

## Cash Sales of Medicare-Covered Items

By: Jeffrey S. Baird, Esq.

For a number of reasons, DME suppliers are focusing on retail cash sales of products...both Medicare-covered products and non-covered products. With lower reimbursement, post-payment audits, and the next round of competitive bidding that will start in less than two years, suppliers understand that they need to reduce their dependency on the Medicare fee-for-service (“FFS”) program. Equally as important, DME suppliers recognize that there are 78 million Baby Boomers who are retiring at the rate of 10,000 per day. Suppliers understand that most Boomers (i) expect to have an active life, (ii) do not want to wait around for Medicare approval, and (iii) want the “Cadillac,” not the “Cavalier,” product.

This confluence of circumstances presents an opportunity for the DME supplier to develop a successful retail business in which the supplier sells products for cash. Some of the cash products will be covered by Medicare, while others will be non-covered items (e.g., stair lifts). As the supplier moves into the retail space, it needs to decide whether its retail business will (i) operate under the same legal entity that has the PTAN, or (ii) operate out of a separate legal entity that does not have a PTAN.

This article focuses on the cash prices that a DME supplier can charge for Medicare-covered items if the retail business operates under the same legal entity that has the PTAN.

Federal law prohibits a supplier from charging Medicare or Medicaid substantially in excess of the company’s usual charges, unless there is good cause. Specifically, 42 U.S.C. § 1320a-7(b)(6)(A) provides, in relevant part, as follows:

The Secretary may exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a-7b (f) of this title):

...

Any individual or entity that the Secretary determines—

(A) has submitted or caused to be submitted bills or requests for payment ... under subchapter XVIII of this chapter or a State health care program containing charges ... for items or services furnished substantially in excess of such individual’s or entity’s usual charges ... for such items or services, unless the Secretary finds there is good cause for such bills or requests containing such charges or costs[.]

The key terms “substantially in excess” and “usual charges” are not defined in the statute. The current regulations issued under the statute, codified at 42 C.F.R. § 1001.701, simply repeat the language of the statute without providing any guidance about the meaning of “substantially in excess” or “usual charges.” The Office of Inspector General (“OIG”) has provided guidance through OIG Advisory Opinions and a guidance letter regarding the meaning of these terms on several occasions, but that guidance has been inconsistent.

The OIG's most recent attempt to clarify the meaning of the statute came in 2003 when the agency published a proposed rule. 68 Fed. Reg. 53,939 (Sept. 15, 2003). In the proposed rule, a provider's "usual charge" was defined as the average or the median of the provider's charges for the same item or service during the previous year, excluding charges for services provided to uninsured patients free of charge or at a substantially reduced rate; charges under capitated contracts; charges under fee-for-service managed care contracts where the provider is at risk for more than 10 percent of its compensation; and charges to Medicare, Medicaid, and other federal health care programs, except TriCare. In other words, the "usual charge" would be the average or median of (i) charges to cash purchasers, (ii) negotiated rates under commercial indemnity and non-risk commercial managed care contracts, (iii) out-of-network payments from commercial payors, and (iv) charges under TriCare contracts.

Under the proposed regulations, a supplier's charge to Medicare would be considered "substantially in excess" of its usual charges if the fee schedule amount for an item (or the submitted charge, if the submitted charge was less than the fee schedule amount) was more than 120 percent of the supplier's usual charge. Stated another way, the supplier would be considered to be in violation of the statute if its "usual charge" for an item was less than 83 percent of the Medicare fee schedule amount (i.e., in excess of a 17 percent discount from the Medicare fee schedule). The statute provides an exception for "good cause" which could allow a supplier's usual charges to be less than 83 percent of the Medicare fee schedule if the supplier can prove unusual circumstances requiring additional time, effort, or expense or increased costs of serving Medicare beneficiaries. However, CMS later withdrew the proposed rule. 72 Fed. Reg. 33,430, 33,432 (June 18, 2007). As a result, while there is no definitive federal guidance on when a supplier's charge to Medicare or Medicaid will be viewed as "substantially in excess" of its "usual charge," a Medicare or Medicaid supplier could be at risk if it sells items for cash at prices lower than a 17 percent discount off the Medicare/Medicaid fee schedule amounts without documented "good cause."

The proposed rule required that the charges of "any affiliated entities providing substantially the same items or services in the same or substantially the same markets" be included when calculating the usual charge of a provider. The term "affiliated entity" was defined as "any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the provider." Notwithstanding this language in the proposed rule, it is my opinion that CMS cannot legally attribute the prices charged by a separate legal entity to the "usual charge" of a Medicare/Medicaid supplier absent a legally enforceable rule.

Because of the restriction discussed above, and for other reasons, there is an advantage to set up a cash sale business as a separate legal entity. The advantages of operating a retail/cash business out of a separate legal entity will be addressed in a future article.

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