Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

In re CMS LCD Complaint: Category III CPT Codes (L25275)
Docket No. A-13-15
Decision No. 2502
March 20, 2013

REMAND OF ADMINISTRATIVE LAW JUDGE DECISION

We reverse the November 9, 2012 decision by an Administrative Law Judge (ALJ) dismissing the Local Coverage Determination (LCD) complaint filed by the beneficiary. *In re CMS LCD Complaint: Category III CPT Codes (L25275)*, DAB CR2663 (2012) (ALJ Decision). As explained below, we conclude that the dismissal was based on an erroneously narrow interpretation of who qualifies as a "treating physician" under the LCD challenge regulations. Accordingly, we remand the case to the ALJ for further proceedings.

Legal Background

An LCD is defined as a Medicare contractor's determination whether to cover a particular Medicare item or service on a contractor-wide basis "in accordance with section 1862(a)(1)(A)" of the Social Security Act (Act).[1] Act § 1869(f)(2)(B); 42 C.F.R. § 400.202. With certain exceptions not relevant here, section 1862(a)(1)(A) of the Act bars Medicare payment for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." That provision is referred to as the "medical necessity" standard. *See, e.g., In re CMS LCD Complaint: Wheelchair Options/Accessories (L11462)*, DAB No. 2389, at 1 (2011). 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. *Id.*

Section 1869(f)(2) of the Act and the regulations at 42 C.F.R. Part 426 permit Medicare beneficiaries denied coverage for items or services on the basis of an LCD to challenge the validity of the LCD by filing an "LCD complaint" before an ALJ. 42 C.F.R.

[1] The current version of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

§§ 426.110, 426.320, 426.400; *see generally* 42 C.F.R. Part 426, subparts C, D. After an LCD complaint is docketed, the ALJ evaluates whether the complaint is "acceptable." *Id.* § 426.410(b). In order to be acceptable, an LCD complaint must include, among other things, a "copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD." *Id.* §§ 426.400(c)(3), 426.410(b)(2). The regulations define "treating physician" as "the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge." *Id.* § 426.110.

If the ALJ determines that the complaint is unacceptable, the ALJ must provide the beneficiary an opportunity to amend the complaint. 42 C.F.R. § 426.410(c)(1). If the ALJ also determines that the amended complaint is unacceptable, the ALJ must issue a decision dismissing that complaint. *Id.* § 426.410(c)(2). The beneficiary may then appeal the dismissal to the Board. *Id.* § 426.465(a)(2). The standard of review that the Board applies is "whether the ALJ decision contains any material error." *Id.* § 426.476(b)(1).

Case Background

The beneficiary filed an LCD complaint challenging an LCD that denies Medicare coverage for a procedure called minimally invasive lumbar decompression (MILD). The ALJ initially found the complaint acceptable under the regulations and issued an order setting further procedures. Approximately a week and a half later, however, the ALJ *sua sponte* issued a Notice of Unacceptable Complaint and Opportunity to Amend Complaint (Notice), in which the ALJ questioned whether the complaint included a written statement from a treating physician, as required under section 426.400(c)(3). Notice at 1. The ALJ stated that it was "unclear" whether the physician from whom the beneficiary had submitted a written statement "fully meets the legal requirements of a treating physician." *Id.* at 2. The ALJ gave the beneficiary 20 days to amend his complaint. *Id.*

The beneficiary submitted an amended written statement from the same physician, in which the physician discussed the MILD procedure in general and described his professional background as a physician specializing in pain management. P. Ex. 2.1 at 1-2. The specialist also detailed his treatment of the beneficiary's lumbar spinal stenosis,[2] including his performance of the MILD procedure on the beneficiary in May 2012 after other treatments failed to relieve the beneficiary's symptoms. *Id.* at 2. The specialist explained that he "believed MILD was reasonable and medically necessary" for the beneficiary. *Id.*

[2] According to the beneficiary, lumbar spinal stenosis is a "common source of low back and leg pain" caused by narrowing of the central lumbar canal. Complaint at 3.

The ALJ dismissed the amended complaint, concluding that it did not include a written statement from the beneficiary's treating physician. ALJ Decision at 1. The ALJ reasoned that the specialist "does not meet the legal definition of a 'treating physician'" because his "role as a physician [is] clearly limited to treatment of the [beneficiary's] lumbar spinal stenosis condition." *Id.* at 3.

