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BY ELECTRONIC DELIVERY

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: Medicare Program; Competitive Acquisition for Certain Durable
Medical Equipment, Prosthetics, Orthotics, and Supplies
(DMEPOS) and Other Issues (CMS-1270-P)**

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the competitive bidding program for certain covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), published in the Federal Register on May 1, 2006 (the Proposed Rule).¹ BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO

¹ 71 Fed. Reg. 25653 (May 1, 2006).

members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new treatments and ensuring patient access to them, BIO believes that it would be inappropriate to include infusion pumps and related drugs in the initial phase of the competitive bidding program. These drugs are commonly delivered through infusion pumps and are used to allow patients with conditions such as cancer, intractable pain, and severe spasticity to receive care in their own homes. The success of these patients' treatments – including avoidance of hospitalization, painful complications, and possibly death – depends on continued access to the most appropriate drugs, through the most appropriate infusion pumps. We believe that implementation of a new, untested payment system that could require many patients to change suppliers would disrupt beneficiary access. Accordingly, we urge CMS to exclude these therapies from the initial phase of the competitive bidding program.

If CMS decides to include infusion pumps and related drugs in the competitive bidding program, BIO urges the agency to issue a second proposed rule, with opportunity for public comment, to discuss in greater detail several important elements of the program. First, although CMS identifies 20 durable medical equipment (DME) policy groups for illustrative purposes,² it does not describe how the groups will be defined for the actual program. We recommend that CMS define these categories narrowly and issue a second proposed rule to allow stakeholders to comment on these important definitions. Second, CMS should protect beneficiary access to the most appropriate therapy by ensuring that each formulation is carried by at least one supplier in each competitive bidding area. Third, CMS proposes to require the single payment amount for each item to be less than the amount that otherwise would be paid under the applicable fee schedule for that item.³ We ask the agency to reconsider this proposal and use a methodology similar to that used in the competitive acquisition program (CAP) for drugs and biologicals to set the single reimbursement amount. Fourth, we urge CMS to reimburse new items appropriately and not to apply the proposed gap-filling process, particularly for drugs and biological products.⁴ Fifth, we believe CMS should not use rates from the competitive bidding program to adjust payment rates for DMEPOS in other areas. Sixth, we request that the agency provide a grace or transition period for beneficiaries when the program becomes effective

² [Id.](#) at 25691.

³ [Id.](#) at 25678.

⁴ [Id.](#) at 25687.

and as new items and geographic areas are added. Seventh, CMS should permit traveling beneficiaries to obtain replacement supplies from any supplier in a competitive bidding area. Finally, the agency should clarify the application of the non-discrimination clause and describe how it intends to verify compliance with it. These comments are discussed in more detail below.

I. CMS Should Exclude Infusion Pumps and Related Drugs from the Competitive Bidding Program (Criteria for Item Selection)

Drugs and biological products should be excluded from the competitive bidding program because they are fundamentally different from other DME items. Unlike many of the products that could be included in the competitive bidding program, each drug or biological product is a unique therapy, with its own distinguishing qualities and handling requirements. Some infusion drugs furnished through an item of DME are single source therapies, for which the Food and Drug Administration (FDA) has identified no therapeutically equivalent products. Others may share a Healthcare Common Procedure Coding System (HCPCS) code with other drugs that have the same name but have different effects on the patient. Additionally, several of these drugs are produced by only one manufacturer and may have limited distribution networks. To protect beneficiary access to the most appropriate therapy, any competitive bidding program would have to include not only every HCPCS code in a category, but also every formulation of every covered single source drug. We believe it would be extremely difficult to design such a program due to the number of products, differences in distribution networks, and specialization of many suppliers.

Furthermore, CMS has little experience with competitive bidding for drugs and thus cannot ensure that it can achieve its desired savings without harming beneficiary access to infusion pumps and related drugs. Although CMS conducted competitive bidding demonstrations for other types of DME, including several of the policy groups named in the Proposed Rule, these demonstrations differed significantly from the proposed program. The demonstrations tested competitive bidding for nebulizer drugs, not infusion drugs and biological products. Unlike several of the infusion pump drugs, most nebulizer drugs are multiple source therapies that do not present as many therapeutic equivalence concerns. In addition, many nebulizer drugs also are produced by at least 10 manufacturers, allowing bidders in the demonstration project a wide choice of manufacturers from which to obtain suitable drugs for most beneficiaries. Given the large number of brands to choose from, it was more likely that the demonstrations' participating suppliers would be able to obtain lower prices on

these drugs than if they were bidding on single source drugs or drugs with a couple of manufacturers. Because the proposed program would cover a different set of products, it is not at all apparent that CMS would have similar success in protecting access to infusion therapies while lowering spending as it did in the nebulizer drug demonstrations.

