

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS-4127-P]

RIN 0938-AO87

Medicare Program; Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process

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

ACTION: Proposed rule.

SUMMARY: This rule proposes the procedures that the Department of Health and Human Services would follow at the Administrative Law Judge and Medicare Appeals Council levels in deciding appeals brought by individuals who have enrolled in the Medicare prescription drug benefit program and the reopening procedures that would be followed at all levels of appeal.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 16, 2008.

ADDRESSES: In commenting, please refer to file code CMS-4127-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4127-P, P.O. Box 8016, Baltimore, MD 21244-8016.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4127-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier)

your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

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

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

b. 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Arrah Tabe-Bedward, (410) 786-7129 (for issues related to reopenings and expedited access to judicial review).

Michael Lipinski, (216) 615-4084 (for issues related to ALJ level appeals policies).

Mary Peltzer, (202) 565-0169 (for issues related to MAC level appeals).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code 4127-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as

they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Abbreviations

Because of the many terms to which we refer by abbreviation in this proposed rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ALJ Administrative Law Judge
CMS Centers for Medicare & Medicaid Services
DAB Departmental Appeals Board
EAJR Expedited Access to Judicial Review
IRE Independent Review Entity
LCD Local Coverage Determination
MAC Medicare Appeals Council
NCD National Coverage Determination
QIC Qualified Independent Contractor

I. Background

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

The voluntary prescription drug benefit program ("Part D") was enacted into law by section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). The MMA specified that the prescription drug benefit would become available on January 1, 2006 for individuals entitled to benefits under Medicare Part A or enrolled under Medicare Part B. On January 28, 2005, the final rule (70 FR 4194) implementing the Part D program appeared in the **Federal Register** (hereinafter "Part D rule"). This rule became effective on March 22, 2005.

Section 1860D-4(h) of the Social Security Act (the Act) provides that Part D plan sponsors follow appeals procedures specified in § 1852(g)(5) of the Act in a manner similar to the manner such requirements apply to Medicare Advantage (MA) organizations for Part C appeals. Part D plan sponsors include a prescription drug plan sponsor, an MA organization offering a Medicare Advantage prescription drug plan (MA-PD plan), a Program of All-Inclusive Care for Elderly (PACE) organization offering a PACE plan, and a cost plan offering qualified prescription drug coverage.

Section 1852(g)(5) of the Act provides that enrollees in MA plans who are dissatisfied with determinations regarding their Part C benefits are

entitled, if they meet the amount in controversy requirement, to a hearing before the Secretary to the same extent as is provided in section 205(b) of the Act and judicial review of the Secretary's final decision as provided in section 205(g) of the Act.

Section 1869(b)(1)(A) of the Act, which sets forth the requirements for Part A and Part B appeals, contains similar language to that set forth in section 1852(g)(5) of the Act and also refers to section 205(b) and (g) of the Act.

These statutory concepts are reflected in the Part D rule and a closely related rule concerning MA organizations that also appeared in the **Federal Register** on January 28, 2005 (70 FR 4588), and became effective March 22, 2005 (hereinafter "Part C rule"). The Part D rule is codified at 42 CFR part 423, and addresses grievances, coverage determinations, reconsiderations, and appeals in subpart M. The Part C rule is codified at 42 CFR part 422, and similarly addresses grievances, organization determinations, and appeals in subpart M. The Part D rule states that, unless otherwise provided, the Part C rules regarding appeals and reopenings will apply "to the extent they are appropriate." (See 42 CFR 423.562(c).) Likewise, the Part C rule governing appeals at the Administrative Law Judge (ALJ) and Medicare Appeals Council (MAC) levels of appeal provides that adjudicators apply the Part A and Part B appeals and reopening

procedures specified in 42 CFR part 405 "to the extent they are appropriate." (see 42 CFR 422.562(d)).

Based on this statutory and regulatory framework, CMS stated in the preamble to the interim final rule entitled "Changes to the Medicare Claims Appeal Procedures," which established new procedures for appeals under Medicare Part A and Part B, that differences in the appeals procedures for Part D enrollees would be addressed in a future Part D rulemaking document (70 FR 11420), (hereinafter, "Part 405, subpart I rule"). The purpose of this rule is to provide guidance on the differences in appeals procedures for Part D enrollees by proposing more detailed regulations to govern Part D appeals (requests for drug benefits and payment) to the ALJ, MAC, and Federal District Court and reopenings of determinations and decisions.

II. Highlights and Organization of the Proposed Rule

[If you choose to comment on issues in this section, please include the caption "HIGHLIGHTS AND ORGANIZATION" at the beginning of your comments.]

This proposed rule contains revisions to Part 423, subpart M of title 42 of the CFR. We are proposing to rename, reorganize, and consolidate similar requirements into one section, and add a new subpart "U". We believe that these changes will maintain or clarify our original intent, making the revised

regulation easier to read and understand. Specifically, we are proposing to rename subpart M, "Grievances, Coverage Determinations, Redeterminations, and Reconsiderations". This subpart will continue to set forth the requirements for Part D sponsors with respect to grievances, coverage determinations, and redeterminations. We are also proposing to add a new subpart U, "Reopenings, ALJ Hearings, MAC review, and Judicial Review" that will set forth the requirements for Part D plan sponsors, the Part D Independent Review Entity (IRE), ALJs, and the MAC with respect to reopenings, ALJ hearings, and MAC review of Part D appeals. In addition, we are proposing to redesignate and reserve § 423.610, § 423.612, § 423.620, § 423.630, and § 423.634. We note that while we are proposing to make conforming changes to the language of some of the redesignated sections, we are not proposing to make any substantive changes to the policies established by those provisions.

Below we are providing a crosswalk table that will enable the reader to easily determine where the requirements will be relocated. The crosswalk lists the current subpart, current section, proposed subpart, and proposed section. For any discussion of the changes we are proposing to make in this rule, we are providing both the current section and the proposed redesignated section and paragraph.

TABLE—CROSSWALK

Current subpart	Current section	Proposed subpart	Proposed section
Subpart M—Grievances, Coverage Determinations, and Appeals.	423.610 Right to an ALJ hearing	Subpart U—Reopening, ALJ Hearings, MAC review, and Judicial Review.	423.1970 Right to an ALJ hearing.
Subpart M—Grievances, Coverage Determinations, and Appeals.	423.612 Request for an ALJ hearing.	Subpart U—Reopening, ALJ Hearings, MAC review, and Judicial Review.	423.1972 Request for an ALJ hearing.
Subpart M—Grievances, Coverage Determinations, and Appeals.	423.620 Medicare Appeals Council (MAC) review.	Subpart U—Reopening, ALJ Hearings, MAC review, and Judicial Review.	423.1974 Medicare Appeals Council (MAC) review.
Subpart M—Grievances, Coverage Determinations, and Appeals.	423.630 Judicial review	Subpart U—Reopening, ALJ Hearings, MAC review, and Judicial Review.	423.1976 Judicial review.
Subpart M—Grievances, Coverage Determinations, and Appeals.	423.634 Reopening and revising determinations and decisions.	Subpart U—Reopening, ALJ Hearings, MAC review, and Judicial Review.	423.1978 Reopening and revising determinations and decisions.

III. Provisions of the Proposed Regulations

A. General Appeals Provisions

[If you choose to comment on issues in this section, please include the caption "GENERAL APPEALS PROVISIONS" at the beginning of your comments.]

Section 1860D–4(h)(1) of the Act, which sets forth the statutory requirements for Part D appeals, requires the Secretary to establish an appeals process that is "similar" to the process used for MA organizations under section 1852(g)(4) and (5) of the Act. Section 1852(g)(5) of the Act

provides the right to a hearing "before the Secretary to the same extent as is provided in section 205(b) of the Act," and to judicial review "of the Secretary's final decision as provided in section 205(g)" of the Act. Thus, an enrollee dissatisfied by reason of the enrollee's failure to receive a Part D

drug to which the enrollee believes he or she is entitled, and at no greater charge than the enrollee believes he or she is required to pay is entitled to a hearing and may also request judicial review of the final decision of the Secretary.

Section 1852(g)(5) of the Act also specifies the amount in controversy needed to pursue a hearing and judicial review. Like section 1852(g)(5) of the Act, section 1869(b)(1)(A) of the Act, which sets forth the statutory requirements for Part A and Part B appeals, provides the right to a hearing “by the Secretary to the same extent as is provided in section 205(b)” and the right to judicial review “of the Secretary’s final decision after such hearing as is provided in section 205(g) of the Act.” Under this authority, we believe that Congress gave us discretion in designing procedural rules for appeals under Part D.

Section 423.562(c) of the Part D rule states that “[u]nless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.” Section 422.562(d) of the Part C rule states that “[u]nless this subpart provides otherwise, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act), apply under this subpart to the extent they are appropriate.” Therefore, as discussed in the preamble to the Part D rule, since § 423.562(c) incorporates part 422, and since part 422 incorporates part 405, the provisions of part 405 apply to Part D appeals to the extent that they are appropriate. (70 FR at 4343).

For these reasons, we propose to provide a similar appeals process for Part D appeals at the ALJ, MAC and judicial review levels as applies to Part A and Part B appeals, to the extent it is appropriate.

The Part 405 regulations at subparts G and H, which continue to apply to certain pending Medicare claims appeals under Medicare Part A and Part B, respectively, were issued before the enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106–554. BIPA made significant changes to Medicare claims appeals procedures. The MMA made further changes to these procedures. Part 405, subpart I,

contains the new BIPA and MMA appeals procedures. Part 405, subpart I, applies to initial determinations issued by Medicare fiscal intermediaries on or after May 1, 2005, and to initial determinations issued by carriers on or after January 1, 2006. Part 405, subpart I, is tailored to the Medicare Part A and Part B claims appeals process, unlike the provisions in subparts G and H, which, in large part, follow the Social Security Administration’s procedures for disability claims. For this reason, we have concluded that it is appropriate to apply the provisions of Part 405, subpart I, to Part D appeals at the ALJ and MAC levels with appropriate modifications to meet the needs of Part D appeals.

B. Parties to the ALJ Hearing and MAC Review

Section 1860D–4(h) of the Act largely incorporates section 1852(g)(5) of the Act. We interpret that section as providing the right to a hearing and to judicial review for an enrollee dissatisfied by reason of the enrollee’s failure to receive a Part D drug to which the enrollee believes he or she is entitled, and at no greater charge than the enrollee believes he or she is required to pay. Section 1860D–4(h)(1) of the Act specifies that “only the Part D eligible individual” is entitled to bring an appeal. Section 423.560 of the Part D rule states that an enrollee is a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Current § 423.610 (proposed § 423.1970) and current § 423.612 (proposed § 423.1972) explain that, if an enrollee is dissatisfied with the reconsideration determination by an IRE, the enrollee may request a hearing before an ALJ, if the amount remaining in controversy meets the threshold requirement established annually by the Secretary. Similarly, under current § 423.620 (proposed § 423.1974), if an enrollee is dissatisfied with the ALJ’s action, the enrollee may request that the MAC review the ALJ’s decision or dismissal. Having the enrollee as the only party to an appeal differs from the Part A and B processes where the term “party” includes a beneficiary, a provider, a supplier, a Medicaid State agency, and CMS and/or its contractors, and from the Part C appeals process where the term “party” includes an enrollee, a provider, an entity with rights with respect to the organization determination, or an MA organization. In light of the Part D statutory and regulatory provisions, this proposed rule makes clear that only the enrollee may request and be a party to an ALJ hearing or MAC review. (We note that

an enrollee may appoint a representative to act on his or her behalf as discussed in § 423.560 and as set forth in § 422.561 and § 405.910. A representative could include an enrollee’s physician).

We are proposing not to make the Part D plan sponsor, the IRE, or CMS a party to an ALJ hearing or the MAC review in a Part D case. The statute and Part D rule do not explicitly provide these entities with party status, unlike Part C where the statute provides that the Secretary shall make an MA organization a party to ALJ hearings. Further, the preamble to the Part D rule (70 FR 4360) states that “[t]he plan is not a party to the ALJ hearing.” As discussed later in the preamble, we recognize that the involvement of CMS, the IRE, and/or the Part D plan sponsor may be necessary to resolve the issue(s) on appeal and we propose to allow these entities to participate in ALJ hearings at the ALJ’s discretion. The participation of Part D plan sponsors in ALJ hearings was also contemplated in the preamble to the proposed Part D rule (69 FR 46632, 46722), which noted that “[a]lthough a PDP sponsor generally is not a party to the IRE appeal and may not request a hearing before an ALJ, the sponsor is considered a party to the ALJ hearing for the limited purpose of participation in the hearing.” We welcome comments on this proposed approach.

C. Timeframes for Deciding Appeals at the ALJ and MAC Levels

[If you choose to comment on issues in this section, please include the caption “TIMEFRAMES FOR DECIDING APPEALS AT THE ALJ AND MAC LEVELS” at the beginning of your comments.]

Part 405, subpart I implements the provisions of section 1869 of the Act that require ALJs and the MAC to complete their actions within 90 days of the date an appeal is timely filed. The Part D statute and rule do not establish timeframes for an ALJ or the MAC to issue a decision. However, we recognize the need to ensure that Part D enrollees receive timely actions on their requests for hearing and review, particularly in cases where the enrollee has not obtained the drug and a delayed decision may seriously jeopardize the enrollee’s life or health or ability to regain maximum function.

We propose to apply a 90-day adjudicatory timeframe to Part D appeals with an expedited process for certain types of appeals. Specifically, we propose that an ALJ and the MAC must provide an expedited decision in situations where the appeal involves one of the issues specified in

§ 423.566(b), but does not include solely a request for payment of Part D drugs already furnished, and when the enrollee's prescribing physician indicates, or the ALJ or the MAC determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life or health or ability to regain maximum function. In these situations, the ALJ and the MAC must issue a decision, dismissal order, or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10-day period beginning on the date the request for hearing or request for review is received.

This process is similar to the expedited process established at the coverage determination, redetermination, and reconsideration levels under the Part D rule at § 423.570, § 423.584, and § 423.600. As discussed in applicable sections below, in order to meet this shortened timeframe, we propose to allow certain requests, objections, decisions, orders, and notices to be conducted orally with written follow-up or documentation and to shorten certain timeframes for receiving certain notices, such as the notice of hearing. All time periods in this proposed rule refer to calendar days.

The statutory and regulatory provisions for appeals under Parts A and B provide appellants the opportunity to request that the appeal be transferred (or "escalated") to the next level of appeal, if the Qualified Independent Contractor (QIC), ALJ, or the MAC do not complete their actions within the statutory deadlines. The Part C and D statutory provisions do not provide for escalation of an appeal to the ALJ, MAC, or Federal District Court levels. We propose to not include provisions regarding escalation in this rule, but instead we are proposing to address the timeliness concerns of Part D enrollees by providing for an expedited process, discussed in greater detail below.

D. Evidence

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

We are proposing to provide enrollees with as much flexibility as possible concerning the evidence that may be presented for an ALJ hearing and MAC review. We also are proposing that the entity that is best suited to review and evaluate the evidence be the entity that receives the evidence for review. Therefore, we are proposing that an enrollee may submit any written

evidence about his or her condition at the time of the coverage determination that he or she wishes to have considered at the hearing. However, we propose where an enrollee wishes to have evidence on changes in his or her condition since the coverage determination considered in the appeal, an ALJ or the MAC will instead remand the case to the Part D plan sponsor. The Part D plan sponsor is in a better position to evaluate the impact of evidence on change in condition because it has the technical expertise needed to review such evidence. This proposal differs from the Part 405, subpart I, rule, because Part A and Part B appeals are retrospective; that is, the service or item at issue was provided or received before the claim is filed. In these situations, evidence of medical necessity is not relevant unless it relates to the beneficiary's medical condition and needs at the time that the beneficiary received the service or obtained the medical product or device. In contrast, some Part D appeals involve an enrollee requesting that the Part D plan sponsor provide him or her with a particular drug ("drug benefit appeals"). In these cases, the enrollee's condition may change during the course of the appeal, and evidence of such a change in condition may impact a Part D plan sponsor's determination regarding whether the enrollee should receive a certain Part D drug.

