DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS–4004–P]

RIN 0938–AL67

Medicare Program: Changes to the Medicare Claims Appeal Procedures

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

ACTION: Proposed rule.

SUMMARY: Under sections 1869 and 1879 of the Social Security Act (the Act), Medicare beneficiaries and, under certain circumstances, providers and suppliers of health care services, may appeal adverse determinations regarding claims for benefits under Medicare Part A and Part B. Section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 amends section 1869 of the Act to substantially revise the Medicare claim appeals process. The statute mandates a series of structural and procedural changes to the existing appeals process, including: The establishment of a uniform process for handling all Medicare Part A and Part B appeals; revised time limits for filing appeals; reduced decision-making time frames throughout all levels of the Medicare administrative appeals system; the introduction of new entities known as qualified independent contractors (QICs) to conduct reconsiderations of contractors' initial determinations or redeterminations; and the establishment of the right to an expedited determination when an individual disagrees with a provider's decision to discharge the individual or terminate services.

This proposed rule sets forth the regulations that would be needed to implement the new statutory provisions.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 14, 2003.

ADDRESSES: In commenting, please refer to file code CMS–4004–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4004–P, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–16–03, 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 commenters 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 could be considered late.

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

FOR FURTHER INFORMATION CONTACT: Michele Edmondson (410) 786–6478 (for issues relating to appeal rights). Jennifer Eichhorn (410) 786–9531 (for issues relating to initial determinations and redeterminations). Arrah Tabe (410) 786–7129 (for issues relating to QIC reconsiderations). Jennifer Collins (410) 786–1404 (for issues relating to ALJ hearings and DAB reviews). Rhonda Greene-Bruce (410) 786–7579 (for issues relating to expedited determinations).

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Timely comments 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.

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Note: The former name of the Centers for Medicare & Medicaid Services (CMS) was the Health Care Financing Administration (HCFA). The terms CMS and HCFA can be used interchangeably.

Since the Social Security Administration (SSA) became an independent agency in 1995 pursuant to Public Law 103–296, it has continued to provide CMS with support for the administration of the Medicare Parts A and B programs pursuant to a Memorandum of Understanding between SSA and DHHS. That support has involved, among other duties, continuing to provide hearings and decisions in Medicare appeals using SSA administrative law judges (ALJs) as well as utilizing SSA offices to forward various Medicare-related paperwork to CMS. While CMS has greatly appreciated SSA's assistance over the years in these areas, at this time CMS is considering taking over these Medicare responsibilities. Our hope is to have this in place on or before October 1, 2003. Until such time as CMS may take over the function, SSA will continue to provide Medicare claimants with the valuable assistance that it has traditionally provided. Thereafter, CMS will assume such responsibilities. CMS will provide appropriate notice to the public as to when such responsibilities will be assumed and also as to the procedures Medicare claimants will follow in dealing with CMS rather than SSA. Therefore, references in this NPRM to SSA, including SSA, ALJs, and field offices, should be read as references to SSA assistance to CMS up to the point in time when CMS takes over the SSA responsibilities.

I. Background

A. Overview of Existing Medicare Program

The original Medicare program consists of two parts. Part A, known as the hospital insurance program, covers

certain care provided to inpatients in hospitals, critical access hospitals, skilled nursing facilities (SNFs), 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+Choice (M+C) program. Under the M+C 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 M+C plan may provide additional health care items and services that are not covered under the original Medicare program.

Under the original Medicare program, a beneficiary may 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) would submit a claim for benefits under the Medicare program to the appropriate government contractor, either a fiscal intermediary (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 regulation, then the contractor would pay the claim. However, the Medicare program does not cover all health care expenses. If the Medicare contractor determines that the medical care is not covered under the Medicare program, it denies the claim. In fiscal year 2001, Medicare contractors adjudicated over 930 million initial claims and approximately 6.7 million claim appeals.

When a contractor denies a claim, it notifies the provider, supplier and/or beneficiary of the denial and offers the opportunity to appeal this decision. The existing appeals 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 M+C program are set forth at subpart M of part 422. After an appellant has exhausted the administrative appeals procedures offered under the Medicare program, the Medicare statute provides the opportunity for a dissatisfied individual to seek review in Federal court.

The regulations in part 405 subpart G, beginning at § 405.700, describe reconsiderations and appeals under Medicare Part A. When a Medicare contractor makes a determination with respect to a Part A claim, the beneficiary, or the provider, in some circumstances, may appeal the determination. (Consistent with section 1861(u) of the Act and 400.202, the term ''provider'' generally includes hospitals, SNFs, home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), and hospices.) The contractor then reconsiders the initial determination. If the contractor upholds the original determination, the appellant may request a hearing before an Administrative Law Judge (ALJ), provided that the amount in controversy is at least $100. (ALJs are employed by the Social Security Administration (SSA), but they adjudicate Medicare appeals under a Memorandum of Understanding between SSA and the Department of Health and Human Services (DHHS.) If the appellant is dissatisfied with the ALJ's decision, he or she may request review by the Departmental Appeals Board (DAB). The component within the DAB that is responsible for Medicare claim appeals is the Medicare Appeals Council (MAC). (Note that although the Medicare appeals regulations in part 405 contain some limited provisions regarding ALJ and MAC proceedings, these proceedings are generally governed by existing SSA regulations at 20 CFR part 404, subparts J.) MAC decisions constitute the final decision of the Secretary of DHHS (the Secretary) and may be appealed to Federal court. In each case, 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 (§ 405.800 *et seq.*). Under these regulations, beneficiaries and suppliers that accept assignment for Medicare claims may appeal to a Medicare contractor for a review of the contractor's initial determination that a claim should not be paid, either in full or in part. (The term ''supplier'' is also defined at § 400.202 and means a physician or other practitioner, or an entity other than a ''provider,'' that furnished health care services under Medicare.) If the contractor's review results in a continued denial of the claim, and the amount in controversy is at least $100, the appellant may request a 2nd level appeal known as a ''fair hearing.'' If the hearing officer upholds the denial, the appellant may request a hearing before an ALJ, provided that the amount in controversy is at least $500. Subsequent aspects of the appeals process for a Part B claim are identical to those described above for a Part A claim.

Quality improvement organizations (QIOs), formerly known as peer review organizations, also make certain types of Medicare determinations, mostly involving inpatient hospital discharges under sections 1154 and 1155 of the Act. These decisions are also subject to ALJ hearings, if the amount in controversy is at least $200. Judicial review is also available if the amount in controversy is $2000. Regulations for these appeals are currently found at 42 CFR part 478. Finally, note that appeals under Medicare Part C are also subject to adjudication by ALJs and the MAC, although these appeals follow an entirely separate path before the ALJ level.

B. Changes to the Appeals Process Under BIPA 2000

Section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106–554, amends section 1869 of the Act to require revisions to the Medicare appeals process. Among the major changes required by the BIPA amendments are—

- Establishing a uniform process for handling Medicare Part A and 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.
- Imposing a 30-day timeframe for certain ''redeterminations'' made by the contractors who made the initial determination.
- 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 appeals at the ALJ Level.
- Imposing 90-day time limits for conducting ALJ and MAC appeals and allowing appellants to escalate a case to the next level of appeal if ALJs or the MAC do not meet their deadlines.
- Imposing ''de novo'' review when the MAC reviews an ALJ decision made after a hearing.

Revised section 1869 also requires that the Secretary establish a process by which an individual may obtain an expedited determination if he/she

receives a notice from a provider of services that the provider plans to terminate services or discharge the individual from the provider. Currently, this right to an expedited review only exists with respect to hospital discharges (under sections 1154 and 1155 of the Act).

The statute specifies that the new appeals provisions are effective for initial determinations made on or after October 1, 2002. As this proposed rule demonstrates, we are making significant efforts to ensure that the public has an opportunity to comment on the procedures used to implement section 521 and to ensure that a rule is in place for implementing section 521. However, as noted in the CMS ruling published October 7, 2002 (67 FR 62478–62482) on this subject, this rulemaking effort is greatly complicated by the possibility of further changes to the statutory appeals provisions. We need to ensure that this statutory mandate will not risk disruptions to other fundamental functions of the Medicare program, such as processing and payment of Medicare claims. Thus, we seek comments on this proposed rule so that we can be in the best possible position for implementation.

Rather than listing here all the detailed provisions of section 521 of BIPA, we will discuss the individual provisions in detail below in the context of the proposed implementing regulations. However, for the convenience of the reader, we are providing below a detailed chart illustrating the current appeals procedures for both Part A and B claims and the new procedures that are required by BIPA:

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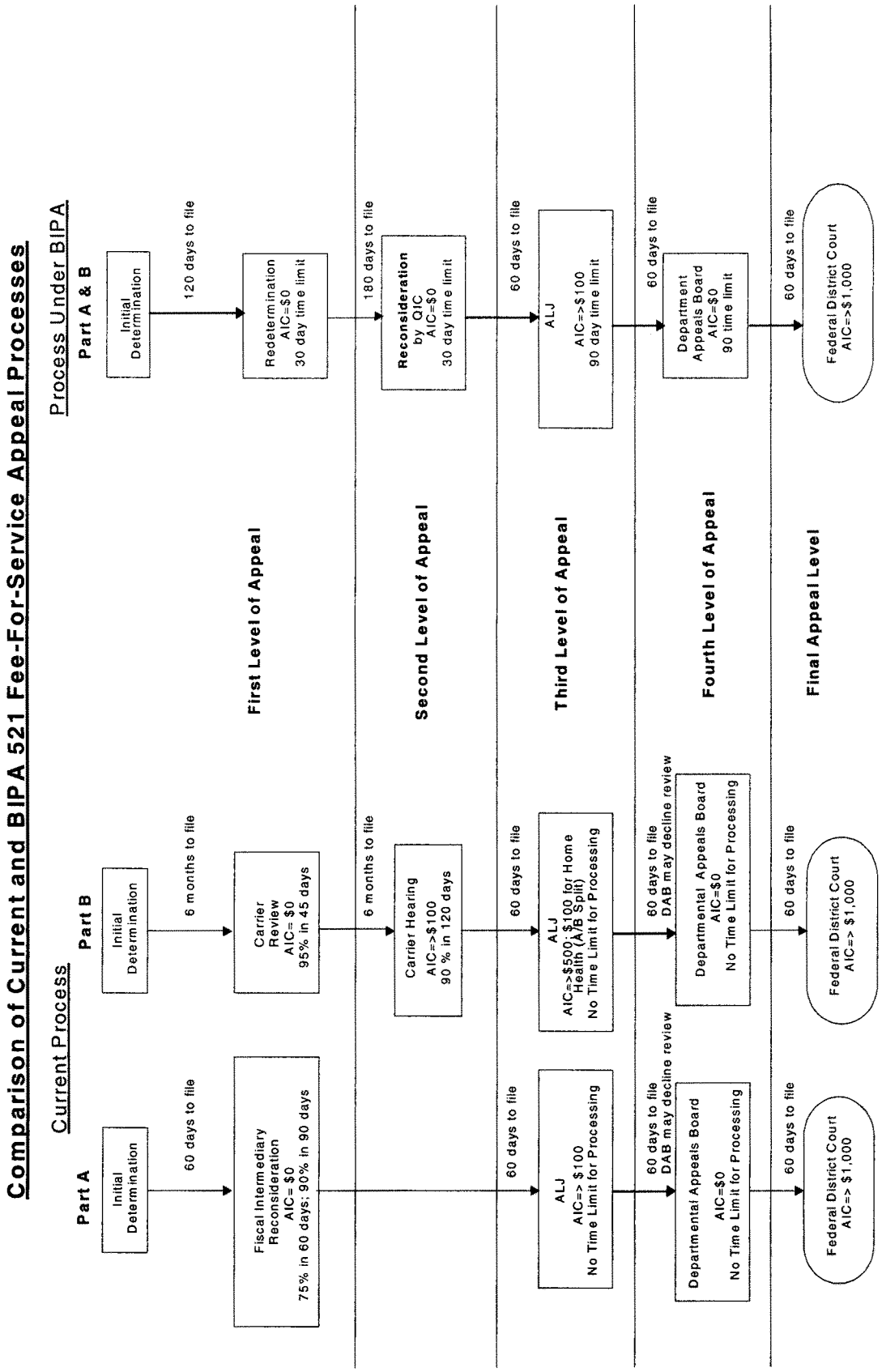

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C. Codification of Regulations

As noted above, 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 needed for an indefinite transition period until all appeals resulting from initial determinations before the implementation of the new procedures required under BIPA are completed. We are considering what rules should apply during the transition period and whether it would be possible or prudent to operate dual appeals systems depending on the date of an initial claim determination. Clearly, the new BIPA provisions make possible a largely uniform set of appeals procedures that can be applied both for part A and B of Medicare. Therefore, this proposed rule would establish a new subpart I of part 405 that will set forth in one location the administrative appeals requirements for Medicare carriers, Fiscal Intermediaries (FIs) and QICs. We note that BIPA section 521 (see 1869(a)(1)(C)) also requires that certain determinations made by QIOs under section 1154(a)(2) be subject to the revised appeals process under section 1869, therefore, we anticipate publishing a separate proposed rule to accommodate needed changes to the existing regulations at 42 CFR parts 476 and 478 regarding QIO determinations and appeals. (In addition, we note that the changes set forth here do not apply for purposes of Part C of Medicare, that is, the Medicare+Choice program. We also intend to address necessary changes to 42 CFR part 422 in future rulemaking.)

We are also proposing to include in new subpart I the provisions needed to govern Medicare claims appeals to ALJs and the MAC. The existing ALJ regulations are quite voluminous and are intended primarily to apply to appeals of SSA disability cases, rather than to Medicare appeals. The need for the Medicare program to establish its own regulations for these upper level appeals has been recognized by many parties, including, most recently, the Office of the Inspector General in its January 2002 report: ''Medicare Administrative Appeals—The Potential Impact of BIPA,'' OEI–04–01–00290. Many of these provisions will effectively carry over the existing requirements with respect to appeals to the ALJ and the MAC, rather than implementing substantive changes. However, both the firm time frames for ALJ and DAB decisions and the opportunity for escalation of cases are provisions that apply only to Medicare claims, and not to SSA disability cases—presenting another compelling argument to take this opportunity to codify the ALJ and MAC requirements for Medicare administrative appeals within the Medicare regulations at Title 42 of the Code of Federal Regulations. Thus, the new subpart I will codify in one location key regulations governing all aspects of Medicare claim appeals, beginning with the statutory requirements that apply to initial determinations and proceeding through all four levels of the administrative appeals process. For the convenience of the reader, regulations contained in existing subparts G and H of part 405 that have not been affected by the changes mandated in section 521 of BIPA generally will be repeated in the new subpart. However, we note that we are not carrying over regulations that deal with challenges to coverage policy (such as §§ 405.732 or 405.860 concerning the review of national coverage decisions), which instead will be dealt with in the regulations implementing section 522 of BIPA concerning the new procedures for appealing coverage policies to ALJs and the DAB. Since we are not eliminating regulations contained in existing subparts G and H, we also will not reflect provisions in subpart I that deal with appeals of carrier decisions that supplier standards are not met, or appeals of a categorization of a device as experimental or investigational (see §§ 405.874–75 and 405.753).

II. General Provisions of the Proposed Rule

A. Overview

Clearly, the changes introduced by section 521 of BIPA are aimed at introducing greater efficiency and accuracy into the Medicare appeals system. The Secretary is equally committed to these goals. However, the introduction of QICs and the establishment of drastically reduced mandatory time frames for appeals decisions do not in themselves provide remedies to the longstanding problems that Congress intended to address in the new BIPA appeals provisions. To make these changes work, we need to examine carefully how the effects of changes at a given level of the appeals process may affect the entire appeals system, as well as to determine how to allocate the limited Medicare resources available to effectuate the changes to the appeals system.

In developing the proposals below, we have carefully considered how best to achieve these goals within the BIPA construct, keeping in mind the limited resources likely available for appeals system changes. We are also acutely aware of the possibility that the volume of appeals could increase significantly with the implementation of BIPA. (The OIG pointed out three reasons that such increases are likely, including the attractiveness of a speedier system, with drastically reduced time frames, the increased control given to appellants through the new escalation provisions, and the reductions in the required amounts in controversy to appeal a denied claim.) We also needed to consider the fact that, although the existing appeals provisions were designed primarily for beneficiary appeals, the overwhelming majority of appeals are now filed by providers and suppliers. We have attempted to reflect this reality by proposing changes that will work efficiently for appellants with some knowledge and experience of the Medicare appeals procedures, while at times incorporating exceptions for beneficiary appellants.

Outlined below are the proposed changes to the Medicare appeals regulations needed to implement section 521 of BIPA. Our general approach is to explain briefly the new statutory provisions, and to point out significant differences with the law or regulations that have been in effect prior to BIPA. For proposed regulations that are substantively unchanged from existing requirements, we have merely consolidated the current regulatory requirements into unified provisions that apply for both Medicare Part A and Part B appeals, consistent with the BIPA approach. In doing so, we have made some editorial changes to increase the clarity and simplicity of the regulations, to the extent that this is possible given the inherent complexity of appeals regulations. The discussion that follows touches only briefly, if at all, on sections of the proposed regulations that do not set forth substantive changes to the existing appeals procedures.

B. Statutory Basis, Definitions, and General Procedures (§§ 405.900–405.902)

Proposed subpart I begins with a brief section (§ 405.900) that sets forth the general statutory authority for the ensuing provisions and establishes that the scope of the subpart is to establish the regulations needed to implement the provisions of section 1869 of the Act concerning initial determinations and appeals. Consistent with section 1869(a)(1) of the Act, § 405.900 (b) specifies that the Secretary shall make initial determinations with respect to whether an individual is entitled to benefits under Medicare Part A or B and with respect to the amount of benefits

available under those parts. Section 405.902 would set forth the definitions for terms used in subpart I that we believe may need clarification. These definitions provide the generally applied meaning for terms that are used throughout the subpart.

For the most part, the definitions presented here are taken directly from the statute, or from existing subparts G or H of part 405, or are essentially self-explanatory. We have not restated in subpart I definitions of terms that are already defined in part 400 of the Medicare regulations, such as ''provider'' or ''supplier'' (see § 400.202) and that have the same meaning in the appeals context. Thus, the term ''supplier'' encompasses physicians, other practitioners, and various entities (such as laboratories or durable medical equipment (DME) suppliers) other than providers that furnish Medicare services. Discussed below are two terms that we believe may need further clarification.

1. Assignment of Appeal Rights

Section 1869(b)(1)(C) provides that an individual's appeal rights may be assigned to the provider or supplier that furnishes the item or service in question. Our proposed definition states that ''assignment of appeal rights'' means the transfer by a beneficiary (the ''assignor'') of his or her right to appeal an initial determination to a provider or supplier (the ''assignee''). Although this definition is relatively straightforward, it is important that this term not be confused with the term ''assignment,'' as defined under existing § 405.802. In that context, assignment refers to the transfer of a claim for payment under Part B of Medicare from a beneficiary to a physician or other supplier. For purposes of Subpart I, the terms ''assignment,'' ''assignor,'' and assignee'' are used to refer only to the transfer of appeal rights, rather than in the more traditional context of payment on an assignment-related basis. A full discussion of our proposals regarding appeal rights is presented below.

2. Party

The meaning of the term ''party'' also has important implications, mainly for purposes of appeal rights and notification requirements. We would simply define party as an individual or entity with standing to appeal an initial determination or subsequent administrative appeal determination. Then, we list in § 405.906(a) who would be considered a party to an initial determination. Beneficiaries are considered parties. Also, in keeping with our previous regulations, physicians or suppliers who have accepted a valid assignment executed by a beneficiary to transfer his or her claim for payment to the physician or supplier, in return for the physician or supplier's promise not to charge more for his or her services than a carrier finds to be a reasonable charge or other approved amount, would also be considered a party. A party also includes a physician liable for refund under section 1842(l) of the Act, a supplier liable for refund under sections 1834(a)(18) and 1834(j)(4) of the Act, or a provider. Additionally, § 405.906(b) identifies parties for purposes of an appeal. A provider or supplier taking assignment of appeal rights under section 1869(b)(1)(C) would be considered a party to an appeal. Also, in accordance with § 405.908, we note that for dually entitled beneficiaries, States have the right to file appeals on behalf of the beneficiary pursuant to Title XIX of the Act.

Proposed § 405.904 provides a general description of the post-BIPA appeals process, much as existing § 405.801 does for the pre-BIPA, part B process. In addition, § 405.904(b) establishes the general rule that the same appeals procedures that are available to beneficiaries, and to individuals acting as representatives of beneficiaries, are also available to a provider and supplier that is a party to a given determination. This section also explains that in some circumstances, a provider's rights to judicial review are limited, unless the beneficiary has formally assigned his or her appeal rights to the provider. Note that although beneficiary appeals and provider and supplier appeals follow identical paths, we are proposing slightly more lenient evidentiary rules for unrepresented beneficiaries or beneficiaries represented by family or friends, given their likely lack of familiarity with Medicare coverage rules and appeals procedures. We would hold State agencies, providers, suppliers, and attorneys to a higher standard based on their presumed knowledge and experience with the Medicare program. We believe that these individuals and entities are essentially ''businesses'' and can be held to a reasonableness standard. These proposals are discussed in detail below.

C. Appeal Rights (§§ 405.906–405.912)

Historically, providers have had limited rights to appeal Medicare initial determinations. Consistent with section 1879(d) of the Act, providers may appeal Medicare determinations only when the determination involves a finding that (i) the item or service was not covered because it constituted custodial care, was not reasonable and necessary, or for certain other reasons; and (ii) the provider knew or could reasonably be expected to know that the service in question was not covered under Medicare (that is, a finding with respect to the limitation of liability provision under section 1879 of the Act). Despite these restrictions, providers have routinely accessed the appeals process in situations where they would otherwise not have appeal rights by acting as a beneficiary's appointed representative.

Another underlying principle of BIPA was the establishment of uniform appeal procedures for providers and suppliers. In keeping with this approach we believe 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. In BIPA, we believe it was the intent of the Congress to ensure that Medicare providers, physicians, and other suppliers had easier access to the Medicare administrative appeals system. As discussed below, Congress expanded the appeal rights of providers, physicians and other suppliers with regard to Medicare appeals by authorizing the assignment of appeal rights.

Therefore, in this rulemaking we are proposing to end the distinction limiting the appeal rights of providers to determinations involving the knowledge aspect of the limitation on liability provision. We propose to allow providers to file for administrative appeal of Medicare initial determinations to the same extent as beneficiaries. With this change, we would achieve consistency in our approach to appeals standing under Parts A and B.

We also would continue to maintain current appeals policies with respect to non-participating providers, physicians and other suppliers. We considered extending appeal rights to non-participating physicians and other suppliers to the same extent as providers. However, we believe that such a change would result in a negative impact on Medicare participation rates and, potentially, a contraction of beneficiary access to care. Also, we note that non-participating physicians and other suppliers may attain party status by securing an assignment of appeal rights from beneficiaries as provided in new section 1869(b)(1)(C).

In this proposed rule, we also clarify our policy with regard to the continuation of an appeal when a beneficiary-appellant dies while an appeal is in progress. Under our current

rules, a substitute entity may be entitled to receive or obligated to make payment for Medicare claims. See 42 CFR part 424 subpart E. If a person becomes financially responsible for Medicare claims under our rules, we are proposing that such person or entity may be made a party to the initial determination and have the right to continue the appeal.

We are proposing to implement these expanded appeal rights in proposed § 405.906, which would clearly identify all individuals or entities that may be a party to an initial determination. This approach identifies parties explicitly and replaces current regulations where party status is conferred to ''* * * any other party whose rights with respect to the particular claim being reviewed may be affected by such review.'' See 42 CFR 405.808. This standard has occasionally led to questions being raised about who should be a party to appeal. In this proposed rule we have attempted to address this issue by generally listing as a party, the individual or entity listed in § 405.906 that has standing to appeal an initial determination and/or a subsequent administrative appeal determination. We believe the list of parties is exhaustive, but welcome comments to rectify any omissions.

Proposed § 405.908 pertains to the right of a Medicaid State agency, which acts as a subrogee, to pursue an appeal on behalf of a beneficiary entitled to benefits under both Medicare and Medicaid. We do not consider a Medicaid State agency to be a party, unless the agency actually pursues a redetermination on behalf of a dually eligible beneficiary. In other words, a Medicaid State agency will not automatically be sent notices on determinations made during the administrative appeals process, nor will the agency be permitted to request reconsiderations or hearings by ALJs or the MAC, unless the agency actually files a request for redetermination for a beneficiary. If a Medicaid State agency files a redetermination it retains party status for the claim throughout the rest of the appeals process. Also, a Medicaid State agency automatically has authorization to file an appeal of a denied claim without following the process prescribed at § 405.910. Section 1912(a) of the Act provides that as a condition of eligibility for medical assistance, an individual must assign the State any rights to payment for medical care from any third party. Thus, to avoid confusion, we have drafted a separate provision acknowledging the right of a Medicaid State agency to pursue an appeal on behalf of a dually eligible individual.

Sections 1869(b)(1)(B) and (C) address provider and supplier representation and assignment issues. To the extent that these provisions represent departures from existing requirements, we believe that they warrant notice and comment rulemaking before they can be implemented. As discussed below, the new statutory provisions include several changes in the existing appointment of representative procedures, which are currently set forth at 20 CFR part 404, subpart R (the provisions that govern SSA disability insurance claims).

