DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–4127–F]

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: Final rule.

SUMMARY: This final rule will implement the procedures that the Department of Health and Human Services will 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. In addition, it will implement the reopening procedures that will be followed at all levels of appeal.

DATES: *Effective date:* This final rule is effective on January 8, 2010.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Abbreviations

Because of the many terms to which we refer by abbreviation in this final 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

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 section 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 sections 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, the 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 final appeals rule is to provide guidance on the differences in appeals procedures for Part D enrollees by implementing 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 Final Rule

This final appeals rule contains revisions to Part 423, subpart M of title 42 of the CFR. We renamed, reorganized, and consolidated similar requirements into one section, and added 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 renamed subpart M, ''Grievances, Coverage Determinations, Redeterminations, and Reconsiderations''. This subpart will continue to set forth the requirements for Part D plan sponsors with respect to grievances, coverage determinations, redeterminations, and reconsiderations. We also added 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 redesignated and reserved § 423.610, § 423.612, § 423.620, § 423.630, and § 423.634. We note that while we made conforming changes to the language of some of these redesignated sections, we did not make any substantive changes to the policies established by those provisions.

Below we are providing a crosswalk table that enables the reader to easily locate where the requirements have been relocated. The crosswalk lists the former subparts and former sections along with the new subparts and new sections as they appear in this final appeals rule.

TABLE—CROSSWALK

Former subpart	Former section	New subpart	New 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 determinations and decisions.

III. Technical Changes Based on Finalization of the Part 405, Subpart I Rule

As indicated above, the purpose of this final appeals rule is to provide guidance on the differences between the Part D appeals procedures and the appeals procedures for Medicare Part A and Part B found in the Part 405, subpart I rule. The final rule for Medicare Part A and Part B claims appeals (referenced above as the Part 405, subpart I rule) published elsewhere in this **Federal Register**, and therefore, for this final rule, it is necessary based on statutory and regulatory framework discussed above in section I, and below in section IV.A., to make a number of technical changes to this final Part D appeals rule in order to be consistent with the provisions contained in the final rule for Part 405, subpart I. These changes are discussed and explained in greater detail in the final Medicare Parts A and B claims appeals rule, and thus, we will not include an extensive discussion of these technical corrections in this preamble. Rather we discuss generally the technical corrections being made in this final appeals rule, and provide references to the sections within the final Parts A and B claims appeals rule preamble for more in depth discussions on these changes.

The technical corrections being made in this final Part D appeals rule include the following:

- Technical corrections to clarify the terms ''final'' and ''binding,'' by reserving the term ''final'' to describe those actions or decisions for which judicial review may be immediately sought.'' *See* §§ 423.1978, 423.1980(a)(1) and (a)(4), 423.2004(c), 423.2046(c), 423.2052(a)(6), 423.2126(a)(1), and 423.2130. For a more detailed discussion on these technical changes, please reference section II.B.5.b. contained in the final rule entitled ''Medicare Program: Changes to the Medicare Claims Appeals Procedures,'' published elsewhere in this issue of the **Federal Register**.
- A number of technical changes are also being made to clarify the decisions or actions issued by adjudicators, and to further clarify the effect of a specific action issued by an adjudicator, and when judicial review may be available; similar technical corrections to clarify which actions, if taken by the ALJ or the MAC, may preclude a party from seeking EAJR, and to clarify that the decision of the review entity to certify or deny a request for EAJR is not subject to further review. These are technical corrections where the terms ''final action'' or ''final decision'' had been used. *See* §§ 423.1990(b)(1)(i), (b)(1)(ii), and (e)(3), 423.2048(a), 423.2100(c) and (d), 423.2048(a), and 423.2110(d)(5). For a more detailed discussion on these technical changes, please reference section II.B.5.b. contained in the final rule entitled ''Medicare Program: Changes to the Medicare Claims Appeals Procedures,'' published elsewhere in this issue of the **Federal Register**.
- A technical correction clarifying that the reopening time frames apply to the reopening of a determination or decision and not to the revision of a determination or decision. *See* § 423.1980(b). For a more detailed discussion on these technical changes, please reference section II.B.7.a. contained in the final rule entitled ''Medicare Program: Changes to the Medicare Claims Appeals Procedures,'' published elsewhere in this issue of the **Federal Register**.
- A technical revision to clarify that ALJs conduct de novo reviews. *See* § 423.2000(d). For a more detailed discussion on these technical changes, please reference section II.B.9.b. contained in the final rule entitled ''Medicare Program: Changes to the Medicare Claims Appeals Procedures,'' published elsewhere in this issue of the **Federal Register**.
- A technical correction regarding the adjudication timeframe when a request for an in-person hearing is granted. *See* § 423.2020(i)(4). For a more detailed discussion on these technical changes, please reference section II.B.9.e. contained in the final rule entitled ''Medicare Program: Changes to the Medicare Claims Appeals Procedures,'' published elsewhere in this issue of the **Federal Register**.
- Technical corrections to the remand provisions to clarify when an ALJ can remand a case to the IRE based on missing information. *See* § 423.2034(a). For a more detailed discussion on these technical changes, please reference section II.B.9.h. contained in the final rule entitled ''Medicare Program: Changes to the Medicare Claims Appeals Procedures,'' published elsewhere in this issue of the **Federal Register**.
- Technical corrections to clarify the appropriate use of subpoenas by an ALJ or the MAC. *See* §§ 423.2036(f)(1), 423.2122(b). For a more detailed discussion on these technical changes, please reference sections II.B.9.i. and II.B.10.b. contained in the final rule entitled ''Medicare Program: Changes to the Medicare Claims Appeals Procedures,'' published elsewhere in this issue of the **Federal Register**.
- A technical correction to clarify the applicability of laws, regulations, and CMS rulings to ALJs and the MAC. *See* § 423.2063(a). For a more detailed discussion on these technical changes, please reference section II.B.9.m. contained in the final rule entitled ''Medicare Program: Changes to the Medicare Claims Appeals Procedures,''

published elsewhere in this issue of the **Federal Register**.

Also, the reader can easily refer to section VI., Provisions of the Final Rule, in this document to see a comprehensive review of the modifications being made to this final rule, most of which are technical corrections made to ensure consistency between this final appeals rule, and the Medicare Part A and Part B claims appeals rule, upon which this rule is modeled.

IV. Summary of the Proposed Provisions and Response to Comments on the March 17, 2008 Proposed Rule

Discussed below are the comments and technical corrections to the proposed rule. We include a brief explanation of each regulatory provision, provide a summary of, and responses to, the comments received, and describe the changes, if any, to be made in finalizing the provision in this rulemaking.

We received 22 public comments on the proposed rule published in the **Federal Register** on March 17, 2008. Most of the comments received were from beneficiary advocacy organizations. Summaries of the public comments and our responses to those comments are set forth below.

On January 12, 2009, we published CMS–4131–FC (74 FR 1494). In that final rule, we added a definition for ''other prescriber'' in § 423.560. We also inserted ''or other prescriber'' after ''prescribing physician'' or ''physician'' throughout subpart M of part 423 in order to authorize non-physician prescribers to carry out the same functions that prescribing physicians currently perform with respect to the coverage determination and appeals processes for the prescription drug program. To ensure consistency with CMS–4131–FC and current CMS policy, we revised §§ 423.2014, 423.2016, 423.2102, and 423.2108 of CMS–4127–F to include ''or other prescriber'' after ''prescribing physician'' or ''physician'' where appropriate.

A. General Appeals Provisions

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)(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 are providing 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), Public Law 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.

Specific comments and our responses to those comments are as follows:

Comment: We received a comment related to the statement in the preamble of the proposed rule that the Social Security Administration (SSA) does not process appeals related to enrollment in or entitlement to Part D. The commenter inquired about the responsible entity and applicable process when a beneficiary has an issue related to Part D enrollment, including eligibility for a special enrollment period.

Response: There currently is no formal appeals process that applies with respect to an application for Part D enrollment. Consistent with §§ 1860D–4(g)(1) and (h)(1) of the Act, only issues involving coverage of Part D benefits can be resolved through the Part D coverage determination and appeals processes. Enrollment disputes are distinct from disputes related to coverage of Part D benefits and therefore, cannot be resolved through the Part D coverage determination and appeals processes. However, beneficiaries not currently enrolled in a Part D plan, or who otherwise have problems related to eligibility and enrollment, may contact 1–800–Medicare and/or a CMS Regional Office (RO) caseworker for assistance in resolving the matter. Customer service representatives and RO caseworkers can resolve a wide range of enrollment issues, including matters related to eligibility for a special enrollment period.

Comment: Commenters believe that the following statement in the preamble's ''Highlights and Organization of the Proposed Rule'' section is misleading and disingenuous: ''We note 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.'' The commenters stated that while some of the changes can be appropriately classified as nonconforming, many more of the general appeals provisions changes, especially those to the timeframes, submission of evidence, ALJ remand criteria and participants at a hearing, are definitely substantive.

Response: We believe that the commenters may have misinterpreted our statement. Our characterization of the changes as non-substantive applies only to the redesignated sections that are specifically referenced in the statement, which include sections 423.610, 423.612, 423.620, 423.630, and 423.634. These provisions have previously gone through the notice of proposed rulemaking process and are now only being redesignated to be included in the new subpart U. These provisions are also being cross-referenced in the new ALJ and MAC provisions that have been drafted to parallel Part 405, subpart I, as appropriate. For example, section 423.612, Request for an ALJ Hearing, has been redesignated as section 423.1972 and is cross-referenced in the new section 423.2014, Request for an ALJ Hearing. Section 423.2014 contains the requirements of § 423.1972 as well as new provisions that parallel Part 405, subpart I, such as specifying the required content of a request for an ALJ hearing.

We agree with the commenters that the new provisions of this rule are substantive in nature and, accordingly, we provided the public an opportunity to comment on these provisions through the notice of proposed rulemaking process. Accordingly, we are finalizing §§ 423.1968, 423.1970, 423.1972, 423.1974, 423.1976, and 423.1978 as noted above, and as discussed in subsection III.

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.

Former § 423.610 (now at § 423.1970) and former § 423.612 (now at § 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. Consistent with § 1869(b)(1)(E)(iii) of the Act, the threshold amounts for ALJ hearings and judicial review must be adjusted annually by the Secretary, beginning in January of 2005, by the percentage increase in the medical care component of the consumer price index (CPI) for all urban consumers (U.S. city average) for July 2003 to the July of the preceding year involved and rounded to the nearest multiple of $10. The amounts are published annually in the **Federal Register**.

Under former § 423.620 (now at § 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 final appeals 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 or other prescriber.)

We proposed 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 will 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 received a few comments relating to the participation of plan sponsors, the IRE, and CMS at ALJ hearings. Those comments are discussed in the section of the preamble relating to participation in an ALJ hearing (§ 423.2010).

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

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 proposed to apply a 90-day adjudicatory timeframe to Part D appeals with an expedited process for certain types of appeals. Specifically, we proposed 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.

In order to meet the shortened timeframes established for expedited appeals, we also proposed 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. We note

that all time periods in this final appeals rule refer to calendar days.

We also proposed to not include provisions regarding escalation, but rather, to address the timeliness concerns of Part D enrollees by providing for an expedited process, discussed in greater detail below.

Specific comments received and responses to those comments are as follows:

Comment: A number of commenters stated that Part D plan sponsors and the IRE routinely fail to issue timely coverage and payment decisions. To help improve this situation, these commenters suggest the proposed rule be revised to state that any ALJ or MAC request that is not responded to within the applicable timeframe is deemed approved.

Response: Clearly, it is important that both Part D plan sponsors and subsequent adjudicators meet the applicable decision making timeframes for Part D appeals. CMS monitors Part D plan sponsor performance on meeting timeliness standards and although we do not believe timeliness issues are widespread, compliance action is taken when systemic problems are identified. Further, we note that the IRE's performance in this regard has been outstanding with a timeliness rate that is consistently close to 100 percent, based on calendar year 2007 data.

