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Medicare: Policy, Advocacy and Education

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Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-4127-P
P.O. Box 8016
Baltimore, MD 21244-8016.

Re: File Code CMS-4127-P
73 Federal Register 14341 (March 17, 2008)

Submitted electronically: <http://www.regulations.gov>

To Whom It May Concern:

California Health Advocates (CHA) submits the following comments to the above-described proposed rules concerning the application of certain appeals provisions to the Medicare prescription drug appeals process. CHA is non-profit organization dedicated to Medicare beneficiary education and advocacy. We thank you for the opportunity to comment.

COMMENTS ON HIGHLIGHTS AND ORGANIZATION SECTION

We take issue with the statement in the Highlights and Organization section of this notice “that while we are proposing to make confirming changes to the language of some of the redesignated sections, we are not proposing to make any substantive changes to the policies established by these provisions” (Page 14343). This is misleading and disingenuous. While some changes can be appropriately classified as nonconforming, many more of the general appeals provisions changes, especially those to the time frames, submission of evidence, ALJ remand criteria and participants at a hearing, are definitely substantive.

COMMENTS ON OTHER GENERAL COMMENTS SECTION

The notice states in this section (page 14346) that CMS is not including in these regulations enrollment or entitlement appeals, because SSA does not perform appeals regarding enrollment in or entitlement to Part D. If that is so, then what entity does perform these appeals, especially, although not limited to, special enrollment period (SEP) eligibility appeals, and where in the regulations is that addressed? Advocates have had clients who have experienced a continuous run-around when trying to challenge an enrollment or entitlement appeal, with their plan, 1-800-MEDICARE, and sometimes the regional office and/or SSA all claiming they are not responsible. A clear statement of where responsibility lies, and the appeals process to use when the responsible entities do not do their job or when the beneficiary disagrees with the decision, is needed to address these problems.

COMMENTS ON PROVISIONS OF THE PROPOSED REGULATIONS

General comments concerning timeframes for deciding appeals at the ALJ and MAC levels

We have three recommendations in regard to timeframes under the proposed regulations. First, enrollee and advocate experience to date with CMS, IRE and Part D sponsor respect for timelines has been dismal, at best. Clearly, something must be done to improve this situation. A suggestion would be that any request not responded to within the designated time frame be deemed approved and the pharmacist be authorized to fill the prescription.

Second, we ask that CMS specify in the regulations, as is stated on page 14345, that “(a)ll time periods in this proposed rule refer to calendar days.” This is not stated anywhere in the proposed regulations and experience to date has been that weekends and holidays have been excluded in timeframe calculations with unfortunate frequency. Including this statement in the regulations themselves will hopefully provide greater assurance of compliance.

Third, throughout the regulations, expedited determinations should be automatic when there has been an expedited decision at a lower level. The decision whether to expedite has already been made. Another decision should not have to be made at any subsequent level(s). This would be crucial even if there were provisions for escalation; without such provisions, it is essential. This is a practical concern from the perspective of the enrollee. Doctors who have already provided statements to the Part D plan to satisfy the requirements for expedited review, as well as medical statements of the need for the drug in question, are often reluctant to keep providing the same information at each level of review. Asking them to re-submit their statement at the ALJ and the MAC levels of review only adds to their already large Part D paperwork burden.

§ 423.1972 Request for an ALJ hearing; § 423.2002(a) Right to an ALJ hearing

These two provisions of the proposed regulations are inconsistent. Section 423.1972(b) requires a beneficiary to request an ALJ hearing within 60 days of the date on the decision by the Independent Review Entity (IRE). Section 423.2002(a)(1), however, says a beneficiary may request within 60 days after receipt of the written notice of the IRE's reconsideration. Meanwhile, § 423.2002 itself is internally inconsistent. Subsection (b)(2), which addresses requests for expedited ALJ hearings, gives an enrollee 60 days from the date of the IRE notice to request the hearing.

The regulations should be consistent, so as to minimize beneficiary confusion, and should be consistent with the time frames for appeals under Parts A and B. The Part D appeals regulations should include the following elements of the Part A/B appeals regulations: all timeframes for beneficiary appeals should begin with the date of receipt of the IRE's decision, with the date of receipt presumed to be five days after the date of the notice, absent evidence to the contrary. Additionally, the regulations should include the language of the Part A/B regulations that provides for an extension of time for requesting an ALJ hearing for good cause. See 42 C.F.R. § 405.1014 (ALJ); § 405.1102 (MAC).

