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Medicare Program: Changes to the Medicare Claims Appeal Procedures; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS–4064–F]

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Medicare Program: Changes to the Medicare Claims Appeal Procedures

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

ACTION: Final rule.

SUMMARY: Under the procedures in this final rule, Medicare beneficiaries and, under certain circumstances, providers and suppliers of health care services can appeal adverse determinations regarding claims for benefits under Medicare Part A and Part B pursuant to sections 1869 and 1879 of the Social Security Act (the Act). Section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) amended section 1869 of the Act to provide for significant changes to the Medicare claims appeal procedures. After publication of a proposed rule implementing the section 521 changes, additional new statutory requirements for the appeals process were enacted in Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). In March 2005, we published an interim final rule with comment period to implement these statutory changes. This final rule responds to comments on the interim final rule regarding changes to these appeal procedures, makes revisions where warranted, establishes the final implementing regulations, and explains how the new procedures will be put into practice.

DATES: *Effective Date:* These regulations are effective on January 8, 2010.

FOR FURTHER INFORMATION CONTACT:

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I. Background

A. Overview of Existing Medicare Program

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

In addition to the original Medicare program, beneficiaries may elect to receive health care coverage under Part C of Medicare, the Medicare Advantage (MA) program. Under the MA program, an individual is entitled to those items and services (other than hospice care) for which benefits are available under Part A and Part B. MA plans may provide additional health care items and services that are not covered under the original Medicare program. Beneficiaries can also elect to receive

prescription drug coverage under Part D of Medicare, which became effective January 1, 2006.

Under the original Medicare program, a beneficiary can generally obtain health services from any institution, agency, or person qualified to participate in the Medicare program. After providing an item or service, the provider or supplier (or, in some cases, a beneficiary) can submit a claim for benefits under the Medicare program to the appropriate government contractor: A fiscal intermediary (FI) (for all Part A claims and certain Part B claims); a carrier (for most claims under Part B); or a Medicare administrative contractor (under Medicare contracting reform, a contractor that processes all types of Part A and Part B claims). If the claim is for an item or service that falls within a Medicare benefit category, is not otherwise excluded by statute or rule, and is reasonable and necessary for the individual as set forth in § 1862(a) of the Social Security Act, then the item or service is covered and the contractor may make payment for the claim. However, the Medicare program does not cover all health care expenses. Therefore, if the Medicare contractor determines that the medical care is not covered under the Medicare program, then it denies the claim.

B. Appeals Procedures Under Previous Regulations

Generally, when a contractor denies a claim, it notifies the provider or supplier, and the beneficiary of the denial and offers the opportunity to appeal the denial. The pre-BIPA appeal procedures for original Medicare are set forth in regulations at 42 CFR part 405, subparts G and H. Separate procedures for appealing determinations made under the MA program are set forth at 42 CFR part 422, subpart M. There is a similar, separate appeals process for the prescription drug program set forth at subpart M of 42 CFR part 423. In addition, we published a proposed rule to describe the appeals procedures that would apply at the ALJ and MAC levels in deciding appeals brought by individuals who have enrolled in the Medicare Part D prescription drug benefit program (73 FR 14342, March 17, 2008). After an appellant has exhausted the administrative appeal procedures offered under the Medicare program, the Medicare statute provides the opportunity for an individual who is dissatisfied to seek review in Federal court.

The regulations in part 405 subpart G beginning at § 405.701 describe reconsiderations and appeals under Medicare Part A, prior to the statutory changes in BIPA and the MMA. As set forth in these regulations, when a Medicare contractor made a determination for a Part A claim, the beneficiary or, in some circumstances, the provider, could appeal the determination. Consistent with sections 1861(u) and 1866(e) of the Act and § 400.202, the term ''provider'' includes hospitals, skilled nursing facilities (SNFs), home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), and hospices, as well as certain clinics, rehabilitation agencies, and public health agencies. Under this process, if a determination was appealed, the contractor would reconsider the initial determination. If the contractor upheld the original determination, a party could request a hearing before an ALJ, provided that the amount in controversy (AIC) was at least $100. If a party was dissatisfied with the ALJ's decision, it could request review by the Departmental Appeals Board (DAB). Under these regulations, the component within the DAB responsible for Medicare claim appeals was the MAC. (Although the Medicare appeals regulations in part 405, subparts G and H, contain some limited provisions regarding ALJ and MAC proceedings, these proceedings were generally governed by the Social Security Administration (SSA) regulations at 20 CFR part 404, subpart J.) MAC decisions generally constituted the final decision of the Secretary and could be appealed to a Federal court. With few exceptions, parties had to complete the lower level of appeal before the appeal could go on to the next level. Pre-BIPA and pre-MMA appeal procedures for Medicare Part B are set forth in 42 CFR part 405 subpart H (§ 405.801, *et. seq.*). Under these regulations, beneficiaries, and suppliers that accepted assignment for Medicare claims could request review of the contractor's initial determination that a claim could not be paid, either in full or in part. (The term ''supplier'' is defined under section 1861(d) of the Act, as amended by section 901(b) of the MMA, and means a physician or other practitioner, a facility, or other entity (other than a provider of services that furnishes items or services) under Medicare.) Suppliers that did not take assignment and providers, in some circumstances, had limited appeal rights under these regulations.

As defined in the pre-BIPA and pre-MMA regulation at § 405.815, if a party to the contractor's review determination was dissatisfied and the amount in controversy was at least $100, the party was entitled to request a second level appeal known as a ''carrier hearing''. If the carrier's hearing officer upheld the denial, a party to the carrier hearing could request a hearing before an ALJ, provided that the action met the amount in controversy requirement. (We published a ruling, CMS Ruling No. 02–1, which implemented the $100 amount in controversy requirement for Part B ALJ hearings specified in section 521 of BIPA for initial determinations made on or after October 1, 2002. *See* 67 FR 62478, 62480 (Oct. 7, 2002). For initial determinations made prior to October 1, 2002, the amount in controversy threshold was $100 for home health services and $500 for all other services.) Subsequent aspects of the appeals process for Part B claims are identical to those described above for Part A claims.

C. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)

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

- Establishing a uniform process for handling Medicare Part A and Part B appeals, including the introduction of a new level of appeal for Part A claims;
- Revising the timeframes for filing a request for Part A and Part B appeals;
- Imposing time limits for ''redetermination'' decisions made by the contractors;
- Establishing 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 the next level of appeal (an ALJ hearing) if reconsiderations are not completed within established time limits;
- Establishing a uniform amount in controversy threshold for appeals at the ALJ level;
- Imposing 90-day time limits for issuing decisions at the ALJ and MAC levels of appeal and allowing appellants to escalate cases to the next level of appeal if an ALJ or the MAC does not meet the 90-day deadline; and
- Requiring ''*de novo*'' review when the MAC reviews an ALJ decision made after a hearing.

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

changes needed to improve the Medicare claims appeal procedures.

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

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted. The MMA includes a number of provisions that made additional changes to the Medicare claim appeals process. To the extent the new statutory language necessitated revisions or additions to our proposed regulations to ensure conformance to the MMA, we have incorporated the needed changes into the interim final rule (70 FR 11420, March 8, 2005), the correcting amendments (70 FR 37700, June 30, 2005 and 70 FR 50214, August 26, 2005) and this final rule. Among the major changes required by MMA are—

- Transferring the ALJ function to the Department of Health and Human Services (Section 931 of the MMA).
- Establishing a process for expedited access to judicial review (Section 932 of the MMA).
- Requiring the full and early presentation of evidence (Section 933(a) of the MMA).
- Requiring the review of a patient's medical records in a QIC reconsideration (Section 933(b) of the MMA).
- Establishing content requirements for appeal determination notices (Section 933(c) of the MMA).
- Revising eligibility requirements for QICs (Section 933(d) of the MMA).
- Precluding administrative or judicial review of a determination by the Secretary of sustained or high levels of payment errors (Section 934(a) of the MMA).
- Creating a separate process for the correction of minor errors or omissions (Section 937 of the MMA).
- Permitting appeals by providers and suppliers when there is no other party available (Section 939 of the MMA).
- Revising appeals timeframes and amounts in controversy (Section 940 of the MMA).

E. Codification of Regulations

The BIPA provisions and the subsequent revisions made under MMA make possible a largely uniform set of appeals procedures that can be applied for both Part A and Part B of Medicare. In the interim final rule, we established a new subpart I of part 405 that sets forth in one location the requirements for fee-for-service claims appeals processed by Medicare carriers, FIs, Medicare administrative contractors, and QICs. Also included in subpart I are the provisions needed to govern Medicare claims appeals to ALJs and the MAC. Thus, 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.

II. Analysis of Appeals Procedures and Responses to Public Comments

A. Overview

Discussed below are the comments and clarifications to the March 2005 interim final rule with comment period implementing section 521 of BIPA and the relevant sections of the MMA. In general, we discuss those sections of the interim final rule on which we received comments from the public or which required editorial changes to improve the clarity and simplicity of the regulations. We include a brief explanation of each regulatory provision, provide a summary of, and responses to, the comments received, and describe the changes, if any, to be made in finalizing the provision in this rulemaking. The changes made in this final regulation are summarized in the section of this preamble entitled ''Provisions of the Final Regulations.''

We received 26 timely comments on the 2005 interim final rule with comment period from individuals, organizations representing providers and suppliers, beneficiary advocacy groups, law offices, health plans, and others. The issues most frequently raised by commenters include: Beneficiary protections; deadlines for filing appeals and timeframes for decision-making; entities entitled to receive notices; differences between an assignee and the beneficiary's appointed representative; the role of the QICs that will perform reconsiderations; evidentiary requirements; the perceived formality of the ALJ procedures, especially proceedings where CMS or one of its contractors enters the process, and the impact on beneficiaries; and whether the nature of an ALJ hearing has changed, how much deference the ALJ gives to CMS' policies and, in general, the manner in which the ALJs conduct hearings. These comments and our responses are discussed below.

B. Appeals

1. Statutory Basis and Scope, Definitions and General Procedures (§ 405.900 Through § 405.904)

In § 405.900, we set forth the general statutory authority for the ensuing provisions and explain that this subpart establishes the requirements for appeals of initial determinations for benefits under Part A and Part B of Medicare. Section 405.902 sets forth the definitions for terms used in subpart I. Section 405.904 provides a general description of the appeals process for entitlement and claims appeals. Additional detailed discussion of these provisions is found in the interim final rule at 70 FR 11427, 11431 through 11432, and 11434 through 11435.

In this final regulation, we are making a technical revision to § 405.902 to define the term contractor, as applicable to the provisions in subpart I. We believe the meaning of the term contractor may have been unclear because, in some instances, we specified the entities that are included in the term contractor whereas, in other instances, we did not provide such detail. Thus, we believe a technical revision to clearly define the term contractor and to ensure that the term is used consistently throughout Subpart I is appropriate. Contractor means an entity that contracts with the Federal government to review and/or adjudicate claims, determinations and/or decisions. This includes, but is not limited to, fiscal intermediaries, carriers, Medicare administrative contractors, qualified independent contractors, and quality improvement organizations (QIOs). Although, based on this definition, the term contractor includes many entities, the meaning of the term contractor for a particular provision is derived from the context. For example, under § 405.920(a), after a claim is filed with the appropriate contractor in the manner and form described in part 424 subpart C, the contractor must determine if the items and services furnished are covered or otherwise reimbursable under title XVIII of the Act. Only fiscal intermediaries, carriers and Medicare administrative contractors make such determinations, so the term contractor means only these three entities in this context. We are also making technical revisions to several sections noted below, in order to remove references to specific contractors (such as QICs and QIOs) when describing the general actions, responsibilities, or authority of contractors. However, there are instances where we continue to use the term contractor and also separately include a reference to QICs in the same provision (for example, § 405.910(i)(2) and § 405.980(a)(4)). In those situations, we are maintaining the separate reference to the QIC in order to highlight the specific responsibilities of

the QIC with respect to reconsiderations.

We received no comments on these sections. Therefore, we are finalizing § 405.900 and § 405.904 without modification. We are finalizing § 405.902, § 405.1000, § 405.1010 and § 405.1012 with modifications, as noted.

2. Parties to an Appeal, Medicaid State Agencies, and Appointment of Representatives (§ 405.906 Through § 405.910)

Section 405.906 discusses parties to the appeals process. More detail is provided on the role of Medicaid State agencies in the appeals process in section 405.908. Section 405.910 describes appointed representatives and the process for becoming an appointed representative. We received several comments with respect to the rights of Medicaid State agencies to file appeals, and the rights and responsibilities of representatives. A summary of the comments and our responses is included below. Additional detailed discussion of these provisions is found in the interim final rule at 70 FR 11423, 11427 through 11431, 11432, 11434 through 11435, 11441, 11444 through 11445, and 11468.

Comment: Several commenters asked CMS to broaden the definition of ''party'' at the initial determination level to include Medicaid State agencies.

Response: As set forth in § 405.906(b)(2), a Medicaid State agency can be a party to a redetermination, reconsideration, hearing or MAC review. Section 405.908 explains the process for a Medicaid State agency to join the appeal as a party. Specifically, in § 405.908, we allow the State agency to file an appeal with respect to ''a claim for items or services furnished to a dually eligible beneficiary only for services for which the Medicaid State agency has made payment, or for which it may be liable.'' Only after Medicare has issued its initial determination on a claim for items or services provided to a dually eligible beneficiary can a determination be made about a State agency's potential liability for all or part of the associated charges, and thus, the Medicaid State agency should not be a party to the initial determination. If the Medicaid program is not financially responsible for the items or services on a particular claim, it follows that the State agency would have no interest in the claim and thus, should not be a party to any appeal of the initial determination. Accordingly, we believe it is appropriate to offer party status to a Medicaid State agency only after there has been a determination on the claim by Medicare, and then only if the State agency makes payment or may be liable to make payment for the items or services on that claim. If these requirements are met, the State agency may file a request for a redetermination and will retain party status through the course of any subsequent appeals for the particular claim.

Comment: One commenter stated that although the interim final rule calls for an adjudicator to contact the party and provide a description of information missing from the appointment of representative form (§ 405.910(d)(1)), there are no provisions explaining how the need to cure a defective appointment affects the time deadline for filing an appeal. The commenter recommended amending the rule to indicate that an appeal filed within time limits remains timely when the only technical flaw is a defective appointment of representative that can be, and is, cured.

Response: Under § 405.910(d)(1), if an appeal request is filed by an individual attempting to represent a party, but the submission contains a defective appointment of representative (AOR) form, the adjudicator will give the party notice of the defect. The adjudicator provides the party and the putative representative with a reasonable timeframe within which to cure the defect. The adjudicator will not dismiss an appeal request filed with a defective AOR provided the defect is cured within the timeframe established by the adjudicator. Thus, in response to the situation described by the commenter, an appeal request filed timely will be considered timely if the party submits a corrected and valid appointment instrument within the timeframe specified by the adjudicator, even if that period extends beyond the time limit for filing the appeal.

However, if the adjudicator does not receive a valid appointment instrument within the timeframe specified by the adjudicator, it may dismiss the appeal request because the individual requesting the appeal is not a proper party to the appeal or does not otherwise have a right to appeal. *See* § 405.952(b)(1), § 405.972(b)(1), § 405.1052(a)(3) and § 405.1114(b). If the appeal request is dismissed, the party or the representative may re-file the request. If the resubmission is untimely, consistent with § 405.942(b), the representative must include an explanation of the circumstances leading to the late filing and request that the contractor consider whether good cause exists to extend the time for filing the appeal.

Comment: One commenter asked that § 405.910(e)(1) be amended to note that an appointment is valid for one year, except as noted in § 405.910(e)(3). We were also asked to clarify whether a representative may be appointed before the issuance of an initial determination. Finally, a commenter asked when an updated appointment of representative form (Form CMS–1696) would be available.

Response: Section 405.910(e)(1) states that once the AOR form is executed, it is valid for one year from the effective date. Section 405.910(e)(2) states that the representative must submit, with each appeal request, a copy of the valid, effective AOR or other conforming written instrument in order to request a redetermination or other appeal on behalf of the party. Thus, a valid, executed AOR will be honored for the duration of the initial appeal request for which it is filed, and for any subsequent appeal request with which it is submitted, provided the initial appeal request is filed within one year of the effective date of the AOR.

In § 405.910(e)(3), we made an exception for appointments signed in connection with Medicare Secondary Payer recovery claims, because liability, no-fault, and worker's compensation claims often take more than one year to resolve. Where an appointment of representative is related to these recovery claims, the appointment is valid from the date that it is signed through the duration of any subsequent appeal. We believe § 405.910(e) is clear on its face and, thus, we are not revising this subsection.

In the interim final rule, we stated that, under § 405.910(a), the appointment of representative provisions apply at the initial determination level and throughout the appeals process. *See* 70 FR 11431. Section 405.910(a) states that ''[a]n appointed representative may act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal.'' In addition, § 405.910(c)(7) states that the AOR form may ''[b]e filed with the entity processing the party's initial determination or appeal.'' Finally, § 405.910(e)(1) states that the effective date of the appointment is the date that the AOR form or other conforming written instrument contains the signatures of both the party and appointed representative. The AOR may be completed prior to the submission of a claim or appeal request, and a representative may assist with the preparation or submission of a claim. (However, consistent with § 405.910(i)(1), notices and other information regarding the initial determination are only sent to the party

to the initial determination, except for Medicare secondary payer claims appeals as discussed in § 405.910(i)(4)). We believe these provisions convey that a representative may be appointed prior to the issuance of an initial determination.

Finally, the revised appointment of representative form, Form CMS–1696, is available online, in both English and Spanish, at *http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage* Representatives at 1–800–MEDICARE can also provide information on how to obtain the appointment of representative form.

Comment: One commenter questioned the authority of CMS to impose a fee review process when an appointed representative for a beneficiary wished to charge a fee for services rendered in connection with an appeal before the Secretary. The commenter contended that beneficiary representatives should be treated like provider representatives who have no fee limitations. The commenter stated that the regulations, specifically, the fee review provisions, decrease the likelihood that a beneficiary will find an advocate to assist in the appeal. The commenter also stated that our regulations increase a beneficiary's need to be represented.

Response: Section 1869(b)(1)(B)(iv) of the Act (captioned, ''Requirements for Representatives of a Beneficiary'') establishes that the provisions of sections 205(j) and 206 (other than subsection (a)(4)) of the Act apply to representation of an individual for Medicare claim appeals in the same manner as they apply to representation of an individual for Social Security claims. By incorporating these sections in § 1869(b)(1)(B)(iv) of the Act, the Congress mandated that, for appeals before the Secretary, appointed representatives, including attorneys, must obtain approval of fees before charging a beneficiary. Consistent with these statutory provisions and the longstanding practice of fee petitions before ALJs, § 405.910(f)(1) requires that an appointed representative for a beneficiary, who wishes to charge a fee for services rendered in connection with an appeal before the Secretary, must obtain approval of the fee from the Secretary.

As noted in the preamble to the interim final rule (70 FR 11429 through 11430) and at § 405.910(f)(1), we do not consider proceedings before the ALJ hearing level (that is, initial determination, redetermination, and reconsideration levels) to be proceedings ''before the Secretary''. Section 206(a) of the Act authorizes the Commissioner of Social Security to prescribe rules and regulations to govern the representation of claimants in proceedings before the Commissioner. This provision has long been interpreted to include only proceedings at the ALJ level and beyond. Thus, we have interpreted appeals before the Secretary of the Department of Health and Human Services (DHHS or the Department) to include only the ALJ level and above. Therefore, the fee petition provisions in § 405.910(f) do not apply to administrative proceedings below the ALJ hearing level. Furthermore, because the clear intent of the fee petition provision of the statute is to protect the interests of individual Medicare beneficiaries, we do not interpret them as applying to non-beneficiary appellants.

The fee petition process described in § 405.910(f) specifically is designed to protect the interests of Medicare beneficiaries by ensuring that the fees charged by a representative are reasonable. This process is not new to these regulations. Rather, it has been a longstanding requirement in both the Medicare and Social Security programs for appeals at the ALJ level. *See* 42 CFR § 405.701(c) and 42 CFR § 405.801(c), incorporating by reference the provisions of 20 CFR part 404, subpart R regarding representation of parties. Thus, we do not believe this regulation will affect a beneficiary's ability to obtain assistance with an appeal.

Further, we do not believe the new appeals process increases the need for a beneficiary to obtain assistance with an appeal. The new appeals process primarily changes certain procedures with respect to appeals filed by providers and suppliers, the entities and individuals who file the vast majority of appeals (for example, the full and early presentation of evidence requirement, and CMS participation as a party or participant at the ALJ level). However, most of these changes do not affect beneficiary initiated appeals. Throughout the process, we have attempted to minimize the impact of the new appeals procedures on beneficiaries. Therefore, we do not believe that the new appeals process increases the need for a beneficiary to obtain assistance with an appeal. Further, where we have made changes to operational procedures, we have developed notices and model language for contractors to provide to parties that explain the new process in clear, plain language. We believe our newly developed notices and forms provide clear instructions to parties at each level of the administrative appeals process. We have also revised Your Medicare Rights and Protections (CMS Publication No. 10112, available to order from 1–800–MEDICARE, or available to view on-line at *http://www.medicare.gov/Publications/Pubs/pdf/10112.pdf)*, which explains, in detail, the various steps in the appeals process. These notices, forms and instructions will provide beneficiaries and their representatives, as well as other parties and advocates, with additional information about the procedures to be followed in the administrative appeals process.

Comment: Two commenters expressed concern regarding the requirement that an appointed representative has an affirmative duty to ''[c]omply with all laws and CMS regulations, CMS Rulings, and instructions'' (§ 405.910(g)(1)(v)). One commenter requested the words ''and instructions'' be struck from the regulation, because an appointed representative should not be bound to comply with CMS instructions any more than a beneficiary, a contractor or an administrative law judge should be. Another commenter stated that it is not uncommon for an attorney or other representative to challenge the validity of CMS rulings, policy instructions and other interpretations, and, as such, it is unreasonable to require a representative to defer to all such policies to the potential detriment of the provider/appellant.

Response: Section 405.910(g)(1)(v) states that an appointed representative has an affirmative duty to comply with all laws and CMS regulations, CMS rulings and instructions. While we appreciate the commenters' concerns, we disagree with the commenters' interpretation of this provision. Providers and suppliers submitting claims on behalf of beneficiaries, and contractors processing claims are, in fact, bound to follow all laws, regulations, rulings and CMS operating instructions. QICs, ALJs and the MAC are bound to follow laws, regulations, rulings, and NCDs, and to afford substantial deference to CMS operating instructions and other program guidance. *See* § 405.968(b) and § 405.1062. As arbiters of fact in the administrative appeals process, QICs, ALJs and the MAC may determine that an instruction should not apply to the facts of a particular case. However, QICs, ALJs and the MAC cannot rule on the validity of the instruction. Similarly, an appointed representative has a duty to comply with such laws, regulations, rulings and instructions. However, an appointed representative is not precluded from challenging the application of that policy or instruction

during the course of an appeal. Thus, we do not believe a representative is unfairly burdened by this requirement, and we believe it is unnecessary to revise § 405.910(g)(1)(v).

Comment: Several commenters asked CMS to reconsider the policy prohibiting the issuance of MSNs to a beneficiary's appointed representative. One commenter stated that sending the notice of initial determination to the appointed representative is necessary to assure that beneficiaries can be effectively represented in the new appeals process. Another commenter indicated that quicker access to initial determination information was needed due to the shorter timeframes for requesting redeterminations and reconsiderations.

Response: Under § 405.910(i)(1), contractors issue initial determination notices (that is, Medicare Summary Notices (MSNs) and Remittance Advice (RAs)) only to the parties to the initial determination, and not to appointed representatives. As we stated in the preamble to the interim final rule (70 FR 11434) and in § 405.910, appointed representatives have the same right as parties to receive information on claims being appealed only after an appeal has been filed. The information included on MSNs covers the entire range of health care services and items billed to Medicare within a 90-day period; similarly, an RA contains comprehensive claims information for all claims processed for a provider or supplier during a specific period. Because the scope of an appointment of representation may vary, an appointed representative may not have authority to receive information on all such services or items. Accordingly, for privacy and confidentiality reasons, contractors must provide MSNs and RAs only to the parties to the initial determination. We believe that a beneficiary can be effectively represented without contractors directly providing the MSNs and RAs to appointed representatives because parties can share their respective notices with their representatives.

We note that our policy with respect to sending the notice of initial determination to the party and not the party's representative is consistent with the decision in *Connecticut Department of Social Services* v. *Leavitt,* 428 F.3d 138 (2d Cir. 2005). The court held that the due process interests of parties are adequately protected by their own receipt of the initial determination notice, and declined to require that contractors send these notices to the appointed representative of a party.

After the initial determination, the contractor, QIC, ALJ and the MAC will send notice of their action and requests for information or evidence to the appointed representative because, unlike the MSN and RA, this information is specific to the claim at issue. We also note that under § 405.910(i)(4), initial determinations and appeal notices that involve Medicare Secondary Payer recovery claims are sent to both the party and the appointed representative. Unlike other initial determinations, Medicare Secondary Payer recovery claims notices of initial determinations are limited to include only information related to the claim at issue.

We believe the current filing timeframes and the quarterly issuance of MSNs provide adequate time for representatives to obtain claims information from beneficiaries, providers and suppliers. Currently, parties have 120 calendar days from the date of an initial determination to file for a redetermination and 180 calendar days from the date the party receives the notice of the redetermination to file a reconsideration. In addition, contractors may extend redetermination and reconsideration filing timeframes (consistent with § 405.942(b) and § 405.962(b)) if a party shows good cause for not meeting the filing timeframe. Coupled with the quarterly issuance of MSNs, we believe individuals representing beneficiaries have ample time to obtain relevant information in order to submit an appeal of an initial determination or redetermination.

Accordingly, we are finalizing sections 405.906 through 405.910 without modification.

3. Assignment of Appeal Rights (§ 405.912)

The procedures for assigning appeal rights from a beneficiary to a provider or supplier are included in § 405.912. We received several comments on the assignment of appeal rights. A summary of the comments and our responses is included below. Additional detailed discussion of this provision is found in the interim final rule at 70 FR 11427 through 11428 and 11430 through 11432.

Comment: We received several comments that requested clarification of when an appointment of a representative or assignment of appeal rights was appropriate, given that participating providers and participating suppliers generally have appeal rights equal to those of the beneficiary.

Response: A number of the comments reflected continued confusion between the appointed representative provisions at § 405.910 and the assignment of appeal rights provisions at § 405.912. Appointing a representative and assigning appeal rights are two different and unrelated actions under the new appeals process. Beneficiaries have the option of either (1) assigning (transferring) their appeal rights to the provider or supplier that provided the item or service at issue, if such person or entity is not a party to the initial determination, or (2) appointing a representative to act on their behalf during the appeal.

As set forth in § 405.912, an assignment of appeal rights constitutes a complete transfer of party status and all appeal rights from a beneficiary to the provider or supplier that (1) provided the item or service at issue to the beneficiary and (2) does not already have party status at the initial determination. Thus, with an assignment of appeal rights, the provider or supplier becomes a party to the appeal in place of the beneficiary.

In contrast, a party may choose to appoint an individual as its representative to assist with an appeal. *See* § 405.902, defining appointed representative, and § 405.910. For example, a beneficiary may appoint his provider or supplier as an appointed representative. Appointing a representative does not transfer a party's appeal rights, nor does it make the appointed representative a party to the appeal. Rather, an appointed representative is simply an individual chosen by a party to act on behalf of the party in exercising his or her appeal rights.

In an overwhelming majority of appeals, there is no need for a beneficiary to assign appeal rights to his provider or supplier. For example, under § 405.906(a)(2) and (a)(3), a supplier who accepts assignment for items or services furnished to a beneficiary, and a provider who files a claim for items or services furnished to a beneficiary, are parties to the initial determination, and thus, may appeal that initial determination to the same extent as the beneficiary.

In limited situations, a provider or supplier will not have party status. For example, if a claim is filed by a non-participating physician who does not accept assignment on the claim, and the claim is denied as a statutory exclusion (such as certain cosmetic surgeries under section 1862(a)(10) of the Act), the physician submitting the claim would not have a direct right to appeal the initial determination made by the

carrier. However, the physician could get party status to file an appeal by obtaining an assignment of appeal rights from the beneficiary for this service. The assignment of appeal rights must be completed in accordance with the procedures set forth in § 405.912.

