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Department of Health and Human Services

Centers for Medicare & Medicaid Services

**42 CFR Parts 405, 413, and 417
Medicare Program; Provider
Reimbursement Determinations and
Appeals; Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 413, and 417

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Medicare Program; Provider Reimbursement Determinations and Appeals

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

ACTION: Final rule.

SUMMARY: Subpart R of 42 CFR part 405 consists of regulations governing Medicare reimbursement determinations, and appeals of those determinations, by health care providers. (For the sake of simplicity, throughout this final rule, we use “reimbursement” to refer to Medicare payment under both the reasonable cost and prospective payment systems.) Under section 1878 of the Social Security Act (the Act) and the subpart R regulations, the Provider Reimbursement Review Board (the Board) has the authority to adjudicate certain substantial reimbursement disputes between providers and fiscal intermediaries (intermediaries). Board decisions are subject to review by the CMS Administrator, and the final agency decision of the Board or the Administrator, as applicable, is reviewable in Federal district court. In addition, under the subpart R regulations, intermediaries have the authority to hold hearings and adjudicate certain other payment and reimbursement disputes with providers. This final rule updates, clarifies, and revises various provisions of the regulations governing provider reimbursement determinations, appeals before the Board, appeals before the intermediaries (for lesser disputes), and Administrator review of decisions made by the Board.

DATES: *Effective Date:* These regulations are effective August 21, 2008.

Applicability Date: These regulations are applicable to all appeals pending as of, or filed on or after August 21, 2008, except as noted in sections II.Y. and III.Y. of this final rule.

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I. Background

A. Legislative and Regulatory History and Development

Section 1878(a) of the Social Security Act (the Act) allows providers to appeal to the Board final determinations made by a fiscal intermediary under section 1861(v)(1)(A) of the Act (reasonable cost reimbursement), as well as certain determinations by the Secretary involving payment under section 1886(d) (inpatient hospital prospective payment) and section 1886(b) (commonly known as the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) payment system) of the Act. In addition, by regulation, providers are given the right to appeal to the Board or fiscal intermediary certain other determinations. A brief discussion of the original cost reimbursement, TEFRA, and prospective payment systems (PPS), and some of the types of determinations that are appealable, follows.

For cost reporting years beginning before October 1, 1983, all providers were reimbursed for Part A (hospital insurance) covered items and services they furnished to Medicare beneficiaries on the basis of reasonable cost. (Reasonable cost is defined at section 1861(v)(1)(A) of the Act and implementing regulations at 42 CFR, part 413.) In 1982, the Congress determined that the reasonable cost reimbursement system should be modified to provide hospitals with better incentives to render services more efficiently. Accordingly, in TEFRA, Public Law 97-248, the Congress amended the Act by imposing a ceiling on the rate of increase of inpatient operating costs recoverable by a hospital under Medicare.

The Social Security Amendments of 1983, Public Law 98-21, added section 1886(d) to the Act, which, effective with cost reporting periods beginning on or after October 1, 1983, changed the method of payment for inpatient hospital services under Medicare Part A for short-term acute care hospitals. The method of payment for these hospitals was changed from a cost-based

retrospective reimbursement system to a system based on prospectively set rates; that is, a PPS. Under Medicare's inpatient hospital PPS, payment is made at a predetermined specific rate for each hospital discharge (classified according to a list of diagnosis-related groups (DRGs)), excluding certain costs that continue to be reimbursed under the reasonable cost-based system.

Other statutory changes expanded the types of providers that are subject to a PPS. The Balanced Budget Act of 1997 (BBA), Public Law 105-33, established a PPS for home health agencies (HHAs), for rehabilitation hospitals, and for all skilled nursing facilities (SNFs). The Balanced Budget Refinement Act of 1999, Public Law 106-113, provided for the establishment of a PPS for long term care hospitals (LTCHs). Although many types of providers are now paid on a prospectively-determined basis, some types of providers (for example, hospices, psychiatric hospitals, and children's hospitals) continue to be paid on a reasonable cost basis.

Payments to providers are ordinarily made through private organizations, known as fiscal intermediaries, under contracts with the Secretary. (The term "intermediary" includes both fiscal intermediaries and Medicare Administrative Contractors for the purpose of this final rule.) For covered items and services reimbursed on a reasonable cost basis, the intermediary pays a provider during a cost reporting year interim payments that approximate the provider's actual costs. Under a PPS, providers are generally paid for each discharge after each bill is submitted.

Regardless of whether the provider is paid under reasonable cost or under a PPS, the provider files an annual cost report after the cost year is completed. The intermediary then reviews or audits the cost report, determines the aggregate amount of payment due the provider, and makes any necessary adjustments to the provider's total Medicare reimbursement for the cost year. This year-end reconciliation of Medicare payment for the provider's cost reporting period constitutes an intermediary determination, as defined in § 405.1801(a). Under § 405.1801(a)(1), § 405.1801(a)(2), and § 405.1803, the intermediary must render the provider with written notice of the intermediary determination for the cost period in a notice of amount of program reimbursement (NPR). The NPR is an appealable determination.

In addition to the NPR, other determinations made by the intermediary or CMS for hospitals and other providers are appealable to the intermediary or Board (depending on

the amount in controversy). These include: A denial of a hospital's request for an adjustment to, or an exemption from, the TEFRA rate of increase ceiling (see § 413.40); a denial of an HHA's or SNF's request for an adjustment to, or an exemption from, the routine cost limits that were in effect prior to a PPS for these providers (see § 413.30); a denial of certain hospice payments (see § 418.311); or a denial of a PPS hospital's request to be classified as a sole community hospital (see § 412.92) or rural referral center. Also, some health care entities (for example, end-stage renal dialysis (ESRD) facilities, rural health clinics (RHCs) and Federally qualified health centers (FQHCs)) are treated as "providers" for purposes of subpart R and have appeal rights before the intermediaries and the Board. Thus, for example, a renal dialysis facility may appeal to the intermediary or the Board a CMS denial of its request for an exception to its composite payment rate (see § 413.194(b)).

If a provider is dissatisfied with some aspect of an appealable intermediary or CMS determination, it may request a hearing before the intermediary or the Board, depending on the amount in controversy. For an amount in controversy that is at least \$1,000 but less than \$10,000, the provider may request an intermediary hearing before the intermediary hearing officer(s) under § 405.1811. If the amount in controversy is at least \$10,000, the provider may request a hearing before the Board under section 1878(a) of the Act and § 405.1835 of the regulations. Alternatively, the provider may request a Board hearing with one or more additional providers under section 1878(b) of the Act and § 405.1837, if the amount in controversy is, in the aggregate, at least \$50,000. (This type of appeal is known as a group appeal.) (Note that under section 1878(f)(1) of the Act, any appeal to the Board by providers under common ownership or control must be brought by these providers as a group regarding any matter involving an issue common to these providers. We interpret this provision to apply only where the amount in controversy for the common issue is at least \$50,000.) Decisions by the intermediary hearing officer(s) or the Board are subject to further review. Prior to the implementation of this final rule, intermediary hearing officers' decisions have been subject to review by a CMS reviewing official pursuant to section 2917 of the *Provider Reimbursement Manual* (PRM), Part 1. Now, § 405.1834 provides for this

review. Also, under this final rule, no provisions remain for judicial review of a final decision of the intermediary hearing officer(s) or CMS reviewing official, as applicable. Board decisions are subject to review by the Administrator or the Deputy Administrator of CMS, under section 1878(f)(1) of the Act and § 405.1875. (The Secretary's review authority under section 1878(f)(1) of the Act has been delegated to the Administrator, and redelegated to the Deputy Administrator, of CMS. For ease of use, throughout this proposed rule, we use the term "Administrator" to refer to either the Administrator or Deputy Administrator, and the term "Administrator review" to review by either official.) A final decision of the Board, or any reversal, affirmation, or modification of a final Board decision by the Administrator, is subject to review by a United States District Court with venue under section 1878(f)(1) of the Act and § 405.1877 of the regulations.

Most of the central provisions of the regulations governing provider reimbursement determinations and appeals are more than 30 years old. On May 27, 1972, we published a final rule (37 FR 10722), which provided for the intermediary determination, NPR, intermediary hearing, and reopening of both intermediary determinations and intermediary hearing decisions. Five months later, the Congress added section 1878 to the Act, which established the Board and provided for review of Board decisions by the Secretary, as well as for judicial review. (See Social Security Amendments of 1972, Pub. L. 92-603, section 243(a), 86 Stat. 1420 (October 30, 1972).) We then, on September 26, 1974, published a final rule (39 FR 34514) that implemented the 1972 amendments to the Act, and revised and redesignated the preexisting rules governing the intermediary determination, NPR, intermediary hearing, and reopening. These regulations were redesignated as Subpart B of Part 405 of Title 42 of the CFR (Subpart R) on September 30, 1977 (42 FR 52826). We have revised these regulations on several occasions, largely in response to various amendments to section 1878 of the Act.

For several reasons, we believe it is necessary and appropriate to revise many of the subpart R regulations governing provider reimbursement determinations and appeals. As noted previously, the principal provisions of the regulations are more than 30 years old. In the intervening period, various issues have arisen regarding provider reimbursement determinations and

appeals. Important parts of the regulations have been the subject of extensive litigation, the results of which indicate a need for reexamination of the rules. Also important is the development of a huge backlog of cases before the Board (which, at the present time, is approximately 6,800 cases). Experience gained through long use of the regulations indicates that revisions to the regulations would lead to a more effective and efficient appeal process. We recognize that the Board's inventory of pending cases is dependent in some ways on factors outside of its control (for example, the number of hearing requests filed). However, we believe that the revisions made in this final rule will help the Board reduce the case backlog (or at least forestall substantial additions to it), and will also reflect changes in the statute, clarify our policy on various issues, and eliminate outdated material. The Board's instructions for providers and intermediaries, as well as the Board's decisions on specific cases brought before it, are available on the CMS Web site, which, as of the date of publication of this final rule, is <http://www.cms.hhs.gov/PRRBReview>.

B. Medicare Modernization Act Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish regular timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 1871(a)(3)(B) of the Act, as amended by section 902 of the MMA, also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation, except under exceptional circumstances. Section 1871(a)(3)(B) of the Act further provides that if the Secretary intends to vary such a timeline with respect to the publication of a final regulation, the Secretary shall publish in the **Federal Register** notice of the different timeline by not later than the timeline previously established with respect to such regulation. On June 22, 2007, a notice was published in the **Federal Register** extending by one year (or until June 25, 2008) the timeframe for publishing this final rule (see 72 FR 34425). Therefore, this final rule has been published within the time limit imposed by section 902 of the MMA.

II. Provisions of the Proposed Rule and Public Comments and Responses

On June 25, 2004, we published a proposed rule in the **Federal Register** (69 FR 35716) that set forth proposed regulations seeking to update, clarify, and revise various provisions of the regulations governing provider reimbursement determinations, appeals before the intermediary hearing officers and the Board, and Administrator review of decisions made by the Board. For purposes of the summary of the proposed provisions and for the comments and responses, we are using the same lettering sequence that appeared in the proposed rule. In each lettered section, we provide a description of our proposals and a summary of the changes from the proposed rule that we have made in this final rule. A more extensive description of the proposals is contained in the proposed rule, and a brief summary of the changes appears at section III.

A. Definitions of Entities That Review Intermediary Determinations or Decisions by Such Entities; Definition of Reimbursement (§ 405.1801(a))

We proposed definitions for "intermediary hearing officer"; "CMS reviewing official"; "CMS Reviewing official procedure"; "Administrator review"; and "reviewing entity." We received no comments on these proposed definitions and we are adopting them without change. We note that we incorrectly stated that we were proposing a definition for "reimbursement."

B. Calculating Time Periods and Deadlines (§ 405.1801(a) and § 405.1801(d))

We proposed specific provisions to address the timeframes for appealing determinations, including those for determining the beginning and end of a specific appeal period. Generally, we proposed to calculate the beginning period of an appeal as the date a party receives a triggering notice, and the end period for an appeal as the date by which a reviewing entity must receive the party's submission. We proposed a definition for "date of receipt" with respect to the method we would use to determine the date a document or other material is received by: (1) A party or non-party involved in proceedings before a reviewing entity and (2) a reviewing entity. Specifically, we proposed a rebuttable presumption whereby the receipt date of documents sent by a reviewing entity to providers, intermediaries and other entities would be 5 days after the postmark date. For

materials submitted to a reviewing entity, we proposed the establishment of a presumption that the receipt date is the date the reviewing entity stamps the document "Received." We also proposed that, where a reviewing entity could not conduct business due to extraordinary circumstances beyond its control, the designated time period would resume on the next work day the reviewing entity was again able to conduct business. Finally, we proposed that the last day of a designated time period would be excluded if it fell on a Saturday, Sunday, or Federal legal holiday.

We are amending our proposed definition of "Date of Receipt" in § 405.1801(a) to provide that, where a request for an intermediary or Board hearing, a request to add issues to a Board or intermediary hearing, or any other document or material is transmitted to a reviewing entity by a nationally-recognized, next-day courier service (for example, the U.S. Postal Service Express Mail, Federal Express, UPS, or DHL), the "Date of Receipt" is presumed to be the date of delivery noted by the courier, unless it can be shown by clear and convincing evidence that the materials were received on a different date. We are also amending the definition of "Date of Receipt" to provide that, where a nationally-recognized, next-day courier service is not employed to deliver materials to a reviewing entity, the "Date of Receipt" is presumed to be the date stamped "Received" by the reviewing entity, unless it can be shown by clear and convincing evidence that the materials were received by some other date. The reviewing entity's determination of whether the presumption of the correctness of the date of delivery, or the date stamp, is overcome by clear and convincing evidence is final and binding (that is, it is not subject to further administrative or judicial review).

Comment: One commenter supported our proposal that the timeframe for requesting an intermediary hearing or a Board hearing should run from the date of receipt of the appealable decision. Another commenter agreed that the "5-day presumption" gave an accurate determination of the date of receipt of a document. One commenter suggested that the "5-day presumption" should be used by a reviewing entity when it sends and receives materials.

Three commenters suggested the rule should offer some reassurance that the reviewing entity would, in fact, stamp "Received" on the document on the day of arrival. One of these commenters also suggested using "date of mailing" as a

measure of timeliness. Another commenter stated that date stamps are unverifiable and suggested that the Board should consider an electronic docket system that would allow parties to view the actual dates of receipt of filings and Board actions via the Internet. Another commenter suggested the use of a reliable "intermediary" (for example, the United States Postal Service, because it would provide a single source of date verification) instead of relying solely on the determination of the Board. This commenter suggested that the current "mailbox rule" be retained.

Response: After reviewing all of the comments received regarding the calculation of the various time periods and deadlines set for appealing final determinations, we have decided to adopt our proposals as final, with the modifications noted below, regarding the receipt of documents by a reviewing entity. We continue to believe that the best and most consistent way to establish a beginning and ending date for purposes of determining the various appeal periods is through the use of "date of receipt." (We also note that employing a "date of mailing" can present some practical problems, such as unreadable postmark dates.) With respect to the situation in which a party (or interested non-party) to a proceeding receives a document from a reviewing entity or from another party, we have established a 5-day presumption for receipt of that document. The presumption may be rebutted if a preponderance of the evidence establishes that the document was actually received on a later date. The 5-day presumption does not apply in the case where the reviewing entity is on the receiving end of a document from a party (or non-party) to the proceeding. Except as noted below, the receipt date in this instance is the date the reviewing entity date stamps the document as "Received." We have decided not to include a 5-day presumption for the receipt of documents by reviewing entities because there is a presumption of administrative regularity in agency action. This doctrine presumes that an arm of a Federal agency, such as the Board, will act responsibly, fairly, and legally in its duty to provide an appeals forum for providers of Medicare services. Thus, it is reasonable to presume that the actual receipt date of a document submitted to a reviewing entity is the date the reviewing entity stamps "Received" on the document. Nonetheless, although we believe that materials will be timely and accurately stamped "Received" by the Office of

Hearings, we wish to avoid any confusion or possible prejudice to a provider, as well as any protracted disputes as to when a document was received. We also recognize the importance of the timeframes for both requesting a Board or intermediary hearing and for requesting that issues be added prior to a Board or intermediary hearing. Therefore, we are amending our definition of "Date of Receipt" in § 405.1801, to provide that, where a request for hearing or a request to add issues prior to a hearing, or any other document or material is delivered to a reviewing entity by a nationally-recognized next-day courier service, the "Date of Receipt" shall be presumed to be the date of delivery as noted by that courier service, unless it can be shown by clear and convincing evidence that the material was received on a different date. Further, in order to strongly encourage the use of next-day couriers (especially for requests for appeal and for requests to add issues), we are amending the definition of "Date of Receipt" to provide that, where a nationally-recognized next-day courier service is not employed to deliver materials to the reviewing entity, the "Date of Receipt" shall be presumed to be the date stamped "Received" by the reviewing entity, unless it is established by clear and convincing evidence that the materials were actually received on a different date. In order to prevent collateral litigation, the reviewing entity's determination as to whether clear and convincing evidence exists to establish that the materials were received on a date different from the delivery date or the date stamped "Received" is not subject to further administrative or judicial review. (We considered requiring, upon penalty of refusal to accept, that any request for a hearing or request to add issues be delivered by a next-day courier service.)

Finally, we note that, although it is not feasible at this time for the Office of Hearings to administer an electronic docket system, such a system may be implemented in the future.

Comment: One commenter suggested that the 5-day presumption for receipt of documents from a reviewing entity be five business days instead of five calendar days because of weekends.

Response: We believe that five calendar days is a sufficient period of time (and we note that mail is picked up and delivered on Saturdays).

Comment: One commenter stated that reviewing entities should accept filings via facsimile (fax), with originals to follow, and use the date indicated on the fax as the date of receipt.

Response: The Office of the Attorney Advisor, which assists in the Administrator review process, has allowed parties to submit fax copies. This practice reflects the short timeframes for Administrator review and the small number of appeals that are pending in the office at any one time. In contrast, the Office of Hearings, which assists the Board in its review, has declined to allow fax transmissions of provider requests for Board hearings and other relevant documents. The Office of Hearings' practice reflects the voluminous number of appeals pending in that office and the large number of documents submitted (several of which may be due on the same date), making the acceptance of facsimile transmissions impractical. We are not limiting either the Office of the Attorney Advisor or the Office of Hearings in determining the best office practice for the receipt of documents. Additionally, there may be future technological innovations that will make other modes of submission feasible, which these offices may wish to have the flexibility to adopt. Therefore, we decline to specify in regulations whether the Office of Hearings or Office of Attorney Advisor may or must accept fax transmissions, or hand delivery, or other modes of submission, and, consistent with present practice, will leave it to the discretion of these offices as to the additional types of submission they will accept.

Comment: One commenter requested that we clarify the types of relevant evidence (for example, a provider date stamp) that would prove that materials sent by a reviewing entity were received by a provider beyond the 5-day presumption period.

Response: We decline to specify types of evidence that will necessarily establish that a document was received more than five days after the postmark date. Rather, whether a piece of evidence (for example, an affidavit from the party or a date stamp from the party) is persuasive that a document was received more than 5 days after the postmark date would be determined in context with any other relevant evidence in a particular case.

Comment: One commenter believed that providers should be allowed to request extensions of timeframes for appeal in situations involving employee strikes or extended absence due to illness or maternity leave.

Response: In section II.E. of this final rule, regarding "Provider Requests for Good Cause Extension of Time Period for Requesting Hearing," we state the rule that an appeal period may be extended for "good cause" only in cases

where a provider can establish that it could not reasonably have been expected to submit a hearing request within 180 days due to extraordinary circumstances beyond its control.

C. Providers Under Subpart R; Limited Applicability to Non-Provider Entities (§ 405.1801(b))

We proposed to amend § 405.1801(b)(1) to recognize as a provider under Subpart R each entity recognized under the Act for purposes of provider reimbursement determinations and appeals. In accordance with the definition of “provider of services” in section 1861(u) of the Act, we proposed to recognize specifically a hospital, critical access hospital, SNF, comprehensive outpatient rehabilitation facility, HHA, and hospice program. Also, a RHC and a FQHC would be included in accordance with section 1878(j) of the Act, and an ESRD facility would be recognized under section 1881(b)(2)(D) of the Act. Our proposed revision to § 405.1801(b)(1) would also recognize as a provider any other entity treated as a provider under the Act, in order to ensure recognition in subpart R of any other entity that may qualify as a provider under the Act for purposes of provider reimbursement determinations and appeals. We received no comments on this section and are adopting our proposals without change.

D. Provider Hearing Rights (§ 405.1803(d), § 405.1811, and § 405.1835)

Under section 1878(a) of the Act, and § 405.1835 and § 405.1841 of the regulations, a provider may obtain a Board hearing if it meets three jurisdictional requirements: (1) The provider is dissatisfied with its Medicare reimbursement for a cost reporting period; (2) the amount in controversy is at least \$10,000 (at least \$50,000 for a group appeal); and (3) the provider files a timely request for a hearing to the Board. The same jurisdictional requirements govern provider requests for an intermediary hearing under § 405.1811, except that the amount in controversy requirement is at least \$1,000 but less than \$10,000. In this section of the proposed rule, we proposed changes regarding the first and third jurisdictional requirements; that is, provider dissatisfaction with Medicare reimbursement and the timeliness of hearing requests. We are making several changes to the proposed rule.

Under § 405.1811(a)(1), and § 405.1835 (a)(1), a provider has a right to an intermediary or Board hearing, as

a single provider appeal, for specific items claimed for a cost reporting period covered by an intermediary or Secretary determination, if the provider preserves its right to claim dissatisfaction with the amount of Medicare payment for the specific item(s) at issue. The provider can preserve this right either by claiming the cost on its cost report or, if the provider seeks payment that it believes may not be allowable or may not be in accordance with Medicare policy (for example, if the intermediary lacks discretion to award the reimbursement the provider seeks for the item(s)), by “self-disallowing a specific item(s) by following the applicable procedures for filing a cost report under protest.” We have amended § 405.1811(a)(1) and § 405.1835(a)(1) to be effective for cost reporting periods that end on or after December 31, 2008. This revision will be beneficial to both providers and intermediaries. The delay in the effect of the requirement will benefit providers because they will have additional time to evaluate whether they wish to file a cost report item under protest. This change will also eliminate the transitional administrative burden that intermediaries otherwise would have faced under the proposal, which would have necessitated that providers file requests to amend previously filed cost reports to explicitly file cost report items under protest.

In response to comments, we have clarified § 405.1811(b) and § 405.1835(b) to provide that, where required information is not submitted with the hearing request, the intermediary hearing officer or Board, as applicable, may dismiss with prejudice the appeal, or take any other remedial action that the reviewing entity considers appropriate. We believe that this approach is consistent with the approach we have taken in section § 405.1868 (“Board Actions in Response to Failure to Follow Board Rules”) in which we similarly leave to the Board’s discretion whether to dismiss an appeal or take some other, lesser action.

We are amending proposed § 405.1835(c)(3) to address possible misleading and unnecessary language concerning adding an issue to an appeal of a revised NPR. Proposed § 405.1835(c)(3) stated that a request to add an issue to an appeal is timely if “[t]he Board receives the request to add issues no later than 60 days after the expiration of the applicable 180-day period prescribed in paragraph (a)(3) of this section or, for a request to add issue(s) following a reopening conducted in accordance with and within the period specified in

§ 405.1885(c)(1).” We have deleted the language in § 405.1835(c)(3) pertaining to a request to add issues following a reopening. We note that we did not include such language in the corresponding proposed intermediary hearing officer regulations at § 405.1811(c)(3). Such language is potentially misleading in that it may suggest incorrectly that a notice of reopening is the trigger point for appealing an issue, whereas, in fact, under our longstanding policy (which is reaffirmed in this final rule at § 405.1889), only those matters actually revised and specifically contained in a revised determination following a notice of reopening are appealable. We also believe the language is unnecessary because a revised determination is treated the same under our rules as an original determination for purposes of the time in which to request a hearing or add an issue. Thus, if a revised NPR containing two distinct revisions were issued, and a provider timely appealed one of the revisions (that is, within 180 days after the date of receipt by the provider of the revised NPR), it could add the second revision as an issue within 60 days after the expiration of the 180-day period for appealing the revised NPR.

In § 405.1811(b)(2)(i) and § 405.1835(b)(2)(i), we proposed that a provider would be required to explain its dissatisfaction with the amount of Medicare payment for the specific item(s) at issue by stating why Medicare payment is incorrect for each disputed item. We acknowledge that there may be instances in which a provider may be uncertain as to whether Medicare payment is incorrect because it does not have access to underlying data (for example, data from a State agency). Accordingly, we have revised § 405.1811(b)(2)(i) and § 405.1835(b)(2)(i) to allow a provider to explain why it is unable to determine whether payment is correct as a result of not having access to underlying information.

Further, in response to a commenter’s suggestion that providers be required to list their parent corporation at the time of filing a single appeal so as to assist the Board in identifying providers under common ownership, we are adding new § 405.1835(b)(4) to require a provider under common ownership or control to furnish the name and address of its parent corporation and to provide a statement that: (1) To the best of the provider’s knowledge, no other provider to which it is related by common ownership or control, has pending a request for a Board hearing pursuant to this section or pursuant to

§ 405.1837(b)(1) on any of the same issues contained in the provider's hearing request for a cost reporting period that falls within the same calendar year as the calendar year covered by the provider's hearing request; or (2) a pending appeal(s) exist(s), and the provider name(s) and provider number(s), and the case number(s) (if assigned), for such appeal(s).

Finally, in preparing this final rule, we have corrected minor wording inconsistencies between § 405.1811, which pertains to intermediary hearings, and § 405.1835, which pertains to Board hearings, where appropriate.

Comment: One commenter stated that the section on who is entitled to a hearing should be clarified to include those entities that were formerly providers or the successor organizations that retained responsibility for previously filed cost reports following a change of ownership. In recent years, numerous tax-exempt organizations sold hospital operations and the proceeds went to local charitable foundations. Frequently, those organizations retained responsibility for filed cost reports, and the rules should be clarified to grant hearing rights to those organizations regarding those cost reports.

Response: We made no specific proposal concerning the hearing rights of former providers or successor organizations following a change in ownership. However, we appreciate the concerns raised by the commenter and, therefore, we may seek to address this issue in a future rulemaking or through other instructions.

1. Provider Dissatisfaction With Medicare Reimbursement; Revised Self-Disallowance Policy

We proposed that, in order to preserve its appeal rights, a provider must either claim an item on its cost report where it is seeking reimbursement that it believes to be in accordance with Medicare policy, or self-disallow the item where it is seeking reimbursement that it believes may not be in accordance with Medicare policy (for example, where the intermediary does not have the discretion to award the reimbursement sought by the provider). In order to self-disallow an item, the provider would be required to follow the applicable procedures, which are contained currently in section 115 of the PRM, Part II (CMS Pub. 15-2), for filing a cost report under protest. We stated that we believed our proposal was appropriate under the Supreme Court's decision in *Bethesda Hospital Association v. Bowen*, 485 U.S. 399

(1988). We further stated that we believed that our proposed policy was a reasonable response to statements by the *Bethesda* providers and others that it was necessary, for any reimbursement request in excess of the amount allowed under program policy, to raise the entire payment request before the Board, because it would be improper to include a cost report claim for more payment than is permitted by Medicare policy. We noted that it has been our longstanding policy that a cost report claim at variance with Medicare policy is not improper, provided that the claim is not intended to procure an intermediary determination (or reviewing entity decision) by fraud or similar fault. We are adopting our proposal, effective with cost reporting periods ending on or after December 31, 2008.

Comment: One commenter recommended that the text of section 115 *et seq.* of the PRM, Part II, be placed in the regulations. The commenter noted that these sections of the PRM have not changed since 1980. Another commenter stated that the protested amount line on the cost report is available for situations where a provider is not in agreement with Medicare policy and that CMS should be holding that out as the way to assert differences of opinion with Medicare policy.

Response: We are adopting the proposal, which is essentially a codification of the protested amount line procedures set forth in section 115 *et seq.* of the PRM, Part II. We are modifying the proposal so that the requirement, that a provider self-disallow an item by following the applicable procedures for filing a cost report under protest, is effective for cost reporting periods ending on or after December 31, 2008.

Comment: One commenter stated that the final rule should require that, when a provider self-disallows an item in accordance with the proposed policy, the provider should specifically identify the regulation or other authority the provider is challenging as invalid, and that the appeal should be limited to that challenge. The commenter stated that some providers have been misusing the protested line amount procedure. Specifically, the commenter said that it was aware of instances in which a provider listed a claim related to bad debts in the protested line amount. According to the commenter, the provider was not challenging any policy related to bad debts, but rather lacked the documentation for its bad debts claim and was using the protested amount procedure as a way of avoiding a possible reopening denial based on

Program Memorandum A-01-141 (December 14, 2001). According to the commenter, this program memorandum gives intermediaries discretion to deny a reopening request where a provider was culpable in not adequately documenting its claim and where the claim was reported not under protest, but rather was made in the cost report proper.

Response: Although we encourage providers to identify the specific manual provision, CMS Ruling, regulation, or statutory section that they believe prevents them from receiving payment for the self-disallowed item, we are not requiring through these regulations that they do so. We are attempting to strike a balance between, on the one hand, having providers present enough information so as to put the intermediaries on notice as to actual or potential reimbursement disputes, and, on the other hand, not making it unduly burdensome for providers to file cost reports. For the same reason, we are encouraging, but not requiring, providers to identify in the hearing request the specific authority they believe prevents them from receiving reimbursement for a self-disallowed item. We note, however, that where the authority allegedly preventing reimbursement for the self-disallowed item is a CMS Ruling, regulation or statute, the provider may wish to seek expedited judicial review (EJR) early in the appeals process, in accordance with the procedures under § 405.1842, or the Board may wish to explore granting EJR on its own motion. If the provider does seek EJR or the Board initiates own motion consideration of EJR, the provider would need to identify at that time the specific authority that it believes prevents it from receiving reimbursement for the self-disallowed item. We caution that the fact that we are not requiring by regulation that providers identify in the hearing request the specific authority at issue should not be seen as preventing the Board from issuing instructions that would require providers to do so. Under section 1878(e) of the Act, the Board has the authority to issue instructions governing hearings before it, provided that those instructions are not inconsistent with the statute or regulations of the Secretary.

Finally, although some providers may be using the protested line amount procedures inappropriately, as alleged by the commenter, we do not believe that mischaracterizing a documentation issue (or some other issue) as a self-disallowance prevents an intermediary from denying a reopening request. Program Memorandum A-01-141

Chapter 8, section 60.1 of CMS Pub. 100-06, states that intermediaries should inform providers that, as a general rule, they will not honor reopening requests for audit adjustments based on lack of documentation, but it also does not require intermediaries to allow all requests for reopening audit adjustments that are not based on (or are not characterized by the provider as based on) lack of documentation. Moreover, under the self-disallowance policy contained in this rule, providers should not self-disallow items for which they do not have a good faith belief that the items may not be allowable under Medicare payment policy. Under § 405.1835, in order to preserve its appeal rights, a provider must either include a claim for the specific item on its cost report, or, where it has a good faith belief that the item may not be allowable under Medicare policy, list the item on the cost report. Therefore, if a provider were to simply list an item as a self-disallowed item, when the provider is aware that the issue is one of documentation and not policy, the provider would run the risk that the appeal of that item would be dismissed.

Comment: Several commenters asserted that the proposal that the provider identify an item as a “protested amount” was inconsistent with the Supreme Court’s decision in *Bethesda*. For example, two commenters, using identical language, stated that the Supreme Court concluded that providers could claim “dissatisfaction,” within the meaning of the statute, without incorporating their challenge in the cost reports filed with their fiscal intermediaries, and that our proposal directly contradicted the Supreme Court’s conclusion by mandating that a provider had to claim dissatisfaction by incorporating a challenge into the cost report through either declaring the item as a cost or declaring it as a protested item. One commenter said that the Supreme Court concluded in *Bethesda* that no statute or regulation expressly mandated that a challenge to the validity of a regulation be submitted first to the intermediary, and that it would be futile to submit challenges based on regulations, statutes or CMS’s formal policies to the intermediary before seeking Board review; therefore, the proposed policy was in direct violation of clear statutory authority. Another commenter said that rather than reflecting the reasoning and findings of *Bethesda*, the proposed policy appeared to have adopted the narrowing of *Bethesda* in *Little Company of Mary Hospital and Health*

Centers v. Shalala, 24 F.3d 984 (7th Cir. 1994). According to this commenter, the *Little Company of Mary Hospital* case narrowed the *Bethesda* decision by providing that in order for a provider to be able to self-disallow a cost, there must be a statute, regulation or CMS ruling that makes reimbursement of an item unallowable. This commenter stated that the *Little Company of Mary Hospital* case was the decision of a single circuit and therefore conflicts with the more general proposition of the Supreme Court in *Bethesda*.

Response: It has been our longstanding view that providers that fail to claim on their cost reports costs that are allowable under the Medicare law and regulations cannot meet the “dissatisfaction” requirement. See, for example, *Little Co. of Mary Hosp. & Health Care Ctrs. v. Shalala*, 165 F.3d 1162 (7th Cir. 1999). This proposed change would simply codify in our regulations our longstanding interpretation of “dissatisfaction.”

We continue to believe that our proposed policy that a provider must either include a claim for reimbursement of a cost on its cost report or self-disallow the cost in order for the Board to obtain jurisdiction over an appeal pertaining to that cost is consistent with the Supreme Court’s decision in *Bethesda*. We believe the commenters that specifically mentioned *Bethesda* have misunderstood the import of *Bethesda* on our proposal. In *Bethesda*, providers that submitted their cost reports to their intermediary complied with the Secretary’s regulation by self-disallowing malpractice insurance costs in excess of the regulation. The providers then filed a request for a hearing before the Board to contest the regulation, and the Board dismissed for lack of jurisdiction. Ultimately, the Supreme Court rejected the Secretary’s position that section 1878(a)(1)(A)(i) of the Act, which requires that a provider be dissatisfied with a final determination of its fiscal intermediary, “necessarily incorporates an exhaustion requirement.” The Court found that this “strained interpretation” of a statutory exhaustion requirement was inconsistent with the express language of the statute. (*Bethesda*, 485 U.S. at 404.) The Court agreed that, under section 1878(a)(1)(A)(i) of the Act, a provider’s dissatisfaction with the amount of its total reimbursement is a condition of the Board’s jurisdiction, but held that “it is clear, however, that the submission of a cost report in full compliance with the unambiguous dictates of the Secretary’s rules and regulations does not, by itself, bar the provider from claiming dissatisfaction

with the amount of reimbursement allowed by those regulations. No statute or regulation expressly mandates that a challenge to the validity of a regulation be submitted first to the fiscal intermediary. * * * Thus, [the providers in this case] stand on different ground than do providers who bypass a clearly prescribed exhaustion requirement or who fail to request from the intermediary reimbursement for all costs to which they are entitled under applicable rules. While such defaults might well establish that a provider was satisfied with the amounts requested in its cost report and awarded by the fiscal intermediary, those circumstances are not presented here.” (*Bethesda*, 485 U.S. at 404-05 (emphasis added).) In sum, although the Supreme Court in *Bethesda* held that the Secretary may not rely on section 1878(a)(1)(A)(i) as explicitly requiring providers to present challenges to a regulation to their intermediaries as a condition to the Board’s jurisdiction, the Court specifically recognized that the Secretary could impose an exhaustion requirement by regulation, and that a provider who fails to claim all costs to which it is entitled may fail to meet the jurisdictional prerequisite of dissatisfaction. We note that we are not requiring providers to claim costs or items that they believe may not be in accordance with Medicare payment policy—rather, we are merely requiring that the provider list such items on the cost report by following the protested line amount procedures.

In *Bethesda*, the providers listed on their cost reports the costs at issue, but deliberately did not claim them. As noted by the Ninth Circuit in *Adams House Health Care v. Bowen*, 862 F.2d 1371, 1375 n.3 (9th Cir. 1988), the question was left open by *Bethesda* as to whether the Board is deprived of jurisdiction to hear an appeal concerning a cost that was omitted entirely from the cost report. We interpret section 1878(a)(1) of the Act to mean that a provider is not “dissatisfied” with a final determination of the intermediary or the Secretary regarding any matter that is omitted from the cost report, and that, as a result, the Board does not have jurisdiction to hear an appeal regarding the matter. Although the Supreme Court in *Bethesda* indicated that if a provider were to bypass a “clearly prescribed exhaustion requirement” it “might well” be precluded from raising the issue before the Board, we believe our proposal to be even less than an exhaustion requirement. We believe it to

be more akin to simply a presentment requirement.

We do not believe that the *Little Company of Mary Hospital* decision is inconsistent with the Supreme Court's decision in *Bethesda*. As the Seventh Circuit in *Little Company of Mary Hospital* noted, *Bethesda* "says only that a provider can challenge a rule before the Board even after 'admitting' that the rule is applicable when submitting its expenses to the intermediary," and that *Bethesda* "strongly suggests that a hospital that does not ask its intermediary to reimburse it for all the costs for which it is entitled cannot, on appeal to the Board, first ask for new costs." (24 F.3d at 992–93, emphasis in the original.) Thus, *Little Co. of Mary* was not a narrowing of *Bethesda*, as one commenter asserted. Rather, it was an application of *Bethesda* to the facts before it, facts that mirrored the language quoted above from *Bethesda*.

We recognize that the First Circuit's majority opinion reached a contrary result in *Maine General Medical Center v. Shalala*, 205 F.3d 493 (1st Cir. 2000). Because *Maine General* relied on a pre-*Bethesda* decision that analyzed Board jurisdiction under 42 U.S.C. 1395oo(d), and not 42 U.S.C. 1395oo(a), as required by *Bethesda*, and because it failed to recognize the implications of the *Bethesda* dicta, we believe that *Maine General* was incorrectly decided.

Although no commenters raised the argument that the "dissatisfaction" requirement applies only to the total amount of program reimbursement reflected in the NPR, and that "dissatisfaction" therefore does not need to be expressed with respect to each issue challenged on appeal, we note that a provider successfully made this argument in *Loma Linda University Medical Center v. Leavitt*, 492 F.3d 1065 (9th Cir. 2007). We respectfully submit that the Ninth Circuit erred in its analysis. Although there may be nothing in the statute indicating that dissatisfaction must be expressed with respect to "each claim", there also is nothing in the statute indicating that the Secretary cannot interpret the dissatisfaction requirement in this manner. The statute thus is ambiguous on this point, and the Ninth Circuit should have accorded deference to the Secretary's interpretation, particularly in light of the Secretary's expertise in how the Medicare provider reimbursement process works.

Specifically, an intermediary makes distinct reimbursement determinations for each expense item and then sums these distinct determinations. The "final determination," which here is the NPR,

thus is not simply one total amount. Rather, it is comprised of many individual calculations representing the various items for which the provider seeks payment. A provider rarely, if ever, would challenge before the Board its payment for every discrete item that goes into the total reimbursement figure. Instead, a provider challenges discrete elements of the total amount, only some of which may be reviewed by the Board. Dissatisfaction with total reimbursement thus is based on dissatisfaction with items that result in total reimbursement, and it is completely reasonable to interpret 42 U.S.C. 1395oo(a) to require dissatisfaction to be shown with respect to each issue being appealed.

Moreover, *Bethesda* involved the question of whether the Board had jurisdiction over one particular issue, not whether it had jurisdiction over an entire NPR. *Bethesda* thus implicitly assumes that jurisdiction must be obtained on an issue-specific basis. Furthermore, the facts of *Little Co. of Mary* make clear that, in that case, the provider was dissatisfied with other issues in its NPR. Yet this dissatisfaction with the overall total amount of program reimbursement did not affect the court's decision in that case.

We also note that the Secretary's interpretation of the statutory language at 42 U.S.C. 1395oo(a) is consistent with court decisions related to reopenings. In those cases, the courts refrained from similar attempts to exaggerate the significance of the statutory phrase at 42 U.S.C. 1395oo(a) "total program reimbursement due the provider." *Your Home Visiting Nurse Servs. v. Shalala*, 525 U.S. 449, 453 (1999) (Board lacks jurisdiction over intermediary's "refusal to reopen * * * [which] is not a 'final determination * * * as to the amount,' but rather a refusal to make a new determination"). In *HCA Health Services of Oklahoma v. Shalala*, 27 F.3d 614 (D.C. Cir. 1994), the court noted that "when an intermediary revisits only certain specified determinations contained in the original NPR * * * [p]art of the final determination is obviously contained in that portion of the original NPR which was never revisited, while the remaining elements are clearly to be found in the reopening decision." 27 F.3d at 617 (emphasis added). The court thus recognized that the "final determination" is really comprised of many individual determinations.

Finally, an issue-specific requirement of "dissatisfaction" has a sound policy basis. If providers were able to claim items for the first time during a Board appeal simply because they had

expressed dissatisfaction with respect to other cost items, the Board would be required to assume responsibilities that are more appropriately borne by fiscal intermediaries rather than by a "review" board. Such a system also would provide an end-run around the deadline for filing an accurate cost report, as providers could file "placeholder" appeals with respect to items claimed on their cost reports with the knowledge that they could always make additional claims later.

In any event, even if the Board has jurisdiction under the statute to hear an appeal concerning an item that was omitted entirely from the cost report, whether the cost is one that may be allowable or the item involves a challenge to a binding regulation, manual instruction or CMS Ruling, this jurisdiction is not mandatory. In *Maine General Medical Center v. Shalala*, 205 F.3d 493 (1st Cir. 2000), the majority held that the statute did not deprive the Board of jurisdiction to hear a claim involving a cost omitted from a cost report, but it adopted the Secretary's position that even if the Board had jurisdiction "it would be entirely permissible for the Board to conclude, as a matter of policy, not to hear [the] claim." (*Maine General*, 205 F.3d at 501.) The court continued: "All we hold is that Congress did not, in the statute, require the Board to reach this result by stripping it of jurisdiction. This outcome preserves some flexibility for the agency, which may be exactly what Congress intended. It is not our job to exercise that flexibility for the agency." (*Id.*) See also *Loma Linda*, 492 F.3d at 1072–73 (holding that Board jurisdiction is discretionary).

Sections 1102(a) and 1871(a) of the Act authorize the Secretary to issue regulations for the efficient administration of the Medicare program. Irrespective of whether the Board has jurisdiction under the statute to hear an appeal concerning an item that was omitted entirely from the cost report (and we do not agree with the *Maine General* or *Loma Linda* cases on this point), the requirement that providers either claim an item on their cost reports or, where the item involves a challenge to a binding regulation, manual instruction or CMS Ruling, list the disputed item in accordance with the longstanding instructions contained in section 115 of the PRM, Part II, fits comfortably within our statutory authority to issue regulations to administer the Medicare program and is a reasonable exercise of that authority. Providers are already required, for program integrity reasons, to list "protested items;" that is, items for

which they believe they are entitled to receive payment, but for which they believe that their intermediaries would disallow, on the basis that reimbursement for such items is contrary to regulation or policy interpretation. Under section 115 of the PRM, Part II, providers that do not wish to risk running afoul of the cost report certification process, by including an item on their cost reports that is contrary to Medicare regulations or payment policy, are allowed to include these items on the "protested amount" line on their cost reports. We believe it is reasonable to require providers to notify their intermediaries, via their cost report submission, of all items for which they potentially may be claiming reimbursement. Such a requirement allows the Medicare program to estimate better its potential liabilities and to issue changes or clarifications to its policies, and allows intermediaries to estimate better their workload and audit priorities. Also, if we were to adopt a policy that providers have to list on their cost reports only those items that they believe are in accord with Medicare payment policy, the Board would be required to continue adjudicating disputes as to whether an omitted cost is or is not in accord with Medicare payment policy (because if the omitted cost were in accord with Medicare payment policy, the provider would not have the right to a hearing).

Comment: One commenter stated that it disagreed with the proposed policy that would require providers to identify self-disallowed issues as protested items. Providers have to trust the information with which they are provided when preparing cost reports and follow the directions that have been issued. The individuals who prepare cost reports may not have the background, time, or ability to evaluate or question whether the data provided by government sources or the instructions that have been issued should be challenged. This provision may put undue pressure on individuals who prepare cost reports, and could increase administrative costs as providers seek professional help to identify issues of which the providers may not be aware. According to the commenter, it can take a considerable amount of research and investigation into issues to discover that errors exist in the underlying government data used to prepare the cost report. Once this discovery is made, it seems appropriate that the error be corrected and adjustments made. Providers should not be held responsible for discovering errors made by government bodies.

Another commenter stated that it is impractical to expect providers to file under protest every potential item on their cost reports that may be disallowed under the applicable regulations or manual provisions. Providers are faced with overwhelming numbers of regulatory and policy manual issuances covering a complex array of constantly changing Medicare billing and documentation requirements. According to the commenter, there is no basis in law or equity for CMS's attempt to cut off providers' appeal rights because the providers may not recognize the invalidity of a particular intermediary's interpretation of CMS's regulations and policies at the time they file their cost reports.

Response: We do not believe that there should be any significant difficulty for providers in identifying items for which they believe they should receive payment in derogation of Medicare payment policy. Upon deciding that it does, in fact, wish to challenge Medicare payment policy with respect to one or more item(s) the provider has self-disallowed, the provider should include the item(s) in its request for a hearing, or add the issue later, in accordance with the procedures for adding issues under § 405.1835(c). The Medicare program expects provider personnel, whether on the provider's staff or outside professionals, to have the background, time, and ability to complete and understand the cost reporting requirements.

Comment: One commenter stated that the statute does not require that providers indicate in the cost report that they will be dissatisfied with a final determination, and that CMS is placing form over substance in this regard. This commenter said that, although increasing efficiency within the appeal system is a worthwhile goal, any efficiency gain does not justify providers' loss of their rights to appeal meritorious claims by virtue of inadvertence to procedural requirements that are not obvious.

Response: We do not agree that our requirement amounts to a procedural requirement that is not obvious to providers. The statute at 42 U.S.C. 1395oo(a) requires that a provider express dissatisfaction with a determination of the intermediary or the Secretary. Arguably, therefore, a provider could not be dissatisfied with a determination that does not explicitly or implicitly address an item, because the item is neither claimed nor even listed on the cost report. Moreover, many providers are already availing themselves of the protested line amount

procedures contained in section 115 of the PRM, Part II. In any event, in addition to the legal notice that providers are receiving through this final rule, we anticipate that providers will informally be alerted to the provisions of this rule, including the self-disallowance policy, through hospital associations and other provider organizations, law firms, trade publications and others.

Comment: Several commenters stated that by requiring providers to follow the procedures in the PRM for filing a cost report under protest, more administrative work will be created for the hospitals and the intermediaries because the item or cost has to be manually claimed and the impact manually calculated. The commenters further stated that the intermediaries must manually review each protested cost or item and decide to remove or allow, and that the intermediaries' failure to do so would automatically reimburse providers for the cost or item.

Response: We believe that our self-disallowance policy will not create a significant amount of work for most providers and intermediaries, for several reasons. First, many providers are already using the protested line amount procedures contained in section 115 of the PRM, Part II. Also, the commenters are incorrect that the item or cost has to be manually "claimed" on the cost report.

We do not believe that providing an estimate of the self-disallowed item will prove burdensome to providers. Moreover, if the provider believes that listing the item on the cost report is worthwhile, the provider may have already engaged in an estimate of sorts, and in any event, if the provider does decide to appeal the item, it should estimate the reimbursement effect of the item at that time. Finally, intermediaries are not required to review each protested cost or item to decide to remove or allow that cost or item. Whereas, at one time, items appearing on the protested amount line were "above the line" (that is, they appeared before, and made up part of, the total claim for reimbursement), that is no longer the case. On the current cost report, the protested amount appears "below the line" and is not included in the provider's total claim for reimbursement.

2. Audits of Self-Disallowed Items

We proposed that, where a provider is successful in obtaining reimbursement for a self-disallowed item, the intermediary must audit the item to determine the proper reimbursement effect.

Comment: Three commenters believed that our proposal was unnecessary. One commenter stated that it does not have an objection in principle with the proposal that an intermediary must audit self-disallowed items after a decision awarding them to the provider, and said that its experience has been that in every instance in which providers have successfully challenged a CMS policy, payment has been audited or reviewed for accuracy under the agreement of the parties to the dispute. The second commenter believed that the proposal was unnecessary because CMS already has the right to, and routinely does, instruct its intermediaries to perform additional auditing steps before issuing an NPR as a result of a final agency determination. The third commenter stated that the Board would expect that self-disallowed items would be unaudited.

Response: The final decision awarding reimbursement for a self-disallowed item may come from the Board, the Administrator, or a court. Although we believe that, in most instances, the administrative or judicial body that issues a decision would not specify a dollar figure for reimbursement, the proposal was intended to ensure that intermediaries, in fact, have the opportunity to determine the correct amount of reimbursement after an award is made. We believe that it would be inappropriate for the administrative or judicial body to award a specific amount for reimbursement without the benefit of an audit by the intermediary. Of course, the intermediary could audit the self-disallowed item prior to an award, but this would mean that the intermediary would be spending resources to determine an amount for an item that, under Medicare policy, would not be awarded.

Comment: Three commenters said that the regulations should place a limit on the time an intermediary has to conduct the audit of the awarded self-disallowed item. One commenter stated that the regulations should set forth a reasonable time limit to audit and calculate payment, and that 60 days certainly should be sufficient. The second commenter stated that, whereas the need for an accurate determination of the amount of reimbursement is important, the proposal threatens to prolong indefinitely the closure of the appeal, because no limit is placed on the time the intermediary would have to complete the audit. The third commenter stated that any audit subsequent to a decision to pay a self-

disallowed item should occur within a limited period of time.

Response: We agree that in all cases intermediaries should complete the audit of an awarded self-disallowed item in a reasonable amount of time. We decline to impose a specific time limit on intermediaries for auditing self-disallowed items, however, because what is reasonable in a given case will depend in part on the scope and complexity of the audit and the provider's cooperation, as well as the intermediary's other program priorities.

Comment: Two commenters disagreed with the proposal to permit intermediaries to audit self-disallowed costs that are ultimately awarded during the appeals process. In the first commenter's view, the proposal offends the judicial principle of finality and gives the Medicare program "two bites at the apple." According to the commenter, the intermediary has enough time between the time that a provider appeals a self-disallowed cost and a Board hearing for an intermediary to audit or otherwise evaluate or question the amount of the claim. The other commenter stated that the proposal to require intermediaries to audit eventual awards of self-disallowed costs could result in an entirely new disallowance and appeal based on new grounds. A provider could be forced to litigate the same items multiple times, which would be inconsistent with the due process rights of the provider. Any audit subsequent to a decision to pay a self-disallowed item should be restricted to a determination of the payment amount, and should not open new grounds for disallowance.

Response: We disagree that the proposal is counter to the principle of finality, or that it would give the Medicare program "two bites at the apple." The purpose of the proposal was not to allow the intermediary to relitigate the question of whether the provider is entitled to reimbursement for the self-disallowed item, but rather to ensure that the intermediary has the opportunity to determine the reimbursement effect of the final decision awarding that self-disallowed item. We believe the language in § 405.1803(d)(3), that CMS may require the intermediary to "audit" a self-disallowed item, sufficiently conveys that, under this provision, the intermediary is restricted to determining the amount of program reimbursement, and not whether the item should be allowed. Although the intermediary could audit the self-disallowed item prior to an award, the intermediary would be spending resources to determine the correct amount for an

item that may not, and, at least from the perspective of the program, should not be awarded.

Comment: One commenter stated that one way to minimize the problem of unaudited self-disallowed costs would be to allow the provider and the intermediary to enter into a stipulation regarding whether the self-disallowed costs have been audited. Another commenter stated that a more practical procedure would be for the parties to stipulate the amount in controversy, with an audit by the intermediary, if necessary, at the outset of the appeal, rather than after a possibly lengthy process.

Response: We believe that a stipulation that the amount at issue for a self-disallowed cost that has not been audited may be helpful, but would not be an adequate substitution for our proposal, which would prohibit the award of a specific amount of reimbursement in the absence of an audit. Where the intermediary knows the amount of potential reimbursement during the pendency of an appeal, either because it has audited the issue or otherwise has the necessary information, the intermediary can stipulate to the amount at issue. Intermediaries are in the best position to know their workload priorities and to decide on allocation of their resources. We are not preventing intermediaries from determining the amount at issue prior to a decision awarding the reimbursement at issue; rather, the purpose of the proposal was to prevent intermediaries from being forced to audit the amount of reimbursement prior to a decision favorable to the provider.