However, even in cases where Part D plan sponsors or adjudicators do not meet timeframes, we do not believe the commenters' recommendation is an appropriate remedy. There is no precedent in Part D, or anywhere in the Medicare program, for covering items and services solely on the grounds that a coverage or appeal determination was not made on a timely basis. Furthermore, if the request for coverage or reimbursement were to be deemed favorable solely because the adjudicator missed the decision making timeframe, the request would be covered without receiving any type of review, and possibly lead to the inappropriate coverage of drugs under the Medicare Part D drug benefit program. Instead, in cases where Part D plan sponsors do not meet the applicable timeframes, we have established, under both Parts C and D, a policy that an initial determination or plan-level appeal decision that is not made within the applicable timeframe is deemed unfavorable and the request is forwarded by the plan to the IRE for review. *See* 42 CFR 422.568(f), 422.572(f), 422.590(c) and (f), 423.568(e), 423.572(d), and 423.590(c) and (e). This approach puts in place a mechanism for moving appeals forward when decision making timeframes are missed, and ensures that all requests for Medicare Part D benefits or payment receive review as soon as possible. Under Part D, such review will ensure that payment is appropriate (for example, the drug is not an excluded drug). As noted above, the data we have collected thus far indicates that the IRE is meeting the applicable adjudication timeframes in the overwhelming majority of cases, and we do not expect missed timeframes to be a problem at the ALJ or MAC level. We will continue to monitor timeliness at all levels of appeal, but we do not believe the commenter's suggested approach is appropriate.

Comment: Some commenters recommended that the ALJ and MAC automatically expedite a decision if it was expedited at a lower level of appeal. Given the documentation needed to support a request to expedite an appeal, these commenters felt that requiring enrollees to demonstrate the need for an expedited appeal at each level of the process would be burdensome for enrollees and their physicians.

Response: Although we appreciate the commenters' interest in streamlining the appeals process, we disagree with the recommendation to require ALJs and the MAC to automatically expedite an appeal request if it was expedited at a lower level. If an enrollee's health status improves during the course of an appeal, or an enrollee purchases the drug in dispute while an appeal is pending, expedited status may no longer be warranted. Thus, we believe it is more appropriate for each adjudicator to make an independent determination about whether to expedite a request. In doing so, adjudicators may take into consideration a previous adjudicator's decision to expedite an appeal request. Under § 423.2016(b) and § 423.2108(d) of this rule the decision will be expedited 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 or other prescriber indicates, or the ALJ or the MAC determines, that applying the standard timeframe may seriously jeopardize the enrollee's life, health, or ability to regain maximum function.

Comment: Several commenters noted that the preamble of the proposed rule stated that all time periods refer to calendar days. The commenters requested that the use of ''calendar days'' be explicitly stated in the applicable regulatory provisions.

Response: We agree with the commenters and have revised all ''days'' references in the regulatory provisions to ''calendar days.'' We note that where the regulations provide for a time frame and that time frame ends on a Saturday, Sunday, legal holiday, or any other federal nonwork day, we apply a rollover period that extends the time frame within which an act must be done to the first day after the Saturday, Sunday, legal holiday, or other federal nonwork day.

We are also making a conforming change to the Part D grievance, plan sponsor, and IRE provisions to ensure consistency throughout the Part D appeals process, by changing ''days'' references to ''calendar days'' in 42 CFR 423.564(d)(2), (e)(1), and (e)(2); 423.582(c)(2); 423.584(d)(1) and (d)(2)(i); and 423.600(a).

Comment: Commenters indicated that a provision similar to § 405.1104 and 42 CFR 405.1132 should be added, allowing an enrollee's appeal before an ALJ to be escalated to the MAC and an appeal before the MAC to be escalated to Federal district court if an enrollee does not receive a timely decision from an ALJ or the MAC.

Response: The regulations referenced by the commenters are the result of explicit statutory provisions for appeals under Part A and Part B and there are no parallel statutory requirements for Part C and Part D appeals. We note also that the adjudication timeframes associated with escalated cases would be considerably longer than the decision making timeframes proposed in this rule. [Place holder] As we noted in the Part A and Part B final rule published elsewhere in the **Federal Register**, Part 405, subpart I implemented a 180-day adjudicatory timeframe for reviewing escalated appeals in light of the substantial additional burden on the adjudicator, including locating and acquiring relevant information, performing additional procedural and jurisdictional reviews, and organizing evidence in the case file. Thus, setting the adjudication timeframe by regulation at 180 days for escalated appeals balances the interests of the appellant in timely resolving the disputed appeal and an adjudicator's duty to collect the evidence and perform the administrative tasks necessary to fully and fairly adjudicate an appeal that has not been addressed at the prior level of appeal. However, given the lack of similar statutory direction with respect to Part D appeals, we believe the concerns of enrollees seeking timely decisions from an ALJ and the MAC for Part D appeals are better met by establishing a 90-day adjudicatory timeframe accompanied by an expedited process, similar to the process established at the coverage

determination, redetermination, and reconsideration levels.

D. Evidence

We proposed 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 proposed that the entity that is best suited to review and evaluate the evidence be the entity that receives the evidence for review. We proposed 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 proposed that in instances 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 remand the case to the Part D plan sponsor.

We proposed not to follow the full and early presentation of evidence provisions in Part 405, subpart I, including § 405.1028. For Part D appeals, we proposed that only the enrollee would be a party to the appeal and because the enrollee would not be represented by a provider or supplier we did not propose to include any provisions from Part 405, subpart I, on the full and early presentation of evidence. We proposed, as discussed above, that an enrollee may present new evidence at any time during the appeal.

Specific comments received and responses to those comments are as follows:

Comment: Numerous commenters expressed nonsupport of an ALJ and/or the MAC remanding the appeal to the Part D plan sponsor when an enrollee wishes to have evidence of a change in his or her condition since the coverage determination considered. Commenters suggested that where an enrollee wishes to have such evidence considered, the appeal should be remanded to the Part D IRE instead of to the Part D plan sponsor for a new determination. The commenters expressed concern that the proposal would result in further delays in the adjudication process and force unrepresented beneficiaries to make a strategic decision about whether to forfeit the right to consideration of all evidence, including evidence of a worsening condition, in order to get review by an ALJ or the MAC.

Response: Similar to the regulations found in Part 405, subpart I, an enrollee has been provided under the proposed regulations with as much flexibility as possible to submit evidence throughout the appeals process. We appreciate the commenters' concerns about the impact on the enrollee if the ALJ and the MAC remand a case to the Part D plan sponsor to consider evidence of a change in condition. After further consideration, we agree that remanding these types of cases back to the Part D plan sponsors may prolong the appeals process because the enrollee, if dissatisfied with a Part D plan sponsor's new coverage determination, would have to go through the entire Part D appeals process a second time. Thus, while both the Part D plan sponsor and the Part D IRE have the appropriate medical expertise to provide an effective and efficient review of the evidence related to an enrollee's change in condition, we believe that it is more appropriate for the ALJ and the MAC to remand these cases to the Part D IRE. This approach will ensure that an enrollee who is dissatisfied with the Part D IRE's new decision can immediately appeal that decision to an ALJ without having to navigate the Part D plan sponsor and IRE appeals levels a second time. As the IRE's new decision can immediately be appealed to an ALJ, we also believe that remanding to the Part D IRE instead of to the Part D plan sponsor will aid unrepresented enrollees when making decisions on whether to have evidence of a change in his or her condition since the coverage determination considered. Accordingly, § 423.2034(c) and § 423.2126(b) have been modified to state that the ALJ and the MAC, respectively, will remand a case to the Part D IRE if an enrollee wishes to have the ALJ or MAC consider evidence of a change in condition after the coverage determination was made.

E. Claims and Overpayment

We proposed not to include any references to claims, overpayment, or underpayment since 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.

A specific comment received and response to comment is as follows:

Comment: One commenter expressed concern about the statements in the preamble to the proposed rule that the Part D appeals process does not involve overpayments or underpayments because, unlike Part A and Part B appeals, Part D appeals do not involve claims against the Medicare Trust Fund by enrollees. The commenter believes that this statement overlooks how the Part D program is funded and the statutory obligations of Part D plan sponsors because subsidy payments made by CMS to Part D plan sponsors to pay for covered Part D drugs and low-income qualifying enrollees are Trust Fund dollars.

Response: We continue to believe that the Part D beneficiary appeals process does not involve disputes about claims for reimbursement from the Medicare Trust Fund by enrollees and issues of overpayments or underpayments by the Federal Government. The Part A and Part B appeals process frequently involves claims for direct reimbursement from the Trust Fund by parties to the appeal and issues of large overpayments or underpayments by the Federal Government. Part D plan sponsors cannot be parties under the Part D appeals process and any claim for reimbursement by the enrollee would be made against the Part D plan sponsor, not the Medicare Trust Fund.

F. Other General Provisions

We proposed not 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 since the Part D rule already contains provisions in former § 423.610 (now at § 423.1970), former § 423.612 (now at § 423.1972), and former § 423.630 (now at § 423.1976) regarding the amount in controversy requirements for ALJ hearings and judicial review. Similarly, we did not see a reason to include Part 405, subpart I, references to 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 proposed 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 SSA rules for entitlement and enrollment appeals performed by SSA. We proposed not to include similar references to SSA 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.

We did not receive any comments related to these proposals. Accordingly, we are finalizing § 423.1972 subject to the modification discussed in section III, which changes the word ''days'' to

''calendar days,'' and are finalizing the other provisions without modification.

G. Reopenings (§ 423.1980 Through § 423.1986)

As revised (based on technical corrections discussed above in section III), § 423.1978(a) (former § 423.634(a)) states that a coverage determination, a redetermination, a reconsideration or a decision of an ALJ or the MAC ''that is otherwise 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 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 proposed reopening regulations that generally track the Part A and Part B reopening provisions in § 405.980, § 405.982, § 405.984, and § 405.986. We note that 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 proposed at § 423.1980(a)(1), (a)(3), and (a)(4), and § 423.1984(g) to add language that is consistent with former § 423.634 (now at § 423.1978) on Part D reopenings. Since Part D appeals differ in part from Part A and Part B appeals, we proposed not to include several provisions from § 405.980, § 405.982, and § 405.986.

Specific comments received and responses to those comments are as follows:

Comment: Many commenters asked that CMS acknowledge a Part D enrollee's right to request a reopening of an unfavorable decision. Additionally, these same commenters recommended that we revise the proposed rule to include a provision stating that a request to reopen extends the 60-day timeframe to appeal an unfavorable decision. The commenters argue this regulatory change is necessary because many enrollees believe the deadline to appeal an unfavorable decision is extended when a reopening request is filed.

Response: While enrollees do have a right to request that an unfavorable decision be reopened, reopenings are at the discretion of the adjudicator and an adjudicator's decision about whether to reopen is not subject to appeal. This policy is consistent with the reopening provisions contained in Part 405, subpart I of the regulations. The deadlines for requesting appeals are clearly explained in the decision letters, including the ALJ hearing decisions. While we understand the commenters' concerns regarding the potential effect a denied reopening request may have on appeal rights, we believe that allowing additional time to file an appeal once a reopening is requested would provide an inappropriate extension of the appeals filing time frames. If an enrollee misses the filing deadline for an appeal while awaiting a decision on a reopening request, he or she may request the adjudicator consider granting an extension to the filing time limit consistent with § 423.2014(d). Thus, we are not adopting the commenters' suggestion to extend appeals filing time limits when a reopening is requested.

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

We proposed in this section 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 proposed 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 proposed 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 proposed not to include §§ 405.980(a)(3), (b)(4), and (c)(3), as these sections refer to clerical errors related to claims submissions by providers to fiscal intermediaries and carriers, which is not applicable to Part D.