Comment: A commenter suggested that certain providers, such as clinical laboratories, be exempt from the provision requiring beneficiaries to sign an assignment of appeal rights form (§ 405.912(c)(2)).

Response: In situations where an assignment of appeal rights is appropriate, we believe the signature requirement is necessary for the protection of both the party and the representative, as well as to assist adjudicators in determining the proper parties to the appeal. While we acknowledge it may be difficult in some instances for a provider or supplier to obtain the signature of the beneficiary, the binding nature of the assignment and the effect of the assignment (transferring a beneficiary's appeal rights to an assignee and waiving the right of the provider or supplier to collect payment) make it essential that both parties sign the agreement. This situation, however, may not arise frequently because a supplier that is required to accept assignment on a claim, such as a clinical laboratory, is a party to the initial determination and, therefore, has direct standing to file an appeal. Accordingly, it would be inappropriate for a supplier, who otherwise has party status, to seek assignment of appeal rights from the beneficiary.

Comment: One commenter stated that the regulations indicate that when beneficiaries assign their rights to appeal an individual item or service to a provider or supplier, the provider or supplier must list all items or services provided on the date of service on the assignment form. The commenter recommended that a provider or supplier seeking assignment of appeal rights should have to list only those items or services for which appeal rights are to be assigned.

Response: Section 405.912(c)(3) requires that an assignment of appeal rights ''indicate the item or service for which the assignment of appeal rights is authorized.'' A provider or supplier is not required to list all items or services provided on the date of service on the assignment agreement—just those for which appeal rights are to be assigned. An assignment of appeal rights will only be effective for the items or services listed on the assignment form.

Accordingly, we are finalizing § 405.912 without modification.

4. Initial Determinations (§ 405.920 Through § 405.928)

Sections 405.920 through 405.928 discuss the initial determination process, including how contractors make initial determinations on claims and what types of determinations are considered or not considered initial determinations.

We received several comments with respect to claims submissions and the processing of initial determinations as set forth in the interim final rule. A summary of the comments and our responses are included below. Additional discussion regarding these provisions is found in the interim final rule at 70 FR 11423 through 11424, 11428, and 11432 through 11436.

a. Initial Determinations, Notice of Initial Determinations, and Timeframe for Processing Initial Determinations (§ 405.920 Through § 405.922)

Section 405.920 explains the process a contractor must follow in making an initial determination. Section 405.921 describes the notice of initial determination, including the content of the notice, and § 405.922 discusses the timeframe for processing initial determinations.

Comment: Two commenters recommended that the term ''non-clean claim'' be defined. Commenters also suggested that if a claim is paid at the QIC level or higher, such claims should be considered clean, and that interest should accrue from the date of the original denial in order to provide incentive to expedite claim determinations and assure fairness. Two commenters noted that although contractors must issue an initial determination within 45 days of receipt of a ''non-clean'' claim, the regulations do not provide for any interest payments if the determination is issued after the 45 day time period.

Response: The term ''clean claim'' is clearly defined in statute at sections 1816(c)(2)(B)(i) and 1842(c)(2)(B)(i) of the Act as ''a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim.'' This definition also is set forth in § 405.902. Claims that do not meet this definition are considered ''non-clean claims.'' Therefore, we do not believe that we need to define non-clean claim because the meaning of non-clean claim is sufficiently clear given the meaning of clean claim set forth in § 405.902.

Claims for services that cannot be adjudicated timely at the initial determination level because they lack sufficient documentation and/or require special handling do not come within the definition of clean claims. Claims initially denied and subsequently paid following a favorable appeal decision, or revised following a reopening action, are, by their nature, claims that require special treatment. Often, during an appeal or reopening action, additional substantiating documentation is needed to support the coverage and payment decision. Thus, claims that are adjusted as a result of the effectuation of an appeal decision, and claims that are revised following a reopening action do not fall under the definition of ''clean claim'' set forth in the statute.

Section 1869(a)(2)(A) of the Act, in conjunction with sections 1816(c)(2) and 1842(c)(2) 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 to the individual filing the claim by no later than 45 days after the contractor receives the claim. Additionally, section 1869(a)(2)(A) of the Act, in conjunction with sections 1816(c)(2) and 1842(c)(2) of the Act, requires that interest accrue if clean claims are not processed within 30 calendar days. Thus, reading these provisions together, no interest accrues on non-clean claims, including claims that are adjusted as the result of the effectuation of an appeal decision, and claims that are revised following a reopening action.

Finally, neither the statute nor our regulations provide for escalation, payment of interest or other remedies when the 45-day deadline is missed for non-clean claims. Through various tools used to monitor the performance of our contractors, we attempt to ensure that claim determinations are both timely and accurate. As we noted in the interim final rule, providers and suppliers play a vital role in the contractors' ability to meet their decision-making timeframes. If providers and suppliers submit clean claims, they can avoid the delays that are associated with processing non-clean claims. The more accurate the claim is at initial submission, the greater the ability of the Medicare contractor to process the claim quickly.

Accordingly, we are finalizing §§ 405.920 and 405.921 without modification. We are finalizing § 405.922 with modification as discussed in section II.B.5.a. of this preamble.

b. What Constitutes an Initial Determination and Decisions That Are Not Considered Initial Determinations (§ 405.924 Through § 405.926)

In § 405.924, we describe actions that are initial determinations and are subject to the administrative appeals procedures in subpart I. In § 405.926, we list examples of determinations that are not considered initial determinations and are not subject to the administrative appeals procedures contained in this subpart.

Comment: One commenter questioned the need to maintain the number of home health visits as a determination that constitutes an initial determination (§ 405.924(b)(7)). The commenter stated that this particular item is no longer a relevant factor in determining whether the charges were covered under Medicare Part A or Part B, and suggested that this item be removed from the list of determinations considered initial determinations.

Response: We agree with the commenter and have revised § 405.924 to eliminate paragraph (b)(7), which specifically included the number of home health visits used as an initial determination.

Comment: One commenter stated that under § 405.926(c), issues regarding the computation of the payment amount of program reimbursement of general applicability are not considered initial determinations and, therefore, are not subject to appeal under subpart I. The commenter questioned whether the payment amount of a specific, individual claim is considered an initial determination. The commenter suggested amending § 405.924 and § 405.926 to clarify that individual determinations with respect to payment amounts are initial determinations. In addition, the commenter suggested that we revise § 405.924(c) to state that a provider's notice of non-coverage to the Medicare beneficiary is not an initial determination. The commenter noted that while the provider of service may be the first decision maker regarding Medicare coverage of an item or service, its notice of non-coverage has not been considered an initial determination subject to appeal.

Response: Section 405.920 provides that, after a claim is filed, a contractor must perform certain actions, including determining any amounts payable. Such a determination constitutes an initial determination subject to the subpart I appeals process. Similarly, under § 405.924(b), a payment amount determination with respect to a particular item or service on a claim is an initial determination that is appealable under subpart I. In contrast, § 405.926(c) specifies that ''[a]ny issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule * * *'' is not an initial determination, and is not subject to administrative appeal under subpart I. For example, section 1848(i)(1) of the Act expressly prohibits administrative and judicial review of the components that comprise the Medicare physician fee schedule. Thus, in situations where payment amounts are determined in accordance with statutorily mandated methodologies (such as the physician fee schedule), adjudicators are required to follow such methodologies when making a finding regarding a payment amount. Therefore, we believe that the regulations at §§ 405.920, 405.924, and 405.926 clearly provide that the payment amount of a specific, individual claim is considered an initial determination and also appropriately convey the distinction between a direct challenge to the Medicare payment methodology and an appeal that raises questions regarding a determination of a payment amount for a particular claim. Therefore, we do not believe it is necessary to revise § 405.924 or § 405.926 to provide any further clarification.

We agree with the commenter's statement that a provider's notice of non-coverage does not constitute an initial determination, because it is not a determination made by the Medicare program. Instead, it is an opinion of the provider, and the notices clearly state that they are conveying the provider's opinion with respect to non-coverage. The notices also clearly explain the steps required to obtain a determination by Medicare and how to appeal that determination. Thus, we do not believe it is necessary to revise § 405.924 or § 405.926 to include a provision explicitly excluding such notices from the definition of initial determination.

Comment: One commenter requested that we define the phrase ''sustained or high levels of payment errors'' (§ 405.926(p)) and requested that we specify how such determinations will be made. The commenter also requested that CMS review dismissals on the grounds that the claim involves a sustained or high error rate. The commenter suggested that CMS provide clarification of the implications of such a finding. Finally, the commenter recommended that CMS provide a mechanism for providers to be removed from this ''sanction''.

Response: In section 1893(f)(3) of the Act, added by section 935 of the MMA, Congress placed restrictions on the use of extrapolation to determine overpayment amounts to be recovered from Medicare providers, suppliers or beneficiaries. In order to calculate an overpayment by extrapolation, there must be a determination of either: (1) A sustained or high level of payment error, or (2) a documented educational intervention that has failed to correct the payment error. In addition, in section 1874A(h)(2) of the Act, as added by section 934 of the MMA, Congress required contractors to identify a likelihood of sustained or high level of payment error under section 1893(f)(3)(A) of the Act before initiating non-random pre-payment reviews of a provider or supplier, and in section 1893(f)(3) of the Act, expressly precluded administrative or judicial review of contractor determinations of sustained or high levels of payment errors. Accordingly, we included a conforming provision at § 405.926(p) of the interim final rule providing that determinations of sustained or high levels of payment error are not initial determinations that may be appealed under this subpart. We note, however, that while the determination of whether a provider or supplier has a sustained or high level of payment error is not subject to appeal, the initial or revised determinations made on the underlying claims for items or services would be subject to appeal.

CMS issued operating instructions for determining when a provider or supplier has a sustained or high level of payment error in June 2005: (*http://www.cms.hhs.gov/transmittals/downloads/R114PI.pdf*). Furthermore, we issued a final rule on September 26, 2008 (73 FR 55753) to address when contractors may terminate the non-random pre-payment review of claims submitted by a provider or supplier. The commenter's concerns regarding the practical considerations of determinations of a provider's or supplier's sustained or high error rates are beyond the scope of this regulation. With respect to the suggestion that CMS review dismissals on the grounds that the claim involved a sustained or high error rate, as noted above, while that determination does not constitute an initial determination and is not subject to appeal, any claim denials resulting from the review would constitute initial determinations that may be appealed. Therefore, we do not anticipate any denials of claims solely based on this determination. Rather, the determination of a sustained or high

error rate will be used as the basis for a contractor undertaking further review of claims submitted by the provider or supplier. Finally, we strongly disagree with the commenter's characterization of the determination of a sustained or high error rate as a sanction. This determination does not result in an assessment of civil money penalties, or any other administrative action. Rather, it serves as the basis for a contractor's review of a provider's or supplier's subsequent claim submissions.

Comment: Section 405.926(s) states that claim submissions on forms or formats that are incomplete, invalid, or do not otherwise meet the requirements for a Medicare claim and, as a result, are rejected or returned to the provider or supplier, do not constitute initial determinations. A commenter asked whether this section would preclude review where a claim is suspended for medical review.

Response: A claim suspended for development by a contractor's medical review staff is not considered a claim that is invalid or incomplete as described in § 405.926(s). Thus, § 405.926(s) would not preclude review where a claim is suspended for medical review because it does not apply to this situation. Rather, a claim that is suspended for development is one that appears technically sufficient on its face, but requires additional information in order to make a coverage and payment decision. At the time the claim is suspended for development, an initial determination has not been made, and thus, appeal rights have not attached to the claim. In addition, the medical review staff's decision to suspend a claim for development does not constitute an initial determination that would be subject to appeal. Generally, once the contractor makes a decision regarding coverage and payment and issues an initial determination in the form of a MSN or RA, parties to the initial determination have 120 calendar days to request a redetermination. However, if a contractor denies coverage and payment of a claim because the documentation requested during the medical review of the claim was not submitted within the specified timeframe, any subsequent submission of the requested documentation to the contractor, or any timely request for a redetermination of that claim will be processed under our reopenings policy at § 405.980(a)(2). If a revised determination is issued following the reopening of the claim, the revised initial determination carries with it appeal rights in accordance with § 405.984(a).

Accordingly, we are finalizing § 405.924 with modification as noted above. We are finalizing § 405.926 without modification.

c. Initial Determinations Subject to the Reopenings Process (§ 405.927) and the Effects of Initial Determinations (§ 405.928)

Section 405.927 states that minor errors or omissions in an initial determination must be corrected through the contractor's reopening process under § 405.980(a)(3). Section 405.928 describes the effects of an initial determination. We received no comments on these sections. Accordingly, we are finalizing § 405.927 and § 405.928 without modification.

5. Redeterminations (§ 405.940 Through § 405.958)

Sections 405.940 through 405.958 discuss the redetermination process. We received comments with respect to redetermination decision-making timeframes and other aspects of the redetermination process. A brief overview of the relevant regulatory provisions, a summary of the comments and our responses follow. Additional detailed discussion of the redetermination process is included in the interim final rule at 70 FR 11423, 11428, 11436 through 11443, and 11458.

a. Redetermination Requests (§ 405.940 Through § 405.946)

Section 405.940 establishes the general rule that a person or entity that may be a party to a redetermination under § 405.906(b) and that is dissatisfied with an initial determination may request a redetermination under subpart I. Sections 405.942 and 405.944 then set forth the requirements concerning the timeframes and procedures for filing a redetermination request. Section 405.946 describes the evidence that should be submitted with a redetermination request.

Comment: One commenter asked that we specify when a standardized redetermination request form will be available.

Response: A standardized Form 20027, revised May 1, 2005, is available to beneficiaries and other interested parties and can be used to request a redetermination. Customer service representatives at 1–800–MEDICARE can provide beneficiaries with information on how they may obtain standardized appeal forms. In addition, updated appeal forms will continue to be available on the Internet at *http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage* and *http://www.medicare.gov/Basics/forms/default.asp.* In addition, representatives at 1–800–MEDICARE can also provide information on how to obtain appeals forms.

Further, as noted previously, beneficiaries receive information on the appeals process and instructions for requesting a redetermination (first level appeal) as part of the MSN. Beneficiaries can use the MSN to request an appeal by circling the item or service with which they disagree, explaining why they disagree, signing the MSN, and returning it, or a copy, to the contractor address specified on the notice.

Comment: One commenter suggested that contractors and QICs send an acknowledgment letter to all affected parties to an appeal indicating receipt of the appeal request. Thus, a provider would know if a beneficiary has already appealed a claim denial. The commenter also requested that adjudicators assign a reference number to all appeals. The commenter suggested that the appeal case number not utilize a beneficiary's HIC number, in order to minimize confusion for provider appeals involving multiple beneficiaries.

Response: Due to the volume of redetermination and reconsideration requests, it is not feasible to require contractors or the QICs to send an acknowledgment letter to all parties for each appeal (although we note that QICs send acknowledgment letters to appellants indicating receipt of the request for reconsideration). While having more than one party file an appeal on a claim may appear to be duplicative, we believe it may be in the best interest of a party dissatisfied with the outcome of an initial determination or appeal decision to file an appeal request and submit relevant evidence with respect to the issues in the case because of the full and early presentation of evidence rule. Under this rule, as set forth in § 405.966(a)(2), a provider, supplier, or beneficiary represented by a provider or supplier that is a party to the reconsideration must submit all evidence prior to the issuance of the reconsideration. New evidence submitted at the ALJ hearing by a provider, supplier, or beneficiary represented by a provider or supplier will be excluded from consideration unless the ALJ finds good cause to explain why the evidence was not submitted prior to the issuance of the reconsideration. *See* § 405.1018(c) and § 405.1028. Thus, by filing an appeal, a party can make sure that the evidence it wants considered will not be excluded from consideration. The

contractor or QIC will then consolidate timely appeal requests from multiple parties into one proceeding, as required under § 405.944(c) and § 405.964(c), which will prevent possible disparate appeal decisions.

Every appeal request at each level of the appeals process receives a unique control number. This number is included on notices sent to parties. We acknowledge the commenter's concerns regarding the use of a beneficiary's HIC number as the appeal control number for ALJ hearings. In the past, certain ALJ hearings processed by the Social Security Administration used a beneficiary's HIC number. With the implementation of the new Medicare Appeals System (MAS) to control and track appeals at the QIC and ALJ levels, beneficiary HIC numbers are no longer used for assigning case numbers to an appeal. However, before a new case number has been assigned to an appeal request, beneficiary HIC numbers are helpful when making status inquiries with the QIC or an ALJ because these numbers can be used internally to identify the unique record for the appeal.

In this final regulation, we are making technical revisions to several sections that set forth the deadlines and timeframes that apply to various actions taken by parties, appellants and adjudicators. Throughout subpart I, we use the words ''day'', ''days'' and ''calendar days'' when referring to these timeframes and deadlines. Although we believe parties and potential participants to the appeals process and adjudicators understand these terms are used interchangeably, and that ''days'' means ''calendar days'' unless otherwise stated, we believe technical revisions are necessary to ensure that these terms are used consistently throughout subpart I and to clarify the timeframes and deadlines set forth in the rule. Further, we believe these revisions will reduce potential confusion about the specific date by which an action must be taken by a party or adjudicator.

Therefore, we are revising the following sections to insert the word ''calendar'' before the word ''day'' or ''days'': § 405.922, § 405.942(a)(1), § 405.942(b), § 405.946(b), § 405.950(b)(1), § 405.950(b)(2), § 405.950(b)(3), § 405.962(a)(1), § 405.962(a)(2), § 405.962(b), § 405.966(b), § 405.966(c), § 405.970(a)(2), § 405.970(b)(1), § 405.970(b)(2), § 405.970(b)(3), § 405.970(c), § 405.970(e)(2), § 405.974(b)(1), § 405.974(b)(1)(i), § 405.974(b)(1)(ii), § 405.980(d)(1), § 405.980(d)(2), § 405.980(d)(3), § 405.980(e)(1), § 405.980(e)(2), § 405.980(e)(3), § 405.990(f)(2), § 405.990(f)(4), § 405.990(h)(2), § 405.990(i)(2), § 405.990(j)(1), § 405.1002(a)(1), § 405.1002(a)(3), § 405.1002(a)(4), § 405.1002(b)(2), § 405.1004(a)(1), § 405.1004(a)(3), § 405.1004(a)(4), § 405.1006(e)(1)(ii), § 405.1010(b), § 405.1012(b), § 405.1014(b)(1), § 405.1014(b)(2), § 405.1016(a), § 405.1016(c), § 405.1018(a), § 405.1018(b), § 405.1020(g)(3)(ii), § 405.1022(a), § 405.1024(a), § 405.1028(a), § 405.1036(f)(5)(iv), § 405.1037(c)(5), § 405.1037(e)(2)(iii), § 405.1042(b)(2), § 405.1044(d), § 405.1046(d), § 405.1052(a)(2)(ii), § 405.1052(a)(2)(iii), § 405.1100(c), § 405.1100(d), § 405.1102(a)(1), § 405.1102(a)(2), § 405.1104(a)(2), § 405.1106(b), § 405.1110(a), § 405.1110(b)(2), § 405.1110(d), § 405.1118, § 405.1122(e)(4), § 405.1124(b), § 405.1126(d)(1), § 405.1130, § 405.1132(b), § 405.1136(c)(3), § 405.1136(d)(2), § 405.1140(b)(1), § 405.1140(c)(1), § 405.1140(c)(4), § 405.1140(d).

Finally, to further ensure that beneficiaries and others affected by the rule understand the various time frames and deadlines set forth in the rule, we note that where the regulations provide for a time frame and that time frame ends on a Saturday, Sunday, legal holiday, or any other Federal nonwork day, we apply a rollover period that extends the time frame within which an act must be done to the first day after the Saturday, Sunday, legal holiday, or other Federal nonwork day.

Accordingly, we are finalizing sections 405.940 and 405.944 without modification. We are finalizing sections 405.942 and 405.946 with modification as discussed in this section.

Per the discussion in this section, we also are finalizing the following sections to add the word ''calendar'' in front of the word ''day'' or ''days'': § 405.922, § 405.942(a)(1), § 405.942(b), § 405.946(b), § 405.950(b)(1), § 405.950(b)(2), § 405.950(b)(3), § 405.962(a)(1), § 405.962(a)(2), § 405.962(b), § 405.966(b), § 405.966(c), § 405.970(a)(2), § 405.970(b)(1), § 405.970(b)(2), § 405.970(b)(3), § 405.970(c), § 405.970(e)(2), § 405.974(b)(1), § 405.974(b)(1)(i), § 405.974(b)(1)(ii), § 405.980(d)(1), § 405.980(d)(2), § 405.980(d)(3), § 405.980(e)(1), § 405.980(e)(2), § 405.980(e)(3), § 405.990(f)(2), § 405.990(f)(4), § 405.990(h)(2), § 405.990(i)(2), § 405.990(j)(1), § 405.1002(a)(1), § 405.1002(a)(3), § 405.1002(a)(4), § 405.1002(b)(2), § 405.1004(a)(1), § 405.1004(a)(3), § 405.1004(a)(4), § 405.1006(e)(1)(ii), § 405.1010(b), § 405.1012(b), § 405.1014(b)(1), § 405.1014(b)(2), § 405.1016(a), § 405.1016(c), § 405.1018(a), § 405.1018(b), § 405.1020(g)(3)(ii), § 405.1022(a), § 405.1024(a), § 405.1028(a), § 405.1036(f)(5)(iv), § 405.1037(c)(5), § 405.1037(e)(2)(iii), § 405.1042(b)(2), § 405.1044(d), § 405.1046(d), § 405.1052(a)(2)(ii), § 405.1052(a)(2)(iii), § 405.1100(c), § 405.1100(d), § 405.1102(a)(1), § 405.1102(a)(2), § 405.1104(a)(2), § 405.1106(b), § 405.1110(a), § 405.1110(b)(2), § 405.1110(d), § 405.1118, § 405.1122(e)(4), § 405.1124(b), § 405.1126(d)(1), § 405.1130, § 405.1132(b), § 405.1136(c)(3), § 405.1136(d)(2), § 405.1140(b)(1), § 405.1140(c)(1), § 405.1140(c)(4), and § 405.1140(d).

b. Conduct and Effect of Redeterminations (§ 405.948 Through § 405.958)

Sections 405.948 and 405.950 describe basic procedures contractors follow in conducting redeterminations, including the adjudication timeframes for issuing redetermination notices and exceptions to the timeframes. Section 405.952 contains provisions relating to the withdrawal or dismissal of a request for a redetermination. Sections 405.954 and 405.956 address redetermination decisions and notification rules. Section 405.958 discusses the effect of a redetermination decision.

Comment: One commenter expressed concern that the rule does not provide a process for notifying an appellant of new issues being considered by a contractor during the redetermination. The commenter recommended that § 405.948 be amended to require contractor notification of the appellant about new issues, and to provide an opportunity for the appellant to respond to those issues.

Response: We understand the commenter's concern about ensuring appellants have an opportunity to respond to new issues raised by contractors during the redetermination process. Thus, appellants are strongly encouraged to submit all relevant evidence at the earliest point possible to support their assertion that the initial determination is incorrect. This works to enhance the efficiency and accuracy of the appeals process and enables adjudicators to make more informed decisions at the first level of the appeals process. Given the short timeframes for processing redeterminations and the high volume of requests, it is not feasible to require contractors to send formal notice of new issues raised during the redetermination process.

However, during the course of the redetermination, if a contractor determines that a new issue, distinct from the issues considered at the initial determination, warrants consideration, and the pertinent documentation necessary to make a decision on that issue is missing from the record, it is expected that the contractor will contact the appropriate entity to obtain the missing information prior to rendering its decision. In addition, the contractor's redetermination notice will contain a decision with respect to any new issues, and parties dissatisfied with the outcome may file a request for reconsideration.

Comment: One commenter objected to the provision that where two or more parties requested an appeal on the same initial determination, the contractor's deadline for processing the appeal would be based on the latest filed request (§ 405.950(b)(2)). The commenter argued that the first appellant was placed at a disadvantage in the decision-making timeframe. The commenter suggested that we stipulate in this final regulation that the decision-making timeframe starts with the first appeal request, extending the decision-making time by no more than 14 days from the original deadline, applicable only if a later party's appeal request contained new, relevant evidence.

Response: In sections 405.944(c), 405.950(b)(2), 405.964(c) and 405.970(b)(2) of the interim final rule, we require carriers, FIs, and QICs to consolidate multiple requests for a redetermination, or multiple requests for a reconsideration, into a single proceeding in order to avoid duplication and to issue one appeal decision within 60 days of the latest appeal request. This policy allows time for the adjudicator to carefully review and consider each of the appeal requests, including any additional evidence submitted with the requests. Instances when more than one party files a request for an appeal of the same claim have always been rare, and we do not expect any change in this regard. Therefore, we do not believe that consolidating the decision-making timeframe for appeals requested by multiple parties, such that the decision-making timeframe begins with the latest filed request, creates an impediment to the efficient resolution of appeals or places the first appellant at a disadvantage. To the contrary, we believe that when another party subsequently requests an appeal before a decision has been made on the original request, fairness and efficiency is enhanced by combining the two requests into one case and beginning the decision-making timeframe with the latest filed request to allow adequate time to review each request and the evidence submitted before a decision is made. Finally, we do not believe that extending the decision-making timeframe by no more than 14 days from the original deadline of the first appeal request received only if the later party's appeal request contained new, relevant evidence would allow for careful review and consideration of the appeals request.

Comment: We received several comments objecting to the extension of the decision-making timeframes at the redetermination and reconsideration levels to allow for the submission of new evidence (§ 405.950(b)(3), which incorporates § 405.946(b), for redeterminations, and § 405.970(b)(3), which incorporates § 405.966(b), for reconsiderations). Although most commenters recognized the need to ensure contractors have adequate time to review new evidence, those who objected to this provision believe that the unlimited and automatic extensions of the statutory decision-making timeframes by up to 14 days upon submission of new evidence are contrary to section 1869(a)(3)(C)(ii) of the Act for redeterminations and section 1869(c)(3)(C)(iv) of the Act for reconsiderations. One commenter added that the automatic extensions of the decision-making timeframes contradict the congressional intent behind the establishment of timeframes for lower-level reviews: To expedite the appeals process and avoid the huge backlogs that have plagued the system. Another commenter suggested that only those submissions of evidence initiated by a party should extend the decision-making timeframe, and that additional evidence submitted by a party in response to a request from the Medicare contractor should not result in an extension of the decision-making timeframe.

Response: As stated in the interim final rule, we continue to believe allowing extensions of decision-making timeframes under some circumstances is consistent with the statute. *See* 70 FR 11439, 11445 through 11446. Since the statute imposes decision-making timeframes with the assumption that at the time the appeal is filed, all relevant evidence will be submitted to the adjudicator, we believe extensions that result from late-submitted evidence are consistent with the statute. When an appellant submits new information after the appeal is filed, the adjudicator should not be penalized for an appellant's late submission of evidence. We also believe that appellants should be afforded some flexibility to supplement the administrative record if needed. Thus, the extensions of the decision-making timeframe in § 405.950(b)(3) and § 405.970(b)(3) balance the needs of the party with the needs of the adjudicator by allowing an appropriate timeframe within which the adjudicator can carefully consider additional evidence.

Further, we believe that contractors should be afforded up to an additional 14 calendar days to issue a redetermination decision when the contractor requests missing documentation from a party that is essential to resolving the issues on appeal. We believe the efficiency and cost-effectiveness of the appeals process is greatly enhanced by allowing this additional time to ensure an accurate decision is made at the lowest possible level. The only way to avoid the need for extended decision-making timeframes would be to preclude the submission of additional evidence by appellants after they file their redetermination requests. Although the contractor may extend the deadline when it receives additional evidence, this policy does not mean that in all cases we expect a contractor to take the maximum time to issue the decision.

