued 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 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 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) A request for an in-person hearing shall constitute a waiver of the 90-day time frame specified in § 405.1016.

(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.

§ 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 addresses, or given by personal service, unless the parties have indicated in writing that they do not wish to receive this notice. The notice is mailed or served at least 20 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).

§ 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 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.

§ 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 by the appellant.

(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 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.

§ 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.* 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:

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

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

(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.

§ 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) 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.

(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 out in paragraph (f)(2) of this section with the ALJ within 10 calendar days of receipt of the notice of hearing.

(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 days beginning 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.

§ 405.1037 Discovery.

(a) *General rules.* (1) Discovery is permissible only when CMS 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 hearing.

(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 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 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 for review made by a party other than CMS of a 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.

§ 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 videoconferencing, 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.

§ 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) The appellant 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-day adjudication deadline.

§ 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 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.

§ 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 final 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-day period beginning on the date when the request for hearing is received in the ALJ hearing office, unless the 90-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.

§ 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 either issues a final action 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.

§ 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 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 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(d).

(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 § 405.1020.

(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 final 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.

§ 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 all Medicare contractors, including QIOs, QICs, Medicare Advantage Organizations, Prescription Drug Plans and their sponsors, HMOs, CMPs, HCPPs, 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.

§ 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 CMS Rulings.

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.

§ 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 action or remands a case to the ALJ within 90 days of receipt of the appellant's request for review, unless the 90-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 action or remand the case to the ALJ within 180 days of receipt of the appellant's request for escalation, unless the 180-day period is extended as provided in this subpart.

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

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

(b) 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.

(c) 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.

§ 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 final action or remand the case to the QIC within the latter of 5 days of receiving the request for escalation or 5 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 final action or remand 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 final action or remand order within the statutory time frame.

(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 a final administrative decision for purposes of MAC review.

(c) *No escalation.* If the ALJ's adjudication period set forth in § 405.1016 expires, the case remains with the ALJ until a final action is issued and the appellant does not request escalation to the MAC or the appellant requests escalation to the MAC.

§ 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 may be filed with the MAC or the hearing office that issued the ALJ's decision or dismissal. The appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal. 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 the ALJ hearing office rather than the MAC, the MAC's adjudication period to conduct a review begins on the date the request for review is received by the MAC. Upon receipt of a request for review from an entity other than the ALJ hearing office, the MAC will send written notice to the appellant of the date of receipt of the request and commencement of the adjudication time frame.

(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-day period to issue a final action or remand the case to the ALJ begins on the date the request for escalation is received by the MAC.

§ 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 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's referral to the MAC is made in writing and must be filed with the MAC no later than 60 days after the ALJ's decision or dismissal is issued. The written referral will state the reasons why CMS believes that 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 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 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.

(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 days after receipt of the CMS referral, unless the 90-day period has been extended as provided in this subpart. The MAC may not, however, issue its action before the 20-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 remains the final action in the case.

§ 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 must 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 final action, 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.

§ 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-day adjudication deadline.

§ 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) 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.

(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. (i) 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.

(ii) 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.

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

(iv) 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.

(v) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifed 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(c) of the Act, 42 U.S.C. 405(c).

(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.

§ 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 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.

§ 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 final 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 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.

§ 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 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 days after the date it receives notice of the MAC's decision.

§ 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 days after the date it receives the MAC's notice that the MAC is not able to issue a final action or remand unless the party is appealing an ALJ dismissal.

§ 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 action 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 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 is filed, 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 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.

§ 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 days of the date the party receives the decision of the ALJ or submit a written request for an extension within the 30-day period. The MAC will grant a timely request for a 30-day extension. A request for an extension of more than 30 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 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 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 days after the date of the ALJ's decision, the decision of the ALJ becomes the final decision of the Secretary after remand.

Dated: January 12, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 12, 2005.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–4062 Filed 3–1;–05; 2:07 pm]

BILLING CODE 4120–01–P