Proposed § 405.910 incorporates and modifies several of the current 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. The proposed provisions would eliminate the need for incorporation of the existing SSA regulations as they apply to appeals. Note that under our existing regulations at §§ 405.701 and 405.801, the appointment of representative provisions set forth in 20 CFR part 404 also apply for purposes of initial determinations. This proposed rule would not change the applicability of those provisions with respect to initial determinations; however, we are considering the extent to which the new provisions should also apply to initial determinations and welcome comments on whether we should apply these provisions uniformly.

Since entities or individuals other than beneficiaries may wish to have someone represent their interests in the appeals process, we have defined a representative as an individual authorized by a party, or under State law, to act on the party's behalf in dealing with any levels of the appeals process. Representatives do not have independent party status and may only take action on behalf of the individual or entity they represent. We note that a party may not designate, as an authorized representative, any individual or entity that has been suspended, or otherwise prohibited by law, from participating in the Medicare program.

We have received numerous requests for clarification on how individuals or entities must make out valid appointments consistent with the Privacy Act. An agency that maintains a system of records must ''establish appropriate administrative * * * safeguards to ensure the * * * confidentiality of records and to protect against any anticipated threats or hazards to their security or integrity * * * which could result in substantial harm, embarrassment, inconvenience, or unfairness to any individual on whom the information is maintained.'' The Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(10). As is the case under existing procedures, we want to emphasize that in order to be valid, an appointment must be in writing, and signed by both the party making the appointment and the individual agreeing to accept such appointment. However, to ensure consistency in these proposed provisions, we also would make a change in the case of attorney representatives. Under current regulations, only the party making the appointment needs to sign a statement authorizing the representation. In the case of an attorney representative, the attorney does not have to sign a notice of appointment. Instead, in the absence of information to the contrary, an attorney's assertion that he or she has such authority is accepted as evidence of the attorney's authority to represent the party. In establishing procedures that comply with the Privacy Act, we would now require that attorneys also sign a statement to represent a party.

We appreciate that the signature requirements might be perceived as burdensome; however, we believe that a representative's signature is important because it ensures that adjudicators are sharing and disseminating confidential medical information with the appropriate individuals. In addition, it indicates that the individual whom the party has appointed does in fact accept the role and responsibilities associated with being a representative.

We propose to establish a time frame governing the duration of representation. Even under the BIPA time frames, we recognize that there may be substantial lapses in time between a party's request for an appeal at any given stage of this multi-tiered appeals process, and receipt of a final decision. Thus, we propose that under § 405.910(e) the appointment (1) shall be valid for the life of an individual appeal, and (2) for purposes of appeals of other initial determinations, the authorization shall be considered valid for one year from its original effectuation. For example, if a party makes a valid appointment on January 1, 2003, the representative would be authorized to request multiple appeals on the party's behalf until January 1, 2004. Suppose that a representative requests a redetermination of a denied claim on November 1, 2003 and the contractor affirms the denial on November 30, 2003. Since a party has up to 180 days to file a request for a reconsideration, if the representative files an appeal on March 15, 2004, the appointment of representation would still be valid for purposes of this individual appeal because the rights

associated with it have not expired. However, the representative would not be able to initiate any new appeals on other claims because the appointment would have been valid only through January 1, 2004.

We believe that it would be too burdensome to require representatives to renew representation documentation once an appeal has been undertaken; however, we also believe that a representative's ability to file appeals of future claims should continue for an indefinite period of time. While we propose that representation documentation shall be renewed at least annually (for purposes of filing new appeals), we welcome comments on whether another time frame would be more appropriate.

Prior to its amendment by BIPA, section 1869(b)(1)(D) required the Secretary to apply the provisions of section 206(a) governing the representation of beneficiaries. New section 1869(b)(1)(B)(iv) removes section 206(a)(4), which permits the award of attorney fees (not to exceed 25 percent) from a claimant's entitlement to past-due disability benefits. Therefore, in § 405.910(f), we make explicit that no award of attorney fees may be made against the Medicare trust fund. We recognize that section 1869(b)(1)(B)(iv) requires CMS to apply § 205(j) and 206 provisions to the Medicare appeals process; therefore we welcome comments on those provisions. Specifically, we request comments on petitions to ALJs to review and approve attorney fees. We believe that we should not establish such a process since we do not have authority to award attorney fees. We also welcome comments on procedures to govern the conduct of representatives.

Proposed §§ 405.910(g)–(l) are self-explanatory provisions concerning the responsibilities and rights of a representative. For example, a representative must ensure that a party receives information about appeal decisions, and disclose to a beneficiary any financial risk or liability associated with a non-assigned claim. In the past, there has been some confusion about whether the representative or the party should receive information about the appeal, including the decision. We believe that a representative should have the right to obtain any information applicable to the claim at issue since the representative acts on behalf of the party. Section 405.910(i)–(j) would require adjudicators to send notices of their decisions and otherwise communicate with representatives rather than parties. We considered whether beneficiaries that are represented also should receive copies of decision letters, but decided to maintain the existing provision at 20 CFR § 404.1715. Therefore, any communication with a representative would have the same force and effect as if it had been sent to the party.

Proposed section § 405.910(m) deals with the extent to which a representative may delegate responsibilities. A representative may not designate another individual to act as the representative unless the representative notifies the party of the name of the designee, and the designee's acceptance to comply with the requirements of authorized representation. Also, the represented party must evidence its acceptance of this arrangement by a signed, written consent. We believe that these provisions are necessary to protect the privacy and confidentiality of medical records. They would also provide adjudicators with an effective way to resolve any conflicting information as to who has authority to proceed in an appeal.

The decision on whether to have a representative is left with the party, and we neither encourage nor discourage representation. Therefore, proposed § 405.910(n) gives a party the ability to revoke an appointment for any reason, at any time. To ensure a seamless process, a revocation of an appointment is not effective until the entity processing the appeal receives a signed, written statement from the party. We also propose that the death of a party will terminate the authority of the representative. However, when a party dies, we do not intend to terminate an appeal that is in progress since another individual or entity may be entitled to receive or obligated to make payment for Medicare claims.

In section 1869(b)(1)(C) of the Act, Congress added a new provision that permits Medicare beneficiaries to assign their appeal rights to a provider or supplier of services, pursuant to a written agreement using a form developed by the Secretary. This provision appears similar to the provisions that allow a party to an appeal to appoint a person, including the provider or supplier of services, as a representative for the appeal. Under our current rules, though, in acting as the representative, the provider or supplier does not achieve party status to the appeal; the representative simply acts on behalf of the party. With the new assignment provision, we believe the Congress intended the arrangement to differ from the provision enabling a party to appoint a representative.

Proposed § 405.912 creates new regulatory procedures for the assignment of appeal rights by a beneficiary to a supplier or provider of service. Provider/supplier representation rules impose certain limits'the provider/supplier cannot charge a representation fee for actions in connection with services it furnished, and the provider/supplier must waive any right to payment from the beneficiary for the services at issue if the representation involves a claim where limitation of liability, under section 1879 of the Act, is an issue. Similarly, we believe that a provider or supplier wishing 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. We do not intend, however, to prohibit the provider/supplier from recovery of any coinsurance or deductible, or where the beneficiary signed an advance beneficiary notice accepting responsibility for payment. The nature of assignment means that beneficiaries must relinquish their party status in an appeal, as well as any further rights to appeal on their own behalf. Additionally, BIPA expressly requires us to develop the form that will be used to make an assignment valid, thereby giving us the discretion to determine the requirements of a valid assignment. Thus, the proposed waiver provision is necessary to protect beneficiaries from potential liability in the event the supplier or provider is unsuccessful in the appeals process.

As noted above, an appointment of representation would be valid for one year for any appeal by the individual, and for the duration of the administrative review process for an appeal related to specific items or services. Note that a different standard would apply for assignment purposes. Section 1869(b)(1)(c) clearly indicates that the assignment of appeal rights applies with ''respect to an item or service.'' Accordingly, we are proposing that an assignment would be valid for the duration of the appeals process, but only for the items or services listed on the assignment form. Thus, a supplier or provider of service would need to perfect a valid assignment for subsequent appeals of other items or services.

Like in the representation provisions, we also are proposing rules for the revocation of an assignment. We are soliciting comments on whether an assignment should be irrevocable, particularly since it only applies on a per item or service basis, and thus does

not have any effect on other appeal rights. However, we are concerned about reinstating a beneficiary's appeal rights in the event of abandonment by a provider or supplier. We have proposed that if a beneficiary revokes an assignment, the appeal rights on the item or service at issue would revert to the beneficiary.

D. Initial Determinations (§§ 405.920–405.926)

As noted above, section 1869(a)(1) of the Act continues to provide that the Secretary shall make initial determinations with respect to whether an individual is entitled to benefits under part A or part B and to the amount of benefits available to an individual under those parts. However, section 1869(a)(2)(A) of the Act establishes that, on all claims other than clean claims, the initial determination shall be concluded and a notice of such determination must be mailed by no later than 45 days after receiving the claim, in contrast to the existing 60-day deadline for such non-clean claims. Section 1869(a)(2)(B) currently requires that interest will accrue if clean claims are not processed within 30 days. This standard remains unchanged (as specified in sections 1816(c)(2) and 1842(c)(2) of the Act). Nothing in BIPA, however, requires that interest would accrue on non-clean claims, regardless of whether they are adjudicated within 45 days. The proposed regulations to implement these statutory provisions regarding the timing and notice requirements pursuant to an initial determination are contained in §§ 405.920 and 405.922.

In § 405.920, we require that claims must be filed in the manner and form described in 42 CFR part 424 subpart C, which continues our current policies for filing claims. When a claim is filed with the appropriate carrier or FI, the carrier or FI will determine whether the items and/or services are covered under Part A or Part B of title XVIII. The contractor will then determine any amounts due and make payment accordingly. The parties to the initial determination, as specified in § 405.906, will be notified of the initial determination in writing by the contractor. This notice will also contain the basis for the determination and information on how to request a redetermination. As with our current policy, the Remittance Advice and Medicare Summary Notice will be used as a notice of initial determination.

In accordance with section 1869(a)(2) of the Act, proposed § 405.922 sets forth the time frames for initial Medicare claims determinations. That is, a contractor shall issue initial determinations on clean claims (as defined in § 405.901) within 30 days of receipt and, on all other claims, the contractor shall issue initial determinations within 45 days of receipt.

Our proposed regulations at § 405.922 currently state that all other claims, other than clean claims, must be processed within 45 days of receipt. While we plan to monitor contractors on their compliance with the 45-day standard, we also recognize that 45 days may not be achievable in every case. By definition, non-clean claims are often claims that require additional documentation, and therefore take time to process. Under the current process, providers or suppliers are given 45 days to produce additional medical documentation. Thus, the imposition of a 45-day decision-making time frame on non-clean claims could jeopardize effective medical review. Currently, our plans are to monitor, on average, contractors' compliance with the 45-day standard. However, we do not propose escalation or other remedies when the 45-day deadline is missed.

In existing section 1842(b)(3)(C) of the Act, the Congress provided a special appeals rule in cases where a Part B Medicare claim was not acted upon promptly, defined previously as 60 days following the submission of the claim. The rule provides for an appeal directly to a carrier-hearing officer, bypassing the first level of appeal, the review determination. In BIPA, Congress reduced the time period within which contractors must make initial determinations on claims to 45 days. However, section 1842(b)(3)(C) of the statute was not amended to reflect the change in the appeals process, that is, that the carrier hearing officer appeal was eliminated and effectively replaced by an appeal to the QIC. Our opinion is that the Congress, by implication, repealed this provision as the remedy specified in the statute will no longer exist since the Congress eliminated the carrier fair hearing level of appeal. We considered providing for a reconsideration by the QIC when a claim is not acted upon with reasonable promptness (that is, an initial determination is not issued within 45 days following the date the claim was received by the contractor). However we believe that this is not an economically feasible approach since the QIC will, in essence, simply direct the contractor to process the claim. We also considered the fact that this rule only applies to Part B claims and concluded that it would be confusing and contrary to the general approach mandated by BIPA to have two separate processes. Therefore, we are not carrying over this rule.

Proposed §§ 405.924 and 405.926 list the types of actions that are, and are not, considered initial determinations. In these sections, we have generally maintained current policies concerning initial determinations, although we have unified the existing part A and part B rules. In § 405.924(a) we maintain our longstanding policy that, through a memorandum of understanding with the Secretary, SSA makes initial Part A and Part B entitlement determinations and initial determinations on applications for entitlement. In § 405.924(b), we provide an extensive, but not necessarily exhaustive, list of actions that constitute initial determinations and thus are subject to the administrative appeals rules that follow.

We are proposing to clarify the circumstances under which an appeal may 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 are clarifying this provision to state that the contractor's ''computation of coinsurance'' is considered an initial determination and, thus, may be appealed. In making this proposal we considered that for most Part B services, beneficiaries are responsible for a 20 percent coinsurance payment and, since the 20 percent is calculated by the contractor, a beneficiary may appeal the contractor's computation of the coinsurance amount to be paid by the beneficiary. In instances where the coinsurance amount is not computed by the contractor, but rather it is an amount prescribed by regulation, for example, outpatient services, the issue of whether the coinsurance amount is appropriate is not appealable since it is not an amount computed by the contractor. Also, we are proposing clarifying language specifying that determinations regarding the timeliness of claims submission are initial determinations. We are also clarifying which Medicare secondary payer (MSP) determinations are initial determinations for purposes of this subpart. A determination regarding the applicability of the MSP provisions to a particular claim is an initial determination. A determination that Medicare has a recovery claim against a provider/supplier or beneficiary with respect to items or services that have already been paid by the Medicare program is also an initial determination except where the recovery claim against the provider/supplier is based upon a failure to file

a proper claim as defined in 42 CFR part 411. Finally, under proposed § 405.924(c), we would state that expedited determinations by QIOs under new section 1869(b)(1)(F) are also considered initial determinations.

In proposed § 405.926, we list examples of determinations that are not initial determinations, and therefore not subject to the administrative appeal procedures of this subpart. Again, we continue our longstanding policies in this area, subject to several minor clarifications. First, for certain aspects of initial determinations, there are no administrative appeal rights available. For example, under section 1833(t) of the Social Security Act, administrative appeals are prohibited for issues involving the calculation of coinsurance amounts for outpatient services subject to prospective payment rules, and under 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. In addition, here, too, we have proposed new examples of MSP-related determinations that do not constitute initial determinations for purposes of section 1869 of the Act. We have also clarified that decisions by contractors or QICs with respect to reopenings are not considered initial determinations.

Section 405.928 describes the effects of an initial determination. In proposed § 405.928(a), we would clarify that initial determinations by SSA with respect to an individual's entitlement are binding upon the individual or the individual's estate unless revised or reconsidered under SSA's regulations at 20 CFR 404.907. Then, under § 405.928(b), we would state the general rule that other initial determinations shall be binding upon all parties to the initial determination unless a redetermination is completed in accordance with § 405.940 through §§ 405–950 or the initial determination is revised as a result of a reopening in accordance with proposed § 405.980. Please refer to our discussions on the redetermination and reopenings process below.

E. Redeterminations (§§ 405.940–405.958)

1. Overview of Statute

Section 1869(a)(3) contains certain requirements for redeterminations that are specific to fiscal intermediaries and carriers, and do not apply to the initial determinations made by other entities, such as SSA or QIOs. Section 1869(a)(3) of the Act mandates that FIs and carriers make redeterminations, upon request, with respect to claims for benefits that are denied in whole or in part. Section 1869(a)(3)(B) specifies that an initial determination may not be reconsidered or appealed unless the contractor has made a redetermination of that initial determination and that no redetermination may be made by an individual involved in the initial determination, two requirements that essentially mirror existing policy. The time frames for requesting and carrying out redeterminations are set forth under section 1869(a)(3)(C). A request for a redetermination must be made within 120 days from the date the individual receives the initial determination. The carrier or FI then must make a redetermination decision and notify the parties of the decision within 30 days of receiving the request for redetermination. Under section 1869(a)(3)(D), for purposes of subsequent appeals, a redetermination is considered part of the initial determination. For purposes of contractor performance evaluation, we plan to monitor how effectively fiscal intermediaries and carriers meet the 30-day deadline, on average, for redeterminations. However, we do not propose escalation or other remedies if the carrier or fiscal intermediary does not complete a redetermination within the 30-day time frame.

A critical feature of the new statutory language with respect to redeterminations is that the same provisions apply for these first level appeals of both Part A and Part B claim determinations. Thus, parties wishing to appeal initial determinations will need to meet identical time frames for filing requests for redeterminations and the time frame for redetermination decisions is significantly shorter than the previous time frames for either Part B reviews or Part A reconsiderations. This means, for example, that CMS' contractors must complete all redeterminations within 30 days, even though the cases in need of redetermination may differ considerably in terms of complexity and dollar amounts. (Currently, under sections 1816(f)(2) and 1842(b)(2) of the Act, respectively, contractors now must complete 75 percent of part A reconsiderations within 60 days, and 90 percent within 90 days, while 95 percent of part B reviews must be completed within 45 days.) In developing the proposed regulations needed to implement the new system, we have attempted to construct procedural requirements that can work for all types of redeterminations, while still permitting contractors the flexibility needed to conduct redeterminations using methods that are both efficient and fair to appellants.

2. Redetermination Requests (§§ 405.940–405.946)

Proposed § 405.940 establishes the general rule that any party to an initial determination that is dissatisfied with that determination may request a redetermination. Sections 405.942 and 405.944 then set forth the proposed requirements concerning the time frames and procedures for filing a redetermination request. Consistent with section 1869(a)(3)(C) of the Act, a request for redetermination must be filed within 120 days from the date an individual receives the notice of initial determination. In § 405.942(a)(1), we would establish that the date of receipt of the initial determination is presumed to be 5 days after the date of such notice, unless there is evidence to the contrary. This is consistent with our longstanding policy that we allow 5 days for the individual to receive the notice of initial determination.

Under proposed §§ 405.942(a)(2) and 405.944(a), we propose to continue the current 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 view of the requirement that a contractor must issue a written notice of the redetermination decision within 30 days of a request for redetermination, we strongly considered requiring that all redetermination requests be filed directly with the contractor indicated on the notice of initial determination. Clearly, such a policy would eliminate confusion about where to file appeal requests and promote efficiency—we have often experienced lengthy delays in receiving requests filed with SSA offices, for example. However, we recognize that local SSA offices provide a valuable service to individuals who would like assistance in filing requests for redeterminations. In maintaining this policy for filing requests, we thus propose that the date the redetermination request is considered to be filed means the date the contractor, SSA, or CMS receives the request. As discussed below, however, we also propose under § 405.950 that for purposes of issuing a redetermination decision, the date of timely filing will be considered as the date that the contractor responsible for the redetermination receives the redetermination request. This proposed policy would benefit appellants by promoting flexible access to the appeals system without unfairly reducing the

time a contractor would have to issue a redetermination decision.

Section 405.942(b) contains the proposed rules concerning request for extensions to the time frames for redetermination requests. In general, a contractor may extend the time frame for requesting a redetermination if a party shows good cause for missing the 120-day deadline. In order to request an extension, the party must file a request for the extension with the contractor. The request for extension and request for redetermination must be in writing and state why the request for redetermination was not filed within the required time frame. In order to determine whether a party has shown good cause for missing the deadline, the contractor considers: 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 about the need to file a timely request for redetermination. Proposed § 405.942(b)(3) sets forth examples of ''good cause,'' including serious illness, death or serious illness in the party's immediate family, the destruction or damage of important records due to fire or other accidental cause, incomplete or incorrect information supplied to the party about how or when to request a redetermination from the contractor, lack of notice of initial determination, and evidence of requests made with another Government agency in good faith, within the time limit, where the request did not reach the contractor until after the time period to file a redetermination had expired.

Proposed § 405.944(b) specifies that the request for a redetermination must be in writing and describes the content of the redetermination request. Under our existing regulations, requests for reconsiderations of Part A initial claim determinations have been required to be made in writing (§ 405.711) but request for reviews of Part B initial determinations have been accepted both in writing and orally. However, even for Part B reviews, this policy has never been well understood and has proven very difficult to administer for a number of reasons. First, it is important to recognize that in practice, an oral request for a review generally implied that the review itself would take place over the telephone, usually at the same time as the request. Moreover, although some very simple reviews could be carried out orally, many reviews did not lend themselves to this approach, although the regulations did not limit the availability of oral requests for review. (For example, many cases, such as reviews of DME claims, frequently involve issues that are either too complex to handle in a brief telephone call or require the submission and review of medical documentation and records that are too voluminous to provide over facsimile.) Requests for oral reviews of more complex cases could result in repeated requests for documentation and extended delays in review decisions, even under the longer time frames that were in effect for appeals of Part B initial claim determinations before the implementation of new section 1869 of the Act.

Therefore, in implementing the BIPA provisions, we would require that requests for redeterminations be accepted only in writing. We believe that the best method of accepting requests for redetermination is in writing because it provides a reliable record of the request and promotes the submission of evidence to support the request. (As discussed below, under § 405.946, we propose that parties should present evidence related to the issue in dispute with the request for a redetermination.) This position is consistent with our general belief that an efficient and accurate appeals system will necessitate better notices from CMS concerning the reasons for denials of claims and their appeals and by subsequently encouraging parties to submit relevant evidence as early as possible in the appeals process. Although we recognize that it may be efficient to take some requests by telephone, it would be extremely difficult to offer such a process and still meet the 30-day redetermination decision deadline without severely restricting the types of redeterminations that can be requested over the telephone.

We welcome comments on alternative approaches that are convenient and easy for appellants. We note that providers, suppliers, and beneficiaries can still make inquiries and some adjustments to a claim over the phone, using the telephone number indicated on the Remittance Advice or Medicare Summary Notice. In addition, we are continuing to work with contractors to identify the best methods for conducting redeterminations, such as permitting call back responses to requests for redeterminations. Again, our goals here are to improve the accuracy and efficiency of the appeals process, to make the procedures as accessible and user friendly as possible for appellants, and to avoid causing confusion and dissatisfaction as to the available procedures.

Section 405.944(b) also specifies the required elements of a redetermination request. Requests are to be made on a standard CMS form and when not made on a CMS form must contain the beneficiary's name, the insurance claim (HIC) number, the specific date of service and identification of the item or service with which the party is requesting the redetermination, and the name and signature of the party or appointed representative filing the request. These required elements mirror the requirements contained on the current standard CMS forms to request a review or reconsideration and correspond to the requirements detailed on the Medicare Summary Notice (MSN) that beneficiaries receive. Thus, a beneficiary or beneficiary representative may 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.

Under proposed § 405.944(c), we would specify that if more than one party files a request for redetermination on the same initial determination, the contractor shall consolidate the separate requests into one proceeding. To the extent that two or more entities may have appeal rights on a single request for payment, there is potential for a duplicate administrative process and differing resolution of the appeal. To prevent this occurrence, we are codifying the longstanding practice that when multiple parties request a redetermination, the requests are to be joined into a single administrative action.

As noted above, proposed § 405.946 specifies that when filing a redetermination request, 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. Although we are not proposing to make presentation of evidence a prerequisite to filing an appeal, we believe that encouraging parties to present evidence to support the redetermination request will facilitate the correction of erroneous initial determinations at the earliest possible stage of the appeals system.

Even when appellants are unable to submit relevant documentation along with the request for redetermination, we still wish to encourage appellants to submit documents and make their case at the earliest possible level. Therefore,

proposed § 405.946(b) permits later submission of documentation to be considered as part of the redetermination. However, since it would be difficult to process redeterminations within 30 days when documents are submitted after the request, we propose an automatic 14-day extension of the redetermination decision time frame when an appellant submits evidence after the request.

3. Conduct of Redeterminations (§§ 405.940–405.958)

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 as noted above. Thus, with few exceptions, we are not proposing major changes to the existing procedures for first level appeals of claim determinations. Proposed § 405.948 simply specifies that in conducting a redetermination the contractor would examine the evidence and findings upon which the initial determination was based and any additional evidence submitted by the parties or obtained by the contractor on its own. As with our current process, the individual who makes the redetermination decision must not have been involved in making the initial determination.

Consistent with section 1869 (a)(3)(C)(ii) of the Act, proposed § 405.950(a) would require contractors to issue a written notice of the redetermination decision to the parties within 30 days of receiving a request for redetermination. In general, we will maintain our current policy in calculating the 30-day time frame for decision-making based on the date the request for redetermination is actually received at the contractor. As discussed above, however, if the request is made to an entity other than the contractor (such as an SSA office), we would use the date the request is actually received by the contractor as the date of the request for a redetermination for purposes of calculating the 30-day decision making time frame.

Proposed § 405.952 contains provisions relating to the withdrawal or dismissal of a request for a redetermination. Under § 405.952(a), a party may withdraw a request for redetermination within 14 days of the original request. The withdrawal request must be made in writing to the redetermination contractor. Currently, a withdrawal request may be made at any time before a contractor mails an appeals decision, but we are proposing the 14-day time frame in order to avoid the confusion and uncertainty that can result from decisions and withdrawal requests crossing in the mail. However, a contractor has the option of accepting a late withdrawal request if it has not issued a redetermination decision. For example, a contractor may accept a withdrawal request at any time when the withdrawal is based upon a party entering into an agreement with CMS to compromise the amount of a debt.

Section 405.952(b) would set forth the reasons a contractor will dismiss a request for a redetermination, including:

- If a person or entity who is not a party to an initial determination files a request for redetermination.
- If a request for redetermination does not contain the minimum elements for a redetermination request set forth in proposed § 405.944.
- If a party to an initial determination files a request for a redetermination more than 120 days following receipt of the initial determination from the contractor and does not establish good cause for late filing in accordance with § 405.942(c).
- If the party filing the request dies and there is no information in the record to determine whether there is another party who may be prejudiced by the determination.
- If the party filing the request submits a request for withdrawal.
- If the contractor has not issued an initial determination on the claim for which a redetermination is requested.