Similarly, at the reconsideration level, the QIC's adjudication deadline is extended up to 14 days when a party submits additional evidence not included with the request for reconsideration. However, the extension does not apply to a party's timely submission of evidence in response to a request by a QIC (unless the contractor, in its redetermination notice, informed the party that (1) the documentation was missing from the administrative record, and (2) the documentation must be submitted with the request for reconsideration, and then the party failed to submit such documentation). *See* § 405.956(b)(6), § 405.966(b); 70 FR 11446. As noted above, we believe the adjudication timeframes presuppose a complete record for the adjudicator. Where evidence is missing from the record, and the party is on notice that the evidence must be submitted with the reconsideration request, we believe the extension of the adjudication timeframe is both necessary and consistent with the statute.

Finally, we do not expect an extension of up to 14 days will cause backlogs or significant delays in the appeals process. Rather, we believe this policy will encourage parties to submit evidence as soon as practicable. As stated previously, we urge appellants to submit all necessary documentation with their requests in order to avoid delays.

Comment: One commenter inquired about the process for handling redetermination requests from family members when a beneficiary is deceased. The commenter expressed concern about the ability of a surviving spouse or relative to provide proof of their status as the legally authorized representative of the decedent. The commenter related instances where the surviving family member attempting to pursue an appeal is unable to produce appropriate documentation to prove such status because there is no will or there are no assets to distribute by probate. The commenter stated that appeals should not be dismissed if requisite documents are not provided by surviving family members.

Response: We appreciate the concerns of the commenter regarding the difficulty surviving family members of a deceased beneficiary may have in securing proof of their authority to file an appeal on behalf of the decedent. We routinely require documentation of an individual's authority to file an appeal request on behalf of a party. In part, this is because the individually identifiable health care information that may be shared during the appeals process, including information with respect to a deceased person, cannot be disclosed unless the disclosure is authorized by law or authorized by the individual. In order to protect against an unauthorized disclosure, contractors must obtain documentation of the status of any person attempting to act on behalf of a deceased beneficiary by filing an appeal. For example, if the person attempting to file an appeal on behalf of a deceased beneficiary is authorized under State law to administer the estate, then the contractor must obtain documentation of the individual's authority (that is, as the executor or administrator of the estate) or information regarding the intestate provisions of the relevant State's probate law. Similarly, contractors determine whether an individual meets the requirements set forth in 42 CFR part 424, subpart E if the individual asserts they have assumed a legal obligation to pay for the services. Contractors are not prohibited from assisting individuals to obtain any necessary information. However, whether the beneficiary is living or deceased, absent timely filed evidence that the individual attempting to file an appeal has authority to do so, contractors must dismiss the redetermination request. *See* § 405.952(b)(1).

Comment: We received two comments concerning contractor notices to beneficiaries on appeal issues. One commenter agreed with our policy in § 405.956(a)(2) that contractors should issue written notice to only the appellants when an appeal concerns an overpayment involving multiple beneficiaries who have no financial liability. However, another commenter thought our policies with respect to beneficiary notification could deprive a beneficiary of his or her appeal rights. The commenter stated that when a fully favorable decision is issued to a non-beneficiary appellant, the beneficiary does not receive a copy of the redetermination notice. As a result, the 120 day period to request a redetermination may expire without the beneficiary knowing of the existing appeal. The commenter further noted that a decision that is fully favorable to a provider or supplier may not be fully favorable to the beneficiary. The commenter questioned whether a beneficiary still has appeal rights if the redetermination is not favorable for the beneficiary and what process follows if the evidence submitted by the beneficiary and provider conflict.

Response: We do not believe a beneficiary would be deprived of any appeal rights in the scenario described by the commenter. In the case of a redetermination that is fully favorable (that is, fully reverses a denial of coverage or payment on the initial determination), parties will receive a redetermination notice, MSN, or RA, as applicable. *See* § 405.956(a)(1); Internet Only Manual (IOM) Pub. 100–4, Ch. 29, section 310.5. The MSN and RA will reflect any adjustment made to the claim, including a shift in the financial liability from a provider to a beneficiary, and will contain information regarding further appeal rights.

With respect to the commenter's concern about the subsequent appeal rights of a beneficiary when another party has requested a redetermination, a beneficiary's right to appeal does not depend on his or her status as an appellant at previous levels in the appeals process. Beneficiaries may request a subsequent appeal even if they did not initiate prior appeals (unless they have formally assigned their appeal rights to a provider or supplier and have not revoked the assignment). In the scenario presented by the commenter, if a redetermination request is timely filed by a second party before the redetermination decision is issued, the contractor will consolidate the multiple redetermination requests consistent with § 405.944(c). If a redetermination request from another party is received by the contractor after the redetermination decision is issued, the contractor would treat the redetermination request as misfiled, and would forward the request to the QIC. *See* CMS IOM, Publication 100–4, Chapter 29, Section 320.1.B at (*http://www.cms.hhs.gov/manuals/downloads/clm104c29.pdf*). Finally, in situations where evidence submitted during an appeal conflicts with other evidence in the administrative record, the adjudicator, as an arbiter of fact, is responsible for examining all of the evidence submitted, and making appropriate findings of fact with respect to such evidence.

In this final regulation, we are making technical revisions to several sections that describe the nature and effect of the determinations, decisions, and other actions issued by adjudicators. In subpart I, we refer to these actions as ''final'', ''final and binding'' and ''binding''. Although we believe parties to the appeals process understand the meaning of these terms, we believe technical revisions are necessary so that these terms are used consistently throughout subpart I. These revisions will reduce potential confusion regarding the effect of a determination or decision issued by an adjudicator.

We believe referring to certain decisions or actions as ''final'' or ''final and binding'' may create confusion as to whether the adjudicator's action or decision constitutes a final decision of the Secretary for which judicial review may be sought under section 205(g) of the Act. As described in § 405.1132 and § 405.1136(a), to the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, judicial review is available to a party to a MAC decision, or to an appellant who requests escalation to Federal district court if the MAC does not complete its review of the ALJ's decision (other than MAC review of an ALJ dismissal) within the applicable adjudication period. In addition, judicial review is available when a review entity certifies that a party has met the expedited access to judicial review (EAJR) requirements, or, under § 405.990(f)(4), when the review entity fails to make such certification within the applicable timeframe specified in § 405.990(f)(2). *See* section 1869(b)(2) of the Act; § 405.990. Judicial review is also available under § 405.1140(a) when a Federal district court remands a case for further consideration, the MAC subsequently remands the case to an ALJ, and the ALJ issues a decision that becomes the final decision of the Secretary. We are reserving the term ''final'' to describe those actions or decisions for which judicial review may be immediately sought. Thus, we believe these technical revisions will ensure that parties will be

able to understand when judicial review is available.

When we state that an action or decision is ''binding'' on parties, we mean that the parties are obligated to abide by the adjudicator's action or decision, unless further recourse to challenge the action or decision is available, and a party exercises that right (for example, obtaining a decision at the next level of appeal, or having the adjudicator reopen and vacate the decision or action). When a party may take further action on an adjudicator's action or decision, we specify those actions that may be taken. If a party chooses not to take further action, or further recourse is unavailable to parties, then the adjudicator's decision is binding on the parties, and is final in the sense that no further review of the decision is available.

In summary, when we use the term ''final'' in the regulation text, we mean those actions or decisions for which judicial review may be immediately sought. When we use the term ''binding'' in the regulation text, we mean that the parties are obligated to abide by the adjudicator's action or decision, unless further recourse to challenge the action or decision is available, and a party exercises that right. As such, a final decision of the Secretary is always a binding decision. However, a binding decision may not be a final decision of the Secretary for the purposes of exhausting administrative remedies when seeking judicial review.

We also are making related technical revisions to several sections that describe the decisions or actions issued by adjudicators. In several instances we use the term ''final action'' or ''final decision'' to describe the actions taken or the decisions issued by a QIC, an ALJ, and the MAC. We believe that the meaning of these terms may, at times, be confusing since some of these ''final actions'' or ''final decisions'' may not be final as discussed above. We also believe describing the specific actions that an adjudicator may take, rather than using a generic phrase, such as final action, adds clarity and assists parties in understanding both the effect of a specific action issued by an adjudicator, and when judicial review may be available. Therefore, where we use the terms ''final action'' or ''final decision'', we are making technical revisions to replace those terms, as appropriate, with the specific determinations, decisions or actions that the adjudicator may take. For example, we are revising § 405.1136(a)(2) to remove the phrase ''final action'' and replace it with the phrase ''final decision, dismissal order, or remand order''.

Furthermore, we are making similar technical revisions to § 405.990(b)(1)(i)(A) to replace the term ''final decision'' with the specific actions that, if taken by an ALJ, will preclude a party from seeking EAJR in place of an ALJ hearing, and to § 405.990(b)(1)(i)(B) by adding dismissal orders and remand orders to the description of the actions that, if taken by the MAC, will preclude a party from seeking EAJR in place of MAC review. We believe that the use of the word ''decision'' alone in these subsections does not clearly convey the specific actions of the ALJ or MAC that will preclude a party from seeking EAJR, and thus we believe it is necessary to clearly articulate which actions could preclude such a request. Therefore, we are making the following technical revisions, consistent with the discussion above:

We are revising the following sections to remove the terms ''final'' and ''final and binding'' and replace them with the term ''binding'': § 405.952(e), § 405.958, § 405.972(e), § 405.974(b)(3), § 405.978, § 405.980(a)(1), § 405.980(a)(5), § 405.1004(c) and § 405.1052(a)(6).

We are revising § 405.990(b)(1)(i)(A) to remove the phrase ''final decision'' and replace it with the phrase ''decision, dismissal order, or remand order''.

We are revising § 405.990(b)(1)(i)(B) to add the phrase ''dismissal order, or remand order'' after ''final decision''.

We are revising § 405.990(b)(1)(ii) to remove the term ''final action'' and replace it with the phrase ''decision or dismissal order''.

We are revising § 405.990(f)(3) to remove the words ''final and''.

We are revising § 405.1002(b)(2) and § 405.1112(a) to remove the phrase ''final action'' with replace it with the phrase ''decision or dismissal order''.

We are revising § 405.1046(c) to remove the word ''final'' and replace it with the phrase ''binding on the contractor''.

We are revising § 405.1048(a) to remove the phrase ''either issues a final action'' and replace it with the phrase ''issues a final decision or remand order''.

We are revising § 405.1100(c) and (d) to remove the phrase ''final action'' and replace it with the phrase ''final decision or dismissal order''.

We are revising § 405.1104(a)(2) to remove the phrase ''final action or remand the case to the QIC'', § 405.1104(b)(1) to remove the phrase ''final action or remand'', § 405.1104(b)(2) to remove the phrase ''final action or remand order'', and § 405.1104(c) to remove the phrase ''final action'' and replace them with the phrase ''decision, dismissal order, or remand order''.

We are revising § 405.1104(b)(3) to remove the phrase ''a final administrative decision for purposes of MAC review'' and replace it with the phrase ''the decision that is subject to MAC review consistent with 405.1102(a)''.

We are revising § 405.1106(b) to remove the phrase ''final action or remand the case to the ALJ'', § 405.1132(b) to remove the phrase ''final action or remand'', and § 405.1136(a)(2) to remove the phrase ''final action'' and replace them with the phrase ''final decision, dismissal order, or remand order''.

We are revising § 405.1110(d) to remove the phrase ''remains the final action in the case'' and replace it with the phrase ''is binding on the parties to the ALJ decision.''

We are revising § 405.1126(a) to remove the word ''final''.

We are revising § 405.1130 to add the words ''final and'' before the word ''binding''.

Accordingly, we are finalizing § 405.948, § 405.954, and § 405.956 without modification. We are finalizing § 405.950 with modification as discussed in section II.B.5.a. of this preamble. We are finalizing § 405.952, § 405.958, § 405.972, § 405.974, § 405.978, § 405.980, § 405.984, § 405.990, § 405.1002, § 405.1004, § 405.1046, § 405.1048, § 405.1052, § 405.1100, § 405.1104, § 405.1106, § 405.1110, § 405.1112, § 405.1126, § 405.1130, § 405.1132, and § 405.1136 with modifications, as noted.

6. Reconsiderations (§ 405.960 Through § 405.978)

Sections 405.960 through 405.978 address the reconsideration process. We discuss specific sections and summarize and respond to comments on the reconsideration process below. Additional detailed discussion of the reconsideration process is included in the interim final rule at 70 FR 11423, 11428, 11440, 11441, and 11443 through 11450.

Comment: One commenter suggested that we establish for chain providers an exception to the standard rule requiring reconsiderations to be performed by the QIC for the State in which the service was rendered. In appeals involving providers that have elected a single FI, the commenter recommended that providers have the option of having appeals processed by the QIC for the State in which the provider's home office is located or the State in which the service was rendered.

Response: In determining the workload distribution for appeals among the Part A QICs, CMS issued instructions requiring that, for chain providers that have elected to have their claims processed by a single FI, any related reconsiderations will be processed by the QIC with jurisdiction over the State where the FI is located. Since there are no in-person reconsiderations, we believe it is unnecessary to adjust the jurisdictions to accommodate home office locations. The one exception to this general rule applies to claims currently processed by one of our contractors. Because this contractor processes claims in all 50 States, it would be too burdensome to require one QIC to process all the reconsiderations for those claims. Thus, we determined it was necessary to split that workload among the Part A QICs based on the State in which the service is rendered.

a. Processing Reconsideration Requests (§ 405.960 Through § 405.964)

Section 405.960 states that any person or entity that is a party to a redetermination and is dissatisfied with that determination, may request a reconsideration of the redetermination by a QIC. Section 405.962 specifies that appellants who wish to file a request for reconsideration must do so within 180 calendar days of the date on which the party receives the notice of the redetermination, or within such additional time as CMS may allow. In § 405.964, we set forth the place and method for filing requests for reconsideration.

We received no comments on these sections; however, in this regulation, we are making a technical revision to § 405.962(a). Section 405.962(a) states that requests for reconsideration of a contractor's redetermination must be filed within 180 calendar days from the date the party receives notice of the redetermination, unless the QIC extends the timeframe upon a showing of good cause for the late filing consistent with § 405.962(b). We inadvertently omitted a reference to the different filing timeframe applicable to requests for QIC reconsideration of a contractor's dismissal of a request for redetermination under § 405.974(b). In § 405.974(b)(1), we specify that a party must file the written request for reconsideration of a contractor's dismissal action with the QIC within 60 days after receipt of the contractor's notice of dismissal. While the reconsideration of a dismissal action under § 405.974(b) differs from the reconsideration of a redetermination under § 405.974(a) (for example, a QIC's reconsideration of a dismissal action is not subject to further review under § 405.974(b)(3)), for clarity, we are amending § 405.962(a) to include the reference to the timeframe applicable to requests for QIC reconsideration of contractor dismissals.

Accordingly, we are finalizing § 405.960 and § 405.964 without modification. We are finalizing § 405.962 with modification as noted above, and as discussed in section II.B.5.a. of this preamble.

b. Evidence Submitted With the Reconsideration Request—Full and Early Presentation of Evidence (§ 405.966)

Section 405.966(a) specifies that a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination when filing a request for reconsideration. Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination, prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence. Section 405.966(b) explains that submissions of evidence that do not accompany the request for reconsideration extend the QIC's 60-day decision-making timeframe up to 14 calendar days for each submission. Section 405.966(c) establishes an exception to the full and early presentation of evidence requirement, and permits Medicaid State agencies and beneficiaries, other than those represented by providers or suppliers, to submit additional new evidence after the reconsideration level without establishing good cause for the delayed submission.

Comment: We received many comments concerning the provision that requires a provider or supplier to submit all evidence prior to the QIC reconsideration decision being rendered, unless there is good cause for submitting the evidence later. In general, most commenters were in favor of expediting the appeals process and recognized the value of early evidence submission. However, some commenters argued that this provision was too burdensome for providers, suppliers, and beneficiaries, particularly when they do not have easy access to supporting documentation that may be required, or may not know until after the QIC decision that additional evidence may be necessary or useful. Several commenters requested that CMS include in the regulations a specific list of items, documents or circumstances that constitute good cause for late submission of evidence. Some commenters objected to the limitations completely. One commenter stated that evidence submission should be allowed at any stage of the appeals process, as long as the evidence proved relevant and there was no prejudice to permitting its submission.

Response: The requirement in § 405.966 for the early presentation of evidence by providers and suppliers is based on the statutory requirement contained in section 1869(b)(3) of the Act, as added by section 933(a) of the MMA, which states that a provider or supplier may not, in any subsequent level of appeal, introduce evidence that was not presented at the reconsideration conducted by the QIC, unless there is good cause that precluded the introduction of that evidence at or before the reconsideration. Section 405.966(c)(2) extends the full and early presentation of evidence requirement to beneficiaries represented by providers or suppliers. We recognize that absent advance notice of what documents are needed to support a claim, appellants may have difficulty determining what constitutes relevant evidence for their claim appeals. Thus, § 405.956(b)(6) requires contractor redetermination notices to identify ''specific missing documentation.'' We believe this provision helps appellants, since it should enable appellants to better understand the basis for the unfavorable redetermination and understand the information missing from the record. Ultimately, we believe this can result in a better developed record at the reconsideration level, and will allow the QIC to make more fully informed reconsideration decisions. We do not believe that it is either practical or consistent with the statute to limit the requirement for full and early presentation of evidence by attempting to distinguish categorically between evidence that is readily available to the provider, supplier, or beneficiary and that which is obtained from entities not directly involved in the claim dispute. Limiting the requirement for full and early presentation of evidence to objective medical information would be equally problematic. Given the vast amount of medical services and items that could be involved in a claim dispute, it would be extremely difficult to draw clear distinctions among the numerous types of documentation that might be needed. Nevertheless, where it is not feasible to obtain this documentation prior to issuance of the reconsideration, as indicated in § 405.1028, an ALJ will make a determination on whether good cause

for failure to submit the evidence to the QIC exists. This applies to all documentation, including any items listed in the notice of redetermination.

Finally, § 405.966(c) states that the limitation on the presentation of new evidence does not apply to beneficiary appellants unless they are represented by a provider or supplier or to Medicaid State agencies. Therefore, although contractor redetermination notices will uniformly identify any necessary missing documentation, beneficiaries, except those represented by providers or suppliers, and Medicaid State agencies will still be permitted to introduce evidence after the QIC reconsideration level (although for efficiency reasons, they would be better served by doing so as soon as possible).

We are finalizing § 405.966 with modification as discussed in section II.B.5.a. of this preamble.

c. Conduct and Processing of Reconsiderations (§ 405.968 Through § 405.978)

In § 405.968, we describe the manner in which QICs conduct reconsiderations. In § 405.970, we set forth the timeframes for issuing reconsideration notices. In § 405.972, we explain the process by which a QIC may dismiss, or a party may withdraw, a request for reconsideration. Section 405.974 describes the reconsideration by a QIC of a contractor's determination and a contractor's dismissal of a redetermination request. Section 405.976 discusses the notice requirements for QIC reconsiderations. Finally, § 405.978 explains the effect of a reconsideration.

Comment: Several commenters opposed the elimination of the Part B fair hearing. These commenters believe that appellants will be deprived of an important opportunity to provide adjudicators with clarifications and additional information not contained in the record, and that adjudicators will not have an opportunity to personally assess a beneficiary's physical or mental condition. The commenters suggested that having an in-person hearing at the second level of appeal would reduce the number of cases appealed to the ALJ level, thus speeding up reimbursement to providers and reducing administrative costs. One commenter requested that QICs be encouraged to contact beneficiaries, providers and suppliers with questions or to request input to obtain all relevant evidence.

Response: We continue to believe that providing for an on-the-record review at the QIC level of appeal, rather than an in-person hearing, is consistent with both BIPA and the MMA. Although it certainly could have, the Congress did not provide for hearings by the QICs. Instead, under section 1869(c)(3)(B)(i) of the Act, Congress required QICs to ''review'' initial determinations. In contrast, under section 1869(d)(1) of the Act, the statute specifically provides for a ''hearing'' at the ALJ level. Furthermore, Congress also significantly reduced the decision-making timeframes at all levels of the appeals process. As discussed in the interim final rule, the significantly shortened decision-making timeframes result in appellants receiving a hearing before an ALJ generally within the same timeframe they would have received a ''fair hearing'' under the previous Part B appeals process. *See* 70 FR 11448. Finally, the regulatory provisions at § 405.968(a)(1) regarding QIC reconsiderations continue to allow QICs to contact appellants and obtain any necessary information by phone, or other means.

Comment: One commenter expressed concern that the regulation does not define ''medical record'', nor does it address specific items and services that require physician completion of a Certificate of Medical Necessity (CMN). The commenter suggested that we clarify that the CMN is a medical record and that Congress established the CMN to enable physicians to demonstrate medical necessity.

Response: We do not agree with the commenter's suggestion that it is necessary to define the term ''medical record'' in this regulation. The purpose of this regulation is to implement the changes made to the Medicare claims appeals process as required by BIPA and the MMA. The term ''medical record'' is not a term of art that requires a definition in this regulation, and neither BIPA nor the MMA attach special significance to the term with respect to the claims appeals process. Further, we do not believe it is appropriate to include information related to the completion of the CMN in this regulation. Policies that relate to the completion of the CMN are outside of the scope of this regulation.

Nevertheless, we disagree with the commenter's assertion that completion of the CMN demonstrates definitively that an item or service is medically reasonable and necessary for diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member under section 1862(a)(1)(A) of the Act. CMS' longstanding policy has been that even where a CMN has been provided, contractors may request supporting medical documentation to demonstrate the ''medical necessity'' of items or services. This policy was affirmed in *Gulfcoast Medical Supply, Inc.* v. *Sec'y, Health and Human Servs.,* 468 F.3d 1347 (11th Cir. 2006) and *MacKenzie Medical Supply, Inc* v. *Leavitt* 506 F.3d 341 (4th Cir. 2007). In *Gulfcoast,* the Circuit Court stated that the Medicare statute ''unambiguously permits carriers and the Secretary to require suppliers to submit evidence of medical necessity beyond a CMN.'' In *MacKenzie,* the Circuit Court found that Congress did not unambiguously mandate that the CMN is the only document that can be required of a supplier to show medical necessity.

Comment: We received many comments on § 405.968(b)(2), which requires QICs to give substantial deference to a local coverage determination (LCD), local medical review policy (LMRP), and CMS program guidance, unless the QIC determines, either at a party's request or at its own discretion that the policy does not apply to the facts of the particular case in which case the QIC may decline to follow the policy. Commenters raised many of the same concerns voiced by commenters to the proposed rule. They believe that CMS exceeded its statutory authority by specifying that QICs are bound by LCDs and LMRPs and questioned the propriety of requiring QICs to give deference to policies that they allege sometimes contradict statutes and regulations, are against the intent of BIPA, and are not promulgated through notice and comment rulemaking. These commenters suggested that deference to these coverage policies should be eliminated to preserve fairness and due process. They also noted that QICs are required to have extensive medical, legal, and Medicare program knowledge and so would be well equipped to make decisions without deferring to these policies.

Response: We continue to believe that it is both appropriate and consistent with the statutory intent of BIPA, which added section 1869(c)(3)(B)(ii)(II) of the Act to require QICs to consider LCDs in making their decisions, to require QICs to give substantial deference to LCDs and LMRPs and other CMS program guidance in the appeals they adjudicate if these policies are applicable to a specific case. *See* § 405.968(b)(2). As noted in the proposed rule, the use of consistent review criteria will serve several important purposes, including the identification of recurrent problems with CMS policies, fostering consistency in appeal decisions, and potentially reducing both ALJ appeals volume and the ALJ reversal rate. *See* 67 FR 69312, 69325 and 69328. In addition,

as explained in the interim final rule, Federal courts have considered and applied deference standards in considering the validity of various Medicare policies and have also recognized that ALJs and the MAC properly consider issues relating to deference as well. *See Abiona* v. *Thompson,* 237 F.Supp.2d 258 (E.D.N.Y. 2002), and 70 FR 11458.

We note that section 522 of BIPA provides an explicit process for contesting LCDs. However, we agree with the commenters' assertion that QICs should be able to evaluate whether a particular coverage policy applies in a specific appeal. In response to similar comments on the proposed rule, in the interim final rule, we revised § 405.968(b)(2) to allow QICs to decline to follow an LMRP, LCD or other CMS program guidance either at the request of a party or at its own discretion if a QIC determines that the policy does not apply to the facts of the particular case. However, we also believe that it is necessary to ensure that the QICs, like other appeals adjudicators, give the contractors' coverage policies substantial deference if they are applicable to a particular case. Thus, we require QICs to give substantial deference to LMRPs, LCDs and other CMS program guidance, unless the QIC finds that the policy is not applicable in a particular case. This policy acknowledges the extensive medical expertise and program knowledge within each QIC, and strikes a balance between the need to preserve QIC independence and the need to apply consistent review criteria and to ensure that the established coverage policies are given appropriate consideration.

Comment: One commenter inquired about the QIC's ability to raise or develop new issues. The commenter did not understand how a new issue could develop if the contractor had rendered a redetermination with respect to the claim. The commenter requested that we modify the language of § 405.968(b)(5) to be consistent with other regulatory provisions that reference raising new issues.

Response: A reconsideration is a new and independent review of an initial determination, and we believe adjudicators at the reconsideration level should be permitted to raise and develop any issues that they believe are relevant to the claim(s) in the case at hand. For example, if a claim was denied initially as not medically reasonable and necessary because medical records were not submitted to the carrier as requested, and during the reconsideration, the review of the medical records accompanying the appeal request shows that the services would be excluded for a different reason or under a different statutory authority, the QIC should be permitted to explore the new issues. Furthermore, we note that the policy with regard to raising new issues at § 405.968(b)(5) is consistent with the policy with regard to raising new issues as part of the redetermination in § 405.948. Accordingly, we are not modifying the language in § 405.968(b)(5).

Comment: A number of commenters asked that the final rule include more explicit information about the QICs. In particular, commenters wanted the final rule to identify the minimum qualifications for the QIC panel members and reviewers, clearly define the role of the QIC panel in the reconsideration process, and describe the on-going training that would be made available to the panel members and reviewers. Several commenters recommended that the regulations list specific physician or healthcare specialties that would be included on the QIC panel. Commenters also asked that the final rule spell out the provisions that would be put in place to ensure the QICs' independence. One commenter supported some type of sanction for QICs that failed to issue timely decisions under § 405.970. Finally, a commenter stated that if the QIC's decision contradicts the treating physician's judgment, such as determining an item or service is not medically necessary, despite a physician's certification on a CMN, then the appeals decision should outline circumstances that would justify this finding.

Response: As noted in the interim final rule (70 FR 11449), the requirements for QIC reviewers and the physicians who serve as panel members are contained in section 933 of the MMA and section 521 of BIPA. Specifically, section 1869(c), (e)(3), and (g) of the Act contain provisions regarding the independence of the QICs, qualification requirements for QICs, the role of the QIC panel, and continuing education for QICs with respect to Medicare coverage of items and services. Thus, we do not believe it is appropriate or necessary to address these issues, or the specific physician or health care specialties that would be included on the QIC panel, in any further detail in these regulations. Instead, through the QIC contracting and evaluation processes, we ensure that the QICs are fully compliant with these statutory requirements, including the appropriateness of the members of QIC panels. In fact, we have already taken action to replace a QIC that was having difficulty meeting the performance standards imposed by the statute.

In addition, although we are committed to ensuring that QICs are meeting the statutory decision-making timeframes, we note that Congress has already provided a remedy for those cases in which a QIC fails to issue a timely decision. In section 1869(c)(3)(C)(iii) of the Act and in § 405.970(c), appellants who do not receive a reconsideration within the applicable decision-making timeframe have the right to escalate the appeal to an ALJ. Therefore, we do not believe that the regulations should contain provisions sanctioning QICs for not meeting the applicable decision-making timeframes.

Finally, in the event a QIC's decision contradicts the treating physician's medical judgment, such as determining that an item or service is not medically necessary, we note that § 405.976(b) requires that the notice of reconsideration include a rationale for the decision.

In this final regulation, we are also making a technical revision to § 405.972(b)(3) (discussed below), and further technical revisions to § 405.972(e) and § 405.1004(c) (*see* section II.B.5.b. of this preamble for a discussion of our prior revision). In § 405.972, we explain the process by which a QIC may dismiss, or a party may withdraw, a request for reconsideration. We are revising § 405.972(e) to clarify that when a QIC dismisses a request for review of a contractor's dismissal action, the dismissal is binding and not subject to further review. Similarly, we are revising § 405.1004(c) to clarify that an ALJ's dismissal of a request for review of a QIC's dismissal action is binding and not subject to further review.

