July 12, 2004

BY ELECTRONIC DELIVERY

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on CMS-1428-P (Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates) – New Technology Applications; Other DRG Issues; and ICD-9-CM Coding

Dear Administrator McClellan:

The Biotechnology Industry Organization ("BIO") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS" or the "agency")

proposed rule regarding the hospital inpatient prospective payment system ("PPS") and fiscal year 2005 rates, published in 69 Fed. Reg. 28195 on May 18, 2004 (the "Proposed Rule" or "CMS' Proposal"). BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the

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globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial, and environmental biotechnology products.

BIO continues to be very interested in CMS' Proposal with respect to expeditiously incorporating new technologies and services into the inpatient PPS. As a representative of an industry that is devoted to discovering new cures and ensuring patient access to them, BIO is extremely disappointed with CMS' implementation of the new services and technology provisions under section 1886(d)(5)(K), (L) of the Social Security Act ("SSA"), as created and amended by section 533 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA") and section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Specifically, we are concerned about CMS' handling of add-on payments for new technologies, reclassifications of DRGs, and updates to International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") codes. Regrettably, it seems that, despite numerous instructions from Congress to do so, CMS once again fails to take the necessary steps to ensure that seniors have access to vital, cutting-edge technologies. With each year that CMS misconstrues or inappropriately narrows the statutory and regulatory requirements to provide Medicare beneficiaries with new and innovative therapies, the need to correct these errors only becomes more urgent. Accordingly, we urge CMS to address these issues in the final inpatient PPS rule for fiscal year 2005.

DISCUSSION

I. CMS' Policy on the Start of the Period for Add-On Payments Is Contrary to the Statute and Its Own Regulations ("New Technology Applications")

CMS' consistent pattern of implementing the new technology add-on provision as narrowly as possible, running counter to Congress' intent to promote patient access to new technologies, is evident in the agency's stated position on the duration of the add-on period for qualifying technologies. What is especially troubling about this is that the position stated in the preamble to the Proposed Rule and followed therein is flatly contrary to the statute and the regulations. Accordingly, BIO urges CMS to withdraw the statements suggesting that the 2-3

year period begins on the date the technology is approved by the Food and Drug Administration ("FDA").

In the Proposed Rule, CMS states that the 2-3 year period for collection of cost data begins when the drug or biological receives FDA approval, not when it receives an ICD-9-CM code. 1 This interpretation is contrary to both the statutory language and the regulatory text. The statute requires the collection of cost data for new technologies for "a period of not less than two years and not more than three years *beginning on the date on which an inpatient hospital code is issued with respect to the service or technology*." 2 The statute could hardly be clearer that the 2-3 year period for add-on payments begins on the date a code is issued, irrespective of the date of FDA approval. Further, CMS' regulations require that a "medical service or technology may be considered new within the 2 or 3 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 upon when a new code is assigned and data on the new service or technology become available for DRG recalibration)." 3 The regulation text thus reinforces that a technology's newness should be measured from the issuance of an ICD-9-CM code, potentially lagging months behind the date of FDA approval. In the face of these clear statutory and regulatory directives as to the start of the period for add-on payments, the agency's preamble statement that the 2-3 year period begins with FDA approval must be removed.

BIO urges CMS to apply the statutory and regulatory definition of "new" in the final rule as it re-evaluates the requests for add-on payments rejected in the Proposed Rule as well as in reconsidering applications for add-on payments received in fiscal year 2004, as required by section 503 of the MMA. In particular, we request that CMS reevaluate the application submitted for Natrecor®. This product could meet the newness criteria if CMS were to correctly follow the statute and its own regulations by starting the 2-3 year period at the date of the issuance of an inpatient code for the product. The code for Natrecor® was first effective on

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1 See 69 Fed. Reg. at 28237 ("The 2-year to 3-year period would ordinarily begin with FDA approval, unless there was some documented delay in bringing the product onto the market after that approval. . . ."). In addition, as detailed in Section II below, the agency proposes to use FDA approval as the start date of the period for Xigris®.

2 SSA § 1886(D)(5)(K)(ii)(II) (emphasis added). This language also governs the duration of add-on payments. See SSA § 1886(D)(5)(K)(ii)(III).

3 42 C.F.R. § 412.87(b)(2) (emphasis added).