The beneficiary timely appealed the ALJ Decision to the Board. Although the Board notified the Centers for Medicare & Medicaid Services (CMS) and the contractor of the appeal and gave both entities an opportunity to file a response, neither CMS nor the contractor chose to respond.

Analysis

On appeal, the beneficiary challenges the ALJ's rejection of the specialist's amended written statement based on the ALJ's determination that the specialist does not qualify as the beneficiary's treating physician. The beneficiary contends that the ALJ erred by concluding, in effect, that only a primary care physician, as opposed to a specialist, can be a "treating physician" under the Part 426 regulations. Bene. Br. at 3. According to the beneficiary, the ALJ's interpretation is contrary to the text and intent of the regulations, is "inconsistent with the practice of medicine and standards of care," and conflicts with prior cases in which ALJs and the Board found that specialists qualified as treating physicians under section 426.110. *Id.* The beneficiary also argues that the ALJ's analysis is inconsistent with other Medicare regulations and the Medicare Appeals Council's interpretation of those regulations. *Id.* at 3-4.

We agree that the ALJ's dismissal was based on an overly narrow interpretation of the regulations. We also conclude that the ALJ should have recognized the specialist as the beneficiary's treating physician and accepted the amended complaint.

Our analysis is framed by the Board's longstanding recognition that hearing rights are not lightly to be abrogated. *See, e.g., Hazem Garada, M.D.*, DAB No. 2027, at 7 (2006); *Alden-Princeton Rehab. & Health Care Ctr.*, DAB No. 1978, at 4 (2005). Accordingly, to the extent that the Part 426 regulations are ambiguous about who qualifies as a treating physician and may prepare a written statement of medical necessity for an LCD challenge, the regulations should be construed in favor of accepting the complaint and allowing the challenge to go forward. *See Garada*, at 7; *Glen Rose Med. Ctr. Nursing Home*, DAB No. 1852, at 8 (2002).

In what follows, we explain why we conclude that the ALJ Decision is erroneous.

1. *The authorities relied on by the ALJ do not support his interpretation of the regulations*.

In rejecting the amended complaint, the ALJ based his analysis on the definition of "treating physician" in section 426.110 and the preamble to the final rule that added Part 426 to the regulations. ALJ Decision at 2-3. The language on which he relies, however, does not compel the conclusion that only a primary care physician may be a treating physician under Part 426.

As noted above, section 426.110 defines "treating physician" as "the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge." Although the ALJ quoted the entire definition in his decision, his analysis appears to have focused on the first part – "the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care." The ALJ emphasized that the specialist treated the beneficiary only for lumbar spinal stenosis, as opposed to providing more comprehensive care. ALJ Decision at 2-3. However, the definition goes on to require that a "treating physician" also be the physician responsible for "either approving or providing the service at issue in the challenge." Read as a whole, the text of the definition suggests, or at least permits, the reading that the referenced "care" means care for the condition requiring the service at issue in the challenge – which the specialist provided here – instead of, as the ALJ interpreted it, care in a more global sense. We conclude that this reading is more reasonable than the ALJ's, in that our construction of the regulation better gives "meaning to all its parts," especially in light of the context and purpose of the provision as discussed below. *Ill. Dep't of Children & Family Servs.*, DAB No. 1335, at 13 (1992) (citing Sutherland, *Statutory Construction*, 4th ed., Vol. 2A, § 46.06).

According to the ALJ, the preamble to the final rule adding Part 426 to 42 C.F.R. explained, in reference to public comments about the proposed physician certification requirement in section 426.400(c)(3), that "we continue to believe that the beneficiary's treating physician – not any treating physician – is best suited to determine 'in need' status both because he or she is the primary caregiver and also is responsible for the beneficiary's overall care." ALJ Decision at 2, citing 68 Fed. Reg. 63,692, 63,696 (Nov. 7, 2003). The ALJ reasoned that the specialist does not meet the definition of a "treating physician" because he is not the beneficiary's "primary clinician responsible for her overall care." *Id.* at 3. The ALJ's reliance on the preamble is misplaced. The ALJ failed to consider the context of the cited text and misquoted that text. The section of the preamble on which the ALJ relied responded to the suggestion that <u>non-physician</u> practitioners, as opposed to solely physicians, should be able to document a beneficiary's need for the service at issue in an LCD challenge. *See* 68 Fed. Reg. at 63,696. This

suggestion was rejected on the basis that, "we continue to believe that the beneficiary's treating physician – not any treating *practitioner* – is best suited to determine 'in need' status. . . ." *Id.* (italics added). Thus, the regulation did not limit the type of physician that could be a "treating physician," but instead made clear that only physicians, and not other practitioners, could qualify.

