Roche

Diagnostics

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

March 17, 2009

RE: Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) – CMS-1561-IFC

Dear Ms. Frizzera:

I am writing on behalf of Roche Diagnostics Corporation (Roche) regarding the Interim Final Rule (IFR) implementing changes to the competitive acquisition program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). We concur with your decision to delay the effective date of the IFR on DMEPOS competitive bidding and urge the Centers for Medicare & Medicaid Services (CMS) to engage in further rulemaking before implementing the first round of the program.

Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. Roche has developed a broad range of innovative diabetes management products and services that provide actionable health information to patients, caregivers, and healthcare providers. Our diabetes management products include ACCU-CHEK blood glucose monitoring systems and insulin pumps, both critical for the treatment of diabetes.

The current competitive bidding regulation fails to recognize the importance of testing supplies to diabetes care and provides no safeguards to maintain access to a sufficient range of diabetes testing products. Without such protections, beneficiaries in competitive bidding areas could face disruption in their blood glucose monitoring which would negatively impact both their health and expenditures by the Medicare program. Since these protections were not included in the program as originally designed, we believe additional notice-and-comment rulemaking is necessary. Additional rulemaking would allow interested parties to provide the full scope of valuable insight to help in developing a program that sufficiently addresses these concerns and avoids jeopardizing care provided to some of the Medicare program's most vulnerable beneficiaries.

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Diabetes Testing Supplies Differ from Other Competitive Bidding Items

Diabetes testing supplies are essential to self-monitoring of blood glucose levels which is integral to effective diabetes care. Other items included in the first round of competitive bidding, such as hospital beds, walkers, and support surfaces, do not directly impact treatment options in the same manner. According to the United Kingdom Prospective Diabetes Study (UKPDS), better blood glucose control for people with Type 2 diabetes reduces the risk of many complications including early kidney damage and strokes. Failure to adequately monitor blood glucose levels can lead not only to increased negative health outcomes for beneficiaries but it can also increase Medicare costs as the program pays more to treat these resulting complications.

Regardless of the manufacturer, the purpose of diabetes testing supplies is to support timely and accurate monitoring of blood glucose levels. However, specific products address the individual needs of people with diabetes. Meters and testing equipment can be designed to minimize pain from testing, avoid retesting by ensuring an accurate first test, provide information to beneficiaries with impaired vision, and can include features such as preloaded test strips and lancets for beneficiaries for whom conditions such as arthritis may make operating a monitor difficult. Further, once a beneficiary has become accustomed to a monitoring system and incorporated that specific product into their monitoring routine, shifting to a new system can be disruptive to their care.

To Avoid Disrupting Patient Care, Competitive Bidding Must Include an Adequate Range of Products

As noted, a range of testing supplies are used by people with diabetes and to avoid disrupting care for beneficiaries in the competitive bidding areas, a range of products must be included in the competitive bidding program. Failure to do so could force beneficiaries to adopt new blood glucose monitoring systems and potentially interrupt their testing routine. Disruptions in monitoring could lead to uneven blood glucose control which may result in additional care and intervention. Limiting the products available under competitive bidding may result in short-term savings for Medicare on DMEPOS items but it could have the unintended consequence of increasing Medicare spending on other types of care in the long run.

Blood glucose monitors and test strips cannot be used interchangeably between one brand/model and another brand/model. If a full range of diabetes testing supplies is not available to beneficiaries in the competitive bidding areas, beneficiaries will be forced to replace the blood glucose meters. Such a transition could result in unnecessary costs that would have to be borne by them or the Medicare program. This is especially critical considering the recent analysis of the National Health and Nutrition Examination Survey (NHANES) by epidemiologists at the National Institutes of Health and the Centers for Disease Control and Prevention which asserts that nearly one-third of those 65 and older have diabetes.[1]

The demonstration projects testing the competitive bidding model for DMEPOS products in Florida and Texas did not include diabetes testing supplies. Therefore, CMS does not have

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[1] American Diabetes Association. *Diabetes Care*. Volume 32, Number 2, February 2009.

direct experience with how limitations on those products will actually affect beneficiaries. However, the initial bidding for round 1 showed that suppliers will attempt to limit the range of products provided: more than half the chosen suppliers did not include the most commonly prescribed items in their bids.

To help address this situation, CMS should adopt the standard required by the Medicare Improvements and Patient Protection Act of 2008 (MIPPA) for later rounds of bidding for mail-order diabetes supplies. Specifically, the first round bids should be required to include at least fifty percent of the types of products available. Such a protection will help avoid unnecessary disruption in monitoring for a majority of beneficiaries.

Other Patient Protections are Also Necessary

In addition to access to a sufficient range of products, beneficiaries in competitive bidding areas need additional protections that were not included in the competitive bidding program's original design. Researchers at George Washington University have identified five key areas for beneficiary safeguards and determined that the DMEPOS competitive bidding did not include provisions in most of these areas, including marketing protections and information services.[2] They compared the DMEPOS competitive bidding program design to requirements for the Medicare Advantage (MA) and Medicare prescription drug program and found that many patient protections provided under those competitively bid systems do not apply to the DMEPOS program. Deficiencies noted include the absence of an exceptions process for specific items based on medical necessity and clear access and quality standards.