Section 405.942(c) specifies that when a request for redetermination is dismissed, the contractor will mail a written notice to the parties at their last known addresses. Under proposed § 405.952(d), a dismissal may be vacated at any time within 6 months from the date of the notice of dismissal if good and sufficient cause is shown. An appellant may request QIC reconsideration of a redetermination dismissal. The request for a QIC reconsideration of the decision must be made within 180 days of the redetermination dismissal notice. A dismissal is binding unless it is vacated in accordance with § 405.952(d), or is subject to a reconsideration by a QIC.

Proposed §§ 405.954 and 405.956 address redetermination decisions and notification rules. When the contractor concludes its redetermination, it is responsible for issuing a decision that affirms or reverses, in whole or in part, the initial determination in question. When a decision fully reverses the initial determination, we propose to maintain our current policy that proper notification is achieved through the MSN or the remittance advice notices that are sent to beneficiaries, and providers and suppliers, respectively. We welcome comments on maintaining this policy for decisions that are fully favorable to the appellant.

Under proposed § 405.956(b), for decisions that affirm the initial determination either in whole or in part, a redetermination decision notice must 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 decision; (5) notification to the parties of their right to a reconsideration, the procedures that a party must follow in order to request a reconsideration, and the time limit for requesting a reconsideration; (6) a statement of the specific supporting documentation that must be submitted with a request for a reconsideration; (7) an explanation that if the specific supporting documentation indicated in the notice is not submitted with the request for a reconsideration, this 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.

To a large extent, these requirements are similar to the current instructions concerning the content of contractor appeals decision (for example, Medicare Carriers Manual, section 12002). However, these policies add more detail to the required elements. They also include one major substantive addition—the requirement that notifications identify any specific supporting documentation that must be submitted with a request for a reconsideration. By setting forth clear, detailed requirements for redetermination notices in the regulations, in concert with the proposed requirement for more information about specific supporting documentation that resulted in an unfavorable determination and redetermination, we believe we are setting the stage for the most accurate and efficient reconsideration process possible. In concert with these changes, we believe that placing a requirement for full and early presentation of evidence at the QIC level is fair to appellants and can stem the volume of cases that are now appealed to ALJs and the MAC. As discussed in further detail below, if available supporting documentation that is identified as needed in the redetermination denial notice is not submitted at the QIC level, an appellant who is dissatisfied with a QIC reconsideration decision and

desires an ALJ hearing generally would not be able to introduce such evidence at an ALJ hearing, absent good cause for not submitting the evidence to the QIC.

The proposed redetermination provisions end with the straightforward requirement under § 405.958 that the redetermination decision is binding on all parties unless there is a subsequent QIC reconsideration or a reopening by the contractor consistent with § 405.980.

F. QIC Reconsiderations (§§ 405.960–978)

1. Introduction

Section 1869(b)(1) of the Act entitles any individual dissatisfied with an initial determination of a Part A or Part B claim denial, to file a request, within 180 days, for reconsideration of the initial determination, including the redetermination. In accordance with § 1869(c), reconsiderations are to be processed, generally within 30 days, by entities called qualified independent contractors (QICs). Section 1869(c)(4) requires CMS to contract with no fewer than twelve QICs. The introduction of QICs creates an additional appeals level for Part A claim determinations and replaces the Part B carrier hearing level of appeal. We believe that the QIC process, which will entail reviews of medical necessity determinations by health care professionals, routine participation in ALJ hearings, and mandatory development of an appeals-specific database, can result in significant improvements in the Medicare fee-for-service appeals system. The statute gives CMS a great deal of latitude in designing the reconsideration component of the Medicare appeals process, and we have attempted to use this discretion to design a process that will prove to be impartial, efficient, and accurate.

2. Reconsideration Requests (§§ 405.960–405.966)

Section 1869(a)(3)(B)(i) states that initial determinations made by fiscal intermediaries and carriers may be reconsidered only after the fiscal intermediary or carrier has performed a redetermination of the initial determination. Thus, proposed § 405.960 states that any person or entity who is a party to a redetermination, and is dissatisfied with the determination, may file a request for reconsideration of the redetermination in accordance with the requirements set out in §§ 405.962–966.

Consistent with section 1869(b)(1)(D) of the Act, § 405.962(a) specifies that appellants who wish to file a request for reconsideration must do so within 180 days of the date on which they receive the notice of the redetermination, or within such additional time as CMS may allow. For good cause, the QIC may extend the time frame for filing a reconsideration request. Section 405.942(b)(2) describes the process QICs are to use in determining if good cause for late filing exists. Examples of good cause, as provided in § 405.942(b)(3), would include: Circumstances beyond the appellant's control, including mental or physical impairment that prevented timely filing of the reconsideration request; significant communication difficulties; receipt of incorrect or incomplete information about the subject reconsideration from official sources (for example, CMS, the contractor, QIC or SSA); delay in filing caused by destruction of or damage to the appellant's records; and unusual or unavoidable circumstances, the nature of which demonstrate that the appellant could not reasonably be expected to have been able to file timely. The request for an extension of the reconsideration filing deadline must be in writing, signed by the party requesting the appeal, and state the reason(s) why the appellant did not file the request within 180 days. In addition, the appellant's request for reconsideration must accompany the request for an extension, so that if the QIC grants the extension, it may begin a substantive review of the appeal without further delay.

The QICs' 30-day decision-making deadline, to a large extent, dictates the procedural parameters that need to apply to the reconsideration process. Because of the equally challenging time frames for concluding ALJ and DAB appeals (combined with the provision that unresolved appeals can be escalated to the next level of administrative review, including Federal court), it is essential that the QIC procedures be designed to facilitate timely, accurate decision-making by these new administrative review bodies. As we developed the proposed QIC procedures, we have been careful to balance these efficiency concerns with the need to ensure a consistent, fair process for appellants.

We set forth the place and method for filing a request for reconsideration in § 405.964(a). Existing regulations give appellants wide discretion in terms of where an appeal may be filed. For example, under § 405.964, requests for carrier fair hearings may be filed with not only the carrier, but also at any CMS or SSA office. We recognize that some appellants, especially beneficiaries, rely on SSA offices to assist them in filing an appeal request. While we do not want to create a process that might make it difficult for appellants to file appeals, we cannot ignore the stringent decision-making time frames imposed by the statute. Thus, as an accommodation to appellants, we propose in § 405.964 that in addition to filing reconsideration requests with the QICs, parties be permitted to file their requests with the CMS and SSA offices as well (just as they may now for carrier fair hearings). For purposes of establishing whether an appellant has timely filed a request for reconsideration, a request will be considered filed on the date it is received by the QIC, SSA, or CMS. However, to ensure that QICs have adequate time to adjudicate reconsiderations that they do not receive directly, we subsequently propose under § 405.970(b)(1) that for reconsideration requests submitted to CMS or SSA offices, the QIC's 30-day decision-making period would begin on the date such request is received by the QIC. This policy will allow appellants to continue receiving assistance in filing reconsideration requests, without shortening the QIC's decision-making time frame.

Since multiple parties may request reconsideration of the same claim (for example, a beneficiary and a physician, or a beneficiary and a provider), we propose in §§ 405.964(c) and 405.970(b)(3) that QICs consolidate multiple requests for reconsideration into a single proceeding and issue one reconsideration determination to all parties within 30 days of the latest reconsideration request.

Under our existing regulations, a party's request for a Part A reconsideration or Part B fair hearing must be in writing (see §§ 405.711 and 405.821), but we do not require use of a standard form for making the appeal request. In practice, appellants now use a CMS form, a contractor's form, or submit written requests of their own design. In implementing the BIPA provisions, CMS will develop and make available a standard filing form for reconsideration requests and we considered making use of this form mandatory. However, in § 405.964, we are proposing that reconsideration requests either be made on the standard CMS form, or must contain the key elements captured by that form (for example, name, HIC number, date(s) of service and service(s) at issue). We believe that these requirements are not onerous, as they are the same as those listed on existing forms (Form HCFA–2649 and Form HCFA–1965) used to request Part A reconsiderations and Part B hearings. If the reconsideration request does not contain any one of

these essential elements referenced above, we propose that the QIC dismiss the reconsideration on the basis that the party failed to make out a valid request.

In addition to the basic information required by § 405.964(a), we believe that it is in the appellant's best interest for a reconsideration request to include additional information, including a statement of evidence and allegations of fact or law related to the issue(s) in dispute and an explanation of why the contractor's determination should be reversed. Therefore, proposed § 405.966(a) describes the type of evidence that should accompany reconsideration requests. Although such documentation is not mandatory, we note that proposed § 405.966(a)(2) specifies that failure to submit documentation that was specified as necessary in a redetermination notice generally would preclude the introduction of such evidence for consideration at subsequent appeal levels. We strongly believe that this requirement for the full and early presentation of relevant evidence is critical for accurate QIC decisions and for avoiding backlogs of appeals at the ALJ level that could have been satisfactorily resolved by QICs. Submission of such evidence should not only lead to a more efficient appeal system, but should also facilitate QIC decisions that pertain directly to the concerns of appellants, as opposed to decisions on reconsideration requests that simply state ''I appeal,'' without elaboration.

In the current appeals process, appellants may continually supplement their initial appeal request with additional evidence. Although we agree that appellants should have an opportunity to provide supplementary evidence to support their initial filing of reconsideration requests, allowing appellants multiple opportunities to submit documentation would make it impossible to adjudicate a case within the 30-day decision-making period. In general, we believe that the 180-day reconsideration filing time frame provides parties with sufficient opportunity to gather the information that they need to complete their requests. However, if appellants need to submit additional documentation after their request for reconsideration has been filed we are proposing under § 405.966(b) that such late submission of evidence would result in an automatic 14-day extension of the QIC's 30-day decision-making time frame.

3. Reconsideration Process (§§ 405.968–405.970)

For existing second level appeals of Part B determinations (the fair hearing level), appellants may request one of three types of hearings: In-person, telephone, or on-the-record. We considered applying this concept to QIC proceedings. However, we concluded that such a system was both impractical and unnecessary under the requirements of new section 1869 of the Act. Instead, we believe that only through on-the-record proceedings could QICs be expected to meet the requirements, under section 1869(c)(3)(C), that reconsideration decisions be issued within 30 days of receipt of a timely filed reconsideration request. In addition, nothing in section 1869 requires a hearing at the QIC level. Also, we note that the requirement for a panel of physicians or other qualified health care professionals to conduct reconsiderations of § 1862(a)(1)(A) denials, makes QIC reconsiderations less like the traditional fee-for-service fair hearings, and more like the independent review process that now applies to Medicare+Choice (M+C) appeals. M+C appeals primarily involve reviews by a physician or other qualified health care professional and are currently conducted within 30 days. Therefore, we elected to apply the existing M+C model to QIC reconsiderations and propose making reconsiderations on-the-record reviews. Thus in § 405.968, we define a reconsideration as ''an independent, on-the-record review of an initial determination, including the redetermination, performed by a QIC.'' In conducting reconsiderations, QICs would be required to review the evidence and findings upon which the initial determination was based and any other evidence the parties submit, or the QIC obtains. The QIC then must make an independent determination affirming or reversing, in whole or in part the initial determination in question. We also specify that if an 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)), a QIC's reconsideration must be based on clinical experience and medical, technical, and scientific evidence, to the extent applicable.

Section 405.968 would also reflect the statutory requirements regarding the relevance of national and local coverage determinations, and who conducts reconsiderations. Section 1869(c)(3)(B)(ii)(I) of the Act states that national coverage determinations (NCDs) shall bind the QIC with respect to issuing reconsiderations. However, unlike intermediaries and carriers (including carrier fair hearing officers) QICs would not be required to follow local coverage determinations (LCDs) in making their determinations. Instead, QICs, like ALJs, would be bound only by law, regulations, CMS Rulings, and NCDs. This constitutes an important change from the current appeals system, which has been marked by high reversal rates at the ALJ level. Often these reversals stem from the different criteria applied by Medicare contractors and ALJs in ruling on Medicare payment and coverage issues. Section 1869(c)(3)(B)(ii)(II) does require that QICs ''shall consider'' LCDs in issuing reconsideration decisions, but it provides no guidance on the extent to which QICs are bound by CMS manuals or other instructions. Under § 405.968(b)(3), we propose that QICs be required to ''give deference'' to LCDs, local medical review policies (LMRPs), and CMS program guidance, including manual instructions (for example, the Medicare Coverage Issues Manual, the Medicare Intermediary Manual, the Medicare Carriers Manual). A QIC's decision must explain why it agrees or disagrees with the appellant's reasoning. Although QICs would not be bound by these types of policies, we would require that QIC reconsiderations follow these policies unless the appellant questions the policy and provides a reason that the QIC finds persuasive as to why the policy should not be followed. (See 66 FR 54536 for a detailed explanation of the distinction between LCDs and LMRPs.) We believe that the use of consistent review criteria and the establishment of strong standards to ensure sufficiency of a QIC's rationale for its decisions will serve several important purposes, including better explaining QIC decisions, identifying recurrent problems with CMS policies, and potentially reducing both ALJ appeals volume and the ALJ reversal rate.

Consistent with section 1869(c)(3)(D) of the Act, no physician or health care professional employed by a QIC may review a determination regarding the health care services furnished to a beneficiary if the physician or health care professional was directly responsible for furnishing such services or items. Also, a physician or health care professional may not review a redetermination if the physician or health care professional or a family member of the physician or health care professional has a significant financial

interest in the institution, organization, or agency that provided the health care services. Family is defined in section 1869(c)(1)(ii) as 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), children (including stepchildren and legally adopted children), grandchildren, parents, and grandparents of the physician or health care professional. Section 405.968(c) would also implement the statutory requirement that reconsiderations involving a determination as to whether an item or service is reasonable and necessary under section 1862(a)(1)(A) of the Act, shall include consideration by a panel of physicians or other appropriate health care professionals. Under proposed § 405.968(c)(2), a QIC would be required to designate a panel to consider the facts and circumstances of any case involving a ''reasonable and necessary determination.'' We note that the estimated workload for QICs is expected to be close to 1 million cases per year, the majority of which we believe will involve medical necessity determinations. Given the prohibitively expensive nature of requiring a sitting panel to review each of these million cases, we plan to define what will constitute a panel. One option we are considering is that, rather than requiring that a panel be made up of at least two physicians or health care professionals simultaneously reviewing the issue, we would allow the physicians or health care professionals to review the issue sequentially. This would allow one professional to propose a determination on the matter and a second professional to then review the proposed reconsideration determination.

Section 405.970 sets forth the general requirement that QICs complete their reconsiderations within 30 days of receiving a timely filed request. Proposed § 405.970(c) specifies that, by no later than the close of the 30-day decision-making period, a QIC must issue the parties either a reconsideration decision or a notice stating that the QIC will not be able to complete its review by the decision-making deadline. This notice must also advise the appellant of the right, pursuant to § 1869(c) of the Act, to request escalation of his or her appeal to an ALJ. Under § 405.970(d), appellants must submit a written request directing the QIC to escalate their appeal. Appellants who are anxious to have their cases escalated clearly could make this request before receiving notice of a delay, that is, on their own, rather than in response to a QIC notice. In all instances, while awaiting the appellant's response, the QIC must continue processing the reconsideration ''unless and until it receives a written request from the appellant to escalate the case to an ALJ.'' Section 1869(c)(3)(C)(ii) makes clear that when a QIC fails to meet its reconsideration deadline, an appellant may request an ALJ hearing. Under any system where escalation is at the appellant's option, we believe it is possible that in some instances, the QIC will complete its reconsideration before receiving an escalation request from an appellant. To avoid confusion and establish an efficient system for processing reconsiderations, we propose that whenever a QIC receives an escalation request, the QIC must 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. This provision should lend administrative finality to the QIC process and avoid any uncertainty in the inevitable situations where escalation requests and QIC reconsideration decisions cross in the mail. In cases where such QIC decisions are favorable to appellants, this process will eliminate unnecessary additional delays and administrative burden that appellants would face in ALJ hearings. See the ALJ and DAB portions of this preamble for further discussion of the escalation provisions.

4. Withdrawal or Dismissal of Reconsideration Requests (§ 405.972)

Section 405.972 sets forth provisions for withdrawing and dismissing requests for reconsideration. We are proposing that appellants be able to withdraw their reconsideration request by filing a written request for withdrawal with the QIC within 14 calendar days of filing the reconsideration request. A QIC, however, may accept a withdrawal request at any time when the withdrawal is based upon a party entering into an agreement with CMS to compromise the amount of a debt. A QIC will dismiss a reconsideration request, either entirely or as to any stated issue, pursuant to a timely filed request for withdrawal, or on its own motion. For example, if the person or entity filing for reconsideration does not meet the proper definition of a party, or does not otherwise have a right to reconsideration under § 1869(b) of the Act, the QIC will dismiss the request. The QIC also may dismiss a request for reconsideration where the party fails to file the reconsideration request within 180 days of receipt of the redetermination notice, or if the party fails to make out a valid request consistent with the essential reconsideration requirements identified in § 405.964. In addition, if the party who filed the request dies before the adjudicator renders a decision, and the record does not reflect that some other party may be prejudiced by the redetermination, the QIC will dismiss the reconsideration.

An appellant may request ALJ review of a QIC's dismissal of a request for reconsideration. The request for ALJ review must be filed with an ALJ within 60 days of the date of the QIC's notice of dismissal. Additionally, at any time within 6 months of the date of the QIC's dismissal notice, the QIC may vacate its dismissal of a request for reconsideration if good and sufficient cause is shown.

5. Content and Effect of the Reconsideration Decision (§§ 405.976–978)

With regard to the content of the reconsideration decision notice, we propose in § 405.976 that these decisions be in writing and contain several substantive elements, including: (1) A clear statement as to whether the reconsideration decision is favorable or unfavorable; (2) a summary of the facts; (3) an application of the pertinent laws, regulations, coverage rules, and CMS policies to the facts; (4) an explanation of the medical and scientific rationale for the decision, when the case involves determining whether an item or service is 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), as discussed above, if the QIC's decision conflicts with an LCD, LMRP, or with program guidance, such as a CMS manual instruction, the notice must include the QIC's rationale for doing so. Similarly, consistent with the proposed § 405.976(b)(5), the reconsideration notice must address how any missing documentation affected the reconsideration decision and the evidence limitations at the ALJ hearing level. The notice must also contain key procedural information such as advice to the parties of the right to an ALJ hearing; if appropriate, advice regarding the requirements for use of the expedited appeals process; and a description of the procedure that a party must follow in order to obtain an ALJ hearing or expedited appeal.

Finally, § 405.678 establishes that reconsiderations are final and binding on all parties unless a timely appeal is filed and a higher adjudicative body

overturns the reconsideration decision, or unless the reconsideration is reopened and revised by the QIC.

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

Section 1869(b)(1)(G) of the Act provides for the reopening and revision of any initial determination or reconsidered determination according to guidelines prescribed by the Secretary. These provisions are needed not only for BIPA purposes but to deal with longstanding concerns over the reopening rules for Medicare claim determinations. Over the years these provisions (existing §§ 405.750(b), 405.841, 405.842, and 405.850) have concerned providers, suppliers, physicians, and contractors. Providers have been vocal about the need for reopening for purposes of recovering underpayments at any point beyond 60 days or the initial timely billing period of 15–27 months.

Some providers have commented that some contractors do not grant requests to reopen claims for underpayments and clerical errors. We believe that the goal of the Medicare payment system should be to pay the correct amount. Thus, we believe that the purpose for conducting a reopening should be to change the determinations or decisions that result in either overpayments or underpayments. The proposed provisions below are intended to establish clear and concise rules to enable contractors to reopen claims and appeals in a fair and consistent manner.

Proposed § 405.980(a) establishes that a reopening is a remedial action taken by a carrier, intermediary, QIC, ALJ, or MAC 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. (Note that in this section of the proposed rule, we use the term ''contractors'' to signify carriers, intermediaries, and program safeguard contractors.)

Reopenings often have been misconstrued as a level of the appeals process, so we clarify the conditions for when to use the reopening process instead of the appeals process. We believe that in order to give meaning to the reopening process, we should identify well-defined parameters for how parties must proceed, and how contractors, QICs, ALJs, and the MAC will conduct reopenings. First, unlike the appeals process, a party must establish that good cause exists in order for an adjudicator to grant a request for a reopening. We discuss in detail below the ways that good cause may be established. Because some of the same types of issues may be raised in either process, we believe that a party's appeal rights must be exhausted, or the time limit for appealing must have expired, in order for an adjudicator to grant a request for a reopening and take jurisdiction. A decision on whether to grant a request for reopening is at the sole discretion of the adjudicator and is not subject to appeal.

We also draw the distinction that requests for adjustments to claims resulting from clerical errors must be handled through the reopening process. Therefore, when a contractor makes an adjustment to a claim, the contractor is not processing an appeal, but instead, conducting a reopening. Nevertheless, the revised initial determination that results from the adjustment may be appealed. Finally, some providers argue that contractors will only initiate a reopening for clerical errors when the error can be attributed to the contractor, but not the provider. We make clear in this proposed rule that the clerical error may be that of the contractor or party. We also define clerical error as human and mechanical mistakes such as mathematical, computational, or inaccurate data entry. We welcome comments on other types of mistakes that would warrant reopenings on the basis of clerical errors.

Proposed § 405.980(b)–(e) sets forth the time frames and requirements for reopening initial determinations, redeterminations, reconsiderations, hearing decisions, and reviews, both for those initiated by contractors, QICs, ALJs, the MAC, and those requested by parties. An adjudicator's notice of intent to reopen preserves the time frame by which it is required to initiate a reopening. Either a party may request a reopening, or a contractor may reopen on its own motion, within one year from the date of the notice of the initial determination or redetermination for any reason. We believe that one year is a reasonable time frame for a party to bring issues to the contractor's attention, considering that it is the party's responsibility and obligation to bill and code correctly, discover errors timely, and respond to documentation requests in order to facilitate appropriate payment determinations by the contractors.

A party and a contractor have the same 4-year time frame for initiating reopenings for good cause, but although a party may request a reopening, the contractor may find that there is not adequate reason to reopen the case. A contractor's decision on whether good cause exists is final.

A contractor may 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. In protecting the Medicare Trust Fund, CMS grants contractors the authority to reopen and revise initial determinations on claims that have been procured through similar fault and/or are believed to have been procured through fraud. Under proposed § 405.980, we are proposing significant revisions to existing rules concerning reopening initial determinations procured through similar fault or fraud.

We are proposing a definition for the term similar fault and outline its evidentiary requirements. Similar fault is intended to cover instances where Medicare payment is obtained by those with no legal rights to the funds, but falls short of outright fraud. In order for the initial determination to be procured by similar fault, Medicare funds must have been obtained, retained, converted, or received by a person who knows, or reasonably should be expected to know, that the person has no legal entitlement to those funds. This covers instances where a provider has been paid twice for the same claim (such as through different payors); where the contractor erroneously pays for codes that should not be paid, and the provider does not refund the money; or manipulation of legitimate codes contrary to Medicare policy to obtain a higher reimbursement. Examples of how knowledge can be shown include: Provider bulletins and educational efforts, standard practices in the community, and previous errors that have been brought to the provider's attention.

A contractor may reopen at any time if reliable evidence shows fraud or similar fault. Evidence is reliable if it is relevant, credible, and material. Since a reopening of an initial determination is an administrative action to correct erroneous payments, there is no requirement for a burden of proof. The contractor only must show that its evidence is reliable. If the reopening results in a revised determination that is unfavorable, the affected party has the right to use the administrative appeals process to rebut the contractor's evidence. In the appeals process, however, the contractor's evidence must satisfy the burden of proof placed upon it.

Proposed §§ 405.980(d)(1) and (e)(3) provide 180 days from the date of a reconsideration decision for either a party to request, or a QIC to initiate, a

reopening. Similarly, both the parties and adjudicators at the ALJ and MAC levels also would 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 must establish good cause for a reopening. We considered whether a QIC, ALJ, or the MAC should have to establish good cause like parties in order to reopen matters that did not pertain to overpayments, investigations, or fraud. However, in an effort to propose a more equitable process, we believe that a QIC, ALJ, or the MAC should be held to the same standards as a party and should not be able to arbitrarily reopen its decision. We believe that a party should be able to rely on the finality of an appeal decision without undue concern that an adjudicator may reopen and revise its decision.

Proposed § 405.982–.984 would require contractors, QICs, ALJs, or the MAC to mail notices of revisions based on reopened determinations, reconsiderations, or decisions to the appropriate parties at their last known addresses. The notice must state the rationale and basis for the revision, and the parties' right to appeal. The revision of an initial determination, redetermination, or reconsideration shall be binding upon all parties unless a party files a written request for a subsequent appeal. Where a contractor reopens an initial determination, we considered whether it might be more efficient to allow a party to request a reconsideration by a QIC. However, since a redetermination is the first level of the appeals process, we have proposed that a revised initial determination is final unless a party files a written request for a redetermination.

Proposed § 405.986 creates a section on how a party, contractor, QIC, ALJ, or the MAC must establish good cause for a reopening. We modified and incorporated some of the provisions at §§ 405.750(b) and 405.841 of 42 CFR, and § 404.989 of 20 CFR to establish guidelines on what constitutes good cause for a reopening, such as ''new and material evidence'' and ''error on the face of the evidence.'' The existing provisions have been viewed by some to be ambiguous as to the meaning or context of these terms.

New and material evidence means information that was not available or known at the time the determination or decision was furnished, which, had it been available or known, may have resulted in a different conclusion. Error on the face of the evidence means an obvious mistake in the determination or decision.