Comment: One commenter stated that the regulations should make clear that any dispute with regard to an audit or calculations would remain in the jurisdiction of the entity that rendered the last merits decision.

Response: We decline to require that the entity that awarded the reimbursement for the self-disallowed item maintain continuing jurisdiction in case there is a dispute concerning the audit. We would have no authority to require a court, once having remanded the case for an audit by the intermediary, to retain continuing jurisdiction over the case. The Board or the Administrator may not see the need to maintain continuing jurisdiction over the case, once having ruled for the provider on the self-disallowed item. To the extent that the provider disagrees with the calculation of the audited item, the provider may bring a new appeal to the intermediary or to the Board, if the

provider meets the amount in controversy requirements.

3. Determining Timeliness of Hearing Requests (§ 405.1811 and § 405.1835)

We proposed to revise our regulations to provide that the 180-day period for requesting a Board or intermediary hearing begins on the date of receipt by the provider of the intermediary determination or, where applicable, the expiration date of the 12-month period for issuance of a timely NPR by the intermediary. We received one comment on this issue, which pertained more closely to our proposed definition for "date of receipt" and to our proposal for a presumption that documents from a reviewing entity are received within 5 days of their mailing, unless a preponderance of the evidence establishes that they were received later than the 5-day period. Accordingly, we have addressed this commenter's concerns in section II.B. of this final rule.

4. Contents of Hearing Request

In order to facilitate an early focus by the parties and the reviewing entity on the jurisdictional requirements for a hearing before the Board or intermediary, we proposed that the original hearing request include a demonstration (through argument and supporting documentation) that the provider satisfies the jurisdictional requirements for the hearing request. We also proposed that, in order to facilitate the reviewing entity's ability to determine compliance with our proposed self-disallowance rules, the hearing request must contain a description of the nature and amount of each self-disallowed item and the reimbursement sought for each item. Finally, we proposed clarifying the current requirement that a hearing request include supporting documentary evidence. We stated that we were aware of various cases in which the need to determine Board jurisdiction over a specific matter at issue had been hampered by the absence of the NPR(s) relevant to the appeal, or by confusion about whether the NPR at issue was the initial NPR or a revised NPR issued after reopening (see § 405.1885 and § 405.1889). Because the Board would not be able to make appropriate findings of fact and conclusions of law about its jurisdiction without this information, proposed § 405.1811(b)(3) and § 405.1835(b)(3) would require the hearing request to include each intermediary determination at issue in the appeal.

Comment: One commenter stated that the proposed rule would place an

unreasonable burden on providers to look into the future and defend against unknown jurisdictional challenges that may arise. This commenter proposed that, if jurisdictional documentation must be submitted with the original hearing request, the intermediary should be required to read it and determine within a reasonable period of 60 to 90 days if any jurisdictional issues exist. Arbitrary jurisdictional challenges by intermediaries have increased dramatically in recent years, created additional demands on Board resources, and have caused substantial delays in cases moving through the administrative process. Once the Board has taken jurisdiction over an issue, that decision should have some finality. According to the commenter, if CMS's intent is to reduce the backlog, an administrative process that is fair to both the provider and the intermediary should be established.

Response: We disagree that requiring a brief demonstration in writing that the request for hearing meets the jurisdictional requirements constitutes an unreasonable burden on providers. The party seeking relief before an administrative or judicial tribunal has the burden of demonstrating that the tribunal has jurisdiction over its claim or appeal. In most cases, the jurisdictional question will be straightforward and the provider will either be able to demonstrate easily that the intermediary hearing officer(s) or the Board has jurisdiction, or, at the least the provider will be able to anticipate arguments concerning jurisdictional deficiencies. With respect to the commenter's assertion that some intermediaries make arbitrary jurisdictional challenges, we believe that claims presented by providers, as well as defenses raised by intermediaries, should be made in good faith. If an intermediary has raised a defense, jurisdictional or otherwise, that does not have a reasonable basis in law or fact, or has not raised a reasonable jurisdictional defense in a timely manner, the intermediary's conduct should be reported to the Board, and if the Board believes it to be appropriate, the Board can refer the matter to CMS for possible action. This is not to say that, where an intermediary has raised a jurisdictional defense that is similar to one that it or another intermediary has raised unsuccessfully before, the intermediary would be precluded from raising the jurisdictional defense if it was otherwise reasonable. (However, in that situation, the intermediary should note its jurisdictional objections to the Board in a way so as not to delay the

resolution of the appeal and, if necessary and appropriate, renew its jurisdictional objections in a request for Administrator review of the Board's final determination on the merits.) Similarly, we do not believe that an intermediary should purposely delay making jurisdictional defenses, but, again, the burden is on the provider to demonstrate jurisdiction, and we decline to either impose a specific time period for an intermediary to raise jurisdictional defenses or to provide that, having once determined that jurisdiction exists, the Board is precluded from revisiting the issue. Additional facts that are developed during the course of proceeding before the Board may cause the intermediary to challenge, and the Board to deny, jurisdiction. In civil litigation, jurisdictional defects can generally be raised at any time, even on appeal. Although a court may be obliged to dismiss a case for lack of jurisdiction even where the jurisdictional objection is made at a late stage in the proceedings, it reserves the authority to sanction a party if the party has unreasonably delayed in making the objection. If the Board believes that an intermediary has unreasonably delayed in making a jurisdictional objection, it may refer the matter to CMS for possible action.

Comment: One commenter stated that an issue included in a hearing request may at times be reopened by the intermediary with a partial revision being made. Such a revised determination by the intermediary should not preclude the provider from continuing to appeal the balance of the issue on the basis that it fails to meet the amount in controversy requirement. The Board should preclude any jurisdictional challenge in this situation. There is no need for jurisdictional review in these circumstances.

Response: If a provider satisfies the amount in controversy requirement at the time it files its appeal, a subsequent revision or partial revision to an issue or issues that causes the remaining controversy to go below \$10,000 (or \$50,000 in the case of a group appeal) will not deprive the Board of jurisdiction to hear the appeal. We have added new paragraph (c)(4) to § 405.1839 to clarify this point.

Comment: One commenter stated that the proposed requirements for documenting a provider's position in the original hearing request creates an unreasonable burden due to the time and effort to prepare the documentation. As a result, this requirement would effectively reduce the 180-day filing period, in violation of the statute.

Response: We do not believe that the proposed requirements for documenting a hearing request are onerous. As we stated in the proposed rule (69 FR 35723) requiring providers to include certain information in their hearing requests facilitates an early focus by the parties and the Board that the jurisdictional requirements for a hearing are met.

Comment: One commenter said that the cost of developing documentation could be unnecessary for those issues that are likely to be resolved through the administrative resolution process. Because the resolution process typically results in a provider accepting less than full reimbursement for a disputed issue, if providers are forced to incur the costs of developing documentation, the costs of going forward with a hearing may be justified. As a result, more cases may go to hearing and fewer cases may be settled and withdrawn.

Response: We do not believe that the proposed requirements for documenting a hearing request are onerous. Moreover, we do not believe that a provider would be able to reach an administrative resolution with an intermediary on an issue without developing at least as much documentation as would be needed for a hearing request on that issue.

Comment: One commenter recommended that the final rule add a provision requiring that providers include intermediary documentation on the disallowances appealed, and that the intermediaries in turn be required to provide supporting documentation to providers. Without intermediary supporting documentation, providers cannot, in the hearing request, articulate their position and submit documentation in support of their position. Currently, many intermediaries justify disallowances by citing only general regulatory provisions and do not state why the provider did not meet the cited provisions or what auditing standards were applied. Medicare and Government Accountability Office rules require that the intermediary document reasons for disallowances and undergo supervisory review. The commenter stated that if intermediary disallowances were properly documented, challenges could be narrowed and the case backlog could be reduced.

Response: In § 405.1835(b)(3), we are requiring providers to submit to the Board a copy of the intermediary or CMS determination under appeal. Further, providers must submit any other documentary evidence that they consider necessary to meet the requirements for obtaining a Board

hearing. We agree that intermediaries should provide at least a brief explanation for the adjustment, so as to put the provider on notice as to the reason for the adjustment. However, in light of the huge number of adjustments that intermediaries make, and in view of the fact that many of these adjustments are not (and would not be, regardless of the degree of explanation) appealed, we are not requiring intermediaries to provide extensive and detailed explanations of their adjustments prior to the filing of a hearing request.

We also note that the existing requirements in § 405.1803 dictate that the intermediary include appropriate references to law, regulations, CMS Rulings and program instructions to explain why its determination of the amount of program reimbursement due to the provider differs from the amount claimed by the provider. In addition, we note that the current audit instructions for intermediaries contain similar requirements. (See CMS Pub. 100-06, Chapter 8, General Audit Guidelines, 170, Exhibit VI.) (Further, we believe that the intermediary review and adjustment process is outside the scope of this rulemaking.) Where a provider disagrees with, or has questions concerning, an intermediary's adjustment, the provider may contact the intermediary for further clarification. We note that the 180-day period for requesting a hearing should allow the parties sufficient time to exchange information concerning the basis for the claim and the adjustment and the parties' respective positions concerning the adjustment. If the provider does not receive a satisfactory response from the intermediary concerning the adjustment, the provider may appeal the adjustment. The provider should note in its request for a hearing the basis for the provider's disagreement, or, where the provider believes that it does not have enough information to articulate as full an explanation for its disagreement as it would prefer, the provider may state that, though it believes that it is entitled to a reversal of the adjustment, the provider nevertheless lacks enough information to determine at that point the full basis for its disagreement with the intermediary. In all cases, through pre-hearing conference and other communications, or through formal discovery if need be, the provider and the intermediary should be able to arrive at an understanding of the basis for the provider's claim and the intermediary's adjustment. Ultimately, if the provider does not present a full basis for its claim, it will be difficult to

prevail on its appeal, and if the intermediary does not fully support its disallowance, it will be difficult for the intermediary to defend its adjustment.

Comment: One commenter stated that it did not believe that requiring providers to submit more documentation earlier in the process would have much of an impact on relieving caseload. This commenter believes that a more effective proposal might be to charge the intermediary interest, from the time the provider submits its final position paper until the time the case is resolved, on the amount that is eventually paid to the provider.

Response: We do not have the authority to charge interest against the intermediary, as the commenter suggests. The payment of interest is a waiver of sovereign immunity, which can be effected only through legislation enacted by the Congress.

Comment: One commenter stated that the proposal to require providers to demonstrate in the hearing request that they meet the requirements for a Board hearing and to include a description of the nature and amount of each self-disallowed item and the reimbursement sought for each cost was outside CMS's statutory authority. According to the commenter, the Congress established the Board as an independent tribunal within the Department of Health and Human Services, not subject to CMS's direct oversight or control, permitting CMS only to review a final decision of the Board after it is issued. Under the Medicare statute, only the Board, and not CMS, has full power to make rules and establish procedures, not inconsistent with the provisions of the statute or the regulations of the Secretary, which are necessary or appropriate. This commenter also objected to the proposed requirement, that, where the provider is appealing from a revised NPR, the provider must include the pertinent reopening notice and the initial NPR so that an appropriate determination can be made as to whether a specific matter at issue is within the scope of the revised NPR. CMS's position that providers can appeal only issues that were actually adjusted in revised NPRs is contrary to the doctrine in *Edgewater Hospital v. Bowen*, 857 F.2d 1123 (7th Cir. 1989). The commenter stated that the proposed new requirements for hearing requests would create significant new hurdles for providers and make it much more difficult for providers to meet appeal deadlines.

Response: We disagree that we do not have authority under the Medicare statute to govern procedures for hearings before the Board. As the

commenter notes, section 1878(e) of the Act provides that the Board's operating rules are subject to regulations issued by the Secretary, such as this final rule. With respect to the commenter's point that our proposal that providers may appeal issues only that were actually adjusted in revised NPRs is contrary to the court's decision in *Edgewater Hospital v. Bowen*, we continue to believe that our proposal is well-founded. We respond at length in section II.V. of this final rule (Reopening Procedures) to the assertion that, based on *Edgewater*, we should allow an appeal of a revised NPR to include an appeal of matters that were addressed in a notice of reopening but not actually revised.

Comment: One commenter stated that clarification was necessary because providers were adding issues to an appeal of a revised NPR that were not within the scope of a revised NPR.

Response: We agree that one benefit of requiring providers to document their position in their request for a hearing is alerting the Board as to whether the appeal concerns an issue that was or was not within the scope of a revised NPR.

Comment: Two commenters found confusing the statement in the proposed rule (69 FR at 35723–24) that a hearing request would no longer be required to include documents necessary to support the provider's position on a specific reimbursement matter, because the reviewing entity is required to make a preliminary finding of its jurisdiction before it considers the merits of a particular issue. One of the commenters stated that, in order to determine the merits and preliminary findings of its jurisdiction, the intermediary (for purposes of an intermediary hearing officer proceeding) needs the necessary documents to support the merits of the provider's position. The commenter recommended that all supporting documentation, and not just documentation in support of jurisdiction, be required to be supplied with the hearing request. According to the commenter, documentary evidence should be required in order to facilitate a review and possible resolution of the issues. A reopening request must be accompanied by all supporting documentation, and the same rule should apply with respect to hearing requests.

Response: We note that, because the intermediary hearing officer (or the Board in a Board appeal) must make a preliminary determination of its jurisdiction (that is, whether the request for hearing was timely and whether the amount in controversy requirement was

met) prior to addressing the merits, the provider would not need initially to file documents that pertain only to the merits of the appeal. If, however, the provider believes that there is documentation that is necessary to support a preliminary determination of jurisdiction and that documentation is intertwined with the merits of the appeal, the provider must, under § 405.1835(b)(3), submit that documentation with its hearing request. Likewise, if the intermediary hearing officer or the Board believes that additional documentation is necessary to examine jurisdiction, the reviewing entity may request additional documentation from the provider. We have amended § 405.1840(a)(2) to clarify that, by "preliminary determination of jurisdiction," we mean a determination of whether the request for hearing was timely (either received within 180 days after the date of receipt by the provider of the intermediary or Secretary determination, or the period for receipt was extended under § 405.1836), and whether the amount in controversy requirement was met.

Comment: One commenter questioned whether the Board would have the ability to dismiss an appeal if required information is not submitted with the hearing request. Similarly, another commenter stated that the rule should specify whether an imperfect but timely request would be dismissed or whether there would be an opportunity for the provider to correct the defect.

Response: Proposed § 405.1811(b) and § 405.1835(b) stated that a request for an intermediary or Board hearing "must" be submitted in writing and "must" include certain prescribed items. Although one could fairly conclude that a hearing request that would meet the requirements of proposed § 405.1811(b) or § 405.1835(b) would be a prerequisite to obtaining a hearing, the proposed rule did not state whether a provider that submits a non-conforming request would have the opportunity to cure the request, and if so, whether the provider could have more than one opportunity to cure the request before its appeal would be dismissed. We have clarified § 405.1811(b) and § 405.1835(b) to state that the intermediary or Board may dismiss with prejudice an appeal that does not comply with the requirements of § 405.1811(b) or § 405.1835(b), or take other action as it deems appropriate. We believe that this approach is consistent with the approach we have taken in section § 405.1868 ("Board Actions in Response to Failure to Follow Board Rules") in which we similarly leave to the Board's discretion whether to

dismiss an appeal or take some other, lesser action.

Comment: Two commenters stated that they were concerned that the "detailed" information required for the content of the initial hearing request would unduly burden small, rural, and less sophisticated providers that would not have the ability to file appeals without the assistance of outside expertise. In addition, the proposed contents requirements would remove the Board's flexibility to accept appeals.

Response: We do not believe that the proposed requirement is unduly burdensome, even for "small, rural and less sophisticated providers." As adopted, our proposal requires only that the provider demonstrate that it has met the various requirements for obtaining a hearing. As we stated in the proposed rule (69 FR 35723), the hearing request would no longer need to include documents necessary to support the merits of the provider's appeal.

Comment: One commenter stated that it was concerned with proposed requirements that the provider document and provide argument that its appeal is strictly and demonstrably within the jurisdiction of the appeals panel. Likewise, according to the commenter, the proposed requirements for documentation regarding self-disallowance issues seem to unfairly shift the burden entirely onto the provider, without offering detailed and specific criteria for what is and is not acceptable documentation and standards of argument.

Response: The purpose of proposed § 405.1835(b) was to provide the Board with the information necessary to make a preliminary determination (timeliness and amount in controversy) as to whether it had jurisdiction over the provider's appeal, as well as providing the intermediary with the information necessary to determine whether it would file a jurisdictional challenge with the Board. A provider would not be required to argue its case in detail at this point in the process. Rather, as the moving party, the provider would be required only to demonstrate that it is dissatisfied with an intermediary or Secretary determination and that it has filed its request for a hearing timely and that the amount in controversy is at least \$10,000.

5. Adding Issues to Original Hearing Request (§ 405.1811(c) and § 405.1835(c))

In the proposed rule, we believed it was necessary to amend the regulations addressing the provider's ability to add issues to its original hearing request. Currently, a provider is effectively

allowed to wait for new issues to appear and add issues anytime before the hearing begins. It is our view that, because providers may add issues to a request at any time prior to a hearing, the ability of the Board to conduct hearings and decide cases expeditiously has been seriously compromised. At the time of the publication of the June 25, 2004 proposed rule, there were approximately 10,000 cases at the Board that had yet to be resolved. We believed the availability of such an extended period for adding issues had become a major obstacle to the Board's efforts to reduce its backlog.

The ability of providers to add issues at any time to a hearing request not only has led to larger and more complex cases, but has also meant that the Board's ability to schedule and hold hearings efficiently has been significantly impaired through the practice of some providers of adding issues shortly before the scheduled hearing date. Some providers apparently wish to keep a hearing request open as long as possible in the hope or anticipation of a favorable court case on some reimbursement issue that they can then add to their hearing requests. Therefore, we proposed that, rather than having an open-ended period for adding issues, it would be appropriate and prudent to allow providers a 60-day period for adding issues, commencing with the expiration of the applicable 180-day period for filing the original hearing request. In essence, this additional 60-day period would afford providers an adequate opportunity to appeal all the issues that may have been overlooked in the original hearing request. We examined section 1878(d) of the Act, which gives the Board the power not only to affirm, modify, or reverse the intermediary's determination, but also to make any other revisions on matters covered by the cost report, regardless of whether these matters were considered by the intermediary in its determination. We interpreted this statutory provision to address only the Board's powers over a jurisdictionally proper appeal under section 1878(a) of the Act; therefore, section 1878(d) does not prevent us from limiting the period a provider has to add issues. We believe our proposal to allow a 60-day period for adding issues is an appropriate exercise of the Secretary's general rulemaking authority under sections 1102 and 1871 of the Act.

Comment: Three commenters supported our proposal. One commenter noted that requiring all issues to be identified within our proposed timeframe would add huge efficiencies

to the process. All three commenters stated that providers are afforded ample time to decide which items they wish to appeal during the 180-day appeal period.

Several commenters opposed our proposed change. Some commenters suggested that the proposed rule restricts provider appeal rights, denies access to appeal, and is contrary to the statute. One commenter suggested that the 60-day period is far too brief to allow providers to add issues to appeals, and that CMS has provided no additional information as to how it determines 60 days to be an appropriate period. A few commenters suggested that the Supreme Court's decision in *Bethesda Hospital Association v. Bowen*, 485 U.S. 399 (1988), is informative on this issue. Commenters opined that *Bethesda* made clear that, once jurisdiction for a cost reporting year was established, the only requirement was "that the matter must have been covered by such cost report."

Response: After careful consideration of the comments received in this final rule, we are adopting our proposal to include a 60-day period for a provider to add issues beyond the 180-day period permitted for filing a hearing request. For the efficient administration of the appeals process, we believe our policy of having the appeal resolved as early as possible, while at the same time giving the parties to the hearing ample opportunity to present their cases, is appropriate. Following a given cost reporting year, providers have five months to file a cost report. (See § 413.24(f)(2).) After a cost report is filed, the intermediary typically takes about a year to issue a final determination on an unaudited cost report. We believe it is quite reasonable to expect that from the time it takes to file a cost report to a 240-day period after a final determination has been issued, covering a span of approximately two years or more, a provider should have sufficient opportunity to identify the issues it wishes to appeal for that cost year. The Board will then be able to set a hearing date with full knowledge that the hearing will not be further delayed by the inclusion of last minute issues.

We disagree with those commenters that asserted that there is a statutory right to add issues at any time prior to a hearing. The Medicare statute does not address a timeframe for adding issues to an appeal. The only statutory provision related to the timing of an appeal is found at section 1878(a)(3) of the Act. There, a provider is entitled to request a hearing before the Board if it files a request within 180 days after notice of

the final determination. We believe it is reasonable to read this statutory provision in conjunction with section 1878(d) of the Act to mean that a provider must include in its notice of appeal all the issues it wants to appeal, especially given that section 1878(a)(3) of the Act allows a generous 180-day period to request a hearing. Although we continue to believe that providers should not be allowed to delay interminably the hearings process by adding issues at the last minute before a scheduled hearing date, we believe our approach of providing an additional 60 days beyond the timeframe for requesting a hearing to add issues that may have been overlooked strikes an equitable balance that will serve the interests of the parties to the hearing and the Board.

Section 1878(d) of the Act, the provision upon which some commenters relied as granting a right to providers to add issues at any time, in fact affords no such right. Section 1878(d) of the Act states in relevant part that: "The Board shall have the power to affirm, modify, or reverse a final determination of the fiscal intermediary * * * and to make any other revisions on matters covered by such cost report * * * even though such matters were not considered by the intermediary in making such final determination." We interpret section 1878(d) of the Act as permitting the Board to make revisions to cost report items that directly flow from the determination with which the provider has expressed dissatisfaction and from which the provider has filed a jurisdictionally proper appeal under section 1878(a) of the Act. See *Little Co. of Mary Hosp. and Health Care Ctrs. v. Shalala*, 828 F.Supp. 570, 576 (N.D. Ill. 1993), aff'd 24 F.3d 984 (7th Cir. 1994). However, section 1878(d) of the Act does not pertain to the timing for the inclusion of issues, contrary to the commenters' view.

For similar reasons, we disagree with the commenter that suggested that the Supreme Court's decision in *Bethesda* controls in this situation. As discussed more fully in section II.C. of this final rule, the *Bethesda* decision involved a challenge to the Board's decision that it did not have jurisdiction to consider a cost that was not claimed on the provider's cost report, and did not in any way deal with the question of the timeliness of adding issues to a hearing request. We believe that *Maine General Medical Center v. Shalala*, 205 F.3d 493 (1st Cir. 2000), also discussed in section II.C. of this final rule, is more relevant. In *Maine General*, the court held that the statute did not deprive the Board of jurisdiction to hear a claim involving a

cost omitted from a cost report (a conclusion with which we strongly disagree), but it agreed that "it would be entirely permissible for the Board to conclude, as a matter of policy, not to hear [such a] claim." (*Maine General*, at 501.) The court continued: "All we hold is that Congress did not, in the statute, require the Board to reach this result by stripping it of jurisdiction. This outcome preserves some flexibility for the agency, which may be exactly what Congress intended. It is not our job to exercise that flexibility for the agency." (*Id.*) Similarly, whereas we agree that the statute does not have to be interpreted as preventing the Board from hearing an appeal of an issue that was added subsequent to the submission of the request for hearing, we believe that we retain the authority to prescribe explicitly by regulation the Board's authority to hear issues that were not contained in the request for hearing.

Comment: Several commenters suggested that a deadline for adding issues should be directly related to the imminence of the Board hearing. For example, the deadline should be set with the filing of position papers or tied to a reasonable period prior to the scheduled hearing date, such as 60 or 90 days.

Response: We considered, but ultimately declined to adopt, the approach of requiring that issues be added no later than a set period (for example, 60 or 90 days) prior to the scheduled hearing date. We rejected this approach as potentially unworkable because adding an issue (or multiple issues) even months prior to a scheduled hearing could delay the hearing and interfere with the Board's ability to schedule hearings in a predictable manner.

Comment: One commenter stated that the time in which an issue may be added is solely within the Board's purview. Another commenter suggested that the ability to add issues could be waived by agreement of both the provider and the intermediary.

Response: We disagree with the commenter that suggested that the time for which an issue may be added is (or should be) solely within the Board's purview. Section 1878(e) of the Act gives the Board full power and authority to prescribe rules, to the extent not inconsistent with the regulations of the Secretary. Here, we believe that it is appropriate to regulate the time period for adding issues, rather than allowing the Board to prescribe by rule or determine on a case-by-case basis the time in which to add an issue. The Secretary, not only the Board, has an

interest in ensuring that the appeals process is conducted in an efficient manner. The Secretary also has an interest in gauging at any particular time the Medicare program's potential liabilities due to administrative and judicial appeals, which is made much more difficult if issues may be added at any time, or at some point in time later than the period we proposed. We also believe that, if the Board had the authority to prescribe or to extend, on a case-by-case basis, the time for adding an issue, it could be besieged by requests and objections thereto by the parties. Because we disagree that the Board should have the discretion to prescribe or extend the time for adding an issue, it follows that we also disagree with the commenter that suggested that the timeframe for adding issues could be waived if both the provider and the intermediary agreed to do so. Any process in which the parties could waive the time period for adding issues, without the consent of the Board, is inherently undesirable, as it would have the potential to interfere with the Board's ability to effectively manage its caseload.

Comment: Two commenters suggested that CMS has not furnished any evidence of a cause and effect relationship between the large backlog of cases before the Board and the addition of issues to pending appeals. Another commenter suggested that a comprehensive analysis of the reasons for the large case backlog should be undertaken. Other commenters suggested that our proposal was unnecessary because steps already taken by CMS have significantly reduced the backlog at the Board.

Response: We do not believe that we are required to quantify a cause and effect relationship between the backlog of cases and the addition of issues to a pending appeal, nor is it incumbent upon us to undergo a comprehensive analysis of the reasons for the large backlog at the Board. We believe the Secretary, under sections 1102(a) and 1871(a) of the Act, has the statutory authority to issue regulations for the efficient administration of the Medicare program. The Board's experience with the adding of issues and the resulting increase in the complexity of cases and the delays in cases because of the need to reschedule hearings has convinced us that the proposal is necessary. We also disagree that the proposal is unnecessary because of other measures that have been taken. At the present time there are approximately 6,800 cases pending before the Board. Irrespective of other measures that may have reduced the backlog, the present

number of pending cases is still unacceptable, and can be reduced, or at least better controlled, with this deadline to add issues.

Comment: One commenter suggested that providers should have the right to add to pending appeals an issue arising from a change or clarification in the law. Because intermediaries are prohibited from conducting a reopening based on a change in the law, adding an issue to the appeal is the only available means by which a provider may vindicate its legal rights. Another commenter suggested that a provider should be given a full year after it receives the NPR to evaluate potential issues, and noted that a 1-year timeframe is considerably less than the 3-year timeframe in which an NPR can be reopened. Another commenter suggested that, just as CMS seeks to limit a provider from adding issues beyond 60 days from the expiration of the 180-day appeal period, CMS should also limit an intermediary's right to reopen and revise an NPR beyond 60 days from the issuance of the NPR.

Response: We disagree that because intermediaries are prohibited from conducting a reopening based on a change in law, adding an issue to the appeal is the only means by which a provider may vindicate its legal rights. A provider may vindicate its legal rights by bringing a timely appeal from an NPR and identifying in its request for hearing all issues it wishes to appeal, or by adding any issue within 60 days after the 180-day period for requesting a hearing. As noted above, a provider thus has approximately 2 years after filing its cost report to identify all issues it wishes to bring to the Board.

We disagree with the commenter that suggested that the timeframe for adding issues should be at least a year after it receives the NPR. We also disagree with the commenter that suggested that, if the time to add issues is limited, an intermediary's ability to reopen a previous determination should be similarly limited. As explained above, we believe 240 days after receipt of an NPR is a reasonable time to identify all issues the provider wants to appeal. We also note that the time period for requesting a reopening does not need to correlate to the time period for appealing an issue because the reopening and appeals procedures are separate and distinct. Unlike the effect of allowing an inordinate amount of time to add an issue, the time period for requesting a reopening does not directly impact upon the Board's ability to effectively manage its caseload. Also, the appeals process is mandated by statute, and is designed to give

providers the right to contest matters before the Board (assuming that the timely filing, amount in controversy and other requirements are satisfied). In contrast, the reopening process is a creature of the regulations, allowing an intermediary, through the exercise of its discretion (or upon direction from CMS), to reopen and potentially revise matters covered by a cost report for which, in most cases, the time for appealing the matters at issue has expired. Thus, although there is a lengthy period to request a reopening, there is no right to a reopening.

Comment: A few commenters also requested a technical clarification concerning the end of the proposed timeframe for adding issues; that is, whether the end of the period is 60 days from the date the provider files an appeal, or 60 days from the end of the 180-day period during which the provider may file an appeal.

Response: We proposed that providers could add issues to their hearing requests no later than 60 days beyond the expiration of the 180-day filing period for requesting a Board hearing (or intermediary hearing, as applicable). After careful consideration of all comments received, we continue to believe this policy is fair and strikes an equitable balance for the parties to the hearing and the Board.

Comment: Several commenters suggested that by limiting the timeframe for adding issues, providers would be forced to appeal everything and then weed out issues later, as appropriate, causing even further delays in settling hearings.

Response: We expect that providers will not file frivolous claims. Also, as we stated above, we believe that our proposal provides ample time for providers to identify all issues they wish to appeal. Moreover, the final rule also requires a provider to submit to the Board with its hearing request an explanation for each specific item at issue with the reasons that the provider believes Medicare payment is incorrect, and how and why Medicare payment must be determined differently. This latter requirement should effectively deter any provider from disputing every item on the cost report simply to protect itself on appeal.

Comment: One commenter noted that a provider might not have the necessary information from the intermediary to meet the proposed deadline for adding issues. For example, it can take several months for providers to obtain the intermediary's audit work papers needed to determine the merits of a new issue. Two commenters suggested that CMS could provide the Board with the

authority to extend the deadline for adding issues when it deems an extension to be appropriate.

Response: We would expect that an intermediary will promptly provide its work papers to a provider upon request. If, however, the intermediary has not timely provided documentation to support an adjustment, and the provider is dissatisfied with the determination, the provider must add the issue to its hearing request prior to the 60-day deadline in order to preserve its appeal rights. If, upon receipt of the work papers, the provider is satisfied that the adjustment is correct, the provider should withdraw that issue from the appeal. For the reasons stated above, we are not providing the Board with the authority to extend the deadline for adding issues.

Comment: One commenter suggested that the current policy of adding issues until the hearing is held should continue because providers would have no other reliable recourse to correct errors found in the cost report. This commenter stated that intermediaries were abusing their discretion by refusing to reopen and revise cost reports for clear and obvious errors within 3 years of the issuance of the NPR.

Response: We disagree with the suggestion that providers should be able to add issues until the commencement of the hearing because intermediaries have allegedly abused their discretion in refusing to reopen and revise cost reports. Providers are responsible for identifying all issues that they wish to appeal. Under our proposal, which we are finalizing, providers have ample time to identify all issues they wish to bring before the Board. As stated in an earlier response, the appeals process is different from the reopening process. If intermediaries are allegedly improperly refusing to reopen cost reports, the remedy does not lie with an adjustment to the appeals process. CMS would have to investigate the allegations, determine if the allegations are in fact supportable, and if so, take appropriate action against the intermediary.

E. Provider Requests for Good Cause Extension of Time Period for Requesting Hearing (§ 405.1813 and § 405.1836)

Under current rules, a provider may request an intermediary hearing officer or the Board to extend "for good cause shown" the 180-day period for requesting a hearing. The request must be filed within 3 years of the date of the original NPR. In the proposed rule, we cited a split among the Federal circuit courts of appeals on the basic authority of the Board to extend the 180-day

period. In response to the case law and the case backlog at the Board, we proposed retaining this policy, with certain modifications. We believed that, in many instances, the current 3-year period for requesting an extension was unreasonably lengthy and could result in an increase in the Board's backlog of cases. As a result, we proposed allowing providers a shorter period in which to file for a hearing beyond the normal 180 days, and only in limited specialized circumstances. Thus, the appeals period could be extended "for good cause" only in cases where a provider could establish that it could not reasonably have been expected to submit a hearing request within the 180-day period due to extraordinary circumstances beyond its control. Also, the request could be made only if it was submitted within a reasonable time after the expiration of the 180-day period, and in no event would a request be honored if it was made more than 3 years after the date of the NPR or other determination that the provider wished to appeal. This 3-year outside limit for requesting extension represents the same timeframe that existed in the previous regulations at § 405.1841(b).

We also proposed that the Board or other reviewing entity would be prohibited from granting a "good cause" extension request if the provider attempted to rely on a change in the law, regulations, CMS Rulings, CMS instructions, or other Federal legal provisions as the basis for the extension request. In addition, we proposed that a decision by the Board or other reviewing entity to grant or deny an extension would be reviewable by CMS but would not be subject to judicial review.

We are adopting our proposals. We have made a technical change to proposed § 405.1813(e)(1) concerning the component within CMS to which intermediary hearing officer decisions should be sent. As the CMS Office of Hearings neither currently receives nor reviews such decisions, we changed this provision to indicate only that an intermediary hearing officer decision should be sent to CMS (currently, the decisions are received by the Center for Medicare Management, a component within CMS).

As § 405.1813 and § 405.1836 are virtually identical in their treatment of good cause extension requests for intermediary and Board hearings respectively, we have made minor, non-substantive wording changes to make these sections consistent, wherever possible.

Comment: Several commenters were concerned about the proposed lack of

judicial review of a decision by the Board to grant or deny an extension request. One of these commenters asserted that, because the Board would be prohibited from granting an extension request due to a change in the law or regulations, our proposal constituted a “pre-emptive strike” at precluding judicial review of an issue that challenged a provision of the law or the regulations. Another commenter suggested that a decision by the Board denying a requested extension constituted a final determination and should therefore be subject to judicial review in the same manner that a Board’s decision finding that a provider lacked jurisdiction constituted an appealable final determination.

Response: After a careful review of all of the comments received regarding provider requests for extension, we have decided to finalize our policy as proposed. Our longstanding policy has permitted extensions of the timeframe for requesting hearings only in limited circumstances, and that concept has been carried forward in the final rule. Thus, we have retained a procedure whereby a provider will have the opportunity to request an extension for filing an appeal with the Board, even after the 180-day statutory period for requesting appeal has expired. Moreover, even though we will require that the extension request be made within a reasonable time in all cases, we are retaining the current outside limit of 3 years after the date of the intermediary determination or other determination that the provider wishes to appeal.

With regard to the lack of judicial review following a decision by the Board to grant or deny an extension request, we believe that the Supreme Court’s decision in *Your Home Visiting Nurse Services, Inc. v. Shalala*, 525 U.S. 449 (1999), is informative. In that decision, the Supreme Court ruled that an intermediary’s declination to reopen upon request a determination was not subject to further review, either administratively or by a court. It is important to note that Medicare rules also prohibit an intermediary from reopening a determination at a provider’s request when there is a change in the law or regulations. Just as the reopening of intermediary determinations are governed solely by regulations, so too are decisions made by the Board as to whether an extension request should be granted or denied. Therefore, under sections 1102(a) and 1871(a) of the Act, which give the Secretary authority to issue regulations for the efficient administration of the Medicare program, we believe we are authorized to provide for discretionary

grants and denials of requests to extend the time for requesting a hearing, and to further provide that these discretionary actions are not reviewable by the courts.

We disagree with the commenter that suggested that, because the Board would not be permitted to grant an extension request on the basis that a change in the law or regulations occurred, judicial review of a challenge to a law or regulation would be precluded. Providers are responsible for identifying, at the time of their hearing request or within 60 days following the expiration of the 180-day appeal period, all issues they want to appeal. We also disagree with the commenter that suggested that a decision by the Board denying an extension request should be treated as a final determination, similar to a final appealable determination by the Board finding that the Board lacked jurisdiction. There is an important distinction between these two types of Board decisions. In the first instance, when the Board denies an extension request that alleged good cause, the provider has acknowledged that it failed to meet the statutory 180-day timeframe for requesting an appeal. Therefore, the provider has lost any statutory right to appeal in this situation. In contrast, in a case where the Board issues a decision that it lacks jurisdiction, and dismisses the appeal, the provider does not necessarily concede that it has failed to file a timely appeal or that the Board lacks jurisdiction for some other reason. Therefore, where a provider does not agree that the Board lacked jurisdiction pursuant to the statute, it is entitled to bring an appeal to the Administrator and, if applicable, to Federal district court in order to resolve the issue.

Comment: One commenter suggested that CMS failed to provide sufficient reasons for the removal of the 3-year timeframe, replacing it with an ambiguous “reasonable time” standard. The commenter believed the 3-year period should be retained and, in the event that it is not retained, suggested that the Board be given discretion to determine whether an extension request was made within a reasonable timeframe. The commenter also suggested that there is nothing in the proposed rule that supports prohibiting the reliance on a change in the law or regulations as a reason for finding that “good cause” exists. Another commenter questioned the phrase “reasonable time” and wanted to know how “reasonable time” could be viewed as equaling “no more than three years after the date of the intermediary determination.”

Response: As noted in the proposed rule, we considered eliminating

altogether good cause extensions of the 180-day period for requesting a hearing. We proposed retaining good cause extensions to allow providers to submit hearing requests beyond the 180-day limit only in extraordinary circumstances beyond their control (for example, fire, catastrophe or strike) that existed prior to the expiration of the 180-day appeal period. We believe it is fair and appropriate that, absent extraordinary circumstances, providers should be expected to file their appeals within the 180-day period. Specifically, providers that are dissatisfied with a final determination should file a timely appeal, rather than depend on a right to file late if there is a favorable change in the law at some point after the 180-day appeal period.

We also believe that setting a reasonable time, not to exceed 3 years, for filing a late appeal is appropriate. Again, given that the circumstances giving rise to the claim of good cause for a late filing must exist prior to the expiration of the 180-day appeal period, the purpose of the reasonable time requirement is to allow the provider a sufficient time to recover from the unseen event and gather the necessary records, and make the necessary preparations for filing an appeal. The purpose is not to allow the provider to file a late appeal based on a favorable change in law or other circumstances that could arise after the expiration of the 180-day period. We decline to set a definite period, and instead believe that what constitutes a reasonable time for filing an appeal beyond the timely filing limit should be left to the Board’s discretion (subject to the outside limit of 3 years) based on the particular facts before it. Moreover, because a provider must file a claim under protest to preserve its right to appeal a claim when the provider seeks reimbursement for an amount that may not be allowable under the controlling law, regulations, or policy, we do not consider a subsequent change in the law, regulations, or policy as falling within the “good cause” exception.

Comment: Three commenters suggested that CMS has too much involvement in the Board’s decision-making process. One of the commenters suggested that the Administrator’s ability to review the Board’s decision to grant or deny a good cause extension request was an example of CMS’s intention to gain total oversight over the Board. Another commenter believed that CMS was attempting to usurp the Board’s discretion in determining whether there was good cause to grant an extension. The commenter suggested that only the Board is authorized to

establish the procedures and limitations governing its own independent review of provider appeals. The other commenter suggested that CMS should provide for extensions in circumstances where either CMS employees or appeals personnel contributed to the delays in filing a timely appeal (for example, unreasonable delays in responding to written inquiries).

Response: We disagree with the suggestion that we are overly involved in the Board's decision-making process. Again, we rely upon sections 1102(a) and 1871(a) of the Act, which grant the Secretary the necessary authority to issue regulations for the efficient administration of the Medicare program. It is our view that the parties to a Board hearing may avail themselves of Administrator review following a decision rendered by the Board. That particular policy has never varied throughout the existence of the Board. The Board is independent of CMS and, as an independent body, issues decisions outside of the realm of CMS influence. Section 1878(f)(1) of the Act authorizes the Secretary (delegated to the Administrator of CMS) to reverse, affirm, or modify a decision made by the Board. A decision rendered by the Board to grant or deny a provider a good cause extension request is merely another example of the myriad decisions handed down by the Board that are subject to review by the Administrator.

A provider is required to establish "good cause" before the Board can allow an extension of the 180-day time limit for filing a hearing request. We have not defined all the "extraordinary circumstances" that the provider can rely upon to satisfy a "good cause" extension. Therefore, the Board has the discretion to weigh the factual scenarios presented by a provider and make its decision accordingly.

Finally, in the scenario where a provider believes that CMS or Board personnel are not responding in a timely fashion to written inquiries, in our view, the Board should not grant an extension request for "good cause." Instead, the provider would be expected to protect its rights by filing a timely appeal within the 180-day period prescribed by the Act.

F. Intermediary Hearing Officer Jurisdiction (§ 405.1814)

In the proposed rule, we sought to clarify the scope of an intermediary hearing officer's jurisdiction; that is, appeals that have amounts in controversy of between \$1,000 and \$9,999.

In proposed § 405.1814(a)(1)(ii) (and § 405.1840(a)(2), for Board cases), we required the intermediary hearing officer (and the Board) to make a preliminary determination of the scope of its jurisdiction and notify the parties of its jurisdictional findings, before conducting certain proceedings. For clarity, we have amended these sections by way of a parenthetical to explain that the intermediary hearing officer's (or Board's) preliminary determination of the scope of its jurisdiction consists of a review as to whether the request for hearing was timely and whether the amount in controversy has been met. Also, we removed language from these sections that required the intermediary hearing officer (or Board) to "notify" the parties of such preliminary determination. The latter revision was made primarily because, as most Board cases are settled prior to hearing, it would be costly and inefficient for the Board to notify the parties of preliminary jurisdictional findings. Requiring such notification would unnecessarily slow the ultimate resolution of cases.

For clarity, we also made minor technical changes to other portions of § 405.1814, and conformed language in § 405.1814 to that in § 405.1840 (concerning the Board's jurisdiction), wherever possible.

Comment: One commenter suggested that if an appeal were initially filed as a request for an intermediary hearing, but it was subsequently determined that the amount at issue in the appeal had exceeded \$10,000, the regulations should provide that the appeal must be transferred to the Board.

Response: We agree with the commenter. Our policy is that, when an intermediary hearing officer has initially accepted jurisdiction because the amount in controversy is between \$1,000 and \$9,999, any change increasing the amount in controversy to at least \$10,000 (for example, a more accurate estimate of the amount in controversy or the adding of an issue) will produce a change in forum; that is, the Board will accept jurisdiction. However, where the Board initially accepts jurisdiction after determining that a case has at least \$10,000 in controversy, and that amount is subsequently reduced to a figure below \$10,000 because one or more of the issues has been settled or withdrawn, it is our policy that, notwithstanding the amount in controversy falling to a level below \$10,000, the Board will continue to have jurisdiction and, as a result, may hold a hearing and issue a decision. (We have a similar policy regarding the situation in which a group appeal

initially satisfies the \$50,000 jurisdictional threshold and subsequently falls below that threshold.) We have added paragraph (c)(4) to § 405.1839 to clarify the effect of a change in the amount in controversy.

G. CMS Reviewing Official Procedure (§ 405.1834)

In the proposed rule, we sought to codify the procedures currently located in section 2917 of the PRM for the CMS review of intermediary hearings. The proposed rule stated that the provider, by submitting a proper request, would be entitled to review of the intermediary hearing officer(s) decision, and also proposed that the Administrator would have discretionary, "own motion" review authority. In proposed § 405.1834(d)(2), we stated that the Administrator, through the CMS reviewing official, may exercise his or her discretionary authority to review an intermediary hearing officer decision by accepting review within 60 days after receipt of the decision by CMS's Office of Hearings. We received one comment on this proposal, which is discussed below.

We are making the following changes. First, we have revised the regulation text at § 405.1834(d)(2) to provide that the 60-day period for noticing own motion review begins from the date of the intermediary hearing officer decision. In § 405.1834(e)(2), we are clarifying the proposal that the CMS reviewing official's review of an intermediary hearing officer decision would not be limited to a hearing on the written record if certain criteria are met, including that the CMS reviewing official determines that holding the hearing is preferable, in the interest of administrative efficiency, to remanding the matter to the intermediary. For clarity, in § 405.1834(e)(2)(iii), we are replacing the language "the matter must not be remanded" with "[i]t is not necessary or appropriate to remand the matter to the intermediary hearing officer(s)."

We have made technical changes to proposed § 405.1834(b) and § 405.1834(c), and § 405.1834(e)(3) concerning the component within CMS to which intermediary hearing officer/CMS reviewing official decisions should be sent. As the CMS Office of Hearings neither currently receives nor reviews either of these decisions, we changed these provisions to indicate that intermediary hearing decisions should be sent to the appropriate CMS component for review by a CMS reviewing official. Following the review and issuance of a written decision by a CMS reviewing official, the decision is

then sent to CMS (currently, both intermediary hearing officer decisions and CMS reviewing official decisions are received by the Center for Medicare Management, a component within CMS).

We clarified language in § 405.1834(d)(1), pertaining to own motion review by the Administrator.

In § 405.1834(e)(1) we proposed that the CMS reviewing official must give great weight to “other interpretive and procedural rules and general statements of policy.” We revised the quoted language to read “other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS” in order to be consistent with the language in § 405.1867 regarding the authorities to which the Board is not bound but must give great weight.

Comment: One commenter suggested that the proposed provision at § 405.1834(d)(2) is inconsistent with other provisions that give CMS the right to conduct and complete review within 60 days of the date the provider receives the decision. The commenter was also concerned that there may be a problem with intermediaries sending decisions to the appropriate CMS component at the same time they send them to providers.

Response: We believe that the statutory provision that mandates the Administrator both accept review and render a decision within 60 days of the provider’s receipt of the Board’s decision is unusual and not the optimal procedure for taking review. We continue to believe it would not be appropriate to constrain the CMS reviewing official in this manner when taking review of an intermediary hearing officer decision. We do not share the commenter’s concern that the intermediary hearing officers will unduly delay forwarding their decisions to the appropriate CMS component. Rather, we believe that intermediary officers will promptly forward their decisions to CMS. Moreover, to the extent that a provider is concerned that CMS has not promptly received an intermediary hearing officer decision, the provider may contact CMS to verify its receipt of the decision. Nevertheless, in response to the commenter, we are providing a date certain for the onset of the 60-day period for the CMS reviewing official to notify the provider and the intermediary that he or she is taking own motion review. Therefore, we have revised proposed § 405.1834(d)(2) to provide that the 60-day period for noticing review begins from the date of the intermediary hearing officer decision.

H. Group Appeals (§ 405.1837)

In the proposed rule, we introduced various revisions to clarify and update the regulation to reflect longstanding group appeal procedures. For example, we provided that each provider in a group appeal must satisfy individually the requirements for a single provider appeal (except for the \$10,000 amount in controversy requirement). We also provided that a group appeal must be limited to one legal or factual issue that is common to each provider in the group. Additionally, we clarified the distinction between mandatory and optional uses of group appeal procedures. We also added a new provision that specified the requirements for the contents of a request for a group appeal. We also clarified existing regulations regarding the processing of group appeals pending full formation of the group and issuance of a Board decision.

We are making several changes to the proposed rule, including technical and editorial changes.

We have revised § 405.1837(b)(1) (with respect to mandatory group appeals) and § 405.1837(b)(2) (with respect to optional group appeals) to provide that one or more of the providers in the group may, as a matter of right, appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for purposes of meeting the \$50,000 amount in controversy requirement, and, subject to the Board’s discretion, may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for other purposes, such as convenience. We have added some examples in the text following § 405.1837(b)(1) in order to illustrate the application of—(1) The amount in controversy requirement; and (2) the rules on when a provider under common ownership may (either as a matter of right or as a matter of Board discretion) join a group appeal involving a different cost reporting period than that pertaining to the provider, to specific situations. We have revised the language in § 405.1837(b)(3) to clarify that whereas one or more commonly owned or operated providers may initiate a mandatory group appeal (group appeals brought under § 405.1837(b)(1)), at least two providers are required to initiate an optional group appeal (group appeals brought under § 405.1837(b)(2)).

In proposed § 405.1837(c)(4), we would have required the providers in a group appeal to submit a statement that either—(1) The providers believe that

they meet all the requirements for a group appeal and that the Board can proceed to make jurisdictional findings; or (2) the Board “must defer” making jurisdictional findings until the providers request the Board to do so. Consistent with proposed § 405.1837(c)(4)(ii), proposed § 405.1837(d)(4) and § 405.1837(e)(2) stated that the Board may not make jurisdictional findings until the providers request them. After further consideration, however, it is our position that, if the Board believes at any point in the group appeals process that, for purposes of administrative efficiency, it should make jurisdictional findings, it should be allowed to do so. Accordingly, we have revised § 405.1837(c)(4)(ii) and § 405.1837(e)(2), and have deleted § 405.1837(d)(4).

Likewise, we believe the Board should not be required to make jurisdictional findings before conducting further proceedings in the appeal. The Board is in the best position to know whether, in any given case, it is administratively efficient and proper to conduct proceedings in advance of making jurisdictional findings. Accordingly, we have deleted proposed § 405.1837(d)(3).

We have revised proposed § 405.1837(e) with respect to the procedures for determining that a group is fully formed, to be consistent with the current regulations and the Board’s practice. Proposed § 405.1837(e)(2) would have provided that a group would be fully formed upon notice from the providers to the Board, but did not include a mechanism for determining that the group would be considered fully formed absent such a notice. We believe that it is appropriate for the Board to retain the abilities both to determine that a group is fully formed and that the group appeal should proceed, and to set schedules for the closures of groups, rather than being required to hold open indefinitely the group formation. Accordingly, we have deleted certain language in proposed § 405.1837(e)(2) and have revised § 405.1837(e)(1) to provide that with respect to mandatory group appeals, absent a notice from the providers that the group is fully formed, the Board may issue an order requiring the providers to demonstrate that there is at least one commonly-owned or controlled provider that is a potential addition to the group. With respect to optional group appeals, we have revised § 405.1837(e)(1) to provide that, absent a notice from the providers that the group is fully formed, the Board will issue an order that the group is fully formed or will issue general instructions

that set forth a schedule for the closing of optional group appeals.

We have revised § 405.1837(e)(2) to state that the Board will not dismiss any group appeal hearing request for failure to meet the amount in controversy requirement until the Board has determined that the group is fully formed.

We have deleted language from proposed § 405.1837(e)(5) that stated that the Board must grant a request to join a group appeal if the request is unopposed by the group members and is received by the Board prior to a final decision by the Board on the appeal. Our rationale for this revision is that the Board generally should have the discretion, for purposes of administrative efficiency, to grant or deny a request for joining a group appeal. We note that the Board may modify an order that a group has been fully formed, and thus could allow a provider to join a group appeal that was originally declared fully formed. Note that we have moved the language in proposed § 405.1837(e)(6), which stated that a denial by the Board of a request to join a group is without prejudice to the provider bringing a separate appeal, to § 405.1837(e)(4). We have substantially revised the language of proposed § 405.1837(e)(7) and also incorporated proposed § 405.1837(e)(7) into § 405.1837(e)(4). We proposed that, for purposes of determining the timeliness of any separate appeal, the period from the date of receipt of the provider's original hearing request through the date of receipt by the provider of the Board's denial of the provider's request to join the group appeal, must be excluded from the applicable 180-day period for filing a separate appeal (see § 405.1835(a)(3)) and from the 60-day period for adding issues to any single provider appeal (see § 405.1835(c)(3)). We have revised this language to state that, for purposes of determining timeliness for the filing of any separate appeal and for the adding of issues to that appeal, the date of receipt of the provider's request to form or join the group appeal is considered the date of receipt for purposes of meeting the applicable 180-day period prescribed in § 405.1835(a)(3). We were concerned that our proposal was potentially confusing and could have been disadvantageous for providers that filed the request for a group appeal hearing on or near the end of the deadline for doing so. For example, under our proposal, a provider that filed a request for a Board hearing on a group appeal on the 177th day after receiving its intermediary determination, would have only three days after the Board

denied its request to join the group to file a separate appeal. Under our revision, because the provider's request for a hearing on the group appeal was timely, its subsequent request for a separate hearing also would be timely.

In response to a comment, in revised § 405.1837(e)(5), we provide that, as a general rule, where a provider has appealed an issue through electing to form, or join, a group appeal, it may not subsequently request the Board to transfer that issue to a single provider appeal brought in accordance with § 405.1811 or § 405.1835. We provide an exception to the general rule in the case of a group appeal that does not meet the jurisdictional requirements. Where the Board determines that the requirements for a group appeal are not met (that is, where there has been a failure to meet the amount in controversy or the common issue requirement), it will transfer the issue that was the subject of the group appeal to a single provider appeal (or appeals) for the provider (or providers) that meets (or meet) the requirements for a single provider appeal.

