bbc Insights

Boston Biomedical Consultants, Inc. July 2012

CMS Meeting on the Inherent Reasonableness of Fee Schedule Amounts for Non-Mail-Order Diabetic Testing Supplies

Background

On Monday, July 23, 2012, the Centers for Medicare and Medicaid Services (CMS) held a public meeting to receive comments from suppliers and other interested parties regarding changes in the fee schedule of Medicare payments for non-mail-order diabetes testing supplies. The meeting marked the latest initiative by CMS to control Medicare expenditures for WBG test strips.

In 2005, CMS issued a mandate to reduce costs for Durable Medical Equipment (DME) and supplies used with DME, including WBG test strips and lancets. To recognize immediate cost reductions, CMS first phased in the items and services that would allow it to realize the greatest savings potential, including mail-order diabetic testing supplies, for which there was over $1 billion in annual allowed charges to Medicare during 2011.

CMS utilized a Competitive Bidding Process to reduce costs associated with mail-order WBG testing supplies, a process that led to a >50% fee schedule reduction in nine metropolitan statistical areas (MSAs) (Figure 1).

After rolling out the program in the nine pilot MSAs during January 2011, CMS has launched a nationwide Competitive Bidding process for mail-order WBG testing supplies, with adjusted reimbursement levels set to take effect July 2013.

Figure 1: Pricing Reductions in Competitive (CB) Bidding Areas

City or Local CB Area	Fee Schedule (Non-Mail)	Fee Schedule (Mail)	CB Amount
Charlotte –Gastonia-Concord, NC-SC	$34.85	$30.03	$14.50
Cincinnati-Middletown, OH	$38.74	$33.39	$15.22
Cleveland-Elyria-Mentor, OH	$38.74	$33.93	$15.62
Dallas-Fort Worth-Arlington, TX	$36.24	$31.24	$14.25
Kansas City, MO-KS	$34.35	$29.60	$13.94
Miami-Fort Lauderdale-Pompano Beach, FL	$38.75	$33.40	$15.20
Orlando, FL	$38.75	$33.40	$14.50
Pittsburgh, PA	$38.75	$33.40	$14.50
Riverside-San Bernadino-Ontario, CA	$38.75	$33.40	$13.88
Average of 9 Areas	**$37.55**	**$32.36**	**$14.62**
National Average	**$37.67**	**$32.47**	**----**

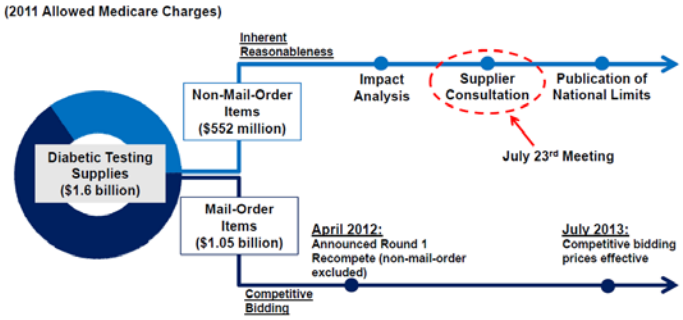
With the exclusion of non-mail-order supplies from the Competitive Bidding program, CMS highlighted the significant disparity between the single payment fee schedule amounts for mail-order ($13.88 to $15.82 in the nine local Round One Rebid MSAs) and non-mail-order diabetic testing supplies ($37.67 nationally). The agency noted that Medicare would reimburse identical products (e.g., 50-count vials of WBG test strips) at two different prices once the new mail-order fee schedule amounts take effect on July 1, 2013.

To address this discrepancy, CMS has elected to pursue Inherent Reasonableness (IR) authority to adjust the Medicare fee schedule amounts for non-mail-order WBG testing supplies. Through this process, CMS

conducted an "impact analysis" to assess the potential impact of new payment limits on the quality of service provided by suppliers. Under the guidelines of the IR process, CMS is required to meet with suppliers anticipated to be affected by the changes in prices and to consider comments from industry prior to implementing new national limits in the Medicare fee schedule for WBG testing supplies.

The July 23 public meeting represented the fulfillment of this requirement. CMS indicated that it would review comments and then determine whether to issue a formal proposal for applying the IR authority to reduce Medicare reimbursement for non-mail-order WBG monitoring supplies. Should the agency move forward with the formal proposal, it would then seek public comments for 60 days following publication, after which it would issue a final ruling (Figure 2).