In addition, although we expect that CMS will learn more about competitive bidding for drugs and biological products from its experience with the CAP, this program has not yet begun to supply drugs to beneficiaries. It remains to be seen if the CAP's bidding and distribution requirements will affect beneficiary access to care. We note, however, that the CAP also includes protections for patient access that CMS has not proposed to provide in the competitive bidding program. Unlike the proposed program, the CAP offers physicians the choice to participate or to obtain drugs for their patients on their own. Under the proposed program, all beneficiaries and physicians would be required to obtain covered products from contracted suppliers. If the selected vendors are not able to ensure access at the single payment amount, beneficiaries may have nowhere else to turn for their critical infusion drugs. Because CMS still has much to learn about using competitive bidding for drugs and biological products, we believe it is essential that CMS take its time to make sure the competitive bidding program is designed to protect beneficiary access to care. We urge CMS to exclude infusion pumps and related drugs and biologicals from the competitive bidding program until it can resolve these and other stakeholder concerns about beneficiary access.

II. If CMS Includes Infusion Pumps and Related Drugs in the Program, It Should Issue a Second Proposed Rule to Define Narrow Categories for these Therapies (Criteria for Item Selection; Submission of Bids Under the Competitive Bidding Program; Regulatory Impact Analysis)

In the Proposed Rule, CMS provides some general information on its criteria for selecting product categories for competitive bidding, but the agency does not provide enough information for stakeholders to comment in detail. It is especially unclear whether CMS intends to establish broad or narrow product categories. CMS proposes to define the term “product category” as a “group of similar items used in the treatment of a related medical condition.”⁵ The Proposed Rule identifies 20 DME policy groups, including infusion pumps and related drugs,

⁵ Id. at 25672.

for illustrative purposes in the Proposed Rule.⁶ CMS acknowledges that these policy groups will not necessarily correspond to the product categories used for competitive bidding.⁷ One of these policy groups is defined broadly as “Infusion Pumps and Related Drugs.”⁸ CMS also notes that intends to promote specialization among suppliers,⁹ suggesting that categories may be defined narrowly. From this limited information, it is unclear how CMS would define a product category for infusion pump drugs. CMS could separate the drugs into different categories based on the medical condition they treat, such as cancer or pain management. Alternatively, CMS could group all of the drugs into a single broad category.

Because CMS’ choice of categories will have a significant effect on bidding and patient access, the agency should issue a second proposed rule to define each category narrowly. CMS proposes to require bidders to submit separate bids for all items in a product category.¹⁰ If CMS defines a category too broadly, it may prevent specialty providers who focus on certain conditions from being able to bid. Similarly, CMS proposes to require physicians who also are DMEPOS suppliers to submit bids.¹¹ These physicians are likely to supply only the drugs related to their practices, and requiring them to supply all DME infusion drugs would be another disincentive, in addition to the administrative burden of preparing a bid, to physician participation. We recommend that CMS apply narrow definitions of product categories to increase the number of potential bidders and ensure patients’ continued access to care from trusted suppliers, such as their own treating physicians. We also recommend that CMS issue a second proposed rule to allow stakeholders the opportunity to comment on these categories.

III. If CMS Includes Infusion Pumps and Related Drugs in the Program, It Should Ensure that Each Brand of Drug is Offered by at Least One Supplier in Each Area (Physician Authorization/Treating Practitioner)

BIO supports CMS’ proposal to allow the physician or treating practitioner to specify a particular product brand or mode of delivery if he or she

⁶ Id. at 25671.

⁷ Id. at 25670.

⁸ Id. at 25671.

⁹ Id. at 25673.

¹⁰ Id. at 25672.