We considered allowing an enrollee in such circumstances to withdraw a pending appeal and seek a new coverage determination from the Part D plan sponsor. However, we believe a remand would streamline the process for the enrollee by eliminating the need for the enrollee to both withdraw a pending appeal and to file a new coverage determination request. Additionally, on remand the Part D plan sponsor would have access to an already developed case file when reviewing newly submitted evidence on change in condition, allowing for a more efficient and effective review by reducing possible delays from developing a new case file. We also note that under our proposal, the enrollee would have the option to continue with his or her appeal at the ALJ or MAC level if he or she did not wish to have change in condition evidence considered.

We do not propose to follow the full and early presentation of evidence provisions in Part 405, subpart I, including § 405.1028. Section 1869(b)(3) of the Act requires the full and early presentation of evidence at the reconsideration level by providers and suppliers absent good cause. Part 405, subpart I, extends this requirement to

beneficiaries represented by providers or suppliers in an effort to ensure that providers or suppliers do not attempt to circumvent the full and early presentation of evidence rules by offering to represent beneficiaries. For Part D appeals, we propose that only the enrollee would be a party to the appeal and because the enrollee would not be represented by a provider or supplier attempting to circumvent this rule we propose to not include any provisions from Part 405, subpart I, on the full and early presentation of evidence. We propose, as discussed above, that an enrollee may present new evidence at any time during the appeal. However, we propose that the ALJ or MAC will not consider evidence on change in condition occurring after the coverage determination is made but will remand the appeal to the Part D plan sponsor if an enrollee wishes to have such evidence examined and considered in the appeal.

E. Claims and Overpayment

[If you choose to comment on issues in this section, please include the caption "CLAIMS AND OVERPAYMENT" at the beginning of your comments.]

The Part A and Part B appeals process may involve claims for reimbursement from the Medicare Trust Fund made by parties to the appeal and issues of over- or underpayment by the Federal Government. In contrast, Part D appeals do not involve claims against the Medicare Trust Fund by enrollees, and, therefore, the Part D appeals process does not involve overpayments or underpayments. Rather, an enrollee may request payment from the Part D plan sponsor in situations where the enrollee has paid for a drug out-of-pocket ("payment appeals"). Therefore, we do not include any references to claims, overpayment, or underpayment in this proposed rule.

F. Other General Comments

[If you choose to comment on issues in this section, please include the caption "OTHER GENERAL COMMENTS" at the beginning of your comments.]

The Part D rule already contains provisions in current § 423.610 (proposed § 423.1970), current § 423.612 (proposed § 423.1972), and current § 423.630 (proposed § 423.1976) regarding the amount in controversy requirements for ALJ hearings and judicial review. Therefore, we see no reason to include language similar to that in § 405.990(j) and § 405.1006 regarding amount in controversy

requirements for Part A and Part B appeals.

Part 405, subpart I, references the applicability of national coverage determinations (NCDs) and local coverage determinations (LCDs). Because neither of these types of coverage policies applies to Part D, we propose not to include any reference to NCDs and LCDs and not to include any provision that applies solely to the application of NCDs and/or LCDs from Part 405, subpart I (for example, language from § 405.1060).

Part 405, subpart I, also refers to the Social Security Administration (SSA) rules for entitlement and enrollment appeals performed by SSA. We are not including similar references to SSA in this proposed rule because SSA does not perform appeals regarding enrollment in or entitlement to Part D.

Finally, Part 405, subpart I includes a provision at § 405.1064 regarding ALJ decisions involving statistical samples. We are not including similar language for Part D appeals because, as discussed above, Part D appeals do not involve overpayment issues. Therefore, statistical samples will not be used in reaching a decision.

IV. Specific Provisions of the Proposed Rule

A. *Reopenings* (§ 423.1980 Through § 423.1986)

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

Current § 423.634(a) (proposed § 423.1978(a)) states that a coverage determination, a redetermination, a reconsideration or a decision of an ALJ or the MAC “that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 422, subpart M of this chapter.” Section 422.616 of subpart M discusses reopenings and states that a determination or decision “that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405 of this chapter.” Therefore, we propose reopening regulations that generally track the Part A and Part B reopening provisions in § 405.980, § 405.982, § 405.984, and § 405.986. These regulations define reopening, explain who may initiate and revise determinations and decisions and when, and the effect of a revised determination or decision.

We believe that it is appropriate to follow the general process set forth in

Part 405, subpart I with additional language proposed at § 423.1980(a)(1), (a)(3), and (a)(4), and § 423.1984(g) that is consistent with current § 423.634 (proposed § 423.1978) on Part D reopenings. Since Part D appeals differ in part from Part A and Part B appeals, we propose not to include several provisions from § 405.980, § 405.982, and § 405.986.

1. Reopenings of Coverage Determinations, Redeterminations, Reconsiderations, Hearings, and Reviews (§ 423.1980)

[If you choose to comment on issues in this section, please include the caption “REOPENINGS OF COVERAGE DETERMINATIONS, REDETERMINATIONS, RECONSIDERATIONS, HEARINGS, AND REVIEWS” at the beginning of your comments.]

This section proposes to track the language of § 405.980 on the general rules and timeframes for reopening determinations and decisions, except as discussed above and below. We are proposing to define reopenings in § 423.1980(a)(1), without referring to overpayments and underpayments because these terms do not apply to Part D appeals, as discussed above. We also are proposing in § 423.1980 not to include the provision in § 405.980(a)(2) that involves situations where a fiscal intermediary or carrier denies a claim because it did not receive information that it requested about a claim during medical review. In addition, we are proposing not to include § 405.980(a)(3), (b)(4), and (c)(3) in this proposed rule. These subsections refer to clerical errors related to claim submissions by providers to fiscal intermediaries and carriers. In Part D, as discussed above, there are no claim submissions, as the beneficiary is not electronically submitting a claim to the Part D plan sponsor or to CMS. Therefore, we do not believe these provisions apply to Part D reopenings. Further, to the extent a clerical error arises (for example, miscalculations or missing information), an enrollee should use the grievance process established by the Part D plan sponsor.

Furthermore, we are not including in § 423.1980 language similar to § 405.980(b)(5) because this provision refers to the NCD/LCD appeals process, and NCDs and LCDs do not apply to Part D.

2. Notice of a Revised Determination or Decision (§ 423.1982)

[If you choose to comment on issues in this section, please include the caption “NOTICE OF A REVISED

DETERMINATION OR DECISION” at the beginning of your comments.]

We are proposing in § 423.1982 to follow the process established for Part A and Part B reopenings regarding notification of revised determinations or decisions. However, unlike § 405.982, proposed § 423.1982 does not refer to revised electronic or paper remittance for full or partial reversals. We are not incorporating this language because revised electronic or paper remittance advice notices are not issued for Part D appeals. Further, we propose language requiring the IRE, ALJ, or the MAC to mail revised determinations or decisions to the Part D plan sponsor.

3. Good Cause for Reopening (§ 423.1986)

[If you choose to comment on issues in this section, please include the caption “GOOD CAUSE FOR REOPENING” at the beginning of your comments.]

Section 423.1986 proposes language similar to § 405.986 regarding good cause for reopening a determination or decision. We believe it is appropriate where possible for Part D reopenings to have the same good cause standards as Part A and Part B reopenings. We are proposing in § 423.1986(b)(1), to include the requirement in § 405.986(b) regarding good cause for reopening a determination or decision based on a change in substantive law or interpretive policy for appeals. However, many Part D appeals involve drug benefit appeals, where an enrollee has not received the drug. With respect to these appeals, we are proposing in § 423.1986(b)(2) that an adjudicator may reopen a determination or decision to apply the current law or CMS or Part D plan sponsor policy (rather than the law or CMS or Part D plan sponsor policy at the time the original coverage determination was made). Because the enrollee has not received the drug, any change to the law or CMS or Part D plan sponsor policies since the initial coverage determination may affect whether the drug should be received.

B. *Expedited Access to Judicial Review* (EAJR) (§ 423.990)

[If you choose to comment on issues in this section, please include the caption “EXPEDITED ACCESS TO JUDICIAL REVIEW” at the beginning of your comments.]

Section 1869(b)(2) of the Act requires the Secretary to establish a process for Part A and Part B appeals where a provider, supplier or a beneficiary may obtain expedited access to judicial review in situations where the Departmental Appeals Board (DAB)

does not have authority to decide the question of law or regulation relevant to the matters in controversy and where there is no material issue of fact in dispute.

Unlike Part A and Part B appeals, there is no statutory requirement for enrollees to have access to an EAJR process for Part D appeals. However, we believe that it is appropriate to provide Part D enrollees with an EAJR process that mirrors the process established for Part A and Part B appeals. Under the Part A and Part B appeal process, a review entity determines whether the DAB has the authority to decide the question of law or regulation relevant to the matters in controversy after finding that there is no material issue of fact in dispute.

If the review entity certifies that the requirements for expedited access to judicial review are met, a party may appeal directly to the United States District Court. Even though the Part D statute does not require this process for Part D, we believe that Part D enrollees would benefit from this process because it provides access to judicial review more quickly in cases where the DAB does not have the authority to decide the question of law or regulation relevant to the matters in controversy and there is no material issue of fact in dispute, resulting in a more efficient appeals process. Therefore, we are proposing in § 423.990 to provide Part D enrollees the opportunity to seek EAJR. We welcome comments on this proposal.

C. Appeals to an ALJ (§ 423.1000 Through § 423.1063)

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

1. General

The Part D rule contains two specific provisions that apply to appeals before an ALJ. Current § 423.610 (proposed § 423.1970) describes an enrollee's right to an ALJ hearing and explains how the amount in controversy requirements may be satisfied. Current § 423.612 (proposed § 423.1972) describes when and where to file a request for hearing, specifies that the time and place of the hearing will be set in accordance with the regulation governing Part A and Part B appeals at § 405.1020, and explains when the ALJ will dismiss a request for hearing because it does not meet the amount in controversy requirement.

We are proposing to follow the process set forth under Part A and Part B for appeals to an ALJ, except as noted above and below. We have tracked the

language in the Part 405 rule for proposed § 423.2000, § 423.2004, § 423.2008, § 423.2030, § 423.2032, § 423.2042, § 423.2044, § 423.2048, § 423.2050, § 423.2054, § 423.2062, and § 423.2063. We believe that it is appropriate for Part D appeals to follow the Part A and Part B appeals procedures set forth in these provisions.

2. Right to an ALJ Hearing (§ 423.2002)

[If you choose to comment on issues in this section, please include the caption "RIGHT TO AN ALJ HEARING" at the beginning of your comments.]

The Part D rule currently at § 423.610(a) (proposed § 423.1970(a)) provides that an enrollee who is dissatisfied with the IRE reconsideration and meets the remaining amount in controversy threshold has a right to a hearing before an ALJ. We are proposing to include this provision in § 423.2002. We are also proposing to include in this section language similar to that in § 405.1002 on how to request an ALJ hearing, what is the date of receipt of the reconsideration, and when a request is considered filed.

We believe it is appropriate to include this information in proposed § 423.2002 because it would be helpful to the enrollee and any representative of the enrollee to understand how to file a request, how we would determine the date of receipt of the reconsideration, and when a request would be considered filed. An enrollee must have a written IRE reconsideration notice before filing a request for an ALJ hearing because the administrative record cannot be forwarded to the ALJ level until the written IRE reconsideration is completed, and the appeal cannot proceed at the ALJ level without the administrative record. We are also proposing in § 423.2002(b) that an enrollee may request an expedited ALJ hearing, if the enrollee meets the amount in controversy threshold and submits a request for an ALJ hearing within 60 days after receipt of the written notice of the IRE's reconsideration where the appeal involves an issue specified in § 423.566(b) but is not solely a request for payment of Part D drugs already furnished, as discussed previously. However, we are also proposing in § 423.2016(b) that the ALJ grant the request only if the enrollee's prescribing physician indicates or the ALJ determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life or health or ability to regain maximum function.

As discussed above, we believe that an expedited process, similar to the

expedited process provided at the lower levels of appeal would benefit enrollees who need quick decisions about Part D drugs due to their health status. We propose at § 423.2002(b)(3) a more informal process for requesting an expedited hearing by proposing to permit an enrollee to make a request for hearing orally. We believe that the oral request would make the initiation of the ALJ appeals process faster and easier for the enrollee. However, for the reasons stated above, an enrollee may only file an oral request for an expedited hearing after receiving the written IRE reconsideration notice. We also are proposing in § 423.2002(b)(4), to require the ALJ hearing office to document and maintain documentation of any oral request.

3. Participation in an ALJ Hearing (§ 423.2010)

[If you choose to comment on issues in this section, please include the caption "PARTICIPATION IN AN ALJ HEARING" at the beginning of your comments.]

In an effort to reduce the administrative burden and to assist the ALJ in resolving the issue(s) in an appeal more appropriately, we introduced specific procedures in Part 405, subpart I, to allow CMS and/or its contractors to participate in, or be a party to, an ALJ hearing. As explained in the preamble to the Part 405, subpart I rule (70 FR 11459–11460), if CMS and/or its contractors participate in an appeal, ALJs may be able to resolve issues of fact and law more quickly and reduce the need for remands for additional factual development.

CMS participation would provide significant benefit to the appeals process, and would assist in creating a more complete record. Section 1860D–4(h) of the Act and the Part D rule neither require nor prohibit participation by CMS and/or its contractors in an ALJ hearing. We recognize that an ALJ may determine that it is appropriate to request additional information from CMS, the IRE, and/or the Part D plan sponsor in order to resolve an appeal. Thus, we are proposing in § 423.2010, to allow CMS, the IRE, and/or the Part D plan sponsor to participate in an ALJ hearing at the ALJ's discretion, in a manner similar to § 405.1010 for Part A and Part B appeals. Participation in an ALJ hearing does not give the entities "party" status. Proposed § 423.2010(c) would give the ALJ discretion about whether to allow CMS, the IRE, and/or the Part D plan sponsor to participate in situations where any of these entities requests participation. The ALJ would be

precluded from drawing any adverse inference if CMS, the IRE, and/or the Part D plan sponsor elected not to participate under proposed § 423.2010(g).

We believe that this proposal would allow an ALJ to decide when an appeal would benefit from participation by one or more of these entities. An ALJ, however, would have the flexibility to balance the interests of the enrollee with the interests of these other entities and to deny a request to participate. We believe this proposal is consistent with the preamble language to the Part D rule (70 FR 4360, 4361), with respect to the role of the Part D plan sponsor, which states, “[t]he plan is not considered a party to the ALJ hearing, but may participate in the hearing at the discretion of the ALJ * * * [u]nlike under MA, the plans do not have the right to request an appeal of an ALJ decision with which the plan disagrees.” We noted in the Part D rule that “[e]ven though plans are not parties to ALJ hearings, we continue to believe that it is important to give plans the ability to participate in ALJ hearings. Therefore, plans may participate in hearings at the ALJ’s discretion.”