We believe that we have exhausted the full range of circumstances that should give rise to good cause, but welcome comments on whether other provisions should be added to apply to good cause. Finally, we would also incorporate the longstanding rule that a change resulting from a judicial decision, legal interpretation, or administrative ruling upon which a determination or decision was made should not constitute a good cause for reopening.

H. Expedited Appeals Process (§ 405.990 Through § 405.992)

We are incorporating the current regulations governing expedited review 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, there will be one regulation 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) of the Act. Therefore, the regulations will no longer limit expedited review to cases involving NCDs based on section 1862(a)(1)(A) of the Act.

In addition, we would establish under proposed § 405.992 the standards that would apply to ALJs and the MAC for policies that are not subject to the expedited appeals process. We are proposing that in general ALJs and the MAC should consider and give deference to an LCD, LMRP, or CMS manual instruction. An ALJ or the MAC may disregard such a policy at a party's request, if the ALJ or the MAC finds the party's explanation of why the policy should be disregarded to be persuasive, finds that the policy has been applied incorrectly, or finds for other reason that the policy is invalid for purposes of the party's appeal. A decision of the ALJ or the MAC would include its rationale for disregarding such a policy. We believe that these provisions will not only lend greater consistency to the appeal decisions, but also ensure that CMS is aware of policies that are being repeatedly overturned by adjudicators.

I. ALJ Hearings

1. Introduction

Consistent with new section 1869 of the Act, this proposed rule contains a series of changes to the existing procedures for ALJ hearings and DAB reviews. In addition, as discussed above, we are proposing in this rule to codify in the Medicare regulations at 42 CFR part 405, subpart I, all the requirements that apply to these proceedings. Most of these regulations have previously been set forth in 20 CFR part 404 of SSA's regulations, which focuses on SSA's disability procedures. These voluminous regulations contain many provisions that are not applicable for Medicare purposes. For the most part, the proposed regulations that are being carried over from part 404 simply incorporate relevant provisions of those rules and do not involve substantive changes. To the extent that the new regulations do make substantive changes, the changes are discussed below.

One of the 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 DAB if an ALJ hearing does not produce a timely decision on an appeal of a QIC reconsideration. How escalation is implemented will affect all aspects of the ALJ and MAC proceedings discussed below. Therefore, before presenting a detailed discussion of our proposals with respect to ALJ and MAC procedures, we believe it is important to first discuss the issues associated with the new escalation requirements.

2. Escalation

a. General Principles

Section 1869(a)(3)(B)(I) provides that ''[n]o initial determination may be reconsidered or appealed under subsection (b) unless the fiscal intermediary or carrier has made a redetermination of that initial determination under [section 1869(a)(3)].'' Section 1869(a)(3)(D) provides that for purposes of pursuing appeals beyond the fiscal intermediary or carrier levels, the redetermination is considered an initial determination. Given the above provisions, it is clear that an appellant may not 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 current regulations, which require an appellant to complete all steps of the appeals process in sequence, except when an appellant invokes the expedited review process described at §§ 405.718 [Part A appeals] and 405.853 [Part B appeals].

After the initial contractor has made its redetermination, however, a case may be advanced to the next level of appeal if an adjudicator does not act on the appeal within the statutory deadline. We call this movement of a case to the next level of appeal ''escalation.'' In this section, we

describe how escalation will affect the procedures the adjudicator will conduct at the next level of appeal.

Sections 1869(c) and (d) provide deadlines for QICs, ALJs, and the MAC within the DAB to issue their decisions. If the adjudicator does not meet the specified deadline, the party requesting the appeal (the appellant) ''may request'' an appeal at the next level without completing the appeal level below. Specifically, the statute allows an appellant to escalate an appeal by (1) requesting an ALJ hearing if the QIC does not decide the appeal within 30 or 44 days (depending on whether the appellant requested additional time to submit evidence to the QIC); (2) requesting a review by the MAC if the ALJ does not decide the appeal within 90 days; and; (3) requesting judicial review in federal district court if the MAC does not complete its review 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.)

If an appellant does not request escalation to the next level, the case will remain with the current adjudicator until a final action is issued. Because there are different procedures at each of the appeals steps, appellants must carefully consider the type of review that is best to resolve their case before deciding to escalate an appeal. For example, appellants who escalate a case from the QIC level to an ALJ will not have the benefit of a review by health care professionals that the QIC provides before they proceed to a hearing. Similarly, when a case is escalated from the ALJ level to the MAC, an appellant will lose the right to present his or her case during an oral hearing; rather, in most circumstances the MAC will issue its action after reviewing the written record. Therefore, appellants who consider escalating their appeals must carefully weigh whether their case will be better served by completing a particular level of appeal or proceeding to the next level.

In addition, appellants who escalate their appeals will, in essence, be waiving their right to obtain a decision within the statutory deadline at the next level. For example, section 1869(d)(1)(A) 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 by the 90th day from the date a request for hearing is timely filed. (Emphasis added.) We interpret this as requiring an ALJ to decide a case within 90 days when the QIC has issued a final action in a case, but not when the appellant has escalated the case to the ALJ level before the QIC issues a decision. A similar distinction is found in the provisions governing MAC review, which provide that the MAC must complete its ''review of a decision'' within 90 days. Therefore, when an appellant escalates an appeal from the QIC to the ALJ level or from the ALJ level to the MAC, the proceedings before the ALJ or MAC are not subject to the 90-day limit.

We believe this interpretation is not only consistent with the statute, but highlights other factors appellants will have to consider when deciding whether escalation is to their advantage. In our experience, ALJs and the MAC are able to decide cases more quickly and completely when the record below has been fully developed and the determination or decision issued below fully addresses the issues that were considered during the appeal. Because appeals that are escalated to the next level will not include a written determination or decision by the adjudicator below, the ALJ, the MAC, and the courts, as applicable, will require more time to determine what issues are properly before them and how they should be resolved.

As we discuss later in this preamble, we are proposing that CMS or its contractors may enter a case as a party at the ALJ level and be accorded the same rights as any other party to an ALJ decision. However, since we do not believe that the 90-day deadlines for the ALJ or the MAC to adjudicate appeals would apply to CMS, we have specifically noted in the regulation text that CMS would not be permitted to escalate a case, for example, from the ALJ to the MAC level, if the ALJ did not meet its adjudication deadline.

As noted above, section 1869(d)(1)(A) of the statute indicates that the 90-day deadline for an ALJ decision is premised on the existence of a QIC decision, and section 1869(d)(2)(A) specifies that the DAB has 90 days to ''conduct and conclude a review of the decision on the hearing'' by an ALJ. Neither the statute nor the legislative history provides any guidance with respect to the appropriate processing time frames for ALJ decisions on cases that have not been reconsidered by a QIC, or for DAB decisions on cases that have not been heard by an ALJ. Although the statute is silent in this respect, we recognize that appellants should not have to wait indefinitely for decisions on their appeals in these situations. We have proposed procedures that we believe will enable adjudicators to meet the statutory decision-making time frames in the vast majority of cases, thus minimizing the likelihood that an appellant would have the option of escalation. However, to the extent that such situations do arise, we believe that it may be appropriate to establish in the final rule specific decision-making time frames for both ALJ hearings and DAB reviews for those cases where there was no previous QIC reconsideration decision, or ALJ hearing decision, respectively. We encourage comments on whether the final rule should include such time frames and, if so, the most appropriate adjudication time frames for these cases.

b. Specific Provisions Affected by Escalation—From the QIC to the ALJ Level

Section 1869(c) provides that a QIC must complete its reconsideration within 30 days or 44 days if the appellant requests an extension. The statute also provides that an appellant may escalate the appeal to the ALJ level if the QIC does not complete the reconsideration within the requisite period. The statute does not specify, however, that appeals will automatically be referred from the QIC to the ALJ level once the 30 or 44-day period expires. Rather, the statute leaves it to the appellant to request escalation to the next level. The statute is silent concerning when the appellant must make this request or the precise effect the request will have on any case development or other adjudication efforts that the QIC may be conducting on the appeal when the escalation request is received.

We considered various options for effectuating this provision, including requiring that the QIC immediately cease its consideration of the appeal as soon as the request for escalation is received. As discussed above, we concluded that this option would be counterproductive for both the appellant requesting escalation and for the appeals system as a whole, including appellants whose claims remain at the QIC level and those whose appeals are already pending at the ALJ level. Specifically, because we expect that QICs will make every effort to issue determinations within the 30 or 44-day time frame, we would expect that many of the cases that are not decided by those deadlines will nonetheless be very close to completion. It would not benefit either the appellant who is requesting escalation or those appellants whose appeals are pending at the ALJ level if we require the QIC to cease deciding a case as soon as a request for escalation is received, particularly if the QIC is close to issuing a determination that will be fully favorable to the appellant.

Therefore, we are proposing that when a QIC receives a request for escalation, the QIC will defer sending the case to the ALJ level for 5 days. If possible, the QIC will complete its adjudication of the case, including issuing a written reconsideration, within the 5-day period. If the determination is fully favorable to all parties, the case will be forwarded to the initial contractor for effectuation. If not, the appellant or another party to the appeal may file a request for ALJ hearing within the 60-day period provided in these regulations. If the QIC is not able to decide the case within the 5-day period, it will notify the appellant and forward the case record to the hearing office that has jurisdiction of the case. The appeal will then be processed according to the rules described in proposed sections 405.1000 *et. seq.*

c. Specific Provisions Affected by Escalation—Escalation at the ALJ and MAC Levels

We are proposing similar procedures when an appellant requests escalation from the ALJ to the MAC level and from the MAC level to federal district court described below.

ALJ Level to the MAC (§ 405.1104)

The appellant must file the request for escalation directly with the ALJ/hearing office assigned to the appeal as well as with the MAC. (The notice that the hearing office issues acknowledging the request for hearing will provide sufficient information for the appellant to direct the escalation request to the appropriate office or ALJ.) Upon receipt of the request for escalation, the ALJ may, if feasible, issue a decision, dismissal or remand if it can be issued within 5 days of the receipt of the request for escalation. (**Note:** a request for escalation to the MAC will be deemed as a waiver of any oral hearing an appellant has requested but not yet received.) If the ALJ's action is fully favorable to all parties to the appeal, the ALJ will forward the case record to the appropriate contractor for effectuation. If the ALJ's action is not fully favorable to all parties, the appellant or another party to the appeal may file a request for MAC review within 60 days of receipt of the ALJ's action.

If the ALJ does not issue an action within the 5-day period, the case record, including the recording of the oral hearing, if any, will be sent to the MAC.

MAC to Federal District Court (§ 405.1132)

Finally, if the MAC does not issue a final action or remand the case to an ALJ for further proceedings within the 90-day adjudication period, the appellant may request that the case be escalated to federal district court if the amount in controversy is $1,000 or more. Similar to the above procedures, the MAC may, if feasible, issue a final action, if it can be issued within 5 days of the request for escalation.

d. Calculating the 90-Day Adjudication Period

Historically, Medicare appeals were conducted using the ALJ and Appeals Council procedures that were devised for appeals of Social Security claims. Those procedures do not mandate any time frames within which either an ALJ or SSA's Appeals Council must complete their actions on an appeal. However, they also provide generous time periods (or none at all) for scheduling or rescheduling hearings at the convenience of the appellant and the adjudicator, opportunities for both prehearing and posthearing conferences, and no limitations on when additional evidence may be submitted to the ALJ, as long as it is received before the decision is issued.

Congress, through BIPA, has now directed us to complete adjudication within specified time frames and, when such time frames are not met, give appellants the option to escalate their cases to the next level of appeal. To provide this level of service to all appellants, we are proposing the following changes to our appeals procedures. First, we are establishing time limits for submission of evidence. Appellants who submit evidence within these limits and comply with other deadlines described elsewhere in this document, will have the right to have their case adjudicated within the specified time period or to escalate it if the time limit is not met. Conversely, we propose to toll the 90-day adjudication period if appellants submit evidence after those specified time periods. For example, the regulations provide that an appellant must submit any additional evidence within 10 days of receiving the notice of hearing. If an appellant submits the evidence on the 20th day, the ALJ may still accept the evidence, but will have an additional 10 days to decide the case. (See § 405.1018)

We believe that this proposal is consistent with the statute and Congressional intent. Congress has clearly indicated that adjudicators must devise procedures compatible with meeting the statutory deadlines. Moreover, we do not believe that Congress meant to allow appellants to escalate appeals if it is the appellant who has delayed the administrative process. We note that such delays, in particular requests for postponement of scheduled hearings, affect the timely resolution of not only the appellant's own case, but our ability to provide timely hearings and decisions for other appellants as well. We believe that by tolling the 90-day adjudication period in those instances in which the appellant causes the delay, we will provide an incentive for more appellants to appear at scheduled hearings and otherwise comply with hearing procedures.

For the same reason, the proposed regulations contain changes to the current process that we anticipate will streamline the hearings and appeals process, thus providing quicker and more focused adjudication. For example, we are proposing to offer appellants at the ALJ level not only in-person hearings, but hearings via telephone and videoconferencing, where available. We are also restricting submission of additional evidence after an oral hearing to the following:

(1) With the permission of the ALJ, provided that the request is made before or during the hearing.

(2) On the ALJ's own motion, if he or she concludes that the evidence is necessary to resolve a material issue in the case.

We are also continuing the current requirement that the notice of hearing must identify the issues to be decided in the case. Although we are requiring appellants to file any objections to the issues within 5 days of the hearing, we encourage parties to alert ALJs as soon as possible if the notice of hearing does not accurately describe the issue to be decided or does not include an issue material to the resolution of the case (see § 405.1024). Similarly, as explained in more detail elsewhere in this preamble, we are proposing to require appellants seeking MAC review to identify those aspects of the ALJ's decision with which they disagree. (We are not proposing this requirement for beneficiaries who are proceeding pro se.) We believe that this requirement will enable the MAC to resolve requests for review more expeditiously. In addition, the MAC will issue final actions after considering the request for review, rather than first advising appellants of a proposed action and providing a comment period. We do not consider it feasible to provide both a proposed and final action within the designated time frame. In addition, because the MAC will now be conducting a de novo review, appellants are on notice that the MAC may alter the ALJ's decision even if it would have been sustained under the pre-BIPA substantial evidence standard (see § 405.1112).

3. Conduct of ALJ Hearing—General Rules (§ 405.1000)

Section 1869(b)(1)(A) of the Social Security Act as amended by BIPA provides that any individual dissatisfied with any initial determination shall be entitled to a reconsideration and, assuming the request for hearing is timely filed and the amount in controversy requirements are met, a hearing to the same extent as is provided in section 205(b) of the Act. Traditionally, the Secretary has granted individuals entitled to a 205(b) hearing an in-person hearing. In addition, current regulations allow an appellant to waive an in-person hearing and request a decision based on the written record. We would continue that policy in this proposed rule. However, given recent technological advances, we will also offer appellants an opportunity for a hearing via telephone or videoconference, as available. (Currently, videoconferencing is only available at selected hearing sites throughout the country. 66 FR 61310 (January 5, 2001)). Recent experience shows that hearings conducted via telephone and videoconferencing advantage both the adjudicator and the appellant, particularly beneficiaries who have difficulty traveling even short distances or providers and suppliers for whom a telephone hearing or a videoconference may be more convenient than a hearing scheduled at a more distant hearing office. We believe that offering these options, where available, will also enable ALJs to complete more cases within the 90-day adjudication period. It may also afford some appellants an opportunity to present their case orally who currently request on-the-record hearings because of transportation or scheduling difficulties.

4. What Actions Are Reviewable by an ALJ? (§ 405.1004)

We have interpreted the current regulations governing the Part A and Part B appeals process as affording a party the right to an ALJ hearing only if the intermediary or carrier hearing officer (CHO), as applicable, has issued a determination or decision on the merits. Consistent with this interpretation, ALJs have dismissed requests for an ALJ hearing when the contractor or CHO has dismissed a request for a reconsideration or carrier hearing.

We propose to revise this policy for appeals filed under BIPA. Specifically, we would give 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. (We expect that res judicata will most often occur when a party asks for another adjudication of a claim for the same service, that is, the same instance of receiving a service.) However, the proposed regulations also specify that if an ALJ decides that a QIC's dismissal was improper, the ALJ will remand to the QIC for a substantive decision.

5. What Authorities Are Binding on an ALJ?

In our May 12, 1997 final rule, we stated that ALJs are bound by the Medicare statute, CMS regulations, CMS Rulings and NCDs based on section 1862(a)(1) of the Act. Under BIPA, all NCDs, based on section 1862(a)(1) or other grounds, are binding on ALJs. We are revising our regulations, including those governing the expedited appeals process, accordingly.

6. Aggregating Claims To Meet the Amount in Controversy (§ 405.1006)

Prior to the enactment of section 521 of BIPA, the statute and regulations provided different amounts in controversy for Part A and Part B hearings and appeals. Under Part A, an appellant could receive 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 could receive 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.

The pre-BIPA aggregations provisions found at former section 1869(b)(2) 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 provision in a final regulation published March 16, 1994. The regulation established two methods of aggregation, one for individual appellants and one for multiple appellants. Individual appellants appealing either Part A and Part B claims were allowed to aggregate two or more claims (within a specified time period), regardless of issue, to meet the jurisdictional minimums for a carrier hearing and ALJ hearing. (Prior to OBRA 1986, this method for aggregating claims had been available to appellants requesting a Part B hearing before a carrier hearing officer.) 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) 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 have been altered as follows:

(ii) Aggregation of claims. In determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve—

(I) the delivery of similar or related services to the same individual by one or more providers of services or suppliers, or

(II) common issues of law and fact arising from services furnished to two or more individuals by one or more providers of services or suppliers.

We are proposing 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. Accordingly, we would no longer allow appellants to aggregate all timely filed claims regardless of issue. We are proposing this change for several reasons. Under the current system, appellants can only appeal beyond the intermediary or carrier levels if their appeal meets the minimum amount in controversy requirements described above. With the creation of the QICs, however, appellants will have access to a review by an independent contractor regardless of a claim's monetary value. We believe that this will provide sufficient due process for those claims that are below the $100 threshold.

Moreover, BIPA has reduced the amount in controversy for a Part B ALJ hearing from $500 to $100. Our experience suggests that the majority of Part A and B appeals that are decided by the QICs will equal or exceed the $100 amount in controversy requirement. Thus, we do not believe that eliminating the more liberal rules

that individual appellants have used to aggregate claims will alter significantly an appellant's access to an ALJ hearing. We believe that continuing to apply the current aggregation rules would hinder ALJs and the MAC from meeting BIPA's 90-day deadlines for completing appeals. The current system, which allows aggregation of claims regardless of issue, has led to cumbersome and lengthy proceedings at both the ALJ and MAC levels. Adjudication is often delayed when an appellant seeks to aggregate a claim with another previously filed appeal; continuing this practice will impair our ability to meet the statutory deadline for the earlier appeal. Moreover, some of the current inefficiencies in the appeals system are caused by cases in which appellants seek to aggregate numerous claims that concern a variety of unrelated services or supplies, each of which has been denied for a different reason. Based on this experience, we believe that allowing appellants to aggregate claims regardless of issue will make it extremely difficult to provide a meaningful review of each issue within the statutory deadlines.

Therefore, we are proposing to limit aggregation for both individual and multiple appellants to the clear language of the statutory provisions. In order to allow individual beneficiaries, providers and suppliers, as well as multiple appellants to aggregate claims, we will allow appellants to aggregate claims to meet the amount in controversy if the claims involve common issues of law and fact or delivery of similar or related services, regardless of whether the services pertain to just one beneficiary or a number of beneficiaries and regardless of how many providers or suppliers provided the services. We will continue our policy, however, of restricting the claims that may be aggregated to those that are appealed within a limited period; to do otherwise would in essence extend the time to file a request for hearing beyond the 60-day time limit. We are also proposing separate rules for claims that are escalated from the QIC to the ALJ level to ensure that only appeals that clearly meet the amount in controversy requirements are escalated to the ALJ level. Finally, given the reduced amount in controversy threshold and the new adjudication deadlines, which will require adjudicators to resolve issues more quickly, we believe it is reasonable to require appellants to explain in their request for aggregation why they believe the claims involve common issues of law and fact or delivery of similar or related services.

7. When CMS or Its Contractors May Participate in an ALJ hearing (§§ 405.1010 and 405.1012)

Existing regulations do not address whether CMS and its contractors could participate in ALJ hearings. Occasions have arisen, however, in which a contractor or an ALJ has determined that an issue in a case could not be resolved without some input from CMS or the contractor. In some cases, ALJs have requested position papers, testimony, or other evidence from CMS or a contractor, but such proceedings have been cumbersome, because the regulations did not provide specific procedures for such input. After reviewing the outcome of other cases, CMS has concluded that the case might have been more appropriately resolved if CMS or the contractor had been parties to the appeal.

New section 1869(c)(3)(J) provides that the QIC will not only prepare the record of the reconsideration when a hearing before an ALJ is requested, but also will ''participate in such hearings as required by the Secretary.'' Consistent with this provision, we are proposing to revise our regulations concerning the conduct of an ALJ hearing to allow participation of a representative of CMS, or another CMS contractor, either at the request of an ALJ or upon the request of the QIC or CMS. Such participation may include filing position papers or providing testimony to clarify factual or policy issues in a case, but will not include those aspects of full party status such as the right to call witnesses or cross-examine the witnesses of another party. Because the role of a participant is non-adversarial, we would allow participation of the QIC, CMS, or CMS's contractors in cases brought by all appellants, including beneficiaries.

An ALJ will not have the authority to require CMS or a contractor to participate in a case. Nor may the ALJ draw any adverse inferences if CMS or a contractor decides not to participate. For example, an ALJ could not consider a party's allegations as accepted as true if CMS or a contractor decides not to participate and counter such allegations. We anticipate, however, that there will be other cases in which CMS or its contractor will want and need to be a full party in a case in order to ensure that the record before the ALJ is fully developed. Accordingly, we are also revising the current regulations to allow CMS or its contractor to enter an appeal at the ALJ level as a party, unless the appeal is brought by an unrepresented beneficiary. When CMS or its contractor enters the case as a party, it will have all the rights of a party, including the right to call witnesses or cross-examine the witnesses of other parties, as well as the right to seek MAC review of an adverse decision. CMS and the contractor, when acting as parties, may also submit additional evidence to the ALJ. An ALJ would not have the authority to require CMS or a contractor to enter a case as a party, nor would an ALJ be able to draw any inferences if CMS does not participate in the case. We believe that these proposed changes will enable adjudicators at the ALJ and, thereafter, the MAC level to resolve issues of fact and law more quickly and reduce the need for remands for additional development.

8. Filing Requests for ALJ Hearing and MAC Review—Time and Place (§§ 405.1014, 405.1016, 405.1106)

Section 1869(b)(1)(D)(ii) provides that ''the Secretary shall establish in regulations time limits for the filing of a request for hearing by the Secretary in accordance with provisions in sections 205 and 206.'' In addition, section 1869(d)(1)(A) provides that ''except 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.'' (Emphasis added.) 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 of the Act gives an appellant 60 days to request a hearing. The current regulations governing appeals of Medicare claims provide the same 60-day period for appealing Medicare cases from the contractor's determination or decision to an ALJ and, thereafter, from the ALJ level to the MAC. We are proposing to continue to require parties to file their appeals to the ALJ level and the MAC within 60 days. As discussed above, for purposes of determining an appellant's right to appeal, we will also continue to use the general principles currently found in 20 CFR 404.933 and 42 CFR 405.722. 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 will also continue to calculate the 60-day period based on the date the appeal is actually received by one of the above offices.

As noted above, ALJs and the MAC must issue their decisions no later than the end of the 90-day period beginning on the date the appeal has been timely filed. Therefore we must determine not only whether an appeal has been timely filed to establish the party requesting review's right to an ALJ hearing or MAC review, but also when the appeal is considered timely filed in order to calculate the 90-day adjudication period. Given these deadlines, we considered requiring all requests for ALJ hearing to be filed directly with the hearing office, and all requests for review to be filed directly with the MAC. This requirement would advantage most parties, since we have experienced significant delays in receiving appeals filed with Social Security and other offices. Again, we recognize that local Social Security offices provide a valuable service to many individuals who want or require assistance in filing their appeals. Similarly, providers and suppliers are accustomed to filing requests for an ALJ hearing or, more rarely, MAC review with CMS's contractors.

Therefore, as with requests for redeterminations and reconsiderations, we are proposing to allow parties to file their appeals with these offices. For purposes of establishing whether the party has filed a timely request, the appeal will be considered filed on the date it is received in one of these offices. However, for purposes of establishing the start date for the 90-day adjudication period, we will define the date that an appeal is timely filed as the date the appeal is received by the ALJ or MAC, as applicable. We believe that this policy will give the parties requesting review access to assistance if needed while not reducing the time the ALJ or MAC will have to decide the case.

In addition, both ALJs and the MAC often receive appeals that have not been filed within the 60-day limit. The current regulations allow parties to ask for an extension of time to file their appeal for ''good cause.'' The regulations further provide examples of circumstances that may establish good cause for late filing, such as a serious illness or death of an immediate family member. In our experience, some parties do not acknowledge that they have filed an appeal after the 60-day period has expired or explain why the appeal is late. In the event that the party requesting review subsequently provides information that establishes good cause for late filing, we will calculate the date the appeal is ''timely filed'' for purposes of beginning the 90-day adjudication period as the date the ALJ or MAC, as applicable, receives the good cause explanation, assuming the ALJ or MAC determines that the explanation provides good cause for filing the appeal late.