In § 405.974(b)(1) and § 405.1004(a), we offer parties an opportunity to appeal a dismissal action to the next adjudicative level and, under § 405.974(b)(3) and § 405.1004(c), the decision of the adjudicator at that subsequent level with respect to the dismissal action is binding and not subject to further review. *See* 70 FR 11444. We did not, however, intend to permit additional opportunities for review of dismissals where the request for review of a dismissal is invalid and thus, subject to dismissal. For example, a contractor dismisses a request for a redetermination. The party then requests that the QIC review the dismissal but the party, without having good cause, does not file this request with the QIC in a timely fashion. In this scenario, the QIC would dismiss the

request for reconsideration of the contractor's dismissal and the party would not be entitled to ALJ review of the QIC's decision.

In allowing review of dismissals at the next adjudicative level, we balance a party's need for review and the need for administrative finality. If a party does not file a valid request for review for a second time, we believe the need for finality in the administrative process outweighs the need for further review. Thus, a QIC's dismissal of a request for review of a contractor's dismissal action, and an ALJ's dismissal of a request for review of a QIC's dismissal are not subject to further review. However, while a party may not request further review in the administrative appeals process when an adjudicator dismisses a request for review of a dismissal, we note that a party may still request the dismissal be vacated consistent with the provisions of § 405.952(d), § 405.972(d), § 405.1054, and § 405.1108(b).

In addition, we are making a technical revision to § 405.972(b)(3). In § 405.972(b)(3), when describing the authority of the QIC to dismiss an untimely filed request for reconsideration, we inadvertently omitted the cross-reference to requests for QIC review of a contractor's dismissal of a redetermination request. The timeframes for filing such requests, which differ from the timeframes for filing a request for reconsideration of a contractor's redetermination decision, are found in § 405.974(b)(1). For clarity, we are amending § 405.972(b)(3) to reference the separate timeframes applicable to appeals of contractor dismissal actions at the redetermination level.

In summary, we are amending § 405.972(b)(3) to include a reference to the timeframe for filing a request for QIC review of a contractor dismissal action, and we are amending § 405.972(e) and § 405.1004(c) to clarify that a QIC's dismissal of a request for a reconsideration of a contractor's dismissal of a request for redetermination, and an ALJ's dismissal of a request for review of a QIC's dismissal of a request for reconsideration is binding and not subject to further review.

Accordingly, we are finalizing §§ 405.968 and 405.976 without modification. We are finalizing §§ 405.970 and 405.974 with modification as discussed in section II.B.5.a. of this preamble. We are finalizing §§ 405.972 and 405.1004 with modifications as noted above, and §§ 405.972, 405.974 and 405.978 with modification as discussed in section II.B.5.b. of this preamble.

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

Sections 405.980 through 405.986 set forth the requirements regarding the reopenings process, including how parties may request reopenings of determinations and decisions, and how contractors, QICs, ALJs, and the MAC will conduct reopenings.

We received several comments with respect to the reopening provisions as set forth in the interim final rule. A summary of the comments and our responses are included below. Additional detailed discussion of the reopening process is included in the interim final rule at 70 FR 11423, 11435, 11447, 11450 through 11453, and 11458.

a. Reopening Actions (§ 405.980)

Section 405.980 describes the general rules for reopening initial determinations, redeterminations, reconsiderations, hearing decisions and MAC review decisions.

Comment: One commenter recommended that CMS create enforcement provisions for the ''good cause'' standard when contractors reopen claims. The commenter believed that contractors often ignore the guidelines set out in regulations and manuals, and recommended that the good cause standard be enforced to ensure fairness and finality for Medicare providers and suppliers.

Response: Contractors are required to follow Federal laws, regulations and manual instructions in their business operations. As noted in the interim final rule in response to a similar comment on the proposed rule (70 FR 11453), our regulations require that contractors abide by the good cause standard for reopening actions as set forth in § 405.980(b) and § 405.986. CMS conducts audits and evaluations of contractor performance in order to assess compliance with Medicare policies. Thus, the necessary monitoring and enforcement mechanisms are already in place and we do not believe it is necessary to add enforcement provisions to these regulations.

Comment: One commenter believed that CMS Change Request 3622 does not comport with § 405.927 and § 405.980(a)(3) with respect to the distinction between claim reopenings and appeals of initial determinations. The commenter stated that the reopening provisions indicate that adjustments resulting from clerical errors are to be processed as reopenings. However, CMS instructions in Change Request 3622, implemented July 5, 2005, state that the Medicare Carrier System (MCS) will deny claims resubmitted with new information (such as diagnosis codes), requiring the provider or supplier to submit an appeal.

Response: Since the publication of the interim final rule, we have issued instructions to carriers to suspend implementation of Change Request 3622. *See http://www.cms.hhs.gov/transmittals/downloads/R104PI.pdf* modified by JSM–05385, dated 06–20–2005. CMS is re-evaluating the duplicate edit policies to determine how best to address the subsequent re-submission of claims in light of the reopening policies and will take into consideration the concerns raised by the commenter.

As noted by the commenter and as discussed in the preamble to the interim final rule, in accordance with § 405.980(a)(3)(iii), contractors will process disputes involving resubmitted claims denied as duplicates through the reopening process. *See* 70 FR 11451. Generally, providers and suppliers should avoid resubmitting claims for previously denied items or services (this does not apply to providers who submit claim adjustments for returned claims). Unless a claim is denied as the result of a clerical error, when a denied claim carries with it appeal rights, providers and suppliers should file appeal requests to dispute the determination that denies items or services on the claim. However, if a provider or supplier decides to resubmit a claim for items or services previously submitted to Medicare, the appeals rights for those items or services flow from the original claim submission and not the subsequent claim submission. Resubmissions of claims for the same items or services do not extend the appeal rights available to a party. Thus, we have instructed contractors to process appeal requests for claims denied as duplicates as reopenings, and the sole issue to be resolved is whether the claim is in fact a duplicate of a previous submission. All other issues not considered clerical errors (that is, coverage and payment issues) must be resolved through an appeal of the first claim. If an appeal is pending on the original submission of the item or service, then the contractor will not process the reopening on the resubmitted claim. To do otherwise could result in duplicate payment for the items or services.

Comment: One commenter expressed concern that a party cannot seek review of a determination not to grant a request for reopening. *See* § 405.926(l),

§ 405.980(a)(5). The commenter argued that not allowing an appeal in this situation places too much authority in the hands of the persons making decisions regarding reopenings.

Response: As noted in our response to a similar comment in the interim final rule, it has been a longstanding principle that failure to grant a request for reopening is not reviewable. *See* 70 FR 11453. The Supreme Court has upheld this concept. *See Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. 449 (1999); *Califano* v. *Sanders,* 430 U.S. 99 (1977). This policy does not violate a party's due process rights, because the administrative appeals process for Medicare claims already affords ample opportunities for a party to challenge claim determinations. The reopenings process simply offers, but does not guarantee, an additional process if a party believes an error on a claim should be corrected, but the party has exhausted his or her appeal rights, or the error is one that should not be resolved through the appeals process. *See* § 405.927.

In § 405.980(a)(3), we indicate that a contractor must refuse to process a reopening request when it disagrees that the dispute involves a clerical error and must ''dismiss'' the reopening request and advise the party of any appeal rights, provided the timeframe to request an appeal has not expired. The use of the term ''dismiss'' in connection with a reopening request does not confer any right to obtain further review of a decision on a reopening request. *See* § 405.926(l) and § 405.980(a)(5).

Comment: Several commenters stated that the definition of ''similar fault'' in § 405.902 is too broad and allows contractors to reopen almost any claim, for any reason and that it requires providers and suppliers to maintain supporting billing records for an indefinite time period, at considerable expense. One commenter cited a difference between the definition of ''similar fault'' in the interim final rule compared to the Medicare Claims Processing Manual, Chapter 29, Appeals of Claims Decisions, section 90.9 Unrestricted Reopenings, and urged CMS to follow the policy as stated in the claims processing manual.

Response: The definition of ''similar fault'' contained in § 405.902 covers situations in which a contractor identifies an inappropriate billing that does not rise to the level of fraud. The definition covers situations where Medicare payment is obtained by an individual or entity with no legal right to the funds, the contractor determines that the individual or entity knows or could reasonably be expected to know that the claims for items or services should not have been paid, and there is no determination by law enforcement that the payment was obtained through an act of fraud. The similar fault provision is appropriately used where fraudulent behavior is suspected, but law enforcement is not proceeding with recovery on the basis of fraud.

With respect to the commenter's concern about indefinite storage of records, we do not believe this regulation will significantly impact providers and suppliers for several reasons. First, it is a longstanding policy in the Medicare program that a claim may be reopened at any time if it was procured by fraud or similar fault. Thus, this regulation does not impose a new burden on providers or suppliers. *See* § 405.750(b)(3)(ii) and § 405.841(c)(1). In addition, State law and Federal conditions of participation have longstanding requirements for the retention of records. Finally, providers and suppliers who submit claims that are in compliance with Medicare program requirements, and do not accept payment for claims which they know, or should reasonably be expected to know, they are not otherwise entitled, will not have claims reopened for fraud or similar fault. Thus, we believe the fraud or similar fault provisions in this regulation will not have a significant impact on providers and suppliers.

In § 405.902 of the interim final rule, we codified the definition of ''similar fault'' for the purposes of reopening initial determinations and appeal decisions. This definition supersedes the definition previously found in our claims processing manual. Based on our experience with the reopenings process, we determined that the previous definition of similar fault did not provide adequate guidance to adjudicators. We believe the new definition more accurately conveys the meaning of similar fault, and makes clear that the fault must be ''similar'' to fraud.

Comment: One commenter asked for clarification on the types of errors that could be corrected through reopenings.

Response: It is not possible to delineate in a regulation all of the types of minor clerical and technical errors that can be addressed through the reopening process. However, we have issued operating instructions to contractors that offer examples of issues that are appropriate to handle as reopenings, and those that should be processed as appeals. *See* IOM 100–4 Chapter 34, Reopening and Revision of Claim Determinations and Decisions (*http://www.cms.hhs.gov/manuals/downloads/clm104c34.pdf*).

Under § 405.980(a)(3), we state that a clerical error includes human and mechanical mistakes on the part of the party or the contractor (that is, mathematical or computational mistakes, inaccurate data entry, or denials of claims as duplicates). Nevertheless, we appreciate the difficulty some providers and suppliers may have in determining whether a claim should be corrected through the reopenings process or the initial determination should be contested through the appeals process. We note that consistent with § 405.980(a)(3), if the contractor determines that an appeal request involves either the correction of a clerical error, or another matter that should be handled through the reopenings process, the appeal request will be treated as a request for a reopening, and the contractor will transfer the appeal request to the reopenings unit for processing. Similarly, if the contractor determines that a request for reopening involves an issue that must be resolved through the appeals process, the reopening request will be denied, and the contractor will advise the party accordingly. Although a contractor's refusal to reopen an initial determination is not subject to appeal, a party may file an appeal request with the contractor, subject to the filing requirements in § 405.942 through § 405.946, if they continue to dispute the initial determination on the items or services at issue. Thus, if it is unclear whether a particular dispute should be resolved as a reopening or as an appeal, a party's best recourse may be to file an appeal request.

In this final regulation, we are making two technical corrections to the introductory clause of § 405.980(b). First, we are replacing the word ''its'' with the word ''an''. This correction ensures that § 405.980(b) is consistent with (1) our longstanding policy as set forth in the interim final rule which allows certain contractors, other than the contractor that issued the initial determination, to reopen an initial determination (*see* 70 FR 11450), and (2) the definition of contractor included as a technical revision in this rule. In the interim final rule, we explained that for the purposes of reopening, the term ''contractors'' includes ''carriers, intermediaries, and program safeguard contractors.'' Program safeguard contractors (PSCs) do not have authority to issue initial determinations (*see* section 1893 of the Act). Thus, PSCs have not issued, and do not issue, initial determinations; however, in order to carry out their functions as authorized under section 1893(b)(1) of the Act (for

example, to conduct medical, utilization and fraud review of claims), PSCs must be able to reopen initial determinations made by other contractors. Including them in this list of ''contractors'' in the interim final rule that can conduct reopenings was meant to be consistent with 1893(b)(1) of the Act. Furthermore, the technical correction discussed above is consistent with our clarification of the term ''contractor'' set forth in this rule. As clarified in this rule, the term ''contractor'' would include, among other entities, PSCs.

We note that certain entities that did not exist when the interim final rule was published (and thus, were not included in the list of entities considered contractors for the purpose of conducting reopenings), would be included in the definition of ''contractor'' as clarified in this rule and may be authorized to reopen initial determinations made by other contractors. For example, recovery audit contractors (RACs) (considered contractors as that term is clarified in this rule) do not issue initial determinations. However, in order to carry out their functions as authorized by section 1893(h)(1) of the Act, they must be able to reopen initial determinations made by other contractors. Under section 1893(h)(1) of the Act, RACs identify underpayments and overpayments and recoup overpayments. In order to identify underpayments and overpayments, and prior to initiating recoupment of an overpayment, RACs must reopen the initial determinations issued by other contractors. Thus, consistent with their authority under section 1893 of the Act, RACs would be permitted to reopen initial determinations under § 405.980. Accordingly, consistent with our policy as set forth in the interim final rule, we are replacing the word ''its'' with ''an'' in the introductory clause of § 405.980(b) to more clearly convey our policy to permit certain contractors, other than those who issue initial determinations, to reopen initial determinations when appropriate.

Second, we are removing the words ''and revise'' from the introductory clause of § 405.980(b). Subsections (c), (d), and (e) of § 405.980, which are analogous to subsection (b), in that they discuss reopening timeframes and requirements for determinations and decisions requested by a party or initiated by a QIC, ALJ, or the MAC, do not include the words ''and revise'' and we inadvertently included these words in subsection (b). The provision, as revised, now reflects our longstanding policy that the timeframes for reopening a determination or decision are measured by the date of the reopening not the date of the revision of the determinations or decisions. *See* 42 CFR § 405.750(b), § 405.841, § 405.842(a); 67 FR 69327; The Carriers Manual, Pub. 14–3 (Claims Process Part 3), Chapter XII, section 12100.4, and The Intermediary Manual, Pub. 13–3 (Claims Process Part 3), Chapter VIII, section 3799.4. With the revisions described above, the introductory clause of § 405.980(b) will read as follows: ''A contractor may reopen an initial determination or redetermination on its own motion —''

Accordingly, we are finalizing § 405.980 with modifications as noted above, with modification as discussed in section II.B.5.b. of this preamble and with modification as discussed in section II.B.5.a. of this preamble.

b. Conduct of Reopenings (§ 405.982 Through § 405.986)

Section 405.982 discusses the provision of notice of a revised determination or decision. Section 405.984 explains the effect of a revised determination or decision and § 405.986 sets forth the good cause standard for reopening a determination or a decision.

Comment: We received several comments concerning the reopening timeframes. Some commenters requested that CMS establish a response and decision-making timeframe for contractors to complete or deny reopening requests from a party. One commenter expressed concern about uncertainty in the timing of the reopening process. The commenter explained that while awaiting a contractor's decision on whether to reopen, the deadline for filing for a redetermination could pass. The commenter suggested that we require adjudicators to find good cause and extend the time limit for filing an appeal if a decision regarding a reopening is not made until after the relevant appeal filing time limit has passed. One commenter requested that the rule allow for 60 days to file an appeal after a contractor denies a reopening request.

Response: We appreciate the many suggestions regarding the processing of reopening requests. With respect to the commenter's concern about uncertainty in the timing of the reopening process, we acknowledge that there are no regulatory timeframes that apply to the processing of the reopening request when a party requests that an adjudicator reopen a determination. Since reopenings are a discretionary activity, we believe it is more appropriate to establish applicable response and decision-making timeframes in our operating instructions to ensure the agency has adequate flexibility to make necessary changes in order to respond to shifts in contractor workload. Current operating instructions to contractors generally require the resolution of party initiated reopening requests within 60 days of receipt of the reopening request. *See* IOM 100–4 Chapter 34 Section 10.7 *http://www.cms.hhs.gov/manuals/downloads/clm104c34.pdf.* If a party misses the filing deadline for an appeal while awaiting a decision on a reopening request, the party may request the adjudicator consider granting an extension to the filing time limit for good cause consistent with § 405.942(b). Thus, we are not amending § 405.980 or § 405.982 to include a timeframe for resolving requests for reopening.

Furthermore, we do not believe it is appropriate to require adjudicators to find good cause to extend filing time limits if an adjudicator's decision with respect to a request for reopening is made after the party's deadline for filing an appeal request has expired. Rather, we believe a decision as to whether good cause exists for extending appeals filing time limits should be made on a case by case basis. Alternatively, a party may consider filing an appeal request (if appeal rights are available) if there is concern that the timeframe for filing a subsequent appeal may expire should the reopening request be denied. If the issue involves a clerical error, consistent with § 405.980(a)(3), the contractor will process the request as a reopening.

We also considered the commenter's suggestion that we allow an additional 60 days following a denial of a reopening request, to file an appeal on the item or service at issue. While we understand the concerns of the commenter regarding the potential effect a denied reopening request may have on appeal rights, we believe that allowing additional time to file an appeal as suggested would provide an inappropriate extension to appeals filing timeframes. Moreover, as we noted in the interim final rule, when a party is unsure whether a dispute regarding an item or service is to be handled as a reopening or an appeal, to ensure that the item or service at issue is reviewed in some manner by the adjudicator, it may be in the party's best interest to request an appeal, provided appeal rights are available. *See* 70 FR 11452. Thus, we are not adopting the commenters' suggestions to extend appeals filing time limits or require a finding of good cause for late filing when decisions on reopenings occur after the filing deadline has passed.

Comment: One commenter objected to the new regulatory definition of new and material evidence in § 405.986(a)(1), stating that it is far more restrictive than prior regulations at 20 CFR § 404.988(b) and § 404.989.

Response: Prior to the issuance of the interim final rule, the reopening process for Medicare claims relied on the regulatory provisions found in 20 CFR § 404.988(b) and § 404.989 that govern the reopening of Social Security disability claims. *See* 42 CFR § 405.750(b) and § 405.841. 20 CFR § 404.988(b) states that a determination or decision may be reopened within four years of the date of the notice of initial determination upon a finding of good cause as defined in 20 CFR § 404.989. In 20 CFR § 404.989, good cause to reopen a determination or decision may be established if (1) new and material evidence is furnished; (2) a clerical error in the computation or recomputation of benefits was made; or (3) the evidence that was considered in making the determination or decision clearly shows on its face that an error was made. The term ''new and material evidence'' was not defined in the regulations used by Social Security, nor was it defined in the Medicare's regulations. However, operating instructions used by Medicare carriers and fiscal intermediaries in processing reopenings have included a definition of new and material evidence for more that 15 years, and this definition served as the basis for the definition of new and material evidence included in § 405.986(a)(1). *See* The Carriers Manual, Pub. 14–3 (Claims Process Part 3), Chapter XII, section 12100.9 and The Intermediary Manual, Pub. 13–3 (Claims Process Part 3), Chapter VIII, section 3799.9. Thus, since we codified existing operating instructions, we disagree with the commenter's assertion that our standard for new and material evidence under § 405.986(a)(1) is far more restrictive than it had been prior to the interim final rule.

Comment: One commenter asked for clarification of § 405.986(b) regarding changes in substantive law or interpretative policy not serving as the basis for reopening a determination. The commenter believed the current wording could be construed as giving the contractor the ability to reopen a case based on local coverage determinations taking effect within one year of the initial determination or redetermination and lead to contractors reopening decisions when coverage is no longer extended to a certain treatment. The commenter stated this could then force providers to repay contractors for payments made while the treatment was covered under a local or national coverage decision. The commenter recommended that the regulation explicitly prohibit the retroactive application of local and national coverage determinations.

Response: While we appreciate the commenter's concern, we note that for purposes of making claim payment determinations, contractors apply the NCD or LCD in place on the day the item or service was provided by the provider or supplier. Furthermore, NCDs and LCDs include effective dates that necessarily make their application prospective. The only exception relates to effectuation of coverage appeals. As explained in § 405.986(b), in order to effectuate a favorable coverage appeal, contractors may reopen the specific claim(s) associated with a challenge to a local or national coverage determination under section 1869(f) of the Act and apply the revised coverage policy, but only to the specific claims at issue. The revised coverage policy would not apply retroactively to any other claims.

Accordingly, we are finalizing § 405.982 and § 405.986 without modification. We are finalizing § 405.984 with modification as discussed in section II.B.5.b. of this preamble.

8. Expedited Access to Judicial Review (§ 405.990)

Section 405.990 sets forth a process under which a party may obtain expedited access to judicial review when a review entity determines that the MAC does not have the authority to decide a question of law or regulation relevant to the matters in dispute, and that there is no material issue of fact in dispute. We received no comments on this section. However, as discussed in this preamble at section II.B.5.b. above, we are making technical revisions to § 405.990 in regards to describing specific determinations, decisions or actions that the adjudicator may take. We are also making revisions to § 405.990, per our discussion in section II.B.5.a.

Accordingly, we are finalizing § 405.990 with modification as discussed in section II.B.5.b. of this preamble and with modification as discussed in section II.B.5.a. of this preamble.

9. ALJ Hearings (§ 405.1000 Through § 405.1064)

Our regulations under § 405.1000 through § 405.1064 describe the procedures for conducting hearings before ALJs. We received several comments regarding these procedures. A brief overview of the relevant regulatory provisions, a summary of the comments, and our responses to those comments are included below. Further discussion regarding the procedures for appeals at the ALJ level is found in the interim final rule at 70 FR 11420, 11422, 11445 through 11446, and 11454 through 11466.

a. Transfer of the ALJ Function

Section 931 of the MMA required transfer of the ALJ function for hearing appeals under title XVIII of the Act (and related provisions of title XI of the Act) from the Commissioner of SSA to the Secretary of the Department of Health and Human Services (DHHS or the Department). The DHHS ALJs are required to be organizationally and functionally independent from CMS and must report to, and be under the general supervision of, the Secretary of DHHS. The DHHS and SSA jointly developed a plan to facilitate the transfer, which was started on July 1, 2005 and completed on October 1, 2005 as required by section 931(b)(1) of the MMA.

Comment: At least one commenter expressed concern about possible delays in processing appeals resulting from the transfer of the ALJ function from SSA to DHHS. The commenter asked DHHS to ensure that during the transition all appeal rights and remedies are available to parties in a timely fashion.

Response: We appreciate the commenter's concern, and note that the transfer of the responsibility for the ALJ function from the Commissioner of SSA to the Secretary of the DHHS was completed October 1, 2005. Staff in the DHHS Office of Medicare Hearings and Appeals (OMHA), the office responsible for administering ALJ hearings, worked closely with staff in the SSA Office of Hearings and Appeals to ensure a smooth transition and worked collaboratively to correct problems, to protect the rights of parties, and to issue timely decisions.

Comment: One commenter complained about the loss of Medicare-experienced SSA ALJs who have not relocated to the new DHHS ALJ offices. The commenter felt strongly that the loss of these ALJs would adversely impact the parties involved in appeals.

Response: The Administrative Procedure Act (APA) (5 U.S.C. 1104, and 3105) provides that ALJs be selected using a merit system of selection administered by the Office of Personnel Management (OPM). OMHA's ALJs are recruited from OPM's pool of qualified candidates and are provided with significant training in the relevant Medicare statutes and regulations. Furthermore, unlike SSA's ALJs, whose

main responsibility was to adjudicate disability and Medicare cases, OMHA's ALJs focus exclusively on Medicare appeals. Therefore, we do not think that parties involved in appeals have been or will be adversely impacted by this transition.

Comment: We received several comments concerning the training provided to the ALJs. One commenter expressed concern about the prospect of having to educate new ALJs about the Medicare regulations and questioned whether these judges would be able to address the highly complex and technical issues associated with Medicare claims appeals. Another commenter asked for more information about how ALJs will be trained and requested that all training material be made available to the public. The same commenter wanted DHHS to allow beneficiary and provider input into ALJ training sessions. Finally, a commenter noted that his inquiries to DHHS regarding ALJ training had been referred to the Public Affairs Office of CMS, which concerned the commenter because DHHS ALJs are required to be independent of CMS.

Response: As stated in the previous response, OMHA's ALJs are provided with significant and comprehensive training. OMHA Headquarters, with cooperation and input from its field office Managing ALJs, conducts a continuous evaluation of the ALJs' training needs. The training provided to the ALJs includes, but is not limited to, a comprehensive review of the following: The Medicare FFS, MA, and Part D programs and appeals processes; the applicable Medicare substantive authorities, such as CMS regulations, rulings, and program guidance; and the processes and procedures associated with conducting an administrative hearing. This comprehensive training provides ALJs with the knowledge and expertise necessary to address the highly complex and technical issues associated with Medicare claims appeals.

It is important for the ALJs to remain independent from the parties that may appear before them, including providers, suppliers and beneficiaries, and CMS and its contractors. Accordingly, with consideration of the statutory requirement at section 931 of the MMA that ALJs be functionally and organizationally independent from CMS, OMHA evaluates each potential trainer to determine whether the trainer, or the training itself, would adversely affect the independence or impartiality of the ALJs, or even present the appearance of a lack of independence or impartiality. OMHA also would apply this impartiality standard in determining whether to permit other individuals or entities, such as beneficiaries and providers, to provide input into an ALJ training session. Requests for copies of materials provided to ALJs during training sessions will be handled in accordance with the DHHS rules regarding requests for information under the Freedom of Information Act (FOIA). Such requests should be filed with the DHHS Freedom of Information Officer following the procedures outlined in 45 CFR Part 5.

Finally, we note that at the time of the publication of the interim final rule on March 8, 2005, OMHA was not in existence. Therefore, inquiries, such as those noted by the commenter concerning ALJ level function and received prior to the establishment of OMHA, were temporarily directed to the CMS Office of External Affairs. Since the establishment of OMHA, such inquiries have been directed to OMHA.

b. ALJ Hearings—General Rules (§ 405.1000 Through § 405.1014)

Section 405.1000 provides an overview of the ALJ hearing process. Section 405.1002 describes the requirements for obtaining an ALJ hearing and § 405.1004 describes the process for obtaining ALJ review of a QIC notice of dismissal. Section 405.1006 sets forth the amount in controversy requirements for ALJ hearings and judicial review. Section 405.1008 describes who may request an ALJ hearing and describes the parties to an ALJ hearing. Section 405.1010 explains the process by which CMS or its contractors may participate in an ALJ hearing, and § 405.1012 explains the process by which CMS or its contractors may choose to become a party to a hearing. Section 405.1014 sets forth the content and filing requirements for ALJ hearing requests.

Comment: One commenter expressed concern that ALJ hearings were no longer considered *de novo* hearings. The commenter stated that the removal of *de novo* status for ALJ hearings will hamper efforts to obtain the optimum amounts of information about each case, and lead to unfair and unjustified denials of legitimate Medicare claims for reimbursement.

Response: As stated in the Office of Medicare Hearings and Appeals; Statement of Organization, Functions, and Delegations of Authority, 70 FR 36386 through 36387, ALJs conduct impartial *de novo* hearings and this standard of review has not changed. Although the statute and implementing regulations place limitations on the submission of evidence, which impacts the scope of review, this limitation does not impact the standard of review for ALJ hearings. Rather, consistent with § 405.1032(a), the ALJ reviews anew all issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. In addition, if evidence presented before the hearing causes an ALJ to question a favorable portion of a determination, the ALJ may consider that issue at the hearing after providing notice to the parties. *See* § 405.1032(a). However, to further clarify that the ALJ conducts a *de novo* review and to eliminate any potential confusion, we are making a technical revision to § 405.1000(d) to state that the ALJ conducts a *de novo* review and issues a decision based on the hearing record.