Further, if these entities do wish to participate, we propose in § 423.2010(b) to require that the request to participate be made within a shorter timeframe. For expedited appeals, any request by CMS, the IRE, and/or the Part D plan sponsor to participate must be made within 1 day of receipt of the notice of hearing (5 days for non-expedited hearings). The ALJ must then notify the entity, the enrollee, and the Part D sponsor, if applicable, of his or her decision on the request to participate within 1 day of receipt of the request (5 days for non-expedited appeals). We propose these limitations due to the very tight timeframes for expedited appeals.

In Part D appeals all requests for an ALJ hearing are brought by enrollees. Even if an enrollee is represented by a provider or supplier, that provider or supplier will not have a direct financial interest in the appeal. Therefore, we are proposing that CMS, the IRE, and the Part D plan sponsor not be a party with a right to request a hearing under Part D. As noted above, this proposed policy is consistent with the applicable statutory and regulatory provisions. Moreover, this proposal is consistent with the preamble to the Part D rule (70 FR at 4360) where we explicitly state that the Part D plan sponsor is not a party to the appeal.

4. Request for an ALJ Hearing (§ 423.2014)

[If you choose to comment on issues in this section, please include the caption “REQUEST FOR AN ALJ HEARING” at the beginning of your comments.]

The Part D rule currently at § 423.612(a) and (b) (proposed § 423.1972(a) and (b)) describes how, where, and when to file a request for an ALJ hearing. We are proposing to include this requirement in § 423.2014. We are also proposing to include in this section language similar to that in § 405.1014 on requests for an ALJ hearing, including the content of a request, where and when to file a request and any extension of time to request a hearing. We believe these provisions appropriately apply to Part D appeals.

Current § 423.612(b) (proposed § 423.1978(b)) states that “[e]xcept when an ALJ extends the timeframe as provided in part 422, subpart M of this chapter, the enrollee must file a request for a hearing within 60 days of the date of the notice of an IRE reconsideration determination.” Similarly, § 422.602(b) of the Part C rule states that “[e]xcept when an ALJ extends the timeframe as provided in part 405 of this chapter, a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination.” Therefore, in proposed § 423.2014, we closely track the language of § 405.1014 regarding the time in which to request a hearing. Additionally, we are proposing in § 423.2014(a)(1) and (a)(2) to require the telephone number of the enrollee and the designated representative, if any, in any request for an ALJ hearing. This information would assist the ALJ in quickly contacting the enrollee or the designated representative, particularly for expedited appeals. Because we are proposing to adopt a specific provision to govern requests for ALJ hearings in Part D appeals, we propose to revise current § 423.612 (proposed § 423.1972) to replace the reference to the regulations in part 422, subpart M, with a cross reference to proposed § 423.2014.

Furthermore, we are proposing to require the plan name and the enrollee’s Medicare health insurance claim number. This information would assist the ALJ in identifying the relevant plan and formulary involved in the appeal. We also are proposing in § 423.2014(a)(7) that an enrollee who seeks an expedited hearing indicate that in his or her request.

As discussed previously, we are proposing in § 423.2014(b), a more informal process for requesting an expedited hearing by proposing to permit an enrollee to make a request for an expedited hearing orally. We believe that the oral request would make the initiation of the ALJ appeals process faster and easier for the enrollee. However, as explained above in the discussion of § 423.2002(b)(3), an enrollee may only file an oral request for an expedited hearing after receiving the written IRE reconsideration notice. This requirement is reflected in § 423.2014(b). A prescribing physician may also provide oral or written support for an enrollee’s request for expedited hearing by an ALJ. In the same section, we also propose to require the ALJ hearing office to document and maintain documentation of this oral request.

Similarly, in § 423.2014(d)(2), we are proposing that an enrollee requesting an expedited hearing be permitted to request orally an extension of time for filing the hearing request and that such request be documented in writing and maintained in the case file by the ALJ hearing office.

5. Timeframes for Deciding an Appeal Before an ALJ (§ 423.2016)

[If you choose to comment on issues in this section, please include the caption “TIMEFRAMES FOR DECIDING AN APPEAL BEFORE AN ALJ” at the beginning of your comments.]

As discussed above, we are proposing to apply a 90-day adjudicatory timeframe to Part D appeals with an expedited process for certain types of appeals. Specifically, we are proposing in § 423.2016(b)(1), that an ALJ would provide an expedited decision in situations where the enrollee requests an expedited hearing, the appeal involves an issue specified in § 423.566(b), but does not include solely a request for payment of Part D drugs already furnished and the enrollee’s prescribing physician indicates, or the ALJ determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee’s life or health or ability to regain maximum function. We also are proposing that the ALJ may consider this standard as met if a lower level adjudicator has granted a request for an expedited appeal. The expedited appeals process is similar to the process established at the Part D plan sponsor and IRE levels under the Part D rule at § 423.570, § 423.584, and § 423.600.

In § 423.2016(b), we are proposing that the ALJ rule on a request for expedited hearing within 5 days of

receiving the request. We also are proposing in this section that the ALJ give the enrollee prompt oral notice of this decision. If the ALJ denies a request for an expedited hearing, the ALJ will explain that the appeal would be processed using the 90-day timeframe, and send an equivalent written notice within 3 days of issuance of the oral notice to the enrollee and to the Part D plan sponsor. We propose in § 423.2016(b)(4), that a decision on a request for an expedited hearing cannot be appealed to the MAC. If the ALJ accepts the request for expedited hearing, we propose in § 423.2016(b)(5), that the ALJ issue a written decision, dismissal order, or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10-day period beginning on the date the request for hearing is received.

Although the timeframe for the issuance of a written decision is somewhat longer than at the lower levels, we believe this is appropriate. The ALJ hearing is more complicated than an IRE reconsideration because it involves the scheduling and conducting of a hearing. The hearing entails the presentation of evidence including testimony by parties and witnesses, necessitates a longer adjudication period.

6. Submitting Evidence Before the ALJ Hearing (§ 423.2018)

[If you choose to comment on issues in this section, please include the caption "SUBMITTING EVIDENCE BEFORE THE ALJ HEARING" at the beginning of your comments.]

We are proposing in § 423.2018 to adopt concepts from § 405.1018 regarding when an enrollee must submit written evidence. However, we also propose in this section to permit an enrollee to submit any written evidence about his or her condition at the time of the coverage determination but require the ALJ to remand a case to the Part D plan sponsor where an enrollee wishes to have evidence considered on changes in his or her condition since the coverage determination.

Additionally, we are proposing in § 423.2018(b) and (c) that an enrollee must submit all written evidence that he or she wishes to have considered at the hearing within 2 days of receiving the notice of hearing for expedited appeals and 10 days for non-expedited appeals. We believe that requiring evidence to be submitted within these timeframes provides the adjudicator sufficient time to review all evidence submitted before the hearing.

7. Time and Place for a Hearing Before an ALJ (§ 423.2020)

[If you choose to comment on issues in this section, please include the caption "TIME AND PLACE FOR A HEARING BEFORE AN ALJ" at the beginning of your comments.]

The Part D rule currently at § 423.612(b) (proposed § 423.1972(a)) describes the time and place for a hearing before an ALJ and requires that it be set in accordance with § 405.1020. Therefore, we are proposing to include in § 423.2020 language similar to that set forth in § 405.1020, including information on the determination of how appearances are made, the notice of a hearing, an enrollee's right to waive a hearing, an enrollee's objection to the time and place of hearing, good cause for changing the time and place of the hearing, the effect of rescheduling a hearing, and an enrollee's request for an in-person hearing.

As discussed previously, we propose a more informal process for expedited hearings by proposing in § 423.2020(e)(3) and (i)(3) to allow objections to the time and place for a hearing and requests for in-person hearings to be made orally, and to require the ALJ hearing office to document all oral objections or requests and maintain such documentation in the case files. We are also proposing in § 423.2020(i)(4) to not waive the adjudication period for expedited hearings when an enrollee's request for an in-person hearing is granted because a waiver of the adjudication period under the circumstances of an expedited appeal could be detrimental to the enrollee's health condition.

8. Notice of a Hearing Before an ALJ (§ 423.2022)

[If you choose to comment on issues in this section, please include the caption "NOTICE OF A HEARING BEFORE AN ALJ" at the beginning of your comments.]

We are proposing to mirror the language in § 405.1022 regarding notice of hearing before an ALJ in § 423.2022. We believe that it is appropriate to apply to Part D appeals procedures similar to the Part A and Part B procedures regarding notice of a hearing. Additionally, as discussed previously, we propose a more informal process with respect to expedited hearings by proposing in § 423.2022(a) to allow ALJs to transmit the notice of the hearing to the enrollee and other potential participants orally followed by an equivalent written notice within one day of the oral notice. Additionally, we are proposing in the same provision that

expedited hearing notices be mailed or served at least 3 days before the hearing.

9. Objections to the Issues and Disqualification of the ALJ (§ 423.2024 and § 423.2026)

[If you choose to comment on issues in this section, please include the caption "OBJECTIONS TO THE ISSUES AND DISQUALIFICATION OF THE ALJ" at the beginning of your comments.]

We are proposing to follow in § 423.2024 and § 423.2026 the language in § 405.1024 and § 405.1026, which discusses the process for objecting to issues in the notice of hearing and disqualification of the ALJ. We believe it is appropriate to allow enrollees to object to the issues described in the notice of hearing and to maintain the processes set forth for Part A and Part B appeals for disqualification of the ALJ for Part D appeals.

Additionally, for expedited hearings, we are proposing in § 423.2024(a) and § 423.2026(b), that an enrollee may submit oral or written notice of objections to issues described in the notice of hearing no later than 2 days before the hearing and orally notify the ALJ no later than 2 days after the date of the notice of hearing about any objections to the ALJ who will conduct the hearing. Further, in the same proposed sections, we are proposing that the ALJ document all objections or requests in writing and maintain the documentation in the case files.

10. When an ALJ May Remand a Case (§ 423.2034)

[If you choose to comment on issues in this section, please include the caption "WHEN AN ALJ MAY REMAND A CASE" at the beginning of your comments.]

We are proposing to include language in § 423.2034 similar to that in § 405.1034 regarding when an ALJ may remand a case. This language is appropriate for Part D appeals because, like Part A and Part B appeals, it may be necessary for an ALJ to remand a case to a lower level. However, for the reasons stated above, we are proposing at § 423.2034(c), to require the ALJ to remand a case to the Part D plan sponsor if the ALJ determines that the enrollee wishes to have evidence on his or her change in condition after the coverage determination considered in the appeal. As stated previously, if the enrollee submits this type of evidence but wishes not to have it considered, the ALJ would be able to proceed with the appeal without considering the evidence on the enrollee's change in condition.

11. Description of an ALJ Hearing Process (§ 423.2036)

[If you choose to comment on issues in this section, please include the caption "DESCRIPTION OF AN ALJ HEARING PROCESS" at the beginning of your comments.]

We reviewed the language in § 405.1036 to determine whether to incorporate similar language in proposed § 423.2036. In general, we follow the procedures set forth for Part A and Part B appeals regarding the right to appear and present evidence, waiver of the right to appear, presenting written statements and oral arguments, waiver of the adjudication period, what evidence is admissible at a hearing, and witnesses at a hearing. With respect to waiver of the right to appear for expedited hearings, we propose at § 423.2036(b), to allow an enrollee to indicate orally that he or she does not wish to appear at a hearing (with appropriate documentation of this request and maintenance of this documentation by the ALJ hearing office). At § 423.2036(b)(2), we propose to allow an enrollee to withdraw his or her waiver in writing. We also propose that by withdrawing his or her waiver, the enrollee agrees to an extension of the adjudication period as specified in § 423.2016 that may be necessary to schedule and hold a hearing. For the reasons discussed above, we are proposing in § 423.2036(e) (what evidence is admissible at a hearing) that an ALJ may not consider evidence on any change in condition of the enrollee after the coverage determination by the plan sponsor.

We are proposing not to include language similar to that in § 405.1036(f) on requests for subpoenas by a party. In Part 405, subpart I, requests for subpoena by a party are limited to instances where discovery has been sought. Discovery is permissible under Part 405, subpart I only when CMS and/or its contractors participate in an ALJ hearing as a party, because it is appropriate to permit discovery when an ALJ hearing is adversarial (that is, whenever CMS and/or its contractor is a party).

For Part D appeals, however, we propose that only an enrollee may be a party, and therefore, Part D appeals will not be adversarial in nature. Thus, we are proposing not to apply to Part D appeals the provisions in § 405.1036(f), which discuss subpoenas at the request of a party, and § 405.1037, which discuss discovery. However, we propose to allow an ALJ to issue a subpoena on his or her own initiative, as under § 405.1036(f) for Part A and Part B

appeals, because an ALJ may need to obtain additional information in order to resolve an issue(s) in a Part D appeal.

In instances when an ALJ issues a subpoena, we intend to follow similar procedures regarding the reviewability and enforcement of subpoenas as outlined in 405.1036(f).

12. Deciding a Case Without a Hearing Before an ALJ and Prehearing and Posthearing Conferences (§ 423.2038 and § 423.2040)

[If you choose to comment on issues in this section, please include the caption "DECIDING A CASE WITHOUT A HEARING BEFORE AN ALJ AND PREHEARING AND POSTHEARING CONFERENCES" at the beginning of your comments.]

We are proposing in § 423.2038 and § 423.2040 to follow the language set forth in § 405.1038 and § 405.1040, which discusses the process for deciding a case without a hearing before an ALJ and prehearing and posthearing conferences. We believe it is appropriate to use these processes for Part D appeals. Additionally, for expedited hearings, we are proposing in § 423.2038(b)(1)(i) and § 423.2040(c), that an enrollee may orally notify the ALJ that he or she does not wish to appear before the ALJ at a hearing and may also orally indicate that he or she does not wish to receive a written notice of the conference.

Further, we are proposing that the ALJ document all objections or requests in writing and maintain the documentation in the case files.

Finally, we are proposing in § 423.2040(c) that, for expedited hearings, the ALJ inform the enrollee of the time, place, and purpose of the conference within a shorter timeframe (at least 2 days before the conference date) than for non-expedited appeals (at least 7 days before the conference date).

13. Notice of an ALJ Decision (§ 423.2046)

[If you choose to comment on issues in this section, please include the caption "NOTICE OF AN ALJ DECISION" at the beginning of your comments.]

We are proposing in § 423.2046 to follow the procedures in § 405.1046 regarding notice of an ALJ decision. We believe it is appropriate to provide a similar notice process in Part D appeals. We are not proposing to include language from § 405.1046(a) regarding overpayment cases involving multiple beneficiaries because Part D appeals do not involve overpayments. We also are proposing in § 423.2046(d), that an ALJ issue a decision, as expeditiously as the

enrollee's health condition requires, but no later than the end of the 10-day period for expedited hearings.

14. Dismissal of a Request for Hearing Before an ALJ (§ 423.2052)

[If you choose to comment on issues in this section, please include the caption "DISMISSAL OF A REQUEST FOR HEARING BEFORE AN ALJ" at the beginning of your comments.]

We are proposing in § 423.2052, to follow the language in § 405.1052 regarding dismissal of a request for an ALJ hearing because we believe that it is appropriate for an ALJ to dismiss Part D appeals for the same reasons as an ALJ would dismiss Part A and Part B appeals. We also are proposing to shorten the timeframes for expedited appeals in two instances.

