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BY ELECTRONIC DELIVERY

New Technology Team
Division of Acute Care, Center for Medicare Management
Centers for Medicare and Medicaid Services
Mail Stop C4-08-06
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: Written Comments for the Town Hall Meeting on the FY 2008 Applications
for New Medical Services and Technologies**

To Whom It May Concern:

As the representative of an industry that is committed to providing better healthcare, the Biotechnology Industry Organization (BIO) believes it is essential that Medicare provide timely access to new therapies. 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. We appreciate this opportunity to testify at today's Town Hall Meeting.

BIO supports the Medicare statute's provisions that are intended to protect beneficiary access to new drug and biological therapies. In the hospital inpatient setting, the new technology add-on payments are intended to ensure that hospitals are reimbursed adequately for providing high quality, cutting edge care. These payments are particularly important because it may take two to three years for costs of using new technologies to be reflected in the data used to set payment rates for diagnosis-related groups (DRGs) under the hospital inpatient prospective payment system (IPPS).

BIO long has been concerned that CMS's interpretation of the new technology add-on provisions has prevented hospitals from receiving adequate reimbursement for many new therapies, discouraging continued investment in research and development of new inpatient therapies. We believe that the low number of applicants and the small percentage of those that are approved are evidence that the system is not working to protect access to new therapies as Congress intended. In the final IPPS rule for fiscal year (FY) 2007, CMS noted that it has received 21 unique applications for add-on payments from FY 2003 to FY 2006 – on average, fewer than 5 per year – and that it approved 6 of those applications.¹ Five applications were denied because they did not meet the “substantial clinical improvement” criteria and another eight were denied

¹ 71 Fed. Reg. 47870, 47997 (August 18, 2006).

because the technology was no longer “new” at the time the application was considered.² This low approval rate of less than 33 percent suggests to us that CMS is applying unreasonable criteria or a flawed process for evaluating applications. Furthermore, such a small likelihood of success may discourage potential applicants from applying for new technology add-on payments in the first place.

We have two concerns with CMS’s criteria for evaluating applications for new technology add-on payments. The first is the unpredictable and opaque application of the “substantial clinical improvement” requirement that prevents worthy technologies from receiving add-on payments and likely discourages many applicants from seeking the payments their therapies deserve. Although CMS has described some of the criteria it considers when evaluating whether a technology meets this requirement, it has not described the types of data needed to support an application. We have tried to deduce the agency’s data requirements from past applicants’ experience, but we have not been able to identify a clear standard.

In some cases, CMS has required applicants to present data showing superiority from prospective clinical trials, while in other cases, CMS has approved applications that lacked this type of data when all of the other available evidence indicated that the technology would be effective. Additionally, CMS has rejected applications that were supported by prospective randomized clinical trial data because the agency determined that those data were not sufficient to demonstrate “substantial clinical improvement.” We strongly recommend that CMS work with stakeholders, including researchers, clinicians, representatives patients, and manufacturers, to develop specific criteria and data quality standards that will make determinations of “substantial clinical improvement” more predictable and transparent. Moreover, these criteria should be reasonable and reflect the challenges small companies face when bringing innovative therapies to market. The Council on Technology and Innovation might be an appropriate entity to help develop these standards.

Our second concern is CMS’s erroneous interpretation of the statute’s standards for identifying a “new” technology. As noted above, from FY 2003 to FY 2006, CMS rejected over one-third of the applications for not being “new,” preventing consideration of whether the technology is a “substantial clinical improvement.” Contrary to the statute and CMS’s own regulations, the agency has said that the two to three-year period for new technologies to receive add-on payments begins on the date the technology is approved by the Food and Drug Administration (FDA).³

Neither the statute nor the regulations refer to the date of FDA approval in determining whether a technology is “new.” Instead, the law requires CMS to use the date on which an “inpatient hospital code,” or International Classification of Diseases – 9th Revision – Clinical Modification (ICD-9-CM) code,⁴ is issued for the service or

² Id.

³ See, e.g., 71 Fed. Reg. 23995, 24068 (April 21, 2006).

⁴ 42 C.F.R. § 412.87(b)(2).

technology.⁵ CMS' regulations also require that a medical service or technology be considered new within two to three years after the "point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration)."⁶

By using the date of FDA approval instead of the date of issuance of an ICD-9-CM code, CMS risks denying add-on payments to deserving new technologies and shortening the period in which approved technologies receive add-on payments. BIO urges CMS to use the issuance date of a new code as the starting date for new technology status, as the statute and its own regulations require. We also ask CMS to clarify how it will determine whether a technology is "new" when it is a new FDA-approved indication of an existing therapy or when a new therapy is appropriately captured under an existing ICD-9-CM code.

BIO appreciates this opportunity to discuss these important issues. If you have any questions, feel free to contact me at (202) 312-9273. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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⁵ Social Security Act § 1886(d)(5)(K)(ii)(II) and (III).

⁶ Id.