



August 29, 2014

BY ELECTRONIC DELIVERY

Marilyn Tavenner
Administrator
Centers for Medicare & 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; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies [CMS–1614–P]

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule regarding payment policies under the End-Stage Renal Disease Prospective Payment published in the Federal Register on July 11, 2014 (the "Proposed Rule").¹ BIO represents more than 1,000 biotechnology companies, state biotechnology centers, academic institutions, and related organizations both in the United States and abroad. BIO members are critical contributors to the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we closely monitor changes to Medicare's reimbursement rates and payment policies for their potential impact on innovation and patient access to drugs and biologicals. To that end, we are concerned that the technical changes outlined in the Proposed Rule in relation to infusion drugs and biologicals indicate that the Agency is considering including infusion drugs in the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) in a future competitive bidding cycle. In the following comments, BIO strongly urges CMS not to expand the DMEPOS CBP to include infusion drugs and biologicals on the basis that: (1) including infused drugs and biologicals in the CBP could result in diminished patient access to these therapies and disincentivize innovation due to inadequate and unpredictable reimbursement; (2) the way in which these therapies are used makes them inappropriate for inclusion in a competitive bidding program; and (3) given recently expressed congressional concerns around the impact of the CBP's implementation on beneficiary health, it would be inappropriate to expand the CBP unless and until such issues are addressed.

¹ 79 Fed. Reg. 40,208 (July 11, 2014).

I. Including infusion drugs in any subsequent competitive bidding cycle would exacerbate concerns around sufficient reimbursement for these important therapies, potentially threatening patients' timely access to critical therapies and incentives for future innovation.

In the Proposed Rule, CMS reaffirms the statutory requirement to reimburse drugs and biologicals administered through infusion pumps covered as durable medical equipment (DME) at 95 percent of the average wholesale price (AWP) in effect on October 1, 2003,² and does not propose to deviate from this requirement for CY 2015.³ However, we are concerned that the “technical changes” CMS proposes in relation to infusion drugs and biologicals indicate that the Agency is considering including infusion drugs in the DMEPOS CBP in a future competitive bidding cycle.

Specifically, CMS introduces the proposed technical changes regarding infused drugs by noting that the regulations governing the implementation of the CBP “did not address payments for drugs . . . which was an oversight.”⁴ Ostensibly to correct this, the Agency proposes to amend the applicable regulations in two places to delineate how infused drugs would be addressed, were they to be included in the CBP. The first is to insert the term “drug” in § 414.412(b)(2) to require that “[t]he bids submitted for each item *or drug* in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C, Subpart D, or Subpart I of this part.”⁵ The second is to add drug-specific text to § 414.414(f) such that “the amounts to be paid to contract suppliers for an item *or drug* under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D *or the same drug under subpart I based on 95 percent of the average wholesale price in effect on October 1, 2003.*”⁶

While these changes do not immediately impact reimbursement for infused drugs, they seem to signal that the Agency is considering including these therapies in an upcoming competitive bidding round. BIO strongly urges CMS not to do so. Reimbursement for infusion drugs is tied to a therapy’s AWP in effect on October 1, 2003, or for new products, the therapy’s initial AWP,⁷ which over time becomes increasingly insufficient to support continued manufacturing of these complex drugs and biologicals, or to incentivize future innovative research and development efforts. CMS has implemented the CBP such that the amount paid for each individual HCPCS code must be *less* than the amount otherwise paid,⁸ which for infusion drugs, would limit reimbursement to less than 95 percent of the *initial* AWP, exacerbating—and potentially hastening—the insufficiency of reimbursement for these therapies over time. To make matters worse, including infusion drugs in the CBP could create a “race to the bottom” among suppliers’ bids, increasing the likelihood that reimbursement for infusion therapies would be insufficient. Thus, the dynamics of the CBP would threaten sustainable payment rates for infusion therapies and, in turn, patients’ timely access to them. In the longer-term, inclusion of infusion drugs in the CBP also may cause innovators to question whether investments in this space can be recouped, impacting their ability to generate funding for research and development, thereby diminishing their ability to invest in future innovation.

² Social Security Act (SSA) § 1842(o)(1)(D).

³ 79 Fed. Reg. at 40,299.

⁴ *Id.* at 40,300.

⁵ *Id.* at 40,314 (emphasis added).

⁶ *Id.* (emphasis added).

⁷ SSA § 1842(o)(1)(D); Claims Processing Manual, ch. 17, § 20.1.3.

⁸ See 42 CFR 414.414(f) (interpreting SSA § 1847(b)(2)(A)(iii)).