First, we propose at § 423.2052(a)(2)(ii), that an ALJ may dismiss a request for expedited hearing when the enrollee (or his or her representative) does not appear at the time and place set for the hearing and has not contacted the ALJ hearing office within 2 days (instead of the standard 10 days for non-expedited appeals) and provided good cause (as determined by the ALJ) for not appearing.

Second, we propose at § 423.2052(a)(2)(iii), that an ALJ may dismiss a request for hearing when the enrollee (or his or her representative) does not appear at the time and place set for the hearing and if the ALJ sends a notice to the enrollee asking why the enrollee did not appear, the ALJ does not receive a response to the notice from the enrollee within 2 days for expedited hearings (and 10 days for non-expedited hearings) or the enrollee does not provide good cause for failing to appear.

We also are proposing at § 423.2052(a)(5), that a request for hearing may be dismissed if the enrollee dies while the request for hearing is pending and the enrollee's representative has no remaining financial interest in the case and does not continue the appeal. Unlike Medicaid State agencies in Part A and Part B appeals, State Pharmaceutical Assistance Programs (SPAPs) do not have an independent right to appeal. While a SPAP may have a financial interest and may wish to pursue an appeal, the SPAP would have authority to do so only if the SPAP was appointed as the enrollee's representative. Therefore, we are proposing that if an SPAP has been appointed as the enrollee's representative, the SPAP could continue an appeal after an enrollee dies provided that the appointment continues to be valid.

Additionally, we are proposing at § 423.2052(b) to follow the language of § 405.1052(b), which requires the ALJ to mail a written notice of dismissal to the enrollee.

D. Appeals to the MAC (§ 423.2100 Through § 423.2134)

[If you choose to comment on issues in this section, please include the caption "APPEALS TO THE MAC" at the beginning of your comments.]

1. General

The Part D rule includes one provision concerning MAC review. Current § 423.620 (proposed § 423.1974) provides that an enrollee who is dissatisfied with an ALJ's hearing decision may request that the MAC review the ALJ decision or dismissal. Further, it states that "[t]he regulations under part 422, subpart M of this chapter regarding MAC review apply to matters addressed by this subpart, to the extent applicable." Section 422.608 of the Part C rule states that "[t]he regulations under part 405 of this chapter regarding MAC review apply to matters addressed by this subpart to the extent that they are appropriate." Therefore, we propose in the provisions regarding MAC review to follow the language in Part 405, subpart I, as appropriate and have tracked the language in the Part 405, subpart I, for proposed § 423.2106, § 423.2116, § 423.2118, § 423.2120, § 423.2128, and § 423.2130. In addition, because we are proposing to adopt a specific provision to govern requests for MAC review in Part D appeals, we propose to revise current § 423.620 (proposed § 423.1974) to replace the reference to the regulations in part 405, subpart I, with a cross reference to proposed § 423.2102.

2. Medicare Appeals Council Review: General (§ 423.2100)

The Part D rule currently at § 423.620 (proposed § 423.1970) provides that an enrollee who is dissatisfied with an ALJ's hearing decision may request that the MAC review the ALJ decision or dismissal. We are proposing to include this requirement in § 423.2100. We are also proposing in § 423.2100 to follow the language of § 405.1100, which describes who may request MAC review, the de novo standard of MAC review, and timeframes for issuing a decision or remand because we believe that Part D appeals should not differ from Part A and Part B appeals with respect to these provisions, except as discussed above. We further propose language in § 423.2100(c) establishing

the 10 day adjudicatory timeframe for expedited reviews.

3. Request for MAC Review When ALJ Issues Decision or Dismissal (§ 423.2102)

We are proposing to include in § 423.2102 language similar to that set forth in § 405.1102 on requests for MAC review when the ALJ issues a decision or dismissal. We believe it is appropriate to include this information in proposed § 423.2102 because it would help the enrollee and any representative of the enrollee to understand how to file a request for MAC review and how the date of receipt of the request would be determined, and when a request would be considered filed. We also are proposing at § 423.2102(a)(2), that an enrollee may request expedited review if the enrollee submits a written request for MAC review within 60 days after receipt of the ALJ's decision or dismissal and the appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

As discussed above, we believe that an expedited MAC review process similar to the expedited process provided at lower levels of appeal would benefit enrollees who need quick decisions about Part D drugs due to their health status. We are proposing at § 423.2102(a)(2), a more informal process for requesting an expedited review by proposing to permit an enrollee to make a request for review orally. We believe that the oral request would make the initiation of the MAC appeals process faster and easier for the enrollee. A prescribing physician may also provide oral or written support for an enrollee's request for expedited review by the MAC. We also are proposing in § 423.2102(a)(2)(ii) to require the MAC to document and maintain documentation of this oral request.

Similarly, in § 423.2102(b)(1), we are proposing that an enrollee requesting an expedited review be permitted to orally request an extension of time for filing the request, and that the request be documented in writing and maintained in the case file by the MAC.

4. MAC Actions When Request for Review Is Filed (§ 423.2108)

We are proposing to follow the requirements in § 405.1108 regarding MAC actions when a request for review is filed, including de novo review of an ALJ's decision. Specifically, we propose in § 423.2108(d) an expedited process for certain types of appeals. We propose in § 423.2108(d)(1), to require the MAC

to provide an expedited decision where an enrollee requests the review, the appeal involves an issue specified in § 423.566(b), but does not include solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician indicates, or the MAC determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life or health or ability to regain maximum function. We also are proposing that the MAC may consider this standard as met if a lower level of adjudicator has granted a request for an expedited appeal.

We are proposing in § 423.2108(d)(2)(i) that the MAC deny a request for expedited review, because the standard for expedited review is not met, within 5 days after receiving the request for expedited review. We also are proposing in § 423.2108(d)(2)(ii) that the MAC would send the enrollee and Part D plan sponsor written notice of the denial within 5 days after receiving the request that explains that the appeal will be processed using the 90-day timeframe. Instead of notifying the enrollee and Part D plan sponsor that the MAC has granted the request for expedited review, we propose to use these resources to process the expedited appeal.

If the MAC accepts the request for expedited review, we propose in § 423.2108(d)(2), that the MAC issue a decision, dismissal order, or remand, as expeditiously as the enrollee's health condition requires, but no later than the end of the 10-day period beginning on the date the request for review is received by the entity specified in the ALJ's written notice of decision. This process is similar to the process established at the coverage determination, redetermination, and reconsideration levels under the Part D rule at § 423.570, § 423.584, and § 423.600.

5. MAC Review on Its Own Motion (§ 423.2110)

On March 23, 2007, CMS published a CMS Ruling (CMS-4083-NR) in the **Federal Register**. The CMS ruling established an interim process for referring Part D cases to the MAC for review under its own motion authority. This ruling permits CMS and its IRE to refer cases to the MAC for own motion review and largely applies the provisions of § 405.1110, with the notable exception of the standard of review.

We propose in this rule to largely follow this Ruling and the requirements set forth in § 405.1110 regarding MAC own motion reviews, with certain

modifications. Proposed § 423.2110, reflects our proposal that the enrollee is the only party to an ALJ hearing and that CMS and/or the Part D IRE may participate as a non-party in the ALJ hearing. Proposed § 423.2110 differs from § 405.1110 in that § 423.2110 applies the same standard of review to such requests whether CMS or IRE simply requested to participate in the ALJ hearing or actually participated in the ALJ hearing. This proposed difference is due to the ALJ having the discretion under proposed § 423.2010 not to allow CMS or the Part D IRE to participate as a non-party in the ALJ hearing. Because ALJs have discretion to deny a CMS or IRE request to participate in an ALJ hearing, we believe it is appropriate under § 423.2110 to apply the same standard of review to requests for MAC own motion review whether CMS or IRE requested to participate or actually participated in the ALJ hearing.

For administrative efficiency, we are proposing to limit to CMS and the Part D IRE the ability to refer a case to the MAC for review under its own motion authority. We expect that most of the referrals would be made through the Part D IRE, because it is responsible for monitoring plan effectuation of favorable decisions and serves as a repository for all completed Part D ALJ case files.

The Part D IRE does not have a financial or business interest in the outcome of the case. Therefore, we believe that the Part D IRE is in the best position to objectively examine whether an ALJ decision warrants review by the MAC. While Part D plan sponsors would not be permitted to refer a Part D case to the MAC for review under its own motion authority, Part D plan sponsors would have the opportunity to communicate with, and provide input to, CMS or the Part D IRE on ALJ decisions that may warrant a referral to the MAC. Given the large number of Part D plans, we believe that limiting own motion referrals to CMS and the Part D IRE is a more streamlined and efficient approach. We welcome comments on this proposed approach.

We also note that CMS Ruling (CM-4083-NR) would be superseded by these regulations upon implementation of a final rule.

6. Content of Request for Review (§ 423.2112)

We are proposing to include in § 423.2112 language similar to that in § 405.1112 on content of a request for review. However, we propose at § 423.2112(a)(4), to require the telephone number of the enrollee to be included in any request for MAC

review. This information would assist the MAC in contacting the enrollee, particularly for expedited appeals. Additionally, we are proposing in § 423.2112(a)(4) to require the plan name and the enrollee's Medicare health insurance claim number. We also are proposing at § 423.2112(a)(4), that an enrollee who seeks an expedited review indicate that his or her request is for an expedited review.

As discussed previously, we propose in § 423.2112(a)(2) a more informal process for requesting an expedited review by proposing to permit an enrollee to make a request for review orally. We believe that the oral request would make the initiation of the MAC appeals process faster and easier for the enrollee. We also are proposing to require the MAC to document and maintain documentation of this oral request.

7. Dismissal of Request for Review (§ 423.2114)

In § 423.2114, we are proposing the process for dismissing a request for review for Part D appeals. The proposed process tracks the Part A and Part B process, except for dismissals involving deceased enrollees. We are proposing at § 423.2114(c), that a request for review may be dismissed if the enrollee dies while the request for review is pending and the enrollee's representative, if any, either has no remaining financial interest in the case or does not continue the appeal. As discussed above, unlike Medicaid State agencies in Part A and Part B appeals, SPAPs do not have an independent right to appeal. While an SPAP may have a financial interest and may wish to pursue an appeal, the SPAP would have authority to do so only if the SPAP was appointed as the enrollee's representative. Therefore, we propose that an SPAP that has been appointed as the enrollee's representative could continue an appeal after an enrollee dies provided that the appointment continues to be valid.

8. What Evidence May Be Submitted to the MAC (§ 423.2122)

We reviewed the language in § 405.1122 to determine whether to incorporate similar language in proposed § 423.2122. In general, we are proposing to follow the procedures for Part A and Part B appeals regarding what evidence may be submitted to the MAC. For the reasons discussed above, we are proposing in § 423.2122(a)(3) that the MAC would not consider evidence on any change in condition after a coverage determination by the plan sponsor that the enrollee wishes to have considered and would remand

such a case to the Part D plan sponsor. Like in § 405.1122, we are proposing in § 423.2122 to allow the MAC to issue a subpoena when it determines certain information is reasonably necessary for a full presentation of a case. We also are proposing in § 423.2122(b) not to include language similar to that in § 405.1122(d) on party requests for subpoenas, as only the enrollee is a party to a Part D appeal, and as a result, there will be no discovery in these appeals. For the reasons set forth above, we are proposing to allow the MAC to issue a subpoena only on its own initiative. In addition, if necessary, the MAC may request enforcement of a subpoena by the Secretary. The time period for the MAC to issue a final action or remand the case would be stayed for 15 days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

9. Oral Argument (§ 423.2124)

We are proposing in § 423.2124, to follow the language similar to that in § 405.1124 because we believe that oral arguments may be necessary in some Part D appeals. We also are proposing in § 423.2124(b) that, for expedited appeals, the enrollee be informed of the time and place of the oral argument at least 2 days before the scheduled date of the oral argument, which is shorter than our proposed 10-day timeframe for non-expedited appeals. We believe that providing notice of an oral argument within these timeframes provides the enrollee sufficient time to prepare for the oral argument.

10. Case Remanded by the MAC (§ 423.2126)

We are proposing in § 423.2126, to mirror the language in § 405.1126 regarding when the MAC may remand a case. This language is appropriate for Part D appeals because it may be necessary for the MAC to remand a case to a lower level. Additionally, we are proposing in § 423.2126(a)(4), that when an ALJ has issued a recommended decision, an enrollee may file with the MAC briefs or other written statements about the facts and law relevant to the case within 20 days of the date on the recommended decision or with the request for review for expedited appeals. As discussed above, we also are proposing in § 423.2126(b), to require the MAC to remand a case to the Part D plan sponsor if the MAC determines that the enrollee wishes to have evidence on his or her change in condition after the coverage determination by the plan sponsor considered in the appeal.

E. Judicial Review (§ 423.2136 Through § 423.2140)

[If you choose to comment on issues in this section, please include the caption “JUDICIAL REVIEW” at the beginning of your comments.]

The Part D rule includes one provision concerning judicial review. Current § 423.630(a) (proposed § 423.1976(a)) provides that an enrollee may request judicial review of an ALJ’s decision if the MAC denied the enrollee’s request for review and the amount in controversy threshold is met. Current § 423.630(b) (proposed § 423.1976(b)) also states that an enrollee may request judicial review of the MAC decision if it is the final agency decision and the amount in controversy threshold is met. To request judicial review, this section states that an enrollee must file a civil action in a District Court of the United States in accordance with section 205(g) of the Act. Finally, current § 423.630(c) (proposed § 423.1976(c)) tells the reader to “[s]ee part 422, subpart M of this chapter, for a description of the procedures to follow in requesting judicial review.”

Section 422.612 explains that part 405 contains a description of the procedures to follow in requesting judicial review. Therefore, we propose to follow the language of the Part 405, subpart I, as appropriate. Thus, we have tracked the language in the Part 405, subpart I, for proposed § 423.2134, § 423.2138, and § 423.2140. We believe that it is appropriate for Part D appeals to follow the Part A and Part B appeals procedures set forth in these provisions. Because we propose to adopt specific procedures for requesting judicial review of final Part D decisions, we propose to delete the cross-reference to Part 422, subpart M, from current § 423.620(c) (proposed § 423.1976(c)) and replace it with a cross-reference to the proposed procedures for requesting judicial review in proposed § 423.2136.

V. Collection of Information Requirements

This document does contain information collection requirements; however, the Paperwork Reduction Act of 1995 exempts the information collection activities referenced in this Proposed Rule. In particular, 5 CFR 1320.4 excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment.

VI. Response to Comments

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

VII. Regulatory Impact Statement

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

A. Overall Impact

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 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). As explained in the analysis that follows, we have determined that this proposed rule is not a major rule since it will impose no consequential costs and will not have an economic effect of \$100 million or more. Accordingly, it is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that a number of Part D plan sponsors (insurers) are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). As indicated above, a number of Part D plan sponsors (insurers) are small entities due to their nonprofit status. Few if any of the Part D plans sponsors meet the SBA size standard for a small insurance firm by having revenues of \$6 million or less in

any 1 year. Individuals and States are not included in the definition of a small entity.

This proposed rule will affect primarily individuals enrolled in Part D plans who appeal Part D plan decisions. It makes no substantive changes in the Part D benefit and deals directly only with appeals procedures administered by Federal employees. To date, the volume of Part D appeals is small and the amounts of money involved, although substantial to many of these individuals, are a very small percentage of aggregate Part D plan costs.

Accordingly, we do not believe that there will be significant economic impacts on Part D plans. Therefore, the Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule will not have any effect on hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$130 million. This proposed rule contains no mandates on State, local, or tribal governments in the aggregate, 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. This proposed rule has no such effects.

