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Survey Finds Competitive Bidding Restricts Access To Diabetes Products

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Due to poor CMS oversight, the competitive bidding system for mail-ordered diabetes testing systems has reduced patient access to the products, the chief advocacy officer of the American Association of Diabetes Educators said Jan. 23, citing a recent survey put out by the association.

Of the 20 firms selected to participate in the program, none offer a set of brands representing 50 percent of the diabetes testing strips available in spite of a provision in the 2008 Medicare Improvements for Patients and Providers Act of 2008 that required successful bidders to offer 50 percent of diabetes testing strips on the market at the time when they bid for the contract to join the mail-order program.

“The problem is CMS’ understanding of how these [20] companies are interpreting the rule. And I think there is a lack of oversight by CMS on this,” AADE Chief Advocacy Officer Martha Rinker said in an interview, for the agency has not taken action against suppliers who have changed their offerings since their bids were accepted.

AADE is a professional organization with a membership primarily composed of diabetes educators, nurses, dieticians and pharmacists. The group also sometimes collaborates with drug and device companies, including **Medtronic Inc., Johnson & Johnson** and **Roche Diagnostics Corp.**

The winning suppliers include Am-Med Diabetic Supplies Inc., Med-Care Diabetic and Medical Supplies Inc. and Kohlls Pharmacy & Homecare, Inc.

Rinker said CMS is letting them and others off the hook, enabling the suppliers to offer customers the cheapest meters, which she said are “probably manufactured across the Pacific somewhere and don’t meet FDA standards.”

“My sense is it’s not a high priority to them [CMS],” Rinker said. “And they see this as a cost savings to them. So if it’s saving them money they’re happy. But as we like to point out to them, patients with diabetes who are not managing their disease are going to cost a lot more in the long run.”

Rinker said that she has heard anecdotally that the program expansion is negatively impacting the sales of the large market leaders. J&J, maker of the *OneTouch* blood glucose monitoring systems, confirmed her observation. “CMS’s single payer amount reduction that was implemented in July

of 2013 has resulted in lower sales per unit for diabetes test strips reimbursed under Medicare,” wrote Dave Detmers, a company spokesman, in an email.

The expansion of CMS’ National Mail Order Medicare Competitive Bidding Program to include the entire nation provided the impetus for the study. Since July 2013, Medicare beneficiaries who purchase diabetes testing supplies via the mail have had to use one of the 20 winning suppliers. In 2011, when the mail-order program was a pilot as part of round one of the Medicare durable medical equipment competitive bidding program, stakeholders issued a similar warning, claiming some winning contractors were making it difficult for beneficiaries to get their preferred brand of diabetic test strips. (See [“Access To Diabetic Test Strips Jeopardized In CMS Competitive Bidding Areas”](#) – [“The Gray Sheet,” Apr. 11, 2011.](#))

The nonprofit advocacy group also charged in the report that the information about the suppliers on Medicare.gov is “inaccurate and misleading.” The report says only three of the suppliers actually offer all of the brands that Medicare.gov says it offers.

CMS has performed its own monitoring of the competitive bidding program in general, which covers other products as well. Government auditing of round one of the program, which included region-restricted competitive bidding for mail-order diabetes supplies, found no evidence of significant beneficiary complaints for product access and no evidence of clinical deficiencies in the bidding regions compared to regions where durable medical equipment were paid higher fee-schedule rates, CMS said early last year. (See [“Medicare Durable Equipment Cuts Will Deepen In Next Round Of Competitive Bidding”](#) – [“The Gray Sheet,” Feb. 4, 2013.](#))

In AADE’s survey, each supplier was contacted by seven different AADE members over the phone. The surveyors identified themselves as diabetes educators and inquired about the availability of the brands listed on Medicare.gov. If at least four of the seven surveyors were told that a brand was available, the brand was deemed to be available from the supplier. None of the suppliers told all seven surveyors that all of its listed brands were available.

"50 Percent Rule" Controversy

The 2008 congressional mandate only required suppliers to offer 50 percent of diabetes testing strips on the market at the time when they bid for the contract to join the mail-order program, but Rinker thinks CMS should go further.

"I would like to they think they do," she said, when asked if CMS has the authority to punish suppliers who no longer offer 50 percent of the diabetes testing strips on the market, but conceded, "I'm not sure they are on the same wavelength as me."

In fact, the report acknowledges that "the 50 percent rule is not a condition of on-going participation in the national CBP [competitive bidding program]."

"While a supplier was required to tell CMS that the supplier intended to offer a wide range of products, because of the manner in which CMS has interpreted and implemented this rule, there is no ongoing obligation on the supplier to actually make available the range of products reported to CMS, or any range of product," it continues.

Among the report's recommendations to CMS were strengthening beneficiary protection requirements "for future rounds of competitive bidding by requiring as a condition of continued participation in the competitive bidding program and not just as a condition of bid acceptance, that all suppliers continue to provide the same mix of brands and models as that which their bid acceptance was based upon."

It also recommended that CMS regularly audit the suppliers and create corrective action plans, regularly update Medicare.gov, improve communications with Medicare beneficiaries with diabetes and create standardized language for suppliers to use when addressing beneficiary questions.

CMS did not return a request for comment from "The Gray Sheet."

Meter Accuracy Concerns

"Not all meters that are on the American market meet regulatory standards. And there has been some evidence comparing meters that the accuracy of some is less than acceptable. It's not anything we've done, it's what others have done in this area," Rinker said.

According to a poll commissioned by AADE, 13 percent of

diabetes patients who administer insulin have experienced health complications due to inaccurate blood glucose readings, including 27 percent of those with type 1 diabetes.

Indeed, clinicians, industry, academics and FDA agreed that certain 510(k)-cleared blood glucose meters do not perform at the regulatory standards for which they were cleared after they hit the market at Diabetes Technology Society sponsored a meeting in May 2013. (See "[Blood Glucose Meter Accuracy Problems Acknowledged By FDA, Industry And Clinicians](#)" – "[The Gray Sheet](#)," May 27, 2013.)

Rinker said the progress hasn't been sufficient since then. "FDA has just given 510(k) clearance to the *Prodigy* [Choice Blood Glucose Monitoring System], and yet they've put a warning on it that you can't use it to titrate insulin. That's what you would think a blood glucose level is for," she said.

The FDA-mandated labeling for the device, manufactured by Prodigy Diabetes Care LLC, states, "Do Not Use The Prodigy Choice® To Calculate Insulin Dosages." The product was cleared in November 2013.

FDA is working on improving the accuracy of the blood glucose monitors and issued two draft guidance documents Jan. 6 providing recommendations that seek to distinguish pre-market submission requirements for blood glucose monitors used in professional health care settings versus over-the-counter self-monitoring by lay-persons. (See "[FDA Distinguishes Pre-Market Expectations For Professional Vs. Home Glucose Meters](#)" – "[The Gray Sheet](#)," Jan. 13, 2014.)

Diabetes testing strips aren't the only diabetes device to be affected by competitive bidding. CMS' implementation of contracts and prices for the round one recompute of Medicare's durable medical equipment includes insulin infusion pumps among its six product categories, a decision Rinker opposes. (See "[Insulin Pumps, Including Sensor-Augmented, Enter Competitive Bidding](#)" – "[The Gray Sheet](#)," Jan. 13, 2014.)

"I think it's an unintended consequence that insulin pumps are part of the class that's going into competitive bidding because they really are individualized pumps. They're not pumps that you would use for more than patient," she said, adding that AADE is working with its partners to remove insulin pumps from the competitive bidding process. 