DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-12-1456

In the case of	**Claim for**
AeroCare Holdings (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiary)	**** (HIC Number)
CIGNA Government Services (Contractor)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated April 2, 2012, which concerned coverage for a formoterol fumarate inhalation solution (formoterol) refill provided to the beneficiary with date of service January 13, 2011. The ALJ determined that the item was not medically reasonable and necessary pursuant to section 1862(a)(1)(A) of the Social Security Act (Act) and thus was not covered by Medicare. The ALJ also held the appellant supplier liable for the non-covered charges under section 1879 of the Act. The appellant has asked the Medicare Appeals Council (Council) to review this action.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. *Id*. § 405.1112(c). The Council enters the appellant's cover letter dated April 16, 2012, request for review (**Form DAB-101**) dated April 14, 2012, and one-page brief into the record as Exhibit (Exh.) MAC-1. The appellant also submitted a copy of the ALJ exhibits including the reconsideration decision and the beneficiary's medical records. We exclude these documents as duplicative, but they are marked for identification purposes as Exh. MAC-2 (Excluded).
As set forth below, the Council reverses the ALJ's decision.

DISCUSSION

The beneficiary is diagnosed with chronic obstructive pulmonary disease (COPD). Exh. 2, at 20, 24-25. On July 16, 2010, a physician prescribed to the beneficiary a one month supply of formoterol and other inhalation solutions refillable up to 12 months. *Id*. at 20. On January 13, 2011, the appellant contacted the beneficiary's wife and confirmed that the beneficiary required a formoterol refill. *Id.* at 21. The appellant shipped the refill on the same day and it was delivered on January 17, 2011. *Id*. at 23. The appellant then submitted a claim for the refill. *See id.* at 44.

Coverage for the refill was denied at all levels of appeal. Dec. at 1-5; Exh. 2, at 3-5, 26-28. As relevant here, the ALJ cited to the Local Coverage Determination (LCD) for Nebulizers (L5007) and to the Medicare Program Integrity Manual (MPIM) (CMS Pub. 100-08), Ch. 4, section 4.26. Dec. at 4. The ALJ noted that Medicare guidelines require that a supplier's contact with the beneficiary regarding refills should take place no sooner than approximately 7 days prior to the delivery or shipping

date. *Id*. The ALJ determined that the record did not contain a refill request and that the appellant contacted the beneficiary on the same day that it filled (i.e., shipped) the prescription. *Id*. The ALJ thus denied coverage and held the appellant liable for the non-covered charges. *Id*. at 4-5.

In the one-page brief submitted to the Council, the appellant argues that it contacted the beneficiary's wife before filling the prescription and that the refill was provided in the appropriate time frame. Exh. MAC-1, at 3. In its brief, the appellant also quoted and highlighted an excerpt from the MPIM, Ch. 5, section 5.2.6. *Id*.

After considering the record and exceptions, we agree with the appellant that the claim at issue met Medicare coverage requirements and we therefore reverse the ALJ's decision. Under the applicable LCD, LCD L5007 (for services performed on or after January 1, 2010, through February 3, 2011), it quotes the MPIM, Ch. 4, section 4.26.1, which provides that, "[c]ontact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the . . . product no sooner than approximately 5 days prior to the end of usage for the current product." The Council notes that the MPIM subsection quoted in the LCD comes from a prior version of that subsection and that subsection was revised with new timeframes for refills effective October 31, 2011. *See* CMS Manual System, Medicare Program Integrity, Transmittal 389, *Proof of Delivery and Delivery Methods*. We also note that in the appellant's brief, the appellant cites to MPIM, Ch. 5, section 5.2.6, but that subsection and its accompanying text were not added until July 1, 2011, and were not effective until August 2, 2011. *See* CMS Manual System, Medicare Program Integrity, Transmittal 378, *Prospective Billing for Refills of DMEPOS Items Provided on a Recurring Basis*. Accordingly, LCD L5007 and the prior version of the MPIM that the LCD cited provide the relevant coverage guidelines to the claim at issue whose date of service is January 13, 2011. Exh. 2, at 44.

The ALJ denied coverage on the grounds that the record did not contain a refill request. Dec. at 4. However, we disagree with the ALJ because the record contains a call log form issued by the appellant that recorded the appellant's contact with the beneficiary's wife regarding the refill on the date of service. Exh. 2, at 21. The form specifies the name of the person the

appellant contacted, the relationship of the person to the beneficiary, a signed and dated signature of the appellant's representative, the product to be ordered, and the current product's usage frequency and remaining dosages. *Id*. The applicable guidelines only require that the supplier contact the beneficiary and deliver refills within a specified timeframe, but do not require a specific type of refill request, such as a written refill request signed by the beneficiary. *See* LCD L5007, *citing* MPIM, Ch. 4, § 4.26.1. We therefore find that the call log evidences that the supplier contacted the beneficiary before shipping the refills in accordance with the applicable guidelines. *Id*.

The ALJ also denied coverage on the grounds that the appellant contacted the beneficiary's wife on January 13, 2011, and shipped the refill on the same day. Dec. at 4; Exh. 2, at 21. However, we find no issue with the appellant's contact being on the same day as the shipment date. The LCD requires that the supplier's contact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery or shipping date. *See* LCD L5007, *citing* MPIM, Ch. 4, § 4.26.1. Here, the appellant's contact with the beneficiary's wife on the same day as the shipping date is well within the 7-day timeframe specified in the LCD. *Id*.

We also find that the appellant's delivery of the refill met the LCD's coverage guideline requiring that the supplier deliver the product no sooner than 5 days prior to the end of the usage for the current product. *See* LCD L5007, *citing* MPIM, Ch. 4, § 4.26.1. The record shows that the refills were delivered to the beneficiary on January 17, 2011. Exh. 2, at 23. It also shows that the beneficiary had eight dosages of the formoterol left on January 13, 2011, and a dosage of formoterol was administered twice daily (i.e., "BID"). *Id*. at 21. Therefore, the beneficiary would have exhausted his current supply of formoterol on January 16, 2011, or January 17, 2011. We thus find that the appellant delivered the refill in the 5-day time frame specified in the LCD. We further find that the record includes a valid prescription for the refill and a valid proof of delivery. *Id*. at 20, 22-23.

For the reasons discussed above, we reverse the ALJ's decision. The formoterol fumarate inhalation solution refill provided to the beneficiary with date of service January 13, 2011, shall be covered by Medicare.

MEDICARE APPEALS COUNCIL

/s/ Stanley I. Osborne, Jr.
Administrative Appeals Judge

/s/ Constance B. Tobias, Chair
Departmental Appeals Board

Date: August 3, 2012