In this final appeals rule, we are clarifying in § 423.1980 that a Part D plan sponsor may request a reopening of a reconsideration, hearing decision, or MAC review decision. Though not explicitly stated, nothing in the proposed rule prevented a Part D plan sponsor from asking an adjudicator to reopen a decision on its own motion. Thus, this option existed for Part D plan sponsors under the proposed rule. To make this option more clear, § 423.1980 of this final appeals rule has been revised to explicitly state that a Part D plan sponsor may ask an adjudicator to reopen a decision on its own motion. We received no public comments on § 423.1980. Accordingly, we are finalizing it subject to this clarification and the modifications discussed in section III, which include removing the term ''final'' and replacing it with ''binding,'' removing the words ''and revise,'' and changing the term ''days'' to ''calendar days.''

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

We proposed 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 proposed language requiring the IRE, ALJ, or the MAC to mail revised determinations or decisions to the Part D plan sponsor. We did not receive any public comments on the proposed provision, and accordingly, are finalizing this provision without modification.

3. Effect of a Revised Determination or Decision (§ 423.1984)

In section 423.1984, we proposed that the revision of a coverage determination or appeal decision is binding unless the determination or decision is appealed and the appeal request is accepted and processed in accordance with the appropriate regulatory provisions. We also proposed to allow only the portion of the coverage determination or appeal decision revised by reopening to be appealed. We did not receive any comments on this section. Therefore, we are finalizing § 423.1984 without modification.

4. Good Cause for Reopening (§ 423.1986)

We proposed in § 423.1986 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 proposed 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 proposed 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.

A specific comment received and response to comment is as follows:

Comment: We received one comment suggesting the proposed good cause standards for reopening should be revised to allow an ALJ to reopen a decision when third party payor error occurs or there is a change in substantive law or interpretive policy. The commenter believes the ALJ should reopen the decision and review it in light of the third party payor error or new law or policy.

Response: As with other Medicare programs, coverage policies in Part D are applied prospectively. Therefore, the coverage policy that applies for purposes of making a coverage determination is the policy that is in place at the time the drug is purchased. If there is a change in substantive law or interpretive policy and the enrollee is requesting benefits (not reimbursement), § 423.1986(b)(2) allows reopenings to consider such changes. With respect to the commenter's request to amend the proposed rule to allow ALJs to reopen decisions in order to consider third party payor error, we note that the rules in part 405, subpart I, upon which the provisions in question are modeled, do not permit reopenings for this reason. Moreover, we do not believe it is necessary to establish a different policy in the Part D program.

Accordingly, we are finalizing § 423.1986 without modification.

H. Expedited Access to Judicial Review (EAJR) (§ 423.1990)

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. We proposed in § 423.990 to provide Part D enrollees the opportunity to seek EAJR and requested specific comments on this proposal.

Specific comments received and responses to those comments are as follows:

Comment: Commenters stated that providing expedited access to judicial review will benefit many enrollees. The commenters suggested that for those enrollees whose claims do not raise issues that can only be resolved by a federal court, a provision similar to 42 CFR 405.1104 and 42 CFR 405.1132 allowing escalation to the MAC or to federal court should be added for instances when an enrollee has not received a decision in a timely manner from an appeal to an ALJ or the MAC.

Response: As discussed previously, we believe that in addition to providing for expedited access to judicial review, providing a 90-day adjudicatory timeframe with an expedited process similar to the process established at the coverage determination, redetermination, and reconsideration levels more appropriately addresses the concerns of enrollees seeking timely decisions from an ALJ and the MAC. Therefore, we are finalizing § 423.1990 with modifications as discussed in section III of this preamble, which include adding additional regulation text language to specify the various actions that may be taken by the ALJ, removing the words ''final and,'' and changing the word ''days'' to ''calendar days.''

I. Appeals to an ALJ (§ 423.2000 Through § 423.2063)

1. General

The Part D rule contains two specific provisions that apply to appeals before an ALJ. Former § 423.610 (now at § 423.1970) describes an enrollee's right to an ALJ hearing and explains how the amount in controversy requirements may be satisfied. Former § 423.612 (now at § 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 proposed to follow the process set forth under Part A and Part B for appeals to an ALJ, except as noted above and below. We 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. Hearing Before an ALJ (§ 423.2000) and Right to an ALJ Hearing (§ 423.2002)

Section 423.2000 provides an overview of the ALJ hearing process. Former § 423.610(a) (now at § 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 proposed to include this provision in § 423.2002. We also proposed 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 (now at § 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.

We also proposed 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 proposed 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.

In addition, we proposed at § 423.2002(b)(2) 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 below, an enrollee may only file an oral request for an expedited hearing after receiving the written IRE reconsideration notice. We also proposed to require the ALJ hearing office to document and maintain documentation of any oral request.

Specific comments received and responses to those comments are as follows:

Comment: Some commenters stated that provisions of the rule are inconsistent. They pointed out that § 423.1972 requires an enrollee to file a request for a hearing within 60 days of the date of the notice of an IRE decision, while § 423.2002(a) requires an enrollee to file a written request for an ALJ hearing within 60 days after receipt of the written notice of the IRE's reconsideration. Commenters also pointed out that while § 423.2002(a) requires an enrollee to file a written request for an ALJ hearing, § 423.2002(b) allows an enrollee to submit a written or oral request for an expedited ALJ hearing. The commenters ask that the regulations be made consistent so to minimize enrollee confusion. The commenters also asked that enrollees be allowed to file oral requests for expedited hearings before receipt of a written IRE reconsideration when the IRE has not issued the written reconsideration notice within the regulatory timeframes and to be allowed to file oral requests for hearings and MAC review for non-expedited appeals.

Response: We do not believe that these regulations are inconsistent, but rather may require additional explanation. Sections 423.2002(a) and (b)(2) as well as § 423.2014(b) and (c) provide more specificity for the requirement in § 423.1972. Section 423.1972, that is, redesignated section 423.612, was drafted consistent with part 405. At the time of the implementation of § 423.612 there were no regulatorily established adjudication timeframes at the ALJ level. In particular, a regulatorily implemented expedited process that includes oral requests for hearings and a 10-day adjudication timeframe did not exist. In §§ 423.2002(a) and (b) and §§ 423.2014(b) and (c) we clarify that a request for hearing must be filed within 60 days after receipt of a written notice of an IRE reconsideration. We require an enrollee to have a written decision because in some instances the IRE will issue an oral notice of reconsideration before issuing the written notice of reconsideration. The Office of Medicare Hearings and Appeals cannot process a request for an ALJ hearing without a written IRE reconsideration, especially under the constraints of a 10-day adjudication period. This also holds true for review by the Medicare Appeals Council. In both circumstances, a written decision from the lower level is necessary to further process the appeal.

In §§ 423.2002(a)(2) and 423.2014(b), we provide an exception to the provision in § 423.2002(a)(1) that requires an enrollee to file a written request for an ALJ hearing. We permit the enrollee to either file a written or oral request for an expedited ALJ hearing. The ability to submit an oral request for an expedited hearing should help preserve time during the expedited process. We do not believe that the filing of oral requests is necessary in non-expedited appeals because there is not the same urgency with respect to an enrollee's health or function that would necessitate the appeals process to move more swiftly.

Comment: Commenters recommended that the filing timeframe begin with the date of receipt of the IRE decision with the date of receipt presumed to be 5 days after the date of the notice, absent evidence to the contrary. The commenters also called for the regulations to be consistent with part 405 by providing for an extension of the filing timeframe when good cause is shown for a late filing.

Response: The timeframe for submitting a request for an ALJ hearing will begin with receipt of the written notice of the IRE reconsideration. As specified in § 423.2002(c), the date of receipt will be presumed to be 5 days after the date of written reconsideration, unless there is evidence to the contrary.

Section 423.2014(d) provides the enrollee the opportunity to request an extension of the 60-day filing timeframe for good cause. This provision is consistent with § 423.1972(b) and Part 405, subpart I. We did not receive any comments on § 423.2000, and thus, are finalizing this provision consistent with the modifications described in section III of this preamble to clarify that the ALJ conducts a *de novo* review. With respect to § 423.2002, we are finalizing this provision subject to the modification discussed in section III, which changes the word ''days'' to ''calendar days,'' and with a technical revision to § 423.2002(b)(3). The inclusion of the ALJ documentation requirement in subsection (b)(3) was a technical error and the requirement has now been placed in a separate subsection. The requirement that the ALJ must document all oral request for expedited hearings in writing and maintain documentation is now specified in § 423.2002(c) and the proposed subsections § 423.2002(c) and (d) have been redesignated as subsections § 423.2002(d) and (e), respectively.

3. Right to ALJ Review of an IRE Dismissal (§ 423.2004) and Parties to the ALJ Hearing (§ 423.2008)

Section 423.2004 describes the process for obtaining ALJ review of a QIC dismissal of a reconsideration request. Section 423.2008 states who may request an ALJ hearing and who is considered a party to the ALJ hearing. We received no comments on these sections. Accordingly, we are finalizing § 423.2004 with the modifications discussed in section III of this preamble to make a technical correction clarifying an ALJ's dismissal action is binding and not subject to further review unless vacated by the MAC, and changing the word ''days'' to ''calendar days.'' We are finalizing § 423.2008 without modification.

4. Participation in an ALJ Hearing (§ 423.2010)

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 proposed 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.

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 through 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 also 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 proposed 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. We proposed in § 423.2010(c) to 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 also 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 proposed 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 plan 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 proposed these limitations due to the very tight timeframes for expedited appeals.

Specific comments received and responses to those comments are as follows:

Comment: Commenters stated that the regulations provide insufficient time for notification to the enrollee of the participation of CMS, the IRE, and/or the Part D plan sponsor. Some commenters also believe that section 423.2010(a) should include a set timeframe by which the ALJ may request the participation of CMS, the IRE, or a Part D plan sponsor, preferably within 5 days of receipt of the hearing request for a non-expedited appeal.

Response: We believe that the regulations provide sufficient notification to the enrollee of any participation by CMS, the IRE, and/or the Part D plan sponsor and that the ALJ should not be subjected to a timeframe for requesting participation by these entities. Section 423.2010(b)(2) requires an ALJ, in a non-expedited appeal, to notify the enrollee of his or her decision on a request to participate by CMS, the IRE, and/or the Part D plan sponsor within 5 days of receipt of the request. Section 423.2010(b)(4) requires an ALJ, in expedited appeals, to notify the enrollee of his or her decision on a request to participate by CMS, the IRE, and/or the Part D plan sponsor within 1 day of receipt of the request. In both instances, an enrollee will know whether CMS, the IRE, and/or the Part D plan sponsor will be participating prior to the hearing.

The ALJ hearing process is a fluid process. ALJs and their staff conduct reviews of the case file, make requests for additional information and accept additional evidence up to and through the date of the hearing. It would not be beneficial to the hearing process to preclude an ALJ from obtaining valuable information due to a timeframe that has no apparent connection to the preservation of enrollee's rights or the appropriate resolution of an appeal.

We believe that participation by CMS, the IRE, and/or the Part D plan sponsor in ALJ hearings for Part D appeals has been constructed in a manner that allows for the resolution of an appeal more efficiently and appropriately while giving proper consideration to the interests of an enrollee. The participation of CMS, the IRE, and/or the Part D plan sponsor may allow the ALJ to resolve issues of fact and law more quickly, reduce the need for remands for additional factual development, and develop a more complete record. However, keeping with the interests of efficiency and fairness, participation is limited to filing position papers or providing written testimony to clarify factual or policy issues in a case. CMS, the IRE, and/or the Part D plan sponsor cannot be called as a witness, cannot call their own witnesses, and cannot cross-examine the witnesses of an enrollee at the hearing. Additionally, under § 423.2042, an enrollee can review and comment on the record, which would include any position papers and written testimony by CMS, the IRE, and/or the Part D plan sponsor, at the hearing or any time before the ALJ's notice of decision is issued. Finally, under the regulations, the ALJ maintains the flexibility to balance the interests of the enrollee with the interests of CMS, the IRE, and/or the Part D plan sponsor to deny a request to participate.