Comment: We received many comments regarding CMS' and its contractors' participation as a party or as a participant in the appeals process as set forth in § 405.1010 and § 405.1012. Several commenters generally objected to CMS or its contractors participating in ALJ hearings, or becoming a party at the ALJ level of appeal. One commenter contended that submission of evidence by CMS or its contractor acting as a party or participant should be prohibited if CMS or its contractor had the opportunity to submit the evidence at the time of the redetermination request. Another commenter objected to submission of position papers and clarifying testimony, stating that CMS should only be permitted to submit materials which ALJs must adhere to, or defer to, pursuant to § 405.1060 through § 405.1063 (that is, NCDs, LCDs, program guidance or CMS Rulings). Some of these commenters felt that CMS participation should be limited only to instances where the ALJ required information from CMS or its contractors.

Response: As discussed in detail in the preamble to the interim final rule in response to similar comments, we continue to believe that limited expansion of CMS' role in the ALJ hearing process is appropriate, necessary and consistent with the statute. *See* 70 FR 11459 through 11460. As previously noted, section 1869(c)(3)(J) of the Act 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.'' We continue to believe that this provision indicates a recognition of the benefit of agency participation in the appeals process.

Based on our experience and the experience of our contractors, there

have been many instances in which an ALJ has determined that input from CMS or a contractor would help resolve a policy issue or clarify factual issues in a case. Prior to the interim final rule, the regulations did not provide specific procedures for ALJs to obtain input from the agency. When ALJs requested position papers, testimony, or other evidence from CMS or a contractor, the process was cumbersome because the regulations did not provide specific procedures for obtaining this input. Thus, consistent with section 1869(c)(3)(J) of the Act, we afford CMS and its contractors the discretion to appear as a party in appeals other than appeals involving unrepresented beneficiaries under § 405.1012. In addition, in § 405.1010, we provide CMS and its contractors the discretion to participate in a more limited role at the hearing by providing assistance in resolving factual or policy issues in a case as a participant in the hearing. Moreover, the Office of Inspector General (OIG) report, as we noted in the preamble to the IFC (OEI–04–97–00160 issued in September 1999), further supports participation by CMS and its contractors in ALJ hearings. *See* 70 FR 11459.

We disagree with the comment that submission of evidence by CMS or its contractors when participating in an ALJ hearing should be prohibited if CMS or its contractors had the opportunity to submit the evidence at the time of the redetermination request. CMS and its contractors are not permitted to participate in the appeals process as a party or participant prior to the ALJ level, and thus, are unable to submit new evidence into the administrative record at the redetermination and reconsideration levels. Therefore, if CMS or its contractors elect to join an appeal as a participant or a party, they should be afforded an opportunity to present evidence, and the ALJ level is the earliest opportunity for this to take place.

We also disagree with the commenter's suggestions that participation by CMS or its contractor should not include the submission of position papers or clarifying testimony, and CMS or its contractor should be restricted to submitting materials to which ALJs must adhere or defer. We continue to believe that CMS or contractor participation at a hearing may assist beneficiaries, as well as adjudicators, in understanding the complex issues raised during claims appeals, and that such participation will assist ALJs and the MAC in creating a fully developed record that resolves issues of fact and law. Participation, as suggested by one commenter, that is limited to the submission of evidence an adjudicator is already required to follow or defer to will have limited usefulness because it will not necessarily take into account the unique factual situations involved in each case before an ALJ. We expect that additional case development resulting from the submission of position papers or clarifying testimony from CMS or its contractors may result in a reduction in the number of cases remanded from the MAC to the ALJ level for additional development, yielding faster decisions for parties and administrative cost savings. Therefore, we believe it is necessary and appropriate for CMS and its contractors to have an opportunity to participate at the ALJ level, and that participation should not be restricted to materials to which the ALJ must adhere or defer.

In addition, we disagree with the comment that CMS or contractor participation should be limited to instances where the ALJ requires information from CMS or its contractor. As noted above, we believe that CMS or contractor participation at a hearing may assist beneficiaries as well as adjudicators in understanding and resolving complex issues raised during appeals. Some appeals may raise factual or policy issues of which the ALJ is not aware, and thus, we believe it is necessary and appropriate to permit CMS and its contractors to participate in ALJ hearings (either as participants or as parties) even if the ALJ does not specifically request information from them.

Thus, for the reasons discussed above, we believe that CMS or contractor participation in ALJ hearings under § 405.1010 and § 405.1012 is necessary and appropriate and should not be limited only to instances where the ALJ requires information from CMS or its contractors. Furthermore, as discussed above, when participating in a hearing as participants or as parties, CMS and its contractors should not be restricted to submitting materials to which the ALJ is required to adhere or defer, and should not be prohibited from submitting position papers and clarifying testimony.

Comment: One commenter viewed the participation provisions as a mechanism for CMS to insert itself as an adversary of the Medicare beneficiary, and objected to the use of Program dollars to fund adversarial actions against beneficiaries trying to obtain Medicare covered benefits. Some commenters objected to the provision prohibiting CMS or its contractors from being called as witnesses if they are participating in an ALJ hearing. Several commenters felt that this provision should be eliminated altogether. Several commenters suggested that if CMS' objective in participating in hearings was to allow for a more thorough examination of all the issues, that goal was not feasible if CMS immunized itself from being called as witness. Finally, one commenter suggested that if the provision regarding participation by CMS or its contractors is retained, an ALJ should be permitted to draw an adverse inference if CMS or its contractors refuse cross examination or withdraw evidence.

Response: We do not believe that participation in a hearing by CMS or its contractor causes the hearing to become an adversarial proceeding against a beneficiary. When an unrepresented beneficiary files a request for hearing, CMS or its contractor may not be a party to the hearing and may only choose to act as a participant. *See* § 405.1010, § 405.1012(a). In general, the role of a participant under § 405.1010 is to provide information that assists the ALJ by clarifying factual or policy issues in a case. When compared to the rights CMS and its contractors are afforded as a party under § 405.1012, the scope of a participant's rights under § 405.1010 is limited. For example, as a participant, CMS and its contractors do not have the right to call witnesses or cross-examine the witnesses of parties. *See* § 405.1010(c). Nor does a participant have a right to object to the issues described in the ALJ's notice of hearing. *See* § 405.1024(a), which applies only to parties. These are cornerstone elements in an adversarial proceeding. Thus, we believe the non-adversarial nature of an ALJ hearing is preserved when CMS or its contractor acts as a participant under § 405.1010.

We also disagree with the commenter's assertion that participation by CMS or its contractor constitutes an inappropriate use of program dollars. As noted above, by conferring authority on the Secretary to determine when the QIC's participation in hearings is appropriate, Congress recognized the benefit of such participation. *See* section 1869(c)(3)(J) of the Act. In addition, as discussed above, we believe that CMS or contractor participation may assist ALJs and the MAC in creating a fully developed record that resolves issues of fact and law, which could result in a reduction in the number of cases remanded from the MAC to the ALJ, thereby yielding faster decisions for parties and administrative cost savings. Furthermore, participating in a hearing reflects one of our agency's top mandates as stewards of the Medicare Trust Fund: ensuring accurate

payments. Thus, we do not believe participation in an ALJ hearing as a participant or as a party constitutes an inappropriate use of program resources.

We also do not agree with the commenters who suggested that we eliminate the provision in § 405.1010(d) that prohibits calling CMS or its contractor as a witness when participating in a hearing under § 405.1010. We believe this prohibition is important in maintaining the non-adversarial manner for such hearings. As previously noted, a participant's role under § 405.1010 is significantly limited when compared to the role of a party under § 405.1012. For example, as a participant, CMS or its contractor can file position papers or provide testimony to help further clarify certain factual or policy issues in the appeal. However, as a participant, CMS or its contractor may not call witnesses or cross-examine the witnesses of a party, nor may it be called as a witness during the hearing. *See* § 405.1010(c) and § 405.1010(d). In contrast, as a party under § 405.1012, CMS or its contractor may exercise all of the rights available to a party (such as, calling witnesses, cross-examining witnesses of other parties, requesting the issuance of subpoenas, objecting to the issues to be decided at the hearing). The election of party status by CMS or its contractor also makes the discovery process available to parties under § 405.1037.

The differences between the role of CMS or its contractor as a participant under § 405.1010 and as a party under § 405.1012 reflect the distinction under our regulations between a less formal, non-adversarial style of hearing (when CMS or its contractor participates as a non-party) and a more formal, adversarial style of hearing (when CMS or its contractor elects party status). (As further discussed below, CMS and its contractors have discretion to determine whether to participate in a hearing and to determine the manner and extent of participation.) Requiring CMS or its contractor to be called as a witness when it is a participant in a hearing under § 405.1010 would blur this distinction and would require CMS or its contractor to take on an adversarial role in the hearing when it has chosen the non-adversarial role of participant under § 405.1010. Thus, in order to maintain the non-adversarial nature of the hearing when CMS or its contractor is a participant under § 405.1010, we believe it is necessary to preclude calling CMS or its contractor as a witness during the hearing. We note that the policy prohibiting CMS or its contractor from being called as a witness when it has chosen to participate as a non-party in the proceeding under § 405.1010 is consistent with the Department's Touhy regulations at 45 CFR Part 2, which leaves to agency discretion the decision of whether to permit agency officials or certain contractors to testify or produce evidence in proceedings in which the agency is not a party.

Furthermore, even though CMS and its contractors cannot be called as witnesses when they participate in a proceeding under § 405.1010, we believe that participation by CMS or its contractors under § 405.1010 still allows for a more thorough examination of the issues. As discussed above, when CMS or its contractors participate under § 405.1010, they may file position papers or provide testimony to clarify factual or policy issues in a case, thereby assisting ALJs and the MAC in creating a fully developed record that resolves issues of fact and law.

Finally, we disagree with commenters who suggested that we permit ALJs to draw an adverse inference if CMS or its contractors refuse cross-examination or withdraw evidence when they participate in the proceeding under § 405.1010. The limited resources and broad programmatic responsibilities facing CMS and its contractors may not allow for participation in all hearings. Thus, while an ALJ may request that CMS or its contractors participate in a hearing or other proceeding, under § 405.1010(a), an ALJ cannot require CMS or its contractors to participate in a case. In addition, an ALJ may not require CMS or its contractor to appear as a witness under § 405.1010(d). Thus, CMS and its contractors have discretion to determine whether to participate in a hearing and to determine the manner and extent of participation. If CMS or its contractor, in exercising this discretion, chooses to participate in the proceeding in the limited, non-adversarial manner provided in § 405.1010, we do not believe that it would be reasonable for the ALJ to draw an adverse inference if CMS or its contractor declines to extend this participation beyond the limits set forth in § 405.1010 (for example, by refusing cross-examination). Furthermore, given the discretion provided to CMS and its contractors to determine whether and how to participate in a proceeding, we do not think it would be reasonable for the ALJ to draw an adverse inference if CMS or its contractor chooses to withdraw evidence. Therefore, we do not believe it is appropriate to amend § 405.1010(f) to permit an ALJ to draw an adverse inference if CMS or its contractor refuses cross-examination or withdraws evidence.

Comment: We received several comments concerning the submission of evidence by CMS or its contractors when participating at the ALJ or MAC levels of the appeals process. These commenters stated that in cases where CMS or its contractors submit new evidence, there should be an opportunity for the parties to respond, without having to show good cause and without delaying the adjudication timeframes.

Response: We disagree with the recommendation that providers and suppliers should not have to show good cause to submit new evidence at the ALJ and MAC levels in response to the submission of evidence by CMS or its contractors, if the agency elects to join the appeal as a party or participant. As noted earlier in this rule, the MMA amended several of the appeals provisions contained in BIPA. Section 1869(b)(3) of the Act, as added by section 933(a) of the MMA, requires that a provider of services or supplier not introduce evidence in any appeal that was not presented at the reconsideration conducted by the QIC, unless there is good cause that precluded the introduction of such evidence at or before the reconsideration. In our regulations at § 405.1018, we extended this requirement to beneficiaries represented by providers and suppliers. However, section 1869(b)(3) of the Act, and the corresponding regulatory provisions, do not apply to CMS or its contractors. To the extent participation by CMS or its contractors raises new issues in the appeal that were not considered during the earlier levels of appeal, this may provide good cause for the introduction of new evidence by parties at the ALJ level.

Finally, in light of the statutory requirement for full and early presentation of evidence, our provision requiring parties to submit evidence with the request for hearing or within 10 days of receipt of the notice of hearing (§ 405.1018), and the need for the ALJ to evaluate the good cause justification for submission of new evidence after the reconsideration as set forth in § 405.1018 and § 405.1028, it is necessary to allow an ALJ additional time to consider whether the new evidence submitted by the appellant or party may be considered at the hearing. We believe that § 405.1018(b), which tolls the ALJ adjudication timeframe when a party submits evidence after the deadline established in § 405.1018(a), is consistent with the statute and with Congressional intent. Congress has clearly indicated that adjudicators must devise procedures compatible with meeting the statutory deadlines.

Moreover, we do not believe it appropriate for appellants to avail themselves of the escalation provisions if the appellant has delayed the administrative process by submitting evidence after the deadline. In addition, we believe that by tolling the 90-day adjudication period as provided in § 405.1018(b) in those instances in which the appellant is responsible for the delay, we provide an incentive for appellants to submit all relevant evidence as soon as possible (preferably with the hearing request), to appear at scheduled hearings, and otherwise comply with hearing procedures. We believe that tolling the ALJ adjudication timeframe when a party submits evidence after the deadline established in § 405.1018(a), balances the party's need to submit new evidence in certain circumstances, with the need to provide the ALJ with sufficient time to evaluate the good cause justification for submitting the new evidence, and to review any such additional evidence that is to be admitted into the administrative record. Furthermore, we believe it is reasonable to toll the decision-making timeframe to allow full and careful consideration of all issues, even if the evidence being considered is in response to evidence submitted by CMS or its contractors.

Comment: We received two comments regarding the availability of attorney's fees when CMS or its contractors participate in an ALJ hearing. Both commenters argued that if CMS or its contractors participate as a party it would turn the hearing into an adversarial proceeding and, under the Equal Access to Justice Act (EAJA), CMS could be obligated to pay attorney's fees and other costs to prevailing appellants.

Response: In our response to an identical question raised on the proposed rule, we indicated that the Department would review its EAJA provisions to determine what, if any, amendments might be necessary to reflect the changes implemented in the interim final rule. *See* 70 FR 11429 through 11430. To date, DHHS has not amended its EAJA regulations to expressly include administrative appeals under this subpart in the list of proceedings in 45 CFR part 13, Appendix A that are considered adversary adjudications, and to which the EAJA rules apply.

In light of the commenter's concern, however, we believe it is appropriate to clarify when a hearing involving claim determinations becomes an adversary adjudication for the purposes of making an application for attorney fees under the Department's EAJA regulations. Only those ALJ hearings in which CMS elects party status under § 405.1012(a) meet the definition of an adversary adjudication as set forth in 45 CFR 13.3(a). The Department's EAJA regulations at 45 CFR 13.3(a) state that the EAJA rules apply only to adversary adjudications. An adversary adjudication is defined as ''an adjudication required to be under 5 U.S.C. 554, in which the position of the Department or one of its components is represented by an attorney or other representative ('the agency's litigating party') who enters an appearance and participates in the proceeding. * * *'' We believe appeals where CMS elects party status fall within this definition.

However, if a non-governmental entity, such as a QIC or other CMS contractor, decides to become a party to an appeal at either an ALJ hearing or MAC review, it does not constitute an adversary adjudication for the purposes of the EAJA, because the Department's position would not be represented by an attorney employed by DHHS. DHHS has previously indicated its position with respect to a contractor-party in 45 CFR part 13, Appendix A, which lists proceedings covered by the Department's EAJA regulations. In that appendix, a Provider Reimbursement Review Board proceeding is considered an adversary adjudication only when DHHS employees appear as counsel for the intermediary. In the context of a hearing or MAC review, if a QIC or other CMS contractor decides to become a party, DHHS would not be represented by its own attorney, and therefore, EAJA would not apply.

Further, we do not believe the Department's EAJA rules cover ALJ hearings or MAC review in which CMS or one of its contractors chooses to participate, but does not enter as a party. Our regulations provide for two completely separate options for CMS or its contractors to participate in an ALJ hearing or MAC review: as a party or as a participant. In electing party status, CMS or its contractor enters an ALJ hearing with all of the rights and responsibilities of other parties as described in § 405.1012, including the right to call witnesses, cross-examine witnesses of the appellant or other party, be subject to cross-examination, and to submit evidence. In contrast, by simply participating in the appeal as a non-party, the agency or its contractors have significantly more limited rights as described in § 405.1010 (that is, the right to submit position papers or to provide testimony to clarify factual or policy issues in the case). More importantly, however, a non-party participant does not have the right to call witnesses or cross-examine the appellant's or other parties' witnesses, and a non-party participant may not be called as a witness at the hearing. Thus, as we have stated in the proposed and interim final rules, the role of CMS or its contractors as a non-party participant is non-adversarial. *See* 67 FR 69332; 70 FR 11459 through 11460. Accordingly, we believe an ALJ hearing or MAC review in which CMS or its contractor is a participant, but not a party, does not fall within the definition of an adversary adjudication for the purposes of applying the provisions of the EAJA.

Finally, we note that the Department's EAJA rules state: ''The Department may reimburse parties for expenses incurred in adversary adjudications if the party prevails in the proceeding and if the Department's position in the proceeding was not substantially justified. * * *'' *See* 45 CFR 13.1. The mere fact that a party prevails in the proceeding does not create a presumption that the Department's position was not substantially justified. Rather, the agency's litigating party is afforded an opportunity to show that the Department's position was reasonable in fact and law, thus avoiding an award of fees and expenses in connection with the proceeding. *See* 45 CFR 13.5(b).

Accordingly, we are finalizing § 405.1008 without modification. We are finalizing § 405.1000 with modification as discussed above, and with modification as discussed in section II.B.1. of this preamble. We are finalizing §§ 405.1002 and 405.1004 with modification as discussed in section II.B.5.b. of this preamble and with modification as discussed in section II.B.5.a. of this preamble. We are finalizing §§ 405.1006 and 405.1014 with modification as discussed in section II.B.5.a. of this preamble. We are finalizing §§ 405.1010 and 405.1012 with modification as discussed in section II.B.1. of this preamble and with modification as discussed in section II.B.5.a. of this preamble.

c. Adjudication Deadlines—ALJ Level (§ 405.1016)

Section 405.1016 sets forth the timeframes for an ALJ to issue hearing decisions, states that timeframes may be extended as provided in subpart I, and also includes provisions to toll timeframes under limited circumstances.

Comment: One commenter objected to the provision that a request for an ALJ hearing is considered timely filed when it is received by the entity specified on the QIC's notice of reconsideration. The commenter noted that the Medicare statute specifies the decisionmaking timeframe beginning on the date the

request for a hearing was timely filed. The commenter felt that many beneficiaries, who had typically filed appeals with the SSA, and may continue to do so, would not get the benefit of the revised statutory timeframes.

Response: We agree with the commenter that the decision-making timeframe begins when a request for hearing is timely filed. However, in order to be timely filed, a hearing request must contain all the required information and be filed with the entity specified in the reconsideration decision within 60 days of receipt of the reconsideration decision. *See* § 405.1014(a) and § 405.1014(b). We believe that directing appellants to only one filing location reduces confusion and eliminates any potential delay in transmitting the request. Thus, all reconsideration decision letters issued by QICs contain the specific OMHA field office address where a request for ALJ hearing must be filed. Although some beneficiaries may continue to file hearing requests with the SSA, we do not believe it is appropriate to recognize SSA field offices as filing locations for ALJ hearing requests pertaining to claims for benefits under Medicare Part A and Part B, because the SSA no longer has a role in the processing of these Medicare appeals. (However, we note that parties may file requests for ALJ hearings pertaining to Part A and Part B entitlement (*see* § 405.924(a)) and Part B Income Related Monthly Adjustment Amounts (IRMAA) directly with OMHA or with SSA offices.) To ensure appeals that are misfiled with the SSA are promptly forwarded to the correct entity, CMS and SSA developed Emergency Message EM–05028 (originally issued on June 23, 2005). This instruction directs SSA staff to immediately forward misfiled Part A and Part B claims appeals to the appropriate OMHA field office and to direct any beneficiaries who attempt to file appeals in-person to send the request to the entity specified in their reconsideration decision letter. Thus, we believe it is reasonable to begin the adjudication timeframe on the date an appeal request is timely filed with the entity specified in the QIC's notice of reconsideration.

Pursuant to § 405.1014(b)(2), if a request for hearing is timely filed with an entity other than the entity specified in the notice of reconsideration, the request is not treated as untimely or otherwise rejected. Rather, the deadline for deciding the appeal under § 405.1016 begins on the date the entity specified in the QIC's reconsideration notice receives the request for hearing. In situations such as this, where an appellant's actions do not meet regulatory requirements and cause a delay in the adjudication process, we think it is both necessary and fair to allow an ALJ the full 90 days afforded by statute, beginning the date the correct ALJ office receives the request, to issue a decision. Section 405.1014(b)(2) states that if the request for hearing is filed with an entity, other than the entity specified in the QIC's reconsideration, the ALJ hearing office must notify the appellant of the date of receipt of the request and the commencement of the 90 day adjudication timeframe.

Comment: We received two comments regarding the decision-making timeframes when cases are escalated. One commenter agreed with the provisions in § 405.970(c)(2) and § 405.970(e)(2)(i) which provide an adjudicator five additional days to complete a decision when an appellant has requested the case to be escalated to the next level. Another commenter disagreed with any extension of the decision-making timeframe in cases involving escalation, and opined that such an extension was not authorized under the statute.

Response: Section 1869(d)(1)(A) of the Act requires an ALJ to hold a hearing on the decision of the QIC, and to render a decision on such hearing within 90 days of the adjudicator's receipt of a request for a hearing (that is timely filed). Section 1869(c)(3)(C)(ii) of the Act provides that a party may escalate an appeal to the ALJ if the QIC fails to mail or provide notice (as applicable) of the decision by the end of the applicable decision-making timeframe. OMHA's adjudication timeframe in case of escalation from a QIC is not explicitly stated in statute. The statute provides only a qualified right for an appellant to escalate an appeal to the ALJ level if the QIC does not timely issue a reconsideration determination. As discussed in the interim final rule, we interpret the 90 day adjudication provision as requiring an ALJ to decide a case within 90 days only when the QIC has issued a final action in a case. *See* 70 FR 11454 through 11456, and 11463. Therefore, we state that, when an appellant escalates an appeal from the QIC to the ALJ level, the proceedings before the ALJ will not be subject to the 90-day limit. Rather, as specified in § 405.1016(c), the ALJ will have up to 180 days to issue a decision, dismissal order, or remand order (unless the time period is otherwise extended as provided in part 405 subpart I). The absence of an actual reconsideration determination and its attendant administrative processes imposes a substantial additional burden on OMHA, including locating and acquiring relevant information from the QIC, performing additional procedural and jurisdictional reviews, and organizing evidence in the case file. Setting the adjudication timeframe by regulation at 180 days for escalated appeals balances the interests of the appellant in timely resolving the disputed appeal and an ALJ's duty to collect the evidence and perform the administrative tasks necessary to fully and fairly adjudicate an appeal that has not been addressed in a reconsideration determination. We note that the 180 day timeframe does not preclude OMHA from adjudicating the appeal more expeditiously if possible.

We are finalizing § 405.1016 with modification as discussed in section II.B.5.a. of this preamble.

d. Submission of Evidence Before the ALJ Hearing (§ 405.1018)

Section 405.1018 states that a provider, supplier or beneficiary represented by a provider or supplier must submit all written evidence they wish to have considered at the hearing with the request for hearing or within 10 days of receiving notice of the hearing. Any evidence that is not submitted prior to the issuance of the QIC reconsideration determination must be accompanied by a written statement explaining why the evidence was not previously submitted to the QIC or a prior decision-maker. We explain in § 405.1018 and § 405.1028 the process an ALJ follows in determining whether good cause exists to allow the new evidence into the administrative record.

Comment: One commenter objected to the provision limiting the submission of evidence after the QIC level of appeal. The commenter stated the appellant should not be penalized by having to draft statements showing good cause for the submission of new evidence at the ALJ level when many times the later submission is due to circumstances that are beyond a party's control.

Response: Section 933(a) of the MMA amended section 1869(b) of the Act to require full and early presentation of evidence by providers and suppliers. Absent good cause for not presenting the evidence prior to the issuance of a reconsideration by the QIC, a provider or supplier is precluded, by statute, from introducing new evidence at the ALJ or MAC levels. Sections 405.1018(c) and 405.1028 implement the good cause requirement. These provisions help to ensure expeditious adjudication, while recognizing that early presentation of evidence is not always possible. We also note that this requirement does not

apply to evidence submitted by beneficiaries, unless they are represented by a provider or supplier. *See* § 405.966(c) and § 405.1018(d); 70 FR 11446.

We are finalizing § 405.1018 with modification as discussed in section II.B.5.a. of this preamble.

e. Time and Place for a Hearing Before an ALJ; Notice of Hearing; Objections to the Issues (§ 405.1020 Through § 405.1024)

In § 405.1020, we set forth the requirements for determining how appearances will be made before the ALJ, for providing notice of a hearing, for waiving a hearing, for changing the time and place of a hearing, and for requesting an in-person hearing. In § 405.1022, we describe the content and processing requirements with respect to the notice of ALJ hearing sent to the parties and other potential participants. In § 405.1024, we explain the procedures parties must follow if they object to the issues described in the ALJ's notice of hearing.

Comment: We received many comments concerning the types of hearings available at the ALJ level. Several of the commenters stated that an appellant should have the right to an in-person hearing before an ALJ. One commenter opined that the reliance on videoteleconferencing (VTC) hearings may be premature. Another commenter questioned the adequacy of hearings by VTC, opining that where credibility and veracity are at issue, in-person hearings will provide the decision maker with the chance to observe all parties, and allow the appellant to observe the reaction of the ALJ to the evidence and tailor presentations accordingly. The commenter also noted that many Medicare beneficiaries have visual, hearing, or even cognitive impairments which create difficulties in viewing VTC screens, hearing telephone conversations or participating in other than face-to-face hearings. Many of these commenters also objected to the requirement that an appellant show good cause before an ALJ will grant an in-person hearing and characterized the good cause standard as vague.

Response: 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 to a hearing to the same extent as is provided in section 205(b) of the Act. Section 1869(b)(1)(A) of the Act does not specify the manner in which hearings must be held. Congress, however, instructed the DHHS to explore the possibility of providing hearings using formats other than in-person hearings. Specifically, the MMA instructed the DHHS to consider the feasibility of conducting Medicare hearings ''using tele- or video-conference technologies.'' *See* section 931(a)(2)(G) of the MMA.

At approximately the same time that MMA was enacted, the SSA finalized regulations that provided for VTC hearings in Medicare and disability appeals. *See* 68 FR 5210 (February 3, 2003). Taking into account SSA's regulations, the Secretary concluded that the expanded use of VTC and telephone hearings for Medicare appeals is appropriate for various reasons. First, contrary to the commenters' assertions, and unlike Social Security disability hearings, where in-person hearings may be needed in order to evaluate an individual's physical ability and/or credibility, Medicare hearings are generally less dependent on the physical presence of the appellant or other witnesses and are, therefore, better suited to VTC hearings. Second, VTC allows ALJs to conduct hearings more quickly, which is particularly important in light of the timeframes mandated by the statute. For parties who might otherwise waive their right to a hearing and request an on-the-record decision because of traveling or scheduling difficulties, VTC hearings can be scheduled locally in a convenient setting where the party has an opportunity to present his/her case orally. Given these benefits, we believe VTC is an efficient and effective method of conducting ALJ hearings. Despite the advantages of VTC, parties have the opportunity to request an in-person hearing, or an ALJ may determine that an in-person hearing is more appropriate than a hearing by VTC or telephone in a particular case. Thus, as explained in the interim final rule, we determined it is appropriate to permit ALJ hearings to be conducted by VTC. *See* 70 FR 11456 through 11457.