II. The characteristics of infusion drugs and biologicals make them ill-suited for inclusion in the CBP.

The characteristics of infused drugs and biologicals make them inappropriate for inclusion in the CBP. This, in part, is because the inherent variation in the volume of infusion drugs and biologicals needed for patients within a competitive bidding area over the term of a competitive bidding contract is much more difficult to predict than for those DME supplies currently included in the program (e.g., infusion pumps, wheelchairs). Suppliers' bids must take into account the predicted utilization in constructing a bid, as the price they may be able to obtain is impacted by the volume they are likely to require. Thus, suppliers' bids are unlikely to be accurate with respect to prices for infusion therapies, which may impact whether suppliers are able to provide these therapies at the median bid price over the contract period. An inability to do so may impact reimbursement for these therapies, while leaving already vulnerable patients without access to a critical aspect of their treatment regimen.

Additionally, there can be clinically meaningful variations between infusion therapies within a given HCPCS code (e.g., in formulations). This is especially true for biologicals that are not easily substitutable because they interact with the human immune system in highly individualized ways. Because the current CBP requires suppliers to make bids at the HCPCS code level, these intra-HCPCS code variations potentially can be obscured. Thus, if infused drugs and biologicals are included in the CBP, BIO is concerned that the choice of formulation could be driven not by the most appropriate infusion therapy for an individual patient, but by the economic need to ensure that costs do not exceed the reimbursement amount set by the CBP.

BIO also asks CMS to consider that handling and storing infused drugs and biologicals requires specialized training that many suppliers may not have. As evidenced by the Competitive Acquisition Program for Part B drugs⁹—begun in 2006 and discontinued after 2008, in part due to a lack of provider willingness to participate¹⁰—the supplier with the most favorable bid is not always the one with the most experience or expertise managing the supply of complex therapies for providers. This can negatively impact the availability of product for providers and their patients when and where they need it.

III. Congressional concerns with the impact of the current CBP on beneficiary health must be addressed before any consideration of expanding the program is undertaken.

On July 25, 2014, 139 members of the House of Representatives from both political parties sent a letter to the Health and Human Services Office of the Inspector General (OIG) requesting that the OIG conduct a thorough and comprehensive study of the impact of the CBP on beneficiary health.¹¹ This request was made due to concerns around the potential to

⁹ Authorized by the Medicare Modernization Act § 303(d), the CAP was based on a competitive bidding system model and meant as an alternative to the Average Sales Price (i.e., buy and bill) methodology for acquiring certain Part B drugs which are administered incident to a physician's services. For more information, see CMS, *Competitive Acquisition for Part B Drugs & Biologicals* (Aug. 20, 2014), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html?redirect=/Competitiveacquisforbios/>.

¹⁰ See e.g., Cys, J, *Lack of interest derails Medicare B drug program*, American Medical News (Nov. 10, 2008), <http://www.amednews.com/article/20081110/government/311109988/1/>.

¹¹ Letter from Various Members of the U.S. House of Representatives to Department of Health and Human Services Inspector General Daniel R. Levinson (July 25, 2014), <http://tomprice.house.gov/sites/tomprice.house.gov/files/Letter%20to%20OIG%20on%20DME.pdf>.

manipulate the bidding process and its impact on beneficiary access to necessary products. The letter specifically identified for study “the process by which CMS develops the composite price from which the median price is derived, as it directly impacts seniors’ access to products and services” and CMS’ enforcement of supplier obligations. This letter follows a similar request by members of the Senate to CMS Administrator Tavenner to wait for the study results of requested OIG work before expanding the CBP program.¹² The senators who authored the letter noted that they had previously asked OIG to study bidding licensures due to similar concerns regarding the potential negative impact of the program’s current implementation on beneficiary health. BIO strongly echoes the concerns voiced by this bipartisan group of lawmakers and urges CMS not to expand the CBP to include infused drugs and biologicals, or any other items, in advance of the release of OIG’s findings and an opportunity for all stakeholders to engage on how to best address these findings.

IV. Conclusion

BIO appreciates the opportunity to provide feedback to CMS on this important topic. For the reasons we have enumerated, we urge CMS not to consider including infusion drugs and biologicals the DMEPOS CBP. Instead, as is the proposal for CY 2015, CMS should continue to maintain reimbursement for infused drugs and biologicals at the statutory rate of 95 percent of AWP. Please do not hesitate to contact me with any questions or if more information is needed.

Sincerely,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy

¹² Letter from Various Members of the U.S. Senate to Centers for Medicare & Medicaid Services Administrator Marilyn Tavenner (May 20, 2014), <http://www.thune.senate.gov/public/index.cfm/2014/5/thune-casey-hoeven-call-on-administration-to-halt-expansion-of-program-prior-to-hhs-ig-review>.