Comment: A commenter expressed concern about the 1-day timeframe provided to CMS, the IRE, and/or the Part D plan sponsor for requesting to participate in an expedited hearing. The commenter believes that the timeframe is too short and that meeting the timeframe will increase expenses because the only way to meet the timeframe with a written response would be by a process more expensive than regular mail.

Response: Under the expedited process, all applicable timeframes have been significantly reduced to facilitate meeting the 10-day adjudication timeframe. Section 423.1010(b)(3) provides CMS, the IRE, and/or Part D plan sponsor, upon receipt of the notice of hearing, 1 day to request to participate in the hearing. We believe that one day is sufficient time to review the notice of hearing, make a determination on whether to participate, and notify the ALJ. We want to emphasize that § 423.2010(b)(3) allows for requests to participate to be made orally or submitted by facsimile to the ALJ hearing office. Therefore, a request to participate, including a written request, should be able to be submitted timely and without any increased costs.

Comment: Some commenters stated that allowing the ALJ to request CMS, IRE, or Part D plan sponsor participation in an ALJ hearing is inappropriate given that the statute did not provide party status to these entities. The commenters stated that it is unclear why participation by these entities would be necessary or valuable. The commenters believe that such participation will add unnecessary confusion to the hearing, blindside the enrollee, and afford these entities a greater role than they are entitled to under the statute, including the opportunity to behave like a party. The commenters urge CMS to deny these entities the right to participate at

the ALJ hearing. If they are allowed to participate, the commenters believe the regulations should more clearly state that ALJs may not rely on statements made by representatives of CMS, the IRE, or a Part D plan sponsor.

Response: We continue to believe that affording the ALJ the discretion to request and allow participation in a hearing by CMS, the IRE, and/or the Part D plan sponsor provides significant benefit to the appeals process by promoting the efficient and accurate resolution of factual and legal issues and by creating a more complete administrative record in the case. These entities cannot be parties to the proceeding, thus we believe that ALJ's should retain the discretion to determine when requesting or allowing CMS, the IRE, or Part D plan sponsor participation in a hearing would be helpful in resolving the issues involved in the appeal. We disagree with the commenters' suggestion that, even if these entities are allowed to participate in the hearing, the regulations should prescribe that the ALJ may not rely on statements made by representatives of these entities. Establishing such a policy would impede an ALJ's ability to make an independent assessment about the information and evidence presented at the hearing. We also disagree that allowing participation gives these entities the ability to behave like a party to the proceedings. These rules specifically prohibit participants from calling witnesses or cross-examining the witnesses of an enrollee. Participation by CMS, the IRE, or the Part D plan sponsor is intended to be non-adversarial and for the purpose of aiding in the clarification of factual or policy issues.

Accordingly, we are finalizing § 423.2010 subject to the modification discussed in section III, which changes the word ''days'' to ''calendar days.''

5. Request for an ALJ Hearing (§ 423.2014)

The Part D rule formerly at §§ 423.612(a) and (b) (now at §§ 423.1972(a) and (b)) describes how, where, and when to file a request for an ALJ hearing. We proposed to include this requirement in § 423.2014. We also proposed 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.

Former § 423.612(b) (now at § 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, we proposed in § 423.2014 to closely track the language of § 405.1014 regarding the time in which to request a hearing. Additionally, we proposed in §§ 423.2014(a)(1) and (a)(2) to require the telephone number of the enrollee and the appointed representative, if any, in any request for an ALJ hearing. This information would assist the ALJ in quickly contacting the enrollee or the appointed representative, particularly for expedited appeals. Because we proposed to adopt a specific provision to govern requests for ALJ hearings in Part D appeals, we proposed to revise former § 423.612 (now at § 423.1972) to replace the reference to the regulations in part 422, subpart M, with a cross reference to § 423.2014.

Furthermore, we proposed 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 proposed in § 423.2014(a)(7) that an enrollee who seeks an expedited hearing indicate that in his or her request.

As discussed previously, we proposed 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)(2), 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 proposed to require the ALJ hearing office to document and maintain documentation of this oral request.

Similarly, in § 423.2014(d)(2), we proposed 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.

Specific comments received and responses to those comments are as follows:

Comment: We received several comments pertaining to oral requests for an expedited ALJ hearing. One commenter expressed concern about the potential of oral requests for hearing to become lost, and therefore suggested that the ALJ be required to provide prompt written confirmation within two business days that the oral request has been received, along with a consumer friendly explanation of the ALJ appeals process and the enrollee's rights and obligations.

Response: While we agree with the commenter's concern that it is possible for oral requests for hearing to become misplaced; we believe that we have sufficiently addressed this concern in § 423.2002(c) and § 423.2014(b) by requiring the ALJ hearing office to document all oral requests in writing and maintain the documentation in the case files. This procedure is similar to the expedited process established at the coverage determination, redetermination and reconsideration levels.

Considering the expedited timeframe, we do not believe that issuing a notice acknowledging receipt of the oral request will add any benefit to the process. Rather, such a notice may cause confusion because the enrollee will receive notices on whether the request for an expedited hearing was granted or denied and/or a notice of hearing shortly after submission of the request for an expedited ALJ hearing. As to the request for a beneficiary-friendly explanation of the process and notification of the enrollee's right and obligations, we believe that the enrollee will be provided with all the necessary information through the notice of IRE reconsideration, the ALJ hearing notice, and interaction with ALJ staff. Accordingly, we are finalizing our proposals subject to the modification discussed in section III, which changes the word ''days'' to ''calendar days.''

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

As discussed above, we proposed to apply a 90-day adjudicatory timeframe to Part D appeals with an expedited process for certain types of appeals. Specifically, we proposed 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 proposed 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 proposed that the ALJ rule on a request for expedited hearing within 5 days of receiving the request. If the ALJ grants the request for expedited hearing, the ALJ will promptly provide the enrollee with oral notice of the decision and subsequently provide written notice of the decision, likely through the notice of hearing. We proposed in § 423.2016(b)(5), that in a granted 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.

If the ALJ denies a request for an expedited hearing, the ALJ will provide prompt oral notice explaining 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 proposed in § 423.2016(b)(4), that a decision on a request for an expedited hearing cannot be appealed to the MAC.

Although the standard and expedited timeframes for the issuance of a written decision are somewhat longer than at the lower levels, we believe they are appropriate. The ALJ hearing is more complicated than the IRE reconsideration because it involves the scheduling and conducting of a hearing. The hearing entails the presentation of evidence including testimony by the enrollee and witnesses, which necessitates a longer adjudication period.

Specific comments received and responses to those comments are as follows:

Comment: Many commenters appreciated the establishment of regulatory adjudication timeframes for Part D appeals at the ALJ and MAC levels. One commenter, however, requested shorter timeframes for both standard and expedited appeals, proposing 45- to 60-day timeframes for standard appeals and 72 hour timeframes for expedited appeals. One entity stated that it supported the proposed 5-day adjudication timeframe for expedited appeals, but noted that the timeframe conflicted with the 10-day expedited adjudication timeframe stated in the preamble.

Response: The 90-day adjudication timeframe for standard appeals is consistent with the statutory and regulatory instruction to apply Part 405, subpart I to Part D appeals, as appropriate. Part 405, subpart I establishes a 90-day adjudication period for Parts A and B appeals. Standard Part D appeals do not have characteristics that would justify deviating from the statutory and regulatory guidance or that would justify treating them differently than standard Parts A and B appeals relative to the adjudication timeframe.

We have established an expedited adjudication timeframe for Part D appeals in situations where 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 or other prescriber 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 or 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.

An ALJ or the MAC will always strive to resolve an appeal as expeditiously as the enrollee's health requires. The 10-day timeframe, which is the maximum time period for expedited appeals, takes into account such factors as federal agencies operating only on business days, receiving the case file from the previous adjudicating entity, complying with all notice requirements, scheduling and holding a hearing, and issuing a written decision.

The 5-day timeframe alluded to by one of the commenters is for ruling on a request for an expedited hearing. The timeframe provides an ALJ with sufficient time to review all the evidence and render an appropriate decision. As a practical matter, the timeframe is truly inconsequential to the enrollee because an ALJ must issue a decision as expeditiously as the enrollee's health condition requires or no later than within the applicable adjudication period. The 10-day expedited adjudication period and 90-day standard adjudication period begin on the day the request for hearing is received. *See* §§ 423.2016(a)(1), (2) and (b)(5)(i) and (ii). Therefore, the time it takes for an ALJ to issue a decision on a request for an expedited hearing will always count towards the applicable adjudication period. For instance, if an ALJ took 5 days to grant a request for an expedited hearing, then the ALJ would only have 5 more days to issue a decision before the applicable 10-day adjudication period expired. This would similarly hold true if the request for an expedited hearing is denied. If the request was denied on the 5th day, then there would be 85 days left in the standard adjudication period.

Accordingly, we are finalizing our proposals subject to the modification discussed in section III, which changes the term ''days'' to ''calendar days.''

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

We proposed in § 423.2018 to adopt concepts from § 405.1018 regarding when an enrollee must submit written evidence. However, we also proposed in this section to permit an enrollee to submit any written evidence that he or she wishes to have considered at the hearing. An ALJ will not consider any evidence submitted regarding a change in the enrollee's condition after the coverage determination was made. As explained above in section IV., D., under the provisions of this final appeals rule, if an enrollee wishes such evidence to be considered, the ALJ will remand the case to the Part D IRE. *See* §§ 423.2034(c), 423.2126(b).

Specific comments received and responses to those comments are as follows:

Comment: We received several comments regarding the timeframes proposed for the enrollee to submit all written evidence to be considered at the hearing. These timeframes require the enrollee to submit evidence within 10 days, for standard appeals, and 2 days, for expedited appeals, of receiving the notice of hearing. Several commenters advised that the proposed regulations are supposed to, but do not mirror the regulations in part 405, which state that the timeframes for admission of evidence do not apply to oral testimony given at a hearing or to evidence submitted by an unrepresented beneficiary. The commenters contend that ''unrepresented beneficiary'' includes beneficiary advocates, who are often not contacted by the beneficiary soon enough to enable compliance. The commenters believe that there should be

no time constraints on the enrollee's ability to submit evidence.

Response: We disagree with the comments that the proposed provisions must be exactly the same as the parallel provisions in part 405. As contained in § 423.562(c) and as discussed in the proposed rule, we will apply the provisions of Part 405 to Part D appeals at the ALJ level with appropriate modifications to meet the needs of Part D appeals.

In § 423.2018 we are adopting concepts from § 405.1018 regarding when an enrollee must submit written evidence. We have proposed 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 the 2-day timeframe provides the adjudicator sufficient time to review all evidence submitted before the hearing and issue a decision as expeditiously as the enrollee's health condition requires or within the 10-day adjudication period.

In response to the comment, we have modified the 10-day timeframe in non-expedited appeals to apply to only represented enrollees. We believe this is more appropriately consistent with part 405. As the commenter noted, the timeframe requirements for the submission of evidence do not apply to unrepresented beneficiaries in part 405. We agree with the commenter that the same exception should apply to unrepresented enrollees in non-expedited appeals. Accordingly, we have revised § 423.2018(b) to include this exception and to make clear that the 10-day timeframe only applies to represented enrollees.

Finally, we also note that ''unrepresented beneficiary'' does not include beneficiary ''advocates.'' Section 423.560 states that an enrollee may have an appointed or authorized representative act on his or her behalf, but does not provide any role or rights for an ''advocate'' in the appeals process.

Therefore, § 423.2018 is finalized with the modification exempting unrepresented enrollees from the 10-day evidence submission timeframe for non-expedited appeals, and subject to the modification discussed in section III, which changes the word ''days'' to ''calendar days.''

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

Former § 423.612(b) (now at § 423.2020(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 proposed 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 proposed 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 also proposed 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.