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

We commend the agency's acknowledgement of the enrollee's right to request a reopening of an unfavorable decision. Upon requesting a reopening, however, many enrollees may believe that the deadline to appeal the unfavorable decision has been extended by their reopening request. This confusion can be devastating – if the request to reopen is denied after the deadline to appeal the unfavorable decision has passed, or if an unfavorable decision is issued upon reopening, the enrollee could lose the right to appeal the claim at issue. For this reason, the regulations should clearly state that a request to reopen extends an enrollee's timeframe to appeal the unfavorable decision and the duration of the extension.

§ 423.1990 Expedited access to judicial review

Providing expedited access to judicial review will benefit many enrollees. However, the proposed regulations currently lack any provision for those enrollees who have appealed to an ALJ or the MAC and have not received a decision in a timely manner, but whose claims do not raise issues that can only be resolved by a federal court. A provision allowing escalation to the MAC or to federal court, similar to 42 C.F.R. § 405.1104 and 42 C.F.R. § 405.1132, respectively, should be incorporated into the Part D regulations.

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

The Part D statute and current rule do not provide for CMS, the IRE, or the Part D sponsor to be a party to the hearing. One has to assume that this is deliberate. The hearing is a non-adversarial forum to allow the plan member, or his or her representative, to present his arguments and position. Allowing the ALJ to request CMS, IRE and/or Part D sponsor participation, or CMS, the IRE and/or the Part D sponsor to request participation in the hearing process - even though not given party status - is thus inappropriate and could be a distinction without a difference. It is also unclear why their participation would be necessary or valuable. Participation will only serve to add unnecessary confusion to the hearing, allow the participant to behave as a party and, even with appropriate advance written notice, which must be made an absolute requirement, blindsides the enrollee.

The experience of advocates to date demonstrates why we are concerned that participation by these entities at an ALJ hearing gives them a greater role than they are accorded under the Medicare statute. Plan sponsors are often represented at ALJ hearings by medical professionals, such as doctors, nurses or pharmacists. Officially, these medical professionals are *participating* in the ALJ hearing as representatives of plan sponsors, and, consequently, no advance notice is given to beneficiaries that any experts will be present at their hearings. Nevertheless, ALJs often turn to these professionals for answers to medical questions that arise during hearings – including general questions (i.e., not pertaining to the particular enrollee’s case) – essentially allowing these plan sponsor representatives to submit expert testimony without any opportunity for the beneficiary to prepare by bringing his or her own expert to the hearing. By allowing them to participate in hearings, ALJs are giving them a greater role than that to which they are entitled, and denying enrollees and their representatives an opportunity to present opposing testimony.

We urge CMS to deny these entities the right to participate at the hearing. If CMS insists on permitting plans to participate, then the regulations should more clearly state that ALJs may not rely on representatives of CMS, the IRE, or a Part D plan sponsor participating in the hearing for expert testimony or information. The regulations should also provide ALJs with the authority to request expert testimony from outside medical professionals who are not connected in any way with the plan, with the IRE, or with CMS. Finally, §423.2010(a) should include a set time frame by which the ALJ may request the participation of CMS, the IRE, or a plan sponsor, preferably within 5 days of receipt of the hearing request for a non-expedited appeal.

§ 423.2016 Timeframes for deciding an appeal before an ALJ

We thank CMS for its decision to extend the 90-day time frame for Part A/B ALJ decisions to decisions concerning Part D cases. We particularly support the decision to provide for expedited hearings and to require decisions to be issued within 10 days. As

CMS acknowledges in the background section, shortened time frames may be critical, particularly where the plan enrollee has not yet obtained a needed prescription.

Section 423.2016(b) says that the ALJ “may consider” the standards for an expedited hearing met if a request for expedited review was granted at a lower level of review. As stated earlier, we ask CMS to require the ALJ to grant expedited consideration to an appeal that has been accorded expedited consideration previously.

§ 423.2018 Submitting evidence before the ALJ hearing

This section requires that an enrollee submit all written evidence to be considered at the hearing with 10 days, 2 days if expedited, of receiving the notice of hearing. These regulations are supposed to, but do not, mirror the regulations in Part 405, which provide that the time frames for admission of evidence do not apply to oral testimony given at a hearing or to evidence submitted by an unrepresented beneficiary—interpreted to include beneficiary advocates who are often not contacted by the beneficiary soon enough to enable compliance. §405.1018. The Medicare A and B rationale is applicable to Medicare D and the same exception for beneficiaries should apply. There should be no limitation on the enrollee’s ability to submit evidence.