Comment: A commenter objected to our proposal to clarify that each provider in a group appeal must satisfy the requirements for a single provider appeal (except for the amount in controversy requirement) as interfering with the Board's statutory authority to establish the procedural requirements governing provider appeals.

Response: We believe our proposal is consistent with what is required by statute. The statute provides for a different amount in controversy requirement for group appeals, but still requires that providers appeal from a final determination of an intermediary or the Secretary and that the appeal be timely.

Comment: One commenter stated that it was generally supportive of the proposals on group appeals, but sought clarification on a few points. This commenter stated that some of the proposals, if adopted, would conflict with the Board's current instructions on group appeals. Therefore, we should be prepared to immediately revise the Board's instructions to avoid confusion.

Response: To the extent that there is any conflict between the provisions of this final rule and the Board's current instructions, the former will control. We anticipate that the Board will make revisions to its current instructions as a result of the publication of this rule.

Comment: Two commenters stated that they supported the proposal to allow groups to aggregate claims across multiple cost reporting periods in order to satisfy the \$50,000 amount in

controversy requirement. One of these commenters believed that the proposal is ambiguous as to whether items may be combined across cost years only for the purpose of meeting the \$50,000 amount in controversy requirement. According to the commenter, providers should be allowed to combine common issues from multiple cost reporting periods, regardless of cost report year end, into one group appeal. Because providers have a variety of cost reporting periods, and some may even have multiple cost reporting periods within one calendar year, there is no reason to require a commonality of cost reporting periods as a requirement for a group appeal.

Response: Our proposals for group appeals were made with the view that, to the extent we have discretion under the statute, we should allow appeals to be brought as group appeals so as to reduce the workload on the Board, as well as the burden on providers and intermediaries. Our specific proposal to allow providers to combine the same item for multiple cost reporting periods into one group appeal was made under the section of the proposed rule pertaining to the amount in controversy requirements. However, we have further examined the issue and believe that providers with different cost reporting periods may, subject to the Board's discretion, raise the same issue in a group appeal, even when the amount in controversy requirement can be satisfied without including all of the multiple cost reporting periods. We have amended § 405.1837(b)(1) and § 405.1837(b)(2) accordingly.

Comment: One commenter stated that, whereas it agrees that it is proper to transfer an issue from an individual appeal to a group appeal, the regulations should specifically state that the amount in dispute for a transferred issue is applied, for purposes of the amount in controversy requirement, only to the group appeal. For example, the commenter stated, if an individual Board appeal had two issues with \$9,000 in dispute for each issue, and one of the issues was transferred to a group appeal, the \$9,000 amount in dispute would be applied to the group appeal for purposes of meeting (or exceeding) the \$50,000 amount in controversy requirement, and the single appeal would be left with one issue with \$9,000 in controversy (in which case the appeal would have to be dismissed for not meeting the \$10,000 minimum).

Response: Our longstanding approach regarding meeting the amount in controversy requirement for single provider appeals is that, as long as the

provider has met the \$10,000 requirement initially, subsequent events (including, but not limited to, withdrawal, transfer or settlement of an issue) that takes the amount below \$10,000 will not deprive the Board of jurisdiction. As noted in section II.I. of this final rule, we are amending § 405.1839(c)(4) to provide specifically that, where a provider or group of providers has requested a hearing before the Board pursuant to § 405.1835 or § 405.1837, and the amount in controversy changes to an amount less than the minimum for a Board appeal due to the settlement or partial settlement of an issue, transfer of an issue to a group appeal, or the abandonment of an issue in an individual appeal, the change in the amount in controversy does not deprive the Board of jurisdiction.

Comment: One commenter noted that proposed § 405.1837(b)(1) states that any commonly owned or controlled provider may not appeal to the Board any common issue in a single provider appeal brought under § 405.1835. The commenter asked whether this meant that providers under common ownership or control cannot appeal an issue at all if the combined amount in controversy does not meet the \$50,000 threshold for a group appeal.

Response: We believe that the language of section 1878(f)(1) of the Act, which requires that any appeal to the Board by providers that are under common ownership or control be brought as a group appeal, can reasonably be read to mean that any appeal by commonly owned or controlled providers that could be brought as a group appeal must be brought as a group appeal. Therefore, if there are, for example, three commonly owned providers that wish to appeal the same issue, but the amount in controversy is \$10,000 for each (so that the \$50,000 amount in controversy requirement for group appeals would not be met), each of the three providers could bring an individual appeal. We have clarified the language in § 405.1837(b)(1) for this purpose.

Comment: One commenter asked whether a provider may add an issue to a group appeal when the provider has appealed one issue of an original NPR, joined a group appeal, and is within the 60-day proposed time limit to add an issue, but is beyond 180-days from the original NPR.

Response: We understand the commenter to be asking whether a provider, having appealed only issue A in an individual appeal, can join a group appeal that involves issue B. The answer depends on whether the

provider first (or concurrently) requests the Board to add issue B to its individual appeal and meets the requirements for adding the issue to its individual appeal. Under § 405.1835(c) of this final rule, a provider may add an issue to its individual appeal if its request to do so meets certain requirements, including the requirement that the Board receive the request no later than 60 days after the expiration of the applicable 180-day appeal period prescribed in § 405.1835(a)(3). If the provider requests and meets the requirements for adding an issue to its individual appeal, it may also request, under § 405.1837(b)(3)(ii), that, upon addition of the issue to the individual appeal, the issue be transferred from the individual appeal to the group appeal. If the provider is beyond the time for adding an issue to its individual appeal, it may not circumvent the time limit for doing so by seeking to appeal that issue through joining a group appeal.

Comment: One commenter noted that, under current Board instructions, a group appeal may be initiated only by two or more providers, but because of varying fiscal year ends and varying dates of NPRs, an appeal on a common issue for one provider may be due to be filed before the time is ripe for other providers to join in the group. Therefore, this commenter supports the proposal to allow a group appeal to be initiated by a single provider, with other providers joining later.

Response: We are clarifying that, although a single provider may initiate a mandatory group appeal, two or more providers are required to initially file an appeal for optional groups pursuant to § 405.1837(b)(3). Our policy for optional group appeals is based upon administrative efficiency concerns. Fundamentally, by definition, a group appeal must ultimately contain two or more providers. Accordingly, without the requirement to meet this definition from the onset of filing an appeal, the Board would be forced to entertain an abundance of requests to transfer to (or create) an individual appeal from single providers who filed a group appeal, but failed to join with another provider before the group closing deadline. We recognize, however, that due to the statutory requirement that providers under common ownership or control must appeal common issues as a group, combined with the fact that these providers may receive their final determinations on a staggered basis, we will allow, pursuant to § 405.1837(b)(3), a single provider that anticipates that a commonly owned or controlled provider will have an identical issue under appeal, to initiate a mandatory

group appeal, despite the administrative efficiency concern above. In the unlikely event that no other providers ultimately appeal the issue, the Board will either transfer the group appeal issue to an existing individual appeal, administratively convert the group case number to an individual case number, or administratively create a new individual case number for the issue if the jurisdictional requirements of § 405.1811 or § 405.1835 are met.

Comment: One commenter believed that the current policy permitting hospitals to file individual appeals and to subsequently transfer common issues to group appeals should be retained. Providers under common ownership should not be precluded from pursuing a common issue in a group appeal if they initially appealed it in an individual appeal. This would allow hospitals time to determine whether an issue is common to other hospitals under common ownership, which is not always evident when one hospital receives a particular adjustment. Similarly, another commenter stated that it is not practical for a commonly owned provider to be required to file the initial appeal request as a group appeal. Not all commonly owned hospitals are centralized or situated in a way that enables them to coordinate initial appeals as a group appeal within the 180-day deadline for seeking a hearing. This commenter suggested that, instead, we could require consolidation of single appeals into a group appeal within a certain time after the single appeals have been filed. The commenter also suggested that providers could be required to list their parent corporation at the time of filing a single appeal to assist the Board in identifying providers under common ownership.

Response: We believe it is reasonable to expect that the parent corporation of commonly owned or controlled providers has a mechanism in place to identify issues that are common to more than one provider and to coordinate any appeals of these issues. Further, we believe that the parent corporation is in a better position than the Board to identify commonly-owned providers. Therefore, we are requiring a commonly owned provider to bring a timely appeal, as—(1) A group appeal (either initiating it or joining it) for an issue that is shared by other provider(s) to which it is related by common ownership; or (2) a single provider appeal for an issue that is peculiar to itself. (By “timely” we mean an appeal that satisfies the time limits stated in § 405.1835(a)(3) and § 405.1835(c).) Where a commonly owned or controlled provider mistakenly files an issue

within a single provider appeal that should have been brought as a group appeal, the Board will transfer the issue to an existing group appeal (or, where applicable, the Board will form a group appeal by transferring the same issue that was filed by two or more commonly owned or controlled providers within single provider appeals). We believe, however, that where a provider has brought a single provider appeal and then wishes to join (or form) a group appeal involving providers to which it is not related, the Board should retain discretion as to whether to deny the provider's request. In order to assist the Board in identifying individual appeals that should have been brought as group appeals (or should have been joined to an existing group appeal), we are amending § 405.1835 to add a new paragraph (b)(4) to require a commonly owned provider to provide the Board with certain information. Specifically, a commonly owned provider must list the name of its parent corporation, and either state that, to the best of its knowledge, no other provider related to it by common ownership or control has an individual or group appeal pending before the Board on the same issue for a cost reporting period that falls within the same calendar year. Alternatively, when an appeal already exists, the provider must give information (for example, the provider name and number) concerning that appeal.

Comment: One commenter stated that, when a group appeal is instituted by one of a small number of hospitals, there may be uncertainty as to whether similar adjustments will be received by one or more of the remaining hospitals. Thus, the final rule should specify that the issue appealed in a group appeal may be redesignated into an individual appeal (or appeals) where an insufficient number of hospitals receives common audit adjustments to meet the \$50,000 amount in controversy requirement. Similarly, another commenter recommended that we allow providers under common ownership or control to change an appeal that was originally brought as a group appeal to an individual appeal under certain circumstances. The commenter gave the following example: Providers A and B are the two members of a chain organization and have a common legal or factual issue. Provider A receives an adjustment from its intermediary on the legal or factual issue and, consistent with existing policy, files a group appeal before all other commonly owned providers (here, Provider B) have received their NPRs. Provider B then receives its NPR from its intermediary,

but the intermediary does not make an adjustment on the same legal or factual issue. In this case, the case cannot proceed as a group appeal. The commenter gave as other examples the situations in which two providers have the same issue, but do not meet the amount in controversy requirement, or when one of the providers has failed to timely appeal.

Response: In regard to the situation in which only one provider, in an organization of commonly owned or controlled providers, has received an adjustment on a particular item, we do not believe that there is "an issue common to such providers." Therefore, the case can proceed as a single provider appeal (provided that the jurisdictional requirements for a single appeal are met). Similarly, where providers timely bring a group appeal, but fail to meet the \$50,000 amount in controversy requirement, the Board will restructure the group appeal as separate single provider appeals for those providers that meet the \$10,000 amount in controversy requirement for single provider appeals. We emphasize, however, that, where a group appeal is redesignated as one or more single provider appeals, the time in which to add issues is unaffected. That is, under § 405.1835(c)(3) as finalized, the Board must receive a request to add an issue no later than 60 days after the expiration of the 180-day period specified in § 405.1835(a)(3) for bringing the appeal. Thus, if a provider brings an appeal involving issue A as a group appeal, on the last day of the 180-day period, and more than 60 days later the group appeal is redesignated as one or more single provider appeals, the provider would not be able to add issue B to its single provider appeal. If, on the other hand, the provider brings a group appeal as to issue A on the 150th day of the 180-day period, and the group appeal is redesignated as a single provider appeal 60 days later, the provider would have an additional 30 days to add issue B to its single provider appeal, as it would have until 60 days after the expiration of the 180-day period to add the issue. We note that, as revised, § 405.1837(e)(4) states that, for purposes of determining timeliness for the filing of any separate appeal and for the adding of issues to that appeal, the date of receipt of the provider's request to form or join the group appeal is considered the date of receipt for purposes of meeting the applicable 180-day period prescribed in § 405.1835(a)(3). We were concerned that our proposal could have been disadvantageous for providers that filed

the request for a group appeal hearing on or near the end of the deadline for doing so. For example, under our proposal, a provider that filed a request for a Board hearing on a group appeal on the 177th day after receiving its intermediary determination, would have only three days after the Board denied its request to join the group to file a separate appeal. Under our revision, because the provider's request for a hearing on the group appeal was timely, its subsequent request for a separate hearing also would be timely. Accordingly, the provider's request to add issues to a subsequent individual appeal is 60 days beyond the applicable 180-day period prescribed in § 405.1835(a)(3) (regardless of when the subsequent separate appeal was created).

Comment: One commenter stated that if an issue is transferred to a group appeal, it should not be transferred back to a single appeal. According to the commenter, when providers transfer an issue to a group appeal and then back to a single appeal, it creates an unnecessary administrative burden for the intermediary and the Board. Also, many providers transfer issues back and forth as a way to hold the issue open until they have accumulated the necessary data.

Response: We agree with the commenter's concern. Accordingly, § 405.1837(e)(5) provides that, apart from the situation where the requirements for a group appeal are not met (that is, where there has been a failure to meet the amount in controversy requirement or the common issue requirement), a provider may not transfer an issue from a group appeal to a single provider appeal. In the situation where a provider has elected to form or join a group appeal, and the requirements for a group appeal ultimately are not met, the Board will transfer the provider's appeal to an individual appeal.

Comment: One commenter noted that proposed § 405.1837(b)(1) requires commonly owned or operated providers to bring as a group appeal "a specific matter at issue that involves a question of fact or interpretation of law, regulations, or CMS rulings that is common to providers * * *". The commenter believes that the proposed regulations should be clarified, because they do not impose a timeframe for common issues among commonly-owned providers that must be brought in group appeals. As drafted, all provider appeals of common issues that were repeated year after year would have to be combined in one group. This would make the groups unworkable in

terms of size and organization, and they would not be able to close their groups when the same issue repeated itself in new fiscal years. Therefore, the final rule should specify that all common issue appeals for fiscal years ending in the same calendar year be included in one group.

Response: We are amending § 405.1837(b)(1) to clarify that commonly owned or operated providers must bring as a group appeal a specific matter at issue that involves a question of fact or interpretation of law, regulations, or CMS rulings that is common to providers and that pertains to cost reporting periods ending in the same calendar year.

Comment: One commenter noted that proposed § 405.1837(c)(3) would require providers to submit “a copy of each intermediary or Secretary determination under appeal, and any other documentary evidence the providers consider necessary to satisfy the hearing request requirements of paragraphs (c)(1) and (c)(2) of this section * * *”. The commenter sought clarification as to exactly what documents would need to be submitted with the group appeal request. Also, it is not clear what the proposed regulation means by “any other documentary evidence the providers consider necessary to satisfy the hearing request requirements.” It is unclear what other documentation is needed.

Response: We are clarifying that, when referring to “intermediary determination,” we do not intend to require that the entire NPR be submitted with the group appeal. It is only necessary to submit the first page of the NPR, showing the date of issuance, along with the page containing the adjusted amount or protested item in dispute. At a minimum, to satisfy the documentation requirements of § 405.1837(c)(3), it is necessary to submit the first page of the final determination (for example, the NPR), showing the date of issuance, together with the pages containing the adjusted amounts or protested items in dispute. Providers should also submit any additional documentation that they consider necessary to satisfy the requirements for obtaining a group appeal.

Comment: One commenter stated that filing a Schedule of Providers with supporting documentation can be a costly endeavor. This commenter recommended that any rule change that affects group appeals be prospective, that is, any pending group appeals should be excepted to avoid unnecessary administrative filings and

potential jurisdictional challenges for otherwise properly pending cases.

Response: We believe that the filing of a consolidated Schedule of Providers with supporting documentation (which is already required by the Board in its current instructions) is necessary; otherwise, the intermediary, the Board, the Administrator, and the courts could be required to review piecemeal jurisdictional documentation. We note further that the current process, which requires providers to submit the Schedule to the intermediary, which, in turn forwards the Schedule to the Board (with comments either challenging or agreeing to the existence of jurisdiction), appears to be working efficiently. Accordingly, we are adopting the proposal without change.

Comment: A commenter stated that sometimes there is more than one disputed fact or question of law pertaining to a single item on the cost report. A common example of this is the disproportionate share hospital (DSH) adjustment, which is determined by a combination of calculations, each of which may have more than one element in dispute. According to the commenter, the Board should have the authority to handle more than one question of fact or law in a group appeal if that would lead to a more efficient resolution. Further, even if the Board wished to split sub issues into separate groups pursuant to proposed § 405.1837(f)(2)(ii), we should clarify that a provider may initiate a single group appeal for a single line item in dispute.

Response: The statute requires that a group appeal involve only a common question (singular) of fact or interpretation of law or regulations. The regulations at § 405.1837(a)(2) further specify that a group appeal involve a single question of fact or interpretation of law, regulations, or CMS Rulings that is common to each provider in the group. What constitutes an appropriate group appeal issue in a given case will be determined by the Board.

Comment: One commenter stated that the present requirement that a group appeal be closed within 12 months is unworkable. For groups involving commonly owned providers, the issuance of NPRs for some would-be members of the group can lag behind substantially the NPRs of those already in the group. Therefore, the commenter was supportive of the proposed change that would allow a group to remain open until the provider notifies the Board that the group is complete. The commenter requested, however, that, if the proposal is finalized, we should make clear that the Board’s current

instructions, that is, those that mandate the closure of all groups by certain deadlines and the creation of a “schedule B” for any would-be members of a group of commonly owned providers that do not have their NPRs, are superseded.

Response: Under new § 405.1837(e)(1), the Board will make a determination that a group formed under § 405.1837(b)(1) (for mandatory group appeals) is fully formed. That determination will be made upon the group notifying the Board that the group is fully formed, or upon an order by the Board, following an opportunity for the group to show why the group should not be considered fully formed. Similarly, under § 405.1837(e)(1), the Board will make a determination that a group formed under § 405.1837(b)(2) (for optional group appeals) is fully formed based upon its judgment in a particular appeal, under the facts and circumstances, that the group is fully formed, or through instructions setting a time limit for keeping non-mandatory group appeals open, after which the group will be considered fully formed. There is no need to specifically state in the regulation text that any contrary instructions of the Board are superseded. Under section 1878(e) of the Act, the provisions of this rule supersede any contrary instructions promulgated by the Board.

Comment: One commenter stated that, although it supported the proposed change to allow groups to remain open past 12 months, commonly owned providers should have the ability to close groups so that they do not remain open indefinitely. It would be in the interest of both the Board and commonly owned providers to close a group so that the appeal may be moved forward, without prejudicing the rights of the remaining providers under common ownership or control. According to the commenter, chain organizations should be able to close a group appeal when a substantial number of providers have been added to the group. Remaining providers could be put into a subsequent group, which would be bound by the decision of the Board in the subsequent group. The commenter believes that this arrangement would be consistent with the language in section 1878(f)(1) of the Act that an appeal by providers under common ownership or control “must be brought by such providers as a group with respect to any matter involving an issue common to such providers.”

Response: We believe that we lack the authority to allow, for the same period, more than one group appeal per issue by commonly owned or controlled

providers. We believe that our proposal that a group appeal involving commonly owned or controlled providers not close until the group notifies the Board that the group is complete would have adequately protected other such providers that would like to join the group appeal.

However, we are adopting our proposal with a modification. We are providing in § 405.1837(e)(1) that the Board may issue an order requiring the group to demonstrate that at least one commonly owned or controlled provider has preserved the issue for appeal, in accordance with § 405.1835, by claiming the relevant item on its cost report or by self-disallowing the item. The provider must not yet have received its NPR or other final determination with respect to an item for a cost year that is within the same calendar year as that covered by the group appeal (or it has received its NPR or other final determination with respect to an item for that time period, and the provider is still within the time to request a hearing on the issue). Once the Board has determined that a group appeal involving commonly owned providers is fully formed, no other provider under common ownership may appeal the issue (either by joining the group or by pursuing an individual appeal) that is the subject of the group appeal, with respect to a cost reporting period that falls within a calendar year covered by the group appeal, unless the Board modifies its determination that the group is fully formed.

Comment: A commenter stated that it realizes that the requirement that commonly owned or operated providers must pursue legal or factual questions through a group appeal is contained in the statute. However, in some cases, hospital chain organizations are divided into regional divisions that operate independently, and therefore could make it difficult for the organization to identify common issues and manage group appeals across regions. According to the commenter, we should establish an exception to allow regional divisions that operate independently to bring separate group appeals.

Response: Our interpretation of the statute is that commonly owned or operated providers must bring "a" group appeal on the same issue. If the Congress had intended to permit separate group appeals, it could have said that the appeal must be brought by "one or more groups." Therefore, at this time, we believe we are constrained to require that commonly owned or operated providers bring only one group appeal for the same issue (regarding cost

reporting periods ending in the same calendar year).

Comment: A commenter noted that proposed § 405.1837(c)(2) requires that the provider provide an explanation for the "disputed cost" or "specific cost" at issue in its request for a group appeal. This provision should be amended to use the more generic term "item" rather than "cost," as there are items claimed on the cost report that may be challenged that are not "costs" *per se* (for example, a DSH payment). The commenter notes that "item" is used at § 405.1837(a).

Response: We agree and have amended § 405.1837(c)(2) accordingly.

Comment: One commenter stated that the use of the phrases "each specific cost at issue" and "each disputed cost" are misleading, because group appeals are limited to one issue.

Response: Proposed § 405.1837(c) used the phrases "each specific cost at issue" and "each disputed cost" because, although a group appeal is limited to a single legal or factual issue, that issue could involve more than one line item on a cost report. As stated above, we have changed the word "cost" to "item" in § 405.1837(c)(2).

I. Amount in Controversy (§ 405.1839)

We sought to clarify in the proposed rule the method for determining the amount in controversy for both individual and group appeals. Under our proposal, the amount in controversy would be determined based only on those particular adjustments that the provider has challenged and would include the combined total of all issues raised by the provider that arise within the same cost year. We also specified that in a single provider appeal, the provider could not aggregate issues across more than one cost year for purposes of meeting the amount in controversy requirement. However, two or more providers would be allowed to aggregate issues across more than one cost year to meet the amount in controversy requirement for a group appeal.

We are adopting our proposals. In addition, we are adding new § 405.1839(c)(4) to provide that, where a provider has requested a hearing before an intermediary in accordance with § 405.1811, and the amount in controversy is subsequently determined to be at least \$10,000 (for example, due to a reassessment of the amount in controversy by the intermediary hearing office or due to adding an issue), the appeal will be transferred to the Board. Where a provider or group of providers has requested a hearing before the Board in accordance with § 405.1835 or

§ 405.1837, and the amount in controversy changes to an amount less than the minimum for a Board appeal due to the settlement or partial settlement of an issue, transfer of an issue to a group appeal, or the abandonment of an issue in an individual appeal, the change in the amount in controversy does not deprive the Board of jurisdiction. This is consistent with our longstanding policy. Where a provider or group of providers has requested a hearing before the Board pursuant to § 405.1835 or § 405.1837, and the amount in controversy changes to an amount less than the minimum for a Board appeal due to a more accurate assessment of the amount in controversy, the Board will not retain jurisdiction.

Comment: One commenter noted that the proposed rule would require that the provider demonstrate that its reimbursement would increase by at least \$10,000 (for an individual appeal) if the appeal is successful, and stated that, although the proposal was helpful because it did not rely upon the reimbursement determination in an NPR, the proposal does not directly address situations in which no NPR exists. The commenter suggested that we clarify that the jurisdictional amount is satisfied if the provider demonstrates that the total disputed program reimbursement for each cost reporting period at issue meets or exceeds the \$10,000 threshold, without regard to whether an NPR or other determination reflects the disputed amount. In the past, confusion has arisen as to whether an amount in controversy for jurisdictional purposes existed before an NPR has been issued. For example, intermediaries may settle cost reports and issue original NPRs, and may subsequently render a final determination impacting the settled cost report. When a provider files an appeal prior to a reopening and issuance of a corrected NPR, issues have arisen regarding how to determine the amount in controversy. The Board has typically decided that the final CMS determinations are appealable, regardless of the issuance of a corrected NPR, and the Board allowed providers to "estimate" the amount in controversy. The commenter stated that it appears that the proposed rule confirms the Board's position.

Response: Regarding an appeal of a final CMS or intermediary determination, a provider satisfies the amount in controversy requirement by establishing that the final determination has a reimbursement effect of least \$10,000 in controversy.

J. Board Jurisdiction (§ 405.1840)

In the proposed rule, we sought to clarify the rules regarding the Board's preliminary determination of jurisdiction following a provider's hearing request. Among other things, at § 405.1840(a)(2), we proposed that the Board should be required to make a preliminary determination regarding jurisdiction in every case, and notify the parties of its jurisdictional findings before proceeding with the case.

In § 405.1840(b)(1), relating to specific matters that are removed from the Board's jurisdiction, we have updated the regulatory citations to the coverage appeals process and the Quality Improvement Organization appeals process. In § 405.1840(c)(2) we corrected a citation to a specific paragraph of § 405.1842, and in § 405.1840(c)(3), we clarified citations to specific paragraphs of § 405.1875.

For a discussion of other changes we made to § 405.1840(a)(2), please refer to section II.F. of this final rule (Intermediary Hearing Officer Jurisdiction).

Comment: One commenter noted that there was no specific timeframe under which the Board was required to issue a decision when the intermediary has made a jurisdictional challenge. The commenter recommended that when the intermediary disputes jurisdiction, the Board should be given a period of 90 days to render a decision.

Response: Although we understand the commenter's concern, we decline to impose a strict timeframe under which the Board would be required to issue a decision regarding a jurisdictional dispute raised by an intermediary. We believe that the Board, based on its own workload priorities, should be given unfettered discretion to set timeframes (with the exception of timeframes for discovery and subpoena requests) on jurisdictional and other pre-hearing matters such as the filing of position papers.

Also, although not the subject of a specific comment, we believe that the notification requirements we imposed on the Board in proposed § 405.1840(a)(2) are unduly restrictive and burdensome. In order to promote our vision of a more streamlined appeals process, we believe we would be ill advised to require the Board in all cases to notify the parties (presumably in writing) of its preliminary findings (that is, whether the request for hearing was timely, and whether the amount in controversy has been met) regarding jurisdiction. In most cases, jurisdiction is readily obtained, and there is essentially no need to formalize in

writing that the Board has accepted jurisdiction. Therefore, we have amended new § 405.1840(a)(2) accordingly. Where the Board finds that it does not have jurisdiction over every specific matter at issue in the appeal, the Board must issue a dismissal decision under § 405.1840(c)(2) and notify each party to the appeal.

K. Expediting Judicial Review (§ 405.1842)

Under section 1878(f)(1) of the Act, a provider in certain situations may immediately seek judicial review of an action of the intermediary involving a question of the statute or regulations whenever the Board determines that it is without authority to decide the issue. If the Board determines that it has jurisdiction over the issue, but it lacks the authority to decide the issue, the provider may obtain expedited judicial review (EJR). The intent of this provision is to eliminate undue delays resulting from a requirement that providers pursue time-consuming and unproductive administrative reviews before they could obtain judicial review of a Board determination. We proposed several changes to § 405.1842 to clarify any confusion surrounding the procedures and the types of cases to which EJR applies.

We are adopting our proposals. We have revised the text at § 405.1842(e)(3)(ii) to clarify that, upon receiving a request for EJR, the Board will have 30 days either to issue an EJR decision (if the request is complete) or issue a written notice to the provider that the provider has not submitted a complete request (describing in detail the further information that is needed to complete that request).

Comment: One commenter noted that the proposed rule would require that, in instances in which a provider request for EJR is deemed incomplete by the Board, the Board must issue a written notice to the provider describing in detail the additional information needed to complete the request. The commenter suggested that the final rule provide that there be a 30-day period for the Board to provide a notice to the provider that the request for EJR is incomplete, and another 30-day period for the provider to respond to the notice of incompleteness. Once a provider responds to the notice of incompleteness, the Board would have 30 days either to issue an EJR decision, or to ensure that the provider has received another notice of incompleteness. The commenter also suggested that intermediaries be required to comply with all of the deadlines applicable to the provider in

the event that the intermediary files a response to the provider's request for EJR.

Response: It was our intent that, upon receiving a request for EJR, the Board would have 30 days either to issue an EJR decision (if the request is complete) or issue a written notice to the provider that the provider has not submitted a complete request (describing in detail the further information that is needed to complete that request). We are clarifying the text at § 405.1842(e)(3)(ii) accordingly. We decline to require that the provider be given 30 days to respond to a notice from the Board that its request for EJR is incomplete. We believe the time period in which to respond should be left to the Board's discretion, because a period shorter or longer than 30 days could be warranted, depending on the facts of the case.

Comment: One commenter stated that the proposed rule would provide that, if any allegedly relevant lawsuit was filed before a final EJR decision, the Board would be precluded from conducting any further proceedings on the EJR decision until the lawsuit was resolved, and that it appears that the proposed policy would apply, regardless of the basis for the lawsuit. The commenter suggested that the final rule provide that the Board be required to conduct further proceedings on an EJR decision when the provider subsequently files a lawsuit brought on jurisdictional grounds other than the Social Security Act. If the Board were allowed to grant EJR, the issues jurisdictionally under the Medicare statute could be added to the pending matter in court, thus preserving judicial resources and avoiding multiple lawsuits.

Response: The commenter is correct that the proposed policy would apply regardless of the jurisdictional basis for the lawsuit. However, we decline to adopt the commenter's suggestion that we make a distinction based on the jurisdictional basis pleaded in the complaint. We do not agree that it would be appropriate for the Board or the intermediary to spend its limited resources to spend time on a Board appeal if the provider has filed a complaint that involves a legal matter that is relevant to a legal issue in the Board appeal. If the court properly has jurisdiction over the appeal, the decision, that it or a higher court renders, may resolve the issue or issues in the Board case, or otherwise inform the Board in reaching a decision, or affect the parties' decision as to whether they should attempt to settle the Board case. On the other hand, where the basis for the court's jurisdiction is defective (which we believe would most likely be

the situation when a provider attempts to file a complaint based on a legal issue related to an appeal still pending before the Board), a contrary rule would not discourage providers from filing improper appeals with the court. We believe our proposal to be in line with the general rule practiced by courts that an appeal to a higher court deprives the lower court of jurisdiction to conduct further proceedings until the appeal is resolved by the higher court.

L. Parties to Proceedings in a Board Hearing or Intermediary Hearing (§ 405.1843 and § 405.1815)

In the proposed rule, we restated the longstanding position that CMS is not a party to a Board hearing. However, because CMS decisions and policies are very often the subject of provider disputes, we stated that we believed it would be important to include CMS in the hearings process, without conferring upon it the status of a party. Therefore, we proposed to authorize intermediaries to designate a representative from CMS (including an attorney) to defend the intermediary's position at a Board hearing. We also proposed that CMS could file *amicus curiae* briefs with the Board in cases having major policy implications, where CMS was not formally designated as the intermediary's legal representative.

We have clarified in § 405.1843(a) and in § 405.1815 that it is the Board or the intermediary hearing officer (and not the intermediary) that determines whether an entity is a related organization of the provider, and that such a determination is made in accordance with the principles enunciated in § 413.17 (and is not, strictly speaking, a determination made "under" § 413.17).

In § 405.1843(b), we have clarified that, although the Board may call as a witness any employee or officer of Health and Human Services or CMS having personal knowledge of the facts and the issues in controversy in an appeal, the Department's *Touhy* regulations at 45 CFR, Part 2 (Testimony by employees and production of documents in proceedings where the United States is not a party) apply as to whether such employee or officer will appear.

We have added § 405.1843(e) to provide that a non-party other than CMS may seek leave from the Board to file *amicus curiae* briefing papers with the Board. We have also added new § 405.1843(f) to provide that the Board may exclude from the record all or part of an *amicus curiae* briefing paper. Where the Board excludes from the record all or part of an *amicus curiae*

briefing paper submitted by CMS, it will state for the record its reason(s) in writing.

Comment: Most of the commenters that addressed this proposal opposed enhanced involvement by CMS before the Board. One commenter suggested that if CMS files a timely *amicus curiae* submission with the Board, that submission should be based upon the record of the case. Upon Administrator review, any information or documentation submitted by CMS that was not included in the hearing record should be prohibited. Another commenter suggested that if CMS is allowed as a non-party to file *amicus curiae* submissions with the Board, other interested non-parties should also be able to file *amicus curiae* submissions. Two commenters suggested that the filing of an *amicus curiae* brief provides a means for CMS to influence the process. One of these commenters suggested unfairness due to a lack of proper inquiry or the absence of cross-examination. Another commenter suggested that CMS should not be permitted to make *amicus curiae* submissions because CMS has sufficient opportunity to address its policies in other forums (for example, proposed rules or instructions). One commenter fully supported the proposal, stating that intermediaries would be better equipped to defend their actions by having a CMS representative handle the case.

Response: We emphasize again that CMS will not be a party to a Board proceeding and, moreover, we do not anticipate that CMS normally will take a proactive role in defending policy positions before the Board. However, we reiterate that many Board appeals are directly the result of a CMS determination, not an intermediary determination, and, where this is the case, we believe it is reasonable to permit CMS an opportunity to defend its rationale for making the determination.

Regarding the commenter that stated that if CMS will be allowed to file *amicus curiae* briefs, other non-parties should also be allowed to make *amicus curiae* submissions, we agree that the Board should retain the discretion on whether to accept them. We have added a new paragraph (e) to § 405.1843 to state that a non-party other than CMS may seek leave from the Board to file an *amicus curiae* brief. The Board will have unfettered discretion to grant leave, and if leave is granted, the Board can accept or reject the brief in whole or in part.

Regarding the commenter that was concerned that an *amicus curiae*

submission filed by CMS with the Board might not be based upon the record of the case, we note that *amicus curiae* submissions in court are generally argumentative and not evidentiary in nature. To the extent that an *amicus curiae* submission purports to rely on evidence not before the Board, the Board may choose to attempt to have the record supplemented by that evidence, as well as to have the discretion to exclude from the record the submission in whole or in part. We have added new paragraph (f) to section § 405.1843 to provide that the Board may exclude, in full or in part, an *amicus curiae* brief submitted by CMS or any other interested non-party (but that where it excludes all or part of an *amicus curiae* brief) submitted by CMS, it must state its reason(s) in writing.

We also disagree with the commenter that suggested that the ability of CMS to file an *amicus curiae* brief somehow places CMS in a position where it can unduly influence the Board decision making process. The Board is an impartial, independent forum, and therefore takes its responsibility seriously in addressing and resolving the matters before it. The Board's only concern is to provide a fair and just hearing process and issue decisions in accordance with the law and regulations. As stated previously, the Board has discretionary authority, after reviewing a submission by CMS, to admit or exclude the submission from the record.

Finally, we disagree with the commenter that suggested that CMS, rather than being able to submit *amicus curiae* briefs to the Board, should address its policies by way of publishing proposed rules or by issuing instructions. During the course of an adversary proceeding where potentially millions of dollars are at issue and significant program policies may be in dispute, the best means of defending existing policies are through effective advocacy and cogent oral and written arguments.

Comment: One commenter suggested that we should acknowledge that CMS is the real party in interest in a Board proceeding so that providers would then have the full right to obtain discovery and testimony from CMS.

Response: After reconsidering the issue, in this final rule we are not providing for discovery against CMS. As explained in section II.N. of this final rule, we are concerned that the ability of CMS to conduct its day-to-day business could be significantly compromised if it is constantly engaged in responding to discovery or forced to seek immediate Administrator review of

Board orders granting discovery. We also believe that discovery disputes concerning CMS, or the Secretary or a Federal agency, which may involve motions to compel or motions for protective orders or other procedural filings, will cause a further backlog of cases before the Board. For these reasons, we have decided that the discovery procedures in § 405.1821 and § 405.1853 will not apply to CMS, the Secretary (or any other component of HHS), or any other Federal agency. We have also revised the procedures for depositions at § 405.1853(e)(2)(ii) to clarify that the Department's Touhy regulations at 45 CFR, Part 2 (Testimony by employees and production of documents in proceedings where the United States is not a party) will apply as to whether an employee or officer of CMS or HHS will appear at a deposition.

Comment: One commenter requested clarification as to whether the intermediary could call a CMS employee as a witness in a case before the Board. Two commenters suggested that proposed § 405.1843 be eliminated and replaced with a provision that, where CMS has made the final determination upon which the Board hearing is based, a CMS representative should be required to testify at the hearing.

Response: Current practice at the Board is that an intermediary will occasionally ask a CMS employee to testify at an oral hearing.

We disagree with the commenters that suggested that § 405.1843 of the regulations be eliminated and replaced with a provision stating that a CMS employee should always be required to testify at a Board hearing when there is a CMS determination that is under dispute. Although CMS's policies and actions bear at least indirectly on each and every hearings dispute before the Board, CMS is not an adversarial party in the Board proceeding. That adversarial responsibility falls upon the intermediary. In most cases, the written submissions made by an intermediary in defense of a CMS determination are clear and succinct and would not require additional evidence, in the form of oral testimony by a CMS employee, to explain the determination.

Comment: One commenter suggested that CMS representation of an intermediary violates the regulation (§ 405.1843(b)) which does not permit CMS to be a party to a Board hearing, unless CMS acts as an intermediary.

Response: Our current regulation at § 405.1843(b) permitted CMS to act as a party to a Board hearing in those cases where we served as a direct dealing

intermediary for a small number of providers. We no longer act as an intermediary, and, for that reason, we proposed deleting the provision that allowed CMS party status at the Board. We have adopted this proposal. We note that when CMS provides representation for an intermediary at a Board hearing, the representation does not in any way elevate CMS to party status.

Comment: Two commenters suggested that no matter how we characterize it, CMS should be considered a party to the Board hearing if it participates at the hearing. One of the commenters stated that, if CMS represents the intermediary at the hearing, the Administrator should not be allowed to review and overturn the Board's decision. Also, prevailing providers should be entitled to legal fees under the Equal Access to Justice Act (5 U.S.C. 504).

Response: We once again reject the suggestion that the proposed limited participation by CMS at future Board hearings should define CMS as a party to the Board hearing. We also disagree with the suggestion that, if we represent the intermediary at the hearing, the Administrator would be required to recuse himself from reviewing the Board decision.

The statute at section 1878(f) of the Act provides for the Secretary's review of a decision of the Board. This review is also consistent with section 557 of the Administrative Procedure Act (APA), which provides agency review of an initial decision. In this review process, the Administrator acts, pursuant to his or her delegated authority, for the Secretary in rendering a final decision. Consequently, the commenter's suggestion that the Administrator should be prohibited from reviewing a Board decision under the proposed circumstances is contrary to the plain language of the controlling law and the statutory framework provided by the APA.

Because CMS is not a party to a Board hearing, we do not believe that the provisions of the Equal Access to Justice Act are applicable relative to the reimbursement of expenses incurred (for example, legal fees, expert witness fees, etc.).

M. Quorum Requirements (§ 405.1845)

Three Board members, at least one of whom is representative of providers of services, constitute a quorum. Current regulations state that, with the provider's approval, the Board Chairman may designate one or more Board members to conduct a hearing and prepare a recommended decision for adjudication by a quorum of Board members.

In order to expedite the resolution of the large number of cases backlogged at the Board, we proposed that the Board Chairman could designate one Board member to conduct a hearing, allowing for more than one hearing to be held simultaneously. The Board Chairman would not be required to obtain the approval of the provider or the intermediary before assigning the case to a single Board member. In our view, the rights of the parties would not be prejudiced because the hearing decision would be issued by a quorum of Board members. We also proposed that a recommended decision would not be needed when less than a quorum conducted the hearing. Board members who were not present at the hearing would be able to review the record of the hearing and make an informed decision based upon that review. Also, we proposed that the Board could offer the parties the option to have a hearing on the written record. Both parties would be required to agree to waive their rights to an oral hearing as a condition for holding a hearing on the written record. We are not making any substantive changes to our proposal. We have clarified in § 405.1845(d)(1) that a quorum is not required to issue a dismissal decision, which reflects current Board practice. We have made a technical change to proposed § 405.1845(f)(2), and, for clarity, we have renumbered proposed § 405.1845(f)(3) as paragraph (g), and accordingly renumbered proposed § 405.1845(g) as paragraph (h).

Comment: One commenter suggested that the interest of justice cannot adequately be served with only one Board member hearing the case in person. The other Board members could not fairly decide a case because they could not adequately adjudge the credibility of witnesses based on only a review of the written transcript of the hearing. Several commenters suggested that the Board should be required to obtain the approval of the provider or the intermediary before assigning less than a quorum to conduct a hearing. Because of the highly technical issues, if a Board member is not present, a simple review of the written record may not be sufficient to render an appropriate decision. Another commenter wanted to know if the full Board could be required to hear a case at the request of either the intermediary or the provider.

Response: We disagree with the commenter that suggested that justice could not be served if only one Board member heard the case in person. Administrative law principles clearly allow for an adjudicator to resolve

disputes without being present at an oral hearing. Consistent with 5 U.S.C. 557(b) of the APA, an administrative officer charged with the decision making (for example, a member of the Board) is not required to personally hear the testimony, but may rely instead on the written record. Although only one Board member may preside at the hearing, a quorum of at least three Board members (at least one of whom is representative of providers) is required to issue a final Board hearing decision. We believe our quorum requirement adequately ensures that the hearing process will be fair and that the resulting decision will reflect the reasoned opinion of the Board and not merely a single member of the Board.

We also disagree with the commenters that suggested that the Board be required to obtain approval of the provider or intermediary before assigning less than a quorum to conduct a hearing. We do not believe that the rights of the parties are prejudiced in any way by not requiring the Board to obtain the permission of one or both of the parties to the hearing. Provided that the hearing decision is issued by at least a quorum of Board members, the parties to the hearing are being afforded procedural due process under the principles of administrative law. As stated above, the APA clearly permits an adjudicative officer to formulate a decision based only upon a review of the written record.

As to the commenter that inquired whether a provider or intermediary could request the full Board membership to hear a case, we note that the Board has the discretionary authority to grant such a request.

Comment: One commenter suggested that there should be at least two Board members present at live hearings to ensure that an individual Board member would not be able to sway the outcome of a Board decision.

Response: We disagree with the suggestion that if only one Board member hears a case, that particular member is in a position to unduly influence the other decision makers. We disagree that fairness and impartiality in the decision making process is ensured only when a minimum of two Board members conduct a hearing.

Comment: One commenter suggested that a provider might be prejudiced if two Board members assigned to a case reflect a "minority" view of the Board. This could lead to inconsistent decisions on the same legal questions by different Board panels. Also, allowing less than five members to decide cases distorts Congress's intention in creating the Board.

Response: Section 1878(h) of the Act requires that the Board be composed of five members, two of whom are representative of providers of services. At least one member must be a certified public accountant, and all of the members must be knowledgeable in provider payment principles. The Board, like all adjudicative bodies, strives for consistency in decision making. However, there may be occasions in which one panel of the Board hearing an appeal on an issue could decide differently from another panel of the Board with respect to the same issue. The Board, at its discretion, may seek to identify issues on which it is divided and ensure that a full complement of the Board (which at any given time may be less than five members) hears those issues. If either party is dissatisfied with a decision issued by the Board, review mechanisms are in place (Administrator, judicial review) to contest the decision. We also disagree with the commenter's statement that all five Board members must decide a case, so that congressional intent will not be distorted. Our longstanding policy, as contained in the regulations, allows for a quorum of at least three Board members (at least one of whom is representative of providers of services) to issue Board hearing decisions. This policy has been implemented for many years, has not been controversial, and has helped to create a more effective and efficient appeals process.

N. Board Proceedings Prior to Hearing; Discovery in Board and Intermediary Hearing Officer Proceedings (§ 405.1853 and § 405.1821)

We proposed several revisions to § 405.1853. Proposed § 405.1853(a) specified the present requirement that, prior to any Board hearing, the intermediary and provider must attempt to resolve legal and factual issues, and following that attempt, must send to the Board joint or separate written stipulations setting forth the specific issues that remain for Board resolution. We proposed removing the requirement that the intermediary ensure that all documentary evidence in support of each party's position is in the record. We proposed continuing the present requirement that the intermediary be required to place in the record a copy of all evidence that it considered in making its determination, and would add, that, where the determination under appeal is a Secretary determination, the intermediary would be responsible for placing in the record all evidence considered by CMS in making the Secretary determination.

In proposed § 405.1853(b), we made several proposals concerning the timing, content and format of position papers. Specifically, we proposed that the Board would set the deadlines for submitting position papers in each case as appropriate, and that the Board would have the authority to extend the deadline for good cause shown.

Proposed § 405.1853(c) and § 405.1853(d) set forth requirements relating to "initial" and "further" status conferences, which could be for a wide variety of purposes.

In § 405.1853(e) and § 405.1821 we proposed changes in discovery procedures for Board and intermediary hearing officer hearings. Proposed § 405.1853(e)(1), and proposed § 405.1821(b)(1) specified the basic requirements for discovery, including the requirement that the matter sought to be discovered must be relevant to the specific subject matter of the Board or intermediary hearing. Proposed § 405.1853(e)(2) specified that the method of discovery permitted would generally be limited to reasonable requests for the production of documents for inspection and copying, and a reasonable number of interrogatories, with depositions permitted in limited circumstances. A party would not be permitted to take an oral or written deposition of another party or a non-party, unless the proposed deponent agrees to the deposition, or the Board finds that the proposed deposition is necessary and appropriate under criteria contained in the Federal Rules of Civil Procedure. We proposed that requests for admissions, or any other form of discovery other than requests for production of documents, interrogatories and depositions would not be permitted. Proposed § 405.1821(b)(2) was similar, except that it would not permit depositions in proceedings before an intermediary hearing officer(s).

In § 405.1853(e)(3), we proposed time limits for requesting discovery. We proposed that a party's discovery request would be timely if the date of receipt of such a request by another party or non-party, as applicable, is no later than 90 days before the scheduled starting date of the Board hearing. A party would not be permitted to conduct discovery any later than 45 days before the scheduled starting date of the Board hearing. We further proposed that, upon request and upon a showing of good cause, the Board could extend the time for making a discovery request or extend the time for performing discovery. The Board would be permitted to extend the time for requesting discovery or for conducting discovery only if the

requesting party establishes that it was not dilatory or otherwise at fault in not meeting the original discovery deadline. If the Board granted the extension request, it would be required to impose a new deadline and, if necessary, reschedule the hearing date so that all discovery ended no later than 45 days before the hearing. Proposed § 405.1821(a) would be similar for proceedings before an intermediary hearing officer(s).

In § 405.1853(e)(4) and § 405.1821(c), we proposed to specify the rights of non-parties with respect to discovery requests. A non-party would have the same rights as a party in responding to a discovery request. These rights would include, but would not be limited to, the right to select and use any attorney or other representative, and to submit discovery responses, objections, motions, or other pertinent materials to the Board.

In § 405.1853(e)(5) and § 405.1821(c)(3), we proposed a specific procedure for motions to compel and for protective orders. In order to conserve Board resources and promote an efficient hearing process, each party would be required to make a good faith effort to resolve or narrow any discovery dispute, including a dispute with a non-party. Any motion to compel discovery and any motion for a protective order, and any response thereto, would have to include a self-sworn declaration describing the movant's or respondent's efforts to resolve or narrow the discovery dispute.

In § 405.1853(e)(6), and in § 405.1821(d)(2), we proposed a general rule, and an exception thereto, for the reviewability of Board or intermediary hearing officer(s) orders on discovery. Generally, any discovery or disclosure ruling issued by the hearing officer(s) or the Board would not be final and would not be subject to immediate review by the Administrator. Rather, such a ruling could be reviewed solely during the course of Administrator review of one of the Board decisions specified as final, or deemed to be final by the Administrator, or of judicial review of a final agency decision. However, we also proposed that, where the Board or hearing officer(s) authorize discovery or compel disclosure of a matter for which a party or non-party made an objection based on privilege, or some other protection from disclosure, that portion of the discovery ruling would be reviewable immediately by the Administrator. We proposed that there would be an automatic stay where the party or non-party, as applicable, notifies the Board or intermediary hearing officer(s) of its intention to seek immediate review. The

duration of the stay would be limited to no more than 15 days in the case of Board proceedings and to no more than 10 days in the case of intermediary hearing officer(s) proceedings. If the Administrator granted a request for review or takes own motion review before the expiration of the stay, the stay would continue until the Administrator or CMS reviewing official renders a written decision, but if the Administrator did not grant or take review within the time allotted for the stay, the stay would be lifted and the Board or hearing officer(s) ruling would not be immediately reviewable.

We have made several changes to our proposals, as discussed below. We note that, in preparing this final rule, we remain concerned that, although under certain circumstances CMS would have had the right to seek immediate Administrator review of a Board disclosure or discovery ruling, the ability of CMS to conduct its day-to-day business could be significantly compromised if it is constantly engaged in responding to discovery or forced to seek immediate Administrator review of Board orders. We also believe that discovery disputes concerning CMS, or the Secretary or a Federal agency, which may involve motions to compel or motions for protective orders or other procedural filings, will cause a further backlog of cases before the Board. For these reasons, we have decided that the discovery procedures in § 405.1821 and § 405.1853 will not apply to CMS, the Secretary (or any other component of HHS), or any other Federal agency. A non-party (other than CMS, or other Federal agency as described above) may only be required to respond to requests for the reasonable production of documents. A party will not be allowed to serve written interrogatories on any non-party, consistent with the general rule that interrogatories are not normally served on non-parties. We have also revised the procedures for depositions at § 405.1853(e)(2)(ii) to clarify that the Department's Touhy regulations at 45 CFR Part 2 (Testimony by employees and production of documents in proceedings where the United States is not a party) will apply as to whether an employee or officer of CMS or HHS will appear at a deposition.

As a result of these changes, we are hopeful that the discovery procedures as finalized will be fair to the parties and will streamline the appeals process. We believe that the current process for seeking documents under the Freedom of Information Act procedures will meet providers' needs for gaining access to information in our possession. We note

that because these procedures are a procedural rule, and hence exempt from notice and comment rulemaking, we would be able to modify the rule's provisions insofar as they relate to CMS (or other Federal agency) through a CMS Ruling or other means.

In § 405.1853(b)(2), we removed the requirement that the Board must find good cause for extending the deadline for submitting a position paper. We believe that, for administrative efficiency and for purposes of fairness, the Board should have wide discretion to extend the time for submitting a position paper, as the facts and circumstances in any given case may so require.

In § 405.1853(b)(3), we have clarified that the "timeframe to be decided by the Board," for purposes of submitting exhibits on the merits of the provider's claim, may be through a schedule applicable to a specific case or through general instructions. We also revised this paragraph to provide that the general rule, that any supporting exhibits regarding jurisdiction must accompany the position paper, is subject to a Board order or general instructions to the contrary.

In § 405.1853(e)(2), we have clarified the reference in the proposed rule to Federal Rules of Civil Procedure (FRCP) 32 governing the allowance of depositions in certain circumstances, and have specifically referenced FRCP 32(a)(3), with respect to the criteria the Board must employ in order to permit the deposition of a witness who does not wish to be deposed.

In § 405.1853(e)(3) and § 405.1821(a)(2) we have modified the proposal's requirement that discovery must be "received" by a certain time, and have instead provided that discovery must be "served" by a certain time, in order to prevent any disagreement and collateral litigation before the Board or the intermediary hearing officer(s) as to when discovery was actually received. With respect to the time period itself, we have changed the timeframe from 90 days before the scheduled date of the hearing, to 120 days before the initially scheduled starting date of the hearing, to ensure that the parties and Board have sufficient time to address any discovery disputes prior to the hearing. We have added clarifying language at § 405.1821(c)(3)(iii)(B) and § 405.1853(e)(5)(vii) to state that nothing in § 405.1821 or § 405.1853 authorizes the intermediary hearing officer or Board to compel any action from the Secretary or CMS. Likewise, in § 405.1821(c)(2) and § 405.1853(e)(4), we have revised language that stated

that a non-party has the “same” rights as any party when responding to discovery requests. Although this statement was generally true under our proposal and remains generally true under this final rule, it is not entirely accurate with respect to CMS or the Secretary or any other Federal agency, as a non-party. Neither an intermediary hearing officer nor the Board may compel CMS or the Secretary or any other Federal agency to respond to discovery or take other action.