Specific comments received and responses to comments are as follows:

Comment: We received several comments regarding the rescheduling of hearings. The commenters stated that, although the good cause examples listed in § 423.2020(g)(3) for requesting the rescheduling of a hearing are not all-inclusive, experience has shown that the examples are often regarded as all-inclusive. The commenters suggested that the provision be more explicit in stating that the examples listed are not the only acceptable situations in which good cause can be found.

Response: Section 423.2020(g)(3) is consistent with the parallel provision in Part 405, § 405.1020(g)(3). Further, the provision clearly states that the good cause examples are not an all-inclusive list. Accordingly, we do not believe the provision requires additional clarification.

Accordingly, § 423.2020 is finalized consistent with the modifications discussed in section III of this preamble, which change the term ''days'' to ''calendar days,'' and provide clarification that when an enrollee's request for an in-person hearing is granted, the ALJ must issue a decision within the adjudication timeframe specified in § 423.2016 (including any applicable extension provided in this subpart), unless the enrollee agrees to waive the adjudication timeframe in writing.

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

We proposed 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. We also proposed 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 proposed in the same provision that expedited hearing notices be mailed or served at least 3 days before the hearing.

A specific comment received and response to comment is as follows:

Comment: A commenter suggested that the ALJ hearing office be required to notify potential hearing participants by fax and/or telephone of an ALJ hearing, particularly in the event of an expedited appeal.

Response: Section 423.2022(a)(1) requires the notice of hearing to be either mailed or otherwise transmitted, or given by personal service. For expedited appeals, § 423.2022(a)(2) provides that notice may also be provided orally followed by an equivalent written notice within one day of the oral notice. If a party or participant indicates a preference for receipt of the notice of hearing by a particular method, we believe that section 423.2022 provides sufficient flexibility for the notice of hearing to be mailed or served by various means, including facsimile and e-mail. We believe that the inherent flexibility of § 423.2022 allows the ALJ hearing process to appropriately adapt to technological advancements and enrollee and participant preferences. Requiring the notice of hearing to be provided in a limited manner would be contrary to our goal of providing flexibility to this process and would not be conducive to an efficient and beneficiary-friendly hearing process.

We are making a technical correction to clarify that other potential participants may also indicate in writing that he or she does not wish to receive notice of a hearing before an ALJ. We are finalizing this provision with this technical correction, and subject to the modification discussed in section III, which changes the term ''days'' to ''calendar days.''

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

We proposed 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 proposed 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 sections, we proposed that the ALJ document all oral objections or requests in writing and maintain the documentation in the case files.

We received no comments on §§ 423.2024 and 423.2026, and therefore, are finalizing them subject to the modification discussed in section III, which changes the word ''days'' to ''calendar days.''.

11. ALJ Hearing Procedures (§ 423.2030) and Issues Before an ALJ (§ 423.2032)

Section 423.2030 establishes general procedures for ALJ hearings, including the procedures that apply when an ALJ determines that there is material evidence missing at the hearing. In § 423.2032 we discuss the types of issues that an ALJ may consider at a hearing, the conditions under which an ALJ may consider new issues at a hearing, and the restrictions imposed on adding new claims to pending appeals. We received no comments on these sections and, therefore are finalizing them without modification.

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

We proposed 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. We proposed 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. However, as discussed in greater detail above in section IV.D., we have revised § 423.2034(c) to require the ALJ to remand a case to the appropriate Part D IRE if the enrollee wishes to have evidence of a change in condition considered. Accordingly, § 423.2034 is finalized with the modifications specified above and that discussed in section III of this preamble, which clarifies when an ALJ can remand a case to the IRE based on missing information.

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

We reviewed the language in § 423.1036 to determine whether to incorporate similar language in proposed § 423.2036. In general, we follow the procedures set forth in 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, wavier 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 proposed 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 proposed to allow an enrollee to withdraw his or her waiver in writing. We also proposed 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. We proposed 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 Part D plan sponsor is made. We have finalized this provision, but have modified proposed § 423.2036(e) by requiring the ALJ to remand the case to the appropriate Part D IRE as set forth in § 423.2034(b)(2).

We also proposed 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, section 1860D–4(h)(1) of the Act states ''only the Part D eligible individual'' is entitled to bring an appeal under Part D. We believe this statutory language prohibits CMS, the IRE, and the Part D plan sponsors from obtaining party status at an ALJ hearing. Thus, we proposed that only an enrollee may be a party, and therefore, Part D appeals will not be adversarial in nature. Accordingly, we also proposed not to apply to Part D appeals the provisions in § 405.1036(f), which address subpoenas issued at the request of a party, and § 405.1037, which address discovery. However, in the limited circumstances described in section 423.2036(f), we proposed to allow an ALJ to issue a subpoena on his or her own initiative 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. We believe this policy will ensure that an ALJ is able to obtain information relevant to an appeal because these entities have access to the documents and records, such as medical records and plan formularies and marketing materials, that are needed in Part D appeals.

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).

Specific comments received and responses to those comments are as follows:

Comment: We received several comments regarding an ALJ's authority to request expert testimony. Commenters suggested that the regulations should provide an ALJ with the authority to request expert testimony from outside medical professionals who are not connected in any way with CMS, the IRE, or the Part D plan sponsor. Numerous commenters also disagreed with our decision not to allow a party to request that the ALJ issue a subpoena in a Part D appeal. The commenters advised that some physicians are reluctant to provide medical records or to participate in the hearing because of the already burdensome nature of the appeals process in Part D cases. Therefore, the ability to request a subpoena may be necessary in order to protect a beneficiary's right to present evidence and state his or her position at the hearing.

Response: The regulations clearly provide an ALJ with authority to request

expert testimony, including medical expert testimony from individuals unassociated with CMS, the IRE, or Part D plan sponsors. As mentioned in § 423.2000(f), if an 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 the testimony. This authority is made even more clear under § 423.2036(f)(1). Section 423.2036(f)(1) states that, ''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.'' This provision grants an ALJ the authority to subpoena medical experts to testify, and addresses the commenters' concerns about physicians reluctant to provide records or testify.

In the event that a physician or other prescriber is reluctant to provide medical records or is unwilling to participate in a hearing, an ALJ has the authority to subpoena the records or the testimony of the physician or other prescriber. Of course, the issuance of a subpoena in such circumstances can only be done by the ALJ on his or her own initiative and only when the ALJ has determined that the information is reasonably necessary for the full presentation of the case.

We continue to believe that the ability for an enrollee to request that the ALJ issue a subpoena is not appropriate in Part D appeals. As set forth in § 405.1036(f), requests for subpoenas by a party are limited to instances where discovery has been sought. Discovery is permissible under part 405 only when CMS and/or its contractors are a party to the ALJ hearing. In Part D appeals, only an enrollee may be a party to the hearing. As such, Part D appeals will not be adversarial in nature, and therefore, the ability for a party to request a subpoena is unnecessary.

Therefore, § 423.2036 is finalized consistent with the modifications described in section III of this preamble, which change the term ''days'' to ''calendar days,'' and make a technical correction to clarify that the ALJ may not issue a subpoena to CMS or the IRE to compel an appearance, testimony, or the production of evidence, or to the Part D plan sponsor to compel an appearance or testimony.

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

We proposed 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 proposed 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 proposed that the ALJ document all objections or requests in writing and maintain the documentation in the case files.

Finally, we proposed 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). We received no comments on these provisions. Therefore, we finalize § 423.2038 without modification, and § 423.2040 subject to the modification discussed in section III, which changes the word ''days'' to ''calendar days.''

15. The Administrative Record (§ 423.2042)

Section 423.2042 explains the requirements applicable to the creation of the administrative record of the ALJ proceedings, and for requesting and receiving copies of the administrative record.

Specific comments received and responses to those comments are as follows:

Comment:

One commenter stated that the costs for obtaining a copy of the administrative record unfairly impact enrollees who cannot afford to pay for a copy of the record. The commenter suggests revising the proposed regulation to allow each enrollee to receive one free copy of his or her administrative record. As an alternative, the commenter suggests adding regulatory language allowing any enrollee who can show he or she is unable to afford a copy of the administrative record to receive one free copy.

Response: The requirements contained in proposed § 423.2042 were carried over from, and are consistent with, the requirements contained in § 405.1042. As the commenter notes, there may be a cost associated with producing a copy of the administrative record for parties who request it. As a general matter we do not believe that a regulatory change to direct this cost to the appeals adjudicators is necessary or appropriate. The regulations do not require an ALJ to charge an enrollee a fee to copy the record, but rather state that the enrollee may be asked to pay the costs of providing such copies. Thus, an enrollee may ask an ALJ to waive any suggested fee based on financial hardship or for any other reason. Also, we do not have any evidence suggesting enrollees are encountering any difficulties requesting copies of case files.

Comment: We received a related comment asking us to amend the regulation to allow Part D plan sponsors, the Part D IRE, or CMS to request a copy of the administrative record. The commenter suggests that receipt of the case file would assist Part D plan sponsors, the IRE, and CMS in making requests for own motion review by the MAC and would also afford participants an opportunity to review the record for accuracy.

Response: We agree with the commenter's assessment that entities making referrals for own motion review should have access to case files when making these determinations. However, we believe the suggested revision is unnecessary. CMS and the IRE are the only entities that may refer cases to the MAC for own motion review under § 423.2110. The Part D IRE is able to access Part D appeals case files because it is the final repository for all such files. In addition, CMS has access to Part D case files as a result of its contracting relationship with the Part D IRE. Thus, the entities responsible for referring cases to the MAC currently have access to any Part D case file that may be referred to the MAC for own motion review. Additionally, § 423.2046(a)(4) requires ALJs to send a copy of the decision to both the IRE that issued the reconsideration and the Part D plan sponsor that issued the coverage determination. To the extent a Part D plan sponsor wants additional information related to the ALJ hearing, it may contact the IRE to request such information. For these reasons, we believe it is unnecessary to revise the proposed regulations to allow Part D plan sponsors, the Part D IRE, or CMS to request a copy of the administrative record.

Accordingly, we are finalizing § 423.2042 without modification.

16. Consolidation of a Hearing Before an ALJ (§ 423.2044)

Section 423.2044 describes the requirements applicable to holding a consolidated hearing before the ALJ. We received no comments on this section and, therefore are finalizing it subject to the modification discussed in section III, which changes the term ''days'' to ''calendar days.''

17. Notice of an ALJ Decision (§ 423.2046) and the Effect of an ALJ's Decision (§ 423.2048)

We proposed 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 did not propose to include language from § 405.1046(a) regarding overpayment cases involving multiple beneficiaries because Part D appeals do not involve overpayments. We proposed 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.

In § 423.2048, we also proposed to follow the policy established in § 405.1048 which explains the effect of an ALJ decision on all parties to the hearing.

Specific comments received and responses to those comments are as follows:

Comment: We received several comments concerning the notice of an ALJ decision. The commenters suggested that § 423.2046(a)(3) include a requirement that a copy of the ALJ decision also be mailed to the enrollee's representative, if one has been appointed. The commenters advised that including this requirement will allow advocates to better assist beneficiaries, saving time and potential confusion.

Response: We believe that the commenters' concern has already been adequately addressed. Section 423.560 defines the rights and responsibilities of an appointed representative. This provision provides an individual either appointed or authorized by State law or other applicable law with all the rights and responsibilities of an enrollee in obtaining a coverage determination and in dealing with any of the levels of the appeals process, including the right to receive a copy of the ALJ decision. Moreover, it has been the standard practice of OMHA and the MAC to send copies of decisions to all appropriately appointed representatives.

Accordingly, we finalize §§ 423.2046 and 423.2048 consistent with the modifications described in section III of this preamble. With respect to § 423.2046, the modifications replace the term ''final'' with ''binding on the Part D plan sponsor,'' and change the word ''days'' to ''calendar days.'' In § 423.2048, the modification replaces the phrase ''issues a final action'' with ''issues a final decision or remand order.''