9. Adjudication Deadlines—ALJ Level (§ 405.1016)

Section 1869(d)(1)(A) 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. (Emphasis added.) We interpret this as requiring an ALJ to decide a case within 90 days only when the QIC has issued a final action in a case. Therefore, when an appellant escalates an appeal from the QIC to the ALJ level, the proceedings before the ALJ are not subject to the 90-day limit.

We are also proposing to toll the 90-day adjudication deadline when an appellant's actions, including delays in submitting evidence or requests for postponement of a hearing, rather than the ALJ's actions, extend the length of the proceedings.

10. Remand Authority (§ 405.1034)

Currently, the regulations governing Medicare appeals do not provide clear guidance concerning if and when an ALJ may remand a case to a contractor for further proceedings. We are proposing including regulations that would require or allow ALJs to remand to the QIC under certain circumstances. First, the regulations would allow an ALJ to review whether or not the QIC erred in dismissing a request for reconsideration and to remand the case to the QIC for a reconsideration determination if the dismissal was improper. The regulations would also require an ALJ to remand a case to the QIC for a new decision if the appellant submits new evidence to the ALJ without providing a good reason for not providing it at the QIC level. (If the ALJ determines that there is good cause for submitting the evidence to the ALJ, the ALJ will include the evidence in the administrative record and decide the case on that record.) As discussed previously, we believe that this requirement will encourage appellants to resolve appeals, if possible, at earlier and less costly steps of the appeals process. Moreover, since most Part A and B appeals pertain to services that have already been provided, most medical and other records relevant to the case should be available during the initial stages in the appeals process. Requiring earlier submission of evidence will also assist ALJs and the MAC to meet their adjudication deadlines, since it will reduce time consuming development of the record. However, because we recognize that the reason for denying a claim may be different at various steps of the appeals process, we would not require an ALJ to remand a case when an appellant submits evidence relevant to an issue that is first identified in the QIC's reconsideration determination.

We would also permit an ALJ to remand the case to a QIC when the record lacks technical information material to resolution of the case that only the contractor, rather than a party, can provide. For example, it may be necessary to examine a contractor's payment history records in order to determine whether a supplier has filed a claim for durable medical equipment that has already been billed for by another supplier. Since such records would not ordinarily be in the possession of a party to the appeal, it may be necessary for the ALJ to remand the case to the QIC, if the initial contractor or the QIC has not included this information in the record submitted to the ALJ.

11. When May an ALJ Consolidate a Hearing? (§ 405.1044)

This proposed rule does not alter the ALJ's ability to consolidate a hearing. However, we have added a provision requiring an ALJ to notify CMS of his or her intent to consolidate hearings (see § 405.1044(c)). We believe that that the consolidation of hearings may affect our decision on whether to participate or invoke party status.

12. When May an ALJ Dismiss a Request for Hearing? (§ 405.1052)

CMS's current regulations do not address this issue; rather, ALJs follow the regulations at 20 CFR 404.957. These regulations were designed to resolve appeals filed by applicants for Social Security retirement and disability benefits. We are proposing new regulations that will address the specific procedural issues that arise in Medicare claims appeals.

a. Effect of the Death of the Beneficiary

The current regulations do not give specific guidance to appellants or adjudicators concerning the effect of the death of a beneficiary on an appeal. We believe that the regulations should provide notice to appellants concerning what will happen to an appeal if the

beneficiary dies either before it is filed or while it is pending. The proposed provisions would identify those circumstances in which the appeal will continue to be adjudicated on the merits versus those that will be dismissed because there is no longer an interested party who may obtain relief.

We are proposing to continue deciding appeals on the merits under the following circumstances.

The appeal involves a claim for benefits under Part A or B in which the beneficiary obtained the service at issue and the beneficiary either paid for the service or has a spouse or estate who continues to be financially liable for the service. In this circumstance, the beneficiary's spouse or estate may continue to pursue the appeal.

The appeal is filed by another party, including a provider of services or supplier, who continues to have a financial interest in the outcome of the appeal.

The appeal involved a service (such as a skilled nursing facility stay) for which payment was made under waiver of liability, but for which the determination was construed as a notice of noncoverage to deny payment to the beneficiary for subsequent dates of service.

The ALJ would dismiss, upon the beneficiary's death, other requests for hearing that do not meet the above criteria. For example, the ALJ could dismiss if the beneficiary or the beneficiary's representative filed the request for hearing but the beneficiary died before the hearing was held, and the beneficiary was not held liable for the services at issue in the QIC's reconsideration. The ALJ would not be required to inquire whether other potentially affected parties wish to continue the appeal unless they participated in the QIC review below. Similarly, a dismissal would occur if the supplier filed the request for hearing as the representative of the beneficiary, but did not have appeal rights on its own (because, for example, it did not take assignment) and the beneficiary died before the request for hearing was filed.

b. Requests for Withdrawal of a Request for Hearing

SSA's regulations at 20 CFR 404.957 now provide that an ALJ may dismiss a request for hearing if the party that requested the hearing asks to withdraw the request. The request may be submitted in writing or made orally at the hearing. Guidelines issued by SSA's Office of Hearings and Appeals further instruct ALJs that the request must indicate that the party withdrawing the request for hearing is aware of the consequences of the withdrawal. Experience shows that some appellants are in fact unaware of the consequences; for example they may equate a request for withdrawal with a request for postponement of the case. In order to avoid unnecessary remands of these cases, we are adding a requirement that the request for withdrawal must contain a clear statement that the appellant is withdrawing the appeal and does not intend to further proceed with the appeal. If the request for withdrawal is filed by an attorney, or other legal professional on behalf of a beneficiary or other appellant, the ALJ may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal. (We note that most local rules governing the professional responsibility of attorneys would require that an attorney advise a client of the effects of withdrawing an appeal.)

c. Res Judicata

SSA regulations at 20 CFR 404.957(c)(1) provide that an ALJ may dismiss a request for hearing based on the doctrine of res judicata. We are including this provision in our new regulations but clarifying that in the Medicare context the issue will most often occur when a party asks for another adjudication of a claim for the same date of service based on the same facts and evidence and the previous decision on the claim is either administratively or judicially final.

d. Abandonment

Currently, an ALJ may dismiss a request for hearing if the appellant does not have a good reason for failing to appear at a scheduled hearing. We will continue to allow ALJs to dismiss a request for hearing for this reason. In addition, if the hearing is rescheduled because the ALJ finds that the appellant had a good reason for failing to appear, the number of days that expire between the first and second scheduled hearing will not be counted toward the 90-day time limit for deciding the case.

J. Review by the Medicare Appeals Council and Judicial Review (§§ 405.1100–405.1140)

1. Introduction

The component of the DAB that decides cases brought under section 521 of BIPA is called the Medicare Appeals Council (MAC). Prior to this rulemaking, the MAC has considered requests for review of Medicare cases under the procedures used by the SSA's Appeals Council. Those regulations are found at 20 CFR 404.966 through 404.982. As with the ALJ regulations discussed above, we are now proposing to incorporate these procedures into 42 CFR of the Medicare regulations. These proposed regulations will incorporate the BIPA provisions governing MAC review and establish procedures that will meet the particular needs of the Medicare appeals process.

2. MAC Review of an ALJ's Action/De Novo Review (§ 405.1100)

Under the current regulations, the MAC may deny or dismiss a request for review, or it may grant the request for review and either issue a decision or remand the case to an ALJ. The MAC may 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. (See Social Security Ruling 95–2c, 60 FR 31753 (June 16, 1985)).

The MAC also has the authority to review an ALJ's action on its own motion, provided that it takes review of the case within 60 days after the date of the hearing decision or dismissal.

In deciding whether to grant a request for review, the MAC considers whether: (1) There appears to be an abuse of discretion by the ALJ; (2) there is an error of law; (3) the actions, findings or conclusions of the ALJ are not supported by substantial evidence; or (4) there is a broad policy or procedural issue that may affect the general public interest. In addition, if new and material evidence is submitted that relates to the period on or before the date of the administrative law judge hearing decision the MAC will review the case if it finds that the administrative law judge's action, findings, or conclusion is contrary to the weight of the evidence currently of record. If the MAC denies review of an ALJ's decision, the ALJ's action, not the denial of review, is the final decision of the Secretary and is reviewable in federal district court on a substantial evidence standard.

BIPA directs the MAC to apply a different standard when reviewing an ALJ's action. Section 1869(d)(2)(B) directs the MAC to conduct a de novo review of an ALJ's decision on a hearing. In addition, section 1869(d)(3)(A) allows parties to request review by the MAC if an ALJ does not issue a decision within the 90-day adjudication period ''notwithstanding any requirements for a hearing for purposes of the party's right to such a review.''

We are proposing to effectuate the MAC's new review process as follows. The MAC may no longer consider ALJ decisions under a substantial evidence standard nor may it ''deny'' review.

Rather, it will review the ALJ's decision de novo. If a case requires additional development or proceedings at the ALJ level, the MAC will remand the case to the ALJ for further action. Otherwise, the MAC will communicate its final action on the case by issuing a final decision or order that adopts, modifies or reverses the ALJ's action, as appropriate.

In addition to requiring any MAC review of an ALJ decision to be de novo, BIPA requires the MAC to complete its action on an ALJ decision within 90 days from the date the request for review is timely filed. In a previous section of this preamble, we have discussed the effect of these provisions on such questions as where and when a request for MAC review may be filed. We believe that the changes in the standard of review and the adjudication deadlines will require the following additional changes to the MAC's current procedures as well.

3. Escalation of an Appeal From the ALJ Level to the MAC (§§ 405.1104, 405.1106, and 405.1108)

Section 1869(d)(3)(A) of the Act, as amended by 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 review.'' As we have explained elsewhere in this preamble, the MAC's consideration of an appeal when it is escalated from the ALJ to the MAC level is not subject to the 90-day adjudication deadline. In addition, we interpret section 1869(d)(3)(A) to mean that only the person or entity who requested the ALJ hearing may escalate the appeal to the MAC if the ALJ does not meet the 90-day adjudication deadline. Where CMS has entered into the case as a party, it may not seek escalation.

Because the statute allows escalation for a MAC review ''notwithstanding any requirements for a hearing,'' the MAC is not required to hold a hearing if the case is escalated to its level. The statute does not describe the type of review that the MAC will conduct when an appeal is escalated before an ALJ action is issued, or what actions the MAC may take upon its review in such circumstances. Because it is possible that the MAC will receive cases escalated both before and after an ALJ hearing has been scheduled or conducted, we believe that the MAC will need the same options for disposing of a case that it would have if in reviewing an ALJ's decision or dismissal order. Therefore, we are proposing that when the MAC reviews a case that is escalated from the ALJ level it may 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. (We will also continue to allow the MAC to hold a hearing, if warranted.)

4. Own Motion Provisions (§ 405.1110)

Under the current regulations, neither CMS nor its contractors are parties to appeals brought under 42 CFR 405, Subparts G and H. However, the regulations provide that in addition to deciding a case appealed by a beneficiary or other party, the MAC may decide on its own motion to review an ALJ's decision or dismissal anytime within 60 days after the date of the action (20 CFR 404.969). We refer to this as the MAC's own motion authority. The cases that the MAC reviews on its own motion are generally referred to it by CMS and its contractors.

We believe that the MAC's own motion authority should be revised to better accommodate the other changes to the appeals process required by BIPA. Moreover, as discussed above, CMS and its contractors, including the QICs, will now have an opportunity to participate in the hearings and appeals process either as parties or not as parties. In keeping with our proposed policy, that when CMS acts as a party it has the same rights as any other party, CMS would have the right to MAC review, using the same procedures that any other party would use. However, we recognize that the statute's adjudication deadlines could impose significant challenges to the MAC to complete all of the cases appealed to them by beneficiaries, providers, suppliers, and other affected third parties in a timely manner. Therefore, we are proposing that when CMS is not acting as a party to the case, the MAC's own motion authority would be limited as follows.

CMS and its contractors (hereafter: CMS) may refer ALJ decisions and dismissals to the MAC for own motion review when they participated (but did not act as a party) in the ALJ proceedings. When a case is referred in this circumstance, the MAC will accept the case for review if there is an error of law, an abuse of discretion, the decision is not consistent with the preponderance of the evidence or record, or there is 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.

CMS may also refer ALJ decisions and dismissals to the MAC for own motion review when it did not participate and did not act as a party in the proceedings below. When a case is referred in this circumstance, the MAC will accept the case for review if the decision or dismissal contains a clear error of law 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.

Cases reviewed under the own motion authority would also be subject to the 90-day adjudication deadline. The deadline will begin when the MAC receives the referral from CMS or its contractors, unless the party who requested the ALJ hearing or another party to the hearing asks for an extension of time to respond to CMS's referral. The regulations will require that CMS send a copy of its own motion referral to all parties to the ALJ's action, as well as the ALJ.

5. New Requirement for Review Requests (§ 405.1112)

The current regulations do not require appellants to include in their requests for review the specific reasons that they disagree with an ALJ's decision or dismissal. As a result, many of the requests for review state only general reasons for appealing, such as ''I disagree with the ALJ's decision'' or ''The decision is not supported by the evidence and is inconsistent with the law.'' Because these appeals do not identify any specific flaw in the decision, the MAC's consideration of the case is very time and labor intensive, including examination of aspects of the decision with which the party may not actually disagree. For example, if an ALJ's decision rules unfavorably on five claims, the party may only believe that the decision is wrong with respect to one claim rather than all five. However, because the current regulations do not require the party to state the reasons for appealing all claims that it believes were incorrectly decided, the MAC is obligated to consider whether all five claims were property decided.

We believe that the MAC will not be able to conduct a de novo review of an ALJ's action within 90 days of the date the request for review is received unless parties requesting review provide more specific reasons for their disagreement with the ALJ's action. Because many beneficiaries have limited experience with the rules governing Medicare

coverage and payment policies, we do not propose requiring them to file specific exceptions with their requests for review unless they are represented by an attorney or other legal professional. Providers, suppliers, and CMS (when it has entered the case as a party) however, must not only be aware of Medicare coverage and payment policies in order to support their claims, but, by regulation, are presumed to have constructive notice of CMS notices, including manual issuances, bulletins, or other written guides and directives from Medicare contractors, as well as **Federal Register** publications containing notice of NCDs. See 42 CFR 411.406(e)(1) and (2). Therefore, we believe it is reasonable to require providers, suppliers, and CMS, as well as third-party appellants such as Medicaid State agencies, to include in their request for review the specific reasons they disagree with an ALJ's action. In addition, we believe it is appropriate to extend this requirement to requests for review filed by attorneys or other legal professionals on behalf of a beneficiary or when a provider, supplier or third party files a request for review as the beneficiary's representative.

In proposing this requirement, we wish to reassure parties that the purpose of requiring the exceptions is to enable the MAC to provide an efficient and focused review of those aspects of an ALJ's action with which the party disagrees. Because the MAC is concerned with the content rather than the form of the appeal, we would not require parties to file formal briefs or other pleadings. However, given the statutory limits, we believe that it is reasonable to require parties to state the basis for their disagreement with an ALJ's action and for the MAC to review de novo only those aspects of an ALJ's action with which the party disagrees. If a party other than an unrepresented beneficiary does not file any exceptions, the MAC will adopt the ALJ's action without comment, unless the ALJ's decision or dismissal contains on its face a clear error of law.

6. Discontinuation of Notice to Parties (§ 405.1128)

The current regulations at 20 CFR 404.973 require that when the MAC decides to review a case, it sends a notice to all parties stating the reasons for review and the issues to be considered. In the context of Social Security appeals this regulation has been interpreted as requiring SSA's Appeals Council to give appellants advance notice and opportunity to comment on any proposed action that is not fully favorable to all appellants. The MAC presently follows this regulation as well.

We do not believe, however, that it is possible or necessary to continue this practice under BIPA. When a party requests the MAC to review a case under BIPA, it is requesting the MAC to review the ALJ's action de novo; therefore, parties are on notice that the MAC's action, whether favorable or unfavorable, may differ considerably from the action being appealed. Since this regulation will also require CMS and its contractors to send a copy of own motion referrals to all parties, the parties to an own motion review will also be on notice that the MAC will be reviewing de novo those aspects of the case challenged by CMS, where CMS in not acting as a party, as applicable and will have the opportunity to file a reply with the MAC. We believe these procedures will satisfy due process while maintaining the MAC's ability to adjudicate appeals within 90 days. Therefore, the proposed regulations allow the MAC to adopt, modify, or reverse an ALJ's action without first providing notice and opportunity to comment on its proposed action (see § 405.1128).

7. Judicial Review (§§ 405.1136–405.1140)

These actions of the proposed rule consolidate and generally mirror the existing regulations with respect to judicial review, now found in 42 CFR 405.857, 20 CFR 404.983–404.984, and 20 CFR 422.210. The only substantive change is to provide that an appellant may request escalation to Federal district court if the MAC does not complete its review of an ALJ decision within the 90-day adjudication period, consistent with section 1869(d)(3)(B) of the Act.

J. Expedited Proceedings (§§ 405.1200–405.1206)

1. Overview of the Statute

Section 1869(b)(1)(F) provides for an expedited appeals process when a beneficiary receives notice from a provider of services that such provider plans to: (1) Terminate services provided to an individual and a physician certifies that failure to continue services is likely to place the beneficiary's health at risk; or (2) plans to discharge the individual from the provider of services. The statute mandates that the beneficiary who receives such notice may request an expedited determination. If he or she is dissatisfied with that determination, that beneficiary may request an expedited reconsideration determination by a QIC. Pursuant to sections 1869(c)(3)(C)(iii) and 1869(c)(3)(C)(iv), the QIC must render a decision within 72 hours unless a beneficiary requests an extension. Section 1869(c)(3)(C)(iii)(III) also mandates that a reconsideration of a discharge from a hospital be conducted in accordance with section 1154(e)(2)–(4).

Historically, Medicare beneficiaries have had a right to an expedited review by a Quality Improvement Organization (QIO, formerly a Peer Review Organization) in situations where they disagreed with a hospital's decision to discharge them. However, in the other provider settings, in order for a beneficiary to access the Medicare appeals process, the individual must: (1) Continue to receive the services up to the date in which he or she believed his or her services should be covered; (2) request the provider of such disputed services to file the claim for payment; and (3) have that claim adjudicated by the Medicare contractor, that is, have the Medicare contractor issue its initial determination. Upon receipt, a beneficiary who was dissatisfied with the contractor's determination then could access the appeals process by requesting a ''Reconsideration'' within 60 days.

Thus, the new BIPA provisions represent a significant change in the existing procedures available to beneficiaries to contest provider decisions to terminate care. Our proposals for implementing these changes are discussed below.

2. Expedited QIO Reviews (§§ 405.1200(a)–(g))

In § 405.1200(a)(1), consistent with the traditional definition of provider at section 1861 of the Act, we propose that the term ''providers'' used in §§ 405.1200 and 405.1202 applies to the following: hospitals, critical access hospitals, home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs). In proposed § 405.1200(a)(2), we would establish that the scope of these provisions includes terminations of services furnished by a non-residential provider and the discharge of a beneficiary from a residential provider of services. This definition would not include reductions in an ongoing course of services.

Consistent with the statute, proposed § 405.1200(b) stipulates that in order for a beneficiary to request an expedited review: the beneficiary must have received notice that a provider intends to terminate services and a physician

must certify that termination of services is likely to place the beneficiary's health at significant risk; or the provider intends to discharge the beneficiary from a provider setting.

We reviewed current notices provided to beneficiaries upon termination of services to determine if existing notices would serve the purposes of this section. We determined that the Advance Beneficiary Notice (ABNs) would meet this need. Before a provider may charge a beneficiary for services that could be covered under Medicare but are not covered in the beneficiary's instant case, CMS regulations implementing section 1879 of the Act require that a provider issue an advance written notice to the beneficiary that the provider does not expect Medicare to pay for those services (see § 411.406). Such an advanced written notice explains that the provider does not expect that Medicare will pay and the provider's reason for that expectation. To comply with this existing section 1879 requirement, HHAs are issuing the HHABN (Home Health Advance Beneficiary Notice, form CMS–R–296); CORFs and hospices are issuing the ABN (Advance Beneficiary Notice, form CMS–R–131); and SNFs are using the SNF NONC (Skilled Nursing Facility Notice Of Non-Coverage). There is a similar notice requirement for inpatient hospitals.

We believe that these existing ABNs are the appropriate vehicles to trigger expedited determination under section 1869 of the Act, because the provider may not charge the beneficiary for services for which Medicare does not pay unless an ABN was provided in advance of furnishing those services, and because an ABN, in the case of an impending termination of provider services, must include a termination date. We will revisit the content of these existing notices to conform with the requirements of this proposed rule and submit such notices for clearance to the Office of Management and Budget through the Paperwork Reduction Act process.

We are not proposing any change in the timing of delivery of these existing notices. Although the inpatient hospital notice of noncoverage is already provided in a way that supports the unique beneficiary liability protections included in the current QIO process, the statute provides no parallel liability protections in the other provider settings. Therefore, we believe that the provision of the current advance beneficiary notices prior to termination will fulfill the intent of the statute. Note, however, that a provider's failure to issue an ABN does not eliminate a beneficiary's right to access the expedited appeals process. If, for example, a beneficiary files a request for an expedited determination following a verbal notification from a provider, the QIO must conduct its review as if a written notice had been given. In such a case, the beneficiary would not be responsible for the cost of care provided prior to the delivery of a valid advance beneficiary notice.

Section 405.1200(b)(2) provides that if a beneficiary does not file a timely request for an expedited determination, the beneficiary may not later access this expedited review process. (Note that the regulations assume that QIOs would likely conduct these determinations. We believe QIOs are the appropriate entity to conduct these expedited reviews of provider terminations, given that they already have the professional medical capabilities to review such medical necessity cases and they are located in every State.) Proposed § 405.1200(c) then establishes the procedures a beneficiary must follow in order to make a valid request for an expedited determination. In this section we give beneficiaries the option of making their request either in writing or by telephone no later than noon of the next day after receipt of the provider's notice. To be consistent with the deadline that QIOs are already familiar with, in regards to the current QIO review of inpatient hospital determinations (beneficiaries must request review of the hospital's decision no later than noon of the next working day), we have established that beneficiaries in these provider settings must request a review by noon. In order to facilitate a quick, accurate determination, we propose under § 405.1200(c) that the requesting beneficiary or representative must be available to answer questions by the QIO, upon request.

Section 405.1200(d) sets forth the procedures that the QIO must follow when it receives a beneficiary's request for an expedited review. Under this section, the QIOs must: notify the provider of the disputed services that a expedited review request has been made; request information such as medical records from the provider; examine the requested necessary medical information; solicit the views of the provider and the beneficiary; and make a decision within 72 hours after receipt of the request for the QIO expedited review and of the information requested from the provider. We would require that the provider submit the information requested by the QIO, no later than close of business on the day after the beneficiary request an expedited determination. Proposed § 405.1200(e) then sets forth the notification requirements when a QIO has made its expedited determination. We are proposing that the QIO immediately notify the beneficiary, physician and provider of its expedited determination, first by telephone and then following up with a written notice that would explain the decision and inform the beneficiary of his or her appeal rights.

Proposed § 405.1200(f) provides that the QIO's expedited determination is binding upon the beneficiary and the provider of the disputed services or stay, absent a beneficiary's request for a QIC reconsideration. If a beneficiary misses the deadline for filing a request for an expedited QIC reconsideration, the beneficiary may request a QIC reconsideration under the general QIC Reconsideration process at § 405.960 *et. seq*.

Section 405.1200(g) discusses the financial liability aspects of the QIO expedited review process. In the inpatient hospital setting, when a beneficiary files for an immediate QIO review by noon of the next working day following receipt of the notice of termination, that beneficiary is not responsible for the additional costs of his or her stay while the review takes place. (See section 1154(e) of the Act.) This financial protection does not exist under the expedited review process for other providers. However, proposed § 405.1200(g) provides that a provider cannot bill a beneficiary for the disputed stay or services until the beneficiary has received an expedited QIO determination; or if an expedited QIC reconsideration determination, if requested. In such situation, if the QIO determines that the services or stay in dispute were medically necessary, the beneficiary is not responsible for the services or stay, as stipulated by the QIO. However, if the QIO determines that the services or stay in dispute were not medically necessary, the beneficiary is responsible for services that extend beyond the appropriate covered services or stay, or as otherwise stated by the QIO.

3. Expedited QIC Reconsiderations (§ 405.1202)

Proposed § 405.1202(a) describes the appeals process for an expedited determination—the expedited QIC reconsideration. Under this section, we propose that, upon receipt of a QIO decision, if the beneficiary is dissatisfied and wants to appeal and receive a decision rendered expeditiously, that beneficiary may request an expedited QIC reconsideration. Section 405.1202(b)

provides that a beneficiary who desires an expedited QIC reconsideration must make that request no later than noon of the next calendar day following receipt of the QIO expedited determination. Consistent with the statute, this section also provides that a beneficiary or representative must be available to talk with the QIC about his or her case when the QIC calls to solicit the beneficiary's views.

Section 405.1202(c) would set forth the procedures that the QIC must follow when conducting its expedited reconsideration. The steps that the QIC must follow are identical to those followed by the QIO except as noted below. Consistent with section 1869(c)(3)(iii), we have established that the QIC render a decision within 72 hours from receipt of the request for an expedited reconsideration and the requested information. In conjunction with this time frame, we would require that if a QIC does not render its decision 72 hours from receipt of the request and information, the QIC must inform the beneficiary of his or her right to have their case escalated to an ALJ; and we set forth the procedures that the beneficiary must follow. In such case, the QIC must immediately notify the provider that such action has been taken. At this point that provider may bill the beneficiary for the services or stay in dispute.

