

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

*In re* LCD Complaints

Category III CPT Codes (L29288)

Contractor: First Coast Service Options, Inc.

Docket No. C-13-521

Decision No. CR3223

Date: May 8, 2014

**DECISION DISMISSING LCD COMPLAINTS**

I dismiss the complaints of two aggrieved parties who challenge the local coverage determination (LCD) involving the minimally invasive lumbar decompression (MILD) procedure. The contractor, First Coast Services Options, Inc. (FCSO), has represented that the relevant LCD provisions are no longer in effect.

**I. Procedural Background**

On February 27, 2013, the Departmental Appeals Board (Board) remanded to me an LCD complaint, previously docketed as C-12-777 and re-docketed on remand as C-13-521, for further proceedings. On March 7, 2013, the Board remanded another LCD complaint, previously docketed as C-12-1011 and re-docketed on remand as C-13-511, for further proceedings. The Board directed that the aggrieved parties' complaints were acceptable on remand and that I should continue to consider the merits of their appeals. On April 18, 2013, I consolidated these two LCD complaints under docket number C-13-521 because both cases involved common questions of law and fact, a challenge to the same provisions of the same LCD denying coverage for the MILD procedure, the same representative for both aggrieved parties, the same contractor, and the same LCD record. Order Acknowledging Acceptable Complaint; Consolidating Cases; and Granting Leave for Aggrieved Party Response (April 18, 2013 Order).

Prior to the remands and consolidation of these cases, FCSO filed the LCD record, the aggrieved parties filed their statements regarding the validity of the LCD record, and FCSO responded to their statements. On April 18, 2013, I granted one of the aggrieved parties leave to file a reply to FCSO's latest filing. The reply was filed on May 21, 2013, along with six additional exhibits. On June 17, 2013, I directed FCSO to review the May 2013 submission and indicate whether the six additional exhibits were significant to the evaluation of the LCD before me. FCSO responded on July 12, 2013.

Pending my review, on January 9, 2014, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination (NCD) "Decision Memo for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433N)" (Decision Memo).<sup>1</sup> In the Decision Memo, CMS determined that percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. CMS determined, however, that it would provide coverage for PILD for Medicare beneficiaries with lumbar spinal stenosis who are enrolled in an approved clinical study that meets certain criteria. The Decision Memo included an explanation that PILD is commercially known as the MILD procedure.

On January 28, 2014, I issued an "Order for Supplemental Briefing" (January 28 Order). I noted that an Administrative Law Judge (ALJ) is not authorized to disregard, set aside, or otherwise review an NCD. 42 C.F.R. § 405.1060(b). I also noted that according to the Decision Memo, the NCD's preliminary language is effective immediately and subject to formal revision and formatting changes prior to the release of the final NCD publication in the National Coverage Determination Manual. I therefore instructed FCSO to brief how issuance of the Decision Memo might affect my review in this case and allowed the aggrieved parties an opportunity to respond. I specifically directed FCSO to address whether it planned to retire the challenged LCD in response to the recent NCD.

FCSO responded to my January 28 Order on February 6, 2014. FCSO acknowledged that I specifically requested that it address whether it planned to retire the LCD. Although it was inferred, FCSO's non-attorney representative did not, however, unequivocally state that FCSO was planning to retire the LCD. FCSO instead represented that the Decision Memo specifically confirmed FCSO's LCD to not cover MILD because it is not reasonable and necessary under the Social Security Act. FCSO also stated that "[w]hen an NCD is communicated the Medicare Administrative Contractor [MAC] awaits specific implementation instructions from CMS via the Program Change Management process" and that "[t]his implementation will . . . entail the amendment of LCD 'Noncovered Services' with removal of the code for the *mild* procedure for the applicable codes in

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<sup>1</sup> The Decision Memo is available at <http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=269>.