18. Removal of a Hearing Request From an ALJ to the MAC (§ 423.2050)

In § 423.2050 we explained the process for the MAC to assume responsibility for holding a hearing if a request for hearing is pending before an ALJ. We did not receive any comments on this section. Therefore, we are finalizing § 423.2050 without modification.

19. Dismissal of a Request for Hearing Before an ALJ (§ 423.2052) and Effect of a Dismissal of a Request for a Hearing Before an ALJ (§ 423.2054)

We proposed 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 proposed to shorten the timeframes for expedited appeals in two instances.

First, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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. In proposed § 423.2054 we explained the effect of a dismissal of a request for ALJ hearing.

Section 423.2052 is therefore finalized consistent with the modifications discussed in section III of this preamble, which replace the word ''final'' with ''binding,'' and change the term ''days'' to ''calendar days.'' We did not receive any comments on § 423.2054 and therefore finalize it without modification.

20. Applicability of Policies Not Binding on the ALJ and MAC (§ 423.2062) and Applicability of Laws, Regulations, and CMS Rulings (§ 423.2063)

In § 423.2062, we proposed that ALJs and the MAC give substantial deference to CMS program guidance, and if they decline to follow such guidance provide an explanation for why the policy is inapplicable. We also proposed that such a determination had no precedential effect.

In § 423.2063, consistent with § 405.1063, we proposed that CMS Rulings be binding on all CMS components and on all HHS components that adjudicate matters under CMS' jurisdiction.

We received no comments on these sections. Therefore, we finalize § 423.2062 without medication and § 423.2063 consistent with the modifications described in section III of this preamble, which clarify the additional authorities that are binding on ALJs and the MAC.

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

1. General

The Part D rule includes one provision concerning MAC review. Former § 423.620 (now at § 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 proposed 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 proposed to adopt a specific provision to govern requests for MAC review in Part D appeals, we proposed to revise former § 423.620 (now at § 423.1974) to replace the reference to the regulations in part 405, subpart I, with a cross reference to § 423.2102.

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

Former § 423.620 (now at § 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 proposed to include this requirement in § 423.2100. We proposed 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 proposed language in § 423.2100(c) establishing the 10 day adjudicatory timeframe for expedited reviews.

We received no comments on this section. Therefore, we have finalized § 423.2100 consistent with the modifications described in section III of this preamble, which clarify the specific types of actions that may be taken by the MAC, and change the word ''days'' to ''calendar days.''

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

We proposed 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 at § 423.2102 because it would help the enrollee and any representative of the enrollee to understand how to file a request for MAC review, how the date of receipt of the request would be determined, and when a request would be considered filed. We also proposed 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.

We proposed at § 423.2102(a)(2)(i), 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 proposed 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 proposed 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.

We received no comments on this section. Therefore we are finalizing our proposed policies subject to the modification discussed in section III, which changes the word ''days'' to ''calendar days.''

4. Where a Request for Review May Be Filed (§ 423.2106)

In § 423.2106 we proposed to follow similar requirements in § 405.1106(a). We received no comments on this section. Therefore we are finalizing § 423.2106 without modification.

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

We proposed 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 proposed in § 423.2108(d) an expedited process for certain types of appeals. We proposed 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 proposed that the MAC may consider this standard as met if a lower level of adjudicator has granted a request for an expedited appeal.

We proposed in § 423.2108(d)(3)(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 proposed in § 423.2108(d)(3)(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 proposed to use these resources to process the expedited appeal.

If the MAC accepts the request for expedited review, we proposed 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.

We received no comments on this section. Therefore, we are finalizing these proposals subject to the modification discussed in section III, which changes the term ''days'' to ''calendar days.''

6. 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 proposed 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-part 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 proposed 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 plan sponsors, we believe that limiting own motion referrals to CMS and the Part D IRE is a more streamlined and efficient approach.

We also note that CMS Ruling (CMS–4083–NR) is superseded by these final regulations.

Specific comments received and responses to comments are as follows:

Comment: One commenter is opposed to the proposed language in § 423.2110(a) that precludes Part D plan sponsors from referring cases to the MAC for review on its own motion. The commenter strongly believes that the Part D plan sponsor should be allowed to refer cases to the MAC. It is the commenter's experience that the Part D plan sponsor is more likely than the IRE to participate in the ALJ hearing and in the best position to challenge the evidence considered by the ALJ. Finally, the commenter believes the Part D plan sponsor should be given due process to defend its coverage determination decisions through the ability to refer cases to the MAC.

Response: We do not agree with the commenter's assertion that Part D plan sponsors should be given the ability to refer cases to the MAC in order to properly defend its coverage determination decisions. The Part D plan sponsors make coverage determinations and adjudicate the first level of appeals, redeterminations of coverage determinations. An enrollee dissatisfied with a redetermination decision has a right to a reconsideration by the IRE, and possibly, to higher levels of appeal. As we have explained earlier in our discussion about party status, we believe that only the enrollee may be a party to a Part D appeal. Part D plan sponsors do not have a right to party status at the ALJ level, nor do they have the right to appeal a decision of the IRE to the ALJ level. Rather, those rights lie solely with the enrollee. However, as the administrators of the Part D drug benefit program, we believe the Part D appeals process is designed to provide Part D plan sponsors the ability to protect their interests. In conducting coverage determinations and redeterminations, Part D plan sponsors are afforded an opportunity to provide detailed explanations of the rationale used to support their decisions. Moreover, the Part D plan sponsors are afforded the opportunity to request to participate at the ALJ hearing level. Part D plan sponsors may also communicate with, and provide input to, CMS or the Part D IRE on ALJ decisions that may warrant a referral to the MAC. Further, in this final appeals rule we are clarifying in § 423.1980 that a Part D plan sponsor may request a reopening of a reconsideration, hearing or review. Thus, for the reasons set forth above, we believe the level of participation afforded to Part D plan sponsors is appropriate and adequate to protect their interests.

Comment: Commenters noted that the IRE is the repository of MAC decisions and the decisions are not available to enrollees or their representatives. Commenters expressed concern over the IRE discussing prior MAC decisions in its request for MAC review and making substantive arguments based on those opinions. The commenters urged a provision be added, which requires CMS or the IRE to provide a redacted copy of any prior MAC decision to which the entity cites with a referral memorandum.

Response: We do not agree that § 423.2110 should be revised to include a provision for redacted copies of prior MAC decisions to be included with referral memorandum submitted to the MAC and copied to the enrollee. MAC decisions are not precedential and are unpublished. While the commenters expressed feelings of unfairness that the IRE, as the repository of official administrative records, has access to unpublished MAC decisions, any legal arguments submitted by CMS or the IRE for review by the MAC are contained in the referral memorandum.

Comment: Commenters proposed that requiring the enrollee submitting comments to the MAC in response to an IRE referral memorandum to send the comments to CMS or the IRE is burdensome to unrepresented enrollees who are unlikely to understand their responsibilities and that the regulation should instead provide that the MAC will send copies of comments submitted by unrepresented enrollees to CMS or the IRE.

Response: We do not believe that the regulations preclude the MAC from assisting an unrepresented enrollee by providing CMS or the IRE with a copy of any submitted comments. However, we believe that shifting responsibility to the MAC to provide CMS or the IRE with a copy of comments submitted by any unrepresented enrollee will add to the time it takes to adjudicate the referral for review. We believe that this added administrative processing time to cases of all unrepresented enrollee claims subject to referral is counter to the interest of the enrollee to receive a decision, as expeditiously as possible, from the MAC.

Accordingly, we are finalizing this section consistent with the modifications described in section III of this preamble, which replace the phrase ''remains the final action in the case'' with the phrase ''is binding,'' and change the word ''days'' to ''calendar days.''

7. Content of Request for Review (§ 423.2112)

We proposed to include in § 423.2112 language similar to that in § 405.1112 on content of a request for review. However, we proposed at § 423.2112(a)(4), to require the telephone number of the enrollee to be included in any request for MAC review. This information will assist the MAC in contacting the enrollee, particularly for expedited appeals. Additionally, we proposed in § 423.2112(a)(4) to require the plan name and the enrollee's Medicare health insurance claim number. We also proposed 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 proposed 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 proposed to require the MAC to document and maintain documentation of this oral request.

Specific comments received and responses to those comments are as follows:

Comment: Numerous commenters expressed belief that the content requirements of the request for review are overly rigid for unrepresented enrollees and enrollees represented by family, friends or other untrained advocates. Commenters urged that if the information is incomplete the MAC must be required to contact the enrollee or representative to obtain missing information and not be permitted to dismiss the appeal unless reasonable inquiries have failed. Commenters also suggested that an enrollee should be allowed to amend a MAC request for review to add missing information, as appropriate, as well as a provision allowing liberal leave to amend the request for review to add issues as appropriate when the enrollee subsequently obtains assistance from a trained advocate.

Response: We disagree with the commenters' characterization of the review request content requirements as being overly rigid. The proposed regulation is similar to the requirements at § 405.1112, which have been used successfully since 2005. As a practical matter, we believe the information required by the regulations is important for the efficient and complete retrieval of the ALJ administrative record by the MAC. We note that the standard review request form is included as an enclosure with every ALJ decision or dismissal, and the instructions for this form direct enrollees to submit a copy of the ALJ decision or dismissal with the request for review. In doing so, enrollees can satisfy most of the content requirements for the request for review. Additionally, we believe it is important to state these requirements in the regulations to ensure that if enrollees or appointed representatives choose not to use the standard form, they will nevertheless know up front what information must be included in the request for review.

Finally, we note that the regulation does not preclude the MAC from contacting an enrollee to obtain missing information to correct any defects, which may impede the MAC from obtaining the administrative record or adjudicating the request for review. As for additional listed requirements for the request for review, § 423.2112(c) clearly indicates that if an enrollee is unrepresented, the MAC will not limit its review to the exceptions raised by the enrollee. Also, if an enrollee subsequently obtains assistance from a trained advocate, we believe that § 423.2120 addresses the commenters' concerns that the subsequently obtained advocate be allowed to amend the request for review and add issues by providing the opportunity for an enrollee or representative to file a brief or other written statements.

Accordingly, we are finalizing this section without modification.

8. Dismissal of Request for Review (§ 423.2114)

In § 423.2114, we proposed the process for dismissing a request for review for Part D appeals. The process tracks the Part A and Part B process, except for dismissals involving deceased enrollees. We proposed 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 proposed 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.

Specific comments received and responses to those comments are as follows:

Comment: Commenters stated that if an enrollee dies while the request for review is pending, the current construction of the regulations does not protect the financial interests of the estate of a deceased beneficiary who paid for prescriptions drugs and was seeking reimbursement for those payments. Commenter suggested that the proceedings may be stayed for up to 90 days to provide time for the estate to review the matter and determine whether to continue the appeal. One commenter suggested that any entity with a financial interest, such as if a nonprofit organization advanced money to purchase necessary medications, should be able to pursue the enrollee's appeal upon the death of the enrollee.

Response: As only an enrollee may request review by the MAC, we disagree that any entity should be able to decide to continue the enrollee's appeal. We believe additional entities without appeal rights are protected by allowing a representative appointed by the enrollee to continue the appeal if the representative has a financial interest in the case. We agree with the commenters that an estate of an enrollee who was seeking reimbursement for paid prescription drugs should also be able to continue the enrollee's appeal. Therefore, in response to comments we are finalizing this provision with a revision to § 423.2114(c) to allow for an appeal to continue if the enrollee died while the request for review is pending and the enrollee's estate or representative, if any, has a remaining financial interest and wants to continue the appeal.

9. Effect of Dismissal of Request for MAC Review or Request for Hearing (§ 423.2116), Obtaining Evidence From the MAC (§ 423.2118), and Filing Briefs With the MAC (§ 423.2120)

Section 423.2116 details the effect of the MAC's dismissal of an enrollee's request for review or request for hearing. Section 423.2118 discusses the evidence an enrollee may request from the MAC, while § 423.2120 informs the enrollee how to file a brief. Both of these proposed sections indicated that the opportunities to comment on the requested evidence and to submit a brief do not count towards the MAC's adjudication deadline. The proposed language is similar to language in §§ 405.1116, 405.1118, and 405.1120. We received no comments on these sections. Therefore, we are finalizing §§ 423.2116, 423.2118 and 423.2120 without modification.