October 1, 2002 such that the product could qualify as "new" through September 30, 2005. We understand that inpatient use and coding for Natrecor® was quite limited during the first year the code was in effect. We urge CMS to give this product the benefit of the full 3-year data collection period allowed by statute to ensure that payments for Natrecor® are established using adequate and representative data.

Should CMS decline to change this policy, we urge the agency to conduct a full analysis of all add-on payment applications and not just those that meet its restrictive definition of "new." For example, the Proposed Rule summarizes the cost and clinical data submitted with Natrecor's® application, but does not conclude whether the data satisfy the criteria. [4] Fully analyzing the cost threshold and substantial improvement criteria for all applicants will provide better insight into the agency's decision making process and help the public understand CMS' complete rationale. Indeed, BIO strongly recommends that CMS address all of the new technology criteria as applied to a pending application in the proposed rule each year, regardless of the proposed basis for denying the application. Through the public comment process, CMS could be convinced that the technology satisfies the criterion that was the basis for the proposed denial, only to identify first in the final rule that it will deny the application for a failure to meet a different criterion. In doing so, the agency will fail to gain the wisdom of the public on the revised basis for denial – a result that is untenable, yet can be avoided by a thorough assessment of each application in the proposed rule.

II. **CMS Should Continue to Make Add-On Payments for Xigris® in Fiscal Year 2005** ("New Technology Applications")

CMS proposes to discontinue making new technology add-on payments for Xigris® in fiscal year 2005 because the agency has concluded that Xigris® no longer is "new," relying on the fact that the product was approved by the FDA on November 21, 2001. [5] BIO is distressed by this decision because we believe it is incorrect as a matter of law, it reflects an inappropriate policy decision in light of the initial delays in implementing the add-on payment for Xigris®, and it will have an adverse impact on patient care. We thus ask CMS to exercise its

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[4] 69 Fed. Reg. at 28243.

[5] 69 Fed. Reg. at 28238.

express statutory authority to continue add-on payments for Xigris® for an additional year.

BIO is concerned that CMS' proposal will deny many of Medicare's most ill beneficiaries access to the only drug approved to treat patients with severe sepsis and a high risk of death. Xigris® is precisely the type of advanced therapy that new technology add-on payments are intended to protect. When the FDA approved Xigris®, Secretary Thompson hailed it as a "hopeful milestone" and "promising development" in the battle against severe sepsis. 6 Without assurance of adequate Medicare reimbursement, though, Medicare beneficiaries will not have the access to Xigris® that Secretary Thompson envisioned. As to Xigris®, this is especially troubling because it is the only existing treatment for severe sepsis. CMS' failure to make add-on payments now not only inhibits access to innovative drugs and biologicals today, but also will have a chilling effect on investment in new technology, harming access to tomorrow's improved therapies. BIO strongly recommends that CMS act now to protect patient access to this important therapy.

In refusing to allow add-on payments in fiscal year 2005, CMS fails to adhere to the SSA's explicit requirements to begin collecting data after the new technology receives a code for payment and to collect data for a minimum of 2-3 years. CMS claims that it has gathered sufficient data on Xigris® because the FDA approved the therapy in November 2001. As detailed above, Congress clearly stated though that data on new technologies are to be collected using unique ICD-9-CM codes, not simply by assuming that the technologies are represented in cost reports. The agency's regulation text reiterates that the issuance of a code begins the 2-3 year period. Accordingly, the starting point for the 2-3 year period for Xigris® is October 1, 2002 – the date a unique ICD-9-CM code for Xigris® became effective – and the statute permits CMS to make add-on payments through September 30, 2005. BIO urges CMS to fulfill its mandate to protect beneficiary access to this life-saving therapy by making add-on payment for the whole 3-year period specified by the SSA.