This section also provides that, if an enrollee wishes to have evidence about changes in his or her condition since the coverage determination considered in an appeal, the submission of the new evidence will result in a remand of the case to the Part D sponsor. This proposal is a sure recipe for disaster and destined to result in further delay.

In the experience of advocates, plan sponsors routinely fail to abide by relevant appeals rules and regulations, unnecessarily – and sometimes dangerously – lengthening the appeals process for enrollees. For instance, submitted appeals, including appropriately documented requests for expedited appeals, are often not responded to in a timely fashion, ignored, or lost altogether, and plan representatives frequently have no knowledge of submitted appeals and cannot give callers information on their status. Remanding a case to a Part D plan sponsor may be equivalent to sending it into a black hole – and the enrollee may go without medically necessary medication as a result. Much of the new evidence will consist of further deterioration in condition that results from the denial of the prescribed medication. Enrollees experiencing a change of or deterioration in condition should not be further penalized by having to go back to the plan and wait longer for an independent review.

If a remand is required, the case should be remanded to the IRE, rather than the Part D plan sponsor.

If remand is required either to the plan or to the IRE, the regulations should include very strict timelines for responding to an appeal, and, if the timelines are not met, the case should automatically be sent to the ALJ.

It is unclear from these proposed regulations whether submitting evidence of changes in condition in support of a pending appeal and submitting a request for a new coverage determination, which could be faster, are mutually exclusive. We ask for clarification of this issue.

§423.2020 Time and place for a hearing before an ALJ

Although the regulations state that the good cause examples for requesting a rescheduling listed in §423.2020(g)(3) are not all inclusive, advocate experience has shown that they are often regarded as such. We request an explicit statement that the need for more preparation time by a representative appointed within 10 days, or 2 days if expedited, of a hearing or a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing are not the only acceptable situations in which good cause can be found.

§ 423.2022 Notice of hearing

The regulations provide insufficient time for notification to the enrollee of the participation of CMS, the IRE, and or the Part D sponsor for the reason stated above.

§ 423.2034 When an ALJ may remand a case

We reiterate our concerns about remanding a case. We object to a remand to the Part D sponsor. We also urge CMS to include in the regulations specific time frames for deciding a remanded case or for forwarding missing information to the appropriate hearing officer, including the ALJ. At a minimum, the Part D plan sponsor and the IRE should be required to forward missing information within 5 calendar days. The IRE should issue a remanded decision within the same time frame for standard and expedited reconsiderations.

§ 423.2036 Description of an ALJ hearing

We disagree with the decision not to apply to Part D § 405.1036(f), which provides for a subpoena at the request of a party. Despite what CMS indicates, the Part D hearings we have attended are adversarial, even when the IRE and the Part D plan sponsor are considered only “participants” and not parties. As we have stated, beneficiaries may need to bring their own experts to counteract the treatment by the ALJ of the plan representatives as medical experts.

Even if the hearing is not adversarial, subpoena power may still be necessary to ensure access to medical records and ensure participation by the beneficiary’s physician at the

hearing. Again, as we have stated, some physicians are reluctant to provide medical records or to participate in the hearing because of the already burdensome nature of the Part D coverage and appeals process. Beneficiaries in some situations may need to request a subpoena to have the testimony and other evidence they need presented before the ALJ.

§ 423.2046 Notice of an ALJ decision

Section (a)(3) of the proposed regulation provides that a copy of the decision will be mailed “to the enrollee.” We propose adding that a copy of the decision will also be mailed to the enrollee’s representative, if one has been appointed. This will allow advocates to better assist beneficiaries, saving time and potential confusion.

§ 423.2048 The effect of an ALJ’s decision

Chapter 18, Section 130.4 of the CMS Prescription Drug Benefit Manual requires the IRE to monitor plans’ effectuation of any decisions/determinations that fully or partially reverse an adverse coverage determination. In our experience, plans often do not promptly and fully effectuate reversals of adverse determinations. Consequently, monitoring of plans’ compliance with reversals is particularly important. We propose that this responsibility also be set forth in the regulations.