¹¹ Id.

determines that a particular item would avoid an adverse medical outcome.¹² CMS would require the contract supplier to furnish the item, assist the physician in finding another contract supplier in the area who can provide the item, or consult with the physician to find a suitable alternative product.¹³ If the physician does not revise the order to use an alternative product, the contract supplier would not be reimbursed for providing a product that does not match the physician's order.¹⁴ BIO thanks CMS for drafting this proposal that recognizes the importance of providing the care as prescribed by the patient's physician. For many patients, a specific brand or formulation of a drug is more effective than other therapies that share the same HCPCS code. Allowing the physician to obtain the exact formulation that is best suited to the patient's needs is essential to ensuring patient access. Similar to the "furnish as written" protection in the CAP, the determination of medical necessity should be made by the physician. His or her medical judgment should not be overruled by the DME supplier.

We are concerned about how this proposal can be reconciled with CMS' plan not to require a contract supplier to provide every brand of product in a HCPCS code.¹⁵ If CMS does not require every supplier to carry every brand, there is no assurance that a supplier will be able to find an alternate supplier in the area to fulfill the physician's order. We recommend that CMS include in its evaluation of bids an assessment of whether the bidding suppliers can provide all brands of each product within a category. CMS should ensure that each brand is carried by at least one supplier in the competitive bidding area.

CMS acknowledges that section 1847(b)(7) of the Social Security Act authorizes the agency to establish separate categories for items within HCPCS codes if the clinical efficiency and value of items within a given code warrants a separate category for bidding purposes.¹⁶ BIO urges CMS to exercise this authority to protect access to infusion drugs and biological products. CMS also notes that it believes the HCPCS process adequately separates items based on their function.¹⁷ As we have explained in comments on other rules and on the HCPCS process, BIO is concerned that the current HCPCS process incorrectly groups therapies that are not interchangeable into a single code. We believe that therapies with unique pharmacologic properties, dosing regimens, mode of administration,

¹² Id. at 25684.

¹³ Id.

¹⁴ Id.

¹⁵ Id.

¹⁶ Id.

¹⁷ Id.

or side-effect profiles should not share a HCPCS code. We have recommended that CMS assign a unique HCPCS code for each biological or brand drug product.¹⁸ If CMS does not create such unique codes, CMS should require suppliers to include at least one National Drug Code (NDC) for each sole source therapy (i.e. biologicals and single source drugs), even when the therapies are billed using the same HCPCS code.

IV. If CMS Includes Infusion Pumps and Related Drugs in the Program, It Should Not Require the Single Price for Each Drug to be Less Than the Otherwise Applicable Reimbursement Amount (Conditions for Awarding Contracts, Determining Single Payment Amounts for Individual Items)

The Medicare statute prohibits the Secretary from awarding a contract to a bidder unless the Secretary finds that the “total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.”¹⁹ CMS interprets this requirement to mean that the bid price for each item must be less than the current fee schedule amount for that item.²⁰ BIO is concerned that this interpretation will discourage bidders and may harm access to care by setting unrealistically low reimbursement rates. Instead, we recommend that CMS seek savings in the aggregate rather than on each item. This interpretation would be similar to CMS’ approach to the CAP for physician administered drugs. Under the CAP, the single payment rate for a particular drug may be more than its average sales price (ASP) based rate, as long as the total anticipated spending for the drug category is less than the ASP-based reimbursement for those drugs. Given that the current reimbursement amounts for eight drugs administered through items of DME are less than their average sales price-based reimbursement rates,²¹ we believe that the proposed requirement could not be satisfied for all drugs. We also note that the competitive bidding demonstration resulted in reduced fees for only 16 out of 27 nebulizer drugs, yet produced an aggregate savings to Medicare.²² We urge CMS to interpret the

¹⁸ BIO, Testimony to Healthcare Common Procedure Coding System Workgroup, May 2006.

¹⁹ Social Security Act § 1847(b)(2)(A)(iii).

²⁰ 71 Fed. Reg. at 25678.

²¹ See April 2006 ASP Pricing File, http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp#TopOfPage.

²² Tommy G. Thompson, Final Report to Congress: Evaluation of Medicare’s Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 2004, http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf.

statute to require an aggregate savings, rather than a reduction in the reimbursement amount for each item.