There are very strong policy reasons for CMS to continue to make add-on payments for Xigris® through fiscal year 2005. BIO is concerned that the available data on Xigris® for the coming year will be inadequate because it was

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6 Statement by HHS Secretary Tommy G. Thompson Regarding FDA Approval of a New Drug to Treat Sepsis, Nov. 21, 2001, available at www.hhs.gov/news/press/2001pres/20011121.html.

the first new technology approved for add-on payments, and providers generally were confused about the use of the new codes and the importance of including them on claims. More significantly, although CMS approved Xigris® for add-on payments effective October 1, 2002, it was not until June 3, 2003 (more than 8 months after that effective date) that the fiscal intermediaries could process claims for add-on payments. 7 In all likelihood, this delay adversely affected the use of the new technology status for the product, calling into question the representativeness of the first year of data available under the ICD-9-CM procedure code for Xigris®. Because of the agency's delay in the proper implementation of the add-on payment, BIO recommends that CMS extend add-on payments for an additional year to ensure that valid and reliable data can be used to determine how to pay for Xigris® under PPS.

If CMS refuses to continue add-on payments for Xigris® throughout fiscal year 2005, we ask that such payments be maintained at least until the agency has analyzed the available data and has classified cases in which Xigris® is administered into an appropriate DRG. The Proposed Rule asserts that the costs of Xigris® are well-represented in DRGs 416, 417, 475, and 483, but provides no explanation of how the agency reached that conclusion. The agency also does not explain where Xigris® cases will be assigned. We ask that CMS provide these explanations in the final rule, as required by law.

Finally, we hope CMS will reconsider its decision not to create a unique DRG for severe sepsis, especially if add-on payments for Xigris® are terminated as proposed. The Proposed Rule concludes that "a subset of patients with severe sepsis does [not] exist to the degree that a separate DRG classification is justified" and that a clinically coherent set of patients with severe sepsis cannot be accurately identified. 8 We strongly disagree. Severe sepsis is a significant cause of morbidity and mortality worldwide and within the Medicare population. More than 750,000 cases of severe sepsis occur in the U.S. each year, and at least 220,000 of those cases involve Medicare beneficiaries. Moreover, the Society of Critical Care Medicine and the American College of Chest Physicians developed a consensus conference definition of severe sepsis in 1992. This definition – "a systemic inflammatory response to infection association with acute organ

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7 See Program Memorandum A-02-124, available at http://www.cms.hhs.gov/manuals/pm_trans/A02124.pdf.

8 69 Fed. Reg. at 28224.

dysfunction" – has been used widely in research and clinical care and is included in the ICD-9-CM as code 995.92. Overall, we believe a new DRG for severe sepsis will enable hospitals and health care practitioners to better analyze, and therefore improve, treatment options for this deadly disease. We ask CMS to reconsider its decision to maintain the current DRG structure for severe sepsis accordingly.

III. Ensuring the Adequacy of Add-On Payments for New Technologies ("New Technology Applications")

BIO believes that the utility of the new technology process depends on both ensuring that new technologies qualify and that the add-on payment amount is sufficient to ensure that hospitals will provide the technology to Medicare beneficiaries. To the latter end, we urge CMS to abide by the recommendation of Congress in the Conference Report to the MMA that CMS "consider increasing the percent of payment associated with the add-on payments up to the marginal rate used for the inpatient outlier" – *i.e.*, 80 percent. [9] Given the extensive discussion of the new technology process and the amount of add-on payments, we believe that the agency should move to the 80% level in the final rule.

BIO also notes that there was a specific statutory mandate regarding the add-on payment amounts. Section 503(c) of the MMA added SSA section 1886(d)(5)(K)(ix), requiring that before establishing add-on payments for any new technology, the Secretary must seek to identify one or more DRGs associated with the new technology, based on similar clinical or anatomical characteristics and the cost of the new technology, and assign the new technology to these DRGs in lieu of making add-on payments where the average costs of care most closely approximate the costs of care using the new technology. The Proposed Rule is silent on how CMS intends to implement this provision and interpret clinical coherence and payment adequacy. BIO believes that payment should not be deemed to be adequate unless payment under the proposed DRG assignment is equal to or greater than the combination of the maximum add-on payment amount and the DRG payment that would have been made in the absence of assignment of the new technology to a DRG in lieu of an add-on payment. We

9 H. Rep. No. 108-391, at 653 (2003).

urge CMS to adopt this test in the final rule, as well as provide additional information on how the agency intends to implement this new requirement.

IV. Qualification for Add-on Payments for New Technologies Should be DRG-Specific ("New Technology Applications")

In the Proposed Rule's consideration of new technology add-on payment eligibility for the InFUSE™ Bone Graft, CMS notes that "in the September 7, 2001 final rule (66 FR 46915), we stated that if an existing technology was assigned to different DRGs than those in which the technology was initially used, the new use may be considered for new technology add-on payments if it also meets the substantial clinical improvement and inadequacy of payment criteria." 10 The Proposed Rule acknowledges that the agency now is questioning this decision.