We also note that, while the preamble referred to the beneficiary's "overall care," the regulatory text simply requires that the physician have responsibility for "overseeing the beneficiary's care" and the modifier "overall" does not appear in the text. *See* 42 C.F.R. § 426.110. Any physician who is treating a patient has a responsibility for overseeing that patient's care that goes beyond that of a practitioner such as a physician's assistant or physical therapist. The text also uses the term "primary clinician" rather than the term "primary care physician." *See id.* Had the intent been to exclude specialist physicians from certifying medical necessity, different wording could have easily accomplished that result.

2. *Other authorities undermine the ALJ's interpretation of the regulations.*

The text of section 426.400(c)(3) further undermines the ALJ's narrow interpretation of "treating physician." Section 426.400(c)(3) provides that a beneficiary must include with his or her LCD complaint a written statement from a treating physician. It also provides that the statement "may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service." Allowing the treating physician certification to take the form of a written order or other medical records is inconsistent with reading the treating physician certification requirement as limited to a statement from the beneficiary's primary care physician. It is apparent from the facts in this case that a specialist, instead of a primary care physician, may be the physician who orders a particular service or documents the course of treatment in a patient's medical record. As the beneficiary observes, a primary care physician may refer a patient to a specialist when the primary care physician wants the specialist to "determine the most appropriate treatment" for a specific condition and provide that treatment. Bene. Br. at 3. Accordingly, the fact that a specialist could produce a statement in the form described by section 426.400(c)(3) suggests that many types of physicians, including specialists, can be treating physicians for purposes of determining medical necessity.

Moreover, applying the ALJ's interpretation of "treating physician" would, in situations like the present one, frustrate the regulatory intent in providing that a written statement may be in the form of a treatment order or other documentation. The Secretary of Health and Human Services revised the proposed version of section 426.400(c)(3), which did not originally contain that provision, in response to feedback from commenters who "felt that the physician certification requirements imposed unnecessary new paperwork burdens on physicians." 68 Fed. Reg. at 63,696. Yet, under the ALJ's interpretation of the

regulations, in order for a beneficiary to challenge an LCD that relates to a service provided by a specialist, the beneficiary would need a primary care physician to sign off on or otherwise document the need for the service, even if the specialist already had prepared a written statement of medical necessity or the beneficiary's medical records already contained physician orders or treatment records showing the need. Such a rule would increase, rather than reduce, the paperwork burden on primary care physicians. In addition, a primary care physician might not be able to certify that a beneficiary needs a particular service provided by a specialist. As the beneficiary notes, if a primary care physician "could choose among the most appropriate treatment options for a condition," the physician "would approve or provide the treatment him or herself" instead of referring the patient to a specialist. Bene. Br. at 3. Nothing in the regulations, however, suggests that they are meant to bar beneficiaries from challenging LCDs related to particular types of services.

The preamble to the proposed rule adding Part 426 to the regulations also supports a broader interpretation of "treating physician." The preamble explained that the proposed regulations implement section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which created a new administrative review process that allows certain beneficiaries to challenge LCDs and national coverage determinations (NCDs).[3] 67 Fed. Reg. 54,534, 54,536. The preamble noted that although BIPA opened up a new avenue of appeal rights related to LCDs and NCDs, the statute imposes specific standing requirements. *Id.* at 54,536-37. Under those requirements, an LCD or NCD challenge may be "initiated only by individuals entitled to benefits under part A, or enrolled under part B, or both, who are in need of the items or services that are the subject of the coverage determination." *Id.* at 54,537, quoting Act § 1869(f)(5).[4] These individuals are referred to elsewhere in BIPA as "aggrieved parties." *See* Act § 1869(f)(1)(A)(iii), (2)(A)(i), (2)(A)(ii). The purpose of proposing requiring a beneficiary to include a written statement from his or her treating physician with his or her LCD or NCD complaint was to "properly demonstrate that a beneficiary is 'in need'" and thus to "ensure that the individual is an aggrieved party." 67 Fed. Reg. at 54,538, 54,540. Thus, the treating physician certification requirement was implemented to serve a basic gate-keeping function, making sure that only beneficiaries "in need"

[3] NCDs are issued by CMS, apply nationally, and are binding at all levels of administrative review. 42 C.F.R. § 405.1060. A beneficiary may challenge an NCD by filing an "NCD complaint" with the Board. *See* Act § 1869(f)(1)(A)(iii); 42 C.F.R. Part 426, subpart E.