In § 405.1821(d)(2) we have revised the minimum time for the stay in the case of a CMS reviewing official reviewing a discovery ruling from 10 days to 15 days.

Comment: Several commenters disagreed with our proposal to modify the requirement in section § 405.1853(a) that providers must submit position papers to the Board no later than 60 days after the hearing request, and instead allow the Board to set position paper deadlines on a case-by-case basis. One commenter stated that the proposed change would reduce the certainty of timeliness and critical due dates, making case management more difficult for all parties, and that only the Board had authority to establish the appeals process before the Board. Other commenters stated that the Board should not have the authority to arbitrarily remove the reference to the 60-day timeframe for submitting position papers, or to set the deadlines for submitting position papers on a case-by-case basis as the Board deems appropriate, because there would be no consistency.

Response: We disagree that our proposal would reduce the certainty of timeliness and critical due dates and make case management more difficult for all parties. The Board will issue a schedule of due dates for the filing of position papers and other events in each case, and the provider and intermediary will have adequate notice of the deadlines. We also note that it is very common for due dates for position papers to be extended beyond 60 days after the hearing request, and for the Board to set the due dates for other events on a case-by-case basis; we therefore, do not regard the proposal as a significant change in the way proceedings are currently conducted. Finally, we do not agree with the commenter’s point that only the Board has the authority to establish appeals procedures before it. Under section 1878(e) of the Act, the Board has the authority to determine procedures to the extent that they are not inconsistent with the Secretary’s regulations. Moreover, our proposal gives more, not

less, discretion to the Board with respect to the setting of due dates for position papers, as compared to the current regulatory requirements. Changes that may occur from time to time in the volume and relative complexity of the Board’s caseload weigh in favor of allowing the Board flexibility in setting due dates. In order to afford the Board greater flexibility, we are modifying our proposal that the Board may extend, for good cause shown, the deadline for submitting a position paper. We believe that the Board should have the discretion to extend the deadline without a showing of good cause (particularly because the Board has the discretion to set the initial deadline for the filing of the position paper).

Comment: One commenter supported our proposal to remove the current requirement that the intermediary ensure that all documentary evidence in support of each party’s position be in the record. This commenter also agreed with the proposal that the intermediary should be responsible for placing in the record all evidence considered by CMS in making a determination about an issue. The commenter suggested, however, that “all relevant evidence,” regardless of whether that evidence was considered by CMS, be placed in the record. The commenter also stated that the proposal should be expanded to specify the remedy to which a provider is entitled if CMS or the intermediary does not comply with the requirement to place evidence in the record. The proposal should also be expanded to specify the powers that the Board has to compel CMS to produce evidence, including documentary evidence, answers to interrogatories, and depositions of CMS witnesses. Finally, according to the commenter, the rule should provide effective, compulsory measures to ensure compliance by CMS.

Response: We are not adopting the suggestion that the intermediary be required to place “all relevant evidence” in the record, regardless of whether that evidence was considered by CMS. We believe it is unclear whether, and to what extent, evidence that was not considered by CMS is nonetheless “relevant.” If a provider believes other evidence is relevant and therefore deserves to be made part of the record, the provider can move for its admission. Where a provider believes that an intermediary has not fulfilled its obligation to include evidence in the record that was considered by CMS in making a determination, the provider may seek an order from the Board. If the intermediary does not comply with an order of the Board, the Board may refer

the matter to the component of CMS that has oversight of contractors. Also, on review of a final decision of the Board, the Administrator would have the authority to remand to the intermediary, if necessary, to supplement the record. As discussed below in section II.O. in connection with subpoenas, the Board does not have authority to compel CMS to take actions, including placing evidence in the record, answering discovery, or making witnesses available for depositions. However, upon review of a Board decision, the Administrator or a court may order the record to be supplemented with additional information, if necessary. We have added clarifying language at § 405.1821 and § 405.1853(e)(5)(vii) to state that nothing in § 405.1821 or § 405.1853 authorizes the intermediary hearing officer or Board to compel any action from the Secretary or CMS. Likewise, in § 405.1821(c)(2) and § 405.1853(e)(4), we have revised language that stated that a non-party “including HHS and CMS” has the same rights as any party when responding to discovery requests. We have deleted the reference to “HHS and CMS” because the intermediary hearing officer and Board discovery processes do not apply to CMS, HHS or any other Federal agency. The statement remains true with respect to other non-parties.

Comment: One commenter stated that the current backlog of cases at the Board must be reduced. This commenter believes that a more aggressive approach to reducing issues that involve clear errors would be beneficial. According to this commenter, a number of appeals to the Board involve audit errors, clerical errors, or other minor issues that amount to little more than protective appeals. Although the proposal to require providers and intermediaries to attempt to resolve legal and factual issues would seem to be a mechanism to resolve these issues or errors, absent the involvement of the Board or its staff, no resolution occurs, and the appeal drags on to a hearing. The commenter recommended that a mechanism be established by which a provider can identify issues that should be quickly resolvable, and explain why they can be resolved quickly, followed by the Board or its staff convening a conference call to address the issues. In the commenter’s view, bringing the parties together early in the appeal can eliminate some or all issues quickly, minimizing the burden on all involved.

Response: Currently, intermediaries and providers are encouraged to work together to resolve disputes in order to avoid taking an issue to a hearing that

can and should be settled. We believe our proposal will further facilitate the resolution of issues. What the commenter recommends is descriptive of what currently takes place in many cases.

Comment: One commenter noted that, although the proposed rule would encourage an early focus by the parties and the reviewing entity on the jurisdictional requirements for a hearing before the Board, the Board should be required to issue jurisdictional decisions early in the appeals process. There are many instances in which a hearing is held on the merits and the jurisdictional challenge simultaneously. Unless time limits for jurisdictional decisions are imposed, the parties may engage in additional, and possibly unnecessary, work. Preferably, all Board jurisdictional decisions should be rendered before the Board sends the acknowledgment letter establishing due dates for position papers and a tentative hearing date. Moreover, all Board jurisdictional decisions should be published for public viewing.

Response: We decline to impose time limits for jurisdictional decisions at this time. The Board must balance the need for issuing jurisdictional decisions in an expeditious manner so as not to cause the parties possible unnecessary work with the need to schedule hearings and manage its caseload. We will monitor the situation, and, if necessary, we may impose specific time limits or issue guidance through a CMS Ruling, which would be binding on the Board. The Board has published jurisdictional decisions that it feels would provide guidance for intermediaries and providers. It is impractical and unnecessary for the Board to publish every jurisdictional determination.

Comment: One commenter agreed with the proposal to include non-parties, such as CMS, within the Board discovery procedures.

Response: As finalized, the Board discovery procedures will apply to non-parties other than CMS, the Secretary (or other component of HHS) or any other Federal agency. We have decided to except Federal agencies from the intermediary hearing officer and Board discovery processes due to our concerns that a more expanded discovery process could cause significant disruption in their ability to manage their day-to-day activities, and due to our concern that discovery disputes involving CMS or other Federal agencies could cause a further backlog of cases before the Board. The Freedom of Information Act process remains available to providers and others seeking information from CMS or other Federal agency, and CMS

employees are subject to being deposed, or required to testify or produce documents under the Department's Touhy regulations at 45 CFR Part 2.

Comment: One commenter stated that it understood our concern that broad discovery procedures may impact the Board's ability to schedule and hold hearings in an efficient manner, but recommended that we expand the existing types of discovery permitted to include requests for admissions. Requests for admission have been an effective means of narrowing the issues on appeal, and can expedite the appeals process by facilitating settlement and reducing the amount of time necessary for the hearing. Moreover, allowing requests for admissions would be no more onerous to parties than responding to interrogatories. Another commenter stated that we have provided no rational reason why providers should be denied this important discovery tool, which is provided under the FRCP.

Response: We are not including requests for admissions within the permitted types of discovery. We disagree that allowing requests for admissions would be no more onerous than responding to interrogatories. Apart from the burden caused by allowing another form of discovery in addition to interrogatories and requests for production of documents, there are special concerns with respect to requests for admissions. Failure to respond to requests for admissions timely could result in matters being deemed admitted, which could have dire consequences for the non-responding party in the case at hand and possibly for other, similar cases. We believe that the present process, whereby intermediaries and providers stipulate to matters not in dispute, works reasonably well in terms of narrowing issues, expediting appeals, and facilitating settlements. Our proposed revision to § 405.1853 places the duty on intermediaries to expeditiously attempt to join with the provider in resolving specific factual or legal issues and entering into stipulations. We are adopting this proposed revision. We expect that intermediaries will approach this requirement in good faith and will not seek to unduly prolong cases or force the provider to litigate matters that are not fairly in dispute. If a party believes, however, that an intermediary has not fulfilled its obligations, it may complain to the Board, and the Board may refer the matter to CMS if the Board believes it is appropriate to do so.

Comment: One commenter stated that we should consider including a provision whereby the parties could

stipulate that the issues and facts in their case are identical to the issues and facts in one or more cases, and could request that the same Board decision that has been rendered, or will be rendered in the like cases, be applied to their case.

Response: We do not believe it is necessary to amend the regulations to state that the parties may so stipulate. As noted in our previous response, the intermediary must attempt to join with the provider to narrow the factual and legal issues in dispute. We see no reason why the parties could not stipulate that the facts and issues in one case are identical in all material respects to those in another case or cases. The Board has the discretion to consolidate like cases for hearing or (with the parties' consent) to dispense with the hearing in a case and effectively have that case be governed consistently with the decision in another case.

Comment: One commenter stated that the final rule should clarify for discovery deadline purposes that the scheduled starting date of the Board hearing is the specific date the hearing is on the docket, and not the anticipated month of the hearing date listed on the "key dates" letter received from the Board when the appeal is filed.

Response: Proposed § 405.1853(e)(3), which we are adopting, uses the term "scheduled starting date of the Board hearing," which is the specific date on the Board's docket. As discussed more fully below, this final rule references the deadlines to the "initially" scheduled starting date of the hearing, in recognition that hearings are often rescheduled.

Comment: One commenter stated that an incomplete or late response, or no response at all, to a timely-filed request for discovery should be grounds for an extension of discovery.

Response: Proposed § 405.1853(e)(3) would have allowed the Board, for good cause, to extend the time for requesting or conducting discovery. On reexamination of our proposal, we believe that the Board should be allowed to extend the time for requesting or conducting discovery without requiring a showing of good cause. We do not believe it advisable to state that a late or incomplete response, or a non-response, would necessarily lead to an extension of the time to seek or conduct discovery; rather, in any given case, the Board should evaluate the circumstances before it and exercise its discretion to allow or disallow an extension for seeking or responding to discovery.

Comment: One commenter disagreed with our proposal to modify the time

limits for requesting discovery so that a party's discovery request must be received no later than 90 days before the scheduled hearing, and that discovery must be completed no later than 45 days before the scheduled hearing. The commenter noted that current § 405.1853(b) technically allows parties to file discovery requests as late as one day before the hearing. The commenter nevertheless viewed the proposal as an attempt to restrict provider appeal rights through technicalities. Several commenters said that, in order for discovery to be timely, it should be received no later than 60 days prior to the hearing. Also, allowing a party to conduct discovery up to 45 days before the scheduled date of the hearing is excessive, and allowing 30 days for discovery is adequate.

Response: We believe it prudent to set deadlines on requesting, conducting, and responding to, discovery. We believe that it is important to strike an appropriate balance between allowing parties a sufficient time to conduct discovery for case preparation without disrupting the hearing process through last minute discovery requests. Our proposal would have allowed parties to request discovery no later than 90 days before the scheduled date of the hearing and to conduct discovery no later than 45 days before the scheduled date of the hearing. Upon further reflection, we have decided to require that a party's discovery request is timely if it is served no later than 120 days before the initially scheduled starting date of the hearing, unless the Board extends the time for requesting discovery. We have modified the proposal's requirement that discovery must be "received" by a certain time, and instead provided in § 405.1853(e)(3) and § 405.1821(a)(2) that discovery must be "served" by a certain time, in order to prevent any disagreement and collateral litigation before the Board or the intermediary hearing officer(s) as to when discovery was actually received. "Served" has the same meaning as given to that term under the FRCP. We decided to use the initially scheduled starting date of the hearing as the focal point, because using the actual hearing date as the focal point would mean that a new discovery period could be obtained any time the hearing is rescheduled (as is often the case). We also want to ensure that the parties and the Board have sufficient time to address discovery disputes that may arise. We believe that, as finalized, the deadlines for submitting and responding to discovery do not pose significant difficulties for parties (and we note that, as revised in this final

rule, the Board has discretion to extend the deadlines without a finding of good cause) and are necessary for the efficient administration of the hearing process.

We have revised the language in § 405.1853(e)(3)(ii) of the proposed rule that said discovery may not be "conducted" by a party any later than 45 days before the Board hearing, because we were concerned that "conducted" may have been unclear. In revised § 405.1853(e)(3)(ii), we set deadlines for holding a deposition, and for responding to interrogatories and requests for production of documents. Specifically, we have revised this paragraph to state that, in the absence of a Board order or instruction setting a specific starting date for the deposition, a party desiring to take a deposition must give reasonable notice of a scheduled deposition in writing to the deponent. However, in no event may the deposition be conducted later than 45 days before the initially scheduled starting date of the Board hearing, unless the Board extends the time for conducting the deposition. In the absence of a Board order or instruction setting a specific time, a party or non-party must respond to interrogatories or to requests for production of documents within the time allotted by the FRCP or according to a schedule agreed upon by the party requesting discovery and the party or non-party to which the discovery is directed. Responses to interrogatories and requests for production of documents must be served no later than 45 days prior to the scheduled starting date of the Board hearing, unless the Board extends the time for responding.

We have deleted the requirement that the Board may extend the time in which to request discovery or conduct or respond to discovery only upon a showing by the requesting party that it was not dilatory or otherwise at fault in not meeting the original discovery deadline. Upon reexamination, we believe it is better to afford the Board the flexibility to extend discovery deadlines without such a showing.

We are not prescribing deadlines for a time when a party must submit a motion to compel discovery or for a time when a party or non-party must submit a motion for a protective order. Rather, the Board may wish to issue specific instructions as to a time when the motions must be filed.

We have also amended proposed § 405.1853(e)(3)(v) to state that, if the Board grants an extension for requesting or conducting discovery or responding to interrogatories or requests for production of documents, it may set a new hearing date, instead of (as

proposed) being required to set a new hearing date.

Finally, we have made corresponding changes to § 405.1821, with respect to discovery in intermediary hearing proceedings.

Comment: One commenter asked what would happen under the proposal if documentation was received after 45 days. Specifically, the commenter wished to know whether the documentation would be considered by the Board at the hearing, and stated that, if this were the case, the 45-day deadline meant little as timely discovery from the intermediary depended on what the intermediary had to review and from whom the request came. The same commenter also asked what the result would be if documentation was requested and received in the 45-day period, but additional data needed by the intermediary to supplement and test the original documentation arrived after the 45-day period had expired. The commenter also stated that further clarification was needed with regard to what documentation was due within 45 days, and what was due within 90 days.

Response: We believe our revisions to § 405.1853(e)(3)(ii), noted above, address the commenter's concerns. Discovery responses must be served no later than 45 days before the initially scheduled start of the Board hearing, unless the time for responding is extended by the Board. Where a party or non-party files responses late (or not at all), the Board will have the discretion to postpone the hearing or order some other remedy within its authority.

Comment: Several commenters stated that, because it is likely that a party would never agree to a deposition, the rule needs to specify that in certain cases a party must agree to a deposition.

Response: We do not agree that it is likely that a party will never agree to a deposition. Litigants in civil cases routinely agree to appear at depositions, whether in a spirit of cooperation or with the knowledge that the court can compel their attendance if necessary and appropriate. We anticipate that parties before the Board also will generally comply with notices of deposition. Moreover, we have specifically referenced, in the regulations text, Rule 32(a)(3) of the FRCP—this rule will be applied by the Board to allow the taking of a deposition in order to preserve testimony of an individual who might not be otherwise available to appear at the hearing. However, there may be instances in which a party reasonably believes that the time or place of the deposition, or the deposition itself, is unreasonable,

and, therefore may wish to resist appearing. In that situation, the party may petition the Board for a protective order. Conversely, where the party noticing the deposition believes that the deposed party is unreasonable in refusing to appear, it may file a motion to compel with the Board. We do not believe it is possible to state in advance, however, in which types of cases a party will not be allowed to refuse a notice of deposition. Whether a notice of deposition is reasonable or unreasonable will depend on the facts and circumstances of each case and is best left to the Board to manage through its ability to issue protective orders and orders to compel.

Comment: Several commenters (in identical language) said that the proposed duration of the automatic stay (no more than 15 days for Board proceedings, and no more than 10 days for intermediary hearing officer(s) proceedings) is too strict, and that it would be more effective to have the automatic stay for Board and intermediary hearing officer(s) proceedings last no more than 30 days and 15 days, respectively.

Response: The commenters misunderstood our proposals in § 405.1853(e)(6) and § 405.1821(d)(2). We proposed that the duration of the automatic stay could be no less than 15 days for Board proceedings, and no less than 10 days for intermediary hearing officer(s) proceedings. In proposing minimum lengths for the stay, we wanted to ensure that the Administrator would have sufficient time to decide whether to take review of the matter before the stay had expired. Although we continue to believe that the proposed periods are sufficient, in order to ensure that the CMS reviewing official would have sufficient time to review an intermediary hearing officer order, we have revised the minimum time for the stay in § 405.1821(d)(2) to 15 days. With respect to the commenters' suggestion that the automatic stay not last more than 30 days for Board proceedings, and not more than 15 days for intermediary hearing officer(s) proceedings, we decline to restrict the Board or intermediary hearing officer from initially setting a longer stay than the minimum period prescribed, in order to address the possibility that, due to unusual circumstances, the Board or intermediary hearing officer may believe that a longer period is needed for a party to seek review of the discovery order and for the Administrator or CMS reviewing official to decide whether to take review. Likewise, we believe that, as we proposed in § 405.1853(e)(6)(ii)

and § 405.1821(d)(2), if the Administrator or CMS reviewing official decides to take review, the stay should continue until the Administrator or CMS reviewing official issues a decision on the matter, rather than prescribing a set period for which the Administrator or CMS reviewing official may rule, as some cases may be more complex than others, and the Administrator's or CMS reviewing official's other review responsibilities may be more voluminous at one time than at another.

O. Subpoenas (§ 405.1857)

Section 1878(e) of the Act states that the provisions of sections 205(d) and 205(e) of the Social Security Act with respect to subpoenas apply to the Board to the same extent that they apply to the Commissioner of Social Security with respect to title II (Social Security) of the Act. In the proposed rule, we proposed time limits for requesting Board subpoenas that would be similar in some respects to those we proposed for the discovery process. For subpoenas requested for purposes of discovery, a request would be timely if received at least 90 days before the scheduled hearing date. For a subpoena requested for the purpose of compelling attendance of a witness at the hearing, a request would be timely if received at least 45 days before the scheduled hearing. The Board could not issue a discovery subpoena any later than 75 days before the initial scheduled hearing date, and could not issue a hearing subpoena any later than 30 days before the scheduled hearing. The Board would have discretion to extend the timeframes for requesting subpoenas. The Board would also have the authority to issue subpoenas to non-parties. Finally, only the Administrator would have the authority to seek enforcement of a Board subpoena.

We have adopted our proposals, with some modifications. Some of the modifications are parallel to those revisions we made to our discovery proposals in § 405.1853(e). That is, in § 405.1857(a)(2)(i), we revised the deadline by which a request for a subpoena for discovery must be received by the Board, from 90 days before the scheduled starting date of the Board hearing, to 120 days of the initially scheduled starting date of the hearing. The revised time period essentially mirrors the time period for requesting discovery under § 405.1853(e)(3)(i). As explained in section II.N. of this final rule, we decided to use the initially scheduled starting date of the hearing as the focal point, because using the actual hearing date as the focal point would mean that

a new discovery period could be obtained any time the hearing is rescheduled, and we also wish to focus the parties' attention on discovery early in the appeals process. Because we revised the deadline by which the Board must receive a request for subpoena for discovery, we have also revised the deadline for issuing a subpoena, from 75 days before the scheduled starting date of the Board hearing to 90 days before the initially scheduled starting date of the Board hearing. Like the deadline for seeking discovery, however, under this final rule, the deadlines for requesting a Board subpoena for discovery and for the Board to issue a subpoena for discovery, are subject to extension by the Board in its discretion. Likewise, if the Board extends the period for requesting or issuing a subpoena, the Board has the discretion to reschedule the hearing date. The extension procedures also apply to requests for, and issuances of, Board subpoenas for purposes of an oral hearing. (See § 405.1857(a)(4).) We have also made a clarifying change to proposed § 405.1857(d)(2)(v). With respect to the situation where a party or non-party seeks immediate review of a Board subpoena, and the Administrator may, but chooses not to, grant or take own motion review of the subpoena, we have revised the language that stated "the Board's action stands" to "the Board's action is not immediately reviewable." The revision was made in recognition of the fact that the Administrator could review the subpoena in the course of review of a final decision made by the Board. We clarified language in § 405.1857(b)(3) that suggested the Board "must comply" with the FRCP and the Federal Rules of Evidence for guidance. As revised, this paragraph states that the Board "uses" such authorities for guidance.

Finally, we are adding language to proposed § 405.1857(a)(1)(i) to clarify that the Board may not issue a subpoena to CMS or to the Secretary (or to any Federal agency), and we are also removing the references to HHS and CMS in proposed § 405.1857(c)(4), redesignated to § 405.1857(c)(3), in order to prevent any implication that the Board may issue a subpoena to CMS or to the Secretary.

Comment: One commenter stated that an incomplete or late response, or no response at all, to a timely-filed request for discovery should be grounds for an extension of a subpoena request.

Response: Proposed § 405.1857(a)(4) would have allowed the Board, for good cause, to extend the time for requesting or issuing a subpoena. On reexamination of our proposal, we

believe that the Board should be allowed to extend the time for requesting or issuing a subpoena without requiring a showing of "good cause." We do not believe, however, that it is advisable to state that a late or incomplete response, or a non-response to a discovery request, will necessarily lead to an extension of the time to request or issue a subpoena. Rather, in any given case, the Board should evaluate the circumstances before it, and exercise its discretion to allow or disallow an extension for requesting a subpoena, or for permitting itself an extension for issuing a subpoena. We have also decided, for the reasons stated above with respect to the time for requesting and completing discovery, to modify the proposed timeframes for a party to request a subpoena for purposes of discovery and for the Board to issue a subpoena for that purpose. Under the final rule at § 405.1857(a)(2)(i), a party may request a subpoena for purposes of discovery no later than 120 days before the initially scheduled starting date of the Board hearing, and, at § 405.1857(a)(3)(i), the Board may issue a subpoena for that purpose no later than 90 days before the initially scheduled starting date of the Board hearing.

Comment: One commenter opposed the proposal that a Board subpoena may be enforced only by the Administrator. The Board's decision to seek enforcement is interlocutory (that is, non-final) in nature, and therefore is not subject to immediate review by the Administrator. Moreover, even if the Administrator otherwise could review a non-final decision by the Board, section 1878(e) of the Act grants the Board sole authority to decide to initiate judicial action to enforce a Board subpoena.

Response: For the reasons stated in section II.T. of this final rule, we disagree that the Administrator lacks the authority to review non-final orders of the Board. We also disagree that section 1878(e) of the Act grants the Board sole authority to decide whether to pursue judicial enforcement of one of its subpoenas. Under the commenter's view, the Administrator could reverse a decision of the Board on the merits, but would be unable to prevent the Board from seeking any enforcement action that the Administrator would believe was inconsistent with law or agency policy. This position contravenes the well-established principle that the Administrator, on review of Board actions, has all of the powers that the Administrator would have had in making the initial decision. (*See Homan & Crimen v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980); 5 U.S.C. 577(b).)

Moreover, the statute plainly grants the Secretary, and by extension the Secretary's designee, that is, the Administrator, the authority to issue subpoenas and seek enforcement of them, as sections 205(d) and 205(e) of the Act have been incorporated into title XVIII of the Act through section 1872 of the Act. It is not clear how litigation to enforce a subpoena could proceed on behalf of the Administrator if the Administrator, as the Secretary's designee, were opposed to bringing that action.

Comment: One commenter commended us for proposing that non-parties may be subpoenaed by the Board. Another commenter stated that the rule should expressly acknowledge that the Board has the power to subpoena HHS and other government agencies. A provider's appeal rights under section 1878 of the Act would be rendered meaningless if the Board lacked the power to subpoena relevant and material evidence from HHS. This is particularly important in cases where CMS has rendered the determination at issue. Another commenter objected to the proposal that the Administrator may review and overrule a Board decision to subpoena a witness or documents as an affront to the Board's independence. This commenter was concerned that the Administrator might abuse this power to avoid having CMS policy experts testify before the Board.

Response: For the reasons stated in the Administrator's Order dated July 29, 2004, in *Baystate Medical Center v. Mutual of Omaha* (PRRB Case Nos. 96–1822, 87–1579), and in the Administrator's Order dated November 20, 2006, in *Duane Morris Outpatient Blended Rate Group v. Blue Cross Blue Shield Association* (PRRB Case No. 06–2057G), we believe there is no statutory basis for the Board to subpoena HHS and other Federal agencies. The United States and its agencies, as sovereign, are immune from suit, except to the extent to which they consent to be sued. It is also well-settled that a waiver of sovereign immunity "cannot be implied, but must be unequivocally expressed." (*See Franconia Associates v. United States*, 536 U.S. 129, 141 (2002).) There is no indication in the language of sections 205(d) and 205(e) of the Act, or in the legislative history of those sections, that the Congress intended to effect a waiver of sovereign immunity. (Indeed, the fact that the party seeking to enforce the subpoena would be a Federal agency makes it even more unlikely that the Congress intended to waive sovereign immunity, for it cannot be lightly assumed that when the Congress enacted sections 205(d) and (e)

in 1939, it intended to allow one agency to sue another agency.) To the contrary, the use of the words "individual" and "person" in sections 205(d) and 205(e) of the Act indicate that the Congress did not intend to waive sovereign immunity. It is a well-settled rule of statutory construction that "person" does not include the sovereign, unless the statute affirmatively provides otherwise, and this rule is particularly applicable where it is claimed that the Congress intended to waive sovereign immunity. (*See Will v. Michigan Dep't of State Police*, 491 U.S. 58, 64 (1989).) Because the Congress did not waive sovereign immunity in sections 205(d) or 205(e) of the Act, it did not waive it in section 1878(e) of the Act (which grants the Board the subpoena powers contained in sections 205(d) and 205(e)). Because only the Congress, and not Federal agencies, has the authority to waive sovereign immunity, (*see United States v. N.Y. Rayon Importing Co.*, 329 U.S. 654, 660 (1947)), we would be unable to subject HHS and other agencies to the Board's subpoena authority even if we were otherwise so inclined.

We are adding language to proposed § 405.1857(a)(1)(i) to clarify that the Board may not issue a subpoena to CMS or to the Secretary (or to any Federal agency), and we are also removing the references to HHS and CMS in proposed § 405.1857(c)(4), redesignated to § 405.1857(c)(3), in order to prevent any implication that the Board may issue a subpoena to CMS or to the Secretary.

Although the Board does not have the authority to subpoena HHS and other Federal agencies, we do not agree with the commenter that a provider's appeal rights are rendered meaningless in the absence of that authority. In cases in which the provider believes it is necessary to obtain information from HHS (including CMS), the provider may gain access to information through the Freedom of Information Act, which is applicable to all Federal agencies. Most, if not all, agencies (including HHS) also have "Touhy regulations," by which agencies may make documents or witnesses available to the requester if sufficient need is shown, and other criteria are satisfied. Finally, upon review of a final decision of the Board or the Administrator, a court may order that the record be supplemented with additional information.

Comment: Several commenters, in identical language, said that the proposed duration of the automatic stay (no more than 15 days for Board proceedings and no more than 10 days for intermediary hearing officer(s) proceedings) is too strict and that it

would be more effective to have the automatic stay for Board and intermediary hearing officer(s) proceedings last no more than 30 days and 15 days, respectively.

Response: The commenters misunderstood our proposals. We proposed that the duration of the automatic stay could be no less than 15 days for Board proceedings. In proposing a minimum length for the stay, we wanted to ensure that the Administrator would have sufficient time to decide whether to take review of the matter before the stay had expired. We continue to believe that the proposed periods are sufficient. With respect to the commenters' suggestion that the automatic stay not last more than 30 days for Board proceedings, and not more than 15 days for intermediary hearing officer(s) proceedings, we decline to restrict the Board from initially setting a longer stay than the minimum period prescribed, in order to address the possibility that, due to unusual circumstances, the Board may believe that a longer period is needed for a party to seek review of the subpoena and for the Administrator to decide whether to take review. Likewise, we believe that, as we proposed, if the Administrator decides to take review, the stay should continue until the Administrator issues a decision on the matter, rather than prescribing a set period for which the Administrator may rule, as some cases may be more complex than others, and the Administrator's other review responsibilities may be more voluminous at one time compared to another.

P. Record of Administrative Proceedings (§ 405.1865 and § 405.1827)

We proposed to amend § 405.1865 to address with specificity the required contents of the record on appeal and to explain how excluded material is to be treated. In particular, we proposed to specify that all evidence, argument and any other tangible material (admissible or inadmissible) received by the Board, as well as a transcript of the proceedings of any oral hearing before the Board, would be made part of the record of the appeal. Any evidence ruled inadmissible by the Board, and any other material not considered by the Board in making its decision, would, to the extent practicable, have to be clearly identified and segregated in an appendix to the record for the purpose of any review by the Administrator and/or the judiciary. We further proposed that, for purposes of Administrator review, the administrative record would also include all documents and any

other tangible matter submitted to the Administrator by the parties to the appeal or by any non-party, in addition to all correspondence from the Administrator or the Office of the Attorney Advisor and all rulings, orders, and decisions by the Administrator. We also proposed that the Administrator would have the authority to reverse the Board's determination regarding the admissibility of evidence or other matter. Additionally, we proposed corresponding changes, in part, to § 405.1827, relative to the record established at intermediary hearings. We are adopting our proposals.

Comment: One commenter stated that the proposed revision to allow the Administrator to reverse Board determinations on evidence and unilaterally include or exclude evidence could cause the entire administrative process to be viewed negatively. If the Administrator is given the authority to dismiss evidence after the hearing decision has been rendered, there should be a process provided for provider rebuttal or alternative arguments to be filed on the record prior to proceeding to judicial review.

Response: Our proposal was facially neutral, in that it would permit the Administrator to include, where appropriate, evidence that the intermediary or provider wanted included (but that was excluded by the Board), or to exclude, where appropriate, evidence that the intermediary or provider wanted excluded (but that was included by the Board). Because, under longstanding policy, the Board employs a relaxed standard for the introduction of evidence (rather than following the Federal Rules of Evidence), we believe there will be relatively few instances in which the Board does not allow evidence that should have been allowed, or includes evidence that should not have been allowed. In those relatively few instances, however, in which the Board makes an improper (in the Administrator's view) ruling on an evidentiary matter, it is appropriate that, where practicable, the Administrator, as the final agency arbiter, includes within, or excludes the evidence from, the record. Where the Administrator takes review of a case, the parties may comment on the Board's decision, including whether evidence that was excluded by the Board should have been included, and whether evidence that was included by the Board should have been excluded. If the provider does not agree with the Administrator's ruling as to the composition of the record, it may pursue its objections with a court. We believe that, in most cases, a provider

will have advance notice as to any issues concerning the inclusion or exclusion of evidence, but in any instance the provider believes that it was surprised by the Administrator's action, it is adequately protected by pursuing its judicial remedies (it may also seek reopening from the Administrator). We note that in any case in which the Administrator takes review, his or her precise reasoning on legal or policy issues or on the weight to be given certain evidence may be unanticipated by a provider, yet there has never been (nor, we submit, a need for) a formal process to make objections prior to seeking judicial review.

Q. Board Actions in Response to Failure To Follow Board Rules (§ 405.1868)

In the proposed rule, we sought to specify how the Board would exercise its authority under section 1878(e) of the Act to respond to: (1) Intentional delaying tactics by a provider or intermediary; or (2) a failure by the provider or intermediary to timely heed a Board order or rule. We proposed that, if a provider fails to meet a filing or procedural deadline or other requirement set by the Board, the Board may dismiss the hearing request or take other appropriate action. We also proposed that, if the intermediary failed to meet any filing or procedural deadlines or other Board requirements, the Board would have the right to issue a decision based on the written record submitted to that point or to take other appropriate action. (We note, however, that the text of the proposed rule inadvertently failed to reflect this specific proposal, which we have adopted and incorporated into the text of this final rule.)

We have adopted our proposals. We have clarified that the Board's authority, in the situation where an intermediary fails to meet a filing deadline or other requirement established by the Board, does not extend to, as a sanction, reversing or modifying the intermediary or Secretary determination or ruling against the intermediary on a disputed issue of law or fact. We have renumbered proposed § 405.1868(d)(3) as paragraph (e) and made corresponding numbering changes. We have also added paragraphs (f) and (g) as a result of adopting the first and second of our "Three Additional Proposals Under Consideration" (see section II.W. of this final rule). We have also corrected a citation error in § 405.1868(d)(2), which referred to a Board dismissal decision "under [non-existent] paragraph (f)(1) of this section."

Comment: One commenter suggested that, although the provider may be penalized with a dismissal sanction, there is no corresponding sanction for an intermediary. The commenter noted that an intermediary could deliberately fail to file a position paper, have the case heard and decided on the record, and then submit a motion for CMS Administrator review with no provider rebuttal. The commenter believes that the only way the intermediary sanction provision could be effective is if the intermediary would not be allowed to request Administrator review. Another commenter noted that the proposed rule lacked an appropriate sanction against the intermediary for failing, for example, to meet filing deadlines. The commenter suggested that the Board should try to motivate the intermediary into compliance by barring the intermediary from submitting certain evidence, or limiting the materials that the intermediary could submit. Another commenter supported the intermediary sanction proposal and suggested that an intermediary's failure to follow a Board order should be entered in the written record of the proceedings and passed along to CMS as a potential contract violation.

Response: After reviewing all the comments, we are adopting the proposals that we set forth in the proposed rule. Most of the comments we received on this subject came from providers, and reflect a perceived disparate treatment by the Board when a provider, rather than an intermediary, fails to follow a procedural rule or timeframe set by the Board. We proposed two possible actions by the Board, one applicable to a provider and the other applicable to an intermediary. That is, the worst case scenario for a provider would be a dismissal of the appeal by the Board, while the harshest remedy for an intermediary would be the issuance of a decision by the Board based on the written record established at the point of the intermediary's violation. However, we note that, because providers are the proponents of a case, they are responsible for moving the case forward by meeting all deadlines. Additionally, at section 1878(e) of the Act, the Congress has given the Board authority to make rules and establish procedures to carry out its function. Moreover, we note that the Board will have broad discretion to weigh the particular facts at hand in order to decide whether or not an offense merits remedial action. We disagree with the commenter that suggested that an intermediary should not be allowed to request Administrator

review if the Board has sanctioned the intermediary and issued a decision on the record. The commenter is incorrect in suggesting that the provider would be unable to rebut the intermediary's position at the Administrator level. It has been longstanding policy that, when the Administrator accepts review, each party may rebut the other party's legal arguments (although the parties are prohibited from submitting additional factual evidence that is not within the record). Moreover, we believe that any sanction assessed by the Board against a party should factor into a reviewing entity's deliberations. For example, where the Board issues a decision based on the written record because an intermediary did not file a position paper, the Administrator, upon review, may look unfavorably at the intermediary's inaction.

We also disagree with the commenter that believed that the proposed rule did not provide for an effective sanction against the intermediary. Again, we are clarifying that the proposed rule did not identify a complete listing of all potential Board sanctions. The Board has the authority to take appropriate action against either party for procedural violations, but appropriate action does not necessarily mean a dismissal or the early issuance of a decision by the Board. We believe that these provisions will alert both parties that the Board has a mechanism in place to effectively stop a delaying tactic, or to redress other procedural violations. As a result, the parties should be less inclined to ignore procedural requirements and, accordingly, be more motivated to meet the deadlines set by the Board.

Finally, we agree with the commenter that suggested that if an intermediary failed to abide by an order of the Board in a timely fashion, the Board could pass along that information to CMS as a possible contract violation. In § 405.1868(c)(2), we codify the Board's ability to take this action.

Comment: One commenter noted that intermediaries often miss Board deadlines for filing position papers, leaving providers unaware of the arguments the intermediary intends to use at the hearing. The commenter suggested that the final rule should require the Board to bar an intermediary from submitting late evidence and arguments, unless there is a showing of good cause. Another commenter suggested that the intermediary's evidence should be excluded from the hearing when the intermediary is noncompliant with Board rules.

Response: We believe that the Board's authority to sanction either party

pursuant to section 1878(e) of the Act will serve as a strong impetus for the parties to customarily respond in a timely manner to Board-ordered deadlines. As to the commenters' suggestions regarding the possible exclusion of evidence, we note that it is within the Board's discretion to decide whether a party should be barred from submitting late evidence and arguments.

Comment: Two commenters noted that, contrary to our stated intention in the preamble, the proposed regulations text at § 405.1868(c) did not specify that the Board may issue a decision based on the written record to that point when the intermediary fails to meet a filing or procedural deadline set by the Board.

Response: We agree with the commenters and have added new text at § 405.1868(c)(1) to specify that the Board may issue a decision based on the written record when the intermediary fails to meet a filing deadline or other procedural requirement imposed by the Board.

Comment: One commenter noted that, when an intermediary fails to comply with a Board order or deadline, and the Board issues a decision based on the written record, upon review, the Administrator will remand all these cases back to the Board to consider additional arguments. The commenter suggested that, due to intermediary non-compliance, when the Board decides to close the record and issues a decision based on the written record to that point, the Administrator should not be able to remand the case to the Board or consider the arguments not in the record.

Response: We do not agree that in this situation the Administrator would always remand a case back to the Board to consider any missing arguments. We believe that if the Board issues an early decision based on the written record because of an intermediary violation, the Administrator, on review, may regard the intermediary violation in a negative light. Therefore, we would not expect that the Administrator would necessarily remand the matter to the Board for further evidence, unless the Administrator believes that the Board's decision to close the record itself was erroneous.

R. Scope of Board's Authority in a Hearing Decision (§ 405.1869 and § 405.1829)

Section 1878(d) of the Act provides that the Board has the authority to affirm, modify, or reverse the intermediary's findings on each specific matter at issue in the intermediary's determination and to make other revisions on specific matters, regardless

of whether the intermediary has considered those matters in making its determination. In the proposed rule, we sought to clarify that the Board's power to make additional revisions would not authorize the Board to consider or decide a specific matter at issue for which it lacked jurisdiction or for which it was not timely raised in the hearing request. Additionally, we proposed revising the title of § 405.1829 and made certain corresponding changes to this section relative to intermediary hearings. We are adopting our proposals. We have deleted paragraphs §§ 405.1869(b)(2)(i) and (b)(2)(ii) as superfluous.

Comment: One commenter suggested that, because the Board has the authority to affirm, modify, or reverse an intermediary's determination and to make additional revisions, regardless of whether the intermediary considered those matters, the Board should likewise have the authority to direct intermediaries to make reopenings necessary to effect the "flow-through" of issues affecting multiple years. For example, a reversal of interest capitalized by the intermediary in one year, but not subsequently amortized by the provider pending the outcome of the appeal, should be corrected for all years involved.

Response: We disagree with the suggestion that the Board has, or should have, any authority to direct intermediaries to reopen to effect the "flow-through" of issues impacting multiple years. The Board's authority is limited by statute to ruling on appeals that have been brought before it. Therefore, the onus is on the provider to identify, on an annual basis, any disputed items on its cost report for that particular cost year, and, if it chooses, and the amount in controversy requirement is met, to file an appeal before the Board for that cost year. The Board is not empowered to rule on cost years not before it, and generally lacks any equitable powers to direct an intermediary to take any specific action. Moreover, even if we had the authority to confer upon the Board the authority to direct the intermediary to reopen previous cost years, we would not do so. Reopenings generally have been a matter of intermediary discretion, and have not been used as a substitute for appeals. We do have the authority to direct intermediaries to conduct reopenings where we provide explicit notice to the intermediary that the intermediary's determination was inconsistent with the applicable law, regulations, CMS Ruling, or CMS general instructions in effect, based on our understanding of those legal

provisions at the time that the intermediary determination was made (and not based on any change in policy, whether self-realized or directed by a court).

Comment: Two commenters suggested that the proposed clarification would be inconsistent with the plain meaning of section 1878(d) of the Act, because it imposes impermissible limits on the Board's statutory authority to consider all matters covered by the cost report. One of the commenters believed the policy directly contravened the decision by the D.C. Court of Appeals in *HCA Health Services of Oklahoma v. Shalala*, 27 F.3d 614 (D.C. Cir. 1994). In that case, the court stated that "once Board jurisdiction pursuant to subsection (a) [of section 1878 of the Act] obtains, anything in the original cost report is fair game for a challenge by virtue of subsection (d)."

Response: We disagree with the suggestion that our proposal, specifying that the Board can only make additional revisions to an intermediary determination when it has jurisdiction to grant a hearing on the issue and the issue has been timely raised, is inconsistent with the statute. As we stated in our discussion of "Adding Issues to Original Hearing Request" in section II.D., the straightforward language of section 1878(d) of the Act grants the Board the authority to consider a wide range of issues, but does not address the timing for the inclusion of issues. The statutory provision relating to the timing of an appeal is located at section 1878(a)(3) of the Act, wherein it is clearly stated that a provider has the right to request a Board hearing within 180 days after notice of the final determination. Thus, if a provider does not indicate to the Board in a timely fashion that it is dissatisfied with a certain aspect of the final determination, the provider does not satisfy one of the key components for establishing jurisdiction, that is, timeliness. Accordingly, the provider will be unable to dispute that particular issue before the Board. Moreover, we believe that the Board must obtain jurisdiction over an issue before it can rule on the issue. If the Board decides that it lacks jurisdiction over a particular issue, it cannot entertain that issue, despite the language contained in section 1878(d) of the Act. We read section 1878(d) of the Act as permitting the Board to make revisions to cost report line items that flow directly from determinations in which the provider has expressed dissatisfaction and filed a jurisdictionally proper appeal under section 1878(a) of the Act. See *Little Co. of Mary Hosp. and Health Care Ctrs. v.*

Shalala, 828 F. Supp. 570, 576 (N.D. Ill. 1993), *aff'd* 24 F.3d 984 (7th Cir. 1994).

Finally, we disagree that our proposed clarification is contrary to the decision in *HCA Health Services of Oklahoma v. Shalala*. The timing of a request for an appeal is critical to establishing jurisdiction. If a provider does not timely express dissatisfaction to the Board of a particular matter in a final determination and, therefore, does not establish jurisdiction before the Board over that matter, the provider cannot then seek to rely upon section 1878(d) of the Act for relief.

S. Board Hearing Decision and Intermediary Hearing Decision (§ 405.1871, § 405.1831 and § 405.1833)

We proposed to require that the Board's decision, with respect to any issue for which the policy expressed in a CMS instruction (other than a regulation or CMS Ruling) is dispositive, but for which the Board did not affirm the intermediary's adjustment, explain how the Board gave great weight to such instruction (as required by § 405.1867), but did not affirm the intermediary's adjustment.

We are adopting our proposals. We are amending proposed § 405.1871(a)(4) to state that where the Board's decision reverses or modifies an intermediary determination on an issue for which the policy expressed in an interpretive rule (other than a regulation or a CMS Ruling), general statement of policy or rule of agency organization, procedure or practice established by CMS would be dispositive of that issue (if followed by the Board), the Board decision must explain how it gave great weight to such interpretive rule or other such instruction but did not uphold the intermediary's determination on the issue. We are also revising the reference to "general CMS instructions" in proposed § 405.1871(a)(4) to read "other interpretive rules, general statements of policy, and rules of agency organization, procedure or practice established by CMS." We are making a similar change to other sections in the proposed regulations text where the term "general CMS instructions" appeared.

Relative to intermediary hearings, we have made a technical change to § 405.1831(d) concerning the component within CMS to which intermediary hearing officer decisions should be sent. As the CMS Office of Hearings neither currently receives nor reviews such decisions, we amended this provision to indicate that the decisions should be sent to CMS (currently, the decisions are received by the Center for Medicare Management, a component within CMS). Additionally,

we revised § 405.1833 to clarify that an intermediary hearing decision is final and binding unless the decision is reviewed by a CMS reviewing official. Also, intermediary hearing decisions are subject to the provisions of § 405.1803(d).

Comment: One commenter recommended that the preponderance of the evidence standard of proof be replaced with the Generally Accepted Government Auditing Standards' standard, which is "sufficient, competent, and relevant evidence that would persuade a reasonable person of the validity of the findings." Because CMS has issued manual instructions to comply with Government Auditing Standards, it would be inappropriate to impose a higher standard of proof in the appeal than required by auditing standards.

Response: We are not adopting the comment. We believe the preponderance of the evidence standard to be well-understood and widely used by administrative and judicial tribunals. We do not see any inconsistency between Government Auditing Standards, which pertain to whether audit findings are valid, and our proposal, which pertains to the determination of whether the provider has ultimately met its burden of proof regarding a certain issue.

Comment: Two commenters objected to the statement in the preamble that the Board would be required to explain how it has given great weight to CMS instructions (other than regulations and CMS Rulings) when declining to uphold an intermediary's adjustment. The first commenter stated that it was not clear to which instructions the statement was referring. Moreover, according to the commenter, we have failed to identify any valid reason why the Board should give CMS instructions any weight beyond whatever weight they deserve by reason of their own inherent power to persuade. Only substantive rules that have gone through notice and comment rulemaking have the force and effect of law. The second commenter stated that the proposal was inconsistent with the requirements of the Administrative Procedure Act and offends the authority and independence of the Board. In this commenter's view, the Board should merely be required to acknowledge that it had considered and given weight to the instructions. According to this commenter, the proposal suggests that the Administrator will have grounds to reverse the Board's decision if the Board does not follow the instructions, raising this to the same level as statutes or regulations.

Response: Existing § 405.1867 (issued in 1983) provides that "the Board must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as CMS Rulings" and that "[t]he Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure or practice established by CMS." We did not propose to change this provision and we are not doing so. The purpose of the proposal was to require the Board, in order to facilitate Administrator or court review, to explain, where a CMS instruction was seemingly on point, how the Board complied with the existing requirement that it give great weight to the instruction, but nevertheless reversed an intermediary's adjustment. With respect to the commenter's point that it was not clear to which instructions we were referring, the final rule, at § 405.1871(a)(4), uses the language "an interpretive rule (other than a regulation or CMS Ruling), general statement of policy, or rule of agency organization, procedure or practice established by CMS."

We are unsure of the meaning of the first commenter's statements: (1) That we had failed to identify a valid reason why the Board should give CMS instructions any weight beyond whatever weight they deserved by reason of their own inherent power to persuade; and (2) that only substantive rules that have gone through notice and comment rulemaking have the force and effect of law. To the extent that the commenter was arguing that we were proposing that CMS instructions (other than regulations and CMS Rulings) were binding on the Board, this is incorrect. Under current § 405.1867, CMS instructions (other than regulations and CMS Rulings) are not binding on the Board, but rather must be given great weight by the Board, and, again, we did not propose to change this regimen. In many cases, if an instruction is squarely on point and is given great weight by the Board, the instruction may be determinative of the outcome. However, that is not always the case (hence our proposal to explain how an instruction was given great weight but was not determinative). If the commenter was asserting that only substantive rules that have gone through notice and comment rulemaking are entitled to some level of automatic deference by the Board, we disagree. As noted above, § 405.1867 has long provided that CMS instructions other than regulations or CMS Rulings are entitled to great weight by the Board. Moreover, CMS Rulings and some regulations are not substantive (that is,

legislative) rules, and yet CMS Rulings and all CMS regulations are binding on the Board under § 405.1867. Finally, we note that courts are required to give controlling weight to an agency's interpretation of its regulations, unless plainly erroneous or inconsistent with the regulation. See *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994). It would be anomalous if the Board were not required to give great weight to a manual instruction that (unless plainly erroneous or inconsistent with the regulation) would be given controlling weight by a court.

Comment: One commenter suggested a refinement in the proposal that the Board must explain how it gave great weight to a CMS instruction (other than a regulation or CMS Ruling) that would be dispositive of the issue if followed by the Board but nevertheless did not uphold the intermediary's determination. The commenter stated that the requirement should be limited to published instructions distributed or available to providers, which would include policy positions published in the **Federal Register**, but which would not include individual letters to CMS internal components or to other individuals.

Response: By "instructions," we mean an interpretive rule (other than a regulation or CMS Ruling), general statement of policy, or rule of agency organization, procedure or practice established by CMS. The Board is already required, by virtue of § 405.1867, to give great weight to these instructions. For purposes of our proposal, we do not believe it is necessary or advisable to amend the types of instructions for which the Board is required to give great weight.

Comment: One commenter stated that there should be a deadline for decisions to be made by the Board from, as applicable, the date of the hearing, the date of the agreement for an on-the-record hearing, or the date a jurisdictional challenge is submitted. A deadline would assure all the parties that the Board's decision would be issued by a certain date, that follow-up from all parties would not be necessary, and that cases would not get lost in the system. The same commenter also recommended that "the instructions" include various timeframes as guidelines for the Board to follow, which would increase the efficiency of monitoring the cases for all parties.

Response: We decline generally to prescribe by rule the time by which the Board must issue decisions. We believe the Board is in the best position to manage its own docket and determine when it can issue decisions. Some cases

will be more complicated than others or otherwise will take longer to resolve. For example, Board members may or may not be in complete agreement about all of the issues, or there may be Board vacancies that may affect the quorum necessary for issuing a decision. This rule does prescribe the time for the Board to issue an EJR decision (or a determination that the request for EJR is incomplete), because the statute places a time limit on the issuance of EJR decisions by the Board.

T. Administrator Review (§ 405.1875)

In the proposed rule, we offered clarifications to the existing procedures for obtaining Administrator review of a Board decision. For example, we proposed to clarify that the date the Administrator decision is rendered is the date the Administrator signs the decision, not the date the decision is mailed. We also provided a list of the types of final Board decisions that would be subject to immediate review by the Administrator. In addition, we specified that the Administrator would have the authority to remand a matter not only to the Board, but also to any component of HHS or CMS, or to an intermediary.

We are adopting our proposed clarifications. In § 405.1875(b)(1) and § 405.1875(b)(5), pertaining to the illustrative list of criteria for obtaining Administrator review, and in § 405.1875(e)(3)(i), relating to the authorities upon which the Administrator's decision may rely, we have made a technical change, replacing "general CMS instructions" with "other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS." In § 405.1875(e)(3), we revised the language that stated the Administrator's decision "must" rely on certain authorities to the Administrator's decision "may" rely on those authorities, in order not to suggest that the Administrator's decision must rely on an authority (such as a prior decision of the Board), that is on point but not persuasive. (Note that current § 405.1875(g)(4) states that the Administrator "may" rely on prior decisions of the Board, the Administrator and the courts.) We have also made certain organizational changes to paragraphs § 405.1875(c)(1) and § 405.1875(c)(2), moving material from § 405.1875(c)(2) to § 405.1875(c)(1), and have made a number of minor wording changes.

Comment: A commenter objected to our proposal to add § 405.1875(f)(5) to state that the Administrator has the authority to remand a matter to a

component of HHS, CMS, or to an intermediary under appropriate circumstances (including, but not limited to, the purpose of implementing a court's order). According to the commenter, the proposal is inconsistent with section 1878(f) of the Act, which states that a decision of the Board will be final, unless the Administrator reverses, affirms, or modifies the Board's decision. If the Administrator disagrees with the Board's determination, the Administrator can take necessary action without further delaying provider appeal rights. There is no need for the Administrator to remand to a lower component of his or her own agency to obtain necessary input. This commenter also disagreed with our proposal to revise § 405.1877(b) to state that an Administrator remand of a Board decision is not subject to judicial review. The commenter believes that the proposal is without legal support of any kind, and is simply intended to delay indefinitely providers' judicial appeal rights.