Section 405.1202(d) proposes that the QIC issues a notice of its expedited reconsideration determination after it has notified the beneficiary, provider, and physician responsible for the beneficiary's care of its decision via telephone. The telephone notification must be followed by a written notice that includes the detailed rationale for the decision, a statement that explains the beneficiary's subsequent appeal rights (an ALJ Hearing), and the timeframe for filing for the ALJ hearing request. Section 405.1202(e) would establish that the QIC's reconsideration determination is binding in the beneficiary, subject to an ALJ hearing if the beneficiary is dissatisfied with the QIC's decision. There is no expedited ALJ Hearing. Therefore, such dissatisfied beneficiary will have to request an appeal in accordance with the normal ALJ hearing procedures.

Proposed § 405.1202(f) sets forth the coverage rules for beneficiaries during this review. The beneficiary may not be billed for the disputed services or stay until that beneficiary receives an expedited determination by the QIC. However, if the QIC does not render a decision within 72 hours of receipt of the information and the request, the provider may bill the beneficiary for the services or stay in dispute.

4. Special Rules for Inpatient Hospital Discharges (§§ 405.1204 and 405.1206)

The proposed regulations for these sections are identical to the existing inpatient hospital rules for appealing inpatient hospital determinations with one exception. Upon receipt of a QIO determination, the next level of the appeals process would now be the expedited QIC reconsideration, if the beneficiary makes a timely request for expedited reconsideration and remains in the hospital. If the beneficiary is no longer an inpatient in the hospital, or fails to make a timely request for an expedited reconsideration, but is still dissatisfied with the QIO's determination, he or she retains the right to subsequently appeal that determination under the general QIC reconsideration rules.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

IV. Information Collection Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before 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 Paperwork Reduction Act 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.

The PRA exempts the majority of the information collection activities referenced in this proposed rule. In particular, 5 CFR 1320.4 excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals. However, the information collection requirement associated with the initial request to seek a redetermination is subject to the PRA. Current supporting regulations set forth at §§ 405.711 and 405.807 outlining a request for redetermination are currently approved under the PRA. However, due to the revision/consolidation of the current redetermination regulations, we are requesting comment on the proposed requirement referenced below.

Section 405.940 Right to a Redetermination

A person or entity that is a party to an initial determination as described under § 405.920 *et seq.* and is dissatisfied with that determination may request a redetermination in accordance with § 405.942 through § 405.946.

The burden associated with this requirement is the time and effort necessary to request a redetermination that is in accordance with the requirements referenced in § 405.942 through § 405.946. Based upon current data, we estimate that contractors will process 6,800,000 requests for Part B redeterminations and 60,000 for Part A on an annual basis and that it will require an average of 15 minutes to submit a request for a total burden of 1,715,000 annual burden hours.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Attn.: John Burke, Attn: CMS–4004–P, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer Attn: CMS–4004–P.

V. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this rule 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), Public Law 96–354, the Unfunded Mandates Reform Act of 1995, Public Law 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). Because Federal costs to implement this rule would exceed the $100 million threshold, this is a major rule. 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 proposed 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 proposed rule that may, if adopted, 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. We are uncertain how many small entities will be affected by this rule. The design and purpose of the proposed rule is to improve the accuracy and efficiency of the claims review and appeals process, we are confident that it will reduce rather than add burden on small entities. The impact on small rural hospitals is likely to be negligible or slightly positive. Therefore, we are certifying that the proposed 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 proposed 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 $110 million. This rule would not have such an effect on State, local, or tribal governments, or on the private sector.

B. Scope of the Proposed Changes

As discussed in detail above in section II of this preamble, this proposed rule would establish new regulations concerning appeals procedures for Medicare claims determinations, consistent with section 1869 of the Act as amended by section 521 of BIPA 2000. Among the significant changes required by the BIPA amendments are:

- Establishing a uniform process for handling Medicare Part A and 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.
- Imposing a 30-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 determination or redeterminations, and allowing appellants to escalate the case to an ALJ hearing, if reconsiderations are not completed within 30 days.
- Establishing a uniform amount in controversy threshold of $100 for appeals at the ALJ level.
- Imposing 90-day time limits 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.
- Imposing ''de novo'' review when the MAC reviews an ALJ decision made after a hearing.
- Requiring that the Secretary establish a process by which an individual may obtain an expedited determination if he/she receives a notice from a provider of services that the provider plans to terminate services or discharge the individual from the provider.

The proposed rule would 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 2001, for example, Medicare contractors processed almost 932 million claims; of these only about 6 million were appealed. Thus, the number of Medicare claims that enter the administrative appeals system represents only about 0.6 percent of the total number of claims filed with Medicare. Moreover, the 6 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 6 million claims that are appealed. Given the small percentage of claims and appellants involved in the administrative appeals process, we believe that this proposed rule would 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 proposed rule should be overwhelmingly positive.

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

We expect that the changes set forth in this proposed rule would produce substantial improvements in the accuracy and efficiency of the claims appeal process. For the most part, the anticipated positive impact of the proposed rule on providers, physicians and other suppliers would 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 their much greater likelihood to appeal a claim determination. 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 would have a substantive impact on the actual results of claims appeals. That is, there is no reason to believe that the use of QICs, or other changes required by BIPA, would result in any change in the proportion of appeals that result in favorable decisions for providers, suppliers, or beneficiaries. We do believe though 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

major reductions in the need for the elevation of appeals to the slower, more costly levels of the appeals system, such as ALJ hearings and DAB or Federal court review. We welcome comments on all aspects of this impact analysis.

Most of the major changes set forth in this rule, such as the new time frames for appeals decisions, are mandated by the statute and thus not subject to the Secretary's discretion. To the extent that we have exercised discretion, such as 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 change set forth here is the reduction in mandatory time frames for issuing a decision on appeals at all levels. In general, this would mean faster receipt of decisions and, for favorable decisions, faster payment. For example, a provider who appealed a Part A claim determination in FY 2001 waited an average of 64 days for an intermediary to make a decision on a reconsideration request, where under the proposed rule a decision on a Part A redetermination request must be made within 30 days of receipt of the request. 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 would be initiated as soon as a decision is reached. Given the reduced decision-making time frames, payments would be received substantially sooner than under the current system. Similarly, the time frame for a Part B fair hearing decision would be reduced from 120 days to 30 days, with concomitant fiscal advantages to successful appellants. These benefits to appellants would extend to all levels of the Medicare administrative appeals process.

In addition to the new time frames for making decisions, the proposed rule would allow appellants the option of escalating an appeal to an ALJ if the QIC fails to make a decision timely. Escalation also would be available at the appellants' option from the ALJ level to the DAB 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 DAB to Federal court). Clearly, these options would 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.

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

Another important change included in this proposed rule is the requirement that a QIC panel of physicians or other qualified health care professionals conduct reconsiderations when the initial determination being appealed involved 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. We believe that this change would give appellants more confidence that a fair decision has been reached, potentially reducing their need to pursue subsequent appeals. We believe the introduction of physicians and other health care professionals into the appeals process would produce administrative finality at an earlier level of the process and benefit both appellants and the Medicare program.

3. Decision Letters and Documentation Requirements

An important discretionary 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. (Note that the statute establishes specific requirements for notices following QIC reconsiderations, but does not address the content of redetermination notices.) We believe that the proposed policies for more detailed decision notices would provide appellants with the information they need to build their case early in the appeals process. We believe the impact of this requirement would result in 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.

Since the appellant would be informed about specific documentation that is necessary to make a decision, the proposed rule also requires that such identified information be submitted with the next level appeal request. If the information is not submitted to the QIC, but instead surfaces later in the appeals process, the appellant would need to demonstrate good cause why the information was not submitted to the QIC. We believe the end result of these provisions would be that appeals are resolved at the earliest possible administrative level, which is a positive result for all appellants. As discussed in detail in section II.I.10 of the preamble, ALJs would have the authority to remand cases to a QIC when available evidence is not submitted timely.

4. Party Status

In the current regulations, providers may appeal only in limited circumstances. In order to appeal in other circumstances, providers must act as an appointed representative of a beneficiary.

In the proposed rule, we would permit participating providers to appeal to the same extent as beneficiaries or suppliers who take assignment. We believe this change would have several positive impacts on appellants. For example, it would eliminate any confusion providers may have in determining whether they have standing to appeal an initial determination, and it would remove the burden for the provider of obtaining an appointment of representative from a beneficiary. This should also eliminate confusion beneficiaries had in the past about why providers have sought to represent beneficiaries.

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, SSA, and DHHS. Deciding appeals within shorter time frames 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. Section 521 of BIPA not only mandated shorter decision-making time frames and other costly improvements to the already taxed Medicare appeals system, it also created additional opportunities and incentives for providers, suppliers, and beneficiaries to request appeals. Most significantly, the statute no longer provides for any minimum amount in controversy (AIC) below the ALJ level, and lowers the AIC from $500 to $100 for appealing a Part B claim determination to an ALJ. In addition, we

anticipate that the new decision-making time frames could make the appeals process more attractive to potential appellants who previously may have been dissuaded from appealing by the potential delays involved in obtaining a decision on their appeal. Thus, in order to forestall large increases in appeals volume at the higher levels of appeal, we have attempted to craft appeals rules that would ensure not only that appellants receive consistent and accurate decisions at the lowest possible appeals level, but also that appellants are made aware of the reasons for these decisions.

Finally, we note that although the impact of these changes would be positive for the provider, physician, supplier, and beneficiary communities, implementing these procedures would generate substantial costs to the Medicare program. Our most recent estimate is that the changes required at the contractor and QIC level would cost at least $100 million, with additional costs to implement the necessary changes at the ALJ and DAB appeals level.

E. Federalism

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV, part 405 as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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

Authority: Secs. 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 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).

2. Add a new subpart I, consisting of § 405.900 through § 405.1206, to part 405 to read as follows:

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

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

§ 405.900 Basis and scope.

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

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations with respect to 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 appeals of these initial determinations are found at 20 CFR part 404, subparts J and R).

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

(3) Any other initial determination with respect to a claim for benefits under Part A or Part B, including an initial determination made by a qualified 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.

§ 405.902 Definitions.

For the purposes of this subpart, the term—

ALJ stands for an Administrative Law Judge.

Appellant means the beneficiary, assignee or other person or entity that has filed an appeal concerning a particular initial determination. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Assignee means a provider, physician, or other supplier who furnishes items or services to a beneficiary and who has accepted a valid assignment of appeal rights executed by the beneficiary.

Assignment of appeal rights means the transfer by the assignor of his or her right to appeal an initial determination to the assignee.

Assignor means a beneficiary whose provider of services, physician, or supplier has taken assignment of the right to appeal a claim.

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 payment from being made on the claim under title XVIII of the Act.

MAC stands for the Medicare Appeals Council within the Departmental Appeals Board of the 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.

Qualified Improvement Organization (QIO) means an entity that contracts with the Secretary in accordance with sections 1152 and 1153 of the Act and 42 CFR chapter IV, subchapter F, to perform the functions described in section 1154 of the Act and 42 CFR chapter IV, subchapter F, including expedited determinations as described in § 405.1200 through § 405.1206.

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

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

Vacate means to set aside a previous action.

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

(a) *General overview.* 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, and the contractor will perform, a redetermination of the claim. Following the contractor's redetermination, the beneficiary may obtain a reconsideration from the Qualified Independent Contractor (QIC). Following the reconsideration, the beneficiary may obtain a hearing before an Administrative Law Judge (ALJ) if the amount remaining in controversy is at least $100. If the beneficiary 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 file suit in Federal district court if the amount remaining in controversy is at least $1,000.

(b) *Non-beneficiary appellants.* In general, the procedures described in paragraph (a) of this section are also available to an individual representing beneficiaries and to parties other than beneficiaries or their representatives, consistent with the requirements of this subpart I. However, 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 (§ 411.15(g) of this chapter); they were not reasonable and necessary (§ 411.14(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 (§ 409.42(a) and (c)(1) of this chapter); or they were hospice services provided to a non-terminally ill individual (§ 418.22 of this chapter); and

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

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

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

(1) A beneficiary who has filed a claim for payment or has had a claim for payment filed on his or her behalf, or in the case of a deceased beneficiary, or 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. However, payment by a third party payer does not entitle that entity to party status.

(2) A participating physician or other supplier who has filed a claim for items or services furnished to a beneficiary.

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

(b) 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;

(2) A Medicaid State Agency in accordance with § 405.908; and

(3) An assignee who has accepted an assignment of appeal rights from the beneficiary according to § 405.912.

(4) A non-participating physician or other supplier who has accepted assignment in accordance with § 424.55 of this chapter.

(5) A non-participating physician not billing on an assigned basis who, in accordance with section 1842(l) of the Act, is 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

(6) 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, is liable to refund monies collected for items furnished to the beneficiary.

§ 405.908 Medicaid State Agencies.

When a beneficiary is dually eligible for Medicare and Medicaid, the Medicaid State Agency may file a request for an appeal on behalf of the beneficiary. A Medicaid State Agency will only be considered a party when it files a timely redetermination request on behalf of a beneficiary in accordance with 42 CFR parts 940 through 958. If a Medicaid State Agency files a redetermination, it retains party status at the QIC, ALJ, MAC, and judicial review levels.

§ 405.910 Appointed representatives.

The requirements of this section apply for purposes of all administrative actions described in this subpart, subsequent to an initial determination.

(a) *Representative defined.* A representative means 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 under this subpart. Representatives do not have party status and may only take action on behalf of the individual or entity they represent.

(b) *Persons authorized by a party.* A party to an initial determination, redetermination, reconsideration, or hearing may appoint another individual to act on the party's behalf in exercising the right to appeal. A representative may be any individual, or individual associated with an entity, that is competent to act on behalf of the party.

(c) *Persons unauthorized.* A party may not name as a representative an individual or entity that has been disqualified, suspended, or otherwise prohibited by law, from participating in the Medicare program.

(d) *Making out a valid appointment.* For purposes of this subpart, an appointment of representation must—

(1) Be in writing and signed by both the party and individual agreeing to the representation.

(2) Provide a statement authorizing the representative to act on behalf of the party;

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

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

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

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

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

(e) *Duration of appointment.* (1) Unless revoked, an appointment is valid for the life of an individual's appeal of an initial determination.

(2) For purposes of initiation of appeals of other initial determinations, the authorization will be considered valid for 1 year from its original effectuation.

(f) *Representative fees.*

(1) *Attorneys.* No award of attorney fees may be made against the Medicare trust fund.

(2) *Providers and suppliers.* A provider or supplier that furnished items or services to a beneficiary may represent that beneficiary in an appeal under this subpart. That provider or supplier may not charge the beneficiary any fee associated with the representation. In addition, where a provider or supplier furnishes services or items to a beneficiary, the provider or supplier may not represent the beneficiary with respect to the issue described in section 1879(a)(2) of the Act (that is, whether the beneficiary or the provider or supplier, or both, knew or could reasonably have been expected to know that payment would not be made for the items or services), unless the provider or supplier waives the right to payment from the beneficiary with respect to' the services or items involved in the appeal.

(g) *Responsibilities of a representative.* (1) A representative has an affirmative duty to—

(i) Inform the party of how the duty is served;

(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 any beneficiary financial risk and liability of a non-assigned claim;

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

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

(2) An appeal request filed by a provider or supplier acting as a representative of a beneficiary will also include a statement signed by the provider or supplier stating that no financial liability will be imposed on the beneficiary in connection with that representation.

(h) *Authority of a representative.* A representative may, on behalf of the party—

(1) Obtain 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 a representative.* A contractor, QIC, ALJ, or the MAC will send the representative—

(i) Notice and a copy of any administrative action, determination, or decision; and

(ii) Requests for information or evidence.

(j) *Effect of notice or request to a representative.* A notice or request sent to the representative will have the same force and effect as if it had been sent to the party.

(k) *Representative payee.* An appointed representative may not serve as a representative payee unless the appointed representative has satisfied the requirements under title II of the Act.

(l) *Information available to the representative.* The appointed representative may obtain any and all information that is available to the party, applicable to the claim at issue. The representative may not disclose to any one unaffiliated with the appeals process any information about a claim without the party's written consent, except as may be required by law, ordered by a court, or other such authority.

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

(1) The representative provides written notice to the party of the 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 authorized representation.

(2) The beneficiary accepts the designation as evidenced by a signed, written statement.

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

(2) Revocation is not effective until the entity processing the appeal receives a signed, written statement from the party.

(3) The death of the party will terminate the authority of the representative. A party's death does not terminate an appeal that is in progress where another individual or entity may be entitled to receive or obligated to make payment for Medicare claims.

§ 405.912 Assignment of appeal rights.

(a) *Assignment of appeal rights defined.* Assignment of appeal rights means the transfer by a beneficiary of his or her right to appeal an initial determination to a provider or supplier.

(b) *Who may be an assignee.* A provider of service, physician, or other supplier who is not considered a party to the initial determination as defined in § 405.906 and who furnished an item or service to a beneficiary may seek assignment from the beneficiary for that item or service.

(c) *Who may not be an assignee.* An individual or entity who is not a provider of service, physician, or other supplier may not be an assignee. A provider of service, physician, or other supplier who 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.

(d) *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; and

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

(e) *Waiver of right to collect payment.* (1) The assignee must waive the right to collect payment for the item or service for which the assignment is made. If the assignment is revoked under paragraph (h)(2) of this section, then the waiver of the right to collect payment remains valid.

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

(f) *Duration of a valid assignment of appeal rights.* 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, unless the assignment is revoked.

(g) *Rights of the assignee.* When a valid assignment of appeal rights is executed, the assignor transfers all appeal rights 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.

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

(1) In writing by the assignor.

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

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

Initial Determinations

§ 405.920 Initial determinations and notice of initial determination.

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

(a) Determines whether the items and services furnished are covered under title XVIII of the Act;

(b) Determines any amounts payable and makes payment accordingly; and

(c) Notifies the parties to the initial determination of the determination.

(1) The notice must be in writing and sent to the last known address of all parties.

(2) The notice will state the basis for the determination and inform the parties of their right to a redetermination if they are dissatisfied with the outcome of the initial determination.

§ 405.922 Time frame for processing initial determinations.

The contractor will issue initial determinations on clean claims within 30 days of receipt if they are submitted by or on behalf of the individual who received the items and/or services; otherwise, interest must be paid at the rate used for purposes of 31 U.S.C. 3902(a) (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date payment is made. The contractor will issue initial determinations on all other claims within 45 days of receipt.

§ 405.924 Actions that are initial determinations.

(a) *Applications and entitlement of individuals.* The SSA makes an initial determination 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 will specify 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.

(4) A denial of a request for cancellation of a ''request for withdrawal.''

(5) A determination as to whether an individual, previously determined to be 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 beneficiaries by or on behalf of beneficiaries.* The contractor makes an initial determination regarding claims for benefits under Medicare Part A and Part B. The contractor does not make an initial determination on requests for payment that do not meet the requirements of a claim. An initial determination for purposes of this subpart includes, but is not limited to, determinations with respect to—

(1) Whether the items and/or services furnished are covered under title XVIII of the Act;

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

(3) In the case of determinations on the basis of section 1842(l)(1) of the Act, whether the beneficiary or physician knew, or could reasonably have been expected to know at the time the

services were furnished, that the services were not covered;

(4) Whether the deductible has been 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) Determinations regarding 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 Qualified Improvement Organization (QIO) on behalf of the contractor in accordance with § 476.86(c)(1) of this chapter;

(12) Determinations regarding whether a claim was timely filed;

(13) 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 has been an overpayment or underpayment of benefits paid under Part A or Part B, and if so, the amount thereof;

(14) Whether a waiver of adjustment or recovery under sections 1870(b) and (c) of the Act is appropriate when an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) has been made with respect to an individual.

(15) Determinations that 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.

(16) Determinations under the Medicare Secondary Payer provisions of sections 1862(b) of the Act that Medicare has a recovery claim against a provider, physician, supplier, or beneficiary with respect to services or items that have already been paid by the Medicare program except when the recovery claim against the provider, physician, or supplier is based upon its failure to file a proper claim as defined in part 411 of this chapter.

(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, whether an entity meets the conditions for participation in the program, whether 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 amount of program reimbursement or cost report settlement process under Part A of Medicare;

(d) Whether an individual's appeal meets the qualifications for an expedited appeal provided in § 405.990;

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

(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 part 483, subparts C and E of this chapter;

(h) Determinations with respect to a waiver of Medicare Secondary Payer recovery under section 1862(b) of the Act, because that recovery would defeat the purposes of the Act, or would be against equity and good conscience under section 1870(c) of the Act.

(i) Determinations with respect to a waiver of interest;

(j) Determinations with respect to a finding regarding Medicare Secondary Payer applicability other than with respect to a specific claim when the initial determination on that claim for beneficiary or Medicare's recovery claim is being appealed;

(k) Determinations under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery claim against a third party payer with respect to services or items that have already been paid by the Medicare program; and

(l) A contractor's, QIC's, ALJ's, or MAC's decision 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.

§ 405.928 Effect of the initial determination.

(a) An initial determination under § 405.924(a) involving applications and entitlement of individuals to supplementary medical insurance under Part B or hospital insurance under Part A will be binding upon the individual (or the representative of the estate of a deceased beneficiary) unless it is revised or reconsidered in accordance with 20 CFR 404.907.

(b) The initial determination under § 405.924(b) will be 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.

Redeterminations

§ 405.940 Right to a redetermination.

A person or entity that is a party to an initial determination made by a contractor as described under § 405.920 through § 405.928 and is dissatisfied with that 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, a party to an initial determination must file a request for redetermination that meets the requirements of § 405.944 within 120 calendar days from the date the party receives the notice of the initial determination.

(1) For the 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, SSA office, or CMS.

(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 to the initial determination may file a request for an extension of time for filing the redetermination with the contractor. 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 whether good cause exists.* In determining whether a party has good cause for missing a deadline to request a redetermination or reconsideration the contractor considers—

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

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

(iii) Whether the party had 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 for redetermination.

(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 another 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 redetermination 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. Appellants may also file requests for redetermination with SSA offices or CMS.

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

(1) The beneficiary's name;

(2) The health insurance claim number;

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

(4) The name and signature of the party or the appointed 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, the contractor will consolidate the separate requests into one proceeding and issue one redetermination decision.

§ 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 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 30-day decision-making time frame will automatically be extended for 14 calendar days.

§ 405.948 Conduct of a redetermination.

A redetermination consists of an independent review of an initial determination. In conducting a redetermination, the contractor will review 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. A redetermination must be made by an individual who was not involved in making the initial determination.

§ 405.950 Time frame for making a redetermination decision.

(a) *General rule.* The contractor will mail, or otherwise transmit, written notice of the redetermination decision or dismissal to the parties at their last known addresses within 30 calendar days of the date the contractor receives a timely filed request for redetermination.

(b) Exceptions. (1) If a timely request for redetermination is filed with an entity other than the contractor, then the 30-day decision-making time frame begins on the date that request is received by the contractor.

(2) 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 30-day decision-making time frame begins on the date the contractor receives the late-filed request for redetermination, or the extension, whichever is later

(3) 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 decision or dismissal within 30 days of the latest filed request.

(4) If a party submits additional evidence after the request for redetermination has been filed, the contractor's 30-day decision-making time frame will be extended for 14 days, 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 his or her request by filing a written and signed request for withdrawal. The request must be filed with the contractor, within 14 calendar days of the filing of the redetermination request.

(b) *Dismissing a request.* A contractor will dismiss 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 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 timeframe in accordance with § 405.942;

(4) When the party that filed the request for redetermination dies and there is no information in the record to determine whether there is another

party that may be prejudiced by the determination;

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

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

(c) *Notice of dismissal.* A contractor will mail or otherwise transmit a written notice of the dismissal of the redetermination request to the parties at their last known addresses.

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

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

§ 405.954 Redetermination decision.

Upon the basis of the evidence of record, the contractor will make a decision on the claim(s), and/or issue(s), in dispute and, issue a redetermination decision affirming or reversing, in whole or in part, the initial determination in question.

§ 405.956 Notice of a redetermination decision.

(a) *Notification to parties.* Written notice of the redetermination decision must be mailed or otherwise transmitted to all parties at their last known addresses in accordance with the timeframes established in § 405.950.

(b) *Content of the notice.* For decisions that are affirmations, in whole or in part, of the initial determination, the redetermination must be in writing and contain—

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

(2) A summary of the facts;

(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 decision 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 if the specific documentation indicated under paragraph (b)(6) of this section is not submitted with the request for a reconsideration, this evidence will not be considered at an ALJ hearing, unless the appellant demonstrates good cause as to why that evidence was not provided previously; and

(8) Any other requirements specified by CMS.

§ 405.958 Effect of a redetermination decision.

Once a redetermination decision is issued, it becomes part of the initial determination. The redetermination decision is final and binding upon all parties unless—

(a) A reconsideration decision is issued under a request for reconsideration in accordance with § 405.962 and § 405.964; or

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

Reconsiderations

§ 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 Time frame for filing a request for a reconsideration.

(a) *Time frame for filing a request.* Except as provided in paragraph (b) of this section, a party to a redetermination must file a request for a reconsideration that meets the requirements of § 405.964 within 180 calendar days from the date the party receives the notice of the redetermination decision.

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

(2) The request is considered as filed on the date it is received by the QIC, or by an SSA office, or CMS.

(b) *Extending the time for filing a request.—General rule.* If the 180-day period in which to file a request for a reconsideration has expired and a party shows good cause, the QIC may extend the time frame for filing a request for reconsideration.

(1) *How to request an extension.* A party to the redetermination may file a request for an extension of the time for filing the reconsideration with the QIC. 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 time frame; and

(iii) Meet the requirements of § 405.964.

(2) *How the QIC determines whether good cause exists.* In determining whether a party has good cause for missing a deadline to request a reconsideration, the QIC will apply 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. Appellants may also file requests for reconsideration with SSA offices or CMS.