B. Anticipated Effects

This proposed rule has no direct effects on the original Medicare program, since it applies only to the Part D prescription drug program. It would have few direct effects on Part D plans, since it addresses primarily the details

of appeals procedures and process at the ALJ hearing and MAC review levels. Most of the proposed procedures do not vary substantially from existing appeals practices. For example, both under existing practices, upon which this proposed rule is largely modeled, and the proposed rule, neither the government nor the Part D sponsor is a "party" to the appeal and therefore neither incurs any legal costs, unless it chooses to participate in the ALJ hearing or MAC review. However, some provisions would be new. Most importantly, we propose to provide for an expedited appeals process when a delay in obtaining a drug may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. This change would affect spending by Part D and the Medicare program by accelerating coverage of a drug in those cases where the enrollee succeeded in the expedited appeal.

The Part D appeals process is administered in large part by the plans themselves. Our rules require plans to have effective grievance and appeals processes that operate timely and effectively to meet enrollee needs. In addition, we impose substantive standards on issues such as plan formularies and the process for obtaining exceptions from formulary restrictions where medically necessary. We provide for within-plan appeals from initial plan decisions. If a problem cannot be resolved at the plan level, we provide for an independent external review through a CMS contractor. (Cases concerning the quality of care take a different route, through Quality Improvement Organizations.) Only those cases where the problem cannot be resolved at those levels go to the so-called third and fourth levels of appeal for a hearing before an ALJ and review by the Medicare Appeals Council, respectively.

The primary effects of this proposed rule will be to tailor the third and fourth level appeal procedures, designed primarily for the original Medicare program, to the unique aspects of the Part D program. This proposed rule reflects and builds upon recent changes in the third and fourth levels of appeals process for Part A and Part B claims appeals (see the Interim Final Rule at 70 FR 11420 (March 8, 2005)). We note that the effects of that rule were extensively analyzed in the Regulatory Impact Analysis published with the rule. The overall conclusion of that impact analysis was that costs to affected persons and entities would be minimal, although the anticipated costs to the Federal government from revised procedures would be substantial.

As discussed earlier in this preamble, our existing policy is that, unless otherwise provided, Part D procedures will follow the procedures established for appeals under Part A and Part B to the extent they are appropriate. The proposed provisions parallel the Part A and Part B provisions, to the extent appropriate. For example, in this proposed rule we have proposed to eliminate references to national and local coverage determinations because these policies do not apply to Part D. Likewise, we eliminate references to Social Security appeals because they are irrelevant to Part D. We note that such changes do not necessarily imply an actual change in the procedures for processing Part D appeals. The proposed rule would in part simply codify existing practices already in place. Other changes we propose are intended to make the appeals process more flexible and responsive to the needs and circumstances of program participants. For example, a common type of appeal is an appeal from the denial of coverage for a drug used for an "off-label" indication (one that has not been officially approved by the Food and Drug Administration). Medicare Part D pays for many, but not all, "off-label" uses. The process and procedure changes we propose do not directly change the likelihood an enrollee will prevail in appeal, although they may slightly raise the number of such appeals by clarifying the procedures that will apply to such appeals and affording an opportunity to request an expedited appeal. The new expedited appeals procedures will allow us to respond quickly to urgent medical needs of enrollees.

Total enrollment in Part D plans is about 25 million persons (including enrollment in Medicare Advantage Plans that cover prescription drugs). We estimate the total number of third level appeals (ALJ hearings) in fiscal year 2007 to be approximately 350, or about 15 appeals per million enrollees. Only a fraction of these would ever be appealed to the fourth level (MAC review). While the dollar value of these appeals has not been tabulated, the amount is likely to reach several thousand dollars on average (the amount in controversy threshold for an appeal in 2008 is \$120 for ALJ hearings and \$1180 for federal district court review, but the time and effort involved to pursue an appeal is likely to foster appeals most frequently when the amount is considerably higher). Consequently, the annual total of the amounts in controversy is likely to be in the range of several million dollars. In

contrast, total Part D spending in calendar 2007 (which is roughly equivalent to the fiscal year total) is estimated to be approximately \$50 billion dollars. Thus, viewed either in absolute or relative terms, any effects of the proposed rule either on the administrative costs or outcomes of these cases are unlikely to be more than a fraction of one percent of the major rule threshold. Likewise, effects on overall plan costs or benefit payments are likely to be minimal.

Accordingly, we do not believe that these procedures, which include both codifications of existing practices and new procedures for the third and fourth levels of appeal will have any consequential net effect on the Part D program, except to clarify the procedures that will apply to the relatively small number of cases that reach those levels of the appeals process. While the volume of appeal cases may increase slightly, adopting the procedures outlined in this proposed rule would benefit enrollees by clarifying the procedures that will apply to these appeals and affording an opportunity to request an expedited appeal in certain circumstances where a faster decision is necessary in order to protect the life and health of the enrollee. We welcome comments on these conclusions.

C. Alternatives Considered

There are no major alternatives to this proposed rule. We have proposed a number of specific provisions and provided a justification for each, throughout this preamble. We welcome comments on these proposals and on any effects that we may not have anticipated, as well as comments on additional or alternative reforms that could improve the appeals process further.

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

List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

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

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

1. The authority citation for part 423 continues to read as follows:

Authority: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

2. The heading for Subpart M is revised to read as follows:

Subpart M—Grievances, Coverage Determinations, Redeterminations, and Reconsiderations

3. A new § 423.558, is added to Subpart M to read as follows:

§ 423.558 Scope.

(a) This subpart sets forth the requirements relating to the following:

- (1) Part D plan sponsors with respect to grievances, coverage determinations, and redeterminations.

- (2) Part D IRE with respect to reconsiderations; and

- (3) Part D enrollees' rights with respect to grievances, coverage determinations, redeterminations, and reconsiderations.

(b) The requirements regarding Reopenings, ALJ Hearings, MAC review, and Judicial Review are set forth in subpart U of this chapter.

§ 423.562 [Amended]

4. In § 423.562—

A. In paragraph (b)(4)(iv), the cross-reference to “§ 423.610” is removed and the cross-reference to “§ 423.1970” is added in its place.

B. In paragraph (b)(4)(v), the cross-reference to “§ 423.620” is removed and the cross-reference to “§ 423.1974” is added in its place.

C. In paragraph (b)(4)(vi), the cross-reference to “§ 423.630” is removed and the cross-reference to “§ 423.1976” is added in its place.

§ 423.576 [Amended]

5. In § 423.576—

A. The cross-reference to “§ 423.580 through § 423.630” is removed and the cross-references to “§ 423.580 through § 423.604 and § 423.1970 through § 423.1976” are added in its place.

B. The cross-reference to “423.634” is removed and the cross-reference to “§ 423.1978” is added in its place.

§ 423.580 [Amended]

6. In § 423.580, the cross-reference to “§ 423.634” is removed, and the cross-reference to “§ 423.1978” is added in its place.

§ 423.602 [Amended]

7. In § 423.602(b)(2), the cross-reference to “§ 423.610” is removed,

and the cross-reference to “§ 423.1970” is added in its place.

§ 423.604 [Amended]

8. In § 423.604, the cross-reference to “§ 423.612” is removed, and the cross-reference to “§ 423.1972” is added in its place.

§ 423.610 [Removed and Reserved]

9. Section 423.610 is removed and reserved.

§ 423.612 [Removed and Reserved]

10. Section 423.612 is removed and reserved.

§ 423.620 [Removed and Reserved]

11. Section 423.620 is removed and reserved.

§ 423.630 [Removed and Reserved]

12. Section 423.630 is removed and reserved.

§ 423.634 [Removed and Reserved]

13. Section 423.634 is removed and reserved.

14. A new subpart U is added to read as follows:

Subpart U—Reopening, ALJ Hearings, MAC Review, and Judicial Review

Sec.

423.1968 Scope.

423.1970 Right to an ALJ hearing.

423.1972 Request for an ALJ hearing.

423.1974 Medicare Appeals Council (MAC) review.

423.1976 Judicial review.

423.1978 Reopening and revising determinations and decisions.

423.1980 Reopening of coverage determinations, redeterminations, reconsiderations, hearings and reviews.

493.1982 Notice of a revised determination or decision.

423.1984 Effect of a revised determination or decision.

423.1986 Good cause for reopening.

423.1990 Expedited access to judicial review.

423.2000 Hearing before an ALJ: General rule.

423.2002 Right to an ALJ hearing.

423.2004 Right to ALJ review of IRE notice of dismissal.

423.2008 Parties to an ALJ hearing.

423.2010 When CMS, the IRE, or Part D Plan Sponsors may participate in an ALJ hearing.

423.2014 Request for an ALJ hearing.

423.2016 Timeframes for deciding an Appeal before an ALJ.

423.2018 Submitting evidence before the ALJ hearing.

423.2020 Time and Place for a Hearing before an ALJ.

423.2022 Notice of a hearing before an ALJ.

423.2024 Objections to the issues.

423.2026 Disqualification of the ALJ.

423.2030 ALJ hearing procedures.

423.2032 Issues before an ALJ.

423.2034 When an ALJ may remand a case.

423.2036 Description of an ALJ hearing process.

423.2038 Deciding a case without a hearing before an ALJ.

423.2040 Pre-hearing and post-hearing conferences.

423.2042 The administrative record.

423.2044 Consolidated hearing before an ALJ.

423.2046 Notice of an ALJ decision.

423.2048 The effect of an ALJ's decision.

423.2050 Removal of a hearing request from an ALJ to the MAC.

423.2052 Dismissal of a request for a hearing before an ALJ.

423.2054 Effect of dismissal of a request for a hearing before an ALJ.

423.2062 Applicability of policies not binding on the ALJ and MAC.

423.2063 Applicability of CMS rulings.

423.2100 Medicare Appeals Council (MAC) Review: General.

423.2102 Request for MAC review when an ALJ issues decision or dismissal.

423.2106 Where a request for review may be filed.

423.2108 MAC Actions when request for review is filed.

423.2110 MAC reviews on its own motion.

423.2112 Content of request for review.

423.2114 Dismissal of request for review.

423.2116 Effect of dismissal of request for MAC review or request for hearing.

423.2118 Obtaining evidence from the MAC.

423.2120 Filing briefs with the MAC.

423.2122 What evidence may be submitted to the MAC.

423.2124 Oral arguments.

423.2126 Case remanded by the MAC.

423.2128 Action of the MAC.

423.2130 Effect of the MAC's decision.

423.2134 Extension of time to file action in Federal District Court.

423.2136 Judicial review.

423.2138 Case remanded by a Federal District Court.

423.2140 MAC review of ALJ decision in a case remanded by a Federal District Court.

Subpart U—Reopening, ALJ Hearings, MAC Review, and Judicial Review**§ 423.1968 Scope.**

This subpart sets forth the requirements relating to the following:

- (a) Part D sponsors, the Part D IRE, ALJs, and the MAC with respect to reopenings.

- (b) ALJs with respect to hearings.

- (c) MAC with respect to review of part D appeals.

- (d) Part D enrollees' rights with respect to reopenings, ALJ hearings, MAC reviews, and judicial review by a Federal District Court.

§ 423.1970 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is

dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs shall include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(c) *Aggregating appeals to meet the amount in controversy*—(1) *Enrollee*.

Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.1972(b); and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees*. Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.1972(b); and

(iii) The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

§ 423.1972 Request for an ALJ hearing.

(a) *How and where to file a request*. The enrollee must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request*. Except when an ALJ extends the timeframe as provided in § 423.2014(d), the enrollee must file a request for a hearing within 60 days of the date of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with § 423.2020 of this chapter.

(c) *Insufficient amount in controversy*.

(1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.1970, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.1970, the ALJ discontinues the hearing and does not

rule on the substantive issues raised in the appeal.

§ 423.1974 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal as provided in § 423.2102.

§ 423.1976 Judicial review.

(a) *Review of ALJ's decision*. The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision*. The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review*. In order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See § 423.2136 for a description of the procedures to follow in requesting judicial review.)

§ 423.1978 Reopening and revising determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision as provided in § 423.1980 through § 423.1986.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638 of this chapter.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

§ 423.1980 Reopenings of coverage determinations, redeterminations, reconsiderations, hearings and reviews.

(a) *General rules*. (1) A reopening is a remedial action taken to change a final determination or decision, even though the final determination or decision may have been correct at the time it was made based on the evidence of record. Consistent with § 423.1978(a), that action may be taken by—

(i) A Part D plan sponsor to revise the coverage determination or redetermination;

(ii) An IRE to revise the reconsideration;

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

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

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, hearing, or MAC review, no adjudicator has jurisdiction to reopen an issue that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the Part D plan sponsor, IRE, ALJ, or MAC may reopen as set forth in this section.

(3) Consistent with § 423.1978(b), the filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(4) Consistent with § 423.1978(d), the Part D plan sponsor's, IRE's, ALJ's, or MAC's decision on whether to reopen is final and not subject to appeal.

(5) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for drug claims that were already reimbursed by the Part D plan sponsor is not a reopening.

(b) *Timeframes and requirements for reopening coverage determinations and redeterminations initiated by a Part D plan sponsor*. A Part D plan sponsor may reopen and revise its coverage determination or redetermination on its own motion—

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

(2) Within 4 years from the date of the coverage determination or redetermination for good cause as defined in § 423.1986.

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

(c) *Timeframe and requirements for reopening coverage determinations and redeterminations requested by an enrollee*. (1) An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 1 year from the date of the coverage determination or redetermination for any reason.

(2) An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 4 years from the date of the

coverage determination or redetermination for good cause in accordance with § 423.1986.

(d) *Timeframes and requirements for reopening reconsiderations, hearing decisions and reviews initiated by an IRE, ALJ, or the MAC.* (1) An IRE may reopen its reconsideration on its own motion within 180 days from the date of the reconsideration for good cause in accordance with § 423.1986. If the IRE's reconsideration was procured by fraud or similar fault, then the IRE may reopen at any time.

(2) An ALJ or the MAC may reopen a hearing decision on its own motion within 180 days from the date of the decision for good cause in accordance with § 423.1986. If the hearing decision was procured by fraud or similar fault, then the ALJ or the MAC may reopen at any time.

(3) The MAC may reopen its review decision on its own motion within 180 days from the date of the review decision for good cause in accordance with § 423.1986. If the MAC's decision was procured by fraud or similar fault, then the MAC may reopen at any time.

(e) *Timeframes and requirements for reopening reconsiderations, hearing decisions, and reviews requested by an enrollee.* (1) An enrollee who received a reconsideration may request that an IRE reopen its reconsideration within 180 days from the date of the reconsideration for good cause in accordance with § 423.1986.

(2) An enrollee who received an ALJ hearing decision may request that an ALJ or the MAC reopen the hearing decision within 180 days from the date of the hearing decision for good cause in accordance with § 423.1986.

(3) An enrollee who received a MAC decision may request that the MAC reopen its decision within 180 days from the date of the review decision for good cause in accordance with § 423.1986.

§ 423.1982 Notice of a revised determination or decision.

(a) *When adjudicators initiate reopenings.* When any determination or decision is reopened and revised as provided in § 423.1980—

(1) The Part D plan sponsor, IRE, ALJ, or the MAC must mail its revised determination or decision to the enrollee at his or her last known address.

(2) The IRE, ALJ, or the MAC must mail its revised determination or decision to the Part D plan sponsor.

(3) An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

(b) *Reopenings initiated at the request of an enrollee.* (1) The Part D plan sponsor, IRE, ALJ, or the MAC must mail its revised determination or decision to the enrollee at his or her last known address.

