Biotechnology Industry Organization

August 25, 2015

BY ELECTRONIC DELIVERY

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

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program [CMS-1628-P]

Dear Acting Administrator Slavitt:

The Biotechnology Industry Organization (BIO) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule entitled *Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program*[1] (the "Proposed Rule").

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. The innovative therapies our members develop have the potential not only to improve patients' health outcomes, but also to reduce overall healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions, but only if patients have timely access to them.

In the Proposed Rule, CMS proposes a transitional drug add-on payment adjustment, as part of the drug designation process, that we believe has the potential to facilitate the appropriate utilization of new-to-market therapies to drive greater efficiencies in care for the Medicare End-Stage Renal Disease (ESRD) population. Adequate reimbursement for technologies that improve patient health outcomes and/or drive other efficiencies in the provision of care can incentivize their uptake. Moreover, CMS's proposal to utilize the payment adjustment for at least two years will provide a minimum period over which utilization and cost data can be gathered and analyzed to facilitate adding the new technology into the ESRD Prospective Payment System (PPS) bundled payment in future years. However, we are concerned that the proposed eligibility criteria for obtaining the payment adjustment are overly restrictive and will prevent this policy from motivating the provision of high-quality, efficient, and effective care.

Specifically, CMS proposes to impose the following eligibility criteria for the payment adjustment: if a new injectable or intravenous therapy can be used to treat or manage a condition for which there is an ESRD PPS functional category, it is ineligible for the payment

[1] 80 Fed. Reg. 37,808 (July 1, 2015).

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adjustment.[2] Instead, payment for the new therapy is considered to be reflected in the existing ESRD PPS bundled payment. Alternatively, if a new therapy does not treat or manage a condition for which an ESRD PPS functional category currently exists, it is eligible for payment using the transitional drug add-on payment adjustment. This adjustment would result in payment for the new therapy at an amount equal to the Medicare Part B drug payment amount, derived from the average sales price (ASP) methodology (e.g., ASP plus six percent in CY 2015).

BIO is concerned that limiting the eligibility for this payment adjustment to new therapies that do not treat or manage a condition identified by the functional categories effectively excludes all new therapies from obtaining this adjustment. This is the result of the fact that the functional categories represent the spectrum of care that current patients receive in a dialysis facility. Moreover, BIO is concerned with CMS's proposal to link the application of the payment adjustment to the functional categories in the first place. These categories merely denote the spectrum of care associated with treating or managing ESRD, but do not reflect an assessment of the potential for a new therapy to meaningful improve upon the current standard of care. By effectively excluding new therapies from obtaining the payment adjustment, this proposal does little to ensure adequate reimbursement for these therapies. In turn, a lack of adequate reimbursement will diminish the ability of dialysis facilities, already operating on thin margins, to utilize these new therapies, delaying or denying patients' timely access to them. Rather than act as an incentive for innovation in the ESRD space, this proposal will actively maintain a status quo that has been challenged as not advancing innovative treatments at the same pace as treatments for other life-threatening chronic illnesses.[3]

Based on these considerations, BIO urges CMS to expand eligibility for the proposed payment adjustment through decoupling it from a new therapy's place within the 12 functional categories. Instead, CMS should work with stakeholders to develop criteria that are based on evidence that the therapy is new and for which the ESRD PPS bundled payment is determined to be inadequate. CMS also should expressly clarify that this policy applies to all new therapies, including oral equivalents, and should expand the payment adjustment to cover a two-to-three-year period—in line with the Inpatient Prospective Payment System's New Technology Add-on Payment[4]—to ensure that all eligible products receive a full two years of payment adjustments, regardless of when, in the calendar year, they come to market.

BIO also asks CMS to work with stakeholders to establish a robust analytical process to be used to adjust the ESRD PPS bundled payment to include payment for an innovative therapy at the conclusion of the proposed payment adjustment period. The methodology for adjusting the bundle will determine whether reimbursement for the therapy remains adequate to ensure continued patient access. Moreover, including stakeholders in the process of establishing this mechanism can provide the Agency with additional perspective and important information to meet this goal efficiently.

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[2] Id. at 37, 831.
[3] For example, *see* The American Society of Nephrology. 2014 (April 23). Written Testimony before the U.S. Senate Committee on Appropriations in Support of Increased Federal Investments to Spur Innovative Kidney Disease Treatments, available at: http://www.appropriations.senate.gov/sites/default/files/hearings/American%20Society%20of%20Nephrology%20-%20OWT.pdf.
[4] *See* 42 C.F.R. § 412.87(b)(2).

BIO appreciates this opportunity to comment on the Proposed Rule, and we look forward to continuing to work with the Agency to ensure that patients suffering from ESRD have access to the most appropriate therapies to treat and manage their condition. Please contact me at (202) 962-9200 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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