BIO firmly believes that new technologies should be eligible for add-on payments each time their use is expanded to a different DRG. As discussed above, Congress intended the new technology add-on payments to ensure patient access to new therapies during the 2-3 years required to collect data necessary to adjust DRG relative weights. When a technology is used in a different DRG, its costs will not be reflected in the MedPAR data used to set that DRG's relative weight for at least 2 years. Thus, add-on payments may be necessary to ensure patients' access to the new technology during this period. To prohibit such payments merely because the technology received add-on payments for a different indication in a different DRG makes no sense. Thus, BIO urges CMS to affirm its original policy in the final rule.

V. CMS Should Utilize Its DRG Reclassification Authority to Promote Access to New Technologies ("Other DRG Issues" and "New Technology Applications")

In addition to new technology add-on payments, CMS' primary method for adjusting the inpatient PPS to accommodate improved technologies is through reclassifying DRGs. By continually reassessing the DRG structure, CMS can ensure that the changing costs of care due to advancements in technology are appropriately recognized in Medicare's payments to hospitals. These reclassifications are especially important for technologies that do not receive new

10 69 Fed. Reg. at 28240.

technology add-on payments, because patient access to these therapies is completely dependent on the treatments' assignments to appropriate DRGs.

BIO was disappointed that CMS did not implement our members' recommendations to reclassify the DRGs for severe sepsis and for procedures involving the implantation of GLIADEL® Chemotherapy Wafers. Our comments regarding the severe sepsis DRG are included in our comments above related to Xigris®. BIO is also concerned about the agency's DRG reclassification decisions with respect to procedures involving the implantation of GLIADEL® Chemotherapy Wafers. In the Proposed Rule, CMS rejects several options for DRG reassignments for GLIADEL® but then requests further comments on this issue. 11 Although BIO appreciates CMS' willingness to continue to evaluate the product's DRG assignment, the proper recognition of Gliadel® under PPS has been an unresolved issue for far too long. As the only FDA-approved implantable chemotherapy for treatment of high-grade malignant gliomas – and the only product approved by the FDA in the past 20 years to treat these tumors when they are first diagnosed – GLIADEL® is a truly unique, innovative therapy that offers patients improved hope of surviving this aggressive, devastating cancer. Unfortunately, we continue to hear from patients and physicians that access to this life-extending treatment continues to be limited by hospitals that cannot afford to provide it under the current DRG assignment. To ensure that GLIADEL® remains available to patients, we urge CMS to resolve this issue in the final rule.

In the short term, we recommend that CMS assign GLIADEL® cases to DRG 528 (Intracranial vascular procedure with a principal diagnosis of hemorrhage) to ensure adequate reimbursement. Although CMS dismisses this suggestion in the Proposed Rule, we believe it merits reconsideration for two reasons. First, contrary to CMS' initial analysis, procedures using GLIADEL® and the procedures included in DRG 528 are clinically similar. They all involve the implantation of a device, tend to be of an urgent nature, require similarly intense post-operative care and monitoring, and require intensive pre-operative, intra-operative, and post-operative imaging. Second, the average costs of using GLIADEL® wafers are consistent with payment under DRG 528. 12 Instead of subjecting hospitals to a loss of $12,000 to $14,000 per patient who receives

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11 69 Fed. Reg. at 28221-22.

12 The comments submitted by our member company, Guilford Pharmaceuticals, on June 17, 2004, examine these similarities and related financial issues in greater depth.

GLIADEL®, as occurs under the current assignment to DRGs 1 and 2, assignment to DRG 528 would allow hospitals to recover most of their costs. This would remove hospitals' powerful financial disincentive to using GLIADEL®, helping to ensure patient access to a life-extending therapy.

In the longer term, we recommend that CMS create a DRG for intracerebral therapies. As CMS acknowledges in the Proposed Rule, GLIADEL® and similar therapies "represent a significant medical technology that currently offers clinical benefits to patients and holds out the promise of future innovation in the treatment of brain tumors." 13 We agree that such a DRG is clinically and administratively appropriate and believe that it will become even more needed as additional therapies complete their clinical trials and enter the market. We encourage CMS to work with providers and manufacturers to develop this new DRG.