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

(1) The beneficiary's name;

(2) Health insurance claim number;

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

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

(c) *Requests for reconsideration by more than one party.* If more than one party timely files a request for reconsideration on the same claim, the QIC will consolidate the separate requests into one proceeding and issue one reconsideration decision.

§ 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 redetermination decision.

(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 documentation requested in the notice of the redetermination precludes consideration of that evidence at the subsequent appeal level.

(b) *Evidence submitted after the request.* When a party submits additional evidence after filing the

request for reconsideration, the QIC's 30-day decision-making time frame will automatically be extended for 14 calendar days.

§ 405.968 Conduct of a reconsideration.

(a) *General rule.* A reconsideration consists of an independent, on-the-record review of an initial determination, including the redetermination. In conducting a reconsideration, the QIC will review the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit, or 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 be based on the clinical experience, and medical, technical, and scientific evidence of record to the extent applicable.

(b) *Authority of the QIC.* (1) National coverage determinations (NCDs) will bind the QIC with respect to issuing reconsiderations.

(2) Local coverage determinations (LCDs) and local medical review policies (LMRPs) will not bind the QIC with respect to issuing reconsiderations.

(3) A QIC must follow LCDs, LMRPs, and CMS program guidance, such as program memoranda and manual instructions unless the appellant questions the policy and provides a reason why the policy should not be followed that the QIC finds persuasive. A QIC's decision must explain why it agrees or disagrees with the appellant's rationale for not following the policy in question.

(c) *Qualifications of the QIC's reviewers.* (1) Members of a QIC's panel who conduct reconsiderations must have sufficient training and expertise in medical science and/or legal matters.

(2) When a redetermination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of an illness or injury (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.

(d) *Disqualification of a QIC reviewer.* No physician or health care professional employed by a QIC may review determinations regarding—

(1) Health care services furnished to a patient if the 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 the 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. Family means 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), children (including stepchildren and legally adopted children), grandchildren, parents, and grandparents of the physician or health care professional.

§ 405.970 Time frame for making a reconsideration decision.

(a) *General rule.* Within 30 calendar days of the date the QIC receives a timely filed request for reconsideration, the QIC will mail to the parties at their last know addresses, or otherwise transmit, written notice of—

(1) The reconsideration decision;

(2) Its inability to complete its review within 30 days in accordance with paragraphs (c) through (e) of this section; or

(3) Dismissal.

(b) *Exceptions.* (1) If a timely request for reconsideration is filed with an entity other than the QIC, then the 30-day decision-making time frame begins on the date the request is received by the QIC.

(2) 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 30-day decision-making time frame begins on the date the QIC receives the request for an extension.

(3) If a QIC receives timely requests from multiple parties for a reconsideration, consistent with § 405.964(c), the QIC must issue a reconsideration decision, dismissal, or notice that it cannot complete its review within 30 days of the latest filed request.

(4) If a party submits additional evidence after the request for reconsideration has been filed, the QIC's 30-day decision-making time frame will be extended for 14 days, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* (1) Within 30 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:

(i) Notify all parties of the QIC's reconsideration decision, consistent with § 405.976.

(ii) Notify all parties that it cannot complete the reconsideration within 30 days 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.

(iii) Notify all parties that it has dismissed the request for reconsideration.

(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 § 405.976.

(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 request:

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

(ii) Acknowledge the escalation request in writing to all parties and forward the case file to the ALJ.

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

(a) *Withdrawing a request.* A party that files a request for reconsideration may withdraw its request by filing a written and signed request for withdrawal. The request must be filed with the QIC within 14 calendar days of the filing of the reconsideration request.

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

(1) 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;

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

(3) When the party fails to file the reconsideration request within the proper filing time frame in accordance with § 405.970(a);

(4) When the party that filed the request for reconsideration request dies and there is no information in the record to determine whether there is another party that may be prejudiced by the reconsideration;

(5) When the party filing for the reconsideration submits a written request of withdrawal to the QIC; or

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

(c) *Notice of dismissal.* A contractor will mail or otherwise transmit written notice of the dismissal of the reconsideration request to the parties at their last known addresses.

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

(e) *Effect of dismissal.* The dismissal of a request for reconsideration is binding, unless it is appealed to an ALJ under § 405.1004 or vacated under paragraph (d) of this section.

§ 405.974 Reconsideration decision.

(a) *Reconsideration of a contractor determination.* Upon the basis of the evidence of record, the QIC shall make a decision on the claims and/or issues in dispute and issue a reconsideration decision affirming or reversing, in whole or in part, the initial determination 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 will remand the case to the contractor for a redetermination decision.

(3) A QIC's decision with respect to a contractor's dismissal of a redetermination request is final and not appealable to an ALJ.

§ 405.976 Notice of a reconsideration decision.

(a) *Notification to parties.* Written notice of the reconsideration decision must be mailed or otherwise transmitted to all parties at their last known addresses, in accordance with the time frames established in § 405.970(a). The QIC also must promptly notify the entity responsible for payment of claims under Part A or Part B of its reconsideration decision.

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

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

(2) A summary of the facts;

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

(4) In the case of a determination on whether an item or service is reasonable or necessary for the diagnosis or treatment of an illness or injury, an explanation of the medical and scientific rationale for the decision;

(5) A clear statement of the QIC's rationale for its reconsideration decision. If the notice of redetermination indicates that specific documentation be submitted with the reconsideration request, and this documentation was not submitted with the request for reconsideration the statement must—

(i) Indicate how the missing documentation affected the reconsideration decision; and

(ii) Specify that consistent with § 405.956(b)(7), if the documentation requested in the notice of redetermination decision was not submitted with the reconsideration request, this evidence will not be considered at an ALJ hearing, or made part of the administrative record, unless the appellant demonstrates good cause as to why the documentation was not provided with the reconsideration request;

(6) Advice to the parties of their right to an ALJ hearing, including the applicable amount in controversy requirement and aggregation provision;

(7) If appropriate, advice as to the requirements for use of the expedited appeals process set forth in § 405.990;

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

(9) Any other requirements specified by CMS.

§ 405.978 Effect of a reconsideration decision.

A reconsidered determination is final and binding on all parties, unless—

(a) An ALJ decision is issued under either a request for an ALJ hearing made in accordance with § 405.1014 or a request for an expedited appeal under § 405.990; or

(b) The reconsideration decision 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 even though the determination or decision may have been 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 review decision.

(2) A reopening of an initial determination or redetermination may be granted when the following conditions are met:

(i) When good cause is shown as defined in § 405.896; and

(ii) If the time limit to file an appeal has expired; or

(iii) If the issue does not involve a clerical error and appeal rights have been exhausted.

(3) If a contractor issues a denial 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.

(4) Notwithstanding paragraph (a)(5) of this section, a contractor must process clerical errors as reopenings, instead of redeterminations as defined in § 405.940. 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; or

(ii) Inaccurate data entry.

(5) When a party has filed a request for an appeal of an initial determination, redetermination, reconsideration, or hearing, the contractor, QIC, or ALJ no longer has jurisdiction over the claim or appeal and may not reopen it.

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

(7) A Medicare secondary payer recovery claim based upon a provider's or supplier's failure to demonstrate that it filed a proper claim as defined in part 411 of this chapter 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 decision 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 its initial determination or redetermination for good cause as defined in § 405.986.

(3) Within 5 years from the date of the initial determination or redetermination on the claim if—

(i) The contractor discovers a pattern of billing errors; or

(ii) The contractor identifies an overpayment extrapolated from a statistical sample.

(4) At any time if there exists reliable evidence that an initial determination was procured by fraud or similar fault. For the purposes of this section:

(i) ''Reliable evidence'' means evidence that is relevant, credible, and material.

(ii) ''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 it filed a proper claim as defined in part 411 of this chapter.

(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.

(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 decision on its own motion within 180 days from the date of the reconsideration decision for good cause in accordance with § 405.986.

(2) An ALJ may reopen its reconsideration decision on its own motion within 180 days from the date of the reconsideration decision for good cause in accordance with § 405.986.

(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.

(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 decision for good cause in accordance with § 405.986.

(2) A party to a hearing may request that an ALJ reopen its 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.

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. The revised determination or decision must state the rationale and basis for the revision and any right to appeal.

§ 405.984 Effect of a revised determination or decision.

(a) *Initial determinations.* The revision of an initial determination will be binding upon all parties unless a party files a written request for a redetermination in accordance with § 405.942 through § 405.946.

(b) *Redeterminations.* The revision of a redetermination will be binding upon all parties unless a party files a written request for a QIC reconsideration in accordance with § 405.962 through § 405.966.

(c) *Reconsiderations.* The revision of a reconsideration decision will be binding upon all parties unless a party files a written request for an ALJ hearing in accordance with § 405.1014.

(d) *ALJ Hearing decisions.* The revision of a hearing decision will be binding upon all parties unless a party files a written request for a MAC review and the request is accepted in accordance with § 405.1110.

(e) *MAC review.* The revision of a MAC review will be binding upon all parties unless a party files an action in Federal district court.

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

§ 405.986 Good cause for reopening.

(a) *Establishing good cause.* A party, contractor, QIC, ALJ, or MAC must establish good cause for a reopening. 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 existed at the time the determination or decision was made.

(b) *Change in substantive law or interpretative policy.* A contractor or QIC will not find good cause to reopen a claim or appeal if the only reason for reopening is a change resulting from a judicial decision, legal interpretation, or administrative ruling upon which the determination or decision was made.

Expedited Appeals Process

§ 405.990 Expedited appeals process.

(a) *Conditions for use of expedited appeals process (EAP).* A party may use the EAP to request court review in place of an ALJ hearing or Medicare Appeals Council (MAC) review if the following conditions are met:

(1) A QIC has made a reconsideration determination; an ALJ has made a hearing decision; or MAC review has been requested, but a final decision of the MAC has not been issued.

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

(3) The party has filed a request for an ALJ hearing in accordance with § 405.1002, or MAC review in accordance with § 405.1102.

(4) The amount remaining in controversy is $1,000 or more.

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

(b) *Content of the request for EAP.* The request for the EAP must—

(1) Allege that there are no material issues of fact in dispute; and

(2) Assert that the only factor precluding a decision favorable to the requestor is a statutory provision that is unconstitutional or a regulation, national coverage determination, or a CMS Ruling that is invalid.

(c) *Place and time for requesting an EAP.* (1) *Method and place for filing request.* The requestor may include an EAP request in his or her request for an ALJ hearing or MAC review, as applicable, or, if an appeal is already

pending with an ALJ or the MAC, file a written EAP request with the hearing or MAC office where the appeal is being considered.

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

(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.

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

(e) *Determination on request for EAP.* (1) For EAP requests initiated at the ALJ level, an ALJ determines whether all conditions of paragraphs (a) and (b) of this section are met.

(2) If a hearing decision has been issued, the MAC determines whether all conditions of paragraphs (a) and (b) of this section are met.

(f) *Certification for the EAP.* If the party meets the requirements for the EAP, the ALJ or the MAC, as appropriate, certifies in writing that—

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

(2) Except as indicated in paragraph (f)(3) of this section, CMS'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 regulation, CMS Ruling, or national coverage determination;

(4) Except for the provision challenged, the right(s) of the requestor is established; and

(5) The decision made by the ALJ or MAC is final for purposes of seeking judicial review.

(g) *Effect of ALJ or MAC certification.* (1) Following the issuance of the certification described in paragraph (f) of this section, the party waives completion of the remaining steps of the administrative appeals process.

(2) The 60-day period for filing a civil suit in a Federal district court begins on the date of receipt of the ALJ or MAC certification.

(h) *Effect of a request for EAP that does not result in certification.* If a request for the EAP does not meet all the conditions for use of the process, the ALJ or MAC so advises the party and treats the request as a request for hearing or MAC review, as appropriate.

§ 405.992 ALJ and MAC deference to policies not subject to the expedited appeals process.

(a) In general, an ALJ or the MAC gives deference to an LCD, LMRP, or CMS program guidance, such as program memoranda and manual instructions.

(b) A party may request that an ALJ or the MAC disregard an LCD, LMRP, or CMS program guidance. The party's request should explain why the policy should not be followed.

(c) The ALJ or MAC may disregard the policy in question if it finds the party's rationale for why the policy should not be followed to be persuasive, finds that the policy has been applied incorrectly, or finds for other reason that the policy is invalid for purposes of the party's appeal.

ALJ Hearings

§ 405.1000 Hearing before an ALJ: General rule.

If a party is dissatisfied with a QIC's reconsideration or if the adjudication period for the QIC to complete its reconsideration has elapsed, the party may request a hearing. A hearing may be conducted in-person, by videoconference, or by telephone. At the hearing the parties may submit new evidence (subject to the restrictions in § 405.1018 and § 405.1028), examine the evidence used in making the determination under review, and present and question witnesses. In some circumstances, a representative of CMS or its contractor, including the QIC, fiscal intermediary or carrier, hereafter in these regulations ''CMS or its contractor,'' may be present. See § 405.1010 and § 405.1012. The ALJ will issue a decision based on the hearing record. If all parties to the hearing waive their right to appear at the hearing in person or by telephone or videoconference, the ALJ will make a decision based on the evidence that is in the file and any new evidence that may have been submitted for consideration. 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 notify the parties that he is holding the hearing in their absence.

§ 405.1002 Right to 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 amount remaining in controversy after the QIC's reconsideration is $100 or more; or

(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 has expired and the party files the request within the time frame included in § 405.970(d);

(2) The QIC does not issue a final action within 5 days of receiving the request for escalation; and

(3) The amount remaining in controversy after the redetermination was $100 or more.

§ 405.1004 Right to ALJ review of QIC dismissal.

(a) A party to a QIC's dismissal of the 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 amount in controversy is $100 or more.

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

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

To be entitled to a hearing before an ALJ following a reconsideration by a QIC, the amount remaining in controversy must be $100 or more, and for judicial review, following the ALJ hearing and MAC review, the amount remaining in controversy must be $1,000 or more.

(a) The following rules describe how the amount in controversy is calculated and how individual and multiple appellants may combine claims to meet the minimum amount in controversy needed for an ALJ hearing ($100).

(b) *Calculating the amount in controversy.* (1) The amount in controversy 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 coinsurance amounts applicable in the particular case.

(2) Notwithstanding the above, when payment is made for certain excluded 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 would have been charged the beneficiary for

the items or services in question, less any deductible and coinsurance amounts applicable in the particular case, had those expenses not been paid under § 411.400 of this chapter or had that liability not been limited under § 411.402 of this chapter.

(c) *Aggregating claims to meet the amount in controversy*—(1) *Appealing QIC reconsideration determinations to the ALJ level.* Two or more claims may be aggregated by either an individual appellant or multiple appellants to meet the amount in controversy for an ALJ hearing if—

(i) The claims have previously been reconsidered by a QIC; and

(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 reconsideration determinations being appealed; and

(iii) The ALJ determines that the claims the appellant(s) seeks to aggregate involve the delivery of similar or related services or common issues of law and fact. An appellant may combine Part A and Part B claims together to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level to the ALJ level.* Two or more claims may be aggregated by either an individual appellant or multiple appellants 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; and

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

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

(d) *Definitions.* For the purposes of aggregating claims to meet the amount in controversy for an ALJ hearing:

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

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

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

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

(2) State why the appellant(s) believe 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 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 deadline 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 QIC's reconsideration determination are parties to the ALJ hearing. In addition, a representative of CMS or its contractor may be made a party under the circumstances described in § 405.1012.

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

An ALJ may request, but may not require, CMS or one of its contractors, to participate in any proceedings before the ALJ, including the oral hearing, if any. CMS and its contractors, including a QIC, may also elect to participate in the hearing process. Participation may include filing position papers or providing testimony to clarify factual or policy issues in a case, but does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

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

CMS or its contractors, including a QIC, may be a party to an ALJ hearing unless the request for hearing is filed by an unrepresented beneficiary. CMS or the contractor will advise the ALJ that it intends to participate as a party no later than 10 days after receiving the notice of hearing. When CMS or its contractor participates 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 and the contractor, when acting as parties, may also submit additional evidence to the ALJ. The ALJ may not require CMS or a contractor to enter a case as a party.

§ 405.1014 Request for an ALJ hearing.

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

(1) The name, address, and 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 any designated representative.

(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 hearing office, the QIC that issued the reconsideration, CMS, or a local Social Security office. If the request for hearing is timely filed with the QIC, CMS or a Social Security office rather than the hearing office, the 90-day deadline for deciding the appeal begins on the date the request for hearing is received by the hearing office.

(c) *Filing request for escalation.* If an appellant files a request to escalate an appeal to the ALJ level because the QIC has not completed its action within the deadline described in § 405.970, the request for escalation must be filed with both the QIC and the hearing office. A case escalated from the QIC to the ALJ level is not subject to the 90-day adjudication deadline.

(d) *Extension of time to request a hearing.* If the request for hearing is not filed within 60 days of receipt of the QIC's reconsideration determination, an appellant may request an extension. The request for an extension of time must be in writing, and it must give the reasons why the request for a hearing was not filed within the stated time period. If a request for hearing is not timely filed, the 90-day adjudication period does not begin until the hearing office receives this explanation in addition to the request for hearing.

§ 405.1016 Requirement to decide appeal in 90 days.

(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 has been timely filed, unless the 90-day period has been extended as provided in this subpart.

(b) The 90-day adjudication period begins on the date that a timely filed request for hearing is received by the hearing office, or, if it is not timely filed, the date that the hearing office receives a written explanation from the appellant that the ALJ accepts as a good reason for the late filing. If the written explanation is received by the hearing office after the request for hearing is received, the 90-day adjudication period begins when the written explanation is received. *See* § 405.942(b)(2).

(c) The 90-day adjudication period does not apply when an appellant requests escalation of an appeal to the ALJ level because the QIC has not issued a reconsideration determination within the period specified in § 405.970.

§ 405.1018 Submitting evidence before the ALJ hearing.

Parties must submit with the request for hearing (or within 10 days of receiving the notice of hearing) all written evidence they wish to have considered at the hearing. If an appellant 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 received will not be counted toward the 90-day adjudication deadline. Any submission of new evidence that was not considered by the QIC during its reconsideration must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC. The above requirements do not apply to oral testimony given at a hearing, including expert testimony.

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

(a) The ALJ sets the time and place for the hearing, and may change the time and place, if necessary. The ALJ will send a notice of hearing to all parties and the QIC that issued the reconsideration determination advising them of the proposed time and place of the hearing. The notice of hearing will require all parties to the ALJ hearing to reply to the notice as follows:

(1) Acknowledge that the party will attend the hearing at the time and place proposed in the notice of hearing; or

(2) Object to the proposed time and place of the hearing. The party must state the reason for the objection and state the time and place he or she wants the hearing to be held. If at all possible, the request should be in writing. The ALJ will change the time or place of the hearing if the party has good cause, as determined under paragraphs (b) and (c) of this section (section 405.1052(a)(2) provides procedures the ALJ will follow when a party does not respond to a notice of hearing); or

(3) Waive the right to an oral hearing and request that the ALJ issue a decision based on the written evidence in the record. As provided in § 405.1000, 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.

(b) The ALJ will find good cause for changing the time or place of the scheduled hearing and will 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.

(c) In determining whether good cause exists in circumstances other than those set out in paragraph (b) of this section, the ALJ will consider the party's reason for requesting the change, the facts supporting it, and the impact of the proposed change on the efficient administration of the hearing process. Factors affecting the impact of the change include, but are not limited to, the effect on the processing of other scheduled hearings, delays that might occur in rescheduling the hearing, and whether any prior changes were granted the party. Examples of such other circumstances, which a party might give for requesting a change in the time or place of the hearing, include, but are not limited to, the following:

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

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

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

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

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

(6) The appellant lives or has his or her principal place of business closer to another hearing site.

(7) 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.

(d) *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 will not be counted toward the 90-day adjudication deadline.

§ 405.1022 Notice of a hearing before an ALJ.

After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed to the parties 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 will be mailed or served at least 20 days before the hearing. The notice of hearing will contain a statement of the specific issues to be decided and tell the parties that they may designate a person to represent them during the proceedings. The notice will also contain 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. If a party or his or her representative does not acknowledge receipt of the notice of hearing, the hearing office will attempt to contact the party for an explanation. If the party states that he or she did not receive the notice of hearing, an amended notice will be sent to him or her by certified mail or e-mail, if available. See § 405.1020 and § 405.1052 for the procedures we will follow in deciding whether 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.

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. 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. The ALJ will make a decision on the objections either in writing or at the hearing.

§ 405.1026 Disqualification of the ALJ.

An ALJ will not conduct a hearing if he or she is prejudiced or partial with respect to any party or has any interest in the matter pending for decision. If a party objects to the ALJ who will conduct the hearing, the party must notify the ALJ within 10 days of the notice of hearing. The ALJ will consider the party's objections and will decide whether to proceed with the hearing or withdraw. If he or she 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. 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 will consider 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.

After a hearing is requested but before it is held, the ALJ will examine any new evidence submitted with the request for hearing according to § 405.1018 to determine whether the appellant had good cause for submitting the evidence for the first time at the ALJ level. If the ALJ determines that there was not good cause for submitting the evidence first at the ALJ level, and the evidence is of such probative value that it may have a material outcome on the case, the ALJ will remand the case to the QIC for a revised reconsideration. If the revised reconsideration issued on remand is not fully favorable to all parties, any party to that determination may file a new request for an ALJ hearing.

§ 405.1030 ALJ hearing procedures—General.

A hearing is open to the parties and to other persons the ALJ considers necessary and proper. At the hearing, the ALJ looks fully into the issues, questions the parties and other witnesses, and may accept documents that are material to the issues, if the ALJ determines that the party has shown good cause for not submitting the evidence within the period specified in § 405.1018 and § 405.1028. 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 material is in the possession of the appellant, the ALJ will determine whether the appellant had good cause for not producing the evidence earlier. If good cause exists, the ALJ will consider the evidence in deciding the case and the 90-day adjudication period will be tolled from the date of the hearing to the date the evidence is submitted. If the ALJ determines that there was not good cause for submitting the evidence sooner, he may remand the case to the QIC, as provided in § 405.1034. 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. The ALJ may decide when the evidence will be presented and when the issues will be discussed.

§ 405.1032 Issues before an ALJ.

(a) *General.* 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 section, the term ''party'' does not include a representative of CMS or the QIC who 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 will notify 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 between receiving the hearing request and issuing the notice of hearing. The ALJ or any party may raise a new issue; however, the ALJ may only consider a new issue if its resolution—

(i) Will 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.

(2) *Notice of a new issue.* The ALJ will notify all of the parties in the notice of hearing if he or she intends to consider a new issue.

§ 405.1034 When ALJ will remand to the QIC.

(a) The ALJ will remand a case to the QIC that issued the reconsideration in the following circumstances:

(1) The appellant submits new evidence to the ALJ that was not provided to either the contractor or the QIC during their consideration of the appeal, and the appellant does not provide a good reason for first submitting the evidence at the ALJ level. An ALJ will find good cause when the appellant submits new evidence at the ALJ level, the evidence relates to an issue that was the basis for the QIC's unfavorable reconsideration and that issue was not identified as a material issue before the QIC's determination, and the ALJ finds that the appellant had a good reason for submitting the evidence for the first time at the ALJ level, the ALJ will decide the appeal.

(2) The appellant submits new evidence to the ALJ that was not provided to either the contractor or the QIC during its consideration of the appeal, and the appellant acknowledges that he or she does not have a good reason for first submitting the evidence at the ALJ level. In this instance, the appellant may request the ALJ to remand the case to the QIC for further proceedings so that the new evidence may be considered.

(b) An ALJ may also remand a case to the QIC if the written record of the proceedings before the initial contractor or the QIC does not contain information that is essential to resolving the issues on appeal and is information that can only be provided by CMS or its contractors. Examples of that information include claim payment histories or information from the common working file concerning such issues as the number of days remaining in a benefit period.

§ 405.1036 Description of ALJ hearing process.

(a) *The right to appear and present evidence.* Any party to a hearing has the right to appear before the ALJ, either personally or by means of a designated representative, to present evidence and to state his or her position.

(b) *Waiver of the right to appear.* A party may send the ALJ a waiver or a written statement indicating that he or she does not wish to appear at the hearing. The appellant may subsequently withdraw the waiver at any time before the notice of the hearing decision is issued, provided that the appellant agrees to an extension of the 90-day adjudication period that may be necessary to schedule and hold the hearing. Other parties may withdraw the 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 should be provided to the other parties to hearing, if any, at the same time they are submitted to the ALJ.

(d) *Waiver of 90-day adjudication period.* At any time during the hearing process, the appellant may waive the 90-day adjudication deadline for issuing a hearing decision.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence would not be 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 the production of books, records, correspondence, papers, or other documents that are material to an issue at the hearing.

(2) Parties to a hearing who wish to subpoena documents or witnesses must file a written request for the issuance of a subpoena with the ALJ within 10 days of the notice of hearing. The written request must give the names of the witnesses or documents to be produced; describe the address or location of the witnesses or documents with sufficient detail to find them; state the important facts that the witness or document is expected to prove; and indicate why these facts could not be proven without issuing a subpoena.

(3) The hearing office will pay the cost of issuing the subpoena.

(4) The hearing office will pay subpoenaed witnesses the same fees and mileage they would receive if they had been subpoenaed by a Federal district court.

(g) *Witnesses at a hearing.* Witnesses may appear at a hearing. They will 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 material to the issues and will allow the parties or their designated representatives to do so.