Similarly, when analyzing bids for infusion pumps, CMS should take into account the total cost of the entire course of care for the patient. For example, a less costly infusion pump may only work with more costly, dedicated tubing and supplies, creating a more expensive course of care than a more costly pump that would work with any type of tubing and supplies. Moreover, universal tubing and supplies typically can be used both in conjunction with an infusion pump as well as with gravity drip, eliminating the need for the Medicare program to pay for two individual sets. Similarly, a more costly pump is likely to contain features that protect patients against medical errors, potentially preventing hospitalizations or other medical interventions. These features could be critical for patients receiving certain “high risk” drugs or beneficiaries with early dementia or other medical conditions where alerts, alarms, and safety protocols could be life saving. CMS should ensure that bidders bid on a wide range of infusion pumps such that patients have ready access to the model that best meets their needs. Moreover, bidders should be required to bid on the tubing, kits, and supplies that works with the infusion pumps on which they have submitted bids. The agency then should analyze the total cost of the entire course of care for the patient as part of selecting suppliers.

We also are concerned that CMS’ proposes to use an untested methodology to set the single payment amount for that item. CMS proposes to set the single amount at the median of supplier bids that are at or below the pivotal bid.²³ In the demonstration projects, CMS used an adjustment factor to lessen the likelihood of setting payments below the prices bid by winning suppliers. We recommend that CMS use this methodology for the competitive bidding program, too, rather than applying a new, untested rate-setting technique. Using an adjustment factor or a percentile threshold, such as the 90th percentile of winning bids or no lower than 5 percent below the highest winning bid, would help to ensure that the single payment rate is adequate to allow winning bidders to provide access to quality service and appropriate technologies.

In addition, we oppose the proposal to allow contract suppliers to offer rebates if their bid prices are lower than the single payment amount.²⁴ We share the belief of the Program Advisory and Oversight Committee that this

²³ 71 Fed. Reg. at 25679.

²⁴ *Id.* at 25680.

proposal should not be implemented. Rebates could be used to encourage beneficiaries to choose the least expensive treatment option, not the most appropriate treatment option. We also are concerned that allowing suppliers to offer rebates could raise significant fraud and abuse concerns for Medicare suppliers. We urge CMS to eliminate this proposal from the final rule.

V. CMS Must Reimburse New Items Appropriately (Gap-Filling)

When a HCPCS code for a new item of DME is introduced in the middle of a billing cycle, CMS proposes to use a revised gap-filling process to establish a payment amount for the item until the next bidding cycle. Under this process, CMS would establish a payment amount for a new item using the applicable rates for items determined to be comparable.²⁵ This process is more akin to the cross walking methodology for laboratory tests than the gap-filling methodology and assumes that new products will not represent innovation in patient care.

BIO opposes the application of this methodology, particularly for drugs and biological products. As we described above, each drug or biological is a unique therapy and should be reimbursed accordingly. Without assurance of an appropriate reimbursement rate, beneficiaries may be denied access to new treatment options, and further innovation may be discouraged. Rather than using the rate for one drug to establish payment for another, CMS should reimburse new drugs at 95 percent of average wholesale price (AWP), as DME infusion drugs currently are reimbursed, or 106 percent of WAC or 106 percent of ASP, once reported, as it does for new drugs provided by physicians or in hospital outpatient departments and for new drugs added to the CAP between bidding periods. We are concerned about the use of gap-filling for other new items as well. We ask CMS to eliminate this issue from the final rule and use a separate rulemaking process to obtain comments on a more fully-developed proposal that better fosters innovation.

VI. CMS Should Not Use Information from the Competitive Bidding Program to Adjust Payments for DMEPOS in Areas Not Included in a Competitive Bidding Program (Payment Basis)

CMS proposes to exercise its authority, effective January 1, 2009, to use payment information determined under the competitive bidding program to adjust payment amounts for DMEPOS in areas not included in a competitive

²⁵ Id. at 25688.

bidding program, although the agency has not developed a methodology for doing so.²⁶ We urge CMS to take care before exercising this authority. First, the agency should assess the effect of competitive bidding on beneficiary access to quality care in the areas covered by the program. CMS must be able to show that the rates established through competitive bidding do not harm beneficiary access to care before applying those rates to other areas. Second, if CMS decides to use data from competitive bidding to adjust payment rates, it should publish a proposed rule describing its proposed methodology and allow stakeholders ample time to comment before implementing any rate adjustments. The development of another reimbursement methodology for DMEPOS would have significant consequences for beneficiaries, the Medicare program, suppliers, and manufacturers and must be pursued only in a forum that allows for full public notice and opportunity for comment.

