Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: May 15, 2007
Appeal of CMS LCD Complaint: Pneumatic Compression Devices	Civil Remedies CR1534 App. Div. Docket No. A-07-29 Decision No. 2082

REMAND OF
ADMINISTRATIVE LAW JUDGE DECISION

On November 29, 2006, the Complainant filed an appeal of the decision of Administrative Law Judge (ALJ) Keith W. Sickendick, dismissing as untimely filed a complaint challenging the validity of a Local Coverage Determination (LCD) under the federal Medicare program. In re CMS LCD Complaint: Pneumatic Compression Devices, DAB CR1396 (2006) (ALJ Decision). We reverse the dismissal for the reasons explained below, and remand the matter to the ALJ to further develop the record as to whether or when the Complainant received an initial claims denial meeting statutory requirements.

Case background

It is not disputed that the Complainant is an elderly woman who previously had a leg amputated and experiences vascular problems with her remaining leg. RR Attachment at 1-2 (doctor's statement); Contractor Response dated January 23, 2007 (Resp.) at 1. She sought payment for use of a pneumatic compression device. Her first claim for coverage was paid by the contractor but her second claim was denied in February 2006. RR at 1. The contractor reports that its payment of its first claim was in error and has been recouped. Resp. at 1. The contractor asserts that she did not meet the diagnostic criteria for coverage of the

device under LCD No. L11503/Version 8 issued by TriCenturion (the contractor). Id. The contractor also asserts that the criterion specifically challenged here, i.e., that a six-month trial of conservative therapy be attempted before use of the device, is required by a National Coverage Determination (NCD). The relevant NCD is identified as Centers for Medicare & Medicaid Services (CMS) NCD Manual, 100-03, Section 208.6, Pneumatic Compression Devices. On October 19, 2006, the Complainant sought ALJ review of the LCD. The Complainant asks us to overturn the ALJ's dismissal of her complaint as untimely.

Applicable legal authority

Section 1869(f)(2) of the Social Security Act (Act) created a new channel for review of the validity of LCDs issued by Medicare contractors.[1] These challenges address the validity of an LCD policy itself rather than its applicability to particular claims. Only beneficiaries in need of an item or service for which coverage is denied under an LCD may challenge the policy before an ALJ. An ALJ reviewing any LCD is to defer to "reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law" by CMS and its contractors. Section 1869(f)(2)(A)(i)(III) of the Act. This deferential standard is sometimes referred to as the "reasonableness" test or standard. Where the ALJ determines that the LCD record "is incomplete or lacks adequate information to support the validity" of the LCD, the ALJ shall then permit discovery and the taking of evidence before reaching a determination on the validity of the LCD. Section 1869(f)(2)(A)(i)(I) of the Act.

An LCD is issued by a Medicare contractor in a particular region and applies the medical necessity standard for that region but is not binding beyond the issuing contractor. By contrast, an NCD is issued by CMS itself and is binding nationwide. In reviewing appeals of specific claims denials (a process separate from this review of the LCD policy's validity), an ALJ is not bound by an LCD, but is bound by all applicable NCDs. 42 C.F.R. § 405.1062(a).

An LCD applying the medical necessity standard is not binding beyond the issuing contractor, whereas a national coverage determination (NCD) issued by CMS is binding nationwide and can

[1] Section 1869(f) was added to the Act by section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

be challenged only through the NCD appeal process set out in section 1869(f)(1) of the Act.

Procedural regulations governing the ALJ LCD review process and the appeal process to the Board are set out at 42 C.F.R. Part 426. Section 426.400(b) of those regulations provides as follows:

> (b) *Timeliness of a complaint*. An LCD complaint is not considered timely unless it is filed . . . within –
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> (1) 6 months of the issuance of a written statement from each aggrieved party's treating practitioner, in the case of aggrieved parties who choose to file an LCD challenge before receiving the service; or
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> (2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an LCD challenge after receiving the service.

Section 426.444(b)(2) provides that an ALJ "must dismiss any complaint concerning LCD provision(s)" in any case where the "complaint is not timely" under section 426.400(b).

Standard of Review

The Board reviews ALJ decisions on LCD appeals to determine whether the ALJ decision contains any material error. 42 C.F.R. § 426.476(b). Harmless error is not a basis for reversing an ALJ decision under the regulations. 42 C.F.R. § 426.472(b)(4).

Analysis

The ALJ Decision dismissed the complaint as not timely filed. ALJ Decision at 2-3. The ALJ explained that the complaint was dated October 19, 2006. In her complaint, Complainant indicated that she has received the service and she attached to the complaint a copy of the initial claim denial, dated February 22, 2006. The ALJ therefore concluded that the Complainant was seeking a post-service review to which section 426.400(b)(2) applied. Since October 19, 2006 is clearly substantially more than 120 days from February 22, 2006, the ALJ concluded that he had "no option but to dismiss the complaint." Id. at 2.