(2) The IRE, ALJ, or the MAC must mail its revised determination or decision to the Part D plan sponsor.

(3) An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

§ 423.1984 Effect of a revised determination or decision.

(a) *Coverage determinations.* The revision of a coverage determination is binding unless an enrollee submits a request for a redetermination that is accepted and processed in accordance with § 423.580 through § 423.590.

(b) *Redeterminations.* The revision of a redetermination is binding unless an enrollee submits a request for an IRE reconsideration that is accepted and processed in accordance with § 423.600 through § 423.604.

(c) *Reconsiderations.* The revision of a reconsideration is binding unless an enrollee submits a request for an ALJ hearing that is accepted and processed in accordance with § 423.1970 through § 423.1972 and § 423.2000 through § 423.2063.

(d) *ALJ hearing decisions.* The revision of a hearing decision is binding unless an enrollee submits a request for a MAC review that is accepted and processed as specified in § 423.1974 and § 423.2100 through § 423.2130.

(e) *MAC review.* The revision of a MAC determination or decision is binding unless an enrollee files a civil action in which a Federal District Court accepts jurisdiction and issues a decision.

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

(g) *Effect of a revised determination or decision.* Consistent with § 423.1978(c), a revised determination or decision is binding unless it is appealed or otherwise reopened.

§ 423.1986 Good cause for reopening.

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

(1) There is new and material evidence that—

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

(ii) May result in a different conclusion; or

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

(b) *Change in substantive law or interpretative policy—(1) General rule.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision regarding appeals under this section.

(2) An adjudicator may reopen a determination or decision to apply the current law or CMS or the Part D plan sponsor policy rather than the law or CMS or the Part D plan sponsor policy at the time the coverage determination is made in situations where the enrollee has not yet received the drug and the current law or CMS or the Part D plan sponsor policy may affect whether the drug should be received.

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

§ 423.1990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review.*

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

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

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

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

(i) An IRE has made a reconsideration determination and the enrollee has filed a request for an ALJ hearing in accordance with § 423.2002 and a final decision of the ALJ has not been issued; or

(ii) An ALJ has made a decision and the enrollee has filed a request for MAC review in accordance with § 423.2102 and a final decision of the MAC has not been issued.

(2) The requestor is an enrollee.

(3) The amount remaining in controversy meets the threshold requirements established annually by the Secretary.

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

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

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

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

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

(i) A statutory provision that is unconstitutional, or a provision of a regulation that is invalid and specify the statutory provision that the enrollee considers unconstitutional or the provision of a regulation that the enrollee considers invalid, or

(ii) A CMS Ruling that the enrollee considers invalid.

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

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

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

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

(2) Time of filing request. The enrollee may file a request for EAJR—

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

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

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

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

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

(4) If the review entity fails to make a determination within the timeframe specified in paragraph (e)(2) of this section, then the enrollee may bring a civil action in Federal District Court within 60 days of the end of the timeframe.

(f) *Certification by the review entity.* If an enrollee meets the requirements for the EAJR, the review entity certifies in writing that—

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

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

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

(4) But for the provision challenged, the enrollee would receive a favorable decision on the ultimate issue; and

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

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

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

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

(3) The enrollee must satisfy the requirements for venue under section

205(g) of the Act, as well as the requirements for filing a civil action in a Federal District Court under § 423.2136.

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

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

§ 423.2000 Hearing before an ALJ: General rule.

(a) If an enrollee is dissatisfied with an IRE's reconsideration, the enrollee may request a hearing.

(b) A hearing may be conducted in person, by video-teleconference, or by telephone. At the hearing, the enrollee may submit evidence subject to the restrictions in § 423.2018, examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, the Part D plan sponsor, or a representative of CMS, including the IRE, may participate in the hearing as specified in § 423.2010.

(d) The ALJ issues a decision based on the hearing record.

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

(f) The ALJ may require the enrollee to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In that event, however, the ALJ will give the enrollee the opportunity to appear when the testimony is given, but may hold the hearing even if the enrollee decides not to appear.

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

§ 423.2002 Right to an ALJ hearing.

(a) Consistent with § 423.1970(a), an enrollee may request a hearing before an ALJ if—

(1) The enrollee files a written request for an ALJ hearing within 60 days after receipt of the written notice of the IRE's reconsideration; and

(2) The enrollee meets the amount in controversy requirements of § 423.1970.

(b) An enrollee may request that the hearing before an ALJ be expedited if:

(1) The appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished;

(2) The enrollee submits a written or oral request for an expedited ALJ hearing within 60 days of the date of the written notice of an IRE reconsideration determination. The request can only be submitted after the enrollee receives the written IRE reconsideration notice. The request should also explain why applying the standard timeframe may seriously jeopardize the life or health of the enrollee; and

(3) The enrollee meets the amount in controversy requirements of § 423.1970. The ALJ must document all oral requests for expedited hearings in writing and maintain the documentation in the case files.

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

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

§ 423.2004 Right to ALJ review of IRE notice of dismissal.

(a) An enrollee has a right to have an IRE's dismissal of a request for reconsideration reviewed by an ALJ if—

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

(2) The enrollee meets the amount in controversy requirements of § 423.1970.

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

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

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

(c) An ALJ's decision regarding an IRE's dismissal of a reconsideration request is final and not subject to further review.

§ 423.2008 Parties to an ALJ hearing.

(a) *Who may request a hearing.* Only an enrollee (or an enrollee's representative) may request a hearing before an ALJ.

(b) *Who are parties to the ALJ hearing.* The enrollee (or the enrollee's representative) who filed the request for hearing is the only party to the ALJ hearing.

§ 423.2010 When CMS, the IRE, or Part D plan sponsors may participate in an ALJ hearing.

(a) An ALJ may request, but may not require, CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any.

(b) CMS, the IRE, and/or the Part D plan sponsor may request to participate in the hearing process.

(1) For non-expedited hearings, any request by CMS, the IRE, and/or the Part D plan sponsor to participate must be made within 5 days of receipt of the notice of hearing.

(2) Within 5 days of receipt of a request to participate in a non-expedited hearing, the ALJ must notify the entity, the Part D plan sponsor, if applicable and the enrollee of his or her decision on the request to participate.

(3) For expedited hearings, any request by CMS, the IRE, and/or the Part D plan sponsor to participate must be made within 1 day of receipt of the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(4) Within 1 day of receipt of a request to participate in an expedited hearing, the ALJ must notify the entity, the Part D plan sponsor, if applicable, and the enrollee of his or her decision on the request to participate.

(c) The ALJ has discretion not to allow CMS, the IRE, and/or the Part D plan sponsor to participate.

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

(e) When CMS, the IRE, and/or the Part D plan sponsor participates in an ALJ hearing, CMS, the IRE, and/or the Part D plan sponsor may not be called as a witness during the hearing.

(f) CMS, the IRE, and/or the Part D plan sponsor must submit any position papers within the timeframe designated by the ALJ.

(g) The ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

§ 423.2014 Request for an ALJ hearing.

(a) *Content of the request.* The request for an ALJ hearing must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following—

(1) The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

(2) The name, address, and telephone number of the appointed representative, as defined at § 423.560, if any.

(3) The appeals case number assigned to the appeal by the IRE, if any.

(4) The prescription drug in dispute.

(5) The plan name.

(6) The reasons the enrollee disagrees with the IRE's reconsideration.

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

(8) A statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. The ALJ hearing office must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician may provide oral or written support for an enrollee's request for expedited review.

(c) *When and where to file.* Consistent with § 423.1972(a) and (b), the request for an ALJ hearing after an IRE reconsideration must be submitted—

(1) Within 60 days from the date the enrollee receives written notice of the IRE's reconsideration;

(2) With the entity specified in the IRE's reconsideration.

(i) If the request for hearing is timely filed with an entity other than the entity specified in the IRE's reconsideration, the deadline specified in § 423.2016 for deciding the appeal begins on the date the entity specified in the IRE's reconsideration receives the request for hearing.

(ii) If the request for hearing is filed with an entity, other than the entity specified in the IRE's reconsideration, the ALJ hearing office must notify the appellant of the date of receipt of the request and the commencement of the adjudication timeframe.

(d) *Extension of time to request a hearing.* (1) Consistent with

§ 423.1972(b), if the request for hearing is not filed within 60 days of receipt of the written IRE's reconsideration, an enrollee may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. The ALJ hearing office must document all oral requests in writing and maintain the documentation in the case file.

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

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

(5) If a request for hearing is not timely filed, the adjudication period in § 423.2016 begins the date the ALJ grants the request to extend the filing deadline.

§ 423.2016 Timeframes for deciding an Appeal before an ALJ.

(a) *Hearings.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, the ALJ must issue a decision, dismissal order, or remand, as appropriate, no later than the end of the 90-day period beginning on the date the request for hearing is received by the entity specified in the IRE's notice of reconsideration, unless the 90-day period has been extended as provided in this subpart.

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

(b) *Expedited hearings.* (1) Standard for expedited hearing. The ALJ must provide an expedited hearing decision if the appeal involves an issue specified in § 423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician indicates, or the ALJ determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life, health or ability to regain maximum function. The ALJ may consider this standard as met if a lower level adjudicator has granted a request for an expedited hearing.

(2) *Grant of a request.* If the ALJ grants a request for expedited hearing, the ALJ must:

(i) Make the decision to grant an expedited hearing within 5 days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor written notice of the decision. This notice may be provided within the written notice of hearing.

(3) *Denial of a request.* If the ALJ denies a request for expedited hearing, the ALJ must:

(i) Make this decision within 5 days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of the denial that informs the enrollee of the denial and explains that the ALJ will process the enrollee's request using the 90-day timeframe for non-expedited ALJ hearings; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor an equivalent written notice of the decision within 3 days after the oral notice.

(4) A decision on a request for expedited hearing may not be appealed.

(5) *Timeframe for adjudication.* (i) If the ALJ accepts a request for expedited hearing, the ALJ must issue a written decision, dismissal order or remand, as expeditiously as the enrollee's health condition requires, but no later than the end of the 10-day period beginning on the date the request for hearing is received by the entity specified in the IRE's written notice of reconsideration, unless the 10-day period has been extended as provided in this subpart.

(ii) The adjudication period specified in paragraph (b)(5)(i) of this section begins on the date that a timely provided request for hearing is received by the entity specified in the IRE's reconsideration, or, if it is not timely provided, the date that the ALJ grants any extension to the filing deadline.

§ 423.2018 Submitting evidence before the ALJ hearing.

(a) *All hearings.* An enrollee may submit any written evidence that he or she wishes to have considered at the hearing.

(1) An ALJ will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination was made.

(2) An ALJ will remand a case to the Part D plan sponsor where an enrollee wishes evidence on his or her change in

condition after the coverage determination to be considered.

(b) *Non-expedited hearings.* (1) Except as provided in this paragraph, an enrollee must submit all written evidence he or she wishes to have considered at the hearing with the request for hearing or within 10 days of receiving the notice of hearing.

(2) If an enrollee submits written evidence later than 10 days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received is not counted toward the adjudication deadline specified in § 423.2016.

(c) *Expedited hearings.* (1) Except as provided in this section, an enrollee must submit all written evidence he or she wishes to have considered at the hearing with the request for hearing or within 2 days of receiving the notice of hearing.

(2) If an enrollee submits written evidence later than 2 days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received is not counted toward the adjudication deadline specified in § 423.2016.

(d) The requirements of paragraphs (b) and (c) of this section do not apply to oral testimony given at a hearing.

§ 423.2020 Time and place for a hearing before an ALJ.

(a) *General.* Consistent with § 423.1972(b), the ALJ sets the time and place for the hearing, and may change the time and place, if necessary.

(b) *Determining how appearances are made.* (1) The ALJ will direct that the appearance of an individual be conducted by video-teleconferencing if the ALJ finds that video-teleconferencing technology is available to conduct the appearance.

(2) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the enrollee.

(3) The ALJ, with the concurrence of the Managing Field Office ALJ, may determine that an in-person hearing should be conducted if—

(i) The video-teleconferencing technology is not available; or

(ii) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) The ALJ sends a notice of hearing to the enrollee, the Part D plan sponsor that issued the coverage determination, and the IRE that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require the enrollee (and any potential participant from CMS, the IRE, and/or the Part D plan who has requested to participate in the hearing consistent with § 423.2010) to reply to the notice by:

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

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

(d) *An enrollee's right to waive a hearing.* An enrollee may also waive the right to a hearing and request that the ALJ issue a decision based on the written evidence in the record.

(1) As specified in § 423.2000, the ALJ may require the enrollee to attend a hearing if it is necessary to decide the case.

(2) If the ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may still hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In those cases, the ALJ would give the enrollee the opportunity to appear when the testimony is given but may hold the hearing even if the enrollee decides not to appear.

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

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

(3) The objection must be in writing except for an expedited hearing when the objection may be provided orally. The ALJ must document all oral objections to the time and place of an expedited hearing in writing and maintain the documentation in the case files.

(4) The ALJ may change the time or place of the hearing if the enrollee has good cause. (Section 423.2052(a)(2) provides the procedures the ALJ follows when an enrollee does not respond to a notice of hearing and fails to appear at the time and place of the hearing.)

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

(1) The enrollee or his or her representative is unable to attend or to travel to the scheduled hearing because of a serious physical or mental

condition, incapacitating injury, or death in the family; or

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

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

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

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

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

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

(ii) The enrollee's representative was appointed within 10 days of the scheduled hearing for non-expedited hearings (or 2 days for expedited hearings) and needs additional time to prepare for the hearing.

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

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

(v) Transportation is not readily available for an enrollee to travel to the hearing.

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

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the enrollee for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication deadline as specified in § 423.2016.

(i) *An enrollee's request for an in-person hearing.*

(1) If an enrollee objects to a video-teleconferencing hearing or to the ALJ's offer to conduct a hearing by telephone, the enrollee must notify the ALJ at the

earliest possible opportunity before the time set for the hearing and request an in-person hearing.

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

(3) The request must be in writing except for an expedited hearing for which the request may be provided orally. The ALJ must document all oral objections to an expedited video-teleconferencing or telephone hearing in writing and maintain the documentation in the case files.

(4) When an enrollee's request for an in-person hearing is granted, the enrollee is deemed to have waived the adjudicatory timeframe as specified in § 423.2016, except if the ALJ has granted the enrollee's request for an expedited appeal.

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

§ 423.2022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* (1) After the ALJ sets the time and place of the hearing, the notice of the hearing will be mailed or otherwise transmitted to the enrollee and other potential participants, as provided in § 423.2020(c) at their last known addresses, or given by personal service, unless the enrollee has indicated in writing that he or she does not wish to receive this notice.

(2) The notice is mailed or served at least 20 days before the hearing, except for expedited hearings where written notice is mailed or served at least 3 days before the hearing. For expedited hearings, the ALJ may orally provide notice of the hearing to the enrollee and other potential participants but oral notice must be followed by an equivalent written notice within 1 day of the oral notice.

(b) *Notice information.* (1) The notice of hearing contains a statement of the specific issues to be decided and will inform the enrollee that he or she may designate a person to represent him or her during the proceedings.

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

(3) The enrollee will also be told if his or her appearance or that of any other

witness is scheduled by video-teleconferencing, telephone, or in person. If the ALJ has scheduled the enrollee to appear at the hearing by video-teleconferencing, the notice of hearing will advise that the scheduled place for the hearing is a video-teleconferencing site and explain what it means to appear at the hearing by video-teleconferencing.