Specifically, § 405.1020(b) provides that an ALJ, with the concurrence of the Managing Field Office ALJ, may determine that an in-person hearing should be conducted if either (1) VTC technology is not available, or (2) special or extraordinary circumstances exist. The preamble to the interim final rule provides guidance for ALJs in determining whether special or extraordinary circumstances exist, thus warranting the scheduling of an in-person hearing under § 405.1020(b)(2). *See* 70 FR 11457. Section 405.1020(i) provides that a party may file a written objection to a scheduled VTC or telephone hearing, and request an in-person hearing. An ALJ may grant the request, with the concurrence of the Managing Field Office ALJ, upon a finding of good cause. In the preamble to the interim final rule, we provide guidance as to what may constitute good cause for an ALJ to grant a request for an in-person hearing. For example, an ALJ could find good cause to grant a request for an in-person hearing when a party demonstrates that the case presents complex, challenging or novel presentation issues that necessitate an in-person hearing. *See* 70 FR 11457. Similarly, an ALJ may find good cause to schedule an in-person hearing based on a party's proximity to and ability to go to the local hearing office. These provisions ensure that appellants or other parties who believe it is necessary to have an in-person hearing to effectively present and participate in their cases, including parties with physical and cognitive impairments, have the option to request an in-person hearing.

Furthermore, given the volume of hearing requests and short adjudicative timeframes imposed by BIPA, we believe it is reasonable to use a good cause standard in determining when it is appropriate for an ALJ to grant a request for an in-person hearing and reschedule the hearing for a time and place when the party can appear in person before the ALJ, as provided in § 405.1020(i)(5). As explained above, and to avoid the backlogs and delays that historically plagued the hearing process, we believe it is necessary and appropriate to generally conduct hearings by VTC or telephone. However, in § 405.1020(i), we acknowledge that, in some circumstances, it may be appropriate to grant a request to change the type of hearing scheduled and permit an in-person hearing. Thus, ALJs will evaluate in-person hearing requests made under § 405.1020(i) using the good cause standard established in § 405.1020(i)(5), and when appropriate grant a request for an in-person hearing.

Finally, we believe our decision not to provide an exhaustive description of the good cause standard in this regulation benefits parties by affording an ALJ the flexibility to grant an in-person hearing based on factors or circumstances that may be relevant, yet unforeseen at this time.

Comment: Several commenters were concerned about the number of ALJ offices available for in-person hearings as well as the ALJ office locations. Some commenters were concerned that the number of office locations was insufficient, and would impede appellant access to VTC and/or in-person hearings and cause delays in holding hearings. One commenter stated

that a system that relies on VTC and phone hearings and places ALJs in 4 locations around the country does not satisfy the requirements of MMA section 931(b)(3), which requires appropriate geographic distribution of offices to ensure timely access to judges. One commenter stated that since the current ALJ office locations weren't accessible to New York residents, DHHS should establish an ALJ office in New York City, as well as an ALJ office in upstate New York. A few commenters recognized the need to streamline ALJ locations and the ALJ hearing process for efficiency, but asked that DHHS monitor the process to ensure appellant access is not hindered. Several of the commenters opined that with only four ALJ offices, appellants would be forced to use VTC or telephones to conduct hearings rather than incur the expense, loss of income, and inconvenience of traveling to distant offices. Another commenter asked if any provisions would be made to allow travel allowances for appellants.

Response: In determining the number and location of OMHA's field offices, the DHHS thoroughly researched and considered, among other things, the then-current and projected geographic distribution of Medicare claims appeals heard by SSA and Medicare contractor jurisdictions. As a result, Arlington, Virginia, Cleveland, Ohio, Irvine, California, and Miami, Florida were chosen as the four sites for the OMHA field offices. The ALJs in these field offices hold hearings by videoteleconference and telephone, and in-person. Furthermore, VTC hearings are also held at sites other than the ALJ offices. OMHA makes extensive use of VTC to provide appellants with a vast nationwide network of access points for hearings close to their homes. Based on this research and our experience, we believe that the number and distribution of ALJ offices is sufficient and would not delay or impede access to in-person or VTC hearings. Thus, we believe that the number and locations of ALJs throughout the country satisfy the requirements section 931(b)(3) of the MMA, and we do not believe that it is necessary at this time to establish ALJ offices in New York City or in upstate New York.

While many appellants prefer the convenience of a telephone hearing or videoteleconference hearing, there are instances when an in-person hearing is appropriate. OMHA closely monitors appellants' access to the process via internal case tracking systems, appellant feedback during the scheduling of hearings, and appellant feedback during hearings. OMHA's tracking numbers and feedback from appellants reflect an overwhelming preference for telephone hearings. Based on the feedback and raw data received, OMHA adjusts its internal resources and processes accordingly.

Furthermore, when, in accordance with the regulations, the ALJ determines that a hearing will be held in-person, the ALJ will also consider whether it is most appropriate to travel to a location close to the party or to have the party travel to one of the OMHA field offices. In making this determination, the ALJ consults with the party requesting the hearing. OMHA has developed a travel reimbursement policy that it mails with every notice of hearing. Pursuant to this policy, eligible participants are reimbursed for certain expenses incurred in traveling to and from a field office or a VTC site. Thus, we do not believe that appellants are forced to use VTC or telephones to conduct hearings to avoid the expense of in-person hearings. We believe that this policy satisfies the mandate of section 931(b)(3) of the MMA to ensure timely access to judges.

Comment: A commenter noted that § 405.1020(c) requires the ALJ to send a notice of hearing to the contractor that issued the initial determination. The commenter expressed concern that receiving ALJ notices of hearing for every case may be cumbersome, and suggests it may be more efficient to send a notice of hearing to the contractor that processed the initial determination only when the ALJ requests that the contractor be a party or participant.

Response: We agree with the concerns raised by the commenter. We believe sending the notice of hearing to the QIC that processed the reconsideration provides adequate notice to CMS and its contractors of the pending ALJ hearing, and thus it is not necessary to also send notice of the hearing to the contractor that issued the initial determination. However, we note that, the ALJ would send a notice of the hearing to the contractor if an ALJ were to request that the contractor that issued the initial determination participate in, or be a party to, a hearing. Accordingly, we have revised § 405.1020(c) to remove the reference to the ''contractor that issued the initial determination'' from the list of entities that receive notice of the ALJ hearing.

Comment: We received several comments concerning § 405.1020(i)(4), which stipulates that when a request for in-person hearing is granted, the party is deemed to have waived the 90 day timeframe for ALJ decision-making. One commenter noted that § 1869(d)(1)(B) of the Act only provides for a waiver of the time period upon motion or stipulation of the party, and a request for an in-person hearing is not a motion or stipulation to waive the 90 day time period. The same commenter also observed that the regulations do not include a specific timeframe for making a decision in this situation even though Congress legislated set timeframes at every level of appeal. Although all of the commenters agreed that there should be a timeframe attached to these in-person hearings, they were split when it came to recommending a particular timeframe. Some commenters believed strongly that the 90 day timeframe that ordinarily applies to ALJ hearings should apply to in-person hearings. These commenters opined that the intent of BIPA, as amended by the MMA, was to give everyone access to an ALJ hearing within the 90 day timeframe. As such, ALJs should be held to rendering their decision within the 90 day timeframe for all hearing formats. One of these commenters suggested that the reduced number of in-person hearings should enable ALJs to meet the 90 day decision-making timeframe. In contrast, another commenter recommended setting a longer, but still defined, timeframe, such as 120 days, as a reasonable time limit for an in-person hearing. Similarly, another commenter suggested that in the event of an in-person hearing, the ALJ should have 90 days from the date of the hearing (as opposed to 90 days from the date the request for hearing is received) within which to render the decision.

Response: As discussed previously, in making revisions to the administrative appeals process in both BIPA and MMA, Congress did not specify the manner in which ALJ hearings were to be conducted. Thus, while hearings may be conducted in-person, by VTC or by telephone, parties do not have the right to a specific type of hearing, and ALJs are not required to offer an in-person hearing to parties. The Congress instructed the DHHS to consider the use of teleconference and video-teleconference technologies for ALJ hearings. *See* section 931(a)(2)(G) of the MMA. After carefully considering the feasibility of utilizing these technologies, the logistical issues in conducting hearings, and the need to devise procedures compatible with meeting the statutory deadlines, it became clear that VTC and telephone were appropriate methods for holding most ALJ hearings. While a hearing may be conducted in-person, by VTC or by telephone (§ 405.1000(b)), under § 405.1020(b), an ALJ will conduct the hearing by VTC if the technology is

available, thereby establishing VTC as the default method for conducting hearings.

We are mindful, however, that some parties may prefer or require an in-person hearing. Thus, under § 405.1020(b), an ALJ may offer to conduct an in-person hearing when VTC is not available, or if special or extraordinary circumstances exist making an in-person hearing necessary. Additionally, in § 405.1020(i), we afford parties an opportunity to object to a hearing scheduled to be conducted by VTC or telephone, and request an in-person hearing. If the ALJ grants the request for an in-person hearing, in many cases, the ALJ may need additional time beyond the standard 90-day adjudication time period specified in § 405.1016 in order to schedule, prepare for, and conduct an in-person hearing, and issue a decision. Accordingly, § 405.1020(i)(4), as clarified in our correcting amendment to the interim final rule issued June 30, 2005, states that the 90 day adjudication timeframe is waived if a party objects to the ALJ's scheduling of a hearing by VTC or telephone, and the ALJ, with the concurrence of the Managing Field Office ALJ, grants the party's request for an in-person hearing. *See* 70 FR 37700, 37701, 37704.

We have carefully considered the commenter's assertion that section 1869(d)(1)(B) of the Act only provides for a waiver of the adjudication deadline upon motion or stipulation of the party, and that a request for an in-person hearing is not a motion or stipulation to waive the 90-day time period. While we continue to believe that the statutory language is consistent with a reading that a party can be deemed to have waived the adjudication deadline when the party requests and is granted an in-person hearing, after further consideration, we have decided to amend § 405.1020(i) to state that when a party's request for an in-person hearing under § 405.1020(i)(1) is granted, the ALJ must issue a decision within the adjudication timeframe specified in § 405.1016 (including any applicable extensions provided in subpart I), unless the party requesting the hearing waives the adjudication timeframe in writing. We believe that this revised regulation also is consistent with the statutory language.

Commenters also offered recommendations to impose a specific adjudication timeframe for issuing decisions when an ALJ grants a request for an in-person hearing in response to an objection to a scheduled VTC or telephone hearing under § 405.1020(i). Given the revisions to § 405.1020(i) described above, it is no longer necessary to consider adopting these alternative timeframes. Furthermore, under § 405.1036(d), an appellant who waives the 90 day adjudication timeframe may work with the ALJ to establish an alternative decision making timeframe to ensure they have some expectation of when the ALJ will render his or her decision.

Finally, we are making a technical revision to § 405.1022(a) to clarify that even where a party waives receipt of the notice of hearing, the ALJ must still send the notice of hearing to all other parties and potential participants who have not waived their right to receive the notice of hearing, consistent with § 405.1020(c). Section 405.1022(a) provides that the ALJ sets the time and place of the hearing and mails the notice of hearing to the parties and other potential participants as provided in § 405.1020(c) unless the parties have indicated in writing that they do not wish to receive this notice. In turn, under § 405.1020(c)(2), parties to the hearing (and any potential participant from CMS or its contractor who wishes to attend the hearing) are required to reply to the notice of hearing to acknowledge whether they plan to attend the hearing, or to object to the proposed time and/or place of the hearing. In addition, under § 405.1010 and § 405.1012, CMS or its contractor is required to notify the ALJ, appellant, and all other parties identified in the notice of hearing of their intent to participate in the hearing or join as a party within 10 days after receiving the notice of hearing. In order for parties and potential participants from CMS or its contractor (who wish to attend the hearing) to comply with § 405.1020(c)(2), and for CMS and its contractors to provide the ALJ and all parties timely notice of their intent to join as a party or participate in the hearing consistent with § 405.1010(b) and § 405.1012(b), the ALJ must send the notice of hearing to the appropriate parties and potential participants, consistent with § 405.1020(c)(1). Thus, we are revising § 405.1022(a) to clarify that even where a party waives receipt of the notice of hearing, the ALJ must still send the notice of hearing to all other parties and potential participants who have not waived their right to receive the notice of hearing, consistent with § 405.1020(c).

We are finalizing § 405.1020 and § 405.1022 with modifications as noted above and as discussed in section II.B.5.a. of this preamble. We are finalizing § 405.1024 with modification as discussed in section II.B.5.a. of this preamble.

f. Disqualification of the ALJ (§ 405.1026)

In § 405.1026, we state that an ALJ cannot conduct a hearing if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision. We also explain the process that a party must follow if they object to the ALJ assigned to conduct the hearing.

Comment: A number of commenters raised concerns about the independence of the DHHS ALJs. One commenter stated that, under SSA regulations, an ALJ may grant an in-person hearing if the party requesting it states they do not wish to appear by VTC. By contrast, the commenter noted that under DHHS regulations for Medicare appeals, the ALJ must seek the concurrence of the Managing Field Office ALJ in order to grant requests for in-person hearings. Another commenter questioned how an ALJ can be independent and base a decision on the evidence before him or her, if such concurrence is needed in what may be the first motion in the case.

A few commenters also questioned CMS' influence over the ALJs. One commenter recommended that safeguards be put in place to avoid any undue influence on the ALJs' independence. Another commenter viewed the issuance of the new appeals regulation by CMS, and the content of the provisions, as a strong indicator of CMS' intent to influence and control the ALJs' decision-making process. Finally, a commenter stated that formalized procedures in the form of promulgated rules on how the new Office of Medicare Hearings and Appeals will function are necessary to ensure ALJ independence.

Response: The Managing Administrative Law Judge (MALJ) is responsible for the administration of the field office, and is charged with ensuring the just, timely, accurate, and professional adjudication of all Medicare claims appeals whether they are heard in-person, via VTC, or by telephone. MALJ oversight is not intended to impede the judicial independence of the ALJ assigned to the appeal, but rather, such oversight will aid in the coordination of resources needed to successfully carry out an in-person hearing and will also assist the ALJs in fulfilling their responsibility to ensure that appellants receive an appropriate hearing and that appeals are decided in a timely manner.

In terms of structural organization, the DHHS is divided into a series of operational divisions that are administratively and programmatically independent of one another. Each

operational division has its own personnel, administrative support, and programmatic mission. While each operational division is ultimately accountable to the Secretary, they are independent of one another. As described in the June 23, 2005 Office of Medicare Hearings and Appeals; Statement of Organization, Functions, and Delegations of Authority that formally established OMHA, OMHA is part of the Office of the Secretary and is completely separate from CMS. 70 FR 36386. OMHA is under the direction of the Chief Administrative Law Judge who reports directly to the Secretary. 70 FR 36386 through 36387. Thus, consistent with section 931(b)(2) of MMA, Medicare appellants receive hearings before ALJs from an office that is organizationally and functionally separate from CMS.

Section 521 of BIPA amended section 1869 of the Act to substantially revise the Medicare claim appeals process. The statute mandated a series of structural and procedural changes to the existing appeals process, which necessitated the publication of new regulations to implement the statutory changes. Since CMS administers the Medicare program, and is responsible for safeguarding the interests of Medicare beneficiaries, it was the agency's responsibility to issue regulations implementing the BIPA provisions that revised the Medicare claims appeals process. These regulations were first published by CMS in the **Federal Register** as a proposed rule on November 15, 2002. CMS subsequently published an interim final rule with comment period on March 8, 2005, which included responses to the comments submitted on the proposed rule. The MMA mandated that the transfer of ALJ appeals from SSA to DHHS was not to begin earlier than July 1, 2005. Consequently, the proposed and interim final regulations were drafted and issued at a time when OMHA was not in existence. We note that the Medicare Appeals Council has been involved in developing relevant provisions of the proposed rule, interim final rule and this final rule, and OMHA has been involved in developing responses to comments and revisions to relevant regulatory provisions included in this final rule.

Finally, as noted above, the June 23, 2005 Office of Medicare Hearings and Appeals; Statement of Organization, Functions, and Delegations of Authority established OMHA as a part of the Office of the Secretary completely separate from CMS. *See* 70 FR 36386 through 36387. Pursuant to this Statement, OMHA is under the direction of the Chief Administrative Law Judge who reports directly to the Secretary. The Statement further describes the mission, organization and functions of OMHA. We do not believe that additional formalized procedures in the form of promulgated rules on how OMHA functions are necessary to ensure ALJ independence.

Comment: One commenter inquired about the possibility of establishing a complaint mechanism for appellants who feel the ALJ has failed to maintain his/her impartiality.

Response: Section 405.1026(a) establishes that ''[a]n ALJ cannot conduct a hearing if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.'' Under § 405.1026(b), ''[i]f a party objects to the ALJ who will conduct the hearing, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing. The ALJ considers the party's objections and decides whether to proceed with the hearing or withdraw.'' Section 405.1026(c) provides that ''[i]f the ALJ does not withdraw, the party may, after the ALJ has issued an action in the case, present his or her objections to the MAC in accordance with § 405.1100 *et seq.''* Section 405.1026(c) further provides that ''[i]f the case is escalated to the MAC after a hearing is held but before the ALJ issues a decision, the MAC considers the reasons the party objected to the ALJ during its review of the case and, if the MAC deems it necessary, may remand the case to another ALJ for a hearing and decision.'' We believe that the provisions set forth in § 405.1026 provide sufficient procedures by which a party can object to the presiding ALJ for their hearing. Given these safeguards, we believe that the regulation as written sufficiently addresses the commenter's concerns.

Accordingly, we are finalizing § 405.1026 without modification.

g. Review of Evidence Submitted to the ALJ, Hearing Procedures, and Issues Before an ALJ (§ 405.1028 Through § 405.1032)

In § 405.1028, we explain the process for prehearing review of evidence submitted to the ALJ, including the procedures an ALJ follows in determining whether good cause exists to allow the submission of new evidence at the ALJ hearing by a provider, supplier or beneficiary represented by a provider or supplier, and the effect of a finding that good cause does not exist. In § 405.1030, we establish general procedures for ALJ hearings, including the procedures that apply when an ALJ determines that there is material evidence missing at the hearing. In section 405.1032, we discuss the types of issues that an ALJ may consider at a hearing, the conditions under which an ALJ may consider new issues at the hearing, and the restrictions imposed on adding new claims to pending appeals.

Comment: One commenter stated that § 405.1032 appears to allow an ALJ to consider new issues at the hearing that result from the participation by CMS or its contractors. The commenter indicated that this should not be allowed to occur if the matter could not have been reopened under the reopening provisions of § 405.980. The commenter recommended that § 405.1032 be amended to specify that no new issue should be addressed by the ALJ unless the standards for reopening are met.

Response: As noted in § 405.1032(a), ALJs consider the issues raised during previous levels of appeal not decided entirely in a party's favor (although, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, the ALJ notifies the parties before the hearing and may consider it an issue at the hearing). However, there may be instances where the evidence presented to the ALJ brings to light a new issue. Accordingly, under § 405.1032(b), we allow an ALJ to consider new issues at the hearing, subject to the limitations described in § 405.1032(b)(1)(i) and (ii).

In the interest of the efficient resolution of claims appeals, we have developed procedures that foster the early resolution of disputes over claim determinations. With the requirement for the full and early presentation of evidence described above, as well as other provisions, we are attempting to avoid a prolonged and costly appeals process. Thus, we expect under the framework established in subpart I, that parties will raise issues as soon as practicable. It is neither efficient nor effective for parties to wait until the ALJ hearing to raise issues if those issues could have been brought to light and potentially resolved at previous levels. Therefore, in § 405.1032, we placed restrictions on the ability of a party to raise a new issue at the ALJ level. We believe that the restrictions currently set forth in § 405.1032(b) strike a reasonable balance between the need for efficient resolution of claims appeals and the need to consider new issues in certain circumstances.

We agree with the commenter's general description of the provisions of § 405.1032(b). Under § 405.1032(b)(1), an ALJ may raise and consider a new issue at the hearing when the conditions set forth in § 405.1032(b) are met. Like

any other party, when CMS and its contractors elect to be a party to an ALJ hearing under § 405.1012, CMS and its contractors have the right to raise new issues, but the conditions established in § 405.1032(b) must be satisfied before the ALJ may consider a new issue at the hearing. Section 405.1032(b) requires an ALJ to notify all of the parties about the new issue prior to the start of the hearing, and states that an ALJ may only consider a new issue at the hearing if its resolution could have a material impact on the claim(s) that are the subject of the request for hearing, and its resolution is permissible under the rules governing reopening of determinations and decisions. When electing to be a participant under § 405.1010, CMS and its contractors do not have the right to raise new issues at the ALJ level under § 405.1032. Rather, as a participant under § 405.1010, CMS or its contractor may provide evidence to the ALJ, and an ALJ may, in response, raise and consider a new issue at the hearing based on such evidence, consistent with § 405.1032(b)(1).

We believe the regulation is sufficiently clear in explaining that when an ALJ or a party, including CMS or its contractor when it elects party status, raises a new issue, the conditions set forth in § 405.1032(b) must be satisfied in order to have that new issue considered at the hearing. As discussed above, § 405.1032(b) requires, in pertinent part, that if a new issue is to be considered at the hearing, its resolution must be permissible under the rules governing the reopening of determinations and decisions. Thus, we do not believe it is necessary to amend § 405.1032, since we believe the regulation is already consistent with the commenter's suggested amendment regarding the conditions under which an ALJ may consider new issues.

Accordingly, we are finalizing §§ 405.1030 and 405.1032 without modification. We are finalizing § 405.1028 with modification as discussed in section II.B.5.a. of this preamble.

h. Remand Authority (§ 405.1034)

Section 405.1034 discusses when the ALJ can remand a case to the QIC. Section 405.1034(a) of the interim final rule states that in cases where the ALJ believes that the written record is missing information essential to resolving the issues on appeal, and such information can be provided only by CMS or its contractors, ALJs may either remand the case to the QIC that issued the reconsideration, or retain jurisdiction and request that the contractor forward the missing information to the appropriate hearing office.

It has come to our attention that there has been much confusion regarding what we meant by the phrase set forth in § 405.1034(a), ''can be provided only by CMS or its contractors.'' Thus, we are revising § 405.1034 to clarify that the phrase ''can be provided only by CMS or its contractors'' means the information is not publicly available, and is not in the possession of, and cannot be requested and obtained by any of the parties to the appeal. ''Publicly available'' means the information is available to the general public via the Internet, or in a printed publication. For example, information available on a CMS or contractor Web site or included in an official CMS or DHHS publication is publicly available information (for example, provisions of NCDs or LCDs, procedure code or modifier descriptions, fee schedule data, and contractor operating manual instructions). Similarly, medical records and certificates of medical necessity are examples of information that is in the possession of, or could be requested and obtained by, one or more parties to the appeal, even though CMS or its contractors may also possess or be able to request such information.

Furthermore, we are revising § 405.1034(a) to clarify that if the missing information is not information that can be provided only by CMS or its contractors, as clarified above, the ALJ must retain jurisdiction of the case and obtain the missing information on his or her own, or directly from one of the parties. We note that § 405.1028 allows an ALJ, for good cause, to admit new evidence submitted by a provider, supplier, or a beneficiary represented by a provider or supplier. If there is missing information related to this new evidence that is in the possession of, or could be requested and obtained by the provider, supplier or beneficiary represented by a provider or supplier, a remand pursuant to § 405.1034(a) to obtain this missing information would be inappropriate because such information is not information that can be provided only by CMS or its contractors.

Similarly, if information missing from the administrative record relates to a new issue raised for the first time at the ALJ level by the ALJ or a party under § 405.1032(b), the ALJ determines whether the missing information related to the new issue can be provided only by CMS or its contractors, consistent with § 405.1034(a), in determining whether remanding to the QIC or retaining jurisdiction of the case is appropriate.

Accordingly, we are finalizing § 405.1034 with modifications as noted.

i. Description of the ALJ Hearing Process and Discovery (§ 405.1036 and § 405.1037)

Section 405.1036 provides details regarding the ALJ hearing process, including the procedures for the issuance of subpoenas by ALJs. In § 405.1037, we describe the discovery process available at an ALJ hearing when CMS or its contractor elects to participate in the hearing as a party. We received several comments regarding the subpoena and discovery provisions. A summary of the comments and our responses are included below. Detailed discussion of these provisions is included in the interim final rule at 70 FR 11461 through 11462.

Comment: We received several comments concerning subpoena requests at the ALJ level of appeal. The commenters expressed concern that a party may only seek ALJ issuance of a subpoena after all of the steps outlined in § 405.1036(f)(4) regarding discovery have been taken, but the subpoena must be requested within 10 calendar days of the receipt of the notice of hearing. *See* § 405.1036(f)(3). The commenters recommended that the provision be amended to state that the request for subpoena may be filed at any time before the ALJ issues a decision. One commenter suggested that alternatively, a party making a subpoena request should be allowed a ''reasonable'' amount of time to file the request for a subpoena, after the party has exhausted all other required efforts to obtain the records.

Response: We acknowledge that the rule requiring parties to submit subpoena requests within 10 calendar days of receipt of the notice of hearing as set forth in § 405.1036(f)(3) may be difficult to comply with given the requirements for the issuance of subpoenas described in § 405.1036(f)(4). We considered the commenters' suggestions to allow for the submission of subpoena requests anytime prior to the issuance of the ALJ decision, or alternatively, within a reasonable time after exhausting required efforts to obtain the requested information. However, we believe allowing subpoena requests to be submitted at anytime prior to the decision may negatively impact the ability of ALJs to issue hearing decisions within the applicable adjudication timeframes once discovery is complete. Although we agree that it would be appropriate to allow parties a reasonable time to submit subpoena requests after exhausting all other efforts to obtain the necessary records, we must

also consider the need to avoid unnecessary delays in the hearing process and the need to define the timeframe during which discovery will be completed. During the discovery process, parties to the hearing will become aware of any failure to comply with an ALJ's order compelling disclosure. Since a party's request for a subpoena must follow non-compliance with an order to compel disclosure, we believe it is reasonable to require parties to submit a request for subpoena prior to the end of the discovery period established by the ALJ in accordance with § 405.1037(c). Thus, we are amending § 405.1036(f)(3) accordingly. Should an ALJ determine that additional time is necessary in order to issue the subpoena and obtain the information requested or secure an appearance and/or testimony, the ALJ may extend the discovery period in accordance with § 405.1037(c)(4).

Comment: We received two comments concerning the discovery provisions. Both commenters objected to the policy making discovery available only when CMS participates in the hearing as a party. *See* § 405.1037(a). One commenter suggested that any documents relied upon by the contractors in making previous decisions should be discoverable. Another commenter stated that the use of admissions and interrogatories should be allowable under § 405.1037 consistent with the standards applicable to the use of depositions.

Response: Neither BIPA nor the MMA explicitly provides for discovery during ALJ proceedings, and given the evidence requirements and timeframes imposed by BIPA and the MMA, we do not believe that a full discovery process is necessary or even feasible at the ALJ level. Nevertheless, we decided, in response to comments received on the proposed rule, to permit limited discovery in § 405.1037 when CMS or its contractors become a party at the ALJ hearing level. *See* 70 FR 11461 through 11462. We continue to believe it is appropriate to allow only limited discovery in this instance, and that such discovery enhances the fairness of proceedings and the accuracy of decisions. We also believe that, in general, most information relevant to the issues before an ALJ, including documents relied upon by contractors in making their decisions, is obtainable by direct request of a party or the ALJ, or is already included in the administrative record. With respect to our prohibition on the use of interrogatories and admissions, we believe such discovery practices are unnecessary because the factual information typically obtained through the use of admissions and interrogatories is often already included in the administrative record, can be established during a pre-hearing conference under § 405.1040, or can be developed at the hearing. In addition, if an ALJ determines evidence is missing from the record, the ALJ may follow the procedures set forth in § 405.1030(c) to obtain such evidence. Thus, we do not believe it is necessary to include more expansive discovery provisions in the final rule.

Finally, we have determined that it is necessary to make technical revisions to § 405.1036(f) in order to clarify our policies, as discussed below. Section 405.1036(f)(1) authorizes, when it is reasonably necessary for the full presentation of the case, an ALJ to issue subpoenas, on his or her own initiative or at the request of a party, for the appearance and testimony of witnesses, and for a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying.

