



**Statement for the CMS Public Meeting Regarding Inherent Reasonableness of Medicare Fee Schedule Amounts for Non-Mail Order (Retail) Diabetic Testing Supplies  
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**Submitted by Richard Price, Senior Vice President  
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AdvaMed appreciates the opportunity to submit comments regarding CMS's consideration of using inherent reasonableness authority as an alternative to competitive bidding for adjusting Medicare payment amounts for non-mail order diabetic testing supplies. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies, and include those companies that produce diabetes testing supplies (DTS) relied upon by millions of Medicare beneficiaries.

On several occasions in the past, AdvaMed has commended CMS for its decision to preserve the in-person retail pharmacy option for Medicare beneficiaries needing diabetic testing supplies as an alternative to a national mail order program. For beneficiaries needing this option, easy access to in-person guidance and instruction from a local pharmacist is essential for maintaining health and avoiding life-threatening complications and deterioration that can accompany diabetes. It is critical that beneficiaries continue to have access to retail pharmacies where they can obtain both in-person assistance and the brands of testing supplies that they and their physicians have determined are the most appropriate for their needs. In AdvaMed's view, such access would undoubtedly be compromised if Medicare payments for DTS furnished in the retail pharmacy setting do not adequately cover the costs incurred by pharmacies.

AdvaMed urges CMS to be cautious about using price and payment amount information obtained through the Competitive Bidding Program as a proxy or any kind of guide to adjust payments for DTS purchased through retail pharmacies. We have three major concerns about applying data from the mail-order competitive bidding program to retail rate-setting: First, the retail and mail order DTS supply channels differ in many ways including the range products offered. Second, the competitive bidding program prices in the Round 1 Rebid were based on a volume of testing strips that few retail outlets will need to ensure the appropriate supply for its customers. And third, as we have noted in the past, the bid and price-setting process used by CMS for the competitive bidding process for mail order DTS has serious flaws. We do not believe that Round 1 Rebid pricing information should be used in the process for determining appropriateness of DTS pricing amounts in retail settings. We note that the regulatory criteria for determining payment adjustments under the inherent reasonableness authority require that CMS collect pricing data for products used in a particular market.

- 1) Mail order and retail supply channels differ in many ways, thus making price information obtained from one setting inappropriate as a proxy to adjust payments for the other setting.

Our principal observation is that the products available in the two settings and their pricing are fundamentally different. We note that retail pharmacies and mail order suppliers are very different business models, as CMS itself recognized in 2010 proposed and final rules discussing a national mail order program for mail-order DTS. A survey conducted by the American Association of Diabetes Educators (AADE) in August 2011 of 20 Round 1 contract mail order suppliers confirms this. The survey found that one of the differentiating characteristics of the two models is the range of brands available at the two sites. AADE's survey found that contract mail order suppliers offered 38 percent of the products that are said to be offered on the Medicare website. In addition, of the 9 brands that the HHS Inspector General identified in a December 2010 report as the top mail order DTS brands by percent of market share, contract suppliers cover an average of 1.44 brands (16 percent). AADE concluded that "Medicare beneficiaries have fewer choices and limited access to the DTS most commonly selected." AADE added in its report that beneficiaries in areas subject to competitive bidding are being made to either switch to a different testing system or purchase DTS through retail settings where more brands are generally available. Apart from stocking a variety of products to be readily available for beneficiaries, retail outlets have other distinguishing features that make the retail setting a more costly business model. These include operating brick-and-mortar store fronts and having pharmacists available for in-person consultation for diabetes patients with problems or questions about their testing supplies. We believe that it would be challenging for CMS to accurately determine such operating and other costs.

- 2) Most pharmacies will be unable to obtain the same pricing as large national purchasers, such as large mail order suppliers or the very large major chain retailers, because they will not be purchasing the same volumes of product. This differential will be especially large as CMS moves toward National Mail Order, where mail order suppliers will be bidding based on the expectation of having a large national contract with the potential to sell very large numbers of strips per year. Pharmacies without comparable volumes of business cannot be expected to obtain supplies at the same price as mail order suppliers. Therefore, the single payment amount utilized for the national mail-order competitive bidding program should not be perceived as an appropriate price for DTS in the retail setting—even for comparable products, let alone other costs unique to a "bricks and mortar" operation. If retail pharmacies were also subject to the single reimbursement amount paid for mail order supplies, they too might end up limiting the range of products available and beneficiaries would be left with no options for obtaining the specific DTS products recommended by their physicians or those whose functionalities best meet beneficiary needs. This could be especially concerning for beneficiaries whose communities are served by small, independent retail pharmacies.
- 3) AdvaMed has submitted several comment letters to CMS discussing our serious concerns with the bid and price-setting process used by CMS to establish the single payment amounts used in the CBP. We have specifically recommended that the bidding methodology used by CMS require that all bidders be bound by their bids and that payments should not be determined by the median of winning bids but rather by the amounts winning suppliers actually bid. To date, CMS has made no material changes to these processes as it moves beyond Round 1 into the much larger National Mail Order round. Our concern is that CMS will continue using the same framework for determining single payment amounts for DTS as it has in the past, that this flawed framework will be applied directly or indirectly to DTS in retail settings, and that beneficiaries will experience the same limited access to brands in the retail setting that AADE has documented in its survey of mail order suppliers. Experts in competitive bidding share many of AdvaMed's concerns. Our concerns with the bidding process become critical when we read in the notice for this meeting that CMS believes that it has information necessary to determine whether it should adjust payment amounts for non-mail order DTS because it has information generated from the local Round 1 Rebid competitions for mail order DTS and other pricing information. AdvaMed argues that

Round 1 Rebid pricing information should not be considered relevant to the process for determining appropriateness of DTS pricing amounts in retail settings, because of flaws in the underlying bidding process used by CMS in the Round 1 Rebid and also because products available and used by beneficiaries in retail settings are very different from those available through mail-order, as demonstrated by the AADE survey. In addition, bid amounts obtained through a competitive bidding process inherently rely on a perceived increase in volume as competition is driven out of the market. This is not the case in a rate setting mechanism such as inherent reasonableness. We also wonder what “other pricing information” CMS is relying upon and how it might be relevant to beneficiaries’ use of DTS products in the retail setting. Since CMS has not identified the source or sources of this other data, AdvaMed is not in a position to comment upon its usefulness or validity in determining whether the current retail rates are excessive. We urge CMS to disclose this “other pricing information” as soon as possible in the interest of transparency.

In a final rule in 2010, CMS stated that the agency agreed with commenters that it was necessary to preserve beneficiary choice and access to local storefronts for obtaining their diabetic testing supplies. It is critical that an alternative payment method for paying for diabetes testing strips in retail settings not compromise beneficiary access to this option, or to the full range of products their physicians consider to be medically appropriate for their care needs. If CMS decides to proceed with an inherent reasonableness proposal relating to DTS furnished in retail settings, it will need to describe in detail the methods by which it meets the regulatory requirements for using only valid and reliable data to establish payment amounts for these products and the related services provided by bricks and mortar suppliers and living up to its commitment to preserve beneficiaries’ access to the DTS they prefer. We expect to have additional comments if and when such a proposal is made.

We thank you for the opportunity to present our concerns about applying inherent reasonableness adjustments to DTS in retail settings.