(4) The notice advises the enrollee that if he or she objects to appearing by video-teleconferencing or telephone, and wishes instead to have his or her hearing at a time and place where he or she may appear in person before the ALJ, he or she must follow the procedures set forth at § 423.2020(i) for notifying the ALJ of his or her objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the enrollee or his or her representative does not acknowledge receipt of the notice of hearing, the ALJ hearing office attempts to contact the enrollee for an explanation.

(2) If the enrollee states that he or she did not receive the notice of hearing, an amended notice is sent to him or her by certified mail or, if available, fax or e-mail. See § 423.2052 for the procedures the ALJ follows in deciding if the time or place of a scheduled hearing will be changed if an enrollee does not respond to the notice of hearing.

§ 423.2024 Objections to the issues.

(a) If an enrollee objects to the issues described in the notice of hearing, he or she must notify the ALJ in writing at the earliest possible opportunity before the time set for the hearing, and no later than 5 days before the hearing, except for expedited hearings in which the enrollee must submit written or oral notice of objection no later than 2 days before the hearing. The ALJ hearing office must document all oral objections in writing and maintain the documentation in the case files.

(b) The enrollee must provide the reasons for his or her objections.

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

§ 423.2026 Disqualification of the ALJ.

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

(b) If an enrollee objects to the ALJ who will conduct the hearing, the enrollee must notify the ALJ within 10 days of the date of the notice of hearing, except for expedited hearings in which the enrollee must submit written or oral notice no later than 2 days after the date of the notice of hearing. The ALJ must

document all oral objections in writing and maintain the documentation in the case files. The ALJ considers the enrollee's objections and decides whether to proceed with the hearing or withdraw.

(c) If the ALJ withdraws, another ALJ will be appointed to conduct the hearing. If the ALJ does not withdraw, the enrollee may, after the ALJ has issued an action in the case, present his or her objections to the MAC in accordance with § 423.2100 through § 423.2130. The MAC would then consider whether the hearing decision should be revised or a new hearing held before another ALJ.

§ 423.2030 ALJ hearing procedures.

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

(b) *At the hearing.* The ALJ fully examines the issues, questions the enrollee and other witnesses, and may accept documents that are material to the issues consistent with § 423.2018.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing.

(d) *Reopen the hearing.* The ALJ may reopen the hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence pursuant to § 423.1986. The ALJ may decide when the evidence is presented and when the issues are discussed.

§ 423.2032 Issues before an ALJ.

(a) *General rule.* The issues before the ALJ include all the issues brought out in the coverage determination, redetermination, or reconsideration that were not decided entirely in an enrollee's favor. However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the enrollee before the hearing and may consider it an issue at the hearing.

(b) *New issues—(1) General.* The ALJ may consider a new issue at the hearing if he or she notifies the enrollee about the new issue any time before the start of the hearing.

(2) *Content of the new issues.* The new issue may include issues resulting from the participation of CMS, the IRE, and/or the Part D plan sponsor at the ALJ level of adjudication and from any evidence and position papers submitted by CMS, the IRE, and/or the Part D plan sponsor for the first time to the ALJ.

(3) *Consideration of new issues.* The ALJ or the enrollee may raise a new

issue; however, the ALJ may only consider a new issue if its resolution—

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

(ii) Is permissible under the rules governing reopening of determinations and decisions as specified in § 423.1980.

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

§ 423.2034 When an ALJ may remand a case.

(a) *General.* If an ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS, the IRE, and/or the Part D plan sponsor, then the ALJ may either:

(1) Remand the case to the IRE that issued the reconsideration; or

(2) Retain jurisdiction of the case and request that the CMS, the IRE, and/or the Part D plan sponsor forward the missing information to the appropriate hearing office.

(b) *ALJ remands a case to an IRE.*

Consistent with § 423.2004(b), the ALJ will remand a case to the appropriate IRE if the ALJ determines that an IRE's dismissal of a request for reconsideration was in error.

(c) *ALJ remands a case to a Part D Plan Sponsor.* The ALJ will remand a case to the Part D plan sponsor if the ALJ determines that the enrollee wishes evidence on his or her change in condition after the coverage determination to be considered in the appeal.

§ 423.2036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence.* (1) An enrollee has the right to appear at the hearing before the ALJ to present evidence and to state his or her position. An enrollee may appear by video-teleconferencing, telephone, or in person as determined under § 423.2020.

(2) An enrollee may also make his or her appearance by means of a representative, who may make his or her appearance by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

(3) Witness testimony may be given and CMS, IRE, and Part D plan sponsor participation may also be accomplished by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

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

(i) For expedited hearings, an enrollee may indicate in writing or orally that he or she does not wish to appear at the hearing.

(ii) The ALJ hearing office must document all oral waivers in writing and maintain the documentation in the case files.

(2) The enrollee may subsequently withdraw his or her waiver in writing at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the enrollee agrees to an extension of the adjudication period as specified in § 423.2016, that may be necessary to schedule and hold the hearing.

(3) Even if the enrollee waives his or her right to appear at a hearing, the ALJ may require him or her to attend an oral hearing if the ALJ believes that a personal appearance and testimony by the enrollee is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* An enrollee or an enrollee's appointed representative, as defined at § 423.560, may appear before the ALJ to state the enrollee's case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record.

(d) *Waiver of adjudication period.* At any time during the hearing process, the enrollee may waive the adjudication deadline specified in § 423.2016 for issuing a hearing decision. The waiver may be for a specific period of time agreed upon by the ALJ and the enrollee.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court. However, the ALJ may not consider evidence on any change in condition of an enrollee after a coverage determination. If the enrollee wishes for the evidence to be considered, the ALJ must remand the case to the Part D plan sponsor as set forth in § 423.2034(c).

(f)(1) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative, issue subpoenas for the appearance and testimony of witnesses and for the enrollee and/or the Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying.

(2) *Reviewability of an ALJ Subpoena.* A subpoena issued by an ALJ is not subject to immediate review by the MAC. The subpoena may be reviewed solely during the MAC's review specified in § 423.2102 and § 423.2110.

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

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

(ii) The proceedings are stayed for 15 days or until the MAC issues a written decision that affirms, reverses, or modifies the ALJ's subpoena, whichever comes first.

(iii) If the MAC does not take action within the 15 days, then the stay is lifted and the enrollee or non-party must comply with the ALJ's subpoena.

(4) *Enforcement.* (i) If the ALJ determines that an enrollee or person other than the enrollee subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ may request that the Secretary seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(ii) After submitting the enforcement request, the time period for the ALJ to issue a decision, dismissal or remand a case in response to a request for hearing is stayed for 15 days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

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

(iv) The ALJ must promptly mail a copy of the notice and related documents to the individual or entity subject to the subpoena, to the enrollee, and to any other affected person.

(g) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any

questions relevant to the issues and allow the enrollee or his or her appointed representative, as defined at § 423.560.

§ 423.2038 Deciding a case without a hearing before an ALJ.

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

(b) *Enrollee does not wish to appear.*

(1) The ALJ may decide a case on the record and not conduct a hearing if—

(i) The enrollee indicates in writing or, for expedited hearings orally or in writing, that he or she does not wish to appear before the ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available. The ALJ hearing office must document all oral requests not to appear at a hearing in writing and maintain the documentation in the case files; or

(ii) The enrollee lives outside the United States and does not inform the ALJ that he or she wants to appear.

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

§ 423.2040 Prehearing and posthearing conferences.

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

(b) For non-expedited hearings, the ALJ informs the enrollee of the time, place, and purpose of the conference at least 7 days before the conference date, unless the enrollee indicates in writing that he or she does not wish to receive a written notice of the conference.

(c) For expedited hearings, the ALJ informs the enrollee of the time, place, and purpose of the conference at least 2 days before the conference date, unless the enrollee indicates orally or in writing that he or she does not wish to receive a written notice of the conference.

(d) The ALJ hearing office must document all oral requests not to receive written notice of the conference in writing and maintain the documentation in the case files.

(e) At the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the

enrollee consents in writing. A record of the conference is made.

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

§ 423.2042 The administrative record.

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

(2) The record will include marked as exhibits, the documents used in making the decision under review, including, but not limited to, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ admits.

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

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

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

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

(2) If an enrollee requests all or part of the record from the ALJ and an opportunity to comment on the record, the time beginning with the ALJ's receipt of the request through the expiration of the time granted for the enrollee's response does not count toward the adjudication deadline.

§ 423.2044 Consolidated hearing before an ALJ.

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

(b) It is within the discretion of the ALJ to grant or deny an enrollee's request for consolidation. In considering an enrollee's request, the ALJ may consider factors such as whether the issue(s) may be more efficiently decided if the requests for hearing are combined.

In considering the enrollee's request for consolidation, the ALJ must take into account the adjudication deadlines for each case and may require an enrollee to waive the adjudication deadline associated with one or more cases if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

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

(d) Before consolidating a hearing, the ALJ must notify CMS of his or her intention to do so, and CMS may then elect to participate in the consolidated hearing by sending written notice to the ALJ.

(1) For non-expedited hearings, any request by CMS to participate must be made within 5 days of receipt of the ALJ's notice of the consolidation.

(2) For expedited hearings, any request by CMS to participate must be made within 1 day of receipt of the ALJ's notice of the consolidation. Requests may be made orally or submitted by facsimile to the hearing office.

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

§ 423.2046 Notice of an ALJ decision.

(a) *General rule.* Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(1) For expedited hearings, the ALJ issues a written decision within the 10-day adjudication timeframe under § 423.2016(b)(5).

(2) The decision must be based on evidence offered at the hearing or otherwise admitted into the record.

(3) A copy of the decision should be mailed to the enrollee at his or her last known address.

(4) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor that issued the coverage determination.

(b) *Content of the notice.* The decision must be provided in a manner

calculated to be understood by an enrollee and must include—

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

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

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

(c) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ, the ALJ may make a finding as to the amount of payment due. If the ALJ makes a finding concerning payment when the amount of payment was not an issue before the ALJ, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's decision is not final for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's decision is a new coverage determination under § 423.566.

(d) *Timing of decision.* For non-expedited hearings, the ALJ issues a decision no later than the end of the 90-day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 90-day period is extended as provided in § 423.2016. For expedited hearings, the ALJ issues a decision as expeditiously as the enrollee's health condition requires, but no later than the end of the 10-day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 10-day period is extended as provided in § 423.2016.

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

§ 423.2048 The effect of an ALJ's decision.

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

(a) An enrollee requests a review of the decision by the MAC within the stated time period or the MAC reviews the decision issued by an ALJ under the procedures set forth in § 423.2110, and the MAC issues a final action;

(b) The decision is reopened and revised by an ALJ or the MAC under the procedures explained in § 423.1980;

(c) The expedited access to judicial review process at § 423.1990 is used;

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

(e) In a case remanded by a Federal District Court, the MAC assumes jurisdiction under the procedures in § 423.2138 and the MAC issues a decision.

§ 423.2050 Removal of a hearing request from an ALJ to the MAC.

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

§ 423.2052 Dismissal of a request for a hearing before an ALJ.

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

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

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

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

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

(ii) The enrollee did not appear at the time and place of hearing and does not contact the ALJ hearing office within 10 days for non-expedited hearings and 2 days for expedited hearings and provide good cause for not appearing; or

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

respond within 10 days for non-expedited hearings; the ALJ does not receive the enrollee's response within 2 days for expedited hearings or the enrollee does not provide good cause for the failure to appear. For expedited hearings, an enrollee may submit his or her response orally to the ALJ.

(iv) In determining whether good cause exists under paragraph (a)(2) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) the enrollee may have.

(3) The person requesting a hearing has no right to it under § 423.2002.

(4) The enrollee did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in § 423.2014(d).

(5) The enrollee died while the request for hearing is pending and the request for hearing was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not want to continue the appeal.

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

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

(8) Consistent with § 423.1972(c)(1), the ALJ dismisses a hearing request if a request clearly shows that the amount in controversy is less than that required under § 423.1970.

(b) *Notice of dismissal.* The ALJ mails a written notice of the dismissal of the hearing request to the enrollee at his or her last known address. The written notice provides that there is a right to request that the MAC vacate the dismissal action.

(c) Consistent with § 423.1972(c)(2), the ALJ discontinues a hearing and does not rule on the substantive issues raised in the appeal if, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.1970.

§ 423.2054 Effect of dismissal of a request for a hearing before an ALJ.

The dismissal of a request for a hearing is binding, unless it is vacated by the MAC under § 423.2108(b).

§ 423.2062 Applicability of policies not binding on the ALJ and MAC.

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

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

§ 423.2063 Applicability of CMS rulings.

CMS Rulings are published under the authority of the CMS Administrator. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, and on all HHS components that adjudicate matters under the jurisdiction of CMS.

§ 423.2100 Medicare appeals council review: general.

(a) Consistent with § 423.1974, the enrollee may request that the MAC review an ALJ's decision or dismissal.

(b) When the MAC reviews an ALJ's written decision, it undertakes a *de novo* review.

(c) The MAC issues a final action or remands a case no later than the end of the 90-day period beginning on the date the request for review is received (by the entity specified in the ALJ's written notice of decision), unless the 90-day period is extended as provided in this subpart or the enrollee requests expedited MAC review.

(d) If an enrollee requests expedited MAC review, the MAC issues a final action or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10-day period beginning on the date the request for review is received (by the entity specified in the ALJ's written notice of decision), unless the 10-day period is extended as provided in this subpart.

§ 423.2102 Request for MAC review when ALJ issues decision or dismissal.

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

(2) An enrollee may request that MAC review be expedited if the appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

(i) If an enrollee is requesting that the MAC review be expedited, the enrollee submits an oral or written request within 60 days after the receipt of the ALJ's written decision or dismissal. A prescribing physician may provide oral or written support for an enrollee's request for expedited review.

(ii) The MAC must document all oral requests for expedited review in writing and maintain the documentation in the case files.

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

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

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

(1) The request for an extension of time is in writing or, for expedited reviews, in writing or oral. The MAC must document all oral requests in writing and maintain the documentation in the case file.

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

(c) An enrollee does not have the right to seek MAC review of an ALJ's remand or an ALJ's affirmation of an IRE's dismissal of a request for reconsideration.

§ 423.2106 Where a request for review may be filed.

When a request for a MAC review is filed after an ALJ has issued a written decision or dismissal, the request for review must be submitted to the entity specified in the notice of the ALJ's action. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the MAC's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the

ALJ's action, the MAC sends written notice to the enrollee of the date of receipt of the request and commencement of the adjudication timeframe.

§ 423.2108 MAC Actions when request for review is filed.

(a) *General.* Except as specified in paragraph (c) of this section, when an enrollee requests that the MAC review an ALJ's decision, the MAC will review the ALJ's decision de novo. The enrollee requesting review does not have a right to a hearing before the MAC. The MAC will consider all of the evidence admitted into the administrative record. Upon completion of its review, the MAC may adopt, modify, or reverse the ALJ's decision or remand the case to the ALJ for further proceedings. Unless the MAC's review is expedited as provided in paragraph (d) of this section, the MAC must issue its action no later than 90 days after receiving the request for review, unless the 90-day period has been extended as provided in this subpart.

(b) *Review of ALJ's dismissal.* When an enrollee requests that the MAC review an ALJ's dismissal, the MAC may deny review or vacate the dismissal and remand the case to the ALJ for further proceedings.

(c) *MAC dismissal of request for review.* The MAC will dismiss a request for review when the individual or entity requesting review does not have a right to a review by the MAC, or will dismiss the request for a hearing for any reason that the ALJ could have dismissed the request for hearing.