10. 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 proposed to follow the procedures for Part A and Part B appeals regarding what evidence may be submitted to the MAC. We proposed in § 423.2122(a)(3) that the MAC would not consider evidence on any change in condition after a coverage determination by the Part D plan sponsor that the enrollee wishes to have considered and would remand such a case to the Part D plan sponsor. We have finalized this provision but, as discussed above, modified the rule to require the MAC to

remand the case to the Part D IRE. Like in § 405.1122, we proposed 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 proposed 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 proposed 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 decision, dismissal order, 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.

A specific comment and our response to the comment is as follows:

Comment: One commenter suggested that, if a participant at the ALJ hearing, CMS, the IRE, or the Part D plan sponsor should be afforded the opportunity to provide written submissions to the MAC.

Response: We believe that since the Part D plan sponsor is not a party to a request for review, it is appropriate to limit submissions by CMS, the IRE and/or the Part D plan sponsor of briefs or position papers to when the MAC determines it is necessary to resolve the issues in the case as proposed under § 423.2120.

Accordingly, we are finalizing this section consistent with the modifications described in section III of this preamble, which clarify that the MAC may not issue a subpoena to CMS or the IRE to compel the production of evidence, and change the word ''days'' to ''calendar days.''

9. Oral Argument (§ 423.2124)

We proposed 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 proposed 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. We received no comments on this section. Therefore we are finalizing § 423.2124 subject to the modification described in section III of this preamble, which changes the term ''days'' to ''calendar days.''

11. Case Remanded by the MAC (§ 423.2126)

We proposed 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 proposed 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. We also proposed 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 Part D plan sponsor considered in the appeal. We are finalizing this provision consistent with the modifications discussed in sections III and IV of the preamble, which remove the word ''final,'' require the MAC to remand the case to the Part D IRE, and change the word ''days'' to ''calendar days.''

12. Action of the MAC (§ 423.2128), Effect of the MAC's Decision (§ 423.2130), and Extension of Time To File Action in Federal District Court (§ 423.2134)

Section 423.2128 informs the enrollee of the actions the MAC will take when reviewing the administrative record, while § 423.2130 informs the enrollee that the MAC's decision is binding unless reopened or if the decision is modified by a Federal district court. Section 423.2130 also notifies the enrollee that he or she may file an action in a Federal district court within 60 days of receipt of the MAC decision. Section 423.2134 details the requirements for filing for an extension of time to file a civil action. The proposed language is similar to language in §§ 405.1128, 405.1130, and 405.1134. We received no comments on these sections. Therefore, we are finalizing §§ 423.2128, and 423.2134 without modification. We are finalizing § 423.2130 subject to the modifications discussed in section III of the preamble, which add the words ''final and'' before the word ''binding,'' and change the term ''days'' to ''calendar days.''

K. *Judicial Review (§ 423.2136 Through § 423.2140)*

The Part D rule includes one provision concerning judicial review. Former § 423.630(a) (now at § 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. Former § 423.630(b) (now at § 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 mount 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, former § 423.630(c) (now at § 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 proposed to follow the language of the Part 405, subpart I, as appropriate. Thus, we 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 proposed to adopt specific procedures for requesting judicial review of final Part D decisions, we proposed to delete the cross-reference to Part 422, subpart M, from former § 423.620(c) (now at § 423.1976(c)) and replace it with a cross-reference to the procedures for requesting judicial review in proposed § 423.2136. We received no comments on these sections. Therefore we are finalizing § 423.2138 without modification, and §§ 423.2136 and 423.2140 subject to the modification discussed in section III of the preamble, which changes the term ''days'' to ''calendar days.''.

L. Miscellaneous

Specific comments to this section and our responses to those comments are as follows:

Comment: One commenter stated that neither existing regulations nor the proposed rule adequately address appeals that may arise when the Part D plan makes a conditional payment under the MSP rules and subsequently demands repayment from the enrollee if the enrollee is subsequently reimbursed by automobile or liability insurance or by worker's compensation. The

commenter also noted that the proposed rule does not adequately address the process to be followed when an enrollee wishes to appeal or reopen a determination that affects both Part C and Part D benefits. The example cited is a situation where an individual is injured in an automobile accident and requires medical care and prescription drugs and the plan makes conditional payments and subsequently determines that Medicare is the secondary payer and demands repayment. The commenter believes the regulations should clarify whether these appeals can be consolidated or whether the enrollee must pursue separate appeals with the possibility of inconsistent decisions.

The commenter further stated that a determination by a Part D plan that a drug is not covered because another payer is or should be the primary payer should be considered an adverse coverage determination subject to appeal by the enrollee. The commenter believes there is a gap in the regulations on the applicability of the enrollee appeals regulations to determinations by Part D plan sponsors under the MSP rules.

Response: If a Part D plan sponsor makes a decision not to provide or pay for a Part D drug, this action is an adverse coverage determination that is subject to the Part D appeals process. If an adverse coverage determination is made based on the Part D plan sponsor's determination that Medicare is not the primary payer under the MSP rules, we agree with the commenter that this adverse decision is subject to the Part D appeals process. We believe the current Part D regulations are sufficiently clear about the application of the MSP rules. Section 423.462 cross-references the MSP provisions of § 422.108 and provides that the MSP procedures apply to Part D sponsors and Part D plans with respect to the offering of qualified prescription drug coverage in the same way they apply to MA organizations and plans.

With respect to the commenter's example of a plan making conditional payments for medical care and prescription drugs and then demanding repayment, we assume that the commenter is referring to this scenario arising in the context of an MA–PD enrollee. We disagree with the commenter's remark that the rules do not adequately address the process to be followed when an enrollee wishes to appeal or reopen a determination that affects both Part C and Part D benefits. The regulations at part 422 and part 423 clearly establish separate, but similar, appeals processes for Part C and Part D benefits, respectively. Since different adjudication timeframes apply based on whether it is a Part C or a Part D benefit, the appeals need to be processed under the applicable procedure and consolidation would not be appropriate.

Comment: One commenter stated that CMS should require the IRE to provide information on the right to request an ALJ hearing in a consumer-friendly format at a 5th grade reading level in multiple languages. This commenter also believes there should be a standard form for the enrollee to use to request review by an ALJ.

Response: All of the IRE's reconsideration decision notices that are not fully favorable to the enrollee contain an explanation of the enrollee's right to request further appeal before an ALJ and describe the process for obtaining an ALJ hearing. These notices are developed by the IRE in a manner calculated to be understood by the enrollee. We will consider the commenter's specific suggestions for future changes to the IRE's contractual obligations in terms of preparing reconsideration notices, although we do not believe this is an appropriate subject for rulemaking. We agree with the commenter's suggestion that a form should be made available for use by enrollees when requesting an ALJ hearing. The Office of Medicare Hearings & Appeals (OMHA) is developing such a form. However, even after such a form is available, any written request for an ALJ hearing that contains the information set out in § 423.2014(a) of this rule will be accepted as a valid request.

V. Comments Beyond the Scope of the Final Rule

In response to the proposed rule, some commenters chose to raise issues that are beyond the scope of our proposals. In this final rule, we are not summarizing or responding to those comments in this document. However, we will review the comments and consider whether to take other actions, such as revising or clarifying CMS program operating instructions or procedures, based on the information or recommendations in the comments.

VI. Provisions of the Final Rule

For the most part, this final appeals rule incorporates the provisions of the proposed appeals rule. The provisions of the final appeals rule that differ from the proposed appeals rule are as follows:

- In response to a public comment requesting that the use of ''calendar days'' be explicitly stated in the applicable regulatory provisions, we revised the regulatory text to include the word ''calendar'' as appropriate.
- We are also making conforming revisions to the Part D grievance, plan sponsor, and IRE provisions to ensure consistency throughout the Part D appeals process, by changing the word ''days'' to ''calendar days'' in 42 CFR 423.564(d)(2), (e)(1), and (e)(2); 423.582(c)(2); 423.584(d)(1) and (d)(2)(i); and 423.600(a).
- In § 423.1978, § § 423.1980(a)(1) and (a)(4), § 423.2004(c), and § 423.2052(a)(6), we made technical clarifications by removing the term ''final'' or ''final and binding'' and replacing it with ''binding'' to clarify that the actions taken by an adjudicator described in the above sections are not considered final decisions of the Secretary for the purposes of exhausting administrative remedies when seeking judicial review in federal court.
- In § 423.1980(b), we made a technical correction by removing the words ''and revise'' from the introductory sentence, so the sentence will now read: ''A Part D plan sponsor may reopen its coverage determination or redetermination on its own motion— * * *''. As discussed in greater detail in the final Part 405, subpart I rule, published elsewhere in this **Federal Register**, this provision, as revised, reflects our longstanding policy that the timeframes for reopening a determination or decision are measured by the date of the reopening, and not the date of the revision of the determination or decision.
- In § 423.1980(e) we are making a technical correction to clarify that a Part D plan sponsor may request that an IRE reopen its reconsideration, or an ALJ or the MAC reopen the hearing decision within 180 days from the date of the reconsideration or hearing decision for good cause in accordance with § 423.1986.
- In § 423.1990(b)(1)(i), we made a technical correction to replace the phrase ''final decision'' with ''decision, dismissal order, or remand order'' to specify the types of actions that if taken by an ALJ, preclude a request for EAJR and to be consistent with our clarification regarding the term ''final''.
- In § 423.1990(b)(1)(ii), we made a technical correction by adding the phrase ''dismissal order, or remand order'' after ''final decision'' to specify the types of action that, if taken by the MAC, preclude a request for EAJR and to be consistent with our clarification regarding the term ''final''.
- In § 423.1990(e)(3), we made a technical correction by removing the words ''final and'' to make clear that the decision of the review entity to certify

or deny a request for EAJR is not subject to further review.

• In § 423.2000(d), we made a technical revision to clarify that the ALJ conducts a de novo review.

• In § 423.2002(b)(3), we made a technical correction separating out the requirement for the ALJ to document oral hearing requests as subsection (c) and redesignated subsections (c) and (d) as subsections (d) and (e) respectively.

• In § 423.2004(c), we made a technical correction to clarify that an ALJ's dismissal action is binding and not subject to further review unless vacated by the MAC under § 423.2108(b).

• We modified § 423.2018(b) in response to public comments to exempt unrepresented enrollees from the 10-day evidence submission timeframe for non-expedited appeals.

• We clarified § 423.2020(i)(4) to state that when an enrollee's request for an in-person hearing is granted, the ALJ must issue a decision within the adjudication timeframe specified in § 423.2016 (including any applicable extension provided in this subpart), unless the enrollee agrees to waive the adjudication timeframe in writing.

• In § 423.2022(a) we made a technical correction to clarify that other potential participants may also indicate in writing that he or she does not wish to receive notice of a hearing before an ALJ.

• In § 423.2034(a) we clarified when an ALJ can remand a case to the IRE based on missing information.

• In § 423.2034(b)(2) and § 423.2126(b) we modified the final appeals rule in response to public comment to direct an ALJ and the MAC to remand a case to the appropriate Part D IRE when the enrollee wants evidence of a change in condition after the coverage determination is made considered.

• In § 423.2036(f)(1) we made technical corrections to clarify that the ALJ may not issue a subpoena to CMS or the IRE to compel an appearance, testimony, or the production of evidence, or to the Part D plan sponsor to compel an appearance or testimony. Similarly, in § 423.2122(b) we made a technical correction to clarify that the MAC may not issue a subpoena to CMS or the IRE to compel the production of evidence.

• In § 423.2046(c), we made a technical correction by replacing the term ''final'' with ''binding on the Part D plan sponsor'' consistent with our clarification regarding the term ''final.''