In requesting review of the ALJ dismissal, Complainant argues that she was not made aware that her claim was denied because of the challenged LCD provision until October 2006.[2] Complainant's Request for Review (RR) at 1. She explains that information about the reason for the denial was in a letter dated May 7, 2006 which "must have been lost in the mail," until it was furnished to her by the CMS Regional Office at some time in October 2006. Complainant also suggests that her appeal actually began on March 26, 2006 when she sought an explanation for the denial from 1-800-Medicare and also sent a letter to the contractor. She also expresses frustration about being denied an appeal on grounds of timeliness in light of her difficulty in obtaining prompt information from Medicare and in light of her age and disability.

We cannot but be sympathetic to the Complainant's ill health and advanced age. As the ALJ noted, however, neither he nor the Board has discretion to accept a complaint filed after the time set in the regulations. The language used in the regulation is mandatory, i.e., the ALJ "must" dismiss untimely complaints. It is clear that the choice of mandatory language was intentional since the first subsection of the same regulation lists situations in which an ALJ "may" dismiss a complaint. 42 C.F.R. § 426.440.[3]

We turn, therefore, to the Complainant's arguments that the complaint was not untimely. She suggests that the date triggering her appeal period should be the date on which she understood that the LCD was the reason for the denial of coverage. The time period in which to challenge an LCD begins, for those who have already received the service at issue, is specified in the regulation as the date of the "initial claim denial." 42 C.F.R. § 426.400(b)(2).

The statute sets specific requirements, however, for the content of an initial determination denying a claim for benefits.

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[2] Complainant's complaint was dated October 19, 2006. She obviously was aware by that date that the contractor was relying on an LCD. She does not state there when she learned of the applicable LCD, although she does state that she was originally given a different reason for the denial and that "yesterday the Chicago CMS office informed me they need the six-month trial." Notice of Appeal (Oct. 19, 2006) at 1.

Section 1869(a)(4) of the Act. Among other things, that section of the Act provides that –

> (A) the written notice on the determination shall include –
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> > (i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used. . . .

A beneficiary receiving an initial denial notice is then entitled to be provided "upon request, information on the specific provision of the policy, manual, or regulation used . . . ." Section 1869(a)(4)(C) of the Act. This requirement that an initial claims denial include notice of whether an LCD was used is implemented in regulations as well. 42 C.F.R. § 405.921(a)(2)(i).

In this case, the document submitted as the initial claims denial merely states that the "information provided does not support the need for this service or item." Complaint, Attachment 3, at 3 (Medicare Summary Notice, dated Feb. 22, 2006). The February 22, 2006 Medicare Summary notice contains no reference to the use of any LCD in denying the claim. It is, thus, evident that the document as it appears in the record does not meet the statutory requirements to serve as an initial claim denial.

The Complainant did not identify this defect to the ALJ. As a consequence, the ALJ did not develop the record as to whether this document constituted the only claims denial determination provided to the Complainant. We are therefore remanding this matter to the ALJ. The ALJ may take further evidence to determine whether and when the Complainant received a notice of denial of her claim that included a statement that an LCD was used in the denial process. Her period to file a timely complaint would then run from that date. In addition, the ALJ may wish to request that CMS participate to further clarify the record.

There also appears to be a factual dispute in the record about whether the Complainant had been informed, before she obtained the device on a monthly rental basis, that Medicare would not provide coverage. The contractor asserts that an advance beneficiary notice (ABN) was provided by the supplier. Resp. at 1; see also Complaint, Attachment 3, at 3. An ABN would have warned the Complainant that Medicare payment was not anticipated and that she might be responsible for the costs. In her letter of March 26, 2006 to the contractor, the Complainant denies that

she "was informed in writing before receiving the unit that Medicare would not pay," and asserts that the supplier directly billed Medicare "with the anticipation that it would be paid." Complaint, Attachment 3, at 1. The ALJ did not resolve this dispute since it was not relevant to the timeliness issue before him. If, however, the contractor or CMS submits evidence that the information about the use of the LCD in determining that the service was not covered was included in written documents received by the complainant before or along with the Medicare Summary Notice, the ALJ may consider whether such documents should be read together to constitute an adequate initial claim denial.

It is important to reiterate that the LCD challenge process does not replace the claims appeal process in which a beneficiary may contest an individual claims denial directly.[4] An LCD policy challenge, by contrast, may create uncertainty about applicable coverage policy affecting many other beneficiaries served by the

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[4] The preamble to the final procedural regulations applicable here summarizes the differences between the two processes as follows:

> Section 522 of the BIPA [Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000] created a review process that is separate and independent from the claims appeal process. This process will be different, because the nature of the challenge and the relevant evidence is different. The procedures used in this process will be different from the claims appeals process. Review of an LCD or NCD requires examination of an entire policy, or specific provisions contained therein, and not just one claim denial. Therefore, such reviews may lead to changes that impact other beneficiaries if the policies are found to be unreasonable. A beneficiary, thus, may elect to pursue a claims denial through the claims appeal process, seek review of an LCD or NCD using the process in this final rule, or both. In no way does filing a 522 challenge, or a decision on a 522 challenge, affect beneficiary appeal rights or other issues that may arise in the claims appeal process.