It has come to our attention that there has been some confusion regarding the participation regulations at § 405.1010 and § 405.1012 and the use of subpoenas under § 405.1036(f). As discussed above, an ALJ may not require CMS or its contractors to participate in a hearing either as a participant or as a party, and may not draw an adverse inference if CMS or its contractors decide not to participate or be a party in a proceeding before the ALJ. *See* §§ 405.1010(a) and (f) and 405.1012(d). Under these regulations, CMS and its contractors have discretion to determine whether to participate in ALJ proceedings, and to determine the manner and extent of their participation. We are clarifying in this final rule that § 405.1036(f) is not intended to permit the use of subpoenas to circumvent or limit the discretion provided to CMS and its contractors regarding participation in ALJ hearings. Thus, we are amending § 405.1036(f)(1) to clarify that an ALJ may not, on his or her own initiative or at the request of a party, issue a subpoena to CMS or its contractors to compel an appearance, testimony or the production of evidence in the context of a Medicare claim appeal under this subpart.

For similar reasons, we are also amending § 405.1122(d)(1) to clarify that the MAC may not issue subpoenas to CMS or its contractors, on its own initiative or at the request of a party, to compel the production of evidence. Similar to the policies and procedures applicable to ALJ proceedings, CMS and its contractors have discretion to determine whether to participate, and to determine the manner and extent of their participation, in a MAC review. Specifically, in § 405.1124(d) regarding oral argument, the MAC may request, but not require, CMS or its contractor to appear before it if the MAC determines that it may be helpful in resolving issues in a case. In addition, § 405.1124(e) states that the MAC may not draw any inference if CMS or its contractor decides not to participate in an oral argument. Furthermore, under § 405.1110, CMS or its contractors may refer a case to the MAC for review under the MAC's own motion authority. Thus, we are clarifying that § 405.1122(d) is not intended to permit the use of subpoenas to circumvent or limit the discretion provided to CMS and its contractors regarding participation in a MAC review. Finally, we note that the policy prohibiting the issuance of subpoenas to CMS by ALJs and the MAC as described above, is also supported by the long-settled doctrine of sovereign immunity.

Accordingly, we are finalizing §§ 405.1036 and 405.1122 with modifications as noted above. We are finalizing §§ 405.1036 and 405.1037 with modification as noted in section II.B.5.a. of this preamble.

j. Deciding a Case Without an ALJ Hearing, Conferences, the Administrative Record, and Consolidated Hearings (§ 405.1038 Through § 405.1044)

In §§ 405.1038 through 405.1044, we describe various procedures established for the conduct of ALJ hearings. In § 405.1038, we outline the circumstances in which an ALJ may issue a decision without holding a hearing. In § 405.1040, we describe the process for holding prehearing and posthearing conferences. In § 405.1042, we explain the requirements applicable to the creation of the administrative record of the ALJ proceedings, and for requesting and receiving copies of the administrative record. In § 405.1044, we describe the requirements applicable to holding a consolidated hearing before the ALJ. Additional discussion is included in the interim final rule at 70 FR 11464 through 11465.

We received no comments on these sections. However, in § 405.1038(b)(1)(i) we made a technical correction, changing the term ''videoconferencing'' to ''videoteleconferencing'', consistent with the use of the term throughout this regulation.

Accordingly, we are finalizing § 405.1040 without modification. We are finalizing § 405.1038 with the

modification noted above. We are finalizing §§ 405.1042 and 405.1044 with modification as discussed in section II.B.5.a. of this preamble.

k. Notice and Effect of ALJ's Decision (§ 405.1046 Through § 405.1048)

Section 405.1046 sets forth general rules regarding the notice of an ALJ's decision and describes certain limitations on an ALJ's decision, and § 405.1048 explains the effect of an ALJ decision on all parties to the hearing. We received one comment on the effect of an ALJ decision. A summary of the comment and our response are included below. Additional detailed discussion is included in the interim final rule at 70 FR 11466 through 11467.

Comment: We received a comment concerning the effect of an ALJ decision. The commenter urged CMS to state in the regulations that ALJ decisions are entitled to substantial deference by other adjudicators in the appeals process. The commenter believed that cases that have made it to the ALJ level are more likely to be cases concerning issues most important to beneficiaries and providers and, since the ALJ has fully considered such issues, other levels of appeal should benefit from these prior decisions and accord them substantial deference, similar to that which a district court would accord to a decision by another district court within the same circuit.

Response: We disagree with the commenter's recommendation, and note that, in some instances, it would be inappropriate to require other adjudicators to afford substantial deference to ALJ decisions. For example, the MAC is responsible for reviewing certain ALJ decisions and issuing final decisions on those appeals for the DHHS. Section 521 of BIPA added 1869(d)(2)(B) of the Social Security Act to mandate that in reviewing an ALJ decision, the MAC shall review the case *de novo. See* § 405.1100(c), § 405.1108(a). This is an expansion of the scope of review the MAC previously exercised in pre-BIPA appeals. Granting ALJ decisions substantial deference would be inconsistent with the DAB's expanded review authority provided by Congress.

In addition, the coverage and liability determinations made on claims submitted for treatment are largely unique to the specific facts and circumstances of a given case. Thus, it would prove extremely difficult to identify a set of decisions that could be appropriately afforded deference.

Finally, we note that section 931 of the MMA instructed DHHS to assess the feasibility of developing a process to give decisions of the DAB addressing broad legal issues, binding and precedential authority. After thorough consideration, DHHS determined that it is neither feasible, nor appropriate at this time to confer binding, precedential authority upon decisions of the MAC. Because MAC decisions are not given precedential weight, it would be impractical and illogical to afford any form of deference to ALJ decisions. Therefore, we do not believe it is appropriate to adopt the commenter's suggestion to require other adjudicators in the Medicare administrative appeals process to afford substantial deference to ALJ decisions.

We are finalizing §§ 405.1046 and 405.1048 with modification as discussed in section II.B.5.b. of this preamble. Additionally, we are finalizing § 405.1046 with modification as discussed in section II.B.5.a. of this preamble.

l. Removal of a Hearing Request From the ALJ to the MAC, Dismissal of a Request for ALJ Hearing, and the Effect of a Dismissal (§ 405.1050 Through § 405.1054)

In § 405.1050, we explain the process for the MAC to assume responsibility for holding a hearing if a request for hearing is pending before an ALJ. In § 405.1052, we explain the bases under which an ALJ dismisses a request for hearing, and, in § 405.1054, we explain the effect of a dismissal of a request for ALJ hearing. Additional discussion is included in the interim final rule at 70 FR 11465 through 11466. We received no comments on these provisions.

We are finalizing §§ 405.1050 and 405.1054 without modification. We are finalizing § 405.1052 with modification as discussed in section II.B.5.b. of this preamble and with modification as discussed in section II.B.5.a. of this preamble.

m. Applicability of Statutes, Regulations, Medicare Coverage Policies, CMS Rulings and Other Program Guidance (§ 405.1060 Through § 405.1063)

In § 405.1060, we explain the applicability of national coverage determinations (NCDs) to decisions made by fiscal intermediaries, carriers, QIOs, QICs, ALJs, and the MAC. In § 405.1062, we provide that ALJs and the MAC must afford LCDs, LMRPs and CMS program guidance (including program memoranda and manual instructions) substantial deference if they are applicable to a particular case. In § 401.108(c) and § 405.1063, we explain that CMS rulings are binding on all CMS components, on all DHHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

We received several comments with respect to the requirement that ALJs and the MAC afford Medicare local coverage determinations and program guidance substantial deference. A summary of the comments, and our response to those comments are included below. Additional discussion is included in the interim final rule at 70 FR 11457 through 11458.

Comment: We received several comments concerning the provisions requiring ALJs and the MAC to give substantial deference to Medicare LCDs, LMRPs and CMS program guidance, if the pertinent policy or guidance is applicable to the specific case (§ 405.1062). Most of these commenters objected to the substantial deference provisions. Some commenters objected to the presumption of validity attributed to policies and guidance under this provision, and believed it would lead to adjudicators ''rubber-stamping'' the previous appeal decision, while another commenter noted that ALJs and the MAC currently decide whether informal policies are entitled to deference based on Supreme Court precedents.

Response: As noted above and further discussed below, ALJs and the MAC are bound by the Medicare statute, CMS regulations, CMS Rulings, and NCDs. *See* sections 405.1060, 405.1063, 401.108; in addition *see* our discussion at 70 FR 11457 through 11458. In § 405.1062, we explain the degree to which ALJs and the MAC must defer to non-binding CMS program guidance (such as manual instructions and program memoranda), LMRPs and LCDs. ALJs and the MAC consider whether guidance documents, LMRPs and LCDs should apply to a specific claim for benefits. If it is determined that the policy is applicable in the instant case, then the adjudicator must grant substantial deference to the policy. However, if the adjudicator declines to follow a policy in a particular case, the adjudicator must explain why the policy was not followed. The decision to disregard a policy in a specific case does not have precedential effect. *See* § 405.1062(a) and (b). Thus, ALJs will continue their traditional role as independent evaluators of the facts presented in specific, individual cases. Requiring an ALJ to consider CMS policy and give substantial deference to it, if applicable to a particular case, does not alter the ALJ's role as an independent fact finder. *See* 70 FR

11458. Thus we do not believe this regulation will lead to adjudicators ''rubber-stamping'' the previous appeal decision.

In this final regulation, we are making a technical correction to § 405.1063. In § 405.1063, we did not include a provision that expressly stated our longstanding policy, as described in the interim final rule, regarding the applicability of the Medicare statute and CMS regulations to ALJs and the MAC. *See* 70 FR 11457. We are making this correction by adding paragraph (a) to § 405.1063 to specify that ALJs and the MAC are bound by all laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations.

Accordingly, we are finalizing § 405.1060 and § 405.1062 without modification. We are finalizing § 405.1063 with modifications as noted.

n. ALJ Decisions Involving Statistical Samples (§ 405.1064)

In § 405.1064, we explain that when an appeal from the QIC involves an overpayment, and the QIC relied on a statistical sample in reaching its decision, the ALJ must base his or her decision on a review of all claims in the sample. We received two comments regarding this provision. A summary of the comments, and our responses are provided below. Additional detailed discussion is included in the interim final rule at 70 FR 11466.

Comment: Two commenters expressed concern that the regulation does not address the authority of an ALJ to consider challenges to the sampling methodology when an overpayment assessment is estimated through extrapolation, and requested that we clarify our position on this issue in the regulation. One of these commenters also suggested that we include a provision requiring that appellants be given all documentation concerning the contractor's sampling process.

Response: Medicare's longstanding policy has been to allow appellants a full opportunity to challenge issues related to the calculation of overpayments estimated by extrapolation from a sample. We outlined in detail the basis for our authority to extrapolate overpayments in CMS (HCFA) Ruling 86–1, and since 1986, have included procedures for contractors in operating instructions. As explained in Ruling 86–1, we agree with the commenter's assertion that appellants may challenge, and an ALJ may review, the sampling methodology used to calculate the overpayment.

> Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the appellant to take the next step. The appellant could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability [under section 1879 of the Act] where medical necessity or custodial care is at issue). In either case, the appellant is given a full opportunity to demonstrate that the overpayment is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected. (HCFAR 86–1–9, 10)

Adjudicators are bound by CMS rulings. Thus, we do not believe it is necessary to include further clarification in the regulation.

Furthermore, parties may request and receive the information contained in the case file. *See* § 405.1042 and § 405.1118. The case file should include all documentation regarding the sampling methodology used to calculate an overpayment. If such documentation is not in the administrative record, a party may request the pertinent documentation from the contractor or adjudicator. Thus, we believe that appellants already have adequate access to documentation concerning the contractor's sampling process, and that it is not necessary to include an additional provision in the final rule.

Accordingly, we are finalizing § 405.1064 without modification.

10. Review by the Medicare Appeals Council (§ 405.1100 Through § 405.1134)

Sections 405.1100 through 405.1134 set forth the procedures for MAC review of ALJ decisions and dismissals. We received comments with respect to the MAC's standard of review and submission of evidence during MAC review. A brief description of the pertinent regulatory provisions, a summary of the comments, and our responses to the comments follow below. Additional discussion regarding MAC review is included in the interim final rule at 70 FR 11454 through 11456, 11459 through 11464, and 11466 through 11467.

a. MAC Review of an ALJ's Action (§ 405.1100 Through § 405.1120)

Section 405.1100 states that the MAC undertakes a *de novo* review of an ALJ decision, and provides a general description of the MAC review process. Section 405.1102 describes the process for requesting MAC review of an ALJ decision or dismissal. Section 405.1104 describes an appellant's right to request escalation of a case from the ALJ level to the MAC. In § 405.1106, we specify the locations where parties must file requests for MAC review or escalation. Section 405.1108 sets forth the actions a MAC may take upon receipt of a request for review or escalation. Section 405.1110 describes the MAC's authority to review ALJ decisions or dismissals on its own motion. Section 405.1112 sets forth the content requirements for requests for MAC review. Section 405.1114 describes the circumstances in which the MAC dismisses a request for review, and § 405.1116 describes the effect of a dismissal by the MAC. Section 405.1118 explains the process by which a party may request a copy of the administrative record developed at the ALJ hearing and an opportunity to comment on the evidence. Section 405.1120 discusses filing briefs with the MAC.

Comment: Two of the comments we received expressed concern about the standard of review at the MAC level. One commenter suggested modifying § 405.1100 to provide for a ''substantial evidence'' standard of review as is applicable in judicial review, or alternatively, a ''preponderance of evidence'' standard. However, both commenters stated that although § 405.1100 provides for the MAC to undertake *de novo* review of an ALJ decision, the MAC's rules limit the opportunity for face-to-face hearings and restrict a party's right to submit evidence. The commenters indicated that these restrictions do not constitute a *de novo* review.

Response: The *de novo* standard of review that is applicable at the MAC level is statutorily required by section 1869(d)(2)(B) of the Act, as added by BIPA. Thus, the MAC may not review ALJ decisions under a substantial evidence standard as it had under previous rules, nor may it utilize a preponderance of evidence standard to adjudicate appeals. Similarly, the limitation on the submission of evidence set forth in § 405.1122 is required under section 1869(b)(3) of the Act. We note that this limitation restricts the scope of the MAC's review, not the applicable standard of review.

Finally, with respect to the commenter's concern about the limitations on face-to-face hearings, while most cases before the MAC are resolved without oral argument, under § 405.1124, parties may request to

appear before the MAC to present oral argument, or the MAC may determine on its own that oral argument is necessary to decide the issues in the case. The fact that the MAC may not grant a party's request to permit oral argument in a case does not alter the *de novo* standard of review by the MAC.

In this final rule, we are making certain technical revisions to § 405.1106 and § 405.1110, and a technical correction to § 405.1112(a). In § 405.1106(a), parties seeking MAC review of an ALJ hearing decision must send the request for review to the entity specified in the notice of the ALJ's decision, and send a copy of the request to the other parties to the ALJ decision or dismissal. Similarly, when CMS or its contractor refers a case to the MAC for the MAC to consider reviewing under its own motion review authority, in accordance with § 405.1110(b)(2), CMS sends a copy of the referral to the ALJ and to all the parties to the ALJ's action. Furthermore, in § 405.1110(b)(2), a party may file exceptions to CMS' referral to the MAC by submitting written comments to the MAC, to CMS and to all other parties to the ALJ's decision.

We would like to clarify that, for the purposes of MAC review, when an appellant is required to send a copy of the request for review to the ''other parties to the ALJ decision or dismissal'' under § 405.1106(a), this means the appellant must send a copy of the review request to the other parties to the ALJ decision or dismissal who received a notice of the ALJ's hearing decision under § 405.1046(a), or a notice of the ALJ's dismissal under § 405.1052(b). Similarly, if CMS refers a case to the MAC for the MAC to consider under its own motion review authority, when CMS sends a copy of the referral to ''all parties to the ALJ's action'' under § 405.1110(b)(2), this means CMS must send a copy of the referral to all parties to the ALJ's action who received a copy of the ALJ's hearing decision under § 405.1046(a) or a notice of the ALJ's dismissal under § 405.1052(b). Finally, when a party submits written comments regarding CMS' referral to the MAC to ''all other parties to the ALJ's decision'' under § 405.1110(b)(2), this means that the party must send a copy of such comments to all other parties to the ALJ's decision who received a copy of the hearing decision under § 405.1046(a) or a notice of the ALJ's dismissal under § 405.1052(b). We note that if the ALJ sends a copy of the ALJ hearing decision or dismissal to a person or entity that is not a party to the ALJ's decision or dismissal order (for example, a Medicare contractor who has not elected party status at the hearing under § 405.1012), the appellant is not required under § 405.1106(a) to send a copy of the request for MAC review to that person or entity because that person or entity is not a party. *See* § 405.906(b) and § 405.1008(b) for a description of the parties to an ALJ hearing. Pursuant to § 405.906, unless a beneficiary undertakes an assignment of appeal rights under § 405.912, the beneficiary is always considered a party to the ALJ hearing.

If the MAC determines that additional parties should receive a copy of the request for MAC review, the CMS referral to the MAC, or comments regarding CMS' referral to the MAC, the MAC may instruct the party or CMS, as appropriate, to send copies to such party or parties. We believe this will minimize any confusion regarding the parties an appellant or CMS must notify, and will ensure that those parties with an interest in the proceedings will be notified of the status of the appeal action.

We are also making a technical correction to § 405.1112(a) to replace a comma with a semi-colon following the phrase, ''if any''.

Accordingly, we are finalizing §§ 405.1108, 405.1114, 405.1116, and 405.1120 without modification. We are finalizing §§ 405.1102 and 405.1118 with modification as discussed in section II.B.5.a. of this preamble. We are finalizing §§ 405.1100, 405.1104, 405.1106, and 405.1110 with modification as discussed in section II.B.5.b. of this preamble and with modification as discussed in section II.B.5.a. of this preamble. We are finalizing § 405.1112 with modification as discussed in section II.B.5.b. of this preamble. We are finalizing §§ 405.1106, 405.1110, and 405.1112 with additional modifications as noted above.

b. Evidence That May Be Submitted to the MAC and Subpoenas (§ 405.1122)

Section 405.1122 describes the evidence that may be submitted to and considered by the MAC, the process the MAC follows in issuing subpoenas, the reviewability of MAC subpoena rulings, and the process for seeking enforcement of subpoenas.

Comment: One commenter expressed concern about a party's ability to submit new evidence for MAC review. The commenter acknowledged the value of submitting evidence early in the appeals process. However, the commenter believed new evidence should be allowed at the MAC level if the evidence becomes pertinent following the ALJ's decision.

Response: As noted above, the limitation on submission of evidence is set forth at section 1869(b)(3) of the Act. However, we believe that there are certain circumstances in which submission of new evidence for MAC review may be appropriate. We have described these circumstances at § 405.1122. As explained in § 405.1122(a)(1), when the MAC undertakes review of an ALJ decision, the MAC reviews all of the evidence contained in the administrative record. However, as explained in § 405.1122(a)(1), if the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level, the MAC considers any evidence related to that issue if it is submitted with the request for review. In addition, as set forth in § 405.1122(a)(2), if the MAC determines that additional evidence is necessary to resolve the issues in the case, and the hearing record indicates that there were no attempts to obtain such evidence in the proceedings below, the MAC may remand the case to the ALJ to obtain the evidence and issue a new decision.

Consistent with § 405.1122(c), if a provider, supplier, or a beneficiary represented by a provider or supplier, submits new evidence related to issues previously considered by the QIC, the MAC determines whether the party had good cause for submitting the evidence for the first time at the MAC level. The MAC must exclude evidence from consideration if good cause for late filing is not established, and must notify all parties of the exclusion. However, the MAC may remand a case to an ALJ if the new evidence was previously submitted by a provider, supplier, or beneficiary represented by a provider or supplier at the ALJ level, and was excluded from consideration because the ALJ determined that good cause did not exist under § 405.1028, but the MAC determines that good cause for late filing existed under § 405.1028 and the ALJ should have reviewed the evidence. *See* § 405.1122(c)(3). As set forth in § 405.1122(c)(3)(iii), the MAC may also remand a case to an ALJ if the new evidence is submitted by a party that is not a provider, supplier, or beneficiary represented by a provider or supplier. Therefore, we believe the regulations provide an appropriate balance between the need for appellants to submit evidence when the evidence becomes pertinent following the ALJ decision, and the need for the full and early presentation of evidence as required by the statute.

Although we received no comments on § 405.1122(d) through (f), we have determined that it is necessary to make certain technical revisions to these subsections to clarify our policies.

Sections 405.1122(d) through (f) explain the procedures the MAC follows when issuing subpoenas, the review process with respect to MAC rulings on subpoena requests, and the enforcement procedures to be followed if the MAC determines that either a party or non-party has failed to comply with a subpoena. As explained above in section II.B.9.i. of this preamble, we are revising § 405.1122(d)(1) to clarify that the MAC may not issue subpoenas to CMS or its contractors, on its own initiative or at the request of a party, to compel the production of evidence.

In addition, we note that § 405.1122 contains several technical errors that were not corrected in our previous technical correction notice. First, we are correcting the numbering of § 405.1122(e). Second, we are revising paragraph (e)(2)(v) (renumbered in this final rule as paragraph (e)(6)) to replace the word ''lifed'' with the word ''lifted.'' Third, in § 405.1122(f)(1), we are correcting the statutory reference to the process followed by the Secretary when seeking enforcement of a subpoena issued by the MAC; we incorrectly referenced section 205(c) of the Act and 42 U.S.C. 405(c) instead of section 205(e) of the Act and 42 U.S.C. 405(e).

Accordingly, we are finalizing § 405.1122 with modifications as noted and with modification as discussed in section II.B.5.a. of this preamble.

c. Oral Argument, Cases Remanded By the MAC, the Effect of MAC Actions, Escalation to Federal District Court, and Extensions of Time To File Actions in Federal District Court (§ 405.1124 Through § 405.1134)

In § 405.1124, we explain the circumstances in which the MAC may hear oral argument and the procedures that apply when the MAC hears oral argument. Section 405.1126 explains the MAC's remand authority and the procedures that apply when the MAC receives a recommended decision from the ALJ. Section 405.1128 describes the actions the MAC may take after reviewing the administrative record and any additional evidence (subject to the limitations on MAC consideration of additional evidence), and § 405.1130 describes the effect of the MAC's decision.

Section 405.1132 explains the process for an appellant to seek escalation of an appeal (other than an appeal of an ALJ dismissal) from the MAC to Federal district court if the MAC does not issue a decision or dismissal or remand the case to an ALJ within the adjudication period specified in § 405.1100, or as extended as provided in subpart I. Section 405.1134 explains how parties may request an extension of time to file an action in Federal district court.

We received no comments on these provisions. We are finalizing §§ 405.1128 and 405.1134 without modification. We are finalizing § 405.1124 with modification as discussed in section II.B.5.a. of this preamble. We are finalizing §§ 405.1126, 405.1130 and 405.1132 with modification as discussed in section II.B.5.b. of this preamble and with modification as discussed in section II.B.5.a. of this preamble.

11. Judicial Review (§ 405.1136 Through § 405.1140)

Section 405.1136 sets forth the requirements and procedures for filing requests for judicial review of a MAC decision in Federal district court, specifies the Federal district court in which such actions must be filed, and describes the standard of review. Sections 405.1138 and 405.1140 set forth the procedures that apply to cases that are remanded by a Federal district court to the Secretary for further consideration. We received two comments on these provisions. A summary of these comments, and our responses are included below.

Comment: One commenter noted that, in § 405.1136(b), we state that a party to a MAC decision (or an appellant who requests escalation from the MAC to Federal court) must file a civil action 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 primary place of business. The commenter believed that a party should be able to file a civil action in Washington, DC or the judicial district in which a regional office of DHHS exists.

Response: Section 1869(b)(1)(A) of the Act states that any individual dissatisfied with any initial determination shall be entitled to reconsideration of the determination, a hearing by the Secretary to the same extent as is provided in section 205(b) of the Act, and to judicial review of the Secretary's final decision after such hearing as provided in section 205(g) of the Act. Section 205(g) of the Act sets forth the filing requirements for judicial review. Our regulation restates these statutory requirements. We do not have the authority or discretion to alter the filing procedures established in Federal statute.

Comment: A commenter suggested that the standard of review established in § 405.1136(f) restricts Federal judges from applying the Administrative Procedure Act and evolving doctrines of judicial review of administrative decisions that govern other agencies.

Response: We appreciate the commenter's concerns regarding the standard of review applicable to judicial review of Medicare claim determinations. As discussed above, section 1869(b)(1)(A) of the Act provides for judicial review of the Secretary's final decision as provided in section 205(g) of the Act. Section 205(g) of the Act sets forth the standard of review that applies to actions in Federal district court, and our regulation implements these statutory requirements. We do not have the authority or discretion to alter the standard of review established in the statute.

Accordingly, we are finalizing § 405.1138 without modification. We are finalizing § 405.1136 with modification as discussed in section II.B.5.b. of this preamble and with modification as discussed in section II.B.5.a. of this preamble. We are finalizing § 405.1140 with modification as discussed in section II.B.5.a. of this preamble.

III. Provisions of the Final Regulations

In this final rule, we made the following changes to the interim final rule published on March 8, 2005:

- In section 405.902, we are adding a definition for the term contractor.
- In §§ 405.922, 405.942(a)(1), 405.942(b), 405.946(b), 405.950(b)(1), 405.950(b)(2), 405.950(b)(3), 405.962(a)(1), 405.962(a)(2), 405.962(b), 405.966(b), 405.966(c), 405.970(a)(2), 405.970(b)(1), 405.970(b)(2), 405.970(b)(3), 405.970(c), 405.970(e)(2), 405.974(b)(1), 405.974(b)(1)(i), 405.974(b)(1)(ii), 405.980(d)(1), 405.980(d)(2), 405.980(d)(3), 405.980(e)(1), 405.980(e)(2), 405.980(e)(3), 405.990(f)(2), 405.990(f)(4), 405.990(h)(2), 405.990(i)(2), 405.990(j)(1), 405.1002(a)(1), 405.1002(a)(3), 405.1002(a)(4), 405.1002(b)(2), 405.1004(a)(1), 405.1004(a)(3), 405.1004(a)(4), 405.1006(e)(1)(ii), 405.1010(b), 405.1012(b), 405.1014(b)(1), 405.1014(b)(2), 405.1016(a), 405.1016(c), 405.1018(a), 405.1018(b), 405.1020(g)(3)(ii), 405.1022(a), 405.1024(a), 405.1028(a), 405.1036(f)(5)(iv), 405.1037(c)(5), 405.1037(e)(2)(iii), 405.1042(b)(2), 405.1044(d), 405.1046(d), 405.1052(a)(2)(ii), 405.1052(a)(2)(iii), 405.1100(c), 405.1100(d), 405.1102(a)(1), 405.1102(a)(2), 405.1104(a)(2), 405.1106(b), 405.1110(a), 405.1110(b)(2), 405.1110(d), 405.1118, 405.1122(e)(4), 405.1124(b), 405.1126(d)(1), 405.1130, 405.1132(b), 405.1136(c)(3), 405.1136(d)(2),

405.1140(b)(1), 405.1140(c)(1), 405.1140(c)(4), 405.1140(d), we added the word ''calendar'' in front of the word ''day'' or ''days'' to clarify the timeframes referenced therein.

• In § 405.924, we removed paragraph (b)(7), because a determination regarding the number of home health visits used by a beneficiary is no longer considered an initial determination. We are renumbering the remaining paragraphs accordingly.

• In sections 405.952(e), 405.958, 405.972(e), 405.974(b)(3), 405.978, 405.980(a)(1), 405.980(a)(5), 405.1004(c), and 405.1052(a)(6), we made technical corrections by removing the term ''final'' or ''final and binding'' and replacing it with ''binding'' to clarify that the actions taken by an adjudicator described in the above sections are not considered final decisions of the Secretary for the purposes of exhausting administrative remedies when seeking judicial review in Federal court.

• In § 405.962(a) and § 405.972(b)(3), we made a technical correction by adding a reference to § 405.974(b)(1), which, as amended in this final rule, provides for a 60 calendar day filing timeframe to request a reconsideration of a contractor's redetermination dismissal action, as an exception to the 180 calendar day timeframe for filing a request for reconsideration of a contractor's redetermination decision.

• In § 405.972(e), we added a provision to clarify that a QIC's dismissal of a request for reconsideration of a contractor's dismissal action is binding and not subject to further review.

