DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-888

In the case of	**Claim for**
Illinois Valley Community Hospital (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiary)	**** (HIC Number)
National Government Services (Contractor)	**** (ALJ Appeal Number)

On January 25, 2011, the Administrative Law Judge (ALJ) issued a decision concerning Medicare's coverage of self-administered drugs the beneficiary received from Illinois Valley Community Hospital (provider) during her outpatient stay on November 25, through November 28, 2008.[1] The ALJ's decision waived the beneficiary's liability and held the provider liable for the cost of the non-covered, self-administered drugs. By request dated February 4, 2011, and received by the Medicare Appeals Council (Council) on February 14, 2011, the provider asked the Council to review the ALJ's action. *See* 42 C.F.R. § 405.1102.

Subsequently, on March 24, 2011, the Council received a referral from the Centers for Medicare and Medicaid Services (CMS) regarding the same ALJ action. *See* 42 C.F.R. § 405.1110. In an action issued under docket number M-11-1168, the Council declined to take own motion review of the ALJ's decision in the context of the CMS referral because the referral did not provide any additional bases for review of the ALJ's action beyond those already introduced in the provider's request for review.

[1] To limit the potential for confusion, the Council does not refer to any of the parties as the "appellant" in this action. The provider and the beneficiary have alternately served as the "appellant" throughout the various levels of the appeals process.

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. 42 C.F.R. § 405.1112(c).

For ease of reference, the Council retains the numbering used in its action in docket number M-11-1168, and enters the following documents into the record:

Exh. MAC-1	Provider's timely-filed request for review dated February 4, 2011, and correspondence proving that copies of same had been sent to other parties
Exh. MAC-2	CMS memorandum dated March 21, 2011
Exh. MAC-3	Beneficiary's April 4, 2011, response to the CMS memorandum, with enclosures
Exh. MAC-4	Beneficiary's April 18, 2011, response to the provider's request for review, with enclosures

The Council has carefully considered the record before the ALJ, as well as the provider's request for review, the beneficiary's submissions, and where appropriate, the CMS memorandum. As set forth below, the Council finds that the ALJ erred in applying the limitation on liability to the instant case and we reverse the ALJ's decision accordingly.

BACKGROUND

Following a fall, the beneficiary was admitted to the provider's facility as an outpatient for observation care relating to right knee pain on November 25, through November 28, 2008. Exh. 2 at 9, 13-17, 22-23. The parties do not dispute that Medicare covered the outpatient hospitalization. During her outpatient hospital stay, the beneficiary received drugs that are usually self-administered; coverage and payment for these drugs are the subjects of this appeal.

The provider billed Medicare Part B $1,260.25, for the drugs at issue.[2] Exh. 2 at 229. Initially, and upon redetermination, the

[2] The beneficiary's supplemental insurance policy through CIGNA paid $608.20, of this amount. Exh. 2 at 234.

contractor denied coverage for the drugs at issue and held the provider liable for the non-covered charges on the basis that it did not submit sufficiently itemized documentation to support its charges. *Id.*; Exh. 3 at 235-41.

Upon reconsideration, the Qualified Independent Contractor (QIC) determined that Medicare does not cover the drugs at issue because they can be self-administered. Exh. 4 at 251-55 (citing National Government Services, "Local Coverage Article for Process for Determining Self-Administered Drug Exclusions – Medical Policy Article (A47521)").[3] The QIC mentioned, but did not actually apply, section 1879 of the Social Security Act (Act) and ultimately held the beneficiary responsible for the non-covered costs. *Id.* at 254.

On appeal, the ALJ conducted a hearing with the beneficiary's husband via teleconference on January 14, 2011. Hearing CD. In a decision dated January 25, 2011, the ALJ determined that, although the beneficiary would normally be held liable for non-covered charges arising from self-administered medication, the provider is liable in this instance because it did not fulfill its duty to provide information that was sufficiently itemized to the beneficiary. Dec. at 3-4.

As noted above, the provider requested Council review of the ALJ's decision. Exh. MAC-1. The provider disagrees with the ALJ's finding that it did not notify the beneficiary of the services or amounts due. *Id.* In support of its position, the provider asserts that it provided an itemization of her self-administered drugs, and that it also billed the beneficiary's supplemental insurance, which paid a portion of the total bill. *Id.* The provider included a copy of the supplementary insurance company's explanation of benefits (EOB) with its request for review. *Id.* The Council however need not consider whether the provider had good cause for the submission of this document because it is duplicative of evidence already present in the record and therefore does not constitute new evidence. *See* 42 C.F.R. § 405.1122(c).

In addition, as noted above, CMS referred the case to the Council for own motion review. *See* 42 C.F.R. § 405.1110. CMS limited its referral to the issue of liability and states, "it is not disputed that Medicare does not cover self-administered

[3] The contractor's policy article is available through the Medicare Coverage Database available on the CMS website at http://www.cms.gov/medicare-coverage-database (last visited June 13, 2011).

drugs." Exh. MAC-2 at 5. More specifically, CMS asserts that the ALJ erred in holding the provider liable because the limitation on liability provisions of section 1879 of the Act do not apply to cases such as the instant one, where the items at issue are not a covered benefit. *Id.* The Council declined to review the ALJ's decision in the context of the CMS referral in a separate action issued under docket number M-11-1168.

The beneficiary, through her husband, responded to both the CMS memorandum and the provider's request for review. Exhs. MAC-3 – MAC-4. Essentially, the beneficiary maintains that, with the possible exception of a multi-vitamin, the drugs at issue were necessary for her health and well-being, and were not self-administered due to her being in a hospital. Exh. MAC-3. The beneficiary also maintains that the provider did not inform her, or her husband, that Medicare would not cover the medications at issue. *Id.* The Council will consider the beneficiary's more specific contentions in the context of its discussion below.

