March 31, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Temporary Delay in Medicare Round 2019 DME Competitive Bidding Program – Insulin Pumps and Supplies

Dear Administrator Verma:

On February 7, 2017, the Centers for Medicare and Medicaid Services announced that it would temporarily delay moving forward with the next steps of the Medicare Round 2019 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program to allow the new Administration further opportunity to review the program. Our companies – the major manufacturers of durable insulin pumps used in the United States – and the Advanced Medical Technology Association (AdvaMed) support this delay, and we wish to call to your attention problems regarding the proposed new national category for Insulin Pumps and Supplies that justify a review of this product category and the appropriate steps to take moving forward to ensure patient access to advanced insulin pump therapy is not jeopardized.

In brief, we believe that CMS should reconsider whether insulin pumps and related supplies are suitable products for competitive bidding, and should remove these products from the program. If, after considering our collective input as provided here, the agency nevertheless proceeds to include Insulin Pumps and Supplies in Competitive Bidding Round 2019, we believe this category should be tested on a much more limited basis, rather than nationally, in order to assure that the supplier compliance and patient access issues that plagued these products in the External Infusion Pumps and Supplies category of the Round 1 Recompete (R1R) do not recur. Further, we would urge that the rates established in non-competitive bidding areas be reset to the values in the 2015 DMEPOS Fee Schedule, without adjustment based on information from competitive bidding.

The remainder of this letter provides further detail on these issues. We respectfully request your action to address these problems as the Administration reviews the Medicare DME Competitive Bidding Round 2019 program further.

Major Supplier Compliance & Patient Access Problems in First Round of Infusion Pump Bidding

The proposal to include insulin pumps and supplies as a standalone category for national bidding in Competitive Bidding Round 2019 raises several concerns. Insulin pumps and supplies were first subject to competitive bidding in the External Infusion Pumps and Supplies category of the R1R, which was conducted from 2014-2016. That round proved highly problematic. Many winning suppliers failed to comply with the rules of the program\(^1\) and patient access to insulin pumps supplies was compromised in the nine R1R competitive bidding areas (CBA).\(^2\)

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\(^1\) American Association of Diabetes Educators, “Competitive Bidding Program External Infusion Pumps and Supplies – Issues with Supplier Compliance Impacting Beneficiary Access to Insulin Pumps and Related Supplies,” December 2014. Available at the following link:
These problems resulted from the faulty construction of the External Infusion Pumps and Supplies category by CMS, and the requirement that winning suppliers must provide all of the products in the category. This category included 14 disparate HCPCS codes for ambulatory infusion pumps that were never previously furnished together by suppliers. Three of these codes related to insulin pumps and supplies. The requirement to bid on all the codes in the category consequently excluded most of the longstanding suppliers of insulin pumps and supplies from the program – typically a selected set of diabetes-oriented distributors and insulin pump manufacturers. The remaining bidders had little knowledge of the insulin pump market – including prevailing prices to source such products – or the demanding requirements to serve the complex insulin-dependent diabetic population. Consequently, the submitted bid prices for insulin pumps were incorrect and did not reflect the knowledge of experienced suppliers.

Upon immediate implementation of the program, the vast majority of selected vendors failed to furnish insulin pumps and supplies at the single payment amounts derived from their bid prices, and patient access to insulin pumps and supplies was impaired in many of the original 9 CBAs, most acutely in the Miami CBA, where zero contracted suppliers would furnish products as required under the program. To our knowledge, no enforcement ever occurred against suppliers who failed to comply with program requirements.

Based on the troubling R1R experience, CMS removed the External Infusion Pumps and Supplies category from Competitive Bidding Round 2017. While no public explanation was ever provided by CMS for the removal, we supported this action. Despite the documented patient access issues in R1R, CMS subsequently proceeded with a policy in 2016 to adjust national payment rates for insulin pumps and supplies using information from competitive bidding. These artificially deflated rates did not reflect the insulin pump market in the nine R1R CBAs and failed to assure supplier participation and compliance with the program in the CBAs.

**Revisions Needed for Insulin Pumps and Supplies Category in Competitive Bidding Round 2019**

On the basis of the very significant supplier compliance and patient access issues that occurred in R1R for insulin pumps and supplies, we believe the following issues must be addressed by HHS and CMS before proceeding further with insulin pumps in Competitive Bidding Round 2019.

- **Insulin Pump Category.** HHS and CMS should reconsider whether insulin pumps and related supplies are appropriate products for competitive bidding, and should remove these products from the program. Insulin pumps are advanced technology. Patients require detailed training and ongoing support to assure optimal delivery of insulin therapy and compliance with the treatment regimen. Because insulin pumps are a life sustaining device, failure to properly train and support patients can lead to hospitalizations, permanent injuries, and, in extreme cases, even death if a patient receives either too much or too little of the required insulin doses. Suppliers must be fully experienced and knowledgeable in working with complex diabetic patients and be capable and willing to provide substantive 24-hour customer support, 365 days of the year. Both the DME capped rental program and the Medicare national coverage determination for insulin pumps have considerable administrative and documentation requirements (and related costs to meet these requirements) associated with them. Significant investments continue to be made in insulin pump technologies to bring forth new automated

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2 Ibid.; analysis performed by Direct Research, presented by AdvaMed to Sean Cavanaugh, CMS Deputy Administrator and Director, Center for Medicare, March 22, 2016
insulin delivery systems under the FDA’s pathway for Artificial Pancreas Device Systems. There is significant utilization of class III insulin pumps among the Medicare population, even though these devices are excluded from competitive bidding by statute. An additional complication for the insulin pump category is that only one HCPCS code is used for both class II and class III insulin pumps. For all these reasons, HHS and CMS should reconsider whether it is appropriate to include insulin pumps in the competitive bidding program.

- **Limited Bidding Area.** The Competitive Bidding Round 2019 program announcement designated Insulin Pumps and Supplies for national competitive bidding. Since the initial experience with infusion pump competitive bidding demonstrated clear limitations, with negative implications for patient access to medically necessary therapy, we believe it would be inadvisable to move to national bidding for insulin pumps and supplies. If CMS proceeds with insulin pumps in competitive bidding, we believe it should only do so in the nine Round 1 CBAs, and should ensure that a comprehensive evaluation and monitoring plan is in place to assure that program rules are met and continued patient access is guaranteed.

- **Rates in Non-Competitive Bidding Areas.** In 2016, CMS implemented a policy of adjusting DMEPOS rates in non-competitive bidding areas based on information from competitive bidding. As noted above, we believe the rates for insulin pumps and supplies from the R1R External Infusion Pumps category were incorrect, artificially deflated, and not reflective of the market in the nine R1R CBAs. These rates failed to assure supplier compliance with the program in the CBAs, jeopardized patient access, and failed to take into account the substantive training and ongoing support needed to assure safe and effective insulin pump therapy. Consequently, we believe it is inappropriate to use these rates for the purposes of adjusting DMEPOS payment rates in non-competitive bidding areas and we request that CMS restore the values in the 2015 DMEPOS Fee Schedule for the rates in the non-competitive bidding areas.

Combined, we believe these revisions will better assure continued patient access to this medically necessary and beneficial therapy. On behalf of our companies and the Advanced Medical Technology Association, we deeply appreciate your consideration of these recommendations. If you need further information or would like to discuss these issues further, please contact Richard Price at AdvaMed (RPrice@AdvaMed.org; (202) 434-7227).

Sincerely,

Steve Phillips  
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CC: Secretary Tom Price, MD