BIO also believes that the agency should be more proactive regarding DRG reclassifications for new technologies, and the agency's proposed treatment of Natrecor® is instructive as to how the agency could be more proactive. This product's new technology application contained the identification of almost 10,000 cases in fiscal year 2003 in which the product was used. Those cases were used to address the cost threshold in the new technology criteria and the data strongly suggest that the current treatment is inadequate. The agency simply proposes to deny the application because the technology is not new. 14 A disconcerting element of the agency's handling of this situation is that, having found a basis to deny the application, the agency ceases any consideration of the proper treatment of this product. Given the significant amount of data, the agency should assess those data to determine whether a DRG reclassification is warranted after it reevaluates Natrecor's® new technology application. This situation shows the box that new technologies find themselves in – the agency is reluctant to grant new technology applications and fails to consider whether a DRG reclassification is warranted when data are offered. There is significant room for improvement on both ends, and we encourage CMS to make strides on both to ensure that patient access to important, life-extending therapies is not threatened by inappropriate inpatient PPS payments.

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13 69 Fed. Reg. at 28222.

14 69 Fed. Reg. at 28243.

VI. Any New ICD-9-CM Code Should be Permitted to Go Into Effect on April 1 (ICD-9-CM Coding)

Section 503(a) of the MMA requires the Secretary to provide for the addition of ICD-9-CM diagnosis and procedure codes on April 1 of each year, in addition to October 1 of each year. In implementing this provision, CMS proposes to add codes in April only if needed for the purposes of the new technology process. 15 According to CMS, the context of section 503(a) of the MMA is the new technology process and the need for new codes arises most frequently and most acutely where the codes would capture a new technology so that new codes for April 1 should be limited as proposed. 16

BIO firmly disagrees. Because the statute refers to new procedure and diagnosis codes becoming effective April 1 and the agency typically captures new technologies through new procedure codes only, the statute contemplated that codes for purposes outside of the new technology process could be added on April 1. In addition, given the high bar for qualification for add-on payments, BIO submits that for many technologies that would not meet that bar, it would be appropriate for an ICD-9-CM code to be created effective April 1 so that CMS can track the technology and later determine whether a DRG reclassification is warranted. CMS recognizes the value of being able to track new technologies – "this new requirement will improve the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date." 17 BIO therefore recommends that CMS permit any ICD-9-CM diagnosis or procedure code approved by the Coordination and Maintenance Committee to go into effect on April 1 or October 1, whichever is earlier and practicable.

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15 69 Fed. Reg. at 28221. With regard to transition from ICD-9-CM to ICD-10-CM and ICD-10-PCS, we note the statement in the Proposed Rule that the Department of Health and Human Services ("HHS") is studying this issue. Id. BIO supports the recommendation of the National Committee on Vital and Health Statistics that HHS prepare a notice of proposed rulemaking for the implementation of ICD-10, as does Congress. H. Rep No. 108-391, at 797 (2003).

16 69 Fed. Reg. at 28221.

17 Id.

CONCLUSION

BIO remains concerned about the treatment of new technologies under the inpatient PPS. We appreciate CMS' efforts to implement the MMA's requirements, but remain concerned that patient access to cutting-edge therapies is threatened by CMS' unyielding approach to new technology add-on payments and its rigid DRG structure. We ask CMS to take the necessary steps to ensure that the inpatient PPS evolves with, and does not discourage, continued advancements in medical technology.

In particular, we strongly recommend that CMS reassess its position on the duration of the 2-3 year period for add-on payments for new technologies to ensure Medicare beneficiaries' access to life-saving therapies. We also urge CMS to reclassify the DRGs for severe sepsis and GLIADEL® chemotherapy wafers to help hospitals and health care practitioners continue to improve patient outcomes. Finally, we ask CMS to expand its proposal to update ICD-9-CM codes twice each year to all new technologies, not just those seeking add-on payments.

BIO appreciates the opportunity to comment on the significant issues raised in the Proposed Rule and looks forward to working with CMS to ensure that Medicare inpatients continue to have access to new and important drug and biological therapies. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions in the final rule. Please feel free to 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 by,

/s/

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