68 Fed. Reg. 63, 693-94 (Nov. 7, 2003). In a claim appeal case, the ALJ hearing the case is not bound by the LCD provisions, but "will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062. NCDs, however, are binding on ALJs in the claims appeal process. 42 C.F.R. § 405.1060.

contractor using that LCD. It is reasonable, in that case, to provide closure and clarity within a set time period. Nevertheless, in amending the Act to expressly require that the information about use of an LCD be included in the initial claims denial notice, Congress clearly acted to ensure that beneficiaries were made aware of the role of an LCD before the time period in which to challenge that LCD policy could be triggered. We must therefore read the regulation consistent with the statute to refer to an initial claims denial of the kind required by the Act as the event triggering the period in which to challenge the LCD. This reading is consistent with the instructions which CMS posts on its web site for beneficiaries seeking to challenge LCD policy which states as follows:

> If you are entitled to Medicare and have already received the item or service, you must file your request:
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> * within 120 days of the date of the initial denial notice from the Carrier or FI that used the LCD. The Medicare Summary Notice (MSN) you get explains what was charged and what was paid. It also may include a denial notice that explains that an LCD does not cover a certain item or service. This is because that item or service is considered not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the function of a malformed part of the body.

Medicare: Appeals of Local Coverage Determinations, at http://www.medicare.gov/basics/lcds.asp (last updated Apr. 20, 2007). It thus appears that CMS may not consider a Medicare Summary Notice lacking the information that an LCD was used in the denial to constitute an initial claims denial notice for purposes of determining the timeliness of an LCD complaint. The information required to provide notice of claims denial based on an LCD (so as to initiate the appeal period) may, however, have been provided in another document sent to the Complainant along with or separately from the Medicare Summary Notice. The ALJ should make this factual determination in the first instance.

The Complainant also suggests that her efforts to seek clarification of the basis of the denial should be accepted as timely complaints sufficient to preserve her rights. The regulations are clear about the action which must be taken within 120 days in order to initiate a timely LCD challenge. 42 C.F.R. § 426.400(b)(2). A complaint must be sent in writing and must be filed with the office designated to hear these appeals. 42

C.F.R. § 426.400(a). The required contents of a complaint are set out in detail. 42 C.F.R. § 426.400(b). Neither a call to 1-800-Medicare or a letter to the contractor can substitute.

We note, in addition, that the record includes some indications that the Complainant may have a continuing or recurring need for the service and/or may be continuing to use the device. In the event that the ALJ determines on remand that an initial claims denial was indeed perfected more than 120 days before her complaint was filed, she may still have a right to challenge the LCD based on an unmet ongoing need or on the denial of another instance of the service (e.g., rental for a different month).[5] If she has a continuing or recurring need which she is unable to meet due to the LCD noncoverage provisions, and she obtains a suitable physician's statement, she may file at any time in six months thereafter (even if she later again receives the rental service). If she is continuing to use the device, she may submit another claim for it to Medicare and challenge the policy within 120 days of the initial denial of that claim.

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[5] If the complaint here is ultimately dismissed for untimeliness, presuming a claims denial notice was perfected, that would not constitute dismissal for failure to file an acceptable complaint. When a complaint is dismissed as unacceptable, the complainant is precluded from filing another complaint about the same LCD provision for six months. A complaint is unacceptable if, among other things, it does not meet "the requirements for a valid complaint in § 426.400." 42 C.F.R. § 426.410(b)(2). The components of a "valid complaint" are set out in section 426.400(b) and include information about the beneficiary, any person representing the beneficiary, the treating physician's statement, information identifying the relevant LCD provision, a statement from the aggrieved party about the needed service and why the LCD provision is not valid under the reasonableness standard, and any supporting clinical or scientific evidence. The timeliness rules are in section 426.400(a) and are not among the components required for a "valid" complaint. A dismissal for untimely filing does not trigger the six-month bar on filing a new complaint relating to the same provision, although obviously the new complaint must itself meet the timeliness requirements. The distinction makes sense because the rules mandate that an ALJ give a complainant an opportunity to amend an unacceptable complaint before dismissing it but provide no such opportunity in the case of an untimely complaint. 42 C.F.R. § 426.410(c)(1).

We also note that the contractor asserts that the challenged provision in the LCD is compelled by an NCD. Neither the ALJ or the Board has reached this question, in light of the need to resolve the threshold issue of whether the complaint was timely. The Complainant should be aware that the ALJ reviewing the validity of LCD provisions is not empowered to review the validity of NCD provisions. If the specific provision(s) to which the Complainant objects are indeed embodied in an NCD, she would only be able to challenge the validity of the NCD by filing a complaint directly with the Board. The regulations explaining how to file an NCD complaint are at 42 C.F.R. Part 426, Subpart E.

Conclusion

For the reasons explained above, we reverse the ALJ's dismissal of the complaint and remand for further proceedings consistent with this decision.

/s/
Judith A. Ballard

/s/
Sheila Ann Hegy

/s/
Leslie A. Sussan
Presiding Board Member