

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re CMS LCD COMPLAINT:
Intra-Articular Injections of Hyaluronan
(LCD No. L34525)

Docket No. C-17-84

Decision No. CR4823

Date: March 31, 2017

DECISION DISMISSING CASE

I dismiss the complaint filed to dispute Local Coverage Determination (LCD) No. L34525 as an unacceptable complaint because LCD No. L34525 is not applicable to Medicare beneficiary who filed the complaint. This dismissal does not prohibit the beneficiary from filing a complaint against any other LCD that adversely affects her ability to receive the services she needs.

I. Background

The Civil Remedies Division (CRD) received correspondence from the beneficiary on October 31, 2016, in which the beneficiary indicated that she believed that LCD No. L34525 is incorrect because it requires six months to elapse between injections of Hyaluronan and the beneficiary needs the injections at three to four month intervals. CRD docketed the beneficiary's correspondence as a LCD complaint. The beneficiary identified National Government Insurance Services, Inc. (NGS), as the relevant Medicare contractor. Further, the beneficiary indicated her address was in Illinois. Finally, the beneficiary attached a letter from her physician in support of injections every three to four months.

Under 42 C.F.R. § 426.410(b), I am required to first determine if an LCD complaint is "acceptable," including whether it is "valid" under 42 C.F.R. § 426.400. After reviewing the beneficiary's complaint, I concluded that it was not an acceptable and valid LCD complaint. As a result, on November 18, 2016, I issued an Acknowledgement of Receipt

and Order to Aggrieved Party to Amend Unacceptable Complaint (Order) and indicated that CRD docketed the beneficiary's complaint. I also explained that under the applicable regulations, I have to determine if the complaint is acceptable. *See* 42 C.F.R. § 426.410(b). In so doing, I must determine if the complaint meets the requirements for a valid complaint as set forth in 42 C.F.R. § 426.400. Although I concluded that the beneficiary's complaint provided her identifying information and a treating physician written statement, and appeared to be timely, in that she submitted it within 6 months of the October 10, 2016 treating physician statement that she submitted with her complaint, I indicated that the beneficiary's complaint was not an acceptable valid LCD complaint as set forth in 42 C.F.R. § 426.400. Specifically, I informed the beneficiary that the complaint was missing clinical or scientific evidence that showed the LCD is unreasonable, and the beneficiary's statement did not explain why she believes the provisions of the LCD are not valid under the reasonableness standard. I also noted that it was unclear whether the LCD identified in the complaint applied to the beneficiary and whether the appropriate Medicare contractor had been listed.

In the Order, I informed the beneficiary that she had one opportunity to amend her complaint pursuant to the relevant regulation. 42 C.F.R. § 426.410(c)(1). I stated that the beneficiary had 30 days to file an amended complaint that contained the following:

- *LCD-identifying information:* (i) the name of the contractor using the LCD; (ii) Title of the LCD being challenged; (iii) the specific provision of the LCD adversely affecting the aggrieved party.
- *Aggrieved Party statement:* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the LCD is (are) not valid under the reasonableness standard.
- *Clinical or scientific evidence:* Copies of clinical or scientific evidence that support the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the LCD is not reasonable.

CRD sent the Order to the beneficiary as well as to representatives from NGS and the Centers for Medicare & Medicaid Services (CMS).

On November 21, 2016, an Associate General Counsel with NGS sent an email to CRD staff indicating receipt of the Order. NGS counsel stated that LCD No. L34525 was issued by another Medicare contractor called Wisconsin Physicians Services Insurance Corporation (WPS) and not NGS. Therefore, NGS counsel sought confirmation that NGS should have received my Order. In a subsequent email exchange, which included the beneficiary as a recipient on the emails, CRD staff confirmed that NGS was named in the LCD complaint, and NGS counsel confirmed that he represented NGS and that all communication should be made through him.

On December 16, 2016, the beneficiary timely filed an amended complaint that provided clinical or scientific evidence and stated why the beneficiary does not believe the LCD's provision related to the length of time between injections is reasonable. Further, the beneficiary again asserted that NGS is the relevant contractor and that L34525 is the relevant LCD.