(d) *Expedited reviews—*(1) *Standard for expedited reviews.* The MAC must provide an expedited review if the appeal involves an issue specified in § 423.566(b), but does not include solely a request for payment of Part D drugs already furnished, enrollee's prescribing physician indicates, or the MAC determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life or health or ability to regain maximum function. The MAC may consider this standard as met if a lower level adjudicator has granted a request for an expedited appeal.

(2) *Grant of a Request.* If the MAC grants a request for expedited review, the MAC must:

(i) Make this decision within 5 days of receipt of the request for expedited review;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Issue a decision, dismissal order or remand, as expeditiously as the enrollee's health condition requires, but

no later than the end of the 10-day period beginning on the date the request for review is received by the entity specified in the ALJ's written notice of decision.

(3) Denial of a request. If the MAC denies a request for expedited review, the MAC must:

(i) Make this decision within 5 days of receipt of the request for expedited review;

(ii) Give the enrollee and Part D plan sponsor within 5 days of receiving the request written notice of the denial. The written notice must inform the enrollee of the denial and explain that the MAC will process the enrollee's request using the 90-day timeframe for non-expedited reviews.

(4) A decision on a request for expedited review may not be appealed.

§ 423.2110 MAC reviews on its own motion.

(a) *General rule.* The MAC may decide on its own motion to review a decision or dismissal issued by an ALJ. CMS or the IRE may refer a case to the MAC for it to consider reviewing under this authority any time within 60 days after the ALJ's written decision or dismissal is issued.

(b) *Referral of cases.* (1) CMS or the IRE may refer a case to the MAC if, in the view of CMS or the IRE, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS or the IRE may also request that the MAC take own motion review of a case if—

(i) CMS or the IRE participated or requested to participate in the appeal at the ALJ level; and

(ii) In CMS' or the IRE's view, the ALJ's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion.

(2) CMS' or the IRE's referral to the MAC is made in writing and must be filed with the MAC no later than 60 days after the ALJ's written decision or dismissal is issued.

(i) The written referral will state the reasons why CMS or the IRE believes that the MAC should review the case on its own motion.

(ii) CMS or the IRE will send a copy of its referral to the enrollee and to the ALJ.

(iii) The enrollee may file exceptions to the referral by submitting written comments to the MAC within 20 days of the referral notice.

(iv) An enrollee submitting comments to the MAC must send the comments to CMS or the IRE.

(c) *Standard of review*—(1) *Referral by CMS or the IRE when CMS or the IRE participated or requested to participate in the ALJ level.* If CMS or the IRE participated or requested to participate in an appeal at the ALJ level, the MAC exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS or the IRE.

(2) *Referral by CMS or the IRE when CMS or the IRE did not participate or request to participate in the ALJ proceedings.* The MAC will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS or the IRE.

(d) *MAC's action.* (1) If the MAC decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The MAC may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ for further proceedings or may dismiss a hearing request.

(3) The MAC must issue its action no later than 90 days after receipt of the CMS or the IRE referral, unless the 90-day period has been extended as provided in this subpart.

(4) The MAC may not issue its action before the 20-day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the MAC declines to review a decision or dismissal on its own motion, the ALJ's decision or dismissal remains the final agency action in the case.

§ 423.2112 Content of request for review.

(a)(1) The request for MAC review must be filed with the entity specified in the notice of the ALJ's action.

(2) The request for review must be in writing and may be made on a standard form, except for requests for expedited reviews which may be made orally.

(3) The MAC must document all oral requests in writing and maintain the documentation in the case file.

(4) A written request that is not made on a standard form or, for expedited requests, an oral request, is accepted if it includes the enrollee's name and telephone number, the plan name; Medicare health insurance claim number; the ALJ appeal number; the specific Part D drug(s) for which the review is requested; a statement that the enrollee is requesting an expedited review, if applicable; and the name and signature of the enrollee or the representative of the enrollee.

(b) The request for review must identify the parts of the ALJ action with which the enrollee requesting review disagrees and explain why he or she disagrees with the ALJ's decision, dismissal, or other determination being appealed.

(c) The MAC will limit its review of an ALJ's actions to those exceptions raised by the enrollee in the request for review, unless the enrollee is unrepresented. For purposes of this section only, a representative is either anyone with a valid appointment as the enrollee's representative or is a member of the enrollee's family, a legal guardian or an individual who routinely acts on behalf of the enrollee, such as a family member or friend who has a power of attorney.

§ 423.2114 Dismissal of request for review.

The MAC dismisses a request for review if the enrollee requesting review did not file the request within the stated period of time and the time for filing has not been extended. The MAC also dismisses the request for review if—

(a) The enrollee asks to withdraw the request for review;

(b) The individual or entity does not have a right to request MAC review; or

(c) The enrollee died while the request for review is pending and the enrollee's representative, if any, either has no remaining financial interest in the case or does not want to continue the appeal.

§ 423.2116 Effect of dismissal of request for MAC review or request for hearing.

The dismissal of a request for MAC review or denial of a request for review of a dismissal issued by an ALJ is binding and not subject to further review unless reopened and vacated by the MAC. The MAC's dismissal of a request for hearing is also binding and not subject to judicial review.

§ 423.2118 Obtaining evidence from the MAC.

An enrollee may request and receive a copy of all or part of the record of the ALJ hearing, including the exhibits list, documentary evidence, and a copy of

the tape of the oral proceedings. However, the enrollee may be asked to pay the costs of providing these items. If an enrollee requests evidence from the MAC and an opportunity to comment on that evidence, the time beginning with the MAC's receipt of the request for evidence through the expiration of the time granted for the enrollee's response will not be counted toward the adjudication deadline.

§ 423.2120 Filing briefs with the MAC.

Upon request, the MAC will give the enrollee requesting review a reasonable opportunity to file a brief or other written statement about the facts and law relevant to the case. Unless the enrollee requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the MAC will not be counted toward the adjudication timeframe set forth in § 423.2100. The MAC may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to file a brief or position paper if the MAC determines that it is necessary to resolve the issues in the case. The MAC cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor either participates, or decides not to participate in MAC review.

§ 423.2122 What evidence may be submitted to the MAC.

(a) *Appeal before the MAC on request for review of ALJ's decision.* (1) If the MAC is reviewing an ALJ's decision, the MAC will consider the evidence contained in the record of the proceedings before the ALJ, and any new evidence that relates to the period before the coverage determination. If the hearing decision decides a new issue that the enrollee was not afforded an opportunity to address at the ALJ level, the MAC considers any evidence related to that issue that is submitted with the request for review.

(2) If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision.

(3) The MAC will not consider any new evidence submitted regarding a change in condition of an enrollee after a coverage determination is made. The MAC will remand a case to the Part D plan sponsor if the MAC determines that the enrollee wishes to have evidence on his or her change in

condition after the coverage determination considered.

(b) *Subpoenas*. When it is reasonably necessary for the full presentation of a case, the MAC may, on its own initiative, issue subpoenas requiring an enrollee or Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying.

(1) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality or undue burden, was made before the MAC, the Secretary may review immediately that subpoena or a portion of the subpoena.

(2) Upon notice to the MAC that an enrollee or Part D plan sponsor intends to seek the Secretary review of the subpoena, the MAC must stay all proceedings affected by the subpoena, tolling the time period for the MAC to issue a final action or remand a case in response to a request for review for 15 days or until the Secretary makes a decision with respect to the review request, whichever occurs first.

(3) If the Secretary does not grant review within the time allotted for the stay, the stay is lifted and the subpoena stands.

(c) *Enforcement*. (1) If the MAC determines that an enrollee or other person or entity subject to a subpoena issued under this section has refused to comply with the subpoena, the MAC may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(2) After submitting the enforcement request, the time period for the MAC to issue a final action or remand a case in response to a request for review is stayed for 15 days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(3) Any enforcement request by the MAC must consist of a written notice to the Secretary describing in detail the MAC's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or other person or entity subject to the subpoena.

(4) The MAC must promptly mail a copy of the notice and related documents to the enrollee or other person or entity subject to the subpoena, and to any other affected person.

§ 423.2124 Oral argument.

An enrollee may request to appear before the MAC to present oral argument.

(a) The MAC grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The MAC may decide on its own that oral argument is necessary to decide the issues in the case. If the MAC decides to hear oral argument, it informs the enrollee of the time and place of the oral argument at least 10 days before the scheduled date or, in the case of an expedited review, at least 2 days before the scheduled date.

(c) In case of a previously unrepresented enrollee, a newly hired representative may request an extension of time for preparation of the oral argument and the MAC must consider whether the extension is reasonable.

(d) The MAC may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to appear before it if the MAC determines that it may be helpful in resolving the issues in the case.

(e) The MAC cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in the oral argument.

§ 423.2126 Case remanded by the MAC.

(a) *When the MAC may remand a case to the ALJ*. (1) The MAC may remand a case in which additional evidence is needed or additional action by the ALJ is required. The MAC will designate in its remand order whether the ALJ will issue a final decision or a recommended decision on remand.

(2) *Action by ALJ on remand*. The ALJ will take any action that is ordered by the MAC and may take any additional action that is not inconsistent with the MAC's remand order.

(3) *Notice when case is returned with a recommended decision*. When the ALJ sends a case to the MAC with a recommended decision, a notice is mailed to the enrollee at his or her last known address. The notice tells the enrollee that the case was sent to the MAC, explains the rules for filing briefs or other written statements with the MAC, and includes a copy of the recommended decision.

(4) *Filing briefs with the MAC when ALJ issues recommended decision*. (i) An enrollee may file with the MAC briefs or other written statements about the facts and law relevant to the case within 20 days of the date on the recommended decision or with the request for review for expedited

appeals. An enrollee may ask the MAC for additional time to file a brief or written statement. The MAC will extend this period, as appropriate, if the enrollee shows that he or she has good cause for requesting the extension.

(ii) All other rules for filing briefs with and obtaining evidence from the MAC follow the procedures explained in this subpart.

(5) *Procedures before the MAC*. (i) The MAC, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(ii) If the MAC determines that more evidence is required, it may again remand the case to an ALJ for further inquiry into the issues, rehearing, receipt of evidence, and another decision or recommended decision. However, if the MAC decides that it can get the additional evidence more quickly, it will take appropriate action.

(b) *When the MAC must remand a case to the Part D plan sponsor*. The MAC will remand a case to the Part D plan sponsor if the MAC determines that the enrollee wishes evidence on his or her change in condition after the coverage determination to be considered in the appeal.

§ 423.2128 Action of the MAC.

(a) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on MAC consideration of additional evidence in § 423.2122, the MAC will make a decision or remand the case to an ALJ.

(b) The MAC may adopt, modify, or reverse the ALJ hearing decision or recommended decision.

(c) The MAC mails a copy of its decision to the enrollee at his or her last known address, to CMS, to the IRE, and to the Part D plan sponsor.

§ 423.2130 Effect of the MAC's decision.

The MAC's decision is binding unless a Federal District Court issues a decision modifying the MAC's decision or the decision is revised as the result of a reopening in accordance with § 423.1980. An enrollee may file an action in a Federal District Court within 60 days after the date the enrollee receives written notice of the MAC's decision.

§ 423.2134 Extension of time to file action in Federal District Court.

(a) An enrollee may request that the time for filing an action in a Federal District Court be extended.

(b) The request must—

(1) Be in writing.

(2) Give the reasons why the action was not filed within the stated time period.

(3) Be filed with the MAC.

(c) If the enrollee shows that he or she had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards specified in § 405.942(b)(2) or (b)(3) of this chapter.

§ 423.2136 Judicial review.

(a) *General rule.* To the extent authorized by sections 1876(c)(5)(B) and 1860D–4(h) of the Act and consistent with § 423.1976, an enrollee may obtain a court review of a MAC decision if the amount in controversy meets the threshold requirement estimated annually by the Secretary.

(b) *Court in which to file civil action.*

(1) Consistent with § 423.1976(c), any civil action described in paragraph (a) of this section must be filed in the District Court of the United States for the judicial district in which the enrollee resides.

(2) If the enrollee does not reside within any judicial district, the civil action must be filed in the District Court of the United States for the District of Columbia.

(c) *Time for filing civil action.* (1) Any civil action described in paragraph (a) of this section must be filed within the time periods specified in § 423.2130 or § 423.2134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the MAC's decision shall be presumed to be 5 days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in § 423.1990, the civil action must be filed within 60 days after receipt of the review entity's certification, except where the time is extended by the ALJ or MAC, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff enrollee will be notified that he or she has named an incorrect

defendant and is granted 60 days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.

(2) When the Secretary's decision is adverse to an enrollee due to an enrollee's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof an enrollee must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

§ 423.2138 Case remanded by a Federal District Court.

When a Federal District Court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the MAC, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ with instructions to take action and either issue a decision, take other action, or return the case to the MAC with a recommended decision. If the MAC remands a case, the procedures specified in § 423.2140 will be followed.

§ 423.2140 MAC Review of ALJ decision in a case remanded by a Federal District Court.

(a) *General rules.* (1) In accordance with § 423.2138, when a case is remanded by a Federal District Court for further consideration and the MAC remands the case to an ALJ, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the MAC assumes jurisdiction.

(2) The MAC may assume jurisdiction based on written exceptions to the decision of the ALJ that an enrollee files with the MAC or based on its authority under paragraph (c) of this section.

(3) The MAC either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ for further proceedings.

(b) *An enrollee files exceptions disagreeing with the decision of the ALJ.*

(1) If an enrollee disagrees with an ALJ decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the MAC.

(2) Exceptions may be filed by submitting a written statement to the MAC setting forth the reasons for disagreeing with the decision of the ALJ.

(i) The enrollee must file exceptions within 30 days of the date the enrollee receives the decision of the ALJ or submit a written request for an extension within the 30-day period.

(ii) The MAC will grant a timely request for a 30-day extension. A request for an extension of more than 30 days must include a statement of reasons as to why the enrollee needs the additional time and may be granted if the MAC finds good cause under the standard established in § 405.942(b)(2) or (b)(3).

(3) If written exceptions are timely filed, the MAC considers the enrollee's reasons for disagreeing with the decision of the ALJ. If the MAC concludes that there is no reason to change the decision of the ALJ, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ is warranted. In this instance, the decision of the ALJ is the final decision of the Secretary after remand.

(4) When an enrollee files written exceptions to the decision of the ALJ, the MAC may assume jurisdiction at any time. If the MAC assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or remanding the case to an ALJ for further proceedings, including a new decision. The new decision of the MAC is the final decision of the Secretary after remand.

(c) *MAC assumes jurisdiction without exceptions being filed.* (1) Any time within 60 days after the date of the written decision of the ALJ, the MAC may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to the enrollee at his or her last known address.

(3) The enrollee will be provided with the opportunity to file a brief or other written statement with the MAC about the facts and law relevant to the case.

(4) After the brief or other written statement is received or the time allowed (usually 30 days) for submitting them has expired, the MAC will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ for further proceedings, including a new decision.

(d) *Exceptions are not filed and the MAC does not otherwise assume jurisdiction.* If no exceptions are filed and the MAC does not assume jurisdiction over the case within 60 days after the date of the ALJ's written decision, the decision of the ALJ

becomes the final decision of the Secretary after remand.

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Dated: October 4, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Constance B. Tobias,

Chair, The Departmental Appeals Board.

Perry Rhew,

Chief Administrative Law Judge, Office of Medicare Hearings and Appeals.

Approved: December 7, 2007.

Michael O. Leavitt,

Secretary.

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