Response: We recognized in the proposed rule that there is a split of authority on the issue of whether the Administrator has remand authority. We continue to believe, however, that the better view is that he or she does. See *Gulf Coast Home Health Services, Inc. v. Califano*, 1978 U.S. Dist. LEXIS 15069 (D.D.C.). From a textual point of view, the fact that section 1878(f) of the Act states that the Secretary may affirm, reverse, or modify a decision of the Board does not mean that the Administrator (as designee of the Secretary) may not also take the lesser action of remanding a case to the Board. We also discern no reason why the Congress would have wanted the Administrator to issue a final decision in a case that the Administrator believed needed further development. The Administrator and the Office of the Attorney Advisor are not well-situated to take additional testimony or develop further facts, seek additional documentation, clarify or perform additional audit findings, etc. Thus, without authority to remand, the Administrator would be forced to choose between possibly disadvantaging the program or the provider in a case that the Administrator believes is not ripe for decision, but that needs further development. In this case, if the Administrator were to issue a decision against the provider, and the provider were to appeal the decision to a court, the likely and ironic result would be that the court would remand the case back to the Administrator or the Board for further findings. In a decision issued

against the Medicare program, the program would fare worse than the provider in the first example, as CMS cannot appeal a decision of the Administrator. We believe that a more fair and efficient process is for the Administrator to retain the authority to remand to the Board for further action in appropriate circumstances. We also do not agree with the commenter's assertion that our proposed provision, that an Administrator remand order is not judicially reviewable, is without legal foundation. Remand orders of agencies and courts are interlocutory (non-final) in nature and generally are not subject to immediate review.

Comment: One commenter objected to our proposal to allow immediate Administrator review of discovery or disclosure rulings and subpoenas to which objections were made based on privilege or other protection from disclosure. According to the commenter, neither type of interlocutory (that is, non-final) appeal should be permitted, because neither type is defined by statute to be a final decision. If, however, the Administrator should be given the authority to review immediately Board rulings granting discovery or issuances of subpoenas, the Administrator should also have the authority to review Board rulings denying a discovery request or a request to issue a subpoena.

Response: We believe that our proposal is consistent with the statute, because the statute does not specifically prohibit the Administrator from taking immediate review of non-final Board rulings. We also note that the Administrator, on review of Board actions, has all of the powers that he or she would have had in making the initial decision. See *Homan & Crimen v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980); 5 U.S.C. 577(b). Thus, we believe that, just as the Board has the authority to rule on discovery or subpoena matters, so too does the Administrator. In the proposed rule, we explained that it was important that the Administrator be able to take immediate review of Board rulings granting discovery or issuing a subpoena over an objection based on privilege or other protection from disclosure because, once complied with, any harm from an inappropriately ordered disclosure cannot be undone. Experience has shown that objections based on privilege or other protection from disclosure will be infrequently made, but, where asserted, will be made in a good faith belief that disclosure will be unduly burdensome or harmful. Moreover, we believe that objections will be made most often by CMS, or by intermediaries on behalf of CMS, with

respect to CMS records in the custody of intermediaries. Because the Board has no statutory authority to compel production of CMS records (including records subject to the Privacy Act), we believe it is appropriate, as a condition to allowing the Board under our regulations to compel the intermediary to produce CMS records, that the Administrator reserve the right to review immediately a Board order compelling production of CMS records.

We are not adopting the commenter's suggestion that Board orders denying discovery should be subject to immediate review. Although we recognize that, in some cases, it may be inconvenient for an intermediary or provider to proceed with its case without discovery that was requested but inappropriately denied, we believe that the potential inconvenience does not rise to the level of the potential harm that could result from inappropriate disclosures, and thus do not believe that the Board proceedings should be potentially disrupted by appeals of Board orders denying discovery or subpoenas, or that it would be a wise use of CMS's resources to present these appeals to the Administrator for his immediate review. Where the Board denies a party's request for a Board order granting discovery or its request for the Board to issue a subpoena, the party may raise the issue, if necessary, in an appeal of the final decision of the Board to the Administrator or to a court, as applicable.

Comment: One commenter objected to the proposal that the date of the Administrator's decision, for purposes of meeting the 60-day requirement in section 1878(f)(1) of the Act is the date it is signed, instead of the date it is mailed or transmitted. This commenter believes that a signed, but untransmitted, decision is not official and can be withdrawn, changed, or otherwise modified before transmission. Further, the date of mailing or transmission is not subject to tampering and can easily be confirmed. Any internal problems with obtaining timely Administrator decisions or transmission following signing should be the responsibility of the agency, and these shortcomings should not prejudice the providers. Use of the date signed, rather than transmitted, is inconsistent with compliance for every other deadline associated with these rules.

Response: We are adopting our proposal without change. The statute requires that the Board's decision will be final unless the Administrator, within 60 days after the provider of services is notified of the Board's

decision, "reverses, affirms or modifies the Board's decision." We believe that upon the Administrator's signing of a decision, the reversal, affirmation, or modification action is complete. Our interpretation is reinforced by the statute's provision that the time for which a provider must seek judicial review of an Administrator decision does not begin to run until the provider has received the decision. Thus, we believe our proposal is consistent with the language of the statute. We note that the court in *Sun Towers, Inc. v. Heckler*, 725 F.2d 315 (5th Cir. 1984), agreed with this interpretation in rejecting the provider's argument that the Administrator's decision was untimely because it was signed before, but mailed after, the 60th day after the provider received the Board's decision. According to the court in *Sun Towers*, the plain wording of the statute requires only that the Administrator's decision be rendered within 60 days of the provider's receipt of the Board's decision, 715 F.2d at 319, that there is no additional requirement in the statute that the decision be entered on any docket or mailed within 60 days of the provider's receipt of the Board's decision, 715 F.2d at 324, and that, therefore, the Secretary's interpretation that the Administrator's decision is effective upon signing was entitled to deference, 715 F.2d at 324-25.

We are also guided by practical considerations in choosing our interpretation over any other possible interpretation. Under longstanding practice, a signed Administrator decision is returned to the Office of the Attorney Advisor for making copies and for transmitting to the parties. If the Administrator's decision had to be received by the Office of the Attorney Advisor and mailed by the 60th day, the decision would have to be signed several days in advance, thus reducing the already very constricted time period for Administrator review. Although the statute gives the Administrator 60 days after the provider receives the Board's decision to conduct review and render a decision (which by itself is very brief), the period is effectively reduced by our process for seeking Administrator review.

We believe that parties to the Board's decision should have an adequate period in which to decide whether to seek Administrator review, and that, following a notice of intent to review, the parties should have a further period to submit comments on the Board's decision. Therefore, consistent with the existing regulations, we proposed that a party to the Board's decision would have 15 days after receipt of the Board

decision to request that the Administrator review it, and that, upon notice from the Administrator of intent to review the decision, a further 15-day period for submitting comments will be granted. (Having received no comments on this proposal, we are adopting it without change.) If the Administrator decision had to be mailed by the 60th day, we would have to consider reducing the period of time in which the parties could submit comments on the Board's decision.

Finally, we disagree with the commenter that providers are disadvantaged by our proposal. Regardless of whether the Administrator has 60 days in which to sign a decision or 60 days in which to mail a decision, the provider's time in which to seek judicial review of the Administrator's decision does not run until it receives the decision.

Comment: One commenter stated that the criteria we proposed for Administrator review should be exclusive, not illustrative.

Response: We are not adopting the commenter's suggestion. Although we believe we have listed all of the reasons that would motivate the Administrator to take review, we nevertheless have chosen not to make the list exclusive. This is because there can be more reasons than we have listed, and also because we do not want to encourage any litigation on whether the reason given by the Administrator for taking review in any given case actually fits within the criteria specified. By making the list of reasons for review illustrative and not exclusive, the parties may have greater opportunity to seek Administrator review of Board decisions. This is a matter of convenience to providers, as it would allow them to appeal to the Administrator, rather than having to file a lawsuit, and is more than a convenience to the intermediaries, as the intermediaries may not appeal to court an unfavorable Board decision that becomes the final decision of the Secretary because the Administrator did not take review.

Comment: Several commenters stated that, regarding the proposal that the Administrator be able to include or exclude evidence that was excluded or included by the Board, the Administrator should only be able to rule on the record, because it is the record on which the Board based its decision, and it is the only thing a court may use to overturn a Board or Administrator decision.

Response: We believe it is appropriate that, as the Secretary's designee, the Administrator should have the final

administrative say as to whether the Board admitted evidence presented to it that it should have excluded, or excluded evidence presented to it that it should have admitted, or that the record before the Board was incomplete and should be supplemented on remand. Notwithstanding the commenters' assertions, we believe that our proposal is consistent with the authority courts have in reviewing administrative agency decisions, including decisions of the Board or the Administrator.

U. Judicial Review (§ 405.1877)

In the proposed rule, we sought to clarify the existing procedures for timely obtaining judicial review of a Board or Administrator decision. In particular, we proposed to clarify that a provider is not required to seek Administrator review in order to obtain judicial review. In the final rule, we have made certain technical changes to the proposed text, including clarifying language in § 405.1877(c)(3). We have also reorganized proposed § 405.1877(g)(2) and § 405.1877(g)(3) by reversing their order.

Comment: One commenter agreed with the proposal to clarify that, when the Administrator notifies the parties that he will review a Board decision, and does not render a decision within the 60-day period for review, the provider has 60 days from the end of the Administrator review period to file an action for judicial review.

Response: We are adopting the proposal without change. We believe that the clarification will assist providers in understanding the time period for filing for judicial review in this situation.

V. Reopening Procedures (§ 405.1885 through § 405.1889)

Reopening procedures are authorized specifically by our regulations, based on the Secretary's general rulemaking authority in sections 1102(a) and 1871(a) of the Act. The following is a non-exhaustive list of matters that we sought to clarify and revise in the proposed rule:

- CMS retains the ultimate authority as to whether an intermediary may or may not reopen a matter.
- A change in legal interpretation or policy by CMS in a regulation, CMS Ruling, or CMS general instruction (whether self-directed or influenced by a court decision) is not a basis for reopening a determination.
- CMS may direct an intermediary to reopen a determination in order to implement a final agency decision, a final court judgment, or an agreement to

settle an administrative appeal or a lawsuit.

- A decision whether to reopen or not to reopen a determination is not subject to further administrative review or judicial review.

- For own motion reopenings, the notice of reopening must be mailed no later than 3 years after the date of the determination.

- In cases not involving an allegation of fraud, a provider's request for reopening must be received no later than 3 years after the date of the determination; however, the intermediary or reviewing entity may issue the notice of reopening within a reasonable time after the expiration of the 3-year period.

- A final determination may not be reopened after the 3-year period, except where the determination was procured by fraud or similar fault.

- An intermediary may reopen a determination that is pending on appeal before the Board or the Administrator; the intermediary may also reopen a determination for which no appeal has been taken, but for which the time to appeal to the Board has not yet expired.

- An intermediary or reviewing entity is obliged to provide written notice of the reopening, allow the parties an opportunity to present additional evidence, and notify the parties at the conclusion of the reopening of the results, including any revisions.

- Any matter considered during the course of a reopening, but not subsequently revised, is not appealable through any revised determination issued after the reopening; as a corollary, the scope of appeal of a revised determination is limited to the specific revisions that were made in the revised determination.

We are adopting our proposals. We added clarifying language to § 405.1885(a) to emphasize that only the entity that made the original determination or decision may conduct the reopening of the determination or decision. We have also added clarifying language to § 405.1885(b)(2) to state that, if a request for reopening is made timely, for example, shortly before the expiration of the 3-year period specified therein, the request remains timely, notwithstanding that the notice of reopening required by § 405.1887 is issued after the expiration of the 3-year period. We also clarified in § 405.1885(b)(2) that the rules for the date of receipt of a reopening request be consistent with our revised definition of "date of receipt" at § 405.1801(a). We have also added clarifying language to § 405.1885(c)(3) to provide that a matter

may be reopened while it is pending on appeal before the Administrator.

Comment: Two commenters suggested that, if items within the scope of a reopening notice are not in fact revised, and therefore, are not appealable (because the time to appeal the original NPR has expired), providers will be forced to file concurrent appeal and reopening requests in order to protect their appeal rights. Another commenter noted that its intermediary had denied reopening requests solely on the basis that an appeal existed for that year. The commenter wanted intermediaries to be informed that an existing appeal before the Board should not be a factor in considering whether or not to accept or deny a reopening request for the same issues.

Response: Where an intermediary has issued a notice of reopening, the provider should not assume that matters within the scope of the reopening will in fact be revised. Therefore, to the extent that the appeal period has not already run by the time that the provider receives the reopening notice, the provider should file an appeal if it wishes to preserve the right to appeal matters covered by the notice of reopening. (If the time to appeal has already expired by the time the provider receives the notice of reopening, the only way in which the provider may appeal a matter addressed in the notice of reopening is if the matter is specifically revised in a revised determination issued after the notice of reopening.) With respect to the second commenter's point, and with respect to reopenings that are within an intermediary's discretion (that is, CMS has not directed the intermediary to reopen or not to reopen), we agree that an intermediary should not, as a matter of course, deny a request to reopen and revise an item simply because the item is already the subject of an appeal. However, we do not agree that the existence of an appeal or of an appeal right should never be taken into consideration by an intermediary in deciding whether to reopen. Rather, the intermediary should evaluate the totality of the circumstances surrounding the reopening request and decide whether it wishes to reopen.

Comment: Two commenters cited the 7th Circuit decision in *Edgewater Hospital v. Bowen*, 857 F.2d 1123 (7th Cir. 1989), as justification for their opposition to our proposal limiting a provider's right to appeal matters stated in a notice of reopening, but not addressed in a revised determination. One of the commenters agreed with a statement made by the court that "[i]t simply is nonsense to argue that the

only matters which the provider can appeal are those actually changed by the intermediary.” The other commenter suggested that we erroneously misread the *Edgewater* decision, asserting that our attempt to overrule binding judicial precedent was without legal authority.

Response: In the proposed rule (69 FR 35741 through 35742), we explained that the *Edgewater* decision, in which the court held that the provider was entitled to appeal issues that were within the scope of the reopening notice, but were not subsequently revised in the revised NPR, was based on the court’s reading of the regulations. We also noted that in *Edgewater*, the provider still had time to appeal the first NPR at the time that the intermediary issued its notice of reopening. The district court stated that the provider was unaware that the two cost items that it appealed (from the revised NPR) were not going to be revised until it received the revised NPR (at which time it was too late to appeal the items from the original NPR). The court of appeals indicated that its decision may have been based in part on fairness concerns.

We believe that our existing regulations were clear that only if a matter is actually revised as a result of a reopening may that matter be appealed through an appeal of the revised determination. Nonetheless, we believe that we have addressed the *Edgewater* court’s concerns in this final rule by: (1) The language in new § 405.1887(b) and new § 405.1889(b) (both of which explicitly state that a matter that was a subject of a reopening notice but not subsequently revised may not be appealed through an appeal of the revised determination); and (2) putting providers on explicit notice that if they wish to appeal an issue that is contained in an NPR, they should file a timely appeal from that NPR and not assume that the issue will be resolved in a revised NPR (even if the issue is addressed in a notice of reopening). For the sake of clarity, wherever the proposed text stated that a determination or decision was final and binding unless appealed “or reopened,” we have revised the language to read “or reopened and revised.”

As courts have noted, the reopening procedures are strictly a creature of the Secretary’s regulations, and are not required, or specifically authorized, by statute. See *HCA Health Servs. of Oklahoma v. Shalala*, 27 F.3d 614, 618 (D.C. Cir. 1994) and *Albert Einstein Med. Ctr. v. Sullivan*, 830 F. Supp. 846, 851 (E.D. Pa. 1992), *aff’d* 6 F.3d 778 (3d Cir. 1993). We acknowledge that the *Edgewater* decision was based in part on *Bethesda* and the statutory language.

(See *Edgewater*, 857 F.2d at 1132–34.) We also note, however, that the *Edgewater* court’s reasoning was specifically rejected by the Ninth Circuit in *French Hospital Medical Center v. Shalala*, 89 F.3d 1411, 1417 (1996), which relied on the Medicare regulations. (Id. at 1420 n. 11.) In designing the reopening procedures, we have chosen, as is our prerogative, to extend appeal rights only to those matters actually revised following a reopening. Although *Edgewater* stated that it was “illogical” that the plaintiff in the case before it would wish to appeal only the matter that was actually revised and not others that were contained in a notice of reopening, 857 F.2d at 1137, the issue is not what a provider wishes to appeal. Rather, the issue is what a provider should be allowed to appeal. The statute gives a provider the right to appeal matters covered by an initial intermediary determination if the amount in controversy requirement is met and the provider timely requests a Board hearing. If the provider does not pursue its statutory appeal right with respect to a certain item, it loses its right to appeal that item. That right may be resuscitated if that item is actually revised in a revised determination, because, under our longstanding policy, the revised determination is considered a separate and distinct determination to which the intermediary and Board appeals procedures (including the amount in controversy and timely request for hearing requirements) apply. If an item is not actually revised, however, there is no need to extend appeal rights to that matter simply because it was mentioned in a notice of reopening. Courts that rejected providers’ arguments that the issuance of a revised determination subjected the entire cost report to appeal did so on the basis that the statutory deadline for appealing matters would be defeated. (See *Anaheim Mem. Hosp. v. Shalala*, 130 F.23 845, 852 (9th Cir. 1997) and *HCA Health Services of Oklahoma v. Shalala*, 27 F.3d at 620–21 (and cases cited therein)). If we were to allow an appeal of a matter that is addressed in a notice of reopening but not actually revised, there similarly would be a frustration of the statutory deadline for appealing. A matter that is addressed in a reopening, but not revised, remains just as administratively final as an item not addressed in a notice of reopening. To illustrate, suppose a provider claims a certain amount of interest in connection with a borrowing, and the intermediary denies the claim on the basis that the borrowing was unnecessary. If the

intermediary later issues a notice of reopening and the interest issue is addressed in the notice of reopening, the intermediary does not send a check to the provider along with the notice of reopening. To the contrary, the claim for the interest remains denied until such time, if ever, there is a revision to the intermediary’s original adjustment. Apart from traditional notions of administrative finality, there are practical reasons for not structuring the reopening procedures to allow an appeal of a matter that is addressed in a notice of reopening but not subsequently revised. One court noted that allowing the entire cost report to be subject to appeal based on a reopening notice would discourage the Secretary from reopening determinations for fear of being forced to endure a lengthy appeals process on extraneous issues. *Albert Einstein Med. Ctr. v. Sullivan*, 830 F. Supp. at 851. Similarly, if intermediaries knew that they would have to commit resources to defending appeals on matters that are addressed in a notice of reopening but not revised, they may be reluctant to broaden the scope of the notice of reopening. In this regard, we note that there are time limits on issuing a notice of reopening, and intermediaries should be encouraged, rather than discouraged, to include matters in a notice of reopening, even if a closer examination of the matters later may reveal that no revision is appropriate, in order to preserve the opportunity to make revisions.

Comment: Some commenters suggested that there are cases where the intermediary denied valid reopening requests and believe CMS should have the authority to ascertain whether the intermediary complied with CMS policy.

Response: We retain the authority to direct intermediary reopenings; therefore, we may require an intermediary to reopen a determination of that intermediary where we believe it is appropriate (and the time for reopening has not expired).

Comment: Several commenters objected to the proposal that an intermediary denial of a reopening request would not be subject to further review. In particular, commenters suggested that a provider should be entitled to a Board hearing under § 405.1835(a) if an intermediary refuses to reopen when the rules and regulations require the intermediary to do so. It was also suggested that intermediaries have denied reopenings in the past because of personal bias.

Response: Our longstanding policy is that a “decision” to reopen or not reopen is not subject to further

administrative or judicial review. (See *Your Home Visiting Nurse Services, Inc. v. Shalala*, 525 U.S. 449 (1999).) We decline to change our policy. With respect to the suggestion that Board review should be available where an intermediary refuses to reopen, despite the fact that the regulations require the intermediary to do so, the reopening rules as amended require intermediaries to reopen only when directed by CMS to do so. We do not anticipate that intermediaries will fail to comply with a CMS directive to reopen. We have no direct or indirect knowledge of any case where an intermediary denied a reopening due to an alleged personal bias. We suggest that if a provider believes that an intermediary has refused to reopen based on a bias against the provider, the provider should contact CMS. We can investigate any allegations made by a provider, determine if they are in fact supportable and, if so, take appropriate action against the intermediary. CMS could, if appropriate, also direct a reopening.

Comment: Two commenters suggested that because an intermediary must provide written notice of its intention to reopen, it should provide notice quickly; that is, within 30 days of the provider's reopening request. One of these commenters also suggested that all reopened cost reports should be settled within 180 days of receipt of the information necessary to resolve the case.

Response: Although we encourage intermediaries to react to provider requests for reopening as quickly as possible, it would be impractical to have mandated timeframes regarding notices of intention to reopen. Intermediaries have very large workloads and cannot be expected to give immediate attention to each and every provider's written request for reopening. Moreover, as is the case with many reopening requests, an intermediary must often ask a provider to submit additional documentation in support of the provider's allegations. Thus, we do not believe that it is advisable to compel an intermediary to furnish an expedited notice of reopening following a request made by a provider. We expect that intermediaries, within a reasonable time, will either issue a notice of reopening that meets the requirements of § 405.1887, or notify the provider that the intermediary declines to reopen.

Also, due to an intermediary's large workload of cases and the highly technical nature of the cost report and audit process, we do not believe it would be prudent to set timeframes on an intermediary for the resolution of a reopened cost report. (The requirement

that a reopened cost report be resolved within a certain time may serve to discourage an already overtaxed intermediary from granting a reopening request.) Again, we note that intermediary reopenings are discretionary and, therefore, a provider reopening request should not be equated with a timely filed provider appeal request, where timeframes for action are clearly established. We suggest that if a provider believes an intermediary is purposely stalling or is acting in an improper manner relative to a reopening request, the provider should contact CMS so that we can determine if the activity is inappropriate and whether action should be initiated against the intermediary.

Comment: One commenter opposed our proposal to allow an intermediary to unilaterally reopen items on a cost report that are on appeal before the Board. The commenter suggested that we provided no rationale for this policy and cited longstanding Medicare policy that, once the Board accepts jurisdiction over an appeal, only the Board should be involved in making any further determinations on that appealed issue. The commenter believes that if the intermediary reopens while an appeal is pending before the Board, the Board could suspend the case, which would result in a slowing down of the appeals process and an exacerbation of the Board's backlog. The commenter recommended that an intermediary should reopen an issue currently pending at the Board only for purposes of implementing an administrative resolution of that issue. Another commenter suggested that allowing the intermediary to reopen an issue under appeal before the Board has the effect of circumventing the Administrator review process. The commenter suggested that if the intermediary reopens, the provider would drop the issue at the Board and the Administrator would not have the opportunity to adjudicate the issue. Another commenter suggested that it is overly burdensome to require an intermediary, during the course of an appeal, to notify the Board that a reopening has occurred for an issue that is under appeal. The commenter suggested that the provider is the proper entity to notify the Board when an intermediary reopens during an appeal.

Another commenter suggested deletion of the proposal that an intermediary may reopen a determination for which the time to appeal to the Board has not yet expired. This commenter believed the proposal serves no purpose, because a cost report can be reopened anytime within 3 years

of the date of the intermediary's determination.

Response: We disagree with the commenters that suggested that an intermediary should not be permitted to reopen a determination that is being appealed to the Board. We acknowledge that some intermediaries previously would not reopen a determination during the pendency of an appeal. However, we believe that reopening in this instance is justified because of the large volume of work at the Board and the long delays in having cases heard and resolved. Moreover, we are not aware of any legal requirement that would prohibit an intermediary from reopening in this situation. Although we do not expect intermediaries to use this authority frequently, we believe that an intermediary's ability to reopen a determination while a case is before the Board or the Administrator may, in fact, hasten the resolution of the case. We therefore disagree with the commenter that suggested that the appeals process would necessarily be slowed if the intermediary reopened prior to the case being heard. In fact, the reopening could produce a complete resolution of one or all of the issues before the Board or the Administrator.

We disagree with the commenter that suggested that a reopening by an intermediary while a case is pending before the Board would effectively circumvent the Administrator review process. First, the reopening could very well be favorable to a provider, in which case the provider would have no desire to seek Administrator review. Second, we note that any revision to a determination following a reopening may (depending on the amount in controversy remaining) trigger new appeal rights for a provider regarding the revision. If a provider elects to appeal a revised determination following a reopening, the appealed issue(s) may ultimately return to the Board and the Administrator for resolution.

We also disagree with the commenter that suggested that a provider, rather than an intermediary, is the proper party to notify the Board when the intermediary reopens during the course of a Board appeal. Regardless of any possible administrative burden, because the intermediary is the party that initiates a reopening, we believe the intermediary has an affirmative duty to notify not only the provider of the reopening, but also the reviewing entity.

Finally, we disagree with the commenter that suggested that we delete proposed § 405.1885(c)(4), which permits CMS or an intermediary to reopen a determination for which the

time to appeal to the Board has not expired and no appeal has been filed. Although the commenter is correct that a cost report can be reopened anytime within 3 years of the date of the determination, our previous policy was unclear as to whether an intermediary could indeed reopen during the appeals period timeframe. Therefore, we believed a clarification was needed to inform the intermediaries that they have the authority to reopen a determination in the appeal period following the issuance of the determination.

Comment: One commenter suggested that an intermediary should be allowed to reopen a determination that is pending on appeal before the Administrator.

Response: The preamble to the proposed rule stated specifically that the intermediary had such authority (69 FR 35741). We have made corresponding changes to the regulations text at § 405.1885(c)(3) to make clear that a reopening may also be initiated while a case is on appeal before the Administrator.

Comment: One commenter noted that the proposed regulations text at § 405.1885(b)(3) states that “no determination may be reopened after the 3-year period,” unless fraud or similar fault is involved. The commenter suggested that the text does not comport with the preamble comments which permit the intermediary to reopen after the 3-year period if the request for reopening is received by the intermediary towards the end of the 3-year period. Another commenter fully supported our proposal clarifying that a provider’s request to reopen is timely even if received by the intermediary near the end of the 3-year deadline.

Response: We did not include regulations text language that would permit expressly an intermediary to issue a notice of reopening after the expiration of the 3-year reopening period when the request for reopening is received shortly before the expiration of the 3-year period. Accordingly, we are modifying language at § 405.1885(b)(2) to comport the text of the regulations with our proposed policy.

Comment: A commenter suggested that we should define “fraud or similar fault,” because it can be interpreted in many different ways. The commenter suggested that “fraud” should be defined as an intentional deception harming the government and resulting in a criminal conviction. “Similar fault” should be defined as an intentional deception harming the government and resulting in a judgment in a civil proceeding.

Response: We disagree that we need to define “fraud or similar fault” so that an intermediary will be able to better ascertain whether a determination may be reopened after the expiration of the 3-year reopening period. The term “fraud or similar fault” was inserted as original language in our reopening regulations, and we are not aware that intermediaries have had any problem in interpreting its meaning. Without defining the term in regulation, we note that when the intermediary invokes “fraud” as the reason for reopening beyond the 3-year period, the intermediary has concluded that the determination under review was procured by: (1) An intentionally false oral or written representation of a matter or fact; or (2) by concealment of a matter that should have been disclosed. On the other hand, “similar fault” covers determinations that do not rise to the level of fraud. For instance, an intermediary could find that a provider received money that it knew or reasonably should have known it was not entitled to retain.

Comment: A commenter suggested that a provider not be allowed to add issues to a reopening request after the 3-year period has expired.

Response: We note that current Medicare policy prohibits a provider from adding issues to a reopening request after the 3-year period has expired. Reopenings are issue specific; therefore, if a provider receives an NPR that pertains to issues A and B, and it requests a reopening on issue A within the 3-year limit, if it desires the intermediary to reopen issue B, it must also request a reopening of that issue within the 3-year period. Requesting a reopening for one issue does not, whether the intermediary is considering the request, has granted the request, or has issued a revised determination, toll the time for requesting a reopening for any other issue.

Comment: A commenter suggested that a provider would be required only to have “reasonable” accompanying documentation in support of a request for reopening, so that the intermediary, after the 3-year period has expired, could not deny the request due to insufficient support. According to the commenter, the intermediary should also be afforded a specific amount of time either to request additional documentation from the provider or to decide whether it wishes to reopen.

Response: We are not prescribing by regulation any particular documentation or evidence that needs to accompany a reopening request. Therefore, any request that is received by the intermediary within the applicable 3-

year period and puts the intermediary on fair notice as to the matter or matters for which the provider is seeking reopening (including identifying the determination at issue) should satisfy the minimum requirements for requesting a reopening. Because it is within the intermediary’s discretion whether to grant a request to reopen, however, a provider should strive to present the best case possible in support of its request to reopen, which may necessitate, in some cases, sending documentation or other evidence to the intermediary. Because of the large volume of work that the intermediaries process, we decline to impose specific timeframes on the intermediaries for the resolution of provider reopening requests.

Comment: One commenter wanted to know whether, if an intermediary reopens and revises a particular issue on a cost report, that issue would be subject to another 3-year reopening period.

Response: If an intermediary reopens and revises an issue in a cost reporting year, the revision may be appealed in accordance with § 405.1889. Moreover, a new 3-year reopening period would apply to the revised issue. Any issue not revised following a reopening does not carry with it any further appeal rights or a new reopening period with regard to that issue.

Comment: One commenter suggested that the reason that issues are added to Board cases (subsequent to the initial request for hearing) is that the reopening provisions have not been fairly applied in the past. The commenter suggested that the proposed rule reduces the amount of discretion intermediaries have in granting reopenings by prohibiting intermediaries from reopening issues based on a change in legal interpretation or policies.

Response: We disagree with the commenter. We believe that the reopening process is fair. We acknowledge that, because of the wide discretion intermediaries have in deciding whether to reopen or not to reopen, one intermediary may decide differently on a given provider reopening request than another intermediary would based on similar facts. Because reopenings are discretionary, rather than rely upon a reopening request being granted, providers should preserve their appeal rights by including in their request for hearing all issues that they believe were wrongly decided. Finally, we note that, as explained in the August 1, 2002 final rule (67 FR 50096), it has always been Medicare’s policy to prohibit intermediaries from reopening based on

a change in legal interpretation or policy.

Comment: One commenter suggested that we incorrectly cited to two court decisions (*Foothill Presbyterian Hospital v. Shalala*, 152 F.3d 1132 (9th Cir. 1998) and *HCA Health Services of Oklahoma, Inc. v. Shalala*, 27 F.3d 614 (D.C. Cir. 1994)) when we proposed that the scope of appeal of a revised determination is limited to the specific revisions that were made in the determination. The commenter suggested that we are improperly attempting to alter through regulations the scope of the Board's jurisdiction, and that the Board is clearly able to define its own scope of jurisdiction, without interference by CMS.

Response: We disagree with the commenter. Our longstanding reopening policy, as contained in the regulations (that were, in fact, published prior to the formation of the Board) (see § 405.1889), specifies that the scope of appeal of a revised determination is limited to the specific revisions that were made in the revised determination. We cited the cases of *Foothill Presbyterian Hospital v. Shalala* and *HCA Health Services of Oklahoma, Inc. v. Shalala* as examples of court decisions that agreed that the scope of a provider's appeal of a revised determination is limited to the issues that were specifically revised. (We note that in those cases, the courts were not presented with the factual situation in which the provider was attempting to appeal, through an appeal of a revised NPR, a matter that was addressed in a reopening notice but not subsequently revised.) The Board has jurisdiction only over final determinations made by an intermediary or the Secretary, and only matters specifically revised are part of a final determination.

Comment: One commenter noted that there were no deadlines imposed on intermediaries to process reopening requests and issue revised determinations. The commenter suggested that it is unreasonable to have reopenings pending for more than a year, and recommended that we require intermediaries to complete their actions within 1 year of the date of the notice of reopening.

Response: As we stated previously, it would be inappropriate for us to require intermediaries to resolve reopening requests under strict time constraints. We cannot accurately gauge intermediary workloads (reopening requests comprise only a fraction of the workload) and, therefore, we cannot mandate specific timeframes for intermediaries in their processing of provider reopening requests.

W. Three Additional Proposals Under Consideration

In the proposed rule, we stated that we were considering amending the regulations on three matters that did not surface until very late in the development of the rule. They are as follows:

- An *ex parte* contact with a Board staff member concerning a procedural matter in a case should not be considered a prohibited *ex parte* communication.
- Upon receipt of a credible allegation that a party's counsel has a conflict of interest in the party's representation, the Board would be able to order the party to show cause why the case should not be dismissed or why other appropriate action should not be taken.
- Where an intermediary denies reimbursement for a claimed item without auditing the reimbursement effect of that claim, and the intermediary's denial is reversed by the Board, the Administrator, or a court (making the decision final and non-appealable), we may require the intermediary to determine the reimbursement effect of the claim prior to payment.

We are adopting the proposals. Specifically, we have added § 405.1868(f) to state that *ex parte* communications with Board staff concerning procedural matters are not prohibited. We added § 405.1868(g) to provide that upon receipt of a credible allegation that a party's representative has divulged to that party or to the Board information that was obtained during the course of the representative's relationship with an opposing party and that was intended by that party to be kept confidential, the Board will investigate the allegation. Where the Board determines that it is appropriate to do so, it may take remedial action against the party or the representative (such as prohibiting the representative from appearing before it, excluding such information from the record, or if the overall fairness of the hearing has been compromised, dismissing the case). We amended § 405.1803(d) to state that CMS may require the intermediary to audit any item at issue in an appeal or a civil action before any revised intermediary determination or additional Medicare payment, recoupment, or offset may be determined for an item under paragraph (d)(2) of that section. We added § 405.1831(e) and § 405.1871(b)(4), and amended § 405.1875(f)(5), to provide that, where the intermediary's denial of the relief that the provider seeks before

the intermediary hearing officer(s), the Board or the Administrator was based on procedural grounds (for example, the alleged failure of the provider to satisfy a time limit) or was based on the alleged failure to supply adequate documentation to support the provider's claim, and the reviewing entity rules that the basis of the intermediary's denial is invalid, the reviewing entity will remand to the intermediary for the intermediary to make a determination on the merits of the provider's claim.

Comment: In response to our proposal to explicitly state that *ex parte* communications with Board staff concerning procedural matters are not prohibited *ex parte* communications, we received one comment, which was in favor of its adoption.

Response: We are adopting the proposal as new § 405.1868(f). Although *ex parte* communications concerning procedural matters are not prohibited, we strongly encourage parties to avoid them wherever possible. That is, a party should strive to copy the other party(ies) on any written correspondence with Board staff, and, where oral communication with Board staff is to take place, to include the other party(ies) (for example, joining them in a conference call), or, where it is not practical to do so, immediately convey the substance of the oral conversation to the other party(ies).

Comment: We received two comments on our proposal to give the Board the authority to order a party to show cause why it should not dismiss an appeal or take other action where the Board has credible evidence that the party's counsel may have a conflict of interest. One commenter was in favor of the proposal, whereas the second commenter stated that there was no legitimate basis for dismissing a provider's appeal due to a potential or even actual conflict on the part of the provider's representative, and the Board would have no legal authority to take punitive action against the provider. In addition, the latter commenter stated that the suggestion in the proposal that a conflict arose from any use of information obtained from another party while in that party's employ is overbroad and inappropriate because it fails to consider circumstances in which the information was not, or was not intended to be kept confidential, or in which disclosure was expressly permitted by the party from whom the information was obtained.

Response: Our proposal stemmed from our recognition that, not infrequently, persons well-versed in Medicare reimbursement may switch from being a provider representative to

an intermediary representative, or vice versa. In that situation, it would be inappropriate for a representative to use any confidential information obtained during the course of his or her former employment. By "confidential information," we mean information that the representative is not authorized to disclose. We disagree that the Board would not have the authority to dismiss an appeal in a case in which it determines that the provider representative has a conflict of interest. The Board historically has had plenary power to dismiss appeals, even in the absence of a regulation so authorizing, for violation of procedural rules, such as the time in which to file a position paper. (See, for example, *Novacare, Inc. v. Thompson*, 357 F. Supp. 2d 268 (D.D.C. 2005)). We believe that we have the authority to allow the Board to dismiss an appeal, if the overall fairness of the hearing has been compromised, or take other appropriate action, based upon a determination by the Board that a provider representative or an intermediary representative has engaged in misconduct. We have adopted our proposal as new § 405.1868(g).

Comment: We received six comments on our third additional proposal. We received two comments on our specific proposal that, where an intermediary denies reimbursement without auditing the effect of the denial, and that determination is later reversed by a final decision of the Board, the Administrator or a court, CMS may require the intermediary to determine the reimbursement effect of the claim prior to payment. We noted that this proposal was similar to our proposal for auditing self-disallowed costs that are ultimately allowed. We received one comment in favor of this proposal and one comment questioning the scope of the audit. The latter commenter asked in particular what the scope of the audit would be in the example cited in the proposed rule concerning an exception to a provider's ESRD payment rate. The same commenter also asked what the scope of an audit would be in the case in which a provider successfully appeals the issue of whether Medicaid eligible days should be included in the numerator of the Medicaid fraction component of the DSH calculation. That is, would the scope of the audit be restricted to only the Medicaid eligible days issue, or would the intermediary be permitted to look at other potential DSH issues such as total days?

Response: We are adopting this part of the proposal at § 405.1803(d)(3). The scope of the audit will be determined by CMS (in accordance with the decision of the reviewing entity) and will be based

on the particular issue(s) before the reviewing entity or the court. The purpose of the audit will be to determine the reimbursement impact of the issue(s) decided by the reviewing entity or court; the purpose is not to make additional adjustments or to reach other issues that were not appealed by the provider.

Comment: We received four comments on our related proposal that, where an intermediary or CMS determines that reimbursement for an item should be disallowed on one basis and that determination is later reversed, the intermediary should then have the opportunity to determine whether reimbursement should be denied for any other reason. We stated that it is potentially a waste of resources for a decision maker to consider all possible reasons why an item or request (for example, a provider's request for an exception to its ESRD payment rate) would not be allowed where the intermediary has a good faith belief that its determination is correct, and given that the determination may never be challenged or, if challenged, may be upheld. One commenter stated that this proposal, along with the greater body of proposed amendments, is designed to have a chilling effect on the willingness and capacity of providers to appeal legitimate concerns. Another commenter stated that providers expend great resources in preparing for an appeal, and that allowing intermediaries to create new arguments, even after a decision from the Board, would simply lead providers to forego meritorious appeals simply because the intermediary had greater resources than the provider. The appeals process would be futile if a provider could not ever obtain final relief due to the intermediary's repeated use of delay tactics. The third commenter was concerned that this proposal, if adopted, could be interpreted to allow CMS or the intermediary to re-challenge an issue following a Board decision, as long as the basis for the challenge was not originally raised. All issues related to a dispute should be considered in the appeal at the same time. The fourth commenter stated that the intermediary has full opportunity to raise whatever objections it has, with respect to a claimed cost, in connection with its audit and review of the provider's submitted cost report. In the event of an appeal, the intermediary has another opportunity to change or supplement its position in proceedings before the Board. The intermediary should not have a third or potentially endless opportunity, even after a final

administrative or judicial decision on an appeal, to deny payment for reasons not raised before and outside of the usual 3-year reopening period. According to the commenter, this proposal is grossly unfair to providers, particularly in view of the fact that CMS holds the amount in controversy from the time an intermediary effects a disallowance until an appeal is resolved, and is contrary to the Secretary's purported concern about the backlog of pending appeals.

Response: We agree that intermediaries should not be able to delay indefinitely the resolution of an issue on appeal by making an endless series of objections. Our proposal was not designed to prolong unnecessarily cases before the Board or to discourage providers from pursuing appeals. Rather, it was intended to address the difficulties that intermediaries and CMS face in allocating a finite amount of resources among their many responsibilities. We continue to believe that, in the situation in which an intermediary makes a good faith determination that the provider is not entitled to the relief it seeks because it has failed to satisfy a condition that is a necessary prerequisite to that relief, it makes little sense for the intermediary to devote its resources to exploring whether the provider meets other necessary conditions for the relief it seeks. For example, if an intermediary determines that a provider is not entitled to claim an item because it failed to meet a statutory or regulatory deadline, the intermediary should not have to spend resources in determining whether the provider met the substantive requirements for entitlement to the item, to guard against the possibility that a court may declare the denial invalid. (Our proposal was motivated in part by the actual situation in which an intermediary disallowed a provider's claim for a loss on depreciation because the underlying transaction took place after December 1, 1997. The provider subsequently argued that the transaction took place prior to December 1, 1997, due to a special law enacted by the State legislature in 1998 to address specifically the transaction at issue, and also argued that our regulation interpreting the statute as preventing claims for losses on depreciation for transactions that occurred on or after December 1, 1997 was invalid. The provider indicated that it would argue to a court that, if it was successful in its claim that the transaction was timely, the intermediary should be prevented from arguing that the provider did not satisfy the

substantive requirements for claiming a loss on depreciation. The claim at issue involved approximately \$30 million in Medicare reimbursement.) Likewise, if an intermediary determines that a provider has not met a clearly prescribed documentation requirement, and the Board agrees, but the provider is successful in convincing the Administrator or a court to overturn the Board's decision, the provider should not simply be awarded the reimbursement without the intermediary having the opportunity to determine whether the provider was entitled to it on the merits. We are adopting the proposal, but are limiting its applicability to the situation in which the intermediary makes an adjustment on the cost report, or otherwise denies the relief the provider seeks, for procedural reasons (for example, the alleged failure to meet a deadline) or lack of documentation. Where the reviewing entity disagrees with the basis for the denial, it must remand the case to the intermediary for a determination on the merits. We are adding new paragraph (e) to § 405.1831 and new paragraph (b)(4) to § 405.1871 and are amending § 405.1875(f)(5) to effectuate the finalized proposal.

X. Technical Revisions

We proposed certain technical revisions to the following sections: § 413.30(c)(1), § 413.30(c)(2), § 413.40(e)(5), § 413.64(j)(1), § 417.576, and § 417.810. We received no comments on our proposed technical revisions and are adopting them as proposed. We note that we inadvertently failed to include regulations text for our proposed revision to § 413.30(c)(2) and have corrected that omission in this final rule.

Y. Effective Date

This section is new. We proposed no specific effective date, but two commenters made suggestions for an effective date.

Comment: One commenter said that the effective date for the final rule should be for cost reporting periods beginning on or after at least 3 months after the rule is published in the **Federal Register**. In the alternative, the final rule should be effective with respect to cost reports, reopenings, and appeals filed, requested, or issued on or after at least 9 months after the rule is published in the **Federal Register**. Providers need time to put into effect, digest, and react to the massive changes in approach set forth in this final rule. Another commenter said that the final rule should not be applied retroactively to

pending appeals. Particularly troublesome would be an application of the rules that would prohibit a provider from adding issues to an appeal more than 60 days after the filing deadline for the appeal. A retroactive application of the new 60-day limit would violate the due process rights of providers whose otherwise valid claims would be extinguished by a retroactive regulation. Even "grandfathering" current appeals would prejudice some providers. For example, if the proposals on requesting an extension of the time to request a Board hearing were effective upon the issuance of a final rule, providers that have relied on their ability to receive good cause for an extension to file an appeal may be barred from bringing the appeal if it is determined that the amount of time that has passed since the issuance of their NPR is longer than the "reasonable time" to file the appeal. The final rule, if enacted as proposed, would violate a provider's rights by changing the rules of procedure in the middle of the appeal process. The commenter recommended that we issue an interim final rule, which would not apply to currently pending appeals or to currently existing claims that could give rise to an appeal. Use of an interim final rule would allow the public an opportunity to comment on an appropriate effective date.

Response: We do not agree that it is necessary to make the rule effective for cost reporting periods beginning at some point after the effective date of the rule, or that it is necessary to publish this rule as an interim final rule or a final rule with comment. Although the proposed rule was published on June 25, 2004, giving providers adequate notice of the potential provisions of the final rule, we are taking certain precautions to ensure that no provider is disadvantaged by the timing of our procedural changes. First, the rule is generally effective 90 days after publication in the **Federal Register**. Second, we are providing special rules for adding issues to appeals pending as of the effective date, and for requesting an extension of time, for good cause, of the date to seek a Board or intermediary hearing officer hearing. For appeals pending before an intermediary hearing officer(s) or the Board prior to the effective date of this rule, a provider that wishes to add one or more issues to its appeal must do so by the expiration of the later of the following periods: (1) 60 days after the expiration of the applicable 180-day period prescribed in § 405.1811(a)(3) (for intermediary hearing officer hearings) or § 405.1835(a)(3) (for Board hearings); or

(2) 60 days after the effective date of this rule. For appeals filed on or after the effective date of this rule, the provisions of § 405.1811(c) and § 405.1835(c) apply. With respect to requests for good cause extensions under § 405.1813 (intermediary hearing officer hearings) and § 405.1836 (Board hearings), providers that have not filed a timely appeal as of the effective date of this rule and that wish to seek an extension of the time limit for filing an appeal based on good cause, have an additional 60 days after the effective date of this rule to seek an extension without meeting the "reasonable time" requirements of revised § 405.1813 and § 405.1836 (but must meet all other requirements of those sections). Finally, and as noted above in section II.D.1. of this final rule, the requirement that a provider must self-disallow a specific item(s) by following the applicable procedures for filing a cost report under protest, if the provider seeks payment that it believes may not be allowable or may not be in accordance with Medicare policy, is effective for cost reporting periods ending on or after December 31, 2008.

Z. Children's Health Graduate Medical Education Program (CHGME)

This section is new. We made no proposals specific to appeals involving the CHGME program, but received one comment.

Comment: One commenter noted that our proposed rule did not address appeals that may be filed by children's hospitals under the CHGME program. The commenter stated that any appeal under the CHGME program must be placed on a "fast track" for the Board and the Health Resources and Services Administration Administrator. The commenter recommended that a specific set of regulations be created to specifically address the CHGME program's unique timeframes for appeals.

Response: The CHGME payment program, as authorized by section 340E of the Public Health Service Act, 42 U.S.C. 256e, provides funds to children's hospitals to address disparity in the level of Federal funding for children's hospitals that results from Medicare funding for graduate medical education. Public Law 106-310 amended the CHGME statute to extend the program through FY 2005. Under 42 U.S.C. 256e, a children's hospital with a CHGME program is a hospital with a Medicare provider agreement. Therefore, CHGME appeals are governed by Part 405, Subpart J—Expedited Determinations and Reconsiderations of Provider Service Terminations, and

Procedures for Inpatient Hospital Discharges. We do not believe it is necessary at this time to issue regulations that are specific to the CHGME program. Rather, the Board will schedule and hold hearings on any CHGME appeals that may be filed in accordance with the requirements of the regulations at 42 CFR Part 405 Subpart R—Provider Reimbursement Determinations and Appeals. We note that the statute does not require that CHGME appeals be placed on a “fast track.” However, the Board gives expedited treatment to CHGME appeals, because payments to children’s hospitals are based on the hospital’s share of the total amount of direct and indirect Medicare education funding available in any Federal fiscal year (FFY). This funding is part of a fixed payment pool that is distributed prior to the close of each FFY. As a result, appeals before the Board are heard on an accelerated hearing schedule so that a provider’s reimbursement is accurately determined prior to the end of the FFY.

III. Provisions of the Final Rule

For purposes of this section, we are using the same lettering sequence that appeared in the proposed rule and in section II in this final rule. In each lettered section, we provide a listing of the changes from the proposed rule that we have made in this final rule. A detailed description of the proposals is contained in the proposed rule, and a detailed explanation regarding the changes appears at section II in the preamble to this final rule. Certain Minor technical revisions may not be listed in this section III or discussed above in section II.

B. Calculating Time Periods and Deadlines (§ 405.1801(a) and § 405.1801(d))

- Section 405.1801(a)—“Date of Receipt” is revised.
- Section 405.1801(d)—“Calculating time periods and deadlines” is revised.

D. Provider Hearing Rights (§ 405.1803(d), § 405.1811, and § 405.1835)

- Section 405.1811(a)(1)(ii) and § 405.1835(a)(1)(ii)—The provisions of these paragraphs are effective for cost reporting periods that end on or after December 31, 2007.
- Section 405.1811(b) and § 405.1835(b)—These paragraphs are clarified to provide that, where required information is not submitted with the hearing request, the intermediary hearing officer or Board, as applicable, may dismiss with prejudice the appeal,

or take any other remedial action that the reviewing entity considers appropriate.

- Section 405.1835(c)(3)—We have deleted the language in this paragraph pertaining to a request to add issues following a reopening.
- Section 405.1811(b)(2)(i) and § 405.1835(b)(2)(i)—We have revised the hearing rights criteria in these paragraphs to allow a provider to explain why it is unable to determine whether payment is correct as a result of not having access to underlying information.
- Section 405.1835(b)(4)—We are adding this paragraph to require a provider under common ownership or control to furnish additional information regarding its parent corporation and related providers, and to provide: (1) A statement that no other provider to which it is related has a pending hearing request or appeal on any of the same issues contained in the provider’s hearing request for the relevant timeframe; or (2) a statement that a pending appeal(s) exist(s), and the provider name(s) and provider number(s), and the case number(s) (if assigned), for such appeal(s).
- Miscellaneous—We have rectified, where appropriate, minor wording inconsistencies between § 405.1811, which pertains to intermediary hearings, and § 405.1835, which pertains to Board hearings.

E. Provider Requests for Good Cause Extension of Time Period for Requesting Hearing (§ 405.1813 and § 405.1836)

- 405.1813(e)(1)—We have made a technical change concerning the component within CMS to which intermediary hearing officer decisions should be sent.
- Miscellaneous—We have made minor, non-substantive wording changes to make § 405.1813 and § 405.1836 consistent, wherever possible.

F. Intermediary Hearing Officer Jurisdiction (§ 405.1814)

- Section 405.1814(a)(1)(ii)—We have amended § 405.1814(a)(2) (and § 405.1840(a)(2) relating to Board jurisdiction) to explain that the preliminary determination of the scope of the reviewing entity’s jurisdiction consists of a review as to whether the request for hearing was timely and whether the amount in controversy has been met.
- Miscellaneous—We made minor technical changes to other portions of § 405.1814 and conformed language in § 405.1814 to that in § 405.1840, wherever possible.

G. CMS Reviewing Official Procedure (§ 405.1834)

- Section 405.1834(d)(2)—This paragraph has been revised to provide that the 60-day period for noticing review begins from the date of the intermediary hearing officer decision.
- Section 405.1834(e)(2)—We have clarified that the CMS reviewing official’s review of an intermediary hearing officer decision would not be limited to a hearing on the written record if certain criteria are met.
- Miscellaneous—We have made technical changes to proposed § 405.1834(b), § 405.1834(c) and § 405.1834(e)(3) concerning the component within CMS to which intermediary hearing officer/CMS reviewing official decisions should be sent.
- Section 405.1834(d)(1)—We clarified language pertaining to own motion review by the Administrator.
- Section 405.1834(e)(1)(i)—We have revised § 405.1834(e)(1) to state that the CMS reviewing official must give great weight to “other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.”

H. Group Appeals (§ 405.1837)

- Section 405.1837(b)(1)—This paragraph is revised to clarify that commonly owned or operated providers must bring as a group appeal a specific matter at issue that involves a question of fact or interpretation of law, regulations, or CMS rulings that is common to providers and that pertains to cost reporting periods ending in the same calendar year.
- Section 405.1837(b)(1) and § 405.1837(b)(2)—We have revised § 405.1837(b)(1) (with respect to mandatory group appeals) and § 405.1837(b)(2) (with respect to optional group appeals) to provide that one or more of the providers in the group may, as a matter of right, appeal more than one cost reporting period for purposes of meeting the \$50,000 amount in controversy requirement, and, subject to the Board’s discretion, may appeal more than one cost reporting period that is the subject of the group appeal for other purposes, such as convenience. Illustrative examples follow the text of § 405.1837(b)(1).
- Section 405.1837(b)(3)—This paragraph is revised to clarify that, whereas one or more commonly owned or operated providers may initiate a mandatory group appeal, at least two providers are required to initiate an optional group appeal.

• Section 405.1837(c)(2)—This paragraph was revised to use the term “item” rather than “cost.”

• Section 405.1837(c)(4)(ii), § 405.1837(e)(2), § 405.1837(d)(3), and § 405.1837(d)(4)—We have revised § 405.1837(c)(4)(ii) and § 405.1837(e)(2), and have deleted § 405.1837(d)(4) in order to permit the Board to make jurisdictional determinations at any time. We have deleted proposed § 405.1837(d)(3) to permit the Board to conduct various proceedings prior to making jurisdictional findings.