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

(a) *Decision wholly favorable.* If the evidence in the hearing record supports a finding in favor of all the parties on every issue, and neither the QIC nor CMS has given notice of its intention to participate in the hearing, the ALJ may issue a hearing decision without giving the parties prior notice and without holding an oral hearing. However, the notice of the decision will inform the parties that they have the right to an oral hearing and a right to examine the evidence on which the decision is based.

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

(i) All the parties indicate in writing that they do not wish to appear before the ALJ at an oral 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 an oral hearing is not held, the ALJ will make a record of the evidence. The record will include the claims, written statements, certificates, reports, affidavits, and other documents that were used in making the determination under review and any additional evidence the parties to the hearing present in writing. The decision of the ALJ must be based on this record.

§ 405.1040 Prehearing and posthearing conferences.

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. The ALJ will tell the parties of the time, place, and purpose of the conference at least 7 days before the conference date, unless the parties have indicated in writing that they do not wish to receive a written notice of the conference. 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 will be made. The ALJ will issue 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 When a record of a hearing before an ALJ is made.

The ALJ will make a complete record of the hearing proceedings. The tape, other recording, or written transcript, as applicable, will be maintained in the case file, and forwarded with the file to the MAC if a request for MAC review is filed or the case is escalated from the ALJ level to the MAC. The record of the hearing will be prepared as a typed copy of the proceedings 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 the Secretary requests the court to remand the case.

§ 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. 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 such factors 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 will take into account the adjudication deadlines for each case and may require an appellant to waive the 90-day adjudication deadline if consolidation would otherwise prevent the ALJ from deciding all of the appeals at issue within their respective deadlines.

(b) 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 90-day adjudication deadline for any of the consolidated cases.

(c) 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.

(d) 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 will ensure 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 The decision of an ALJ.

(a) *General rule.* 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 included in the record. The ALJ will mail a copy of the decision to all the parties at their last known address and to the QIC that issued the reconsideration determination.

(b) *Timing of decision.* The ALJ will issue a decision by the end of the 90-day period beginning on the date when the request for hearing is received in the hearing office, unless the 90-day period

has been extended as provided in this subpart.

(c) *Recommended decision.* An ALJ will issue 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 will mail 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 and the MAC either issues a final action in response to the request for review or the appeal is escalated to Federal district court under the provisions at § 405.1132;

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

(c) The expedited appeals process is used;

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

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

§ 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 will conduct the hearing according to the rules for hearings before an ALJ. Notice will be 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 request for hearings will be in accordance with the following:

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

(1) At any time before notice of the hearing decision is mailed, the party that requested the hearing 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 contain a clear statement that the appellant is withdrawing the request for hearing and does not intend to further proceed with the appeal. If the request for withdrawal is filed by an attorney, or other legal professional on behalf of a beneficiary or other appellant, 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;

(ii) The party did not appear at the time and place of hearing and does not thereafter contact the hearing office and provide a good reason for not appearing;

(iii) The ALJ sends a notice to the party asking why the party did not appear; and

(iv) The party does not respond to the ALJ's notice within 10 days or does not give a good reason for the failure to appear. In determining good cause, the ALJ will consider any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language), which 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 has not provided a good reason for extending the time for requesting a hearing, as provided in § 405.942(b)(2).

(5) The beneficiary whose claim is being appealed died either before the request for hearing was filed or while the request for hearing is pending and both 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 will consider 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.

(ii) No other parties to the QIC reconsideration determination participated in the proceedings before the QIC. For purposes of applying this provision, participation means that the party either filed the request for QIC reconsideration or submitted evidence or comments to the QIC during its consideration of the case.

(6) The ALJ decides that there is cause to dismiss a hearing request entirely or to refuse to consider any one or more of the issues because the doctrine of *res judicata* applies in that a Medicare contractor, 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 or issues, 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 hearing office attempts to schedule a hearing and is unable to locate the appellant after making reasonable efforts to do so.

(b) *Notice of dismissal.* The ALJ will mail a written notice of the dismissal of the hearing request to all parties at their last known address. The notice will state 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.

Medicare Appeals Council Review

§ 405.1100 Medicare Appeals Council review: General.

The party who requested an ALJ hearing (the appellant) or any other party to the hearing may request that the Medicare Appeals Council (MAC) review an ALJ's decision or dismissal. Under certain circumstances, 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. The MAC reviews an ALJ's decision *de novo.* When reviewing an ALJ's decision, 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 has been extended as provided in this subpart.

§ 405.1102 Request for MAC review when ALJ issues decision.

(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 appellant 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 explained in § 405.942(b)(2).

(b) A party does not have the right to seek MAC review of an ALJ's remand to a QIC.

(c) For purposes of requesting MAC review (§ 405.1102 through § 405.1138), 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.

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 90-day adjudication period described in § 405.1016 may request a MAC review if—

(a) The appellant files a written request with the ALJ and the MAC to escalate the appeal to the MAC after the 90-day adjudication period has expired; and

(b) The ALJ does not issue a final action or remand the case to the QIC within 5 days of receiving the request for escalation.

§ 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, the hearing office that issued the ALJ's decision or dismissal or a Social Security office. If the request for hearing is timely filed with the hearing office or a Social Security office rather than the MAC, the MAC's 90-day period to conduct a review begins on the date the request for review is received by the MAC.

(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 90-day adjudication deadline, the request for escalation must be filed with both the ALJ and the MAC. Appeals that are escalated from the ALJ level to the MAC are not subject to the 90-day MAC adjudication deadline.

§ 405.1108 MAC actions when request for review or escalation is filed.

(a) 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 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 dismiss the request for an ALJ 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 ALJ 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 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 its contractors (hereafter: CMS) 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 its 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 will be 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 should review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ 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. Copies of any comments submitted to the MAC must be sent to CMS and all other parties to the ALJ's decision.

(c) *Standard of review*—(1) *Referral by CMS after participation at ALJ level.* If CMS or its contractor participated in an appeal at the ALJ level, the MAC will exercise 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. The MAC may adopt, modify, or reverse the decision or dismissal or may remand the case to an ALJ for further proceedings. 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 90-day 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 review should identify the parts of the ALJ action with which the party requesting review disagrees and explain why he or she believes that the ALJ's findings and conclusions are wrong. For example, if the party requesting review believes that the ALJ's action is inconsistent with a

statute, regulation, ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(b) 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 will dismiss 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 will also dismiss 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 either before the request for review was filed or while the request for review is pending and both 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, and, in considering this issue, the MAC will consider 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 parties to the ALJ decision participated in the proceedings before the ALJ. For purposes of applying this provision, participation means that the party either filed the request for an ALJ hearing, submitted evidence or written statements to the ALJ, or appeared at the hearing.

§ 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. The dismissal of a request for hearing by the MAC is also binding and not subject to judicial review.

§ 405.1118 Obtaining evidence from MAC.

A party may request and receive copies or a statement of the documents or other written evidence upon which the hearing decision or dismissal was based and a copy of the transcript of oral evidence. However, the party will be asked to pay the costs of providing these copies unless there is a good reason they should not pay. 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 comment period will not count 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 each 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 receipt of the request to submit the brief and ending with the date the brief is received by the MAC will not count toward the 90-day adjudication deadline. 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.

§ 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 will limit 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 will consider 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 parties or 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 has been 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 parties or 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.

§ 405.1124 Oral argument.

A party may request to appear before the MAC to present oral argument. The MAC will grant 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. In addition, 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 will tell the parties of the time and place of the oral argument at least 10 days before the scheduled date. The MAC may also request, but not require, CMS or its contractor to appear before it if the MAC determines that it would be helpful in resolving the issues in the case.

§ 405.1126 Case remanded by the MAC.

(a) *When the MAC may remand a case.* 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 has been 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 briefs or other written statements about the facts and law relevant to the case with the MAC

within 20 days of the date that the recommended decision is mailed. 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 they had good cause for missing the deadline.

(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 its proceedings and issue its decision according to the procedures explained in this subpart.

(2) If the MAC believes 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 Decision of the MAC.

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. The MAC may adopt, modify or reverse the ALJ hearing decision or recommended decision. A copy of the MAC's decision will be mailed to the parties at their last known address.

§ 405.1130 Effect of the MAC's decision.

The MAC's decision is binding on all parties unless the party files an action in Federal district court, or the decision is revised. 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.

If the MAC does not issue a final action or remand the case to an ALJ within the 90-day adjudication period as extended as provided in this subpart, the appellant may request that the appeal be escalated to Federal district court. Upon receipt of a request for escalation, the MAC may—

(a) Issue a final action or remand the case to an ALJ, if that action is issued within 5 days of receipt of the request for escalation; or

(b) If the MAC is not able to issue a final action or remand 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 may file an action in a Federal district court within 60 days after the date it receives notice of the MAC's decision.

§ 405.1134 Extension of time to file action in Federal district court.

Any party to the MAC's decision or to an expedited appeals process certification may request that the time for filing an action in a Federal district court be extended. The request must be in writing, and it must give the reasons why the action was not filed within the stated time period. The request must be filed with the MAC, or if it concerns an expedited appeals process agreement certified by an ALJ, with the ALJ. 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, we use the standards explained in § 405.942(b)(2).

§ 405.1136 Judicial review.

(a) General rule. 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 90-day adjudication period, may obtain a court review if the amount remaining in controversy is $1,000 or more. The party, including an appellant who requests escalation to Federal district court if the MAC does not complete its review of the ALJ's decision within the 90-day adjudication period, may obtain court review by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act.

(b) *Court in which to file civil action.* 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. If the party does not reside within any such judicial district, or if such 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.* 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. For purposes of these sections, the date of receipt of the notice of the MAC's decision or notice of the MAC's receipt of the appellant's request for escalation shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary. Where a case is certified for judicial review pursuant to the expedited appeals process in § 405.990, the civil action must be filed within 60 days after receipt of the ALJ or MAC certification, except where the time has been extended by the ALJ or MAC, as applicable, upon a showing of good cause.

(d) *Proper defendant.* Where any civil action described in paragraph (a) of this section is filed, the Secretary of HHS, shall, in his or her official capacity, be the proper defendant. Any such civil action properly filed shall survive notwithstanding any change of the person holding the office of Secretary of HHS or any vacancy in such office. 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 has named an incorrect defendant and will be 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 Part B if the regulation was promulgated, or the instructions issued, before January 1, 1991.

(f) *Standard of review.* 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. In addition, 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 court.

When a Federal court remands a case to the Secretary for further consideration, 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 issue a decision or return the case to the MAC with a recommended decision. If the case is remanded by the MAC, the procedures explained in § 405.1140 will be followed.

§ 405.1140 MAC review of ALJ decision in a case remanded by a Federal court.

(a) *General rule.* In accordance with § 405.1138, when a case is remanded by a Federal court for further consideration, the decision of the ALJ will become the final decision of the Secretary after remand on that case unless the MAC assumes jurisdiction of the case. The MAC may assume jurisdiction based on written exceptions to the decision of the ALJ that the party files with the MAC or based on its authority under paragraph (c) of this section. The MAC will either make a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remand 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 the decision of the ALJ, 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 exceptions must be filed within 30 days of the date the party receives the decision of the ALJ or an extension of time in which to submit exceptions must be requested in writing within the 30-day period. A timely request for a 30-day extension will be granted by the MAC. 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.

(2) If written exceptions are timely filed, the MAC will consider 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, even after the 60-day time period which applies when a party does not file exceptions. If the MAC assumes jurisdiction, it will make a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or remand 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.* 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. Notice of this action will be mailed to all parties at their last known address. 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. After the briefs or other written statements have been 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 case, the decision of the ALJ becomes the final decision of the Secretary after remand.

Expedited Determinations and Reconsiderations

§ 405.1200 A beneficiary's right to an expedited determination.

(a) *Applicability.* (1) For purposes of §§ 405.1200 through 405.1206, *provider of services* is defined, in accordance with section 1861(u) of the Act, as a hospital, critical access hospital, home health agency (HHA), skilled nursing facility (SNF), hospice program, or comprehensive outpatient rehabilitation facility (CORF).

(2) *Scope.* The expedited determination and reconsideration provisions contained in §§ 405.1200 through 405.1206 apply to terminations of services furnished by a non-residential provider and the discharge of a beneficiary from a residential provider of services.

(b) *Beneficiary's right to an expedited determination by the QIO.* (1) A beneficiary who has received notice that a nonresidential provider plans to terminate their services, or that a residential provider plans to discharge the beneficiary, is entitled to an expedited determination by the QIO in the State in which the beneficiary is receiving provider services when—

(i) The beneficiary disagrees with the nonresidential provider of those services that services being furnished should be terminated and a physician who is treating the beneficiary in relation to the services the beneficiary is receiving in the provider certifies that failure to continue the provision of that service(s) may place the beneficiary's health at significant risk; or

(ii) The residential provider notifies the beneficiary of its plans to discharge the beneficiary from that provider of services.

(2) If a beneficiary does not contest the termination decision in a timely manner, that beneficiary may not later assert the expedited review process under this section.

(c) *Procedures the beneficiary must follow.* (1) A beneficiary must submit the request for an expedited determination to the QIO in the State in which the beneficiary is receiving those provider services, in writing or by telephone no later than noon of the next calendar day following receipt of the provider's notice of termination.

(2) The beneficiary or his or her representative must be prepared to answer questions and/or supply information that the QIO may request in order to conduct its review.

(d) *Procedures the QIO must follow.* (1) On the date that the QIO receives the request for an expedited determination under paragraph (c) of this section, it must immediately notify the provider of those services that a request for an expedited determination has been made.

(2) The provider of those services must supply any information the QIO requires to conduct its review and must make it available by phone or in writing, by close of business of the day after the QIO notifies the provider of the request for an expedited determination. This information includes, but is not limited to, medical records and a copy of the provider's written notice of termination if one was issued to the beneficiary.

(3) The QIO must examine the medical records that pertain to the services in dispute.

(4) The QIO must solicit the views of the beneficiary that requested the expedited determination.

(5) The QIO must provide an opportunity for the provider/practitioner to explain why the termination or discharge is appropriate.

(6) The QIO must make its determination no later than 72 hours after receipt of the request for an expedited determination and the requested information.

(e) *Notice of an expedited initial determination.* (1) The QIO must immediately notify the beneficiary, beneficiary's physician, and the provider of services, of its determination. The QIO's initial notification shall be done by telephone and subsequently with a written notice.

(2) A written notice of the expedited determination must contain the following:

(i) The basis for the determination.

(ii) A detailed rationale for the reconsidered determination.

(iii) A statement explaining the Medicare payment consequences of the determination and the beneficiary's date of liability.

(iv) A statement informing the beneficiary of his or her appeal rights including the name and phone number of the qualified independent contractor that he or she must appeal to.

(v) The time period for filing the subsequent appeal.

(f) *Effect of an expedited determination.* The expedited determination is binding upon the beneficiary and provider of those disputed services, absent reconsideration by a QIC in accordance with § 405.1202. A beneficiary who does not file a timely request for an expedited QIC reconsideration subsequently may request a QIC reconsideration under § 405.960 of this subpart, but the coverage protections described in paragraph (g) of this section would not extend through those reconsiderations.

(g) *Coverage during QIO review.* When a beneficiary files an appeal in accordance with paragraph (c) of this section, the beneficiary may not be billed for any disputed services. The QIO decision may result in beneficiary liability, however.

§ 405.1202 Right to an expedited reconsideration by a QIC.

(a) *Beneficiary's right to an expedited QIC reconsideration.* A beneficiary that has received an expedited determination from a QIO as specified in § 405.1200, and is dissatisfied with that determination, may request an expedited reconsideration by the designated QIC.

(b) *Procedures the beneficiary must follow.* (1) A beneficiary must submit the request for an expedited reconsideration to the QIC no later than noon of the next calendar day following receipt of the QIO's written determination notice. This request may be made in writing or by telephone.

(2) The beneficiary or his or her representative must be available to answer questions and/or supply information that the QIO may request to conduct its review.

(c) *Procedures the QIC must follow.* (1) On the date that the QIC receives the request for an expedited reconsideration in accordance with paragraph (b) of this section, it must immediately notify the provider of those disputed services that a request has been made. The QIC must conduct a review regardless of whether the beneficiary will be liable for the services or stay in dispute.

(2) The QIC must request and review any information that it needs to make an expedited reconsideration determination. This information includes, but is not limited to, the beneficiary's medical records.

(3) The QIO and the provider of the disputed services must supply any information that the QIC requires to conduct its review, and must make it available, by telephone or in writing, by the close of business of the day after the beneficiary received the QIO expedited determination notice.

(4) The QIC must solicit the views of the beneficiary that requested the expedited determination.

(5) The QIC must render its reconsideration determination no later than 72 hours from receipt of the request for an expedited reconsideration and the information requested to make its decision.

(6) If the QIC does not render a decision within 72 hours of receipt of the request and the information, the QIC must notify the beneficiary and inform that beneficiary of his or her right to have this case escalated to the ALJ hearing level if—

(i) The beneficiary filed a timely expedited appeal before the QIC; and

(ii) The amount remaining in controversy after the QIO determination is $100 or more.

(7) The QIC must notify the beneficiary, in writing, of the rules for escalation under § 405.1002 (Right to ALJ hearing when QIC does not issue reconsideration determination timely).

(d) *Notice of an expedited reconsideration determination.* The QIC must render its expedited reconsideration determination and notify the beneficiary, the physician of the beneficiary who requested the expedited reconsideration determination, and the provider of those services no later than 72 hours from receipt of the request for review.

(1) The QIC's initial notification shall be done by telephone and followed by a written notice.

(2) A written notice of the expedited reconsideration determination must contain the following:

(i) The basis for the reconsidered determination.

(ii) Detailed rationale for the reconsidered determination.

(iii) A statement explaining the Medicare payment consequences of the reconsidered determination and the beneficiary's date of liability.

(iv) A statement informing the beneficiary of his or her subsequent appeal rights in accordance with § 405.1000 (Right to ALJ hearing when QIC issues reconsideration determination) and the time period for filing that appeal.

(v) The amount in controversy in accordance with the rules at § 405.1004 (Amount in controversy for ALJ hearing and judicial review).

(e) *Effect of an expedited reconsideration.* The reconsidered determination is binding upon the beneficiary and provider of those disputed services and is subject to review in accordance with § 405.1000 (Right to ALJ hearing when QIC issues reconsideration determination).

(f) *Coverage during QIC review.* When a beneficiary files an appeal in accordance with paragraph (b)(1) of this section, the beneficiary may not be billed for any disputed services until a QIC reconsidered determination has been rendered. The QIC decision may result in beneficiary liability, however.

§ 405.1204 Expedited appeals of inpatient hospital discharges.

(a) *Beneficiary's right to an expedited initial determination with respect to an inpatient hospital discharge.* (1) A beneficiary who has received a notice of noncoverage may request an expedited determination by the QIO when a hospital (acting directly or through its utilization review committee) with physician concurrence, determines that inpatient care is no longer necessary. A beneficiary who requests an expedited QIO review may remain in the hospital with no additional financial liability as specified in paragraph (e)(2) of this section.

(2) A beneficiary who fails to request an expedited initial determination in accordance with paragraph (c) of this section and remains in the hospital may still request an expedited initial determination, but the financial liability rules of paragraph (e)(2) of this section do not apply.

(b) *Beneficiary's right to other review.* (1) A beneficiary who fails to request an expedited determination in accordance with paragraph (c)(1)(iii) of this section and remains in the hospital may still request an expedited review at any time during the course of his or her inpatient hospital stay. The QIO will render a decision in accordance with paragraph (d)(5)(ii) of this section and the financial liability rules of paragraph (e)(2) of this section do not apply.

(2) A beneficiary who fails to request an expedited initial determination in accordance with paragraph (c)(1)(iii) of this section, and is no longer an inpatient in the hospital, may still request QIO review within 30 calendar days after receipt of the hospital's written termination notice or at any time for good cause. The QIO will

render a decision in accordance with paragraph (d)(5)(iii) of this section and the financial liability rules of paragraph (e)(1) of this section do not apply.

(c) *Procedures the beneficiary must follow.* For the expedited appeal process, the following rules apply:

(1) The beneficiary must submit the request for an expedited determination—

(i) To the QIO that has an agreement with the hospital under part 475 of this chapter;

(ii) In writing or by telephone; and

(iii) By noon of the first working day after he or she receives written notice that the hospital has determined that the hospital stay is no longer necessary.

(2) The beneficiary (or his or her representative), upon request by the QIO, must be prepared to discuss his or her case with the QIO.

(d) *Procedures the QIO must follow.* On the date that the QIO receives the beneficiary's request:

(1) The QIO must notify the hospital that the beneficiary has filed a request for immediate review.

(2) The hospital must supply any information, including medical records, that the QIO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the first full working day after the day the beneficiary receives notice of the proposed discharge.

(3) The QIO must examine the pertinent records pertaining to the services.

(4) The QIO must solicit the views of the beneficiary who requested the expedited determination.

(5)(i) The QIO must make a determination and notify the beneficiary, the hospital, and physician of its determination by close of business of the first working day after it receives all requested pertinent information.

(ii) When the beneficiary did not request an expedited initial determination in accordance with paragraph (c)(1)(iii) of this section and remains an inpatient in the hospital, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 2 working days following receipt of the request and pertinent information.

(iii) When the beneficiary did not request an expedited initial determination in accordance with paragraph (c)(1)(iii) of this section and is no longer an inpatient in the hospital, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 30 calendar days after receipt of the request.

(e) *Coverage during QIO expedited review.* (1) In general, if the beneficiary remains in the hospital after receiving the advanced written notice of termination, and the hospital, the physician who concurred in the hospital's determination on which the advanced written notice of termination was based, or the QIO subsequently finds that the beneficiary requires an acute level of inpatient hospital care, the beneficiary is not financially responsible for continued care until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence from the physician responsible for the beneficiary's care or the QIO and notifies the beneficiary.

(2) *Timely filing.* If a beneficiary files a request for an expedited determination by the QIO in accordance with paragraph (c)(1)(iii) of this section, the beneficiary is not financially responsible beneficiary for inpatient hospital services furnished before noon of the calendar day after the date the beneficiary (or his or her representative) receives a written expedited determination by the QIO.

(3) *Untimely filing.* (i) When a beneficiary does not file a request for an expedited determination by the QIO in accordance with paragraph (c)(1)(iii) of this section and remains an inpatient in the hospital, that beneficiary may be responsible for charges that extend beyond the date specified on the hospital's advance written notice of termination or as otherwise stated by the QIO.

(4) *Hospital requests expedited review.* When the hospital requests review in accordance with § 405.1206, and the QIO concurs with the hospital's decision, a hospital may not charge a beneficiary until the date specified by the QIO.

(f) *Notice of an expedited determination.* (1) When a QIO renders an expedited determination in accordance with paragraph (d)(5) of this section, it must notify the beneficiary, physician, and hospital of its decision, by telephone and in writing. The QIO's initial notification must be done telephonically and subsequently with a written notice.

(2) A written notice of the expedited initial determination must contain the following:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) A statement explaining the Medicare payment consequences of the expedited determination and date of liability, if any.

(iv) A statement informing the beneficiary of his or her appeal rights including the name and phone number of the QIC that he or she must appeal to if he or she disagrees with this decision.

(v) The time period for filing reconsideration review by the QIC.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the beneficiary, physician, and hospital.

(1) *When beneficiary remains in hospital.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with this determination, he or she must request an appeal subject to § 405.1202.

(2) *When beneficiary is no longer an inpatient in the hospital.* If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, this determination is subject to the general QIC reconsideration rules set forth in §§ 405.960 through 405.978 of this subpart.

§ 405.1206 Hospital requests expedited QIO review.

(a) If the hospital (acting directly or through its utilization review committee) believes that the beneficiary does not require further inpatient hospital care but is unable to obtain the agreement of the physician, it may request an expedited determination by the QIO.

(b) *Procedures hospital must follow.* (1) The hospital must (acting directly or through its utilization review committee) notify the beneficiary (or his or her representative) that it has requested that review.

(2) The hospital must supply any pertinent information the QIO requires to conduct its review and must make it available by phone or in writing, by close of business of the first full working day immediately following the day the hospital submits the request for review.

(c) *Procedures the QIO must follow.* (1) On the date that the QIO receives the request for review by the hospital, it must review any pertinent information submitted by the hospital.

(2) The QIO must examine the pertinent records pertaining to the services.

(3) The QIO must solicit the views of the beneficiary in question.

(4) The QIO must make a determination and notify the beneficiary, the hospital, and physician within 2 working days of either the hospital's request or receipt of any pertinent information submitted by the hospital.

(d) *Notice of an expedited determination.* (1) When a QIO renders

an expedited determination as stated in paragraph (c)(4) of this section, it must notify the beneficiary, physician, and hospital of its decision, by telephone and in writing. The QIO's initial notification must be done telephonically and subsequently with a written notice.

(2) A written notice of the expedited initial determination must contain the following:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) A statement explaining the Medicare payment consequences of the expedited determination and date of liability, if any.

(iv) A statement informing the beneficiary of his or her appeal rights including the name and phone number of the qualified independent contractor (QIC) that he or she must appeal to if that beneficiary is dissatisfied with the QIO's determination.

(v) The time period for filing the subsequent appeal.

(e) *Effect of an expedited initial determination.* The initial determination is binding upon the beneficiary, physician, and hospital.

(1) *When beneficiary remains in hospital.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with this determination, he or she must request an appeal in accordance with § 405.1204 (QIC expedited reconsideration).

(2) *When beneficiary has been discharged.* When the beneficiary is no longer an inpatient in the hospital and subsequently chooses to appeal this decision, he or she must file an appeal in accordance with §§ 405.960 through 405.978.

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

Dated: September 25, 2002.

Thomas A Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 25, 2002.

Tommy G. Thompson,

Secretary.

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