While the MA and prescription drug programs do differ significantly from the DMEPOS program in scope and design, we believe that additional protections are needed for the DMEPOS program to ensure appropriate care for beneficiaries living in competitive bidding areas. In particular, Roche recommends that CMS propose specific new protections regarding telemarketing and the quality and accessibility of materials provided to beneficiaries affected by the competitive bidding program. In the awards made last year, CMS included a number of entities that had no prior experience with diabetes systems, supplies, or services. We understand that prior experience is not required for suppliers entering the regular Medicare program, but the competitive bidding program presents additional challenges to suppliers and to Medicare. CMS has, in our view, a higher obligation to assure that new entrants, in particular, will be stable and able to provide quality services to the beneficiaries that will rely upon them. Consequently, we urge CMS to revisit the financial, experience, performance, and quality standards applicable to diabetes testing supply vendors in the competitive bidding program.

CMS Should Plan for Improvements in Implementation

The initial bidding experience demonstrated that strategic incentives in the competitive bidding approach can lead to erroneous prices. Roche recognizes that CMS anticipates payment amounts determined by competitive bidding to be below the DMEPOS fee schedule amounts. However,

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[2] Rosenbaum, Sara, et al, "Medicare Competitive Acquisition: Implications for Persons with Diabetes", George Washington University, June 18, 2008.

the amounts determined by the initial round of bidding were unexpectedly low. This outcome may have occurred because the competitive bidding structure provides gaming opportunities for individual suppliers. A supplier could submit a low bid with the expectation that it will secure a slot as a selected supplier but that the competitive payment amount will exceed the bid. This scenario is extremely beneficial to a supplier if that supplier is the only one to attempt it. However, if multiple suppliers submit exceptionally low bids, the resulting payment amount can be pushed to unsustainably low levels. We believe this occurred in the initial round of bidding. To remedy this situation, CMS should propose additional protections that would eliminate opportunities for suppliers to submit bids at price levels for which they do not expect to actually provide the covered items or perhaps for CMS to even predetermine the market basket of the most commonly prescribed systems that the bid is based upon in order to ensure patient access.

In addition, last summer's implementation of competitive bidding, though quickly halted, nonetheless revealed a number of implementation problems. In several instances, selected suppliers had little direct experience in furnishing DME or no or limited physical presence in the areas they were expecting to serve and anecdotal reports suggested beneficiaries in those areas had difficulty obtaining needed items. Information was provided to beneficiaries that was inaccurate or inappropriate, including erroneously notifying beneficiaries that did not live within a competitive bidding area that they were part of the program. CMS education materials were not provided in a timely manner, arriving in some cases the day before the program went into effect. Whether all of the problems that were emerging are now sufficiently evident is open to question. We believe that CMS should solicit information from and work with stakeholders to help it insure that these and other problems are sufficiently addressed.

Expanding Competitive Bidding to Other Routes of Supply is Inappropriate

The IFR requested comment on expanding competitive bidding to diabetes testing supplies through means other than mail-order. Such a change would eliminate an option for beneficiaries whose preferred product is not offered by a mail order supplier to obtain their supplies from a retail pharmacy. Such an option is especially important in the absence of a mechanism to appeal product denials based on medical necessity.

Roche appreciates that CMS does not intend for competitive bidding to impact Medicare beneficiaries' and their health care providers' choice of blood glucose monitors. Ensuring that the mail order program remains voluntary is a critical element in protecting the ability of Medicare beneficiaries to obtain their diabetes testing supplies from a retail pharmacy.

Researchers at George Washington University stated that the welfare of the 7.5 million poorest Medicare beneficiaries, 40% of all beneficiaries, should be of primary consideration in determining whether to expand competitive bidding. Further, they concluded that a Medicare policy which limits access to blood glucose testing supplies and outlets could widen rather than

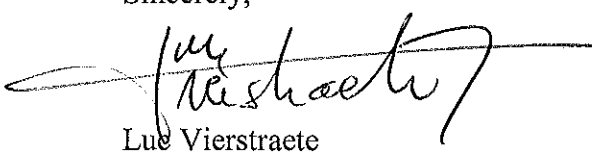
reduce health disparities for the very Medicare beneficiaries who historically are at risk because of income, race, and ethnicity.[3]

While we recognize the complexity of differentiating the mail order sector from other means of providing supplies, given the importance of testing supplies to diabetes care and the vulnerability of this patient population, we believe it is inappropriate to consider expanding competitive bidding for diabetes supplies at this time.

Conclusion

In conclusion, Roche recommends that additional patient protections be adopted in the first round of competitive bidding, including a requirement to cover a sufficient range of products, explicit telemarketing protections, and requirements for providing accurate, understandable, and accessible information. In addition, CMS should revise the methodology for determining competitive payment amounts to discourage artificially low bids. Since such protections are not currently incorporated into the program, we believe additional rulemaking is necessary and would provide CMS with the appropriate input to ensure that the competitive bidding program adequately maintains access to items essential to diabetes care. Failure to do so could result in poor health outcomes for beneficiaries and inadvertently result in higher costs for the Medicare program.

Sincerely,



Luc Vierstraete
Senior Vice President and General Manager
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[3] Rosenbaum, Sara, et al, "Medicare Competitive Acquisition: Implications for Persons with Diabetes."