• Section 405.1837(e)(1) and § 405.1837(e)(2)—We have deleted certain language in proposed § 405.1837(e)(2) and have revised § 405.1837(e)(1) to provide that, with respect to mandatory group appeals, absent a notice from the providers that the group is fully formed, the Board may issue an order requiring the providers to demonstrate that there is at least one commonly owned or controlled provider that is a potential addition to the group. With respect to optional group appeals, we have revised § 405.1837(e)(1) to provide that, absent a notice from the providers that the group is fully formed, the Board will issue an order that the group is fully formed or will issue general instructions that set forth a schedule for the closing of optional group appeals.

• Section 405.1837(e)(2)—This paragraph is revised to provide that the Board will not dismiss any group appeal hearing request for failure to meet the amount in controversy requirement until the Board has determined that the group is fully formed.

• Section 405.1837(e)(5), § 405.1837(e)(6)—We have deleted language from proposed § 405.1837(e)(5) that stated that the Board must grant a request to join a group appeal if the request is unopposed by the group members and is received by the Board prior to a final decision by the Board on the appeal. We have revised this paragraph to provide that, as a general rule, where a provider has appealed an issue through a group appeal, it may not subsequently request the Board to transfer that issue to a single provider appeal. We provide an exception to the general rule in the case of a group appeal that does not meet the jurisdictional requirements where the Board determines that the requirements for a group appeal are not met. We have moved the language in proposed § 405.1837(e)(6), which stated that a denial by the Board of a request to join a group is without prejudice to the provider bringing a separate appeal, to § 405.1837(e)(4). We have also

incorporated proposed § 405.1837(e)(7) into § 405.1837(e)(4).

I. Amount in Controversy (§ 405.1839)

• Section 405.1839(c)(4)—We are adding this paragraph to provide that, where a provider has requested a hearing before an intermediary and the amount in controversy is subsequently determined to be at least \$10,000, the appeal will be transferred to the Board. Where the amount in controversy changes to an amount less than the minimum for a Board appeal due to the settlement, transfer or abandonment of an issue, the Board retains jurisdiction. Where the amount in controversy changes to an amount less than the minimum for a Board appeal due to a more accurate assessment of the amount in controversy, the Board will not retain jurisdiction.

J. Board Jurisdiction (§ 405.1840)

• Section 405.1840(b)(1)—We have updated the regulatory citations to the coverage appeals process and the Quality Improvement Organization appeals process.

• Section 405.1840(c)(2) and § 405.1840(c)(3)—In paragraph § 405.1840(c)(2) we corrected a citation to a specific paragraph of § 405.1842, and in § 405.1840(c)(3), we clarified citations to specific paragraphs of § 405.1875.

• For a discussion of other changes we made to § 405.1840(a)(2), please refer to section III.F. (Intermediary Hearing Officer Jurisdiction) above.

K. Expedited Judicial Review (§ 405.1842)

• Section 405.1842(e)(3)(ii)—We have revised this paragraph to clarify that, upon receiving a request for EJR, the Board will have 30 days either to issue an EJR decision (if the request is complete) or issue a written notice to the provider that the provider has not submitted a complete request.

L. Parties to Proceedings in a Board Hearing or Intermediary Hearing (§ 405.1843 and § 405.1815)

• Section 405.1843(a) and § 405.1815—We have clarified in § 405.1843(a) and in § 405.1815 that it is the Board or the intermediary hearing officer (and not the intermediary) that determines whether an entity is a related organization of the provider, and that such a determination is made in accordance with the principles enunciated in § 413.17.

• Section 405.1843(b)—We have clarified this paragraph to state that, although the Board may call as a witness any employee or officer of HHS

or CMS having personal knowledge of the facts and the issues in controversy in an appeal, the Department's Touhy regulations at 45 CFR, Part 2 apply as to whether that employee or officer will appear.

• Section 405.1843(e) and § 405.1843(f)—We have added § 405.1843(e) to provide that a non-party other than CMS may seek leave from the Board to file *amicus curiae* briefing papers with the Board. We have also added new § 405.1843(f) to provide that the Board may exclude from the record all or part of an *amicus curiae* briefing paper.

M. Quorum Requirements (§ 405.1845)

• Section 405.1845(d)(1)—We have clarified that a quorum is not required to issue a dismissal decision, which reflects current Board practice.

• Section 405.1845(f)(2), § 405.1845(g) and § 405.1845(h)—We have made a technical change to proposed § 405.1845(f)(2), and, for clarity, we have renumbered proposed § 405.1845(f)(3) as § 405.1845(g), and accordingly have renumbered proposed § 405.1845(g) as § 405.1845(h).

N. Board Proceedings Prior to Hearing; Discovery in Board and Intermediary Hearing Officer Proceedings (§ 405.1853 and § 405.1821)

• Section 405.1853(b)(2)—We removed the requirement that the Board must find “good cause” for extending the deadline for submitting a position paper.

• Section 405.1853(b)(3)—We clarified that the “time frame to be decided by the Board,” for purposes of submitting exhibits on the merits of the provider's claim, may be through a schedule specific to a given case or through general instructions. We also revised this paragraph to provide that the general rule, that any supporting exhibits regarding jurisdiction must accompany the position paper, is subject to a Board order or general instructions to the contrary.

• Section 405.1853(e)(2)(i)—This paragraph has been revised to provide that neither CMS, the Secretary nor any Federal agency is subject to the Board discovery process. A party may propound written interrogatories only to another party, and not to a non-party.

• Section 405.1853(e)(2)(ii)—This paragraph has been revised to specifically reference Rule 32(a)(3) of the FRCP governing the allowance of depositions in certain circumstances. We have also revised this paragraph to provide that the Department's Touhy regulations at 45 CFR, Part 2 (Testimony by employees and production of

documents in proceedings where the United States is not a party) will apply as to whether an employee or officer of CMS or HHS will appear at a deposition.

- Section 405.1853(e)(3)(i)—This paragraph has been revised to provide that (unless the time is extended by the Board), discovery requests must be served no later than 120 days before the initially scheduled starting date of the hearing.

- Section 405.1853(e)(3)(ii)—This paragraph has been revised to clarify language concerning when discovery may be “conducted,” and to provide that, in the absence of an order or instruction by the Board setting a schedule for the holding of a deposition, a party desiring to take a deposition shall give reasonable notice in writing to the deponent of a scheduled deposition, and unless the Board orders otherwise, the deposition may not be held any later than 45 days before the initially scheduled starting date of the Board hearing. Responses to interrogatories or requests for production of documents must be served no later than 45 days before the initially scheduled starting date of the Board hearing, unless the Board orders otherwise. The requirement that the Board must find “good cause” to extend the period for discovery has been deleted.

- Section 405.1853(e)(3)(iv)—We have deleted the requirement that the Board may extend the time to request, conduct, or respond to discovery only upon a showing by the requesting party that it was not dilatory or otherwise at fault.

- Section 405.1853(e)(3)(v)—We have clarified that, upon granting an extension request, the Board has the discretion to reschedule the hearing date (without being required to find that such rescheduling is “necessary”).

- Section 405.1853(e)(4), § 405.1853(e)(5)(vii)—We have added clarifying language at § 405.1853(e)(5)(vii) to state that nothing in § 405.1853 authorizes the intermediary hearing officer or Board to compel any action from the Secretary or CMS. Accordingly, at § 405.1853(e)(4), we have revised language that stated that a non-party has the “same” rights as any party when responding to discovery requests.

- We have made corresponding changes throughout § 405.1821, with respect to discovery in intermediary hearing proceedings, where appropriate.

O. Subpoenas (§ 405.1857)

- We are adding language to proposed § 405.1857(a)(1)(i) to clarify that the Board may not issue a subpoena to CMS

or to the Secretary (or to any Federal agency).

- Section 405.1857(a)(2)(i)—We have revised the deadline by which a request for a subpoena for discovery must be received by the Board from 90 days before the date of the hearing to 120 days of the initially scheduled starting date of the hearing.

- Section 405.1857(a)(3)(i)—We have revised the deadline for issuing a subpoena from 75 days before the date of the hearing to 90 days before the initially scheduled starting date of the Board hearing.

- Section 405.1857(a)(4)—We have eliminated the subparagraphs to § 405.1857(a)(4) and have revised this paragraph to provide that the Board may extend the deadlines for requesting a Board subpoena and for the Board to issue a subpoena without a finding of “good cause.” We have also revised this paragraph to provide that, if the Board grants an extension to the deadline for requesting a Board subpoena or for the Board to issue a subpoena, the Board has the discretion to reschedule the hearing date without a finding that it was “necessary” to do so.

- Section 405.1857(b)(3)—We have clarified this paragraph to state that the Board “uses” (rather than “must comply” with) the FRCP and the Federal Rules of Evidence for guidance.

- Section 405.1857(c)(3)—This section is redesignated from proposed § 405.1857(c)(4) and the references to HHS and CMS are removed.

- Section 405.1857(d)(2)(v)—With respect to the situation where a party or non-party seeks immediate review of a Board subpoena, and the Administrator may, but chooses not to, grant or take own motion review of the subpoena, we have revised the language that stated “the Board’s action stands” to “the Board’s action is not immediately reviewable.”

Q. Board Actions in Response To Failure To Follow Board Rules (§ 405.1868)

- Section 405.1868(c)(1)—We have added this paragraph to provide that, if the intermediary fails to meet any filing or procedural deadlines or other Board requirements, the Board may issue a decision based on the written record submitted to that point or take other appropriate action.

- Section 405.1868(c)—We have added language at the end of this paragraph to clarify that the Board’s authority, in the situation where an intermediary fails to meet a filing deadline or other requirement established by the Board, does not extend to, as a sanction, reversing or

modifying the intermediary or Secretary determination or ruling against the intermediary on a disputed issue of law or fact.

- Miscellaneous—We have renumbered proposed § 405.1868(d)(3) as § 405.1868(e) and made corresponding numbering changes. We have also added § 405.1868(f) and § 405.1868(g) as a result of adopting the first and second of our “Three Additional Proposals Under Consideration” (see section II.W. of this final rule).

R. Scope of Board’s Authority in a Hearing Decision (§ 405.1869 and § 405.1829)

- Section 405.1869(b)(2)(i), § 405.1869(b)(2)(ii)—We have deleted these paragraphs as superfluous.

S. Board Hearing Decision and Intermediary Hearing Decision (§ 405.1871, § 405.1831 and § 405.1833)

- Section 405.1871(a)(4) and § 405.1831(c)—We are revising the proposed rule’s reference to “general CMS instructions” to read “other interpretive rules, general statements of policy, and rules of agency organization, procedure or practice established by CMS.”

- Section 405.1831(d)—We have made a technical change concerning the component within CMS where intermediary hearing officer decisions should be sent.

T. Administrator Review (§ 405.1875)

- Section 405.1875(b)(1) and § 405.1875(b)(5)—We have made a technical change, replacing “general CMS instructions” with “other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.”

- Section 405.1875(e)(3)—We have clarified language to state that the Administrator’s decision “may” (instead of “must”) rely on certain authorities.

- Miscellaneous—We have made certain organizational changes to paragraphs § 405.1875(c)(1) and § 405.1875(c)(2), moving material from § 405.1875(c)(2) to § 405.1875(c)(1), and have made a number of minor wording changes.

U. Judicial Review (§ 405.1877)

- Minor technical changes were made to this section.

V. Reopening Procedures (§ 405.1885 Through § 405.1889)

- Section 405.1885(a)—Clarifying language has been added to emphasize that only the entity that made the

original determination or decision may conduct the reopening of the determination or decision.

- Section 405.1885(b)(2)—We added clarifying language to state that if a request for reopening is made timely, the request remains timely notwithstanding that the notice of reopening required by § 405.1887 is issued after the expiration of the 3-year period. We also clarified that the calculation of the date of receipt for a reopening request must be consistent with the definition of “date of receipt” in § 405.1801(a).

- Section 405.1885(c)(3)—We added clarifying language to provide that a matter may be reopened while it is pending on appeal before the Administrator.

W. Three Additional Proposals Under Consideration

- Section 405.1868(f)—We have added this section to address *ex parte* communications with Board staff.

- Section 405.1868(g)—We have added this section to provide the Board with authority to address allegations that a party’s representative has divulged confidential information obtained during the course of the representative’s relationship with an opposing party.

- Section 405.1803(d)—We have revised this section to state that CMS may require the intermediary to audit any item at issue in an appeal or a civil action before any revised intermediary determination or additional payment, recoupment, or offset may be determined under paragraph § 405.1803(d)(2) of that section.

- Section 405.1831(e) and § 405.1871(b)(4)(added) § 405.1875(f)(5)(amended)—We have added § 405.1831(e) and § 405.1871(b)(4), and have revised § 405.1875(f)(5), to provide that, where the intermediary’s denial of relief was based on procedural grounds or on the failure to supply adequate supporting documentation, and the reviewing entity rules that the basis of the intermediary’s denial is invalid, the reviewing entity will remand to the intermediary to make a determination on the merits.

X. Technical Revisions

- Section 413.30(c)(2)—We have added language, that was consistent with our proposal, but which was inadvertently omitted from the proposed text, to state that the time required by the intermediary to review a request for a SNF exception is considered good cause for the SNF to request an intermediary hearing.

Y. Effective Date

- The rule is generally effective 90 days after publication in the **Federal Register**.

- For appeals pending before an intermediary hearing officer(s) or the Board prior to the effective date of this rule, a provider that wishes to add one or more issues to its appeal must do so by the expiration of the later of the following periods:

- ++ Sixty days after the expiration of the applicable 180-day period prescribed in § 405.1811(a)(3) (for intermediary hearing officer hearings).

- ++ Section 405.1835(a)(3) (for Board hearings); or (ii) 60 days after the effective date of this rule. For appeals filed on or after the effective date of this rule, the provisions of § 405.1811(c) and § 405.1835(c) apply.

- With respect to requests for good cause extensions under § 405.1813 (intermediary hearing officer hearings) and § 405.1836 (Board hearings), providers that have not filed a timely appeal as of the effective date of this rule and that wish to seek an extension of the time limit for filing an appeal based on good cause, have an additional 60 days after the effective date of this rule to seek an extension without meeting the “reasonable time” requirements of revised § 405.1813 and § 405.1836 (but must meet all other requirements of those sections).

- As noted above in section II.D.1. of this final rule, the requirement that a provider must self-disallow a specific item(s) by following the applicable procedures for filing a cost report under protest, if the provider seeks payment that it believes may not be allowable or may not be in accordance with Medicare policy, is effective for cost reporting periods ending on or after December 31, 2008.

IV. Collection of Information Requirements

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

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

For the purpose of discussion, below is a summary of the information collection requirements (ICRs) associated with the hearing process. Because these collection requirements are collected in accordance with an administration action or audit or both, they are not subject to the PRA, as stipulated under 5 CFR 1320.4.

A. Information Collection Requirements (ICRs)—The Introduction § 405.1801

Section 1801(b) states that in order to be paid for covered services furnished to Medicare beneficiaries, a provider must file a cost report with its intermediary as specified in § 413.24(f). For the purposes of this subpart, the term “provider” includes a hospital, hospice program, critical access hospital, comprehensive outpatient rehabilitation facility, renal dialysis facility, Federally qualified health center, home health agency, rural health clinic, skilled nursing facility, and any other entity included under the Act. The burden associated with this requirement is the time and effort associated with a provider completing and submitting a cost report. While this requirement is subject to the PRA, it is currently approved under the following OMB control numbers.

Provider type	OMB Control No.	Expiration date
Hospital	0938–0050	05/31/2008
Hospice Program	0938–0758	01/31/2008
Critical Access Hospital	0938–0050	05/31/2008
Comprehensive Outpatient Rehabilitation Facility	0938–0037	01/31/2008
Renal Dialysis Facility	0938–0236	**06/30/2007
Federally Qualified Health Center	0938–0107	06/30/2008

Provider type	OMB Control No.	Expiration date
Home Health Agency	0938-0022	**04/30/2007
Rural Health Clinic	0938-0107	06/30/2008
Skilled Nursing Facility	0938-0463	**04/30/2007

** We have initiated the OMB approval process to obtain reapproval of the currently approved information collection request.

B. ICRs Regarding the Right to Intermediary Hearing; Contents of, and Adding Issues to, Hearing Request § 405.1811

This section outlines the criteria a provider must meet to request an intermediary hearing. As stated in § 405.1811(b), a provider's request for an intermediary hearing must be submitted in writing to the intermediary. The request must demonstrate that the provider meets all of the requirements for an intermediary hearing, explain the dissatisfaction for each item at issue, and contain a copy of the intermediary or Secretary's determination under appeal.

In addition to the initial hearing request described in § 405.1811(b), § 405.1811(c) explains the criteria providers must meet to add issues to a hearing request that has already been filed. The specific Medicare payment issues must be submitted in writing to the intermediary hearing officer. The request to add additional issues to a hearing request must be received no later than 60 days after the expiration date of the applicable 180-day time limit.

The burden associated with the requirements listed in both § 405.1811(b) and § 405.1811(c) is the time and effort associated with drafting and submitting the written requests to the intermediary hearing officer. While these requirements impose burden, we believe they are exempt from the PRA as defined in 5 CFR 1320.4. Information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

C. ICRs Regarding Good Cause Extension of the Time Limit for Requesting an Intermediary Hearing § 405.1813

As stated in § 405.1813(a)(3), an intermediary must dismiss any hearing requests received after the 180-day time limit, except that the hearing officer may extend the deadline if the provider demonstrates good cause. A provider must explain, in writing, why it could not file the hearing request in a timely manner.

The burden associated with this requirement is the time and effort associated with drafting and submitting the written request for a deadline extension. While this requirement imposes a burden, we believe it is exempt from the PRA as defined in 5 CFR 1320.4. Information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

D. ICRs Regarding CMS Reviewing Official Procedure § 405.1834

Section 405.1834(a) states that a provider, dissatisfied with a final decision by the intermediary hearing officer(s), may request further administrative review of the decision. Section 405.1834(c) explains the submission criteria for such a request. The Office of Hearings cannot receive the request later than 60-days after the provider receives the final decision of the intermediary hearing officer. The request must be in writing with an attached copy of the intermediary hearing officer decision in question, and any additional supporting information.

The burden associated with this requirement is the time and effort associated with drafting the written request for further administrative review, gathering the necessary supporting information, and submitting the request to the Office of Hearings. While this requirement imposes burden, we believe it is exempt from the PRA as defined in 5 CFR 1320.4. Information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

E. ICRs Right to Board Hearing; Contents of, and Adding Issues to, Hearing Request § 405.1835

Section 405.1835(a) discusses the criteria a provider must meet to request a Board hearing. Section 405.1835(b) states a provider's request for a Board hearing must be submitted in writing to the Board. In addition, § 405.1835(b) outlines the required contents of the written submission to the Board. The request must demonstrate that the

provider meets all of the requirements for a Board hearing, explain the provider's dissatisfaction for each item at issue, and contain a copy of the intermediary or Secretary's determination under appeal.

Section 405.1835(c) explains the criteria providers must meet to add issues to a hearing request that has already been filed. The specific Medicare payment issues must be submitted in writing to the Board. The Board cannot receive the request to add additional issues to a hearing request later than 60-days after the expiration date of the applicable 180-day time limit.

The burden associated with the information collection requirements listed in both § 405.1835(b) and § 405.1835(c) is the time and effort required to draft and submit the written requests to the Board. While these requirements impose burden, we believe they are exempt from the PRA as defined in 5 CFR 1320.4. Information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

F. ICRs Regarding Good Cause Extension of Time Limit for Requesting a Board Hearing § 405.1836

As stated in § 405.1836(a), the Board must dismiss any hearing requests received after the 180-day time limit. However, the Board may extend the deadline if the provider demonstrates good cause. A provider must explain, in writing, why it could not file the hearing request in a timely manner.

The burden associated with this requirement is the time and effort necessary to draft and submit a written explanation showing good cause. While this requirement imposes a burden, we believe it is exempt from the PRA as defined in 5 CFR 1320.4. Information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

G. ICRs Regarding Group Appeals
§ 405.1837

Providers have the right to a Board hearing as an individual or as a part of a group appeal with other providers. Sections 405.1837(a)(1 through 3) list the eligibility criteria associated with submitting a Board hearing request as part of a group appeal. Section 405.1837(b) discusses the usage and filing of group appeals. Specifically, § 405.1837(b)(1) states that two or more providers under common ownership or control must bring a group appeal on an issue that is common to the providers and for which there is an aggregate amount in controversy of at least \$50,000. Under § 405.1837(b)(2), two or more providers not under common ownership or control may bring a group appeal on an issue involving at least \$50,000. A written request for a Board hearing as a group must be submitted in accordance with the criteria listed in § 405.1837(c).

Section 405.1837(e)(2) explains that the Board may make jurisdictional findings under § 405.1840 at any time. This section also explains that providers may request jurisdictional findings by notifying the Board in writing. The written request must notify the Board that the group appeal is fully formed or that the providers believe they have satisfied all of the requirements for a group appeal hearing request.

Section 405.1837(e)(4) states that a provider may submit a request to the Board to join a group appeal. The request must be granted by the Board unless it is opposed by any of the existing group members. In addition, the provider must make the request prior to Board issuance of one of the decisions specified in § 405.1875(a)(2).

While all of the aforementioned requirements in § 405.1837 impose burden, we believe they are exempt from the PRA as defined in 5 CFR 1320.4. Information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

H. ICRs Regarding Amount in Controversy § 405.1839

Section 405.1839(a) discusses the amount in controversy requirements for single provider appeals. This requirement pertains to both intermediary hearings and Board hearings. The provider is required to demonstrate that if the appeal were successful, the provider's total program reimbursement for each cost reporting

period under appeal increases by at least \$1,000 but by less than \$10,000 for an intermediary hearing or by at least \$10,000 for a Board appeal.

Similarly, § 405.1839(b) explains that groups must satisfy the amount in controversy requirement as well. The group must demonstrate that in the event of a successful appeal, the total program reimbursement for the cost reporting periods under appeal increases by a minimum of \$50,000.

All of the information collection requirements listed in § 405.1839 are exempt from the PRA as defined in 5 CFR 1320.4. The information collection is part of an administrative action. Information collections conducted or sponsored during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation, or audit are not subject to the PRA.

I. ICRs Regarding Expedited Judicial Review § 405.1842

The burden associated with this section is detailed in § 405.1842(d). Providers have the right to request expedited judicial review of a legal question relevant to a specific matter at issue in a Board appeal. The Board must have jurisdiction to conduct a hearing on the matter and must determine that it lacks the authority to decide a legal question. Specifically, a provider must submit a request in writing to the Board and to each party to the appeal. The request must contain the information specified in § 405.1842(d)(1) and § 405.1842(d)(2).

The burden associated with this requirement is the time and effort necessary for a provider to draft and submit the written request to the Board and to each party to the appeal. While this requirement imposes a burden, we believe it is exempt from the PRA as defined in 5 CFR 1320.4. Information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

V. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA), September 16, 1980, Pub. L. 96-354, section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995, Public Law No. 104-4, and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits

of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities. The only burden attached to this final rule is the information collection burden associated with filing a request for an intermediary or Board hearing. This proposed rule does not impose any new paperwork burdens on providers. It will merely require providers to prepare their hearing requests in a more expedited fashion. Moreover, this final rule will lessen the time it takes small entities to pursue appeals and receive decisions.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing analyses for section 1102(b) of the Act because we have determined, and we certify, that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals. Again, the only impact on small rural hospitals would be the potential increase in the amount of time a provider would need to file a request for an intermediary or Board hearing. This final rule does not impose any new paperwork burdens on providers. It merely proposes requiring providers to prepare their hearing requests in a more expedited fashion.

Moreover, this final rule will lessen the time it takes rural hospitals to pursue appeals and receive decisions.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

List of Subjects

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.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

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

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart R—Provider Reimbursement Determinations and Appeals

■ 1. The authority citation for part 405, subpart R continues to read as follows:

Authority: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C.

405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

■ 2. Section 405.1801 is amended by—
 ■ A. In paragraph (a), removing “’s” from Administrator’s in the term “Administrator’s review”.

■ B. In paragraph (a), removing the definition of “date of filing” and “date of submission of materials.”

■ C. In paragraph (a), adding a definition for “CMS reviewing official.”

■ D. In paragraph (a), revising the definition for “Date of receipt.”

■ E. In paragraph (a), adding the definitions of “CMS reviewing official procedure”, “Intermediary hearing officer(s)”, and “Reviewing entity” in alphabetical order.

■ E. Revising paragraph (b).

■ F. Adding a new paragraph (d).

The revisions and additions read as follows:

§ 405.1801 Introduction.

(a) Definitions. * * *

* * * * *

CMS reviewing official means the reviewing official provided for in § 405.1834.

CMS reviewing official procedure means the review provided for in § 405.1834.

* * * * *

Date of receipt means the date a document or other material is received by either of the following:

(1) *A party or an affected nonparty.* A party or an affected nonparty, such as CMS, involved in proceedings before a reviewing entity.

(i) As applied to a party or an affected nonparty, the phrase “date of receipt” in this definition is synonymous with the term “notice,” as that term is used in section 1878 of the Act and in this subpart.

(ii) For purposes of an intermediary hearing, if no intermediary hearing officer is appointed (or none is currently presiding), the date of receipt of materials sent to the intermediary hearing officer is presumed to be the date that the intermediary stamps “Received” on the materials.

(iii) The date of receipt by a party or affected nonparty of documents involved in proceedings before a reviewing entity is presumed to be 5 days after the date of issuance of an intermediary notice or a reviewing entity document. This presumption, which is otherwise conclusive, may be overcome if it is established by a preponderance of the evidence that such materials were actually received on a later date.

(2) *A reviewing entity.* For purposes of this definition, a reviewing entity is

deemed to include the Office of the Attorney Advisor. The determination as to the date of receipt by the reviewing entity to which the document or other material was submitted is final and binding as to all parties to the appeal. The date of receipt of documents by a reviewing entity is presumed to be the date—

(i) Of delivery where the document or material is transmitted by a nationally-recognized next-day courier (such as the United States Postal Service’s Express Mail, Federal Express, UPS, DHL, etc.); or

(ii) Stamped “Received” by the reviewing entity on the document or other submitted material (where a nationally-recognized next-day courier is not employed). This presumption, which is otherwise conclusive, may be overcome if it is established by clear and convincing evidence that the document or other material was actually received on a different date.

Intermediary hearing officer(s) means the hearing officer or panel of hearing officers provided for in § 405.1817.

Reviewing entity means the intermediary hearing officer(s), a CMS reviewing official, the Board, or the Administrator.

(b) *General rules.* (1) *Providers.* In order to be paid for covered services furnished to Medicare beneficiaries, a provider must file a cost report with its intermediary as specified in § 413.24(f) of this chapter. For purposes of this subpart, the term “provider” includes a hospital (as described in part 482 of this chapter), hospice program (as described in § 418.3 of this chapter), critical access hospital (CAH), comprehensive outpatient rehabilitation facility (CORF), renal dialysis facility, Federally qualified health center (FQHC), home health agency (HHA), rural health clinic (RHC), skilled nursing facility (SNF), and any other entity included under the Act. (FQHCs and RHCs are providers, for purposes of this subpart, effective with cost reporting periods beginning on or after October 1, 1991).

(2) *Other nonprovider entities participating in Medicare Part A.* (i) Providers of services, as well as, other entities (including, but not limited to health maintenance organizations (HMOs) and competitive medical plans (CMPs) (as described in § 400.200 of this chapter)) may participate in the Medicare program, but do not qualify as providers under the Act or this subpart.

(ii) Some of these non-provider entities are required to file periodic cost reports and are paid on the basis of information furnished in these reports. These non-provider entities may not obtain an intermediary hearing or a

Board hearing under section 1878 of the Act or this subpart.

(iii) Some other hearing will be available to these nonprovider entities, if the amount in controversy is at least \$1,000.

(iv) For any nonprovider hearing, the procedural rules for a Board hearing set forth in this subpart are applicable to the maximum extent possible.

* * * * *

(d) *Calculating time periods and deadlines.* In computing any period of time or deadline prescribed or allowed under this subpart or authorized by a reviewing entity the following principles are applicable:

(1) The day of the act, event, or default from which the designated time period begins to run is not included.

(2) Each succeeding calendar day, including the last day, is included in the designated time period, except that, in calculating a designated period of time for an act by a reviewing entity, a day is not included where the reviewing entity is unable to conduct business in the usual manner due to extraordinary circumstances beyond its control such as natural or other catastrophe, weather conditions, fire, or furlough. In that case, the designated time period resumes when the reviewing entity is again able to conduct business in the usual manner.

(3) If the last day of the designated time period is a Saturday, a Sunday, a Federal legal holiday (as enumerated in Rule 6(a) of the Federal Rules of Civil Procedure), or a day on which the reviewing entity is unable to conduct business in the usual manner, the deadline becomes the next day that is not one of the aforementioned days.

(4) For purposes of paragraph (d) of this section, the reviewing entity is deemed to also include—

(i) The intermediary, if the intermediary hearing officer(s) is not yet appointed (or none is currently presiding); and

(ii) The Office of the Attorney Advisor.

■ 3. Section 405.1803 is amended by:

■ A. In the first sentence of paragraph (a) introductory text, remove the citation “(see § 405.1835(b))” and add “(as described in § 405.1835(a)(3)(ii))” in its place.

■ B. In the second sentence of paragraph (b), remove the phrase “after the date of the notice.” and add “after the date of receipt of the notice.” in its place.

■ C. Adding new paragraph (d).

The addition reads as follows:

§ 405.1803 Intermediary determination and notice of amount of program reimbursement.

* * * * *

(d) *Effect of certain final agency decisions and final court judgments; audits of self-disallowed and other items.*

(1) This paragraph applies to the following administrative decisions and court judgments:

(i) A final hearing decision by the intermediary (as described in § 405.1833 of this subpart) or the Board (as described in § 405.1871(b) of this subpart).

(ii) A final decision by a CMS reviewing official (as described in § 405.1834(f)(1) of this subpart) or the Administrator (as described in § 405.1875(e)(4) of this subpart) following review of a hearing decision by the intermediary or the Board, respectively.

(iii) A final, non-appealable judgment by a court on a Medicare reimbursement issue that the court rendered in accordance with jurisdiction under section 1878 of the Act (as described in § 405.1842 and § 405.1877 of this subpart).

(2) For any final agency decision or final court judgment specified in paragraph (d)(1) of this section, the intermediary must promptly, upon notification from CMS—

(i) Determine the effect of the final decision or judgment on the intermediary determination for the cost reporting period at issue in the decision or judgment; and

(ii) Issue any revised intermediary determination, and make any additional program payment, or recoup or offset any program payment (as described in § 405.371 of this subpart), for the period that may be necessary to implement the final decision or judgment on the specific matters at issue in the decision or judgment.

(3) CMS may require the intermediary to audit any item, including any self-disallowed item, at issue in an appeal or a civil action, before any revised intermediary determination or additional Medicare payment, recoupment, or offset may be determined for an item under paragraph (d)(2) of this section.

(4) For any final settlement agreement, whether for an appeal to the intermediary hearing officer(s) or the Board or for a civil action before a court, the intermediary must implement the settlement agreement in accordance with paragraphs (d)(2) and (d)(3) of this section, unless a particular administrative or judicial settlement agreement provides otherwise.

■ 4. Section 405.1811 is revised to read as follows:

§ 405.1811 Right to intermediary hearing; contents of, and adding issues to, hearing request.

(a) *Criteria.* A provider (but no other individual, entity, or party) has a right to an intermediary hearing, as a single provider appeal, for specific items claimed for a cost reporting period covered by an intermediary or Secretary determination for the period, but only if—

(1) The provider has preserved its right to claim dissatisfaction with the amount of Medicare payment for the specific item(s) at issue, by either—

(i) Including a claim for a specific item(s) on its cost report for a period if the provider seeks payment that it believes to be in accordance with Medicare policy; or

(ii) Effective with cost reporting periods that end on or after December 31, 2008, self-disallowing a specific item(s) by following the applicable procedures for filing a cost report under protest, if the provider seeks payment that it believes may not be allowable or may not be in accordance with Medicare policy (for example, if the intermediary lacks discretion to award the reimbursement the provider seeks for the item(s)).

(2) The amount in controversy (as determined in accordance with § 405.1839 of this subpart) is at least \$1,000 but less than \$10,000; and

(3) Unless the provider qualifies for a good cause extension under § 405.1813 of this subpart, the date of receipt by the intermediary of the provider's hearing request must be—

(i) No later than 180 days after the date of receipt by the provider of the intermediary or Secretary determination; or

(ii) When the intermediary determination is not issued (through no fault of the provider) within 12 months of the date of receipt by the intermediary of the provider's perfected cost report or amended cost report (as specified in § 413.24(f) of this chapter), no later than 180 days after the expiration of the 12-month period for issuance of the intermediary determination. The date of receipt by the intermediary of the provider's perfected cost report or amended cost report is presumed to be the date the intermediary stamped “Received” unless it is shown by a preponderance of the evidence that the intermediary received the cost report on an earlier date.

(b) *Contents of request for an intermediary hearing.* The provider's

request for an intermediary hearing must be submitted in writing to the intermediary, and the request must include the elements described in paragraphs (b)(1) through (b)(3) of this section. If the provider submits a hearing request that does not meet the requirements of (b)(1), (b)(2), or (b)(3) of this section, the intermediary hearing officer may dismiss with prejudice the appeal, or take any other remedial action he or she considers appropriate.

(1) A demonstration that the provider satisfies the requirements for an intermediary hearing as specified in paragraph (a) of this section, including a specific identification of the intermediary or Secretary determination under appeal.

(2) An explanation, for each specific item at issue (as described in paragraph (a)(1) of this section), of the provider's dissatisfaction with the intermediary or Secretary determination under appeal, including an account of—

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it allegedly does not have access to underlying information concerning the calculation of its payment); and

(ii) How and why the provider believes Medicare payment should be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item, a description of the nature and amount of each self-disallowed item and the reimbursement sought for any item.

(3) A copy of the intermediary or Secretary determination under appeal, and any other documentary evidence the provider considers necessary to satisfy the hearing request requirements of paragraphs (b)(1) and (b)(2) of this section.

(c) *Adding issues to the hearing request.* After filing a hearing request in accordance with paragraphs (a) and (b) of this section, a provider may add specific Medicare payment issues to the original hearing request by submitting a written request to the intermediary hearing officer, only if the following requirements are met:

(1) The request to add issues complies with the requirements of paragraphs (a)(1) and (b) of this section as to each new issue.

(2) The specific matters at issue raised in the initial hearing request and the matters identified in subsequent requests to add issues, when combined, satisfy the requirements of paragraph (a)(2) of this section.

(3) The intermediary hearing officer receives the request to add issues no later than 60 days after the expiration of the applicable 180-day period prescribed in paragraph (a)(3) of this section.

■ 5. Section 405.1813 is revised to read as follows:

§ 405.1813 Good cause extension of time limit for requesting an intermediary hearing.

(a) A request for an intermediary hearing that is received by the intermediary after the applicable 180-day time limit prescribed in § 405.1811(a)(3) of this subpart must be dismissed by the intermediary hearing officer(s), except that the hearing officer(s) may extend the time limit upon a good cause showing by the provider.

(b) The intermediary hearing officer(s) may find good cause to extend the time limit only if the provider demonstrates in writing it could not reasonably have been expected to file timely due to extraordinary circumstances beyond its control (such as a natural or other catastrophe, fire, or strike), and the provider's written request for an extension is received by the intermediary hearing officer(s) within a reasonable time (as determined by the intermediary hearing officer(s) under the circumstances) after the expiration of the applicable 180-day limit prescribed in § 405.1811(a)(3) of this subpart.

(c) The intermediary hearing officer(s) may not grant a request for an extension under this section if—

(1) The provider relies on a change in the law, regulations, CMS Rulings, or general CMS instructions (whether based on a court decision or otherwise) or a CMS administrative ruling or policy as the basis for the extension request; or

(2) The date of receipt by the intermediary of the provider's extension request is later than 3 years after the date of the intermediary or other determination that the provider seeks to appeal.

(d) If an extension request is granted or denied under this section, the intermediary hearing officer(s) must give prompt written notice to the provider, and mail a copy to each party to the appeal. The notice must include an explanation of the reasons for the decision by the hearing officer(s) and the facts underlying the decision.

(e)(1) A decision denying an extension request under this section and dismissing the appeal is final and binding on the provider, unless the dismissal decision is reviewed by a CMS reviewing official in accordance with § 405.1834(b)(2)(i) of this subpart

or reopened and revised by the intermediary hearing officer(s) in accordance with § 405.1885 through § 405.1889 of this subpart. The intermediary hearing officer(s) promptly mails the decision to the appropriate component of CMS (currently the Center for Medicare Management) (as specified in § 405.1834(b)(4) of this subpart).

(2) A decision granting an extension request under this section is not subject to immediate review by a CMS reviewing official (as described in § 405.1834(b)(3) of this subpart). Any decision may be examined during the course of CMS review of a final jurisdictional dismissal decision or a final hearing decision by the intermediary hearing officer(s) (as described in § 405.1834(b)(2)(i) and § 405.1834(b)(2)(ii) of this subpart).

■ 6. A new § 405.1814 is added to read as follows:

§ 405.1814 Intermediary hearing officer jurisdiction.

(a) *General rules.* (1) After a request for an intermediary hearing is filed under § 405.1811 of this subpart, the intermediary hearing officer(s) must do the following:

(i) Determine in accordance with paragraph (b) of this section whether or not it has jurisdiction to grant a hearing on each of the specific matters at issue in the hearing request.

(ii) Make a preliminary determination of the scope of its jurisdiction (that is, whether the request for hearing was timely, and whether the amount in controversy requirement has been met), if any, over the matters at issue in the appeal before conducting any of the following proceedings:

(A) Determining its authority to decide a legal question relevant to a matter at issue (as described in § 405.1829 of this subpart);

(B) Permitting discovery (as specified in § 405.1821 of this subpart); or

(C) Conducting a hearing (as specified in § 405.1819 of this subpart);

(2) The hearing officer(s) may revise a preliminary jurisdictional determination at any subsequent stage of the proceedings in an appeal, and it must promptly notify the parties of any revised determination.

(3) Under paragraph (c)(1) of this section, each intermediary hearing decision (as described in § 405.1831 of this subpart) must include a final jurisdictional finding for each specific matter at issue in the appeal.

(4) If the hearing officer(s) finally determines it lacks jurisdiction over every specific matter at issue in the appeal, it issues a jurisdictional

dismissal decision under paragraph (c)(2) of this section.

(5) Final jurisdictional findings and jurisdictional dismissal decisions by the hearing officer(s) are subject to the CMS reviewing official procedure in accordance with paragraph (d) of this section and § 405.1834(b)(2)(i) and (b)(2)(ii) of this subpart.

(b) *Criteria.* Except for the amount in controversy requirement, the jurisdiction of the intermediary hearing officer(s) to grant a hearing is determined separately for each specific matter at issue in the intermediary or Secretary determination for the cost reporting period under appeal. The hearing officer(s) has jurisdiction to grant a hearing over a specific matter at issue in an appeal only if the provider has a right to an intermediary hearing under § 405.1811. Certain matters at issue are removed from the jurisdiction of the intermediary hearing officer(s); these matters include, but are not limited to, the following:

(1) A finding in an intermediary determination that expenses incurred for certain items or services furnished by a provider to an individual are not payable under title XVIII of the Act because those items and services are excluded from coverage under section 1862 of the Act and part 411 of the regulations. Review of these findings is limited to the applicable provisions of sections 1155, 1869, and 1879(d) of the Act, and of subpart I of part 405 and subpart B of part 478, as applicable.

(2) Certain matters affecting payments to hospitals under the prospective payment system, as provided in section 1886(d)(7) of the Act and § 405.1804 of this subpart.

(3) Any self-disallowed item except as permitted in § 405.1811(a)(1)(ii) of this subpart.

(c) *Final jurisdictional findings, and jurisdictional dismissal decisions by intermediary hearing officer(s).* (1) In issuing a hearing decision under § 405.1831 of this subpart, the intermediary hearing officer(s) must make a final determination of its jurisdiction, or lack thereof, for each specific matter at issue in the hearing decision. Each intermediary hearing decision must include specific findings of fact and conclusions of law as to the jurisdiction of the hearing officer(s), or lack thereof, to grant a hearing on each matter at issue in the appeal.

(2) If the hearing officer(s) finally determines it lacks jurisdiction to grant a hearing for every specific matter at issue in an appeal, it must issue a jurisdictional dismissal decision. Each jurisdictional dismissal decision by the hearing officer(s) must include specific

findings of fact and conclusions of law explaining the determination that there is no jurisdiction to grant a hearing on each matter at issue in the appeal. A copy of the jurisdictional dismissal decision must be mailed promptly to each party to the appeal.

(3) A jurisdictional dismissal decision by the intermediary hearing officer(s) under paragraph (c)(2) of this section is final and binding on the parties, unless the decision is reviewed by a CMS reviewing official in accordance with § 405.1834 of this subpart or reopened and revised by the intermediary hearing officer(s) in accordance with § 405.1885 through § 405.1889 of this subpart.

(d) *CMS reviewing official review.* Any finding by the intermediary hearing officer as to whether it has jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative review, except as provided in this paragraph. The intermediary hearing officer's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of CMS reviewing official review of one of the intermediary hearing officer decisions specified in § 405.1834(b)(2) of this subpart.

■ 7. Section 405.1815 is revised to read as follows:

§ 405.1815 Parties to proceedings before the intermediary hearing officer(s).

When a provider files a request for an intermediary hearing in accordance with § 405.1811 of this subpart, the parties to all proceedings before the intermediary hearing officer(s) are the provider and, if applicable, any other entity found by the intermediary hearing officer(s) to be a related organization of the provider under the principles enunciated in § 413.17 of this chapter. The parties must be given reasonable notice of the time, date, and place of any intermediary hearing. Neither the intermediary nor CMS may be made a party to proceedings before the intermediary hearing officer(s).

■ 8. Section 405.1821 is revised to read as follows:

§ 405.1821 Prehearing discovery and other proceedings prior to the intermediary hearing.

(a) *Discovery rule: Time limits.* (1) Limited prehearing discovery may be permitted by the intermediary hearing officer(s) upon request of a party, provided the request is timely and the hearing officer(s) makes a preliminary finding of its jurisdiction over the matters at issue in accordance with § 405.1814(a) of this subpart.

(2) A prehearing discovery request is timely if the request by a party is served no later than 120 days before the initially scheduled starting date of the intermediary hearing, unless the intermediary hearing officer(s) extend the time for requesting discovery.

(3) In the absence of a specific schedule for responses set by the intermediary hearing officer(s), responses to interrogatories and requests for production of documents are due according to the schedule agreed upon by the party serving discovery and the party to which the discovery is directed. Responses by a party to interrogatories or requests for production of documents must be served no later than 45 days before the initially scheduled start of the intermediary hearing, unless the intermediary hearing officer(s) orders otherwise. Responses by a nonparty to requests for production of documents must be served no later than 75 days after the date the requests were served on the nonparty, unless the party requesting the documents and the nonparty to which the requests are directed agree on a different time for responding, or unless the intermediary hearing officer(s) extends the time for responding.

(4) Before ruling on a request to extend the time for requesting discovery or for responding to discovery, the hearing officer(s) must give the other parties to the appeal and any nonparty subject to a discovery request a reasonable period to respond to the extension request.

(5) If the extension request is granted, the hearing officer(s) sets a new deadline and has the discretion to reschedule the hearing date.

(b) *Discovery criteria.* (1) *General rule.* The intermediary hearing officer(s) may permit discovery of a matter that is relevant to the specific subject matter of the intermediary hearing, provided the matter is not privileged or otherwise protected from disclosure and the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate. In determining whether to permit discovery, and in fixing the scope and limits of any discovery, the hearing officer(s) uses the Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence for guidance.

(2) *Limitations on discovery.* Any discovery before the intermediary hearing officer(s) is limited as follows:

(i) A party may request of another party, or of a nonparty other than CMS, the Secretary or any Federal agency, the reasonable production of documents for inspection and copying.

(ii) A party may request another party to respond to a reasonable number of written interrogatories.

(iii) A party may not request admissions, take oral or written depositions, or take any other form of discovery not permitted under this section.

(c) *Discovery procedures. Rights of nonparties: Motions to compel or for protective order.* (1) A party may request discovery of another party to the proceedings before the intermediary hearing officer(s) or of a nonparty other than CMS, HHS or other Federal agency. Any discovery request filed with the intermediary hearing officer(s) must be mailed promptly to the party or nonparty from which the discovery is requested, and to any other party to the intermediary hearing (as described in § 405.1815 of this subpart).

(2) If a discovery request is made of a nonparty to the intermediary hearing, the nonparty has the rights any party has in responding to a discovery request. The rights of the nonparty include, but are not limited to, the right to select and use any attorney or other representative, and to submit discovery responses, objections, or motions to the hearing officer(s).

(3) Each party and nonparty is required to make a good faith effort to resolve or narrow any discovery dispute, regardless of whether the dispute is with another party or a nonparty.

(i) A party may submit to the intermediary hearing officer(s) a motion to compel discovery that is permitted under this section, and a motion for a protective order regarding any discovery request may be submitted to the hearing officer(s) by a party or nonparty.

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

(iii) The hearing officer(s) must—

(A) Decide the motion in accordance with this section and any prior discovery ruling; and

(B) Issue and mail to each party and any affected nonparty a discovery ruling that grants or denies the motion to compel or for protective order in whole or in part, if applicable, the discovery ruling must specifically identify any part of the disputed discovery request upheld and any part rejected, and impose any limits on discovery the hearing officer(s) finds necessary and

appropriate. Nothing in this section authorizes the intermediary hearing officer to compel any action from the Secretary or CMS.

(d) *Reviewability of discovery or disclosure rulings.* (1) *General rule.* A discovery ruling issued in accordance with paragraph (c)(3) of this section, or a disclosure ruling (such as one issued at a hearing), is not subject to immediate review by a CMS official (as described in § 405.1834(b)(3) of this subpart). A discovery ruling may be examined solely during the course of CMS review under § 405.1834 of this subpart of a jurisdictional dismissal decision (as described in § 405.1814(c)(2) of this subpart) or a hearing decision (as described in § 405.1831 of this subpart) by the intermediary hearing officer(s).

(2) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the intermediary hearing officer(s), that portion of the discovery or disclosure ruling may immediately be reviewed by a CMS reviewing official in accordance with § 405.1834(b)(3).

(i) Upon notice to the intermediary hearing officer that the provider intends to seek immediate review of a ruling, or that the intermediary or other affected nonparty intends to suggest that the Administrator through the CMS reviewing official, take own motion review of the ruling, the intermediary hearing officer stays all proceedings affected by the ruling.

(ii) The intermediary hearing officer must determine, under the circumstances of a given case, the length of any stay, but in no event may the stay be less than 15 days.

(iii) If the Administrator through the CMS reviewing official—

(A) Grants a request for review, or takes own motion review, of a ruling, the ruling is stayed until such time as the CMS reviewing official issues a written decision that affirms, reverses, modifies, or remands the intermediary hearing officer's ruling.

(B) Does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ruling is not subject to immediate review.

(e) *Prehearing conference.* The intermediary hearing officer(s) has discretion to schedule a prehearing conference. A prehearing conference may be conducted in person or telephonically, at the discretion of the intermediary hearing officer(s). When a panel of intermediary hearing officers is designated, the panel may appoint one

or more hearing officers to act for the panel for any prehearing conference or any matter addressed at the conference.

■ 9. Section 405.1827 is revised to read as follows:

§ 405.1827 Record of proceedings before the intermediary hearing officer(s).

(a) The intermediary hearing officer(s) must maintain a complete record of all proceedings in an appeal.

(b) The record consists of all documents and any other tangible materials timely submitted to the hearing officer(s) by the parties to the appeal and by any nonparty (as described in § 405.1821(c) of this subpart), along with all correspondence, rulings, orders, and decisions (including the final decision) issued by the hearing officer(s).

(c) The record must include a complete transcription of the proceedings at any intermediary hearing.

(d) A copy of the transcription must be made available to any party upon request.

■ 10. Section 405.1829 is amended by—

■ A. Revising the section heading.

■ B. In paragraph (a), the parenthetical phrase “(see 42 CFR 401.108)” is removed and add “(as described in § 401.108 of this chapter)” in its place.

■ C. Revising paragraph (b).

The revisions are to read as follows:

§ 405.1829 Scope of authority of intermediary hearing officer(s).

* * * * *

(b)(1) If the intermediary hearing officer(s) has jurisdiction to conduct a hearing on the specific matters at issue under § 405.1811, and the legal authority to fully resolve the matters in a hearing decision (as described in § 405.1831 of this subpart), the hearing officer(s) must affirm, modify, or reverse the intermediary's findings on each specific matter at issue in the intermediary or Secretary determination for the cost year under appeal.

(2) The intermediary hearing officer(s) also may make additional revisions on specific matters regardless of whether the intermediary considered the matters in issuing the intermediary determination for the cost year, provided the hearing officer(s) does not consider or decide any specific matter for which it lacks jurisdiction (as described in § 405.1814(b) of this subpart) or which was not timely raised in the provider's hearing request.

(3) The authority of the intermediary hearing officer(s) under this paragraph to make the additional revisions is limited to those revisions necessary to fully resolve a specific matter at issue if—

(i) The hearing officer(s) has jurisdiction to grant a hearing on the specific matter under § 405.1811 and § 405.1814 of this subpart; and

(ii) The specific matter was timely raised in an initial request for an intermediary hearing filed in accordance with § 405.1811(b) of this subpart or in a timely request to add issues to an appeal submitted in accordance with § 405.1811(c) of this subpart.

■ 11. Section 405.1831 is revised to read as follows:

§ 405.1831 Intermediary hearing decision.

(a) If the intermediary hearing officer(s) finds jurisdiction (as described in § 405.1814(a) of this subpart) and conducts a hearing the intermediary hearing officer(s) must promptly issue a written hearing decision.

(b) The intermediary hearing decision must be based on the evidence from the intermediary hearing (as described in § 405.1823 of this subpart) and other evidence as may be included in the record (as described in § 405.1827 of this subpart).

(c) The decision must include findings of fact and conclusions of law on jurisdictional issues (as described in § 405.1814(c)(1) of this subpart) and on the merits of the provider's reimbursement claims, and include appropriate citations to the record evidence and to the applicable law, regulations, CMS Rulings, and other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(d) A copy of the decision must be mailed promptly to the intermediary, to each party and to the appropriate component of CMS (which currently is the Center for Medicare Management).

(e) When the intermediary's denial of the relief that the provider seeks before the intermediary hearing officer(s) was based on procedural grounds (for example, the alleged failure of the provider to satisfy a time limit), or was based on the alleged failure to supply adequate documentation to support the provider's claim, and the intermediary hearing officer(s) rule(s) that the basis of the intermediary's denial is invalid, the intermediary hearing officer(s) remands to the intermediary for the intermediary to make a determination on the merits of the provider's claim.

■ 12. Section 405.1833 is revised to read as follows:

§ 405.1833 Effect of intermediary hearing decision.

An intermediary hearing decision issued in accordance with § 405.1831 of

this subpart is final and binding on all parties to the intermediary hearing and the intermediary unless the hearing decision is reviewed by a CMS reviewing official in accordance with § 405.1834 of this subpart or reopened and revised by the intermediary hearing officer(s) in accordance with § 405.1885 through § 405.1889 of this subpart. Final intermediary hearing decisions are subject to the provisions of § 405.1803(d) of this subpart.

■ 13. A new § 405.1834 is added to read as follows:

§ 405.1834 CMS reviewing official procedure.

(a) *Scope.* A provider that is a party to, and dissatisfied with, a final decision by the intermediary hearing officer(s), upon submitting a request that meets the requirements of paragraph (c) of this section, is entitled to further administrative review of the decision, or the decision may be reviewed at the discretion of the Administrator. No other individual, entity, or party has the right to the review. The review is conducted on behalf of the Administrator by a designated CMS reviewing official who considers whether the decision of the intermediary hearing officer(s) is consistent with the controlling legal authority (as described in § 405.1834(e)(1) of this subpart) and the evidence in the record. Based on the review, the CMS reviewing official issues a decision on behalf of the Administrator.

(b) *General rules.* (1) A CMS reviewing official may immediately review any final decision of the intermediary hearing officer(s) as specified in paragraph (b)(2) of this section.

