

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re CMS LCD COMPLAINT:
Hyperbaric Oxygen

Docket No. C-15-1248

Decision No. CR3932

Date: June 3, 2015

DECISION DISMISSING LCD COMPLAINT

An Aggrieved Party's doctor filed a letter challenging an unidentified Local Coverage Determination (LCD) for Hyperbaric Oxygen Therapy. After providing an opportunity for the Aggrieved Party to amend it, I must dismiss the Aggrieved Party's amended complaint as unacceptable because the challenge still does not meet the regulatory requirements.

Background

The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program and contracts with carriers and intermediaries (Medicare contractors) to act on its behalf in determining and making payments to providers and suppliers of Medicare items and services. Social Security Act (Act) §§ 1816, 1842. Medicare contractors issue LCDs, written determinations addressing whether, on a contractor-wide basis, a particular item or service is covered through Medicare. Act § 1869(f)(2)(B); *see also* 42 C.F.R. § 400.202.

A Medicare beneficiary who could be denied coverage for an item or service based on an LCD may challenge that LCD before an administrative law judge (ALJ) as an aggrieved party. The aggrieved party initiates the review by filing a written complaint that meets the criteria specified in the governing regulations. 42 C.F.R. §§ 426.400; 426.410(b)(2). After the LCD complaint is docketed, the ALJ evaluates whether the complaint is "acceptable." 42 C.F.R. § 426.410(b). An ALJ does not have authority to review the merits of an "unacceptable complaint." *See* 42 C.F.R. §§ 426.405(d)(7); 426.410(c)(2). If the complaint is determined to be unacceptable, the ALJ must provide the aggrieved party 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 the LCD complaint. 42 C.F.R. § 426.410(c)(2). If a complaint is determined unacceptable after one amendment, the beneficiary is precluded from filing again for six months after being informed that the complaint is unacceptable. 42 C.F.R. § 426.410(c)(3).

On January 16, 2015, the Aggrieved Party's doctor filed the LCD challenge on behalf of one of his patients who was a Medicare beneficiary. The Medicare beneficiary, in his opinion, would benefit from Hyperbaric Oxygen Therapy (HBO) for her Complex Regional Pain Syndrome (CRPS) and Reflex Sympathetic Dystrophy (RSD). The case was assigned to me on March 16, 2015.

I evaluated the complaint as required by 42 C.F.R. § 426.410(b), (c) and (d) and found that it was unacceptable. I advised the Aggrieved Party, through an order dated March 23, 2015, why the complaint was unacceptable, and I granted her an opportunity to amend it. I also advised the Aggrieved Party that if she did not submit an amended, acceptable complaint, I was required to issue a decision dismissing the complaint as unacceptable. *See* 42 C.F.R. § 426.410(c). On April 22, 2015, the Aggrieved Party filed her amended complaint.

Discussion

I find the Aggrieved Party's amended complaint is unacceptable, and I must dismiss it because it does not meet all of the regulatory requirements for an acceptable challenge to the LCD.

In her amended complaint, the Aggrieved Party discussed her personal need for HBO and, in support of her challenge, also provided the following documents: a list of the medical treatments she received; a January 16, 2015 letter from Dr. Paul Thombs and a April 22, 2015 letter from Dr. Marti Friednash indicating that based on one study, HBO therapy may be helpful to patients with CRPS, and a screen shot from the Medicare contractor's (Novitas Solutions, Inc.) provider website.

Upon reviewing the Aggrieved Party's April 22, 2015 amended complaint, I find that it still does not comply with all of the regulatory requirements needed for an acceptable LCD challenge. The Aggrieved Party still has not identified the title and number of the LCD that she is challenging, nor the specific provision of the LCD that adversely affected her, as required by 42 C.F.R. § 426.400(c)(4)(ii) and (iii). The Aggrieved Party also did not explain why the provisions of the LCD are not valid under the reasonableness standard, as required by 42 C.F.R. § 426.400(c)(5). Additionally, the Aggrieved Party did not provide copies of clinical or scientific evidence that support her complaint (other than the article submitted with Dr. Thombs' letter) along with an explanation as to why she thinks the evidence shows that the LCD is not reasonable, as required by 42 C.F.R.