• In § 423.2048(a), we made a technical correction by replacing the phrase ''issues a final action'' with ''issues a final decision or remand order'' to clarify the types of actions issued by the MAC that cause an ALJ decision to not become binding, and to be consistent with our clarification regarding the term ''final''.

• We added § 423.2063(a) to clarify the additional authorities that are binding on ALJs and the MAC. The original paragraph is reassigned to subsection (b).

• In § § 423.2100(c) and (d), we made technical corrections by replacing the phrase ''final action'' with ''final decision, dismissal order'' to specify the types of actions that may be taken by the MAC and to be consistent with our clarification regarding the term ''final''.

• In § 423.2110(d)(5), we made a technical correction by replacing the phrase ''remains the final action in the case'' with the phrase ''is binding'' to be consistent with our clarification regarding the term ''final''.

• We modified § 423.2114(c) in response to public comments asking us to allow an appeal to continue when the enrollee dies while the request for review is pending and the enrollee's estate has a remaining financial interest and wants to continue the appeal.

• In § 423.2126(a)(1), we made a technical correction by removing the word ''final'' consistent with our clarification regarding the term ''final''.

• In § 423.2130, we made a technical correction by adding the words ''final and'' before the word ''binding'' consistent with our clarification regarding the term ''final''.

VII. 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 Final Rule. In particular, 5 CFR 1320.4 excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment.

VIII. Regulatory Impact Statement

A. Overall Impact

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

Executive Order 12866 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 final appeals 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 $7 million or less in any 1 year. Individuals and States are not included in the definition of a small entity.

This final appeals rule will affect primarily individual's 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 or Federal contractors. 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 final appeals 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 604 of the RFA. For purposes of section

1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule will not have any effect on hospitals. Therefore, the Secretary has determined that this final appeals 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 $133 million. This final appeals rule contains no mandates on State, local, or tribal governments in the aggregate, or on the private sector in the amount of $133 million in any 1 year.

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 final appeals rule will not impose substantial direct requirement costs on State and local governments, preempt State law, or otherwise have Federalism implications.

B. Anticipated Effects

This final appeals 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 procedures do not vary substantially from existing appeals practices. For example, under the existing practices upon which this final appeals rule is largely modeled, 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 are new. Most importantly, we will 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. Although this change will require plans to provide coverage for drugs more quickly whenever enrollees obtain a favorable decision in an expedited appeal, we do not expect it to affect actual spending by Part D and the Medicare program.

The Part D appeals process is administered in large part by the Part D plan sponsors themselves. Our rules require Part D plan sponsors 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 these lower 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 final appeals 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 final appeals rule reflects and builds upon recent changes in the third and fourth levels of appeals process for Part A and Part B claims appeals, published elsewhere in this **Federal Register**. 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 provisions parallel the Part A and Part B provisions, to the extent appropriate. For example, in this final appeals rule we eliminated references to national and local coverage determinations because these policies do not apply to Part D. Likewise, we eliminated 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. In addition, this final appeals rule will simply codify existing practices already in place. Other changes are intended to make the appeals process more flexible and responsive to the needs and circumstances of Part D enrollees. 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 proposed 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.

As of August 2009, total enrollment in Part D plans is about 27 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 $1,180 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 this final appeals 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 the third and fourth levels of the appeals process. While the volume of appeal cases may increase slightly, adopting the procedures outlined in this final appeals rule will benefit enrollees by clarifying the procedures that will apply to these upper levels of 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. In the proposed rule, we solicited public comments on these conclusions.

C. Alternatives Considered

In the proposed rule, we indicated that no major alternatives existed even though we proposed a number of specific provisions and provided justification for each in the preamble. Therefore, we solicited comments on the 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 final 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 amends 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, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

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

■ 2. The heading for Subpart M is revised to read as set forth above.
■ 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.

(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. Section 423.562 is amended by—
■ 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.

§ 423.564 [Amended]

■ 5. Section 423.564 is amended by—
■ A. In paragraph (d)(2), the word ''days'' is removed and ''calendar days'' is added in its place.
■ B. In paragraph (e)(1), the word ''days'' is removed and ''calendar days'' is added in its place.
■ C. In paragraph (e)(2), the word ''days'' is removed and ''calendar days'' is added in its place, and the phrase ''30-day'' is removed and ''30 calendar day'' is added in its place.

§ 423.576 [Amended]

■ 6. Section 423.576 is amended by—
■ 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]

■ 7. Section 423.580 is amended by removing the cross-reference to ''§ 423.634'', and adding in its place the cross-reference to ''§ 423.1978''.

§ 423.582 [Amended]

■ 8. Section § 423.582(c)(2) is amended by removing the phrase ''60-day'' and adding in its place ''60 calendar day''.

§ 423.584 [Amended]

■ 9. Section 423.584 is amended by—
■ A. In paragraph (d)(1), the phrase ''7-day'' is removed and ''7 calendar day'' is added in its place.
■ B. In paragraph (d)(2)(i), the phrase ''7-day'' is removed and ''7 calendar day'' is added in its place.

§ 423.600 [Amended]

■ 10. Section 423.600(a) is amended by removing the word ''days'' and adding in its place ''calendar days''.

§ 423.602 [Amended]

■ 11. Section 423.602(b)(2) is amended by removing the cross-reference to ''§ 423.610'', and adding in its place the cross-reference to ''§ 423.1970''.

§ 423.604 [Amended]

■ 12. Section 423.604 is amended by removing the cross-reference to ''§ 423.612'', and adding in its place the cross-reference to ''§ 423.1972''.

§ 423.610 [Removed and Reserved]

■ 13. Section 423.610 is removed and reserved.

§ 423.612 [Removed and Reserved]

■ 14. Section 423.612 is removed and reserved.

§ 423.620 [Removed and Reserved]

■ 15. Section 423.620 is removed and reserved.

§ 423.630 [Removed and Reserved]

■ 16. Section 423.630 is removed and reserved.

§ 423.634 [Removed and Reserved]

■ 17. Section 423.634 is removed and reserved.

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

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

Sec.

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 calendar 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 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 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 binding determination or decision, even though the binding 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 binding 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 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 of this chapter 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 calendar 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 calendar 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 calendar 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 or a Part D plan sponsor.* (1) An enrollee who received a reconsideration or a Part D plan sponsor may request that an IRE reopen its reconsideration decision within 180 calendar days from the date of the reconsideration for good cause in accordance with § 423.1986.

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

(3) An enrollee who received a MAC decision or a Part D plan sponsor may request that the MAC reopen its decision within 180 calendar 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 or a Part D plan sponsor.* (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, dismissal order, or remand order 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, dismissal order, or remand order 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 calendar 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 calendar 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 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 calendar 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 calendar 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 calendar 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 conducts a de novo review and 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 calendar 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 calendar 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.

(c) The ALJ must document all oral requests for expedited hearings in writing and maintain the documentation in the case files.

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

(e) For purposes of meeting the 60 calendar 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 calendar 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 calendar days after the date of the written dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar 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 binding and not subject to further review. The dismissal of a request for ALJ review of an IRE's dismissal of a reconsideration request is binding and not subject to further review, unless vacated by the MAC under § 423.2108(b).

§ 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 calendar days of receipt of the notice of hearing.

(2) Within 5 calendar 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 calendar day of receipt of the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(4) Within 1 calendar 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 or other prescriber 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 calendar 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 calendar 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 calendar 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 calendar 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 or other prescriber 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 calendar 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 calendar 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 calendar 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 calendar 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 calendar 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 calendar 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 IRE 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, a represented enrollee must submit all written evidence he or she wishes to have considered at the hearing with the request for hearing or within 10 calendar days of receiving the notice of hearing.

(2) If a represented enrollee submits written evidence later than 10 calendar 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.

(3) The requirements of this subsection do not apply to unrepresented enrollees.

(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 calendar days of receiving the notice of hearing.

(2) If an enrollee submits written evidence later than 2 calendar 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 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 calendar days of the scheduled hearing for non-expedited hearings (or 2 calendar 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 ALJ must issue a decision within the adjudicatory timeframe as specified in § 423.2016 (including any applicable extensions provided in this subpart), unless the enrollee requesting the hearing agrees to waive such adjudication timeframe in writing.

(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 or other potential participant indicates in writing that he or she does not wish to receive this notice.

(2) The notice is mailed or served at least 20 calendar days before the hearing, except for expedited hearings where written notice is mailed or served at least 3 calendar 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 calendar 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 calendar days before the hearing, except for expedited hearings in which the enrollee must submit written or oral notice of objection no later than 2 calendar 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 calendar 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 calendar 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.* (1) If an ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS, the IRE, and/or the Part D plan sponsor, then the ALJ may either:

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

(ii) 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.

(2) If the information is not information that can be provided only by CMS, the IRE, and or the Part D plan sponsor, the ALJ must retain jurisdiction of the case and obtain the information on his or her own, or directly from the enrollee.

(3) ''Can be provided only by CMS, the IRE, and/or the Part D plan sponsor'' means the information is not publicly available, is not in the possession of the enrollee, and cannot be requested and obtained by the enrollee. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. It includes, but is not limited to, information available on a CMS, IRE or Part D Plan sponsor website or information in an official CMS or HHS publication.

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

(1) 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.

(2) The ALJ will remand a case to the appropriate Part D IRE 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 IRE as set forth in § 423.2034(b)(2).

(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. An ALJ may not issue a subpoena to CMS, or the IRE to compel an appearance, testimony, or the production of evidence, or to the Part D plan sponsor to compel an appearance or testimony.

(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 calendar 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 calendar 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 calendar 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 calendar 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 calendar 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 calendar 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 calendar 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 calendar 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 binding on the Part D plan sponsor 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 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 90 calendar 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 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 10 calendar 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 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 decision or remand order;

(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) *Dismissal of a request for a hearing.* 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 calendar days for non-expedited hearings and 2 calendar 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 calendar days for non-expedited hearings; the ALJ does not receive the enrollee's response within 2 calendar 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 binding 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) *Discontinuation of a hearing.* 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 laws, regulations and CMS Rulings.

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

(b) CMS Rulings are published under the authority of the 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 decision, dismissal order, or remands a case no later than the end of the 90 calendar 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 calendar 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 decision, dismissal order or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar 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 calendar 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 calendar 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 calendar days after the receipt of the ALJ's written decision or dismissal. A prescribing physician or other prescriber 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 calendar 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 calendar days after receiving the request for review, unless the 90 calendar 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 or other prescriber 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 calendar 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 calendar 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 calendar days of receipt of the request for expedited review;

(ii) Give the enrollee and Part D plan sponsor within 5 calendar 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 calendar day timeframe for non-expedited reviews.

(4) *Decision on a request.* 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 calendar 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 calendar 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 calendar 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 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

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

(5) If the MAC declines to review a decision or dismissal on its own motion, the ALJ's decision or dismissal is binding.

§ 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 estate or 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 CD 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 IRE 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. The MAC may not issue a subpoena to CMS, or the IRE to compel the production of evidence.

(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 calendar 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 calendar 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 calendar days before the scheduled date or, in the case of an expedited review, at least 2 calendar 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 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 calendar 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 IRE.* The MAC will remand a case to the appropriate Part D IRE 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 final and 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 calendar 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 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in § 423.1990, the civil action must be filed within 60 calendar 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 calendar 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 calendar days of the date the enrollee receives the decision of the ALJ or submit a written request for an extension within the 30 calendar day period.

(ii) The MAC will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar 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) of this chapter.

(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 calendar 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 calendar 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 calendar days after the date of the ALJ's written decision, the decision of the ALJ becomes the final decision of the Secretary after remand.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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

Dated: *July 30, 2009.*

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: *November 24, 2009.*

Constance B. Tobias,

Chair, The Departmental Appeals Board.

Dated: *November 24, 2009.*

Irwin Schroeder,

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

Approved: *September 1, 2009.*

Kathleen Sebelius,

Secretary.

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