(i) Nonfinal decisions and other nonfinal actions by the intermediary hearing officer(s) are not immediately reviewable, except as provided in paragraph (b)(3) of this section.

(ii) The CMS reviewing official exercises this review authority in response to a request from a provider party to the appeal that meets the requirements of paragraph (c) of this section or may exercise his or her discretion to take own motion review.

(2) A CMS reviewing official may immediately review the following:

(i) Any final jurisdictional dismissal decision by the intermediary hearing officer(s), including any finding that the provider failed to demonstrate good cause for extending the time in which to request a hearing (as described in § 405.1813(e)(1) and § 405.1814(c)(3) of this subpart).

(ii) Any final intermediary hearing decision (as described in § 405.1831 of this subpart).

(3) Nonfinal decisions and other nonfinal actions by the intermediary hearing officer(s) are not subject to the CMS reviewing official procedure until the intermediary hearing officer(s) issues a final decision as specified in paragraph (b)(2) of this section (as described in § 405.1813(e)(2), § 405.1814(c) and (d), and § 405.1821(d)(1) of this subpart), except that the CMS reviewing official may immediately review a ruling, authorizing discovery or disclosure of a matter, where there is a claim of privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden.

(4) In order to facilitate the Administrator's exercise of this review authority, the intermediary hearing officer(s) must promptly send copies of any decision specified in paragraph (b)(2) of this section or § 405.1821(d)(2) of this subpart to the appropriate component of CMS (currently the Center for Medicare Management).

(i) All requests for review by a CMS reviewing official and all written submissions to a CMS reviewing official under paragraphs (c) and (d) of this section also must be sent to the appropriate component of CMS.

(ii) The appropriate CMS component examines each intermediary hearing officer decision that is reviewable under paragraph (b)(2) of this section or § 405.1821(d)(2) of this subpart, along with any review requests and any other submissions made by a party in accordance with the provisions of this section, in order to assist the Administrator's exercise of this review authority.

(c) *Request for review.* (1) A provider's request for review by a CMS reviewing official is granted if—

(i) The date of receipt by the appropriate CMS component of the review request is no later than 60 days after the date of receipt by the provider of the intermediary hearing officer decision; or

(ii) The request seeks review of a decision listed in paragraph (b)(2) of this section, and the provider complies with the requirements of paragraph (c)(2) of this section.

(2) The provider must submit its request for review in writing, attach a copy of the intermediary decision for which it seeks review and include a brief description of all of the following:

(i) Those aspects of the intermediary hearing officer decision with which the provider is dissatisfied.

(ii) The reasons for the provider's dissatisfaction.

(iii) Any argument or record evidence the provider believes supports its position.

(iv) Any additional, extra-record evidence relied on by the provider, along with a demonstration that such evidence was improperly excluded from the intermediary hearing (as described in § 405.1823 of this subpart).

(3) A provider request for immediate review of an intermediary hearing officer ruling authorizing discovery or disclosure in accordance with paragraph (b)(3) of this section must—

(i) Be made as soon as practicable after the ruling is made, but in no event later than 5 business days after the date it received notice of the ruling; and

(ii) State the reason(s) why the ruling is in error and the potential harm that may be caused if immediate review is not granted.

(d) *Own motion review.* (1) The Administrator has discretion to take own motion review of an intermediary hearing officer decision (regardless of whether the decision was favorable or unfavorable to the provider) or other reviewable action.

(2) In order to exercise this authority, the CMS reviewing official must, no later than 60 days after the date of the intermediary hearing officer's decision, notify the parties and the intermediary that he or she intends to review the intermediary hearing officer decision or other reviewable action.

(3) In the notice, the CMS reviewing official identifies with particularity the issues that are to be reviewed, and gives each party (as described in § 405.1815 of this subpart) and affected nonparty a reasonable period to comment on the issues through a written submission complying with paragraph (c)(2) of this section.

(e) *Review procedure.* (1) In reviewing an intermediary hearing officer decision specified in paragraph (b)(2) of this section, the CMS reviewing official must—

(i) Comply with all applicable law, regulations, and CMS Rulings (as described in § 401.108 of this chapter), and afford great weight to other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS;

(ii) Subject to paragraph (e)(1)(iii) of this section, limit the review to the record of the proceedings before the intermediary hearing officer(s) (as described in § 405.1827 of this subpart) and any written submissions by the parties under paragraphs (c)(2) or (d) of this section; and

(iii) Consider additional, extra-record evidence only if he or she determines that the evidence was improperly excluded from the intermediary hearing (as described in § 405.1823 of this subpart).

(2) Review of an intermediary decision specified in paragraph (b)(2) of this section is limited to a hearing on the written record in accordance with paragraph (e)(1)(ii) of this section, unless the CMS reviewing official determines that—

(i) Additional, extra-record evidence may be considered in accordance with paragraph (e)(1)(iii) of this section;

(ii) An oral hearing is necessary for consideration of the extra-record evidence; and

(iii) It is not necessary or appropriate to remand the matter to the intermediary hearing officer(s).

(3) Upon completion of the review of an intermediary hearing decision specified in paragraph (b)(2) of this section, the CMS reviewing official issues a written decision that affirms, reverses, modifies, or remands the intermediary hearing decision. A copy of the decision must be mailed promptly to each party, to the intermediary, and to the appropriate component of CMS (currently the Center for Medicare Management).

(f) *Effect of a decision: Remand.* (1) A decision of affirmation, reversal, or modification by the CMS reviewing official is final and binding on each party and the intermediary. No further review or appeal of a decision is available, but the decision may be reopened and revised by a CMS reviewing official in accordance with § 405.1885 through § 405.1889 of this subpart. Decisions of a CMS reviewing official are subject to the provisions of § 405.1803(d) of this subpart. A decision by a CMS reviewing official remanding an appeal to the intermediary hearing officer(s) for further proceedings under paragraph (f)(2) of this section is not a final decision.

(2) A remand to the intermediary hearing officer(s) by the CMS reviewing official must—

(i) Vacate the intermediary hearing officer decision;

(ii) Be governed by the same criteria that apply to remands by the Administrator to the Board under § 405.1875(f)(2) of this subpart, and require the intermediary hearing officer(s) to take specific actions on remand; and

(iii) Result in the intermediary hearing officer(s) taking the actions required on remand and issuing a new intermediary hearing decision in

accordance with § 405.1831 and § 405.1833 of this subpart.

■ 14. Section 405.1835 is revised to read as follows:

§ 405.1835 Right to Board hearing; contents of, and adding issues to, hearing request.

(a) *Criteria.* A provider (but no other individual, entity, or party) has a right to a Board hearing, as a single provider appeal, for specific items claimed for a cost reporting period covered by an intermediary or Secretary determination, only if—

(1) The provider has preserved its right to claim dissatisfaction with the amount of Medicare payment for the specific item(s) at issue, by either—

(i) Including a claim for specific item(s) on its cost report for the period where the provider seeks payment that it believes to be in accordance with Medicare policy; or

(ii) Effective with cost reporting periods that end on or after December 31, 2008, self-disallowing the specific item(s) by following the applicable procedures for filing a cost report under protest, where the provider seeks payment that it believes may not be allowable or may not be in accordance with Medicare policy (for example, if the intermediary lacks discretion to award the reimbursement the provider seeks for the item(s)).

(2) The amount in controversy (as determined in accordance with § 405.1839 of this subpart) is \$10,000 or more; and

(3) Unless the provider qualifies for a good cause extension under § 405.1836 of this subpart, the date of receipt by the Board of the provider's hearing request is—

(i) No later than 180 days after the date of receipt by the provider of the intermediary or Secretary determination; or

(ii) If the intermediary determination is not issued (through no fault of the provider) within 12 months of the date of receipt by the intermediary of the provider's perfected cost report or amended cost report (as specified in § 413.24(f) of this chapter), no later than 180 days after the expiration of the 12 month period for issuance of the intermediary determination. The date of receipt by the intermediary of the provider's perfected cost report or amended cost report is presumed to be the date the intermediary stamped "Received" unless it is shown by a preponderance of the evidence that the intermediary received the cost report on an earlier date.

(b) *Contents of request for a Board hearing.* The provider's request for a

Board hearing must be submitted in writing to the Board, and the request must include the elements described in paragraphs (b)(1) through (b)(4) of this section. If the provider submits a hearing request that does not meet the requirements of paragraphs (b)(1), (b)(2), or (b)(3) of this section, the Board may dismiss with prejudice the appeal, or take any other remedial action it considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a Board hearing as specified in paragraph (a) of this section, including a specific identification of the intermediary's or Secretary's determination under appeal.

(2) An explanation (for each specific item at issue, see paragraph (a)(1) of this section) of the provider's dissatisfaction with the intermediary's or Secretary's determination under appeal, including an account of all of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it does not have access to underlying information concerning the calculation of its payment).

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item, a description of the nature and amount of each self-disallowed item and the reimbursement or payment sought for the item.

(3) A copy of the intermediary or Secretary determination under appeal, and any other documentary evidence the provider considers necessary to satisfy the hearing request requirements of paragraphs (b)(1) and (b)(2) of this section.

(4) With respect to a provider under common ownership or control, the name and address of its parent corporation, and a statement that—

(i) To the best of the provider's knowledge, no other provider to which it is related by common ownership or control, has pending a request for a Board hearing pursuant to this section or pursuant to § 405.1837(b)(1) on any of the same issues contained in the provider's hearing request for a cost reporting period that falls within the same calendar year as the calendar year covered by the provider's hearing request; or

(ii) Such a pending appeal(s) exist(s), the provider name(s), provider number(s), and the case number(s) (if assigned), for such appeal(s).

(c) *Adding issues to the hearing request.* After filing a hearing request in

accordance with paragraphs (a) and (b) of this section, a provider may add specific Medicare payment issues to the original hearing request by submitting a written request to the Board, only if the following requirements are met:

(1) The request to add issues complies with the requirements of paragraphs (a)(1) and (b) of this section as to each new issue.

(2) The specific matters at issue raised in the initial hearing request and the matters identified in subsequent requests to add issues, when combined, satisfy the requirements of paragraph (a)(2) of this section.

(3) The Board receives the request to add issues no later than 60 days after the expiration of the applicable 180-day period prescribed in paragraph (a)(3) of this section.

■ 15. Section 405.1836 is added to read as follows:

§ 405.1836 Good cause extension of time limit for requesting a Board hearing.

(a) A request for a Board hearing that the Board receives after the applicable 180-day time limit prescribed in § 405.1835(a)(3) of this subpart must be dismissed by the Board, except that the Board may extend the time limit upon a good cause showing by the provider.

(b) The Board may find good cause to extend the time limit only if the provider demonstrates in writing it can not reasonably be expected to file timely due to extraordinary circumstances beyond its control (such as a natural or other catastrophe, fire, or strike), and the provider's written request for an extension is received by the Board within a reasonable time (as determined by the Board under the circumstances) after the expiration of the applicable 180-day limit specified in § 405.1835(a)(3).

(c) The Board may not grant a request for an extension under this section if—

(1) The provider relies on a change in the law, regulations, CMS Rulings, or general CMS instructions (whether based on a court decision or otherwise) or a CMS administrative ruling or policy as the basis for the extension request; or

(2) The date of receipt by the Board of the provider's extension request is later than 3 years after the date of the intermediary or other determination that the provider seeks to appeal.

(d) If an extension request is granted or denied under this section, the Board must give prompt written notice to the provider, and mail a copy of the notice to each party to the appeal. The notice must include a detailed explanation of the reasons for the decision by the Board and the facts underlying the decision.

(e)(1) If the Board denies an extension request and determines it lacks jurisdiction to grant a hearing for every specific matter at issue in an appeal, it must issue a Board dismissal decision dismissing the appeal for lack of Board jurisdiction. This decision by the Board must be in writing and include the explanation of the extension request denial required under paragraph (d) of this section, in addition to specific findings of fact and conclusions of law explaining the Board's determination that it lacks jurisdiction to grant a hearing on each matter at issue in the appeal (as described in § 405.1840(c) of this subpart). A copy of the Board's dismissal decision must be mailed promptly to each party to the appeal (as described in § 405.1843 of this subpart).

(2) A Board dismissal decision under paragraph (e)(1) of this section is final and binding on the parties, unless the decision is reversed, affirmed, modified, or remanded by the Administrator under § 405.1875(a)(2)(ii) and § 405.1875(e) or § 405.1875(f) of this subpart, no later than 60 days after the date of receipt by the provider of the Board's decision.

(i) This Board decision is inoperative during the 60-day period for review of the decision by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands that decision, within the period.

(ii) A Board decision under paragraph (e)(1) of this section that is otherwise final and binding may be reopened and revised by the Board in accordance with § 405.1885 through § 405.1889 of this subpart.

(3) The Administrator may review a Board decision granting an extension request solely during the course of an Administrator review of one of the Board decisions specified as final, or deemed final by the Administrator, under § 405.1875(a)(2) of this subpart.

(4) A finding by the Board or the Administrator that the provider did or did not demonstrate good cause for extending the time for requesting a Board hearing is not subject to judicial review.

■ 16. Section 405.1837 is revised to read as follows:

§ 405.1837 Group appeals.

(a) *Right to Board hearing as part of a group appeal; criteria.* A provider (but no other individual, entity, or party) has a right to a Board hearing, as part of a group appeal with other providers, for specific items claimed for a cost reporting period covered by an intermediary or Secretary determination for the period, only if—

(1) The provider satisfies individually the requirements for a Board hearing under § 405.1835(a), except for the \$10,000 amount in controversy requirement under § 405.1835(a)(2) of this subpart;

(2) The matter at issue in the group appeal involves a single question of fact or interpretation of law, regulations, or CMS Rulings that is common to each provider in the group; and

(3) The amount in controversy is, in the aggregate, \$50,000 or more, as determined in accordance with § 405.1839 of this subpart.

(b) *Usage and filing of group appeals.*

(1) *Mandatory use of group appeals.*

(i) Two or more providers under common ownership or control that wish to appeal to the Board a specific matter at issue that involves a question of fact or interpretation of law, regulations, or CMS Rulings that is common to the providers, and that arises in cost reporting periods that end in the same calendar year, and for which the amount in controversy is \$50,000 or more in the aggregate, must bring the appeal as a group appeal.

(ii) One or more of the providers under common ownership or control may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for purposes of meeting the \$50,000 amount in controversy requirement, and, subject to the Board's discretion, may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for other purposes, such as convenience.

(iii) A group appeal involving two or more providers under common ownership or control must consist entirely of providers under common (to all) ownership or control.

(iv)(A) *Example 1:* A, B, C and D are commonly owned providers that wish to appeal issue X. This issue was adjusted on A, B and C's CY 2004 cost reports, and on D's CY 2005 cost report. The amount in controversy is more than \$50,000 in the aggregate for providers A, B and C, and more than \$10,000 for provider D. Providers A, B and C must appeal issue X as a group appeal. Provider D may pursue an individual appeal to the Board under the procedures set forth in § 405.1835 of this subpart, or if the Board agrees, Provider D may join the group appeal. (If Provider D joins the group appeal, the calendar years in the group appeal would then be 2004 and 2005, and any provider related to Providers A through D by common ownership or control would be required to appeal issue X for its cost reporting period ending in 2004 or 2005 through the group appeal.)

(B) *Example 2:* A, B and C are commonly owned providers that wish to appeal issue X. This issue was adjusted on A, B and C's CY

2004 cost reports. The amount in controversy is less than \$50,000 in the aggregate for providers A, B and C (\$10,000 for A, \$10,000 for B and \$7,000 for C). Providers A, B and C cannot appeal issue X as a group appeal. Provider A, if it wishes, and provider B, if it wishes, may pursue an individual appeal to the Board under the procedures set forth in § 405.1835 of this subpart. Provider C may not pursue an individual appeal to the Board, because the amount in controversy is less than \$10,000; however, it may pursue an appeal to the intermediary under the procedures set forth in § 405.1811 of this subpart.

(2) *Optional group appeals.* (i) Two or more providers not under common ownership or control may bring a group appeal before the Board under this section, if the providers wish to appeal to the Board a specific matter at issue that involves a question of fact or interpretation of law, regulations, or CMS Rulings that is common to the providers. Alternatively, any provider may appeal to the Board any issues in a single provider appeal brought under § 405.1835 of this subpart.

(ii) One or more of the providers bringing a group appeal under this paragraph may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for purposes of meeting the \$50,000 amount in controversy requirement, and, subject to the Board's discretion, may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for other purposes, such as convenience.

(3) *Initiating a group appeal.* With respect to group appeals brought under paragraph (b)(1) of this section, one or more commonly owned or operated providers must make a written request for a Board hearing as a group appeal in accordance with paragraph (c) of this section. Any group appeal filed by a single provider must be joined by related providers on common issues in accordance with paragraphs (b)(1) and (e) of this section. With respect to group appeals brought under paragraph (b)(2) of this section, two or more providers may submit—

(i) A written request for a Board hearing as a group appeal in accordance with paragraph (c) of this section; or

(ii) A request to the Board in accordance with paragraph (e)(4) of this section that a specific matter at issue in a single provider appeal, filed previously under § 405.1835 of this subpart, be transferred from the single appeal to a group appeal.

(c) *Contents of request for a group appeal.* The request for a Board hearing as a group appeal must be submitted in

writing to the Board, and the request must include all of the following:

(1) A demonstration that the request satisfies the requirements for a Board hearing as a group appeal, as specified in paragraph (a) of this section.

(2) An explanation (for each specific item at issue; see § 405.1835(a)(1)) of each provider's dissatisfaction with its intermediary or Secretary determination under appeal, including an account of—

(i) Why the provider believes Medicare payment is incorrect for each disputed item;

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item; and

(iii) If the provider self-disallows a specific item, a description of the nature and amount of each self-disallowed item and the reimbursement sought for each item.

(3) A copy of each intermediary or Secretary determination under appeal, and any other documentary evidence the providers consider necessary to satisfy the hearing request requirements of paragraphs (c)(1) and (c)(2) of this section, and a precise description of the one question of fact or interpretation of law, regulations, or CMS Rulings that is common to the particular matters at issue in the group appeal; and

(4) A statement that—

(i) The providers believe they have satisfied all of the requirements for a group appeal hearing request under paragraph (a) of this section and requesting the Board to proceed to make jurisdictional findings in accordance with § 405.1840; or

(ii) The Board is requested to defer making jurisdictional findings until the providers request the findings in accordance with paragraph (e)(2) of this section.

(d) *Board's preliminary response to group appeal hearing requests.* (1) Upon receipt of a group appeal hearing request, the Board must take any necessary ministerial steps.

(2) The steps, include, for example—

(i) Acknowledging the request;

(ii) Assigning a case number to the appeal; or

(iii) If applicable, transferring a specific matter at issue from a single provider appeal filed under § 405.1835 of this subpart to a group appeal filed under this section.

(e) *Group appeal procedures pending full formation of the group and issuance of a Board decision.* (1) A provider (or providers) may file a group appeal hearing request with the Board under this section before each provider member of the group identifies or complies with paragraphs (a)(1) and

(a)(2) of this section, or before the group satisfies the \$50,000 amount in controversy requirement under paragraph (a)(3) of this section. Proceedings before the Board in any partially formed group appeal are subject to the provisions of paragraphs (e)(2), (e)(3), and (e)(4) of this section. The Board will determine that a group appeal brought under paragraph (b)(1) of this section is fully formed upon a notice in writing from the group that it is fully formed. Absent such a notice from the group, the Board may issue an order, requiring the group to demonstrate (within a period of not less than 15 days) that at least one commonly owned or controlled provider has preserved the issue for appeal by claiming the relevant item on its cost report or by self-disallowing the item, but has not yet received its final determination with respect to the item for a cost year that is within the same calendar year as that covered by the group appeal (or that it has received its final determination with respect to the item for that period, and is still within the time to request a hearing on the issue). The Board determines that a group appeal brought under paragraph (b)(2) of this section is fully formed upon a notice in writing from the group that it is fully formed, or following an order from the Board that in its judgment, that the group is fully formed, or through general instructions that set forth a schedule for the closing of group appeals brought under paragraph (b)(2) of this section. When the Board has determined that a group appeal brought under paragraph (b)(1) of this section is fully formed, absent an order from the Board modifying its determination, no other provider under common ownership or control may appeal to the Board the issue that is the subject of the group appeal with respect to a cost reporting period that falls within the calendar year(s) covered by the group appeal.

(2) The Board may make jurisdictional findings under § 405.1840 at any time, including, but not limited to, following a request by the providers for the jurisdictional findings. The providers may request jurisdictional findings by notifying the Board in writing that the group appeal is fully formed, or that the providers believe they have satisfied all of the requirements for a group appeal hearing request, and the Board may proceed to make jurisdictional findings. The providers must include with the notice any additional information or documentary evidence that is required for group appeal hearing requests. The Board does not dismiss a group appeal

hearing request for failure to meet the \$50,000 amount in controversy requirement until the Board has determined, in accordance with paragraph (e)(1) of this section, that the group is fully formed.

(3) If the Board makes a preliminary determination of jurisdiction to conduct a hearing as a group appeal under this section, the Board then takes any further actions in the appeal it finds to be appropriate under this subpart (as described in § 405.1840(a) of this subpart). The Board may take further actions, even though the providers in the appeal may wish to add other providers to the group in accordance with paragraph (e)(4) of this section. The Board must make separate jurisdictional findings for each cost reporting period added subsequently to the group appeal (as described in § 405.1837(a) and § 405.1839(b) of this subpart).

(4) A provider may submit a request to the Board to join a group appeal anytime before the Board issues one of the decisions specified in § 405.1875(a)(2). By submitting a request, the provider agrees that, if the request is granted, the provider is bound by the Board's actions and decision in the appeal. If the Board denies a request, the Board's action is without prejudice to any separate appeal the provider may bring in accordance with § 405.1811 of this subpart, § 405.1835 of this subpart, or this section. For purposes of determining timeliness for the filing of any separate appeal and for the adding of issues to such appeal, the date of receipt of the provider's request to form or join the group appeal is considered the date of receipt for purposes of meeting the applicable 180-day period prescribed in § 405.1835(a)(3) of this subpart.

(5)(i) Except as specified in paragraph (ii) of this paragraph, when a provider has appealed an issue through electing to form, or joining, a group appeal under the procedures set forth in this section, it may not subsequently request that the Board transfer that issue to a single provider appeal brought in accordance with § 405.1811 or § 405.1835 of this subpart.

(ii) *Exception.* When the Board determines that the requirements for a group appeal are not met (that is, when there has been a failure to meet the amount in controversy or the common issue requirement), it transfers the issue that was the subject of the group appeal to a single provider appeal (or appeals) for the provider (or providers) that meets (or meet) the requirements for a single provider appeal.

(f) *Limitations on group appeals.* (1) After the date of receipt by the Board of a group appeal hearing request under paragraph (c) of this section, a provider may not add other questions of fact or law to the appeal, regardless of whether the question is common to other members of the appeal (as described in § 405.1837(a)(2) and (g) of this subpart).

(2) The Board may not consider, in one group appeal, more than one question of fact, interpretation of law, regulations, or CMS Rulings that is common to each provider in the appeal. If the Board finds jurisdiction over a group appeal hearing request under § 405.1840 of this subpart—

(i) The Board must determine whether the appeal involves specific matters at issue that raise more than one factual or legal question common to each provider; and

(ii) When the appeal is found to involve more than one factual or legal question common to each provider, the Board must assign a separate case number to the appeal of each common factual or legal question and conduct further proceedings in the various appeals separately for each case.

(g) *Issues not common to the group appeal.* A provider involved in a group appeal that also wishes to appeal a specific matter that does not raise a factual or legal question common to each of the other providers in the group must file a separate request for a single provider hearing in accordance with § 405.1811 or § 405.1835 of this subpart, or file a separate request for a hearing as part of a different group appeal under this section, as applicable.

■ 17. Section 405.1839 is revised to read as follows:

§ 405.1839 Amount in controversy.

(a) *Single provider appeals.* (1) In order to satisfy the amount in controversy requirement under § 405.1811(a)(2) of this subpart for an intermediary hearing or the amount in controversy requirement under § 405.1835(a)(2) of this subpart for a Board hearing for a single provider, the provider must demonstrate that if its appeal were successful, the provider's total program reimbursement for each cost reporting period under appeal increases by at least \$1,000 but by less than \$10,000 for an intermediary hearing, or by at least \$10,000 for a Board hearing, as applicable.

(2) *Aggregation of claims.* For purposes of satisfying the applicable amount in controversy requirement for a single provider appeal to the intermediary or the Board, the provider may aggregate claims for additional program payment for more than one

specific matter at issue, provided each specific claim and issue is for the same cost reporting period. Aggregation of claims from more than one cost reporting period to meet the applicable amount in controversy requirement is prohibited, even if a specific claim or issue recurs in the appeal for multiple cost years.

(b) *Group appeals.* (1) In order to satisfy the amount in controversy requirement under § 405.1837(a)(3) of this subpart for a Board hearing as a group appeal, the group must demonstrate that if its appeal were successful, the total program reimbursement for the cost reporting periods under appeal increases, in the aggregate, by at least \$50,000.

(2) *Aggregation of claims.* (i) For purposes of satisfying the amount in controversy requirement, group members are not allowed to aggregate claims involving different issues.

(A) A group appeal must involve a single question of fact or interpretation of law, regulations, or CMS Ruling that is common to each provider (as described in § 405.1837(a)(2) of this subpart).

(B) The single issue that is common to each provider may exist over different cost reporting periods.

(ii) For purposes of satisfying the amount in controversy requirement, a provider may appeal multiple cost reporting periods and different providers in the group may appeal different cost reporting periods.

(c) *Limitations on change in Medicare reimbursement.* (1) In order to satisfy the applicable amount in controversy requirement for a single provider appeal or a group appeal, an appeal favorable to the provider(s) on all specific matters at issue in the appeal increases program reimbursement for the provider(s) in the cost reporting period(s) at issue by an amount that equals or exceeds the applicable amount in controversy threshold.

(2) The applicable amount in controversy requirement is not satisfied if the result of a favorable appeal decreases program reimbursement for the provider(s) in the cost reporting year(s) at issue in the appeal.

(3) Any effects that a favorable appeal might have on program reimbursement for the provider(s) in cost reporting period(s) not at issue in the appeal have no bearing on whether the amount in controversy requirement is satisfied for the cost year(s) at issue in the appeal.

(4) When a provider (or group of providers) has requested a hearing before an intermediary under § 405.1811 of this subpart, and the amount in controversy is subsequently determined

to be at least \$10,000 (for example, due to a reassessment of the amount in controversy by the intermediary hearing office or due to adding an issue), the appeal is transferred to the Board. The Board is not bound by any jurisdictional finding of the intermediary hearing officer(s).

(5) When a provider or group of providers has requested a hearing before the Board under § 405.1835 or § 405.1837 of this subpart, and the amount in controversy changes to an amount less than the minimum for a Board appeal due to—

(A) The settlement or partial settlement of an issue, transfer of an issue to a group appeal, or the abandonment of an issue in an individual appeal, the change in the amount in controversy does not deprive the Board of jurisdiction.

(B) A more accurate assessment of the amount in controversy, the Board does not retain jurisdiction.

■ 18. A new § 405.1840 is added to read as follows:

§ 405.1840 Board jurisdiction.

(a) *General rules.* (1) After a request for a Board hearing is filed under § 405.1835 or § 405.1837 of this part, the Board must determine in accordance with paragraph (b) of this section, whether or not it has jurisdiction to grant a hearing on each of the specific matters at issue in the hearing request.

(2) The Board must make a preliminary determination of the scope of its jurisdiction (that is, whether the request for hearing was timely, and whether the amount in controversy requirement has been met), if any, over the matters at issue in the appeal before conducting any of the following proceedings:

(i) Determining its authority to decide a legal question relevant to a matter at issue (as described in § 405.1842 of this subpart).

(ii) Permitting discovery (as described in § 405.1853 of this subpart).

(iii) Issuing a subpoena (as described in § 405.1857 of this subpart).

(iv) Conducting a hearing (as described in § 405.1845 of this subpart).

(3) The Board may revise a preliminary determination of jurisdiction at any subsequent stage of the proceedings in a Board appeal, and must promptly notify the parties of any revised determination. Under paragraph (c)(1) of this section, each expedited judicial review (EJR) decision (as described in § 405.1842 of this subpart) and hearing decision (as described in § 405.1871 of this subpart) by the Board must include a jurisdictional finding for

each specific matter at issue in the appeal.

(4) If the Board finally determines it lacks jurisdiction over every specific matter at issue in the appeal, the Board must issue a dismissal decision under paragraph (c)(2) of this section.

(5) Final jurisdictional findings and dismissal decisions by the Board under paragraphs (c)(1) and (c)(2) of this section are subject to Administrator and judicial review in accordance with paragraph (d) of this section.

(b) *Criteria.* Except with respect to the amount in controversy requirement, the jurisdiction of the Board to grant a hearing must be determined separately for each specific matter at issue in each intermediary or Secretary determination for each cost reporting period under appeal. The Board has jurisdiction to grant a hearing over a specific matter at issue in an appeal only if the provider has a right to a Board hearing as a single provider appeal under § 405.1835 of this subpart or as part of a group appeal under § 405.1837 of this subpart, as applicable. Certain matters at issue are removed from jurisdiction of the Board. These matters include, but are not necessarily limited to, the following:

(1) A finding in an intermediary determination that expenses incurred for certain items or services furnished by a provider to an individual are not payable under title XVIII of the Act because those items or services are excluded from coverage under section 1862 of the Act and Part 411 of the regulations. Review of these findings is limited to the applicable provisions of sections 1155, 1869, and 1879(d) of the Act and of Subpart I of Part 405 and Subpart B of Part 478 of the regulations, as applicable.

(2) Certain matters affecting payments to hospitals under the prospective payment system, as provided in section 1886(d)(7) of the Act and § 405.1804 of this subpart.

(3) Any self-disallowed cost, except as permitted in § 405.1835(a)(1)(ii) and § 405.1837(a)(1) of this subpart.

(c) *Board's jurisdictional findings and jurisdictional dismissal decisions.* (1) In issuing an EJR decision under § 405.1842 of this subpart or a hearing decision under § 405.1871 of this subpart, as applicable, the Board must make a separate determination of whether it has jurisdiction for each specific matter at issue in each intermediary or Secretary determination under appeal. A decision by the Board must include specific findings of fact and conclusions of law as to whether the Board has jurisdiction to grant a hearing on each matter at issue in the appeal.

(2) Except as provided in § 405.1836(e)(1) and § 405.1842(f)(2)(i) of this subpart, where the Board determines it lacks jurisdiction to grant a hearing for every specific matter at issue in an appeal, it must issue a dismissal decision dismissing the appeal for lack of Board jurisdiction. The decision by the Board must include specific findings of fact and conclusions of law explaining the Board's determination that it lacks jurisdiction to grant a hearing on each matter at issue in the appeal. A copy of the Board's decision must be mailed promptly to each party to the appeal (as described in § 405.1843 of this subpart).

(3) A dismissal decision by the Board under paragraph (c)(2) of this section is final and binding on the parties unless the decision is reversed, affirmed, modified or remanded by the Administrator under § 405.1875(a)(2)(ii) and § 405.1875(e) or § 405.1875(f) of this subpart, no later than 60 days after the date of receipt by the provider of the Board's decision. The Board decision is inoperative during the 60-day period for review of the decision by the Administrator, or in the event the Administrator reverses, affirms, modifies or remands that decision within that period. A final Board decision under paragraphs (c)(2) and (c)(3) of this section may be reopened and revised by the Board in accordance with § 405.1885 through § 405.1889 of this subpart.

(d) *Administrator and judicial review.* Any finding by the Board as to whether it has jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative and judicial review, except as provided in this paragraph. The Board's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of Administrator review of one of the Board decisions specified as final, or deemed to be final by the Administrator, under § 405.1875(a)(2) of this subpart, or during the course of judicial review of a final agency decision as described in § 405.1877(a) of this subpart, as applicable.

§ 405.1841 [Removed]

- 19. Section 405.1841 is removed.
- 20. Section 405.1842 is revised to read as follows:

§ 405.1842 Expedited judicial review.

(a) *Basis and scope.* (1) This section implements provisions in section 1878(f)(1) of the Act that give a provider the right to seek EJR of a legal question relevant to a specific matter at issue in a Board appeal if there is Board

jurisdiction to conduct a hearing on the matter (as described in § 405.1840 of this subpart), and the Board determines it lacks the authority to decide the legal question (as described in § 405.1867 of this subpart, explains the scope of the Board's legal authority).

(2) A provider may request a Board decision that the provider is entitled to seek EJR or the Board may consider issuing a decision on its own motion. Each EJR decision by the Board must include a specific jurisdictional finding on the matter(s) at issue, and, where the Board determines that it does have jurisdiction on the matter(s) at issue, a separate determination of the Board's authority to decide the legal question(s).

(3) The Administrator may review the Board's jurisdictional finding, but not the Board's authority determination.

(4) The provider has a right to seek EJR of the legal question under section 1878(f)(1) of the Act only if—

(i) The final EJR decision of the Board or the Administrator, as applicable, includes a finding of Board jurisdiction over the specific matter at issue and a determination by the Board that it has no authority to decide the relevant legal question; or

(ii) The Board fails to make a determination of its authority to decide the legal question no later than 30 days after finding jurisdiction over the matter at issue and notifying the provider that the provider's EJR request is complete.

(b) *General.* (1) *Prerequisite of Board jurisdiction.* The Board (or the Administrator) must find that the Board has jurisdiction over the specific matter at issue before the Board may determine its authority to decide the legal question.

(2) *Initiating EJR procedures.* A provider or group of providers may request the Board to grant EJR of a specific matter or matters under appeal, or the Board on its own motion may consider whether to grant EJR of a specific matter or matters under appeal. Under paragraph (c) of this section, the Board may initiate own motion consideration of its authority to decide a legal question only if the Board makes a preliminary finding that it has jurisdiction over the specific matter at issue to which the legal question is relevant. Under paragraphs (d) and (e) of this section, a provider may request a determination of the Board's authority to decide a legal question, but the 30-day period for the Board to make a determination under section 1878(f)(1) of the Act does not begin to run until the Board finds jurisdiction to conduct a hearing on the specific matter at issue in the EJR request and notifies the

provider that the provider's request is complete.

(c) *Board's own motion consideration.* (1) If the Board makes a finding that it has jurisdiction to conduct a hearing on a specific matter at issue in accordance with § 405.1840(a) of this part, it may then consider on its own motion whether it lacks the authority to decide a legal question relevant to the matter at issue.

(2) The Board must initiate its own motion consideration by issuing a written notice to each of the parties to the appeal (as described in § 405.1843 of this subpart). The notice must—

(i) Identify each specific matter at issue for which the Board has made a finding that it has jurisdiction under § 405.1840(a) of this part, and for each specific matter, identify each relevant statutory provision, regulation, or CMS Ruling; and

(ii) Specify a reasonable period of time for the parties to respond in writing.

(3) After considering any written responses made by the parties to its notice of own motion consideration, the Board must determine whether it has sufficient information to issue an EJR decision for each specific matter and legal question included in the notice. If necessary, the Board may request additional information regarding its jurisdiction or authority from a party (or parties), and the Board must give any other party a reasonable opportunity to comment on any additional submission. Once the Board determines it needs no further information from the parties (or that any information has not been rendered timely), it must issue an EJR decision in accordance with paragraph (f) of this section.

(d) *Provider requests.* A provider (or, in the case of a group appeal, a group of providers) may request a determination by the Board that it lacks the authority to decide a legal question relevant to a specific matter at issue in an appeal. A provider must submit a request in writing to the Board and to each party to the appeal (as described in § 405.1843 of this subpart), and the request must include—

(1) For each specific matter and question included in the request, an explanation of why the provider believes the Board has jurisdiction under § 405.1840 of this subpart over each matter at issue and no authority to decide each relevant legal question; and

(2) Any documentary evidence the provider believes supports the request.

(e) *Board action on provider requests.* (1) If the Board makes a finding that it has jurisdiction to conduct a hearing on a specific matter at issue in accordance

with § 405.1840(a) of this part, then (and only then) it must consider whether it lacks the authority to decide a legal question relevant to the matter at issue. The Board is required to make a determination of its authority to decide the legal question raised in a review request under paragraph (d)(1) of this section by issuing an EJR decision no later than 30 days after receiving a complete provider request as defined in paragraph (e)(2) of this section.

(2) *Requirements of a complete provider request.* A complete provider request for EJR consists of the following:

(i) A request for an EJR decision by the provider(s).

(ii) All of the information and documents found necessary by the Board for issuing a decision in accordance with paragraph (f) of this section.

(3) *Board's response to provider requests.* After receiving a provider request for an EJR decision, the Board must review the request, along with any responses to the request submitted by other parties to the appeal (as described in § 405.1843 of this subpart). The Board must respond to the provider(s) as follows:

(i) Upon receiving a complete provider request, issue an EJR decision in accordance with paragraph (f) of this section no later than 30 days after receipt of the complete provider request. If the Board does not issue a decision within that 30-day period, the provider has a right to file a complaint in Federal district court in order to obtain EJR over the specific matter(s) at issue.

(ii) If the provider has not submitted a complete request, issue no later than 30 days after receipt of the incomplete request a written notice to the provider describing in detail the further information that the provider must submit in order to complete the request.

(f) *Board's decision on EJR: Criteria for granting EJR.* Subject to paragraph (h)(3) of this section, the Board is required to issue an EJR decision following either the completion of the Board's own motion consideration under paragraph (c) of this section, or a notice issued by the Board in accordance with paragraph (e)(3)(i) of this section.

(1) The Board's decision must grant EJR for a legal question relevant to a specific matter at issue in a Board appeal if the Board determines the following conditions are satisfied:

(i) The Board has jurisdiction to conduct a hearing on the specific matter at issue in accordance with § 405.1840 of this subpart.

(ii) The Board lacks the authority to decide a specific legal question relevant

to the specific matter at issue because the legal question is a challenge either to the constitutionality of a provision of a statute, or to the substantive or procedural validity of a regulation or CMS Ruling.

(2) The Board's decision must deny EJR for a legal question relevant to a specific matter at issue in a Board appeal if any of the following conditions are satisfied:

(i) The Board determines that it does not have jurisdiction to conduct a hearing on the specific matter at issue in accordance with § 405.1840 of this subpart.

(ii) The Board determines it has the authority to decide a specific legal question relevant to the specific matter at issue because the legal question is neither a challenge to the constitutionality of a provision of a statute, nor a challenge to the substantive or procedural validity of a regulation or CMS Ruling.

(iii) The Board does not have sufficient information to determine whether the criteria specified in paragraph (f)(1)(i) or (f)(1)(ii) of this section are met.

(3) A copy of the Board's decision must be sent promptly to—

(i) Each party to the Board appeal (as described in § 405.1843 of this subpart) and

(ii) The Office of the Attorney Advisor.

(g) *Further review after the Board issues an EJR decision.* (1) *General rules.*

(i) Under § 405.1875(a)(2)(iii) of this subpart, the Administrator may review, on his or her own motion, or at the request of a party, the jurisdictional component only of the Board's EJR decision.

(ii) Any review by the Administrator is limited to the question of whether there is Board jurisdiction over the specific matter at issue; the Administrator may not review the Board's determination of its authority to decide the legal question.

(iii) An EJR decision by the Board becomes final and binding on the parties unless the decision is reversed, affirmed, modified, or remanded by the Administrator under § 405.1875(a)(2)(iii) and § 405.1875(e) or § 405.1875(f) of this subpart no later than 60 days after the date of receipt by the provider of the Board's decision.

(iv) A Board decision is inoperative during the 60-day period for review by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands that decision within that period.

(v) Any right of the provider to obtain EJR from a Federal district court is

specified at paragraphs (g)(2) and (g)(3) of this section (when the Board issues a timely EJR decision) and paragraph (g)(4) of this section (in the absence of a timely Board decision).

(vi) A final Board decision under paragraph (f) of this section, and a final Administrator decision made upon review of a final Board decision (as described in § 405.1875(a)(2) and (e) of this subpart) may be reopened and revised in accordance with § 405.1885 through § 405.1889 of this subpart.

(2) *Board grants EJR.* If the Board grants EJR, the provider may file a complaint in a Federal district court in order to obtain EJR of the legal question. If the Administrator renders, no later than 60 days after the date of receipt by the provider of the Board's decision granting EJR, a decision finding that the Board has no jurisdiction over the matter at issue, the Board's decision is rendered nonfinal and the provider has no right to obtain judicial review based on the Board's decision (as described in § 405.1877(a)(3) and (b)(3) of this subpart).

(3) *Board denies EJR.* If the Board's decision denies EJR because the Board finds that it has the authority to decide the legal question relevant to the matter at issue, the Administrator may not review the Board's authority determination, and the provider has no right to obtain EJR. If the Board denies EJR based on a finding that it lacks jurisdiction over the specific matter, the provider has no right to obtain EJR unless—

(i) The Administrator renders timely a final decision reversing the Board, finding the Board has jurisdiction over the matter at issue, and remanding to the Board; or

(ii) A court reverses the Board's or Administrator's decision as to jurisdiction, the Administrator remands to the Board, and the Board subsequently issues on remand from the Administrator an EJR decision granting EJR on the basis that it lacks the authority to decide the legal question.

(4) *No timely EJR decision.* The Board must issue an EJR decision no later than 30 days after the date of a written notice under paragraph (e)(3)(i) of this section, when the provider submits a complete request for EJR. If the Board does not issue an EJR decision within a 30-day period, the provider(s) has a right to seek EJR under section 1878(f)(1) of the Act.

(h) *Effect of final EJR decisions and lawsuits on further Board proceedings.*

(1) *Final decisions granting EJR.* If the final decision of the Board (or the Administrator), as applicable (as described in § 405.1842(g)(1) and

§ 405.1875(e)(4) of this subpart), grants EJR, the Board may not conduct any further proceedings on the legal question. The Board must dismiss—

(i) The specific matter at issue from the appeal.

(ii) The entire appeal if there are no other matters at issue that are within the Board's jurisdiction and can be fully decided by the Board.

(2) *Final decisions denying EJR.* If the final decision:

(i) Of the Board denies EJR solely on the basis that the Board determines it has the authority to decide the legal question relevant to the specific matter at issue, the Board must conduct further proceedings on the legal question and issue a decision on the matter at issue in accordance with this subpart.

Exception: If the provider(s) file(s) a lawsuit pertaining to the legal question, and for a period that is covered by the Board's decision denying EJR, the Board may not conduct any further proceedings under this subpart on the legal question or the matter at issue before the lawsuit is finally resolved.

(ii) Of the Board (or the Administrator) denies EJR on the basis that the Board lacks jurisdiction over the specific matter at issue, the Board (or the Administrator) must, as applicable, dismiss the specific matter at issue from the appeal, or dismiss the appeal entirely if there are no other matters at issue that are within the Board's jurisdiction and can be fully decided by the Board. If only the specific matter(s) is dismissed from the appeal, judicial review may be had only after a final decision on the appeal is made by the Board or Administrator, as applicable (as described in § 405.1840(d) and § 405.1877(a) of this subpart). If the Board or the Administrator, as applicable, dismisses the appeal entirely, the decision is subject to judicial review under § 405.1877(a) of this subpart.

(3) *Provider lawsuits.* (i) If the provider files a lawsuit seeking judicial review (whether on the basis of the EJR provisions of section 1878(f)(1) of the Act or on some other basis) pertaining to a legal question that is allegedly relevant to a specific matter at issue in a Board appeal to which the provider is a party and that is allegedly not within the Board's authority to decide, the Office of the Attorney Advisor must promptly provide the Board with written notice of the lawsuit and a copy of the complaint.

(ii) If the lawsuit is filed after a final EJR decision by the Board or the Administrator, as applicable (as described in § 405.1842(g)(1) and § 405.1875(e)(4) of this subpart), on the

legal question, the Board must carry out the applicable provisions of paragraphs (h)(1) and (h)(2) of this section in any pending Board appeal on the specific matter at issue.

(iii) If the lawsuit is filed before a final EJR decision is issued on the legal question, the Board may not conduct any further proceedings on the legal question or the matter at issue until the lawsuit is resolved.

■ 21. Section § 405.1843 is revised to read as follows:

§ 405.1843 Parties to proceedings in a Board appeal.

(a) When a provider files a request for a hearing before the Board in accordance with § 405.1835 or § 405.1837 of this subpart, the parties to all proceedings in the Board appeal include the provider, an intermediary, and, where applicable, any other entity found by the Board to be a related organization of the provider under the principles enunciated in § 413.17 of this chapter.

(b) Neither the Secretary nor CMS may be made a party to proceedings in a Board appeal.

(1) The Board may call as a witness any employee or officer of the Department of Health and Human Services or CMS having personal knowledge of the facts and the issues in controversy in an appeal.

(2) The regulations at 45 CFR Part 2 (Testimony by employees and production of documents in proceedings where the United States is not a party) apply as to whether such employee or officer will appear.

(c) An intermediary may designate a representative from the Secretary or CMS, who may be an attorney, to represent the intermediary in proceedings before the Board.

(d) Although CMS is not a party to proceedings in a Board appeal, there may be instances where CMS determines that the administrative policy implications of a case are substantial enough to warrant comment from CMS (as described in § 405.1863 of this subpart). CMS—

(1) May file *amicus curiae* (friend of the court) briefing papers with the Board in accordance with a schedule to be determined by the Board.

(2) Must promptly mail copies of any documents filed with the Board to each party to the appeal.

(e) A nonparty other than CMS may seek leave from the Board to file *amicus curiae* briefing papers with the Board.

(f) The Board may exclude from the record all or part of an *amicus curiae* briefing paper. When the Board excludes from the record all or part of

an *amicus curiae* briefing paper submitted by CMS, it states for the record its reason(s) in writing.

■ 22. Section 405.1845 is amended by—

■ A. Revising the section heading.

■ B. Revising paragraphs (c) and (d).

■ C. Adding paragraphs (e) through (h)

The revisions and additions read as follows:

§ 405.1845 Composition of Board; hearings, decisions, and remands.

* * * * *

(c) *Composition of the Board.* The Secretary designates one member of the Board as Chairperson. The Chairperson coordinates and directs the administrative activities of the Board and the conduct of proceedings before the Board. CMS provides administrative support for the Board. Under the direction of the Chairperson, the Board is solely responsible for the content of its decisions.

(d) *Quorum.* (1) The Board must have a quorum in order to issue one of the decisions specified as final, or deemed final by the Administrator, under § 405.1875(a)(2)(i), (a)(2)(iii), and (a)(2)(iv), but a quorum is not required for other Board actions.

(2) Three Board members, at least one of whom is representative of providers, are required in order to constitute a quorum.

(3) The opinion of the majority of those Board members issuing a decision specified as final, or deemed as final by the Administrator, under § 405.1875(a)(2), constitutes the Board's decision.

(e) *Hearings.* The Board may conduct a hearing and issue a hearing decision (as described in § 405.1871 of this subpart) on a specific matter at issue in an appeal, provided it finds jurisdiction over the matter at issue in accordance with § 405.1840 of this part and determines it has the legal authority to fully resolve the issue (as described in § 405.1867 of this subpart).

(f) *Oral hearings.* (1) In accordance with paragraph (d) of this section, the Board does not need a quorum in order to hold an oral hearing (as described in § 405.1851 of this subpart). The Chairperson of the Board may designate one or more Board members to conduct an oral hearing (where less than a quorum conducts the hearing). Because the presence of all Board members is not required at an oral hearing, the Board, at its discretion, may hold more than one oral hearing at a time.

(2) *Waiver of oral hearings.* With the intermediary's agreement and the Board's approval, the provider (or, in the case of group appeals, the group of providers) and any related organizations

(as described in § 405.1843(a) of this subpart) may waive any right to an oral hearing and stipulate that the Board may issue a hearing decision on the written record. An on-the-written-record hearing consists of all the evidence and written argument or comments submitted to the Board and included in the record (as described in § 405.1865 of this subpart).

(g) *Hearing decisions.* The Board's hearing decision must be based on the transcript of any oral hearing before the Board, any matter admitted into evidence at a hearing or deemed admissible evidence for the record (as described in § 405.1855 of this subpart), and any written argument or comments timely submitted to the Board (as described in § 405.1865 of this subpart).

(h) *Remands.* (1) Except as provided in paragraph (h)(3) of this section, a Board remand order may be reviewed solely during the course of Administrator review of one of the Board decisions specified in § 405.1875(a)(2) of this subpart, or of judicial review of a final agency decision as described in § 405.1877(a) and (c)(3) of this part, as applicable.

(2) The Board may order a remand requiring specific actions of a party to the appeal. In ordering a remand, the Board must—

(i) Specify any actions required of the party and explain the factual and legal basis for ordering a remand;

(ii) Issue the remand order in writing; and

(iii) Mail the remand order promptly to the parties and any affected nonparty, such as CMS, to the appeal.

(3) A Board remand order is not subject to immediate Administrator review unless the Administrator determines that the remand order might otherwise evade his or her review (as described in § 405.1875(a)(2)(iv) of this subpart).

■ 23. Section 405.1853 is revised to read as follows:

§ 405.1853 Board proceedings prior to any hearing; discovery.

(a) *Preliminary narrowing of the issues.* Upon receiving notification that a request for a Board hearing is submitted, the intermediary must—

(1) Promptly review both the materials submitted with the provider hearing request, and the information underlying each intermediary or Secretary determination for each cost reporting period under appeal.

(2) Expeditiously attempt to join with the provider in resolving specific factual or legal issues and submitting to the Board written stipulations setting forth

the specific issues that remain for Board resolution based on the review; and

(3) Ensure that the evidence it considered in making its determination, or, where applicable, the evidence the Secretary considered in making his or her determination, is included in the record.

(b) *Position papers.* (1) After any preliminary narrowing of the issues, the parties must file position papers in order to narrow the issues further. In each case, and as appropriate, the Board establishes the deadlines as to when the provider(s) and the intermediary must submit position papers to the Board.

(2) The Board has the discretion to extend the deadline for submitting a position paper. Each position paper must set forth the relevant facts and arguments regarding the Board's jurisdiction over each remaining matter at issue in the appeal (as described in § 405.1840 of this subpart), and the merits of the provider's Medicare payment claims for each remaining issue.

(3) In the absence of a Board order or general instructions to the contrary, any supporting exhibits regarding Board jurisdiction must accompany the position paper. Exhibits regarding the merits of the provider's Medicare payment claims may be submitted in a timeframe to be decided by the Board through a schedule applicable to a specific case or through general instructions.

(c) *Initial status conference.* (1) Upon review of the parties' position papers, one or more members of the Board may conduct an initial status conference. An initial status conference may be conducted in person or telephone, at the discretion of the Board.

(2) The Board may use the status conference to discuss any of the following:

(i) Simplification of the issues.

(ii) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement.

(iii) Stipulations and admissions of fact or as to the content and authenticity of documents.

(iv) Whether the parties can agree to submission of the case on a stipulated record.

(v) Whether a party may waive appearance at an oral hearing and submit only documentary evidence (the admissibility of which is subject to objection from other parties) and written argument.

(vi) Limitation of the number of witnesses.

(vii) Scheduling dates for the exchange of witness lists and of proposed exhibits.

(viii) Discovery as permitted under this section.

(ix) The time and place for the hearing.

(x) Potential settlement of some or all of the issues.

(xi) Other matters that the Board deems necessary and appropriate. The Board may issue any orders at the conference found necessary and appropriate to narrow the issues further and expedite further proceedings in the appeal.

(3) After the status conference, the Board may—

(i) Issue in writing a report and order specifying what transpired and formalizing any orders issued at the conference; and

(ii) Require the parties to submit (jointly or otherwise) a proposed report and order, in order to facilitate issuance of a final report and order.

(d) *Further status conferences.* Upon a party's request, or on its own motion, the Board may conduct further status conferences where it finds the proceedings necessary and appropriate.

(e) *Discovery.* (1) *General rules.* (i) Discovery is limited in Board proceedings.

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

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

(iv) The applicable provisions of the Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence serve as guidance for any discovery that is permitted under this section or by Board order.

(2) *Limitations on discovery.* Any discovery before the Board is limited as follows:

(i) A party may request of another party, or of a nonparty other than CMS, the Secretary or any Federal agency, the reasonable production of documents for inspection and copying.

(ii) A party may also request another party to respond to a reasonable number of written interrogatories.