Figure 2: Inherent Reasonableness (IR) Process



Meeting Overview

The July 2012 meeting provided the opportunity for stakeholders to offer their comments directly to CMS representatives. The CMS panel did not provide responses to the oral comments despite requests for feedback. Key comments from the meeting can be summarized as follows:

Independent Pharmacy Owners

- Procurement costs of WBG testing supplies are significantly higher for independent pharmacies, as compared to those for national pharmacy chains/mail-order suppliers. If the fee schedule amount is reduced, many smaller pharmacies will realize a loss with the sale of each 50-count box of WBG test strips to a Medicare beneficiary
- Limited pricing data exists indicating that current costs of WBG testing supplies are in fact excessive in the retail channel, as claimed by CMS
- Purchasing supplies at retail has become a need for patients who can no longer access their brand of choice from mail-order distributors in the nine pilot MSAs of the Competitive Bidding program
- Many pharmacists provide face-to-face training with individuals, a process which leads to improved testing adherence, and subsequently reduces the cost of long-term care for payors.

Mail-Order Distributors

- Price reductions for non-mail-order suppliers would lead to significant cost reductions for both CMS and patients
- Despite their higher purchasing costs for WBG monitoring products, independent pharmacies can reduce procurement costs by utilizing group purchasing programs
- Statistics indicate that diabetes complications did not rise following the implementation of Competitive Bidding in the nine pilot MSAs, supporting the notion that CMS can reduce annual allowed charges without sacrificing quality of care for diabetes patients.

Other Participants

- A study from the American Association of Diabetes Educators (AADE) found that of the nine top mail-order brands by market share identified by the Office of Inspector General in 2009, contractor suppliers offered, on average, only 1.44 of the brands, or 16% under the mail-order Competitive Bidding Program in the nine pilot MSAs. (Consultants' Note: For Round Two nationwide Competitive Bidding, CMS has mandated that contract winners must provide at least 50% of all different types of WBG monitoring supplies on the market by brand names and that contract winners are prohibited from providing incentives for Medicare beneficiaries to switch their brands)

- In the Federal Register notice announcing the July 23rd public meeting, CMS indicated that it considered both the price points achieved in each of the nine Competitive Bidding areas as well as a review of "other pricing information for the diabetic testing supplies in general" before determining the non-mail-order fee schedule for WBG monitoring supplies to be "excessive." Stakeholders encouraged CMS to provide greater transparency into the decision-making process by publishing the "other pricing information" for this determination.

Of note, representatives from leading manufacturers of WBG testing supplies were present at the meeting, but did not provide public comment.

Consultants' Analysis

Implementation of CMS' proposal to apply IR authority to adjust Medicare payment for non-mail-order WBG testing supplies would significantly impact the U.S. WBG Monitoring market. In the event that reimbursement of WBG test strips obtained through retail is reduced to levels present in the nine Competitive Bidding MSAs, a ~50% reduction in reimbursement would result. Such a reduction would not only reduce distributor margins, but would also prompt distributors to seek lower pricing from manufacturers. There is also the possibility that private insurers would seek similar reimbursement levels, exerting additional downward pricing pressure.

Changes in the fee schedule for non-mail-order WBG testing supplies could also lead to share gains among secondary competitors. As explained by owners of independent pharmacies during the meeting, reductions in the fee schedule of non-mail-order products would prevent local pharmacies from purchasing products below the reimbursed levels. As a result, community pharmacies would no longer be able to provide WBG monitoring products to Medicare beneficiaries. Under this scenario, customers of independent pharmacies would likely migrate to either mail-order suppliers, which have increasingly opted to provide low-cost WBG monitoring products to preserve margins, or large retail pharmacy chains, many of which offer private label WBG meters/strips.

Of note, CMS' proposal comes at a time when the FDA is evaluating tightened accuracy guidelines for WBG test strips, with the consequent need for R&D investment by manufacturers, ultimately exerting more pressure on profitability.

In sum, CMS' consideration of applying the IR authority to adjust reimbursement for non-mail-order WBG test supplies carries the real potential to exert a significant impact on pricing, distribution, and market share within the U.S. WBG Monitoring market. Given this potential, there will likely continue to be considerable feedback from all players in the WBG Monitoring market, ranging from manufacturers to distributors, retailers, and patients. It remains uncertain how CMS will strike the balance among the competing interests of the agency and these stakeholders.

For More Information Please Contact Us

Boston Biomedical Consultants, Inc.
410 Totten Pond Road, Ste 300
Waltham, MA 02451
781-890-5060
info@bostonbiomed.com
www.bostonbiomed.com

Rick Sullivan, Senior Market Analyst
Christopher Ludwig, Senior Consultant