• In § 405.980(b), we made technical corrections by (1) replacing the word ''its'' with the word ''an'', and (2) removing the words ''and revise'' from the introductory sentence, so the sentence will now read: ''A contractor may reopen an initial determination or redetermination on its own motion— * * *''. We are replacing the word ''its'' with ''an'' to more clearly convey our longstanding policy to permit certain contractors, other than those who issue initial determinations, to reopen initial determinations when appropriate. In addition, removing the words ''and revise'' reflects our longstanding policy that the timeframes for reopening a determination or decision are measured by the date of the reopening not the date of the revision of the determination or decision.

• In § 405.990(b)(1)(i)(A), we made a technical correction to replace the phrase ''final decision'' with ''decision, dismissal order, or remand order'' to specify the types of actions that, if taken by an ALJ, preclude a request for EAJR and to be consistent with our clarification regarding the term ''final''.

• In § 405.990(b)(1)(i)(B), we made a technical correction by adding the phrase '', dismissal order, or remand order'' after ''final decision'' to specify the types of actions that, if taken by the MAC, preclude a request for EAJR and to be consistent with our clarification regarding the term ''final.''

• In § 405.990(b)(1)(ii), we made a technical correction by replacing the phrase ''final action'' with ''decision or dismissal order'' in order to clarify the nature of the QIC's action and to be consistent with our clarification regarding the term ''final.''

• In § 405.990(f)(3), we made a technical correction by removing the words ''final and'' to state that the decision of the review entity to certify or deny a request for EAJR is not subject to further review.

• In § 405.1000(c), we removed the phrase '', including the QIC, QIO, fiscal intermediary or carrier'' consistent with our revision to § 405.902 in which we define the term contractor.

• In § 405.1000(d), we made a technical revision to clarify that the ALJ conducts a *de novo* review.

• In § 405.1002(b)(2), we made a technical correction by replacing the words ''final action'' with ''decision or dismissal order'' in order to state the nature of the QIC's action and to be consistent with our clarification regarding the term ''final.''

• In § 405.1004(c), we made a technical correction to clarify that an ALJ's dismissal of a request for review of a QIC's dismissal action is binding and not subject to further review unless vacated by the MAC under § 405.1108(b).

• In § 405.1010(a) and § 405.1012(a), we made technical corrections by removing the phrase '', including a QIC'' consistent with our revision to § 405.902 in which we define the term contractor.

• In § 405.1020(c)(1), we removed the reference to, ''the contractor that issued the initial determination'' in specifying which entities are to receive notice of the ALJ hearing.

• We revised § 405.1020(i)(4) to state that when a party's request for an in-person hearing under § 405.1020(i)(1) is granted, the ALJ must issue a decision within the adjudication timeframe specified in § 405.1016 (including any applicable extensions provided in this subpart) unless the party requesting the hearing agrees to waive such adjudication timeframe in writing.

• In § 405.1022(a), we made a technical revision to clarify that when a party waives its right to receive the notice of hearing, the ALJ must still send the notice of hearing to all other parties and potential participants who have not waived their right to receive the notice of hearing, consistent with § 405.1020(c).

• In § 405.1034(a), we made several clarifications to the provisions allowing an ALJ to remand a case to the QIC. We explain that the phrase ''can be provided only by CMS or its contractors'' means the information is not publicly available and is not in the possession of and cannot be requested and obtained by any of the parties to the appeal. We explain that the term ''publicly available'' refers to information that is available to the general public via the Internet, or in a printed publication. We clarify that if the missing information is not information that can be provided only by CMS or its contractors (as that phrase is clarified above), the ALJ must retain jurisdiction of the case and obtain the missing information on his or her own, or directly from one of the parties.

• In § 405.1036(f)(1), we clarified that an ALJ may not issue subpoenas to CMS or its contractors, to compel an appearance, testimony or the production of evidence.

• In § 405.1036(f)(3), we revised the time period for submitting requests for subpoenas to an ALJ, and now require parties to submit a request for a subpoena no later than the end of the discovery period established by the ALJ under § 405.1037(c).

• In § 405.1038(b)(1)(i), we changed the term ''videoconferencing'' to ''videoteleconferencing'' consistent with the use of the term throughout this regulation.

• In § 405.1046(c), we made a technical correction by replacing the term ''final'' with ''binding on the contractor'' consistent with our clarification regarding the term ''final.''

• In § 405.1048(a), we made a technical correction by replacing the phrase ''either issues a final action'' with ''issues a final decision or remand order'' to clarify the types of actions issued by the MAC that cause an ALJ decision to not become binding, and to be consistent with our clarification regarding the term ''final.''

• Added § 405.1063(a) to clarify the additional authorities that are binding on ALJs and the MAC. The original paragraph in § 405.1063 is reassigned to subsection (b).

• In § 405.1100(c) and § 405.1100(d), we made technical corrections by replacing the phrase ''final action'' with ''final decision or dismissal order'' to specify the actions taken by the MAC

and to be consistent with our clarification regarding the term ''final.''

• In § 405.1104(a)(2) we made a technical correction by replacing the phrase ''final action or remand the case to the QIC'' with ''decision, dismissal order, or remand order'' to specify the actions taken by the MAC and to be consistent with our clarification regarding the term ''final.''

• In § 405.1104(b)(1), we made a technical correction by replacing the phrase ''final action or remand'' with ''decision, dismissal order, or remand order'' to specify the actions taken by the MAC and to be consistent with our clarification regarding the term ''final.''

• In § 405.1104(b)(2), we made a technical correction by replacing the phrase ''final action or remand order'' with ''decision, dismissal order, or remand order'' to specify the actions taken by the MAC and to be consistent with our clarification regarding the term ''final.''

• In § 405.1104(b)(3), we made a technical correction by replacing the phrase ''a final administrative decision for purposes of MAC review'' with the phrase ''the decision that is subject to MAC review consistent with § 405.1102(a)'' in order to clarify the effect of the QIC decision and to be consistent with our clarification regarding the term ''final.''

• In § 405.1104(c), we made a technical correction by replacing the phrase ''final action'' with the phrase ''decision, dismissal order, or remand order'' in order to specify the actions taken by the MAC and to be consistent with our clarification regarding the term ''final.''

• In § 405.1106(a), we clarified the meaning of the phrase ''other parties to the ALJ decision or dismissal.''

• In § 405.1106(b), we made a technical correction by replacing the phrase ''final action or remand the case to the ALJ'' with the phrase ''final decision, dismissal order, or remand order'' in order to specify the actions taken by the MAC and to be consistent with our clarification regarding the term ''final.''

• In § 405.1110(b)(2), we clarified the meaning of the phrases ''all parties to the ALJ's action'' and ''all other parties to the ALJ's decision.''

• In § 405.1110(d), we made a technical correction by replacing the phrase ''remains the final action in the case'' with the phrase ''is binding on the parties to the ALJ decision'' consistent with our clarification regarding the term ''final.''

• In § 405.1112(a), we made a technical correction by replacing the phrase ''final action'' with the phrase ''decision or dismissal order'' in order to specify the actions taken by the ALJ and to be consistent with our clarification regarding the term ''final''. We also made a technical correction by replacing a comma with a semi-colon following the phrase ''if any.''

• In § 405.1122(d)(1), we clarified that the MAC may not issue subpoenas to CMS or its contractors to compel the production of evidence.

• We made a technical correction in paragraph § 405.1122(e)(2)(v), correcting the word ''lifed'' to read ''lifted.''

• We renumbered the paragraphs in § 405.1122(e).

• In § 405.1122(f)(1), we corrected the reference to the Social Security Act regarding the Secretary's authority to seek enforcement of subpoenas from ''section 205(c) of the Act, 42 U.S.C. 405(c)'' to ''section 205(e) of the Act, 42 U.S.C. 405(e).''

• In § 405.1126(a), we made a technical correction by removing the word ''final'' consistent with our clarification regarding the term ''final.''

• In § 405.1130, we made a technical correction by adding the words ''final and'' before the word ''binding'' consistent with our clarification regarding the term ''final.''

• In § 405.1132(b), we made a technical correction by replacing the phrase ''final action or remand'' with ''final decision, dismissal order, or remand order'' to specify the actions taken by the MAC and to be consistent with our clarification regarding the term ''final.''

• In § 405.1136(a)(2), we made a technical correction by replacing the phrase ''final action'' with ''final decision, dismissal order, or remand order'' to specify the actions taken by the MAC and to be consistent with our clarification regarding the term ''final.kathe''

IV. Collection of Information Requirements

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

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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

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

Appointed Representatives (§ 405.910)

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

The burden associated with this requirement is the time and effort of the individual or entity to prepare an appointment of representation containing all of the required information of this section. In an effort to reduce some of the burden associated with this requirement, we have developed a standardized form that the individual/entity may use. This optional standardized form is currently approved under OMB# 0938–0950.

We estimate that approximately 13,413 individuals and entities will elect to appoint a representative to act on their behalf each year. Because we have developed the optional standardized form, we estimate that it should only take approximately 15 minutes to supply the required information to comply with the requirements of this section. Therefore, we estimate the total burden to be 3,353 hours on an annual basis.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this final rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* CMS Desk Officer, CMS 4064–F; *Fax:* (202) 395–6974; or *E-mail: OIRA_submission@omb.eop.gov.*

V. Regulatory Impact Statement

We have examined the impact of this final rule under the criteria of Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Orders 13258 and 13422 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As detailed above, this final rule makes only minimal changes to the existing Medicare claims appeals procedures. Thus, this rule will have negligible financial impact on beneficiaries, providers or suppliers.

Therefore, this does not constitute a major rule and, consistent with Executive Order 12866, we are not preparing an RIA.

The RFA requires agencies, in issuing certain rules, to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. 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 RIA for a rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As noted above, this final rule makes only minimal changes to the existing appeals procedures and thus, does not have a significant impact on small entities or the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that would include any Federal mandate that may result in expenditure in any one year by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). In 2009, the threshold is approximately $133 million. This rule will not meet this threshold, in any 1 year, with respect to expenditures by State, local, or Tribal governments, in the aggregate, or by the private sector.

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

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 405

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

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Part 405 as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 is revised to read as follows:

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

■ 2. Section 405.902 is amended by adding the definition of contractor in alphabetical order to read as follows:

§ 405.902 Definitions.

* * * * *

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

* * * * *

§ 405.922 [Amended]

■ 3. Section 405.922 is amended by removing the phrase ''30 days'' and adding in its place the phrase ''30 calendar days.''

§ 405.924 [Amended]

■ 4. Section 405.924 is amended by—
■ A. Removing paragraph (b)(7).
■ B. Redesignating paragraphs (b)(8) through (b)(15) as paragraphs(b)(7) through (b)(14), respectively.

§ 405.942 [Amended]

■ 5. Section 405.942 is amended by—
■ A. In paragraph (a)(1), removing the phrase ''5 days'' and adding in its place the phrase ''5 calendar days''.
■ B. In paragraph (b) introductory text, removing the phrase ''120-day'' and adding in its place the phrase ''120 calendar day''.

§ 405.946 [Amended]

■ 6. Section 405.946(b) is amended by removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day''.

§ 405.950 [Amended]

■ 7. Section 405.950 is amended by—
■ A. In paragraph (b)(1), removing the phrase ''120-day'' and adding in its place the phrase ''120 calendar day'', and removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day''.
■ B. In paragraph (b)(2), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.
■ C. In paragraph (b)(3), removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day''.

■ 8. Section 405.952 is amended by revising paragraph (e) to read as follows:

§ 405.952 Withdrawal or dismissal of a request for redetermination.

* * * * *

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

■ 9. Section 405.958 is amended by revising the introductory text to read as follows:

§ 405.958 Effect of a redetermination.

In accordance with section 1869(a)(3)(D) of the Act, once a

redetermination is issued, it becomes part of the initial determination. The redetermination is binding upon all parties unless—

* * * * *

■ 10. Section 405.962 is amended by—

■ A. Revising paragraph (a) introductory text.

■ B. In paragraph (a)(1), removing the phrase ''5 days'' and adding in its place the phrase ''5 calendar days''.

■ C. In paragraphs (a)(2) and (b)(1), removing the phrase ''180-day'' and adding in its place the phrase ''180 calendar day''.

The revision reads as follows:

§ 405.962 Timeframe for filing a request for a reconsideration.

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

* * * * *

§ 405.966 [Amended]

■ 11. Section 405.966 is amended by—

■ A. In paragraph (b), removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day''.

■ B. In paragraph (c), removing the phrase ''14-day'' and adding in its place the phrase ''14 calendar day''.

§ 405.970 [Amended]

■ 12. Section 405.970 is amended by—

■ A. In paragraph (a)(2), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ B. In paragraph (b)(1), removing the phrase ''180-day'' and adding in its place the phrase ''180 calendar day'', and removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day''.

■ C. In paragraph (b)(2), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ D. In paragraph (b)(3), removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day'', and removing the phrase ''14 days'' and adding in its place the phrase ''14 calendar days''.

■ E. In paragraph (c) introductory text, removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ F. In paragraph (e)(2) introductory text, removing the phrase ''5 days'' wherever it appears and adding in its place the phrase ''5 calendar days''.

■ 13. Section 405.972 is amended by revising paragraphs (b)(3) and (e) to read as follows:

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

* * * * *

(b) * * *

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

* * * * *

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

■ 14. Section 405.974 is amended by—

■ A. In paragraph (b)(1) introductory text, removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ B. In paragraph (b)(1)(i), removing the phrase ''5 days'' and adding in its place the phrase ''5 calendar days''.

■ C. In paragraph (b)(1)(ii), removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day''.

■ D. Revising paragraph (b)(3).

The revision reads as follows:

§ 405.974 Reconsideration.

* * * * *

(b) * * *

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

■ 15. Section 405.978 is amended by revising the introductory text to read as follows:

§ 405.978 Effect of a reconsideration.

A reconsideration is binding on all parties, unless—

* * * * *

■ 16. Section 405.980 is amended by—

■ A. Revising paragraphs (a)(1) introductory text and (a)(5).

■ B. In paragraph (b) introductory text, removing the phrase ''and revise its'' and adding in its place the word ''an''.

■ C. In paragraphs (d)(1), (d)(2), and (d)(3), removing the phrase ''180 days'' wherever it appears and adding in its place the phrase ''180 calendar days''.

■ D. In paragraphs (e)(1), (e)(2) and (e)(3), removing ''180 days'' and adding in its place the phrase ''180 calendar days''.

The revisions are as follows:

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

(a) * * *

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

* * * * *

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

* * * * *

■ 17. Section 405.990 is amended by—

■ A. Revising paragraphs (b)(1)(i)(A), (b)(1)(i)(B), (b)(1)(ii), and (f)(3).

■ B. In paragraphs (f)(2), (f)(4) and (h)(2), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ C. In paragraph (i)(2), removing the phrase ''90-day'' and adding in its place the phrase ''90 calendar day''.

■ D. In paragraph (j)(1), removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day''.

The revisions are as follows:

§ 405.990 Expedited access to judicial review.

* * * * *

(b) * * *

(1) * * *

(i) * * *

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

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

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

* * * * *

(f) * * *

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

* * * * *

■ 18. Section 405.1000 is amended by revising paragraphs (c) and (d) to read as follows:

§ 405.1000 Hearing before an ALJ: General rule.

* * * * *

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

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

* * * * *

■ 19. Section 405.1002 is amended by—

■ A. In paragraph (a)(1), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ B. In paragraph (a)(3), removing the phrase ''5 days'' and adding in its place the phrase ''5 calendar days''.

■ C. In paragraph (a)(4), removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day''.

■ D. Revising paragraph (b)(2) to read as follows:

§ 405.1002 Right to an ALJ hearing.

* * * * *

(b) * * *

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

* * * * *

■ 20. Section 405.1004 is amended by—

■ A. In paragraph (a)(1), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ B. In paragraph (a)(3), removing the phrase ''5 days'' and adding in its place the phrase ''5 calendar days''.

■ C. In paragraph (a)(4), removing the phrase ''60-day'' and adding in its place the phrase ''60 calendar day''.

■ D. Revising paragraph (c) to read as follows:

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

* * * * *

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

§ 405.1006 [Amended]

■ 21. Section 405.1006(e)(1)(ii) is amended by removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ 22. Section 405.1010 is amended by—

■ A. Revising paragraph (a).

■ B. In paragraph (b), removing the phrase ''10 days'' and adding in its place the phrase ''10 calendar days''.

The revision reads as follows:

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

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

* * * * *

■ 23. Section 405.1012 is amended by—

■ A. Revising paragraph (a).

■ B. In paragraph (b), removing the phrase ''10 days'' and adding in its place the phrase ''10 calendar days''.

The revision reads as follows:

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

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

* * * * *

§ 405.1014 [Amended]

■ 24. Section 405.1014 is amended by—

■ A. In paragraph (b)(1), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ B. In paragraph (b)(2), removing the phrase ''90-day'' where it appears and adding in its place the phrase ''90 calendar day''.

§ 405.1016 [Amended]

■ 25. Section 405.1016 is amended by—

■ A. In paragraph (a), removing the phrase ''90-day'' where it appears and adding in its place the phrase ''90 calendar day''.

■ B. In paragraph (c), removing the phrase ''180-day'' where it appears and adding in its place the phrase ''180 calendar day''.

§ 405.1018 [Amended]

■ 26. Section 405.1018(a) and (b) is amended by removing the phrase ''10 days'' and adding in its place the phrase ''10 calendar days''.

■ 27. Section 405.1020 is amended by—

■ A. Revising paragraph (c)(1).

■ B. In paragraph (g)(3)(ii), removing the phrase ''10 days'' and adding in its place the phrase ''10 calendar days''.

■ C. Revising paragraph (i)(4).

The revisions read as follows:

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

* * * * *

(c) * * *

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

* * * * *

(i) * * *

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

* * * * *

■ 28. Section 405.1022 is amended by revising paragraph (a) to read as follows:

§ 405.1022 Notice of a hearing before an ALJ.

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

* * * * *

§ 405.1024 [Amended]

■ 29. Section 405.1024(a) is amended by removing the phrase ''5 days'' and adding in its place the phrase ''5 calendar days''.

§ 405.1028 [Amended]

■ 30. Section 405.1028(a) is amended by removing the phrase ''10 days'' and adding in its place the phrase ''10 calendar days''.

■ 31. Section 405.1034 is amended by revising paragraph (a) to read as follows:

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

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

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

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

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

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

* * * * *

■ 32. Section 405.1036 is amended by—

■ A. Revising paragraphs (f)(1) and (f)(3).

■ B. In paragraph (f)(5)(iv), removing the phrase ''15 days'' and adding in its place the phrase ''15 calendar days''.

The revisions read as follows:

§ 405.1036 Description of an ALJ hearing process.

* * * * *

(f) * * *

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

* * * * *

(3) Parties to a hearing who wish to subpoena documents or witnesses must file a written request for the issuance of a subpoena with the requirements set forth in paragraph (f)(2) of this section with the ALJ no later than the end of the discovery period established by the ALJ under § 405.1037(c).

* * * * *

§ 405.1037 [Amended]

■ 33. Section 405.1037 is amended by—

■ A. In paragraph (c)(5), removing the phrase ''45 days'' and adding in its place the phrase ''45 calendar days''.

■ B. In paragraph (e)(2)(iii), removing the phrase ''15 days'' and adding in its place the phrase ''15 calendar days''.

§ 405.1038 [Amended]

■ 34. Section 405.1038(b)(1)(i) is amended by removing the word ''videoconferencing'' and adding in its place the word ''videoteleconferencing''.

§ 405.1042 [Amended]

■ 35. Section 405.1042(b)(2) is amended by removing the phrase ''90-day'' and adding in its place the phrase ''90 calendar day''.

§ 405.1044 [Amended]

■ 36. Section 405.1044(d) is amended by removing the phrase ''10 days'' and adding in its place the phrase ''10 calendar days''.

■ 37. Section 405.1046 is amended by—

■ A. Revising paragraph (c).

■ B. In paragraph (d), removing the phrase ''90-day'' where it appears and adding in its place the phrase ''90 calendar day''.

The revision reads as follows:

§ 405.1046 Notice of an ALJ decision.

* * * * *

(c) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ, the ALJ may make a finding as to the amount of payment due. If the ALJ makes a finding concerning payment when the amount of payment was not an issue before the ALJ, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's decision is not binding on the contractor for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's decision is a new initial determination under § 405.924.

* * * * *

■ 38. Section 405.1048 is amended by revising paragraph (a) to read as follows:

§ 405.1048 The effect of an ALJ's decision.

* * * * *

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

* * * * *

§ 405.1052 [Amended]

■ 39. Section 405.1052 is amended by—

■ A. In paragraphs (a)(2)(ii) and (a)(2)(iii), removing the phrase ''10 days'' and adding in its place the phrase ''10 calendar days''.

■ B. In paragraph (a)(6), removing the word ''final'' and adding in its place the word ''binding''.

■ 40. Section 405.1063 is revised to read as follows:

§ 405.1063 Applicability of laws, regulations and CMS Rulings.

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

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

§ 405.1100 [Amended]

■ 41. Section 405.1100 is amended by revising paragraphs (c) and (d) to read as follows:

§ 405.1100 Medicare Appeals Council review: General.

* * * * *

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

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

§ 405.1102 [Amended]

■ 42. Section 405.1102 is amended by—

■ A. In paragraph (a)(1), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ B. In paragraph (a)(2), removing the phrase ''5 days'' and adding in its place ''5 calendar days''.

■ 43. Section 405.1104 is amended by revising paragraphs (a)(2), (b) and (c) to read as follows:

§ 405.1104 Request for MAC review when an ALJ does not issue a decision timely.

(a) * * *

(2) The ALJ does not issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in § 405.1016.

(b) *Escalation.* (1) If the ALJ is not able to issue a decision, dismissal order, or remand order within the time period set forth in paragraph (a)(2) of this section, he or she sends notice to the appellant.

(2) The notice acknowledges receipt of the request for escalation, and confirms that the ALJ is not able to issue a decision, dismissal order, or remand order within the statutory timeframe.

(3) If the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of this section or does not send the required notice to the appellant, the QIC decision becomes the decision that is subject to MAC review consistent with § 405.1102(a).

(c) *No escalation.* If the ALJ's adjudication period set forth in § 405.1016 expires, the case remains with the ALJ until a decision, dismissal order, or remand order is issued or the appellant requests escalation to the MAC.

■ 44. Section 405.1106 is revised to read as follows:

§ 405.1106 Where a request for review or escalation may be filed.

(a) When a request for a MAC review is filed after an ALJ has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's action. The appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal who received a copy of the hearing decision under § 405.1046(a) or a copy of the notice of dismissal under § 405.1052(b). Failure to copy the other parties tolls the MAC's adjudication deadline set forth in § 405.1100 until all parties to the hearing receive notice of the request for MAC review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the MAC's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the MAC sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication timeframe.

(b) If an appellant files a request to escalate an appeal to the MAC level because the ALJ has not completed his or her action on the request for hearing within the adjudication deadline under § 405.1016, the request for escalation must be filed with both the ALJ and the MAC. The appellant must also send a copy of the request for escalation to the other parties. Failure to copy the other parties tolls the MAC's adjudication deadline set forth in § 405.1100 until all parties to the hearing receive notice of the request for MAC review. In a case that has been escalated from the ALJ, the MAC's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the MAC.

■ 45. Section 405.1110 is amended by—

■ A. In paragraph (a), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ B. Revising paragraphs (b)(2) and (d) to read as follows:

§ 405.1110 MAC reviews on its own motion.

* * * * *

(b) * * *

(2) CMS' referral to the MAC is made in writing and must be filed with the MAC no later than 60 calendar days after the ALJ's decision or dismissal is issued. The written referral will state the reasons why CMS believes the MAC must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's action who received a copy of the hearing decision under § 405.1046(a) or the notice of dismissal under § 405.1052(b), and to the ALJ. Parties to the ALJ's action may file exceptions to the referral by submitting written comments to the MAC within 20 calendar days of the referral notice. A party submitting comments to the MAC must send such comments to CMS and all other parties to the ALJ's decision who received a copy of the hearing decision under § 405.1046(a) or the notice of dismissal under § 405.1052(b).

* * * * *

(d) *MAC's action.* If the MAC decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The MAC may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ for further proceedings or may dismiss a hearing request. The MAC must issue its action no later than 90 calendar days after receipt of the CMS referral, unless the 90 calendar day period has been extended as provided in this subpart. The MAC may not, however, issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the MAC does not act within the applicable adjudication deadline, the ALJ's decision or dismissal is binding on the parties to the ALJ decision.

■ 46. Section 405.1112 is amended by revising paragraph (a) to read as follows:

§ 405.1112 Content of request for review.

(a) The request for MAC review must be filed with the MAC or appropriate ALJ hearing office. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare health insurance claim number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's decision or dismissal order, if any; if the party is requesting escalation from the ALJ to the MAC, the hearing office in which the appellant's request for hearing is pending; and the name and signature of the party or the representative of the party; and any other information CMS may decide.

* * * * *

§ 405.1118 [Amended]

■ 47. Section 405.1118 is amended by removing the phrase ''90-day'' and adding in its place the phrase ''90 calendar day''.

■ 48. Section 405.1122 is amended by—

■ A. Revising paragraph (d)(1).

■ B. Redesignating paragraph (e)(2)(i) as paragraph (e)(2).

■ C. Redesignating paragraphs (e)(2)(ii) through (e)(2)(v) as paragraphs (e)(3) through (e)(6), respectively.

■ D. In new redesignated paragraph (e)(4), removing the phrase ''15 days'' and adding in its place ''15 calendar days''.

■ E. In new redesignated paragraph (e)(2)(6), removing the word ''lifed'' and adding in its place the word ''lifted''.

■ F. In paragraph (f)(1), removing the reference to ''section 205(c) of the Act, 42 U.S.C. 405(c).'' and adding in its place the reference ''section 205(e) of the Act, 42 U.S.C. 405(e).''.

The revision reads as follows:

§ 405.1122 What evidence may be submitted to the MAC.

* * * * *

(d) * * *

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

* * * * *

§ 405.1124 [Amended]

■ 49. Section 405.1124(b) is amended by removing the phrase ''10 days'' and adding in its place the phrase ''10 calendar days''.

§ 405.1126 [Amended]

■ 50. Section 405.1126 is amended by—

■ A. In paragraph (a), removing the word ''final'' from the last sentence.

■ B. In paragraph (d)(1), removing the phrase ''20 days'' and adding in its place the phrase ''20 calendar days''.

■ 51. Section 405.1130 is revised to read as follows:

§ 405.1130 Effect of the MAC's decision.

The MAC's decision is final and binding on all parties unless a Federal district court issues a decision modifying the MAC's decision or the decision is revised as the result of a reopening in accordance with § 405.980. A party may file an action in a Federal district court within 60 calendar days after the date it receives notice of the MAC's decision.

■ 52. Section 405.1132 is amended by revising paragraph (b) to read as follows:

§ 405.1132 Request for escalation to Federal court.

* * * * *

(b) A party may file an action in a Federal district court within 60 calendar days after the date it receives the MAC's notice that the MAC is not able to issue a final decision, dismissal order, or remand order unless the party is appealing an ALJ dismissal.

■ 53. Section 405.1136 is amended by—

■ A. Revising paragraph (a)(2).

■ B. In paragraphs (c)(3) and (d)(2), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

The revision reads as follows:

§ 405.1136 Judicial review.

(a) * * *

(2) If the MAC's adjudication period set forth in § 405.1100 expires and the appellant does not request escalation to Federal district court, the case remains with the MAC until a final decision, dismissal order, or remand order is issued.

* * * * *

§ 405.1140 [Amended]

■ 54. Section 405.1140 is amended by—

■ A. In paragraph (b)(1), removing the phrase ''30 days'' wherever it appears and adding in its place the phrase ''30 calendar days'', and removing the phrase ''30-day'' wherever it appears and adding in its place the phrase ''30 calendar day''.

■ B. In paragraph (c)(1), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

■ C. In paragraph (c)(4), removing the phrase ''30 days'' and adding in its place the phrase ''30 calendar days''.

■ D. In paragraph (d), removing the phrase ''60 days'' and adding in its place the phrase ''60 calendar days''.

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

Dated: February 6, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 6, 2009.

Kathleen Sebelius,

Secretary.

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