DISCUSSION

As a preliminary matter, the Council turns to the beneficiary's contentions regarding her outpatient status while hospitalized. Before the Council, the beneficiary expresses her belief that the underlying hospital stay should not have been characterized as an "outpatient" service because she was admitted directly from the emergency room and remained hospitalized for three nights. Exh. MAC-3. The beneficiary's husband also states that both his, and her, medications have been covered during other hospitalizations. *Id.* However, the issue of whether the underlying hospital stay was appropriately billed as outpatient, as opposed to inpatient, services is not properly before the Council. The record does not contain any indication that the contractor's initial determination on the provider's claim for outpatient hospital services was appealed by either party.

Medicare Coverage for Self-Administered Drugs

Contrary to the position advanced by CMS in its referral memorandum, the parties do indeed dispute whether the drugs at issue are covered by Medicare. *See* Exh. MAC-3 – MAC-4. Specifically, the beneficiary asserts that, with the possible exception of a multi-vitamin, the drugs at issue were necessary for her health and well-being, and were not self-administered in

the hospital setting. Exh. MAC-3. The beneficiary also asserts that the drugs at issue seem to have been mistakenly classified as over-the-counter medications or that the beneficiary had a choice about their use. *Id.* Thus, the Council must consider whether Medicare covers the drugs at issue.

Medicare is a defined-benefit program. Section 1832(a) of the Act provides that benefits under Medicare Part B include "medical and other health services." The Act further defines "medical and other health services" as including "services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills." Act at § 1862(s)(2)(A).

The program regulations establish that Medicare Part B pays for hospital services and supplies furnished incident to a physician service to outpatients, including drugs and biologicals *that cannot be self administered*. 42 C.F.R. § 410.27 (emphasis supplied). The Medicare Benefit Policy Manual (MBPM) further explains: "The Medicare program provides limited benefits for outpatient drugs. The program covers drugs that are furnished 'incident to' a physician's service provided that the drugs are not usually self-administered by the patients who take them." MBPM, Pub. 100-02, Ch. 15 at § 50 (Drugs and Biologicals). The MPBM also provides that "in order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must: be of a form that is not usually self-administered." *Id.* at § 50.3 (Incident-to Requirements).

With very narrow exceptions not applicable here, drugs administered orally, via suppository, and topical application are considered to be "usually self-administered by the patient." *Id.* at § 50.2.B. For the purposes of this coverage exclusion, "usually" means that a drug is self-administered by more than 50 percent of Medicare beneficiaries and "by the patient" refers to Medicare beneficiaries as a collective whole. *Id.* at § 50.2.C-E.

Therefore, the appropriate inquiry is whether the drugs at issue were of a form that is not usually self-administered by the patient. MBPM, Ch. 15 at §§ 50-50.3. This inquiry is objective in nature; it does not take into account whether this

beneficiary actually administered these drugs to herself. It also does not distinguish between over-the-counter medications and drugs requiring a prescription like many of those at issue. In this case, the beneficiary received medications in the form of an inhaler, tablets and pills which were taken orally, and an ointment which was applied topically. Exh. 2 at 102, 190-92. Thus, the record supports a finding that the drugs at issue are excluded from Medicare coverage and do not fall under the "incident to" coverage provisions of section 1861(s)(2)(A). 42 C.F.R. § 410.27; MBPM, Ch. 15 at §§ 50-50.3.

Responsibility for the Non-Covered Charges

Before the Council, the provider and the beneficiary each raise contentions regarding their knowledge of, or their provision or receipt of information related to, Medicare's non-coverage of the drugs at issue. Exhs. MAC-1, MAC-3 – MAC-4. The relative knowledge of the parties, however, is not a consideration before the Council. As accurately identified by CMS, the limitation on liability pursuant to section 1879 of the Act does not apply to this case. Exh. MAC-2 at 5.

The beneficiary takes exception to CMS' statement that Medicare does not have the authority to hold the provider liable. Exh. MAC-3. The beneficiary reasons that Medicare has such authority because other adjudicators held the provider liable for the non-covered charges earlier in the appeals process. *Id.* The beneficiary's confusion on this point is understandable given that both the contractor and the ALJ erred in their consideration and assignment of liability below.

Medicare limits the liability of providers, suppliers, and beneficiaries for items and services that are not medically reasonable and necessary where there is no prior knowledge of noncoverage. Act at § 1879. However, in this case, the denial of coverage is not based on a finding that the items at issue were not medically reasonable and necessary under the provisions of section 1862(a)(1) of the Act. Instead, the coverage denial is based on a finding that the drugs at issue could be self-administered, and are thus excluded from coverage.

As explained in the MBPM:

> If a beneficiary's claim for a particular drug is denied because the drug is subject to the "self-administered drug" exclusion, the beneficiary may

> appeal the denial. Because it is a "benefit category" denial and not a denial based on medical necessity, an Advance Beneficiary Notice (ABN) is not required. A "benefit category" denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under § 1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug.

MBPM, Ch. 15 at § 50.2.I (Beneficiary Appeals); *see also* Medicare Claims Processing Manual, Pub. 100-04, Ch. 30 at § 20.2 (Denials for Which the Limitation On Liability Does Not Apply).

Thus, the ALJ erred in applying section 1879's limitation on liability provisions to this case. The provider was not required to issue an Advanced Beneficiary Notice (ABN) to the beneficiary, and the beneficiary remains responsible for the cost of the non-covered, self-administered drugs at issue.

DECISION

It is the decision of the Medicare Appeals Council that the self-administered drugs furnished to the beneficiary during her outpatient hospital stay on November 25, through November 28, 2008, are not covered by Medicare. The beneficiary is responsible for the non-covered charges.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

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

Date: June 16, 2011