[4] In contrast to BIPA's restriction of standing to beneficiaries "in need" of a particular item of service, precursor bills to what became BIPA included standing provisions that would have enabled providers of services and device manufacturers and suppliers to file LCD and NCD challenges. *See, e.g.*, Medicare Patient Appeals Act of 1999, H.R. 2356, 106th Cong. (1999).

challenge LCDs and NCDs. A written statement from a specialist can perform this function just as well as a statement from a primary care physician. What is important is that the certifying physician is overseeing the beneficiary's care for the condition requiring the service at issue in the challenge and either approving or providing that service.[5]

It is also relevant that, as the beneficiary notes, section 410.32(a) does not require diagnostic tests to be ordered by a primary care physician in order to be covered by Medicare. Bene. Br. at 3-4. Section 410.32(a) provides that, for diagnostic tests to be covered under Medicare Part B, the tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." The definition of "treating physician" in section 410.32(a) clearly does not focus on the type of physician that orders a test, but instead on whether the physician is treating the beneficiary for the condition that necessitates the test. Accordingly, section 410.32(a) provides some support for interpreting "treating physician" in section 426.110 in a similar manner.

In addition, the beneficiary correctly points out that ALJs and the Board have accepted specialists as treating physicians in other cases. Bene. Br. at 3. For example, ALJs have found acceptable LCD complaints that included a written statement from an allergist-immunologist. *See In re CMS LCD Complaint: Homeopathic Medicine & Transfer Factor*, DAB CR1989, at 1 n.1 (2009); Order dated Oct. 12, 2005, *In re CMS LCD Complaint: Non-Coverage of Transfer Factor*, Docket No. C-05-183. The Board likewise has accepted an NCD complaint in which the treating physician written statement came from an ophthalmologist. *See* Acknowledgment dated July 6, 2004 & Ex. H to Amended Complaint dated March 26, 2004, *In re NCD Complaint: Ocular Photodynamic Therapy for Age-Related Macular Degeneration*, Docket No. A-02-75. These decisions do not require us to accept the specialist as the beneficiary's treating physician in this case. But the fact that CMS did not argue that those complaints were not acceptable (and has not defended the ALJ Decision here) may indicate that CMS itself does not read the regulations as narrowly as the ALJ did here.

Based on the authorities discussed above, including the authorities relied on by the ALJ, we conclude that the ALJ materially erred by interpreting the Part 426 regulations as requiring an LCD complaint to include a written statement from a primary care physician. Section 426.110 does not restrict the types of physicians that may qualify as treating physicians.

[5] The regulation would thus preclude a physician not actually overseeing the beneficiary's care from making a certification as an expert witness or consultant.

3. *The amended complaint is acceptable under the regulations.*

We conclude that the specialist's amended written statement confirms that he meets the definition of "treating physician" in section 426.110. In the statement the specialist explained that he has been "the physician with primary responsibility for treating [the beneficiary]'s lumbar spinal stenosis" since October 2011. P. Ex. 2.1, at 2. He also explained that he "performed the MILD procedure on" the beneficiary in May 2012 after other treatments failed to relieve the beneficiary's symptoms. *Id.* These statements establish that he is "the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge."

We also conclude that the amended written statement fulfills the requirements of section 426.400(c)(3). In the statement the specialist stated that he believes the MILD procedure "was reasonable and medically necessary" for the beneficiary. P. Ex. 2.1, at 2. Thus, the signed statement certifies that the beneficiary "needs the service that is the subject of the LCD" the beneficiary is challenging.

Accordingly, the amended complaint is acceptable under the regulations, and the ALJ should not have dismissed it.

Conclusion

For the reasons explained above, we reverse the ALJ Decision and remand the case to the ALJ to consider the amended complaint on its merits.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Judith A. Ballard
Presiding Board Member