

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

*In re* LCD Complaint:

Bioengineered Skin Substitutes for the Treatment of Diabetic and Venous Stasis Ulcers  
of the Lower Extremities  
LCD ID Number: L34285  
Contractor: Cahaba GBA, LLC

Docket No. C-17-457

Decision No. CR4832

Date: April 25, 2017

**DECISION DISMISSING COMPLAINT**

The Civil Remedies Division (CRD) of the Departmental Appeals Board, United States Department of Health & Human Services (HHS), received correspondence from the Aggrieved Party, dated February 22, 2017, and filed via the DAB E-File system on March 20, 2017, seeking review of the local coverage determination (LCD) regarding Bioengineered Skin Substitutes for the Treatment of Diabetic and Venous Stasis Ulcers of the Lower Extremities, LCD L34285.

In an Order dated March 22, 2017, I acknowledged receipt of the Aggrieved Party's complaint. I explained that, pursuant to the applicable regulations, I am required to determine if the complaint is acceptable. *See* 42 C.F.R. § 426.410(b). I further explained that I must determine whether the complaint meets the requirements for a valid complaint as set forth in 42 C.F.R. § 426.400. In my March 22, 2017 Order, I informed the Aggrieved Party that I had determined that the complaint did not constitute an acceptable valid LCD complaint as set forth in 42 C.F.R. § 426.400.

To be timely, a complaint must be filed within six months of the issuance of a written statement from an aggrieved party's treating practitioner, in the case of an aggrieved party who chooses to file an LCD challenge before receiving the service; or within 120

days of the initial denial notice in the case of an aggrieved party who chooses to file an LCD challenge after receiving the service. 42 C.F.R. § 426.400(b). The components of a valid complaint under 42 C.F.R. § 426.400(c) include the following:

1. *Beneficiary identifying information:*
  - (i) Name.
  - (ii) Mailing Address.
  - (iii) State of residence, if different from mailing address.
  - (iv) Telephone number.
  - (v) Health Insurance Claim number, if applicable.
  - (vi) Email address, if applicable.
2. *If the beneficiary has a representative*, the representative-identifying information must include the representative's name, mailing address, telephone number, email address, if any and a copy of the written authorization to represent the beneficiary.
3. *Treating Physician Written Statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD. This 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.
4. *LCD-identifying information.*
  - (i) Name of the contractor using the LCD.
  - (ii) Title of the LCD being challenged.
  - (iii) The specific provision (or provisions) of the LCD adversely affecting the aggrieved party.
5. *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.
6. *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.

In the instant case, the Aggrieved Party filed the complaint before receiving the service, and he filed a written statement from his treating practitioner as required by 42 C.F.R. § 426.400(b). As previously stated, in order to be timely and acceptable, the Aggrieved Party must have filed the complaint within *six months* of the date of the treating