(iii)(A) A party may not take the deposition, upon oral or written examination, of another party or a nonparty, unless the proposed deponent agrees to the deposition or the Board finds that the proposed deposition is necessary and appropriate under the

criteria set forth in Federal Rules of Civil Procedure 26 and 32(a)(3) in order to secure the deponent's testimony for a Board hearing.

(B) The regulations at 45 CFR Part 2 (Testimony by employees and production of documents in proceedings where the United States is not a party) apply as to whether an employee or officer of CMS or HHS will appear for a deposition.

(iv) A party may not request admissions or take any other form of discovery not authorized under this section.

(3) *Time limits.* (i) A party's discovery request is timely if the date the request is served on another party or nonparty, as applicable, is no later than 120 days before the initially scheduled starting date of the Board hearing, unless the Board extends the time for the request.

(ii)(A) *Depositions.* (1) In the absence of an order or instruction by the Board setting a schedule for the holding of a deposition, a party desiring to take a deposition must give reasonable notice in writing to the deponent of a scheduled deposition.

(2) A deposition may not be held any later than 45 days before the initially scheduled starting of the Board hearing, unless the Board orders otherwise.

(B) *Responses.* (1) In the absence of a Board order or general instructions of the Board setting a schedule for responses, responses to interrogatories and requests for production of documents are due according to the schedule agreed upon by the party serving discovery and the party to which the discovery is directed or within the time allotted by the Federal Rules of Civil Procedure.

(2) Responses by a party to interrogatories, and responses by a party or nonparty to requests for production of documents must be served no later than 45 days before the initially scheduled starting date of the Board hearing, unless the Board orders otherwise.

(iii) Before ruling on a request to extend the time for requesting discovery or for conducting or responding to discovery, the Board must give the other parties to the appeal and any nonparty subject to a discovery request a reasonable period to respond to the extension request.

(iv) The Board has the discretion to extend the time in which to request discovery or conduct or respond to discovery.

(v) If the Board grants the extension request, it sets a new discovery deadline and has the discretion to reschedule the hearing date.

(4) *Rights of nonparties.* If a discovery request is made of a nonparty to the Board appeal, the nonparty has the rights any party has in responding to a discovery request. The rights of the nonparty include, but are not limited to, the right to select and use any attorney or other representative, and to submit discovery responses, objections, or motions to the Board.

(5) *Motions to compel or for protective order.* (i) Each party is required to make a good faith effort to resolve or narrow any discovery dispute, regardless of whether the dispute is with another party or a nonparty.

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

(iii) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute.

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

(v) The Board must decide any motion in accordance with this section and any prior discovery ruling.

(vi)(A) The Board must issue and mail to each party and any affected nonparty a discovery ruling that grants or denies, in whole or in part, the motion to compel or the motion for a protective order, if applicable.

(B) The discovery ruling must—

(1) Specifically identify any part of the disputed discovery request upheld and any part rejected, and

(2) Impose any limits on discovery the Board finds necessary and appropriate.

(vii) Nothing in this section authorizes the Board to compel any action from the Secretary or CMS.

(6) *Reviewability of discovery and disclosure rulings.* (i) *General rule.* A Board discovery ruling, or a Board disclosure ruling, such as one issued at a hearing, is not subject to immediate review by the Administrator (as described in § 405.1875(a)(3) of this subpart). The ruling may be reviewed solely during the course of Administrator review of one of the Board decisions specified as final or deemed to be final, by the Administrator, under § 405.1875(a)(2) of this subpart, or of judicial review of a final agency decision as described in § 405.1877(a) and (c)(3) of this subpart, as applicable.

(ii) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the Board, that portion of the discovery or disclosure ruling may be reviewed immediately by the Administrator in accordance with § 405.1875(a)(3)(i) of this subpart. Upon notice to the Board that a party or nonparty, as applicable, intends to seek Administrator review of the ruling,—

(A)(1) The Board must stay all proceedings affected by the ruling.

(2) The Board determines the length of the stay under the circumstances of a given case, but in no event may the length of the stay be less than 15 days after the day on which the Board received notice of the party or nonparty's intent to seek Administrator review.

(B) If the Administrator—

(1) Grants a request for review, or takes own motion review, of a ruling, the ruling is stayed until the time the Administrator issues a written decision that affirms, reverses, modifies, or remands the Board's ruling.

(2) Does not grant a request or take own motion review within the time allotted for the stay, the stay is lifted and the ruling is not subject to immediate review.

■ 24. Section 405.1857 is revised to read as follows:

§ 405.1857 Subpoenas.

(a) *Time limits.* (1) The Board may issue a subpoena—

(i) To a party to a Board appeal or to a nonparty other than CMS or the Secretary or any Federal agency, requiring the attendance and testimony of witnesses or the production of documents for inspection and copying, provided the Board makes a preliminary finding of its jurisdiction over the matters at issue in accordance with § 405.1840(a) of this subpart.

(ii) At the request of a party for purposes of discovery (as described in § 405.1853 of this subpart) or an oral hearing (as described in § 405.1845 of this subpart); and

(iii) On its own motion solely for purposes of a hearing.

(2) The date of receipt by the Board of a party's subpoena request may not be any later than for subpoenas requested for purposes of—

(i) Discovery, 120 days before the initially scheduled starting date of the Board hearing; and

(ii) An oral hearing, 45 days before the scheduled starting date of the Board hearing.

(3) Subject to paragraph (4) of this section, the Board may not issue a subpoena any later than for purposes of a—

(i) Discovery subpoena, 90 days before the initially scheduled starting date of the Board hearing; and

(ii) Hearing subpoena, whether issued at a party's request or on the Board's own motion, 30 days before the scheduled starting date of the Board hearing.

(4) The Board may extend the deadlines specified in paragraphs (a)(2) and (a)(3) of this section provided the Board gives each party to the appeal and any nonparty subject to the subpoena request or subpoena a reasonable period of time to comment on any proposed extension. If the Board extends a deadline, it retains the discretion to reschedule the hearing date.

(b) *Criteria.* (1) *Discovery subpoenas.* The Board may issue a subpoena for purposes of discovery if all of the following are applicable:

(i) The subpoena was requested in accordance with the requirements of paragraph (c)(1) of this section.

(ii) The party's discovery request complies with the applicable provisions of § 405.1853(e) of this part.

(iii) A subpoena is necessary and appropriate to compel a response to the discovery request.

(2) *Hearing subpoenas.* The Board may issue a subpoena for purposes of an oral hearing if—

(i) The party's subpoena request meets the requirements of paragraph (c)(1) of this section;

(ii) A subpoena is necessary and appropriate to compel the attendance and testimony of witnesses or the production of documents for inspection or copying, provided the testimony or documents are relevant and material to a matter at issue in the appeal but not unduly repetitious (as described in § 405.1855 of this subpart); and

(iii) The subpoena does not compel the disclosure of matter that is privileged or otherwise protected from disclosure for reasons such as case preparation, confidentiality, or undue burden.

(iv) The subpoena does not impose undue burden or expense on the party or nonparty subject to the subpoena, and is not otherwise unreasonable or inappropriate.

(3) *Guiding principles.* In determining whether to issue, quash, or modify a subpoena under this section, the Board uses the applicable provisions of the Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence for guidance.

(c) *Procedures.* (1) *Subpoena requests.* The requesting party must mail any subpoena request submitted to the Board promptly to the party or nonparty subject to the subpoena, and to any other party to the Board appeal. The request must—

(i) Identify with particularity any witnesses (and their addresses, if known) or any documents (and their location, if known) sought by the subpoena, and the means, time, or location for securing any witness testimony or documents;

(ii) Describe specifically, in the case of a hearing subpoena, the facts any witnesses, documents, or tangible materials are expected to establish, and why those facts cannot be established without a subpoena; and

(iii) Explain why a subpoena is appropriate under the criteria prescribed in paragraph (b) of this section.

(2) *Contents of subpoenas.* A subpoena issued by the Board, whether on its own motion or at the request of a party, must be in writing and either sent promptly by the Board to the party or nonparty subject to the subpoena by certified mail or overnight delivery (and to any other party and affected nonparty to the appeal by regular mail), or hand-delivered. Each subpoena must—

(i) Be issued in the name of the Board, and include the case number and name of the appeal;

(ii) Provide notice that—

(A) The subpoena is issued in accordance with section 1878(e) of the Act and § 405.1857 of this subpart; and

(B) CMS must pay the fees and the mileage of any witnesses, as provided in section 205(d) of the Act.

(iii) If applicable, require named witnesses to attend a particular proceeding at a certain time and location and to testify on specific subjects; and

(iv) If applicable, require the production of specific documents for inspection or copying at a certain time and location.

(3) *Rights of nonparties.* If a nonparty to the Board appeal is subject to the subpoena or subpoena request, the nonparty has the rights any party has in responding to a subpoena or subpoena request. The rights of the nonparty include, but are not limited to, the right to select and use any attorney or other representative, and to submit responses, objections, motions, or any other pertinent materials to the Board regarding the subpoena or subpoena request.

(4) *Board action on subpoena requests and motions.* After issuing a subpoena

or receiving a subpoena request, the Board must do the following:

(i) Give the party or nonparty subject to the subpoena or subpoena request a reasonable period of time for the submission of any responses, objections, or motions.

(ii) Consider the subpoena or subpoena request, and any responses, objections, or motions related thereto, under the criteria specified in paragraph (b) of this section.

(iii)(A) Issue in writing and mail promptly to each party and any affected nonparty an order granting or denying any motion to quash or modify a subpoena, or granting or denying any subpoena request in whole or in part; and

(B) Issue, if applicable, an original or modified subpoena in accordance with paragraph (c)(2) of this section.

(d) *Reviewability.* (1) *General rules.* (i) If the Board issues, quashes, or modifies, or refuses to issue, quash, or modify, a subpoena under paragraphs (c)(2) or (c)(4) of this section, the Board's action is not subject to immediate review by the Administrator (as described in § 405.1875(a)(3) of this subpart).

(ii) Any Board action on a subpoena may be reviewed solely during the course of Administrator review of one of the Board decisions specified in § 405.1875(a)(2) of this subpart, or of judicial review of a final agency decision as described in § 405.1877(a) and (c)(3) of this subpart, as applicable.

(2) *Exception.* (i) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the Board, the Administrator may review immediately that portion of the subpoena in accordance with § 405.1875(a)(3)(ii) of this subpart.

(ii) Upon notice to the Board that a party or nonparty, as applicable, intends to seek Administrator review of the subpoena, the Board must stay all proceedings affected by the subpoena.

(iii) The Board determines the length of the stay under the circumstances of a given case, but in no event may the stay be less than 15 days after the day on which the Board received notice of the party or nonparty's intent to seek Administrator review.

(iv) If the Administrator grants a request for review, or takes own motion review, of the subpoena, the subpoena or portion of the subpoena, as applicable, is stayed until the time as the Administrator issues a written decision that affirms, reverses, modifies,

or remands the Board's action on the subpoena.

(v) If the Administrator does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the Board's action is not immediately reviewable.

(e) **Enforcement.** (i) If the Board determines, whether on its own motion or at the request of a party, that a party or nonparty subject to a subpoena issued under this section has refused to comply with the subpoena, the Board may request the Administrator to seek enforcement of the subpoena in accordance with section 205(e) of the Act.

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

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

■ 25. Section 405.1865 is revised to read as follows:

§ 405.1865 Record of administrative proceedings.

(a)(1) The Board and, if applicable, the Administrator must maintain a complete record of all proceedings in each appeal.

(2) For proceedings before the Board, the administrative record consists of all evidence, documents and any other tangible materials submitted by the parties to the appeal and by any nonparty (as described in § 405.1853(e)(4) and § 405.1857(c)(3) of this subpart), along with all Board correspondence, rulings, subpoenas, orders, and decisions.

(3) The term "record" is intended to encompass both the unappended record and any appendix to the record (as described in § 405.1865(b) of this subpart).

(4) The record includes a complete transcription of the proceedings at any oral hearing before the Board.

(5) A copy of any transcription must be made available to any party upon written request.

(b) Any evidence ruled inadmissible by the Board (as described in § 405.1855 of this subpart) and any other submitted matter that the Board declines to consider (whether as untimely or otherwise) must be, to the extent practicable, clearly identified and

segregated in an appendix to the record for purposes of any further review (as described in § 405.1875 and § 405.1877 of this subpart).

(c) To the extent applicable, the administrative record also includes all documents (including written submissions) and any other tangible materials to the Administrator by the parties to the appeal or by any nonparty (as described in § 405.1853(e)(4) and § 405.1857(c)(3) of this subpart), in addition to all correspondence from the Administrator or the Office of the Attorney Advisor and all rulings, orders, and decisions by the Administrator. The provisions of paragraph (b) of this section also pertain to any proceedings before the Administrator, to the extent the Administrator finds evidence inadmissible or declines to consider a specific matter (whether as untimely or otherwise).

§ 405.1867 [Amended]

■ 26. Section 405.1867 is amended by revising the section heading and the first sentence to read as follows:

§ 405.1867 Scope of Board's legal authority.

In exercising its authority to conduct proceedings under this subpart, the Board must comply with all the provisions of Title XVIII of the Act and regulations issued thereunder, as well as, CMS Rulings issued under the authority of the Administrator as described in § 401.108 of this subchapter. * * *

■ 27. A new § 405.1868 is added to read as follows:

§ 405.1868 Board actions in response to failure to follow Board rules.

(a) The Board has full power and authority to make rules and establish procedures, not inconsistent with the law, regulations, and CMS Rulings, that are necessary or appropriate to carry out the provisions of section 1878 of the Act and of the regulations in this subpart. The Board's powers include the authority to take appropriate actions in response to the failure of a party to a Board appeal to comply with Board rules and orders or for inappropriate conduct during proceedings in the appeal.

(b) If a provider fails to meet a filing deadline or other requirement established by the Board in a rule or order, the Board may—

(1) Dismiss the appeal with prejudice;

(2) Issue an order requiring the provider to show cause why the Board should not dismiss the appeal; or

(3) Take any other remedial action it considers appropriate.

(c) If an intermediary fails to meet a filing deadline or other requirement established by the Board, the Board may—

(1) Take other actions that it considers appropriate, such as—

(i) Issuing a decision based on the written record submitted to that point; or

(ii) Issuing a written notice to CMS describing the intermediary's actions and requesting that CMS take appropriate action, such as review of the intermediary's compliance with the contractual requirements of § 421.120, § 421.122, and § 421.124 of this chapter; and

(2) Not use its authority to take an action such as, a sanction, reversing or modifying the intermediary's or Secretary's determination for the cost reporting period under appeal, or ruling against the intermediary on a disputed issue of law or fact in the appeal.

(d)(1) If the Board dismisses the appeal with prejudice under this section, it must issue a dismissal decision dismissing the appeal. The decision by the Board must be in writing and include an explanation of the reason for the dismissal. A copy of the Board's dismissal decision must be mailed promptly to each party to the appeal (as described in § 405.1843 of this subpart).

(2) A dismissal decision by the Board is final and binding on the parties unless the decision is reversed, affirmed, modified, or remanded by the Administrator under § 405.1875(a)(2)(ii), and § 405.1875(e) or § 405.1875(f) of this part, no later than 60 days after the date of receipt by the provider of the Board's decision.

(i) The Board decision is inoperative during the 60-day period for review by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands the decision within the period.

(ii) The Board may reopen and revise a final Board decision in accordance with § 405.1885 through § 405.1889 of this subpart.

(e)(1) Any action taken by the Board under this section other than dismissal of the appeal is not subject to immediate Administrator review (as described in § 405.1875(a)(3) of this subpart) or judicial review (as described in § 405.1877(a)(3) of this subpart).

(2) A Board action other than dismissal of the appeal may be reviewed solely during the course of Administrator review of one of the Board decisions specified as final, or deemed to be final by the Administrator, under § 405.1875(a)(2) of this subpart or of judicial review of a final agency

decision as described in § 405.1877(a) of this subpart, as applicable.

(f) *Ex parte* communications with Board staff concerning procedural matters are not prohibited.

(g) Upon receipt of a credible allegation that a party's representative has divulged to that party, or to the Board information that was obtained during the course of the representative's relationship (such as legal counsel or employee) with an opposing party and that was intended by that party to be kept confidential, the Board—

(1) Investigates the allegation; and

(2) May take remedial action when it determines that it is appropriate to do so, against the party or the representative (such as prohibiting the representative from appearing before it, excluding such information from the record, or if the overall fairness of the hearing has been compromised, dismissing the case).

■ 28. Section 405.1869 is revised as follows:

§ 405.1869 Scope of Board's authority in a hearing decision.

(a) If the Board has jurisdiction to conduct a hearing on a specific matter at issue under section 1878(a) or (b) of the Act and § 405.1840 of this subpart, and the legal authority to fully resolve the matter in a hearing decision (as described in § 405.1842(f), § 405.1867, and § 405.1871 of this subpart), section 1878 of the Act, and paragraph (a) of this section give the Board the power to affirm, modify, or reverse the intermediary's findings on each specific matter at issue in the intermediary determination for the cost reporting period under appeal, and to make additional revisions on specific matters regardless of whether the intermediary considered the matters in issuing the intermediary determination. The Board's power to make additional revisions in a hearing decision does not authorize the Board to consider or decide a specific matter at issue for which it lacks jurisdiction (as described in § 405.1840(b) of this subpart) or which was not timely raised in the provider's hearing request. The Board's power under section 1878(d) of the Act and paragraph (a) of this section to make additional revisions is limited to those revisions necessary to resolve fully a specific matter at issue if—

(1) The Board has jurisdiction to grant a hearing on the specific matter at issue under section 1878(a) or (b) of the Act and § 405.1840 of this subpart; and

(2) The specific matter at issue was timely raised in an initial request for a Board hearing filed in accordance with § 405.1835 or § 405.1837 of this subpart,

as applicable, or in a timely request to add issues to a single provider appeal submitted in accordance with § 405.1835(c) of this subpart.

(b)(1) If the Board has jurisdiction to conduct a hearing on a specific matter at issue solely under § 405.1840 and § 405.1835 or § 405.1837 of this subpart, as applicable, and the legal authority to fully resolve the matter in a hearing decision (as described in § 405.1842(f), § 405.1867, and § 405.1871 of this subpart), the Board is authorized to do the following:

(i) Affirm, modify, or reverse the intermediary's or Secretary's findings on each specific matter at issue in the intermediary or Secretary determination under appeal.

(ii) Make additional revisions on each specific matter at issue regardless of whether the intermediary considered these revisions in issuing the intermediary determination under appeal, provided the Board does not consider or decide a specific matter for which it lacks jurisdiction (as described in § 405.1840(b) of this subpart) or that was not timely raised in the provider's hearing request.

(2) The Board's authority under this section to make the additional revisions is limited to those revisions necessary to resolve a specific matter at issue.

■ 29. Section 405.1871 is revised to read as follows:

§ 405.1871 Board Hearing Decision.

(a)(1) If the Board finds jurisdiction over a specific matter at issue and conducts a hearing on the matter (as described in § 405.1840(a) and § 405.1845(e) of this subpart), the Board must issue a hearing decision deciding the merits of the specific matter at issue.

(2) A Board hearing decision must be in writing and based on the admissible evidence from the Board hearing and other admissible evidence and written argument or comments as may be included in the record and accepted by the Board (as described in § 405.1845(g) and § 405.1865 of this subpart).

(3) The decision must include findings of fact and conclusions of law regarding the Board's jurisdiction over each specific matter at issue (see § 405.1840(c)(1)), and whether the provider carried its burden of production of evidence and burden of proof by establishing, by a preponderance of the evidence, that the provider is entitled to relief on the merits of the matter at issue.

(4) The decision must include appropriate citations to the record evidence and to the applicable law, regulations, CMS Rulings, and other interpretive rules, general statements of

policy, and rules of agency organization, procedure, or practice established by CMS. Where the Board's decision reverses or modifies an intermediary determination on an issue for which the policy expressed in an interpretive rule (other than a regulation or a CMS Ruling), general statement of policy or rule of agency organization, procedure or practice established by CMS would be dispositive of that issue (if followed by the Board), the Board decision must explain how it gave great weight to such interpretive rule or other such instruction but did not uphold the intermediary's determination on the issue.

(5) A copy of the decision must be mailed promptly to each party to the appeal.

(b)(1) A Board hearing decision issued in accordance with paragraph (a) of this section is final and binding on the parties to the Board appeal unless the hearing decision is reversed, affirmed, modified, or remanded by the Administrator under § 405.1875(a)(2)(i), § 405.1875(e), and § 405.1875(f) of this subpart, no later than 60 days after the date of receipt by the provider of the Board's decision.

(2) A Board hearing decision is inoperative during the 60-day period for review of the decision by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands that decision within the period.

(3) A Board hearing decision that is final under paragraph (b)(1) of this section is subject to the provisions of § 405.1803(d) of this subpart, unless the decision is the subject of judicial review (as described in § 405.1877 of this subpart).

(4) A final Board decision under paragraph (a) and (b) of this section may be reopened and revised by the Board in accordance with § 405.1885 through § 405.1889 of this subpart.

(5) When the intermediary's denial of the relief that the provider seeks before the Board is based on procedural grounds (for example, the alleged failure of the provider to satisfy a time limit) or is based on the alleged failure to supply adequate documentation to support the provider's claim, and the Board rules that the basis of the intermediary's denial is invalid, the Board remands to the intermediary for the intermediary to make a determination on the merits of the provider's claim.

§ 405.1873 [Removed].

■ 30. Section 405.1873 is removed and reserved.

■ 31. Section 405.1875 is revised to read as follows:

§ 405.1875 Administrator review.

(a) *Basic rule: Time limit for rendering Administrator decisions, Board decisions, and action subject to immediate review.* The Administrator, at his or her discretion, may immediately review any decision of the Board specified in paragraph (a)(2) of this section. Nonfinal decisions or actions by the Board are not immediately reviewable, except as provided in paragraph (a)(3) of this section. The Administrator may exercise this discretionary review authority on his or her own motion, or in response to a request from: a party to the Board appeal; CMS; or, in the case of a matter specified in paragraph (a)(3)(i) or (a)(3)(ii) of this section, another affected nonparty to a Board appeal. All requests for Administrator review and any other submissions to the Administrator under paragraph (c) of this section must be sent to the Office of the Attorney Advisor. The Office of the Attorney Advisor must examine each Board decision specified in paragraph (a)(2) of this section, and each matter described in § 405.1845(h)(3), § 405.1853(e)(6)(ii), or § 405.1857(d)(2) of this subpart, of which it becomes aware, together with any review requests or any other submission made in accordance with the provisions of this section, in order to assist the Administrator's exercise of this discretionary review authority. The Board is required to send to the Office of the Attorney Advisor a copy of each decision specified in paragraphs (a)(2)(i) and (a)(2)(iii) of this section upon issuance of the decision.

(1) The date of rendering any decision after the review by the Administrator must be no later than 60 days after the date of receipt by the provider of a reviewable Board decision or action. For purposes of this section, the date of rendering is the date the Administrator signs the decision, and not the date the decision is mailed or otherwise transmitted to the parties.

(2) The Administrator may immediately review:

- (i) A Board hearing decision (as described in § 405.1871 of this subpart).
- (ii) A Board dismissal decision (as described in § 405.1836(e)(1) and (e)(2), § 405.1840(c)(2) and (c)(3), § 405.1868(d)(1) and (d)(2) of this subpart).

(iii) A Board EJR decision, but only the question of whether there is Board jurisdiction over a specific matter at issue in the decision; the Administrator may not review the Board's determination in a decision of its

authority to decide a legal question relevant to the matter at issue (as described in § 405.1842(h) of this subpart).

(iv) Any other Board decision or action deemed to be final by the Administrator.

(3) Any decision or action by the Board not specified in paragraph (a)(2)(i) through (a)(2)(iii) of this section, or not deemed to be final by the Administrator under paragraph (a)(2)(iv) of this section, is nonfinal and not subject to Administrator review until the Board issues one of the decisions specified in paragraph (a)(2) of this section, except the Administrator may review immediately the following matters:

(i) A Board ruling authorizing discovery or disclosure of a matter for which an objection was made based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden (as described in § 405.1853(e)(6)(ii) of this subpart).

(ii) A Board subpoena compelling disclosure of a matter for which an objection was made based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden (as described in § 405.1857(d)(2) of this subpart).

(b) *Illustrative list of criteria for deciding whether to review.* In deciding whether to review a Board decision or other matter specified in paragraphs (a)(2) and (a)(3) of this section, either on his or her own motion or in response to a request for review, the Administrator considers criteria such as whether it appears that—

(1) The Board made an erroneous interpretation of law, regulation, CMS Ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(2) A Board hearing decision meets the requirements of § 405.1871(a) of this subpart.

(3) The Board erred in refusing to admit certain evidence or in not considering other submitted matter (as described in § 405.1855 and § 405.1865(b) of this subpart), or in admitting certain evidence.

(4) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to the issuance of a CMS Ruling or other directive needed to clarify a statutory or regulatory provision.

(5) The Board has incorrectly found, assumed, or denied jurisdiction over a specific matter at issue or extended its authority in a manner not provided for by statute, regulation, CMS Ruling, or

other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(6) The decision or other action of the Board requires clarification, amplification, or an alternative legal basis.

(7) A remand to the Board may be necessary or appropriate under the criteria prescribed in paragraph (f) of this section.

(c) *Procedures.* (1) *Review requests.* (i)(A) A party to a Board appeal or CMS may request Administrator review of a Board decision specified in paragraph (a)(2) of this section or a matter described in paragraph (a)(3) of this section.

(B) A nonparty other than CMS may request Administrator review solely of a matter described in paragraph (a)(3)(i) or (a)(3)(ii) of this section.

(ii) The date of receipt by the Office of Attorney Advisor of any review request must be no later than 15 days after the date the party making the request received the Board's decision or other reviewable action.

(iii) A request for review (or a response to a request) must be submitted in writing, identify the specific issues for which review is requested, and explain why review is or is not appropriate, under the criteria specified in paragraph (b) of this section or for some other reason.

(iv) A copy of any review request (or response to a request) must be mailed promptly to each party to the appeal, the Office of the Attorney Advisor, and, as applicable, CMS, and any other affected nonparty.

(2) *Exception to time for requesting review.* If a party, or nonparty, as applicable, seeks immediate review of a matter described in § 405.1875(a)(3)(i) or (a)(3)(ii) of this subpart, the request for review must be made as soon as practicable, but in no event later than 5 business days after the day the party or nonparty seeking review received notice of the ruling or subpoena. The request must state the reason(s) why the ruling was in error and the potential harm that may be caused if immediate review is not granted.

(3) *Notice of review.* (i) When the Administrator decides to review a Board decision or other matter specified in paragraphs (a)(2) or (a)(3) of this section, respectively, whether on his or her own motion or upon request, the Administrator must send a written notice to the parties, CMS, and any other affected nonparty stating that the Board's decision is under review, and indicating the specific issues that are being considered.

(ii) The Administrator may decline to review a Board decision or other matter, or any issue in a decision or matter, even if a request for review is submitted in accordance with paragraph (c)(1) or (c)(2) of this section.

(4) *Written submissions on review.* If the Administrator accepts review of the Board's decision or other reviewable action, a party, CMS, or, another affected nonparty that requested review solely of a matter described in paragraph (a)(3)(i) or (a)(3)(ii) of this section, may tender written submissions regarding the review.

(i) The date of receipt by the Office of the Attorney Advisor of any material must be no later than 15 days after the date the party, CMS or other affected nonparty submitting comments received the Administrator's notice under paragraph (c)(3) of this section, taking review of the Board decision or other reviewable matter.

(ii) Any submission must be limited to the issues accepted for Administrator review (as identified in the notice) and be confined to the record of Board proceedings (as described in § 405.1865 of this subpart). The submission may include—

(A) Argument and analysis supporting or taking exception to the Board's decision or other reviewable action;

(B) Supporting reasons, including legal citations and excerpts of record evidence, for any argument and analysis submitted under paragraph (c)(4)(ii)(A) of this section;

(C) Proposed findings of fact and conclusions of law;

(D) Rebuttal to any written submission filed previously with the Administrator in accordance with paragraph (c)(4) of this section; or

(E) A request, with supporting reasons, that the decision or other reviewable action be remanded to the Board.

(d) *Ex parte communications prohibited.* All communications from any party, CMS, or other affected nonparty, concerning a Board decision (or other reviewable action) that is being reviewed or may be reviewed by the Administrator must—

(1) Be in writing.

(2) Contain a certification that copies were served on all other parties, CMS, and any other affected nonparty, as applicable.

(3) Include, but are not limited to—

(i) Requests for review and responses to requests for review submitted under paragraph (c)(1) or (c)(2) of this section; and

(ii) Written submissions regarding review submitted under paragraph (c)(4) of this section. The Administrator does

not consider any communication that does not meet these requirements or is not submitted within the required time limits.

(e) *Administrator's decision.* (1) Upon completion of any review, the Administrator may render a written decision that—

(i) For purposes of review of a Board decision specified in paragraph (a)(2) of this section, affirms, reverses, or modifies the Board's decision, or vacates that decision and remands the case to the Board for further proceedings in accordance with paragraph (f)(1)(i) of this section; or

(ii) For purposes of review of a matter described in paragraph (a)(3) of this section, affirms, reverses, modifies, or remands the Board's discovery or disclosure ruling, or subpoena, as applicable, and remands the case to the Board for further proceedings in accordance with paragraph (f)(1)(ii) of this section.

(2) The date of rendering of any decision by the Administrator must be no later than 60 days after the date of receipt by the provider of the Board's decision or other reviewable action. The Administrator must promptly mail a copy of his or her decision to the Board, to each party to the appeal, to CMS, and, if applicable, to any other affected nonparty.

(3) Any decision by the Administrator may rely on—

(i) Applicable provisions of the law, regulations, CMS Rulings, and other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(ii) Prior decisions of the Board, the Administrator, and the courts, and any other law that the Administrator finds applicable, whether or not cited in materials submitted to the Administrator.

(iii) The administrative record for the case (as described in § 405.1865 of this subpart).

(iv) Generally known facts that are not subject to reasonable dispute.

(4) A timely decision by the Administrator that affirms, reverses, or modifies one of the Board decisions specified in paragraph (a)(2) of this section is final and binding on each party to the Board appeal (as described in § 405.1877(a)(4) of this subpart).

(i) If the final Administrator decision follows review of a Board hearing decision, the Administrator's decision is subject to the provisions of § 405.1803(d) of this subpart, unless that final decision is the subject of judicial review (as described in § 405.1877 of this subpart).

(ii) The Administrator, in accordance with § 405.1885 through § 405.1889 of this subpart, may reopen and revise a final Administrator decision.

(iii) A decision by the Administrator remanding a matter to the Board for further proceedings in accordance with paragraph (f) of this section is not a final decision for purposes of judicial review (as described in § 405.1877(a)(4) of this subpart) or the provisions of § 405.1803(d).

(f) *Remand.* (1) A remand to the Board by the Administrator has the effect for purposes of review—

(i) With respect to a Board decision specified in paragraph (a)(2) of this section, vacating the Board's decision and requiring further proceedings in accordance with the Administrator's decision and this subpart; or

(ii) With respect to a matter described in paragraph (a)(3) of this section, affirming, reversing, modifying, or remanding the Board's remand order, discovery ruling, or subpoena, as applicable, and returning the case to the Board for further proceedings in accordance with the Administrator's decision and this subpart.

(2) The Administrator may direct the Board to take further action for the development of additional facts or new issues, or to consider the applicability of laws or regulations other than those considered by the Board. The following are not acceptable bases for remand:

(i) Presentation of evidence existing at the time of the Board hearing that was known or reasonably may be known.

(ii) Introduction of a favorable court ruling, regardless of whether the ruling was made or was available at the time of the Board hearing or at the time the Board issued its decision.

(iii) Change in a party's representation, regardless when made.

(iv) Presentation of an alternative legal basis concerning an issue in dispute.

(v) Attempted retraction of a waiver of a right, regardless when made.

(3) After remand, the Board must take the actions required in the Administrator's remand order and issue a new decision in accordance with paragraph (f)(1)(i) of this section, or issue under paragraph (f)(1)(ii) of this section an initial decision or a further remand order, discovery ruling, or subpoena ruling, as applicable.

(4) Administrator review of any decision or other action by the Board after remand is, to the extent applicable, subject to the provisions of paragraphs (a)(2) or (a)(3) of this section.

(5) In addition to ordering a remand to the Board, the Administrator may order a remand to any component of

HHS or CMS or to an intermediary under appropriate circumstances, including, but not limited to, for the purpose of effectuating a court order (as described in § 405.1877(g)(2) of this subpart). When the intermediary's denial of the relief, that the provider sought before the Board and that is under review by the Administrator, was based on procedural grounds (such as the alleged failure of the provider to satisfy a time limit) or was based on the alleged failure to supply adequate documentation to support the provider's claim, and the Administrator rules that the basis of the intermediary's denial is invalid, the Administrator remands to the intermediary for the intermediary to make a determination on the merits of the provider's claim.

■ 32. Section 405.1877 is revised to read as follows:

§ 405.1877 Judicial review.

(a) *Basis and scope.* (1)

Notwithstanding the provisions of 5 U.S.C. 704 or any other provision of law, sections 205(h) and 1872 of the Act provide that a decision or other action by a reviewing entity is subject to judicial review solely to the extent authorized by section 1878(f)(1) of the Act. This section, along with the EJR provisions of § 405.1842 of this subpart, implements section 1878(f)(1) of the Act.

(2) Section 1878(f)(1) of the Act provides that a provider has a right to obtain judicial review of a final decision of the Board, or of a timely reversal, affirmation, or modification by the Administrator of a final Board decision, by filing a civil action in accordance with the Federal Rules of Civil Procedure in a Federal district court with venue no later than 60 days after the date of receipt by the provider of a final Board decision or a reversal, affirmation, or modification by the Administrator. The Secretary (and not the Administrator or CMS itself, or the intermediary) is the only proper defendant in a civil action brought under section 1878(f)(1) of the Act.

(3) A Board decision is final and subject to judicial review under section 1878(f)(1) of the Act only if the decision—

(i) Is one of the Board decisions specified in § 405.1875(a)(2)(i) through (a)(2)(iii) of this subpart or, in a particular case, is deemed to be final by the Administrator under § 405.1875(a)(2)(iv) of this subpart; and

(ii) Is not reversed, affirmed, modified, or remanded by the Administrator under § 405.1875(e) and § 405.1875(f) of this subpart within 60 days of the date of receipt by the

provider of the Board's decision. A provider is not required to seek Administrator review under § 405.1875(c) first in order to seek judicial review of a Board decision that is final and subject to judicial review under section 1878(f)(1) of the Act.

(4) If the Administrator timely reverses, affirms, or modifies one of the Board decisions specified in § 405.1875(a)(2)(i) through (a)(2)(iii) of this subpart or deemed to be final by the Administrator in a particular case under § 405.1875(a)(2)(iv) of this subpart, the Administrator's reversal, affirmation, or modification is the only decision subject to judicial review under section 1878(f)(1) of the Act. A remand of a Board decision by the Administrator to the Board vacates the decision. Neither the Board's decision nor the Administrator's remand is a final decision subject to judicial review under section 1878(f)(1) of the Act (as described in § 405.1875(e)(4), § 405.1875(f)(1), and § 405.1875(f)(4) of this subpart).

(b) *Determining when a civil action may be filed.* (1) *General rule.* Under section 1878(f)(1) of the Act, the 60-day periods for Administrator review of a decision by the Board, and for judicial review of any final Board decision, respectively, both begin to run on the same day. Paragraphs (b)(2), (b)(3) and (b)(4) of this section identify how various actions or inaction by the Administrator within the 60-day review period determine the scope and timing of any right a provider may have to judicial review under section 1878(f)(1) of the Act.

(2) *Administrator declines review.* If the Administrator declines any review of a Board decision specified in § 405.1875(a)(2) of this subpart, whether through inaction or in a written notice issued under § 405.1875(c)(3) of this subpart, the provider must file any civil action seeking judicial review of the Board's final decision under section 1878(f)(1) of the Act no later than 60 days after the date of receipt by the provider of the Board's decision.

(3) *Administrator accepts review and renders timely decision.* When the Administrator decides to review, in a notice under § 405.1875(c)(3) of this subpart, any issue in a Board decision specified as final, or deemed as final by the Administrator, under § 405.1875(a)(2) of this subpart, and he or she subsequently renders a decision within the 60-day review period (as described in § 405.1875(a)(1) of this subpart), the provider has no right to obtain judicial review of the Board's decision under section 1878(f)(1) of the Act.

(i) If the Administrator timely reverses, affirms, or modifies the Board's decision, the provider's only right under section 1878(f)(1) of the Act is to request judicial review of the Administrator's decision by filing a civil action no later than 60 days after the date of receipt by the provider of the Administrator's decision (as described in § 405.1877(a)(3) of this subpart).

(ii) If the Administrator timely vacates the Board's decision and remands for further proceedings (as described in § 405.1875(f)(1)(i) of this subpart), a provider has no right to judicial review under section 1878(f)(1) of the Act of the Board's decision or of the Administrator's remand (as described in § 405.1877(a)(3) of this subpart).

(4) *Administrator accepts review and timely decision is not rendered.* If the Administrator decides to review, in a notice under § 405.1875(c)(3) of this subpart, any issue in a Board decision specified as final, or deemed to be final by the Administrator, under § 405.1875(a)(2), but he or she does not render a decision within the 60-day review period, this subsequent inaction constitutes an affirmation of the Board's decision by the Administrator, for purposes of the time in which to seek judicial review. In this case, the provider must file any civil action requesting judicial review of the Administrator's final decision under section 1878(f)(1) of the Act no later than 60 days after the expiration of the 60-day period for a decision by the Administrator under § 405.1875(a)(1) and § 405.1875(e)(2) of this subpart.

(c) *Statutory limitations on and preclusion of judicial review.* The Act limits or precludes judicial review of certain matters at issue. Limitations on and preclusions of judicial review include the following:

(1) A finding in an intermediary determination that expenses incurred for items and services furnished by a provider to an individual are not payable under title XVIII of the Act because those items or services are excluded from coverage under section 1862 of the Act, and the regulations at 42 CFR Part 411, is not reviewable by the Board (as described in § 405.1840(b)(1) of this subpart) and is not subject to judicial review under section 1878(f)(1) of the Act; the finding is subject to judicial review solely in accordance with the applicable provisions of sections 1155, 1869, and 1879(d) of the Act, and of Subpart I of Part 405 and Subpart B of Part 478, as applicable.

(2) Certain matters affecting payments to hospitals under the prospective payment system are completely

removed from administrative and judicial review, as provided in section 1886(d)(7) of the Act, and § 405.1804 and § 405.1840(b)(2) of this subpart.

(3) Any Board remand order, or discovery or disclosure ruling or subpoena specified in § 405.1875(a)(3)(i) through (a)(3)(ii) of this subpart, or a decision by the Administrator following immediate review of a Board remand order, discovery ruling, or subpoena, is not subject to immediate judicial review under section 1878(f)(1) of the Act. Judicial review of all nonfinal Board actions, including any such Board remand order, discovery or disclosure ruling, or subpoena (except as provided in § 405.1857(e) of this subpart), is limited to review of a final agency decision as described in § 405.1877(a) of this subpart.

(d) *Group appeals.* If a final decision is issued by the Board or rendered by the Administrator, as applicable, in any group appeal brought under § 405.1837, those providers in the group appeal that seek judicial review of the final decision under section 1878(f)(1) of the Act must file a civil action as a group (as described in § 405.1877(e)(2) of this subpart) for the specific matter at issue and common factual or legal question that was addressed in the final agency decision in the group appeal.

(e) *Venue for civil actions.* (1) *Single provider appeals.* A civil action under section 1878(f)(1) of the Act requesting judicial review of a final decision of the Board or the Administrator, as applicable, in a single provider appeal under § 405.1835 of this subpart must be brought in the District Court of the United States for the judicial district in which the provider is located or in the United States District Court for the District of Columbia.

(2) *Group appeals.* A civil action under section 1878(f)(1) of the Act seeking judicial review of a final decision of the Board or the Administrator, as applicable, in a group appeal under § 405.1837 of this subpart must be brought in the District Court of the United States for the judicial district in which the greatest number of providers participating in both the group appeal and the civil action are located or in the United States District Court for the District of Columbia.

(f) *Service of process.* Process must be served as described under 45 CFR Part 4.

(g) *Remand by a court.* (1) *General rule.* Under section 1874 of the Act, and § 421.5(b) of this chapter, the Secretary is the real party in interest in a civil action seeking relief under title XVIII of the Act. The Secretary has delegated to the Administrator the authority under

section 1878(f)(1) of the Act to review decisions of the Board and, as applicable, render a final agency decision. If a court, in a civil action brought by a provider against the Secretary as the real party in interest regarding a matter pertaining to Medicare payment to the provider, orders a remand for further action by the Secretary, any component of HHS or CMS, or the intermediary, the remand order must be deemed, except as provided in paragraph (g)(3) of this section, to be directed to the Administrator in the first instance, regardless of whether the court's remand order refers to the Secretary, the Administrator, the Board, any other component of HHS or CMS, or the intermediary.

(2) *Procedures.* (i) Upon receiving notification of a court remand order, the Administrator must prepare an appropriate remand order and, if applicable, file the order in any Board appeal at issue in the civil action.

(ii) The Administrator's remand order must—

(A) Describe the specific requirements of the court's remand order;

(B) Require compliance with those requirements by the pertinent component of HHS or CMS or by the intermediary, as applicable; and

(C) Remand the matter to the appropriate entity for further action.

(iii) After the entity named in the Administrator's remand order completes its response to that order, the entity's response after remand is subject to further proceedings before the Board or the Administrator, as applicable, in accordance with this subpart. For example—

(A) If the intermediary issues a revised intermediary determination after remand, the provider may request a Board hearing on the revised determination (as described in § 405.1803(d) and § 405.1889 of this subpart); or,

(B) If the intermediary hearing officer(s) or the Board issues a new decision after remand, a decision may be reviewed by a CMS reviewing official or the Administrator, respectively (as described in § 405.1834 and § 405.1875(f)(4) of this subpart).

(3) *Exception.* The provisions of paragraphs (g)(1) and (g)(2) of this section do not apply to the extent they may be inconsistent with the court's remand order or any other order of the court regarding the civil action.

(h) *Implementation of final court judgment.* (1) When a final, non-appealable court judgment is issued in a civil action brought by a provider against the Secretary as the real party in

interest regarding a matter affecting Medicare payment, a court judgment is subject to the provisions of § 405.1803(d) of this subpart.

(2) The provisions of paragraph (h)(1) of this section do not apply to the extent they may be inconsistent with the court's final judgment or any other order of a court regarding the civil action.

■ 33. Section 405.1885 is revised to read as follows:

§ 405.1885 Reopening an intermediary determination or reviewing entity decision.

(a) *General.* (1) A Secretary determination, an intermediary determination, or a decision by a reviewing entity (as described in § 405.1801(a) of this subpart) may be reopened, for findings on matters at issue in a determination or decision, by CMS (with respect to Secretary determinations), by the intermediary (with respect to intermediary determinations) or by the reviewing entity that made the decision (as described in § 405.1885(c) of this subpart).

(2) A determination or decision may be reopened either through own motion of CMS (for Secretary determinations), the intermediary or reviewing entity, by notifying the parties to the determination or decision (as specified in § 405.1887), or by granting the request of the provider affected by the determination or decision.

(3) An intermediary's discretion to reopen or not reopen a matter is subject to a contrary directive from CMS to reopen or not reopen that matter.

(4) If CMS directs an intermediary to reopen a matter, reopening is considered an own motion reopening by the intermediary. A reopening may result in a revision of any matter at issue in the determination or decision.

(5) If a matter is reopened and a revised determination or decision is made, a revised determination or decision is appealable to the extent provided in § 405.1889 of this subpart.

(6) A determination or decision to reopen or not to reopen a determination or decision is not a final determination or decision within the meaning of this subpart and is not subject to further administrative review or judicial review.

(b) *Time limits.* (1) *Own motion reopening of a determination not procured by fraud or similar fault.* An own motion reopening is timely only if the notice of intent to reopen (as described in § 405.1887 of this subpart) is mailed no later than 3 years after the date of the determination or decision that is the subject of the reopening. The date the notice is mailed is presumed to

be the date indicated on the notice unless it is shown by a preponderance of the evidence that the notice was mailed on a later date.

(2) *Request for reopening of a determination not based on fraud or similar fault.*

(i) A reopening made upon request is timely only if the request to reopen is received by CMS, the intermediary, or reviewing entity, as appropriate, no later than 3 years after the date of the determination or decision that is the subject of the requested reopening. The date of receipt by CMS, the intermediary, or the reviewing entity of the request to reopen is conclusively presumed to be the date of delivery by a nationally-recognized next-day courier, or the date stamped "Received" by CMS, the intermediary or the reviewing entity (where a nationally-recognized next-day courier is not employed), unless it is shown by clear and convincing evidence that CMS, the intermediary, or the reviewing entity received the request on an earlier date.

(ii) A request to reopen does not toll the time in which to appeal an otherwise appealable determination or decision.

(iii) A request to reopen that is received within the 3-year period described in this paragraph is timely, notwithstanding that the notice of reopening required under § 405.1887 of this subpart is issued after such 3-year period.

(3) *Reopening of a determination procured by fraud or similar fault.* A Secretary or intermediary determination or decision by the reviewing entity may be reopened and revised at any time if it is established that the determination or decision was procured by fraud or similar fault of any party to the determination or decision.

(c) *Jurisdiction for reopening.* Jurisdiction for reopening an intermediary determination or intermediary hearing decision rests exclusively with the intermediary or intermediary hearing officer(s) that rendered the determination or decision (or, when applicable, with the successor intermediary), subject to a directive from CMS to reopen or not reopen the determination or decision. Jurisdiction for reopening a Secretary determination, CMS reviewing official decision, a Board decision, or an Administrator decision rests exclusively with CMS, the CMS reviewing official, Board or Administrator, respectively.

(1) *CMS-directed reopenings.* CMS may direct an intermediary or intermediary hearing officer(s) to reopen and revise any matter, subject to the time limits specified in paragraph (b) of

this section, and subject to the limitation expressed in paragraph (c)(2) of this section, by providing explicit direction to the intermediary or intermediary hearing officer(s) to reopen and revise.

(i) *Examples.* An intermediary determination or intermediary hearing decision must be reopened and revised if CMS provides explicit notice to the intermediary that the intermediary determination or the intermediary hearing decision is inconsistent with the applicable law, regulations, CMS ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS in effect, and as CMS understood those legal provisions, at the time the determination or decision was rendered by the intermediary. CMS may also direct the intermediary to reopen a particular intermediary determination or decision in order to implement a final agency decision (as described in § 405.1833, § 405.1871(b) and § 405.1875 of this subpart), a final, non-appealable court judgment § 405.1877, or an agreement to settle an administrative appeal or a lawsuit, regarding the same determination or decision.

(ii) [Reserved]

(2) *Prohibited reopenings.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS, whether made in response to judicial precedent or otherwise, is not a basis for reopening a CMS or intermediary determination, an intermediary hearing decision, a CMS reviewing official decision, a Board decision, or an Administrator decision, under this section.

(3) *Reopening by CMS or intermediary of determination currently on appeal to the Board or Administrator.* CMS or an intermediary may reopen, on its own motion or on request of the provider(s), a Secretary or intermediary determination that is currently pending on appeal before the Board or Administrator.

(i) The scope of the reopening may include any matter covered by the determination, including those specific matters that are appealed to the Board or the Administrator.

(ii) The intermediary must send a copy of the notice required under § 405.1887(a) to the Board or to the Administrator, through the Office of the Attorney Advisor, specifically informing that the matter(s) to be addressed by the reopening is currently under appeal to the Board or to the Administrator or is

covered by the same determination that is under appeal.

(4) *Reopening of determination within the time for appealing that determination to the Board.* CMS or an intermediary may reopen, on its own motion or on request of the provider(s), a Secretary or intermediary determination for which no appeal was taken to the Board, but for which the time to appeal to the Board has not yet expired, by sending the notice specified in § 405.1887(a) of this subpart.

■ 34. Section 405.1887 is revised to read as follows:

§ 405.1887 Notice of reopening; effect of reopening.

(a) In exercising its reopening authority under § 405.1885, CMS (for Secretary determinations), the intermediary or the reviewing entity, as applicable, must provide written notice to all parties to the determination or decision that is the subject of the reopening. Notices of—

(1) Reopening by a CMS reviewing official or the Board must be sent promptly to the Administrator.

(2) Intermediary reopenings of determinations that are currently pending before the Board or the Administrator must meet the requirements specified in § 405.1885(c)(3) and (c)(4) of this subpart.

(b) Upon receipt of the notice required under § 405.1887(a) of this subpart, the parties to the prior Secretary or intermediary determination or decision by a reviewing entity, as applicable, must be allowed a reasonable period of time in which to present any additional evidence or argument in support of their positions.

(c) Upon concluding its reopening, CMS, the intermediary or the reviewing entity, as applicable, must provide written notice promptly to all parties to the determination or decision that is the subject of the reopening, informing the parties as to what matter(s), if any, is revised, with a complete explanation of the basis for any revision.

(d) A reopening by itself does not extend appeal rights. Any matter that is reconsidered during the course of a reopening, but is not revised, is not within the proper scope of an appeal of a revised determination or decision (as described in § 405.1889 of this subpart).

■ 35. Section 405.1889 is revised to read as follows:

§ 405.1889 Effect of a revision; issue-specific nature of appeals of revised determinations and decisions.

(a) If a revision is made in a Secretary or intermediary determination or a

decision by a reviewing entity after the determination or decision is reopened as provided in § 405.1885 of this subpart, the revision must be considered a separate and distinct determination or decision to which the provisions of § 405.1811, § 405.1834, § 405.1835, § 405.1837, § 405.1875, § 405.1877 and § 405.1885 of this subpart are applicable.

(b)(1) Only those matters that are specifically revised in a revised determination or decision are within the scope of any appeal of the revised determination or decision.

(2) Any matter that is not specifically revised (including any matter that was reopened but not revised) may not be considered in any appeal of the revised determination or decision.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 36. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1861(v)(1)(A), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

■ 37. The heading for part 413 is revised to read as set forth above.

■ 38. Section 413.30 is amended by revising the last sentence in each of paragraphs (c)(1) and (c)(2) to read as follows:

§ 413.30 Limitations on payable costs.

* * * * *

(c) * * *

(1) * * *. The time required by CMS to review the request is considered good cause for the granting of an extension of the time limit for requesting an intermediary hearing or a Provider Reimbursement Review Board (Board) hearing as specified in § 405.1813 and § 405.1836 of this chapter, respectively.

(2) * * *. The time required by the intermediary to review the request is considered good cause for the granting of an extension of the time limit for requesting an intermediary hearing or a Board hearing as specified in § 405.1813 and § 405.1836 of this chapter, respectively.

* * * * *

■ 39. Section 413.40 is amended by revising paragraph (e)(5) to read as follows:

§ 413.40 Ceiling on the rate of increase in hospital inpatient costs.

* * * * *

(e) * * *

(5) *Extending the time limit for review of NPR.* The time required to review the request is considered good cause for the granting of an extension of the time limit for requesting an intermediary hearing or a Board hearing as specified in § 405.1813 and § 405.1836 of this chapter, respectively.

* * * * *

■ 40. Section 413.64 is amended by revising the last sentence in paragraph (j)(1) to read as follows:

§ 413.64 Payments to providers: Specific rules.

* * * * *

(j) * * *

(1) * * *. The interest begins to accrue on the first day of the first month following the 180-day period described in § 405.1835(a)(3)(i) or (a)(3)(ii) of this chapter, as applicable.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 41. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e-5, and 300e-9); and 31 U.S.C. 9701.

§ 417.576 [Amended]

■ 42. In § 417.576—A. Amend paragraph (d)(4) by removing the phrase “a hearing in accordance with subpart R of part 405 of this chapter” and adding in its place “a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter”; and

■ B. Amend paragraph (e)(2) by removing the phrase “a hearing under subpart R of part 405 of this chapter” and adding in its place “a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter”.

§ 417.810 [Amended]

■ 43. In § 417.810—

■ A. Amend paragraph (c)(2) by removing the phrase “a hearing as provided in part 405, subpart R of this chapter” and adding in its place “a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter”; and

■ B. Amend paragraph (d)(3) by removing the phrase “a hearing on the determination under the provisions of part 405, subpart R of this chapter” and adding in its place “a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter”

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

Dated: November 6, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 5, 2008.

Michael O. Leavitt,

Secretary.

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