§423.2108 Standard for expedited treatment

As discussed with ALJ review, we urge that §423.2108(d) provide that the MAC “must,” rather than “may,” consider the standard for expedited review met if a lower level of adjudicator has granted a request for an expedited appeal.

§423.2110 MAC reviews on its own motion

We agree with CMS that limiting requests for MAC review of the IRE and excluding plans from making such requests is a reasonable approach that promotes administrative efficiency. We have concerns, however, about the bases for these requests. As noted in the background statement, the IRE is the repository of MAC decisions. Such decisions are not available to enrollees or their representatives. Advocates have seen several situations where the IRE has discussed particular prior MAC decisions in its request for MAC review and has made substantive arguments based on those opinions. This practice denies enrollees the most basic due process rights since they do not even have access to the documents that are being used to argue against their coverage claim. Without such access, an enrollee is unable to determine whether the IRE is accurately characterizing the holding of the MAC or whether the facts of the cited cases are comparable to their

own. The practice also violates the privacy rights of the beneficiaries named in the cited cases, since the IRE memoranda often disclose private medical facts.

We urge CMS to add to the regulation a provision that requires that any case the IRE cites to the MAC must be provided to the enrollee or the enrollee's representative in redacted form and that all references to prior decisions protect the privacy of beneficiaries. If such cases are not provided to the enrollee, the MAC should be precluded from relying upon them in its decision.

Advocates also have seen instances where the IRE has participated in ALJ hearings and cited MAC cases to the ALJ, and not always accurately. We urge CMS to include the same requirement in the regulations governing ALJ hearings as well.

This regulation at §423.2110(b)(2)(iv) also requires that an enrollee submitting comments to the MAC must send the comments to CMS or the IRE. This requirement is a burden on unrepresented enrollees who are unlikely to understand their responsibilities. The regulation should instead provide that the MAC will send copies to CMS or the IRE.

§423.2112 Content of request for review

We are concerned that the current requirements for the content of requests for review are overly rigid for unrepresented enrollees and for enrollees who are represented by family, friends or other untrained advocates. We urge instead that, if the information required in §423.2112(a)(4) is incomplete, the MAC must be required to contact the enrollee or representative to obtain such missing information and not be permitted to dismiss the appeal unless reasonable inquiries have failed. We also are concerned that §423.2112(c) is overly harsh in situations where a request for review is initially filed for an enrollee by a representative who is a friend, relative or other lay advocate and the enrollee subsequently obtains assistance from a trained advocate. To accommodate such situations, we urge a provision allowing liberal leave to amend the request for review to add issues as appropriate.

§423.2114 Dismissal of request for review

CMS is proposing 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 written, the provision does not protect what could be substantial financial interests of the estate of a deceased beneficiary who had paid for prescription drugs and was seeking reimbursement for those payments. When a beneficiary dies, the beneficiary's appointment of a representative, like any power of attorney, expires. Yet, when a reimbursement is at issue, the estate still has a claim against the plan sponsor. Thus the regulation should provide instead that, where a claim is for reimbursement, the proceeding may be stayed for up to 90 days to provide time for the authorized representative of the estate to review

the matter and determine whether to continue the appeal. A similar provision should be added to the provisions covering ALJ hearings.

Sec 423.2122 What evidence may be submitted

We reiterate our comments in the ALJ section opposing the requirement that a case must be remanded to the plan if a beneficiary seeks to have evidence of a change in medical condition considered. This requirement is particularly onerous at the MAC level where, even with expedited treatment, a beneficiary can have been without needed medication for a considerable length of time and the likelihood of a worsening of condition is increased. Low income beneficiaries unable to cover the costs of medication while pursuing an appeal are particularly vulnerable and should not be required to make strategic decisions about whether to forfeit the right to consideration of all evidence, including evidence of a worsening medical condition, in order to get review by the MAC.

COMMENTS ON REGULATORY IMPACT ANALYSIS

In the section entitled *Alternatives Considered* CMS invites comments on additional or alternative reforms that could improve the appeals process further. An immediate response to this invitation is to request that reforms not be limited to the third and fourth levels of appeals only, but that reforms also address the coverage determination, redetermination and reconsideration regulations, such as providing for automatic approval of a coverage request which has not been timely decided.

Thank you for the opportunity to submit comments on this important topic. Please feel free to contact us if you have any questions.

Sincerely

David Lipschutz
Interim President/CEO and Staff Attorney
California Health Advocates