Following receipt of the beneficiary's amended complaint, I issued an Order for NGS to Clarify Effect of LCD No. L34525. In that order, I noted the beneficiary's response. I also indicated that a review of LCD No. L34525 shows that WPS and not NGS issued it. However, I stated that the LCD indicates that it applies to Medicare Part B beneficiaries located in Illinois, the state of the beneficiary's residence. *See* LCD No. L34525 at 1. But, I also noted that according to CMS's website, it appeared that NGS is responsible for Medicare Part B matters for Illinois, although it seemed that when LCD No. L34525 was published, WPS had that responsibility. Therefore, I directed NGS to file a response to the following questions so that I may determine whether the beneficiary filed an acceptable complaint:

- 1) Does LCD No. L34525 currently apply to Medicare Part B beneficiaries located in Illinois based on WPS's initial inclusion of residents of that state when WPS was the relevant Medicare contractor;
- 2) Did NGS ever adopt LCD No. L34525 after NGS took over Illinois from WPS; and
- 3) Has NGS even adopted an LCD on the same subject as LCD No. L34525 and, if so, indicate the LCD number.

NGS, through counsel, timely responded to my order. NGS answered the first two questions in the negative, but answered the third in the positive and provided a copy of Local Coverage Article No. A52420 (NGS Ex. A) and LCD No. L33394 (NGS Ex. B). These documents have been effective since October 1, 2015, and they cover Medicare Part B beneficiaries in Illinois. NGS Ex. A at 1-2; NGS Ex. B at 1-2.

I gave the beneficiary an opportunity to reply to NGS's response. The beneficiary timely filed a reply; however, she neither disputed that LCD No. L34525, issued by WPS, was no longer applicable to individuals in Illinois nor that NGS had ever adopted LCD No. L34525.

II. Analysis

An "aggrieved party" may initiate review of an LCD by filing a written complaint. 42 C.F.R. § 426.400(a). Among other things, a valid LCD complaint must include information about the LCD being challenged, such as the contractor using the LCD and

the title of the LCD. 42 C.F.R. § 426.400(c)(4)(i), (ii). An administrative law judge must evaluate the LCD complaint to ensure that it is a valid complaint; however, if it is not, then it is an unacceptable complaint that must be amended. 42 C.F.R. § 426.410(b). The administrative law judge must provide the aggrieved party one opportunity to amend the LCD complaint; however, if it is not appropriately amended, then the administrative law judge must issue a decision dismissing the complaint. 42 C.F.R. § 426.410(c)(1), (2).

In the present case, the beneficiary has filed a complaint concerning an LCD that no longer covers individuals who live in Illinois. The beneficiary, when given an opportunity to amend her complaint, did not challenge an LCD issued by NGS, the Medicare contractor who is responsible for Medicare Part B in Illinois.

Because the beneficiary filed a complaint against LCD No. L34525 and the beneficiary is not covered by that LCD, the beneficiary is not properly an “aggrieved party” under the regulations because the LCD she identified does not presently deny her coverage of the service she seeks. 42 C.F.R. § 426.110 (defining *Aggrieved Party* to include an individual “in need of coverage for a service that is denied based on an applicable LCD (in the relevant jurisdiction) . . .”). An administrative law judge may not conduct a hearing on an LCD complaint when it is sought by a “non-aggrieved party.” 42 C.F.R. § 426.405(d)(1). Further, an administrative law judge must dismiss an LCD complaint that is not filed by an “aggrieved party.” 42 C.F.R. § 426.444(b)(3). Therefore, because the beneficiary did not amend her LCD complaint to challenge an LCD issued or adopted by NGS, I must dismiss her complaint. 42 C.F.R. § 426.410(c)(2).

Because I dismiss the beneficiary’s complaint against LCD No. L34525, she may not file another complaint against LCD No. L34525 for six months. 42 C.F.R. § 426.410(c)(3). If the beneficiary determines that the LCD identified by NGS in this proceeding or any other NGS LCD adversely affects her ability to receive Medicare Part B services she needs, then she may file a complaint against that LCD at any time since the complaint I am dismissing is limited to LCD No. L34525.

III. Conclusion

I dismiss the complaint against LCD No. L34525.

/s/
Scott Anderson
Administrative Law Judge