VII. CMS Should Provide a Grace or Transition Period and Closely Monitor Patient Access After Implementation (Terms of Contract)

In order to minimize disruption to patient care, CMS should provide a grace or transition period of at least 90 days during which beneficiaries could obtain items subject to competitive bidding from non-contract suppliers. These suppliers would be paid under the applicable fee schedule. Such a transition is particularly necessary for patients receiving a course of infusion therapy through a pump. CMS should ensure that beneficiaries are not forced to switch infusion pumps or related drugs on a given day in a given city merely because the competitive acquisition program becomes effective. To do so would disrupt care and could have a detrimental effect on patient care and clinical response, as we learned from the recent Medicare Part D implementation. CMS has the legal authority to provide a grace or transition period. Doing so is imperative for patient care.

During and after implementation of the competitive acquisition program, CMS should closely monitor patient access to DMEPOS items and provide a mechanism for monitoring and responding to complaints. The final rule should include a detailed discussion of this program, including a wide range of patient safeguards. Specifically, CMS should designate ombudsmen for each competitive bidding area to address and resolve beneficiary complaints. Moreover, the ombudsmen could work to minimize disruptions in care and to ensure high

²⁶ Id. at 25664.

quality of care for beneficiaries.

VIII. CMS Should Allow Beneficiaries Who Travel to Obtain DMEPOS from Any Supplier (Payment Basis)

CMS proposes to allow a beneficiary who travels to obtain covered items from a contract supplier in the area the beneficiary is visiting.²⁷ If the item the beneficiary needs is not subject to competitive bidding in that area, however, the beneficiary may obtain the item from any supplier with a valid Medicare number.²⁸ We believe these requirements may be unduly burdensome for beneficiaries. Unless CMS provides each beneficiary with a detailed list of competitive bidding areas, suppliers, and covered supplies in each area, beneficiaries will have no way of knowing whether the area they are visiting is a competitive bidding area or whether their prescribed DMEPOS is subject to competitive bidding in that area. They also would not be able to identify the suppliers who offer the specific brand of item used by the beneficiary. Rather than requiring beneficiaries to research suppliers thoroughly or carry a directory with them when they travel, CMS should allow beneficiaries who travel to obtain replacement supplies from any supplier in a competitive bidding area.

IX. CMS Should Clarify the Application of the Nondiscrimination Clause (Terms of Contract)

The proposed rule would require contracts with suppliers to include a nondiscrimination clause to assure “that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers.”²⁹ The Proposed Rule does not explain how CMS would ensure that this standard is met, however. We believe that suppliers should be encouraged to offer the widest range of items to all beneficiaries, whether or not they are in a competitive bidding area. Suppliers also should not use the competitive bidding program as an excuse to limit the items they offer to beneficiaries outside bidding areas. We recommend that CMS clarify the application of this clause and describe how it intends to verify compliance with it.

²⁷ Id.

²⁸ Id.

²⁹ Id. at 25681.

X. Conclusion

BIO appreciates this opportunity to comment on our concerns about the Proposed Rule. We strongly recommend that CMS exclude DME infusion pumps and related drugs from the competitive bidding program to protect beneficiary access to these important therapies. Drugs and biological products are fundamentally different than other DME items, and we urge CMS to carefully consider the numerous stakeholder concerns before including infusion pumps and related drugs in the competitive bidding program.

If CMS nonetheless does not exclude these therapies, we urge the agency to define bidding categories for these therapies narrowly and evaluate bids to ensure that each brand or formulation is offered by at least one supplier in each area. We also recommend that CMS apply any spending limit for these therapies in the aggregate rather than requiring each supplier's price to be below the otherwise applicable reimbursement rate. Moreover, we urge CMS to reimburse all new drugs and biological products appropriately, using either 95 percent of the therapy's AWP or 106 percent of its WAC or ASP, once available. We urge the agency to provide a grace or transition period to protect beneficiaries when the program is enacted and as new items and geographic areas are added. We also ask the agency not to apply competitive bidding rates to other areas, to permit traveling beneficiaries to obtain replacement supplies from any supplier in the competitive bidding area, and to clarify the application of the non-discrimination clause.

We look forward to working with CMS to protect Medicare beneficiaries' access to new and advanced therapies. We hope our suggestions will help CMS address these important issues in the final rule. Please contact me at 202-312-9273 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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