MCS (system for physician services) and FISS (system for hospital services) . . . . Once CMS issues implementation instructions via a Change Request, the MAC will publish an article outlining the NCD decision including guidance on the limited coverage.” (Emphasis in original). FCSO’s representative concluded:

In summary, the First Coast LCD “Noncovered Services” as it applies to the non coverage of the *mild* procedure from 2011 to early 2014 was validated by the NCD. All claims for this service from 2011 to early 2014 should be non covered since the . . . LCD “Noncovered Services” is given due deference. . . . Effective with CMS’ NCD implementation, [the contractor] may cover certain claims for the *mild* procedure . . . as outlined by CMS. . . . Future claims not meeting the requirements of the NCD should be denied as not reasonable and necessary per the NCD.

FCSO February 6, 2014 Response at 1-2.

The aggrieved parties do not dispute that MILD is a PILD procedure. Instead, the aggrieved parties urge that I continue to consider their LCD complaint for other reasons. They assert that:

The Decision Memorandum has no legal impact and should be given no evidentiary weight because (1) the Decision Memorandum and its evidence and analysis were not the basis of the LCD and are not in the LCD record, (2) the Decision Memorandum was based on different evidence, a different analysis and resulted in conditional coverage, and (3) the Decision Memorandum is pre-decisional and no NCD exists as a result of the Decision Memorandum.

Aggrieved Parties’ March 7, 2014 Supplemental Briefing at 4.

On March 20, 2014, I instructed the staff attorney assisting me to contact FCSO to ascertain when it expected to receive the CMS implementation instructions its representative referenced in its supplemental brief. In a responsive electronic mail communication dated March 20, 2014, FCSO’s representative informed the staff attorney unequivocally that FCSO was no longer relying on the LCD since CMS issued the Decision Memo on January 9, 2014. I instructed the staff attorney to provide the aggrieved parties an opportunity to respond to FCSO’s clarification. The aggrieved parties chose not to respond.

## **II. Dismissal**

Only LCDs that are currently effective may be challenged. 42 C.F.R. § 426.325(a). An ALJ must dismiss a case when a contractor notifies the ALJ that an LCD provision is no longer in effect. 42 C.F.R. § 426.444(b)(6). An ALJ does not have the authority to deny

a contractor the right to reconsider, revise, or retire an LCD. 42 C.F.R. § 426.405(d)(12). A contractor may retire an LCD or LCD provision under review before the date the ALJ issues a decision regarding that LCD. Retiring an LCD or LCD provision under review has the same effect as a decision under 42 C.F.R. § 426.460(b). 42 C.F.R. § 426.420(a).

FCSO now fully represents that, since January 9, 2014 when the PILD NCD became effective, the LCD provisions at issue here are no longer effective and will not be used further to adjudicate any MILD claims. Although the aggrieved parties may dispute the merits of the Decision Memo and the PILD NCD, I am unable to continue my review of the LCD record if FCSO is clearly no longer relying upon the LCD when processing claims for the MILD procedure. The Board conducts a review for any challenge to an NCD that may be used as a basis for future denial of coverage. *See* 42 C.F.R. § 426.300(b).

The aggrieved parties may now receive individual claim review without the contractor applying the retired LCD to adjudicate their claim. *See* 42 C.F.R. § 426.460(b)(1). Individual claim review without application of the disputed LCD provides the aggrieved parties with the same relief as if I had found the LCD in question invalid under the reasonableness standard. *Id.*; *see* 68 Fed. Reg. 63,692, 63,698 (Nov. 7, 2003).

For the reasons discussed above, I dismiss the aggrieved parties' complaints because FCSO has informed me that the LCD provisions it used to consider whether to cover the MILD procedure have not been in effect since January 9, 2014. If for some reason FCSO were to use the challenged LCD provisions to continue to deny coverage for MILD, the aggrieved parties may use that determination as a basis for me to vacate this dismissal.

\_\_\_\_\_/s/\_\_\_\_\_  
Joseph Grow  
Administrative Law Judge