BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Kerry N. Weems, Acting 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; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates [CMS-1390-P]

Dear Acting Administrator Weems:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the hospital inpatient prospective payment systems (PPS) for operating and capital-related costs and fiscal year (FY) 2009 rates, published in the Federal Register on April 30, 2008 (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 members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

In the Proposed Rule, CMS completes the phase-in of Medicare Severity Diagnosis Related Groups (MS-DRGs) and calculation of relative weights based on costs rather than charges. These changes were intended to improve payment accuracy, and we are pleased to see that the Proposed Rule provides evidence that these changes will, in fact, produce reimbursement rates that better reflect severity of illness and complexity of care. For example, under the fully-phased-in MS-DRGs, the relative weight for cases involving High-Dose

1 73 Fed. Reg. 23528 (April 30, 2008).

Interleukin 2 (HD-IL2) for the treatment of metastatic renal cell cancer or melanoma with major complications or comorbidities (MCC) will increase, resulting in a payment rate that better reflects the true costs of providing this complex therapy. In addition, we appreciate CMS providing guidance for pursuing a new ICD-9-CM diagnosis code to identify patients that have previously received thrombolytic stroke treatment in order to assist in the determination of appropriate reimbursement for stroke cases.

BIO also commends CMS for proposing to address the effects of charge compression on certain advanced technologies. We are pleased that CMS recognizes the need to take "concrete steps"[2] toward resolving this problem, although the proposals do not affect payment for drugs, biological therapies, or other advanced technologies. We urge CMS to consider carefully recommendations that would provide an immediate solution to charge compression, including our proposal to address both charge compression and reimbursement for critical pharmacy services under the outpatient prospective payment system (OPPS). CMS should address these proposals, along with RTI's completed analysis, in the OPPS proposed rule for calendar year 2009 and should implement a solution to address charge compression in 2009.

Regarding new technologies for which add-on payments are sought, BIO supports the a date no earlier than July 1 for Food and Drug Administration (FDA) approval, but we recommend that CMS establish the date through a subregulatory annual announcement rather than in regulation to give the agency flexibility regarding application of the deadline. In conjunction with this change, we also urge CMS to reconsider its policy that a technology is eligible for add-on payments for two to three years from the later of the date of issuance of a new code or FDA approval. We remain concerned that CMS's narrow interpretation of the new technology add-on provisions prohibits worthy technologies from qualifying, potentially delaying patient access to these therapies, and make suggestions to improve the process.

BIO thanks CMS for helping to promote quality improvement by renaming the MS-DRGs for septicemia with mechanical ventilation (MS-DRGs 870-872) to include "severe sepsis" in the titles. We also applaud CMS's ongoing efforts to encourage hospitals to improve the quality of care provided through reporting of quality data and payment adjustments for hospital-acquired conditions. We

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2 Id. at 23544.

support the addition of several quality measures to the set to be reported in FY 2009 and recommend that CMS work with stakeholders to develop additional measures to address medication errors and coordination of care. BIO also encourages CMS to lead the development outcomes-based measures to replace the current process-based measures. We support the proposed application of hospital-acquired payment provisions to glycemic control events and encourage CMS to continue to work with stakeholders to determine whether other conditions may appropriately be addressed through this provision or other CMS quality-improvement policies.

These comments are discussed in more detail below.

I. CMS Must Adopt an Immediate Solution to Address the Effects of Charge Compression on Payment for Drugs and Biological Therapies (Refinement of the MS–DRG Relative Weight Calculation)

BIO appreciates CMS's efforts to refine the IPPS to provide more accurate reimbursement, but we believe that true payment accuracy cannot be achieved until the effects of charge compression are addressed. As CMS explains in the Proposed Rule, charge compression is the practice of applying a higher percentage markup to lower cost items and a lower percentage markup to higher cost items.[3] When CMS applies a single cost-to-charge ratio (CCR) to hospitals' charges for all drugs and biological therapies, it underestimates the costs of higher cost therapies and overestimates the costs of lower cost therapies. As a result, Medicare's payment rates for cases involving the use of advanced drug and biological therapies may be inadequate and may limit beneficiaries' access to appropriate, high quality care.

For many years, BIO has urged CMS to address charge compression, and we applaud CMS for recognizing the importance of this problem and for working to understand and address it. We are pleased that CMS now recognizes the need to take "concrete steps" toward resolving this problem, but these proposals address certain medical devices only; would not improve the accuracy of payment for drugs, biological therapies, or other advanced technologies; and would not have any effect on payments until 2012.[4] We believe that this longstanding defect in Medicare's payment calculations for drugs and biological therapies needs

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3 Id. at 23542.
4 Id. at 23544.

to be addressed immediately. We urge CMS to take action now to ensure that drug and biological therapies are appropriately reimbursed in 2009.

Last year, RTI reported to CMS that there is evidence of charge compression in the pricing for IV solutions when compared to therapeutic drugs.[5] The report recommended measures CMS could take in the short-term and long-term to produce more accurate estimates of the costs of these treatments.[6] CMS chose not to implement these recommendations for FY 2008, and asked RTI to expand its analysis to include the OPPS.[7] CMS explains that it prefers to "introduce any methodological adjustments to both payment systems at the same time" because both the IPPS and OPPS rely on cost-based weights.[8]

We agree that CMS must address charge compression under both the inpatient and outpatient prospective payment systems. Unfortunately, the interim report of RTI's expanded analysis does not include the key sections on the impact of regression-adjusted CCRs on the OPPS.[9] Without this analysis, it is difficult to recommend a solution for both payment systems. Although we recognize that the rulemaking process is separate for the IPPS and the OPPS, we urge CMS to ensure that the OPPS sections of the RTI report are released before or at the same time as the OPPS rule to give stakeholders sufficient time to review the analysis and make suggestions.

We also urge CMS to implement the immediate solution we have proposed to address charge compression and payment for pharmacy services in the OPPS. As we discussed in our comments to the final OPPS rule for 2008 and at the APC Panel meeting, we support an approach that would reallocate overhead costs that are disproportionately attributed to lower-cost drugs and biological therapies due to charge compression from lower-cost drugs to high-cost drugs. Specifically, we urge the agency to reimburse separately paid drugs at no less than

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5 Kathleen Dalton, A Study of Charge Compression in Calculating DRG Relative Weights, Jan. 2007, at 10, http://www.cms.hhs.gov/reports/downloads/Dalton.pdf.

6 Id. at 16.

7 73 Fed. Reg. at 23543. CMS also commissioned a study from RAND regarding the combined effect of implementing regression-based CCRs and a hospital-specific relative value (HSRV) methodology for calculating MS-DRG weights.

8 73 Fed. Reg. at 23543.

9 Kathleen Dalton et al., Refining Cost to Charge Ratios for Calculating APC and DRG Relative Payment Weights, April 2008, at 30-31, http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200804.pdf.

their Average Sales Price (ASP) plus six percent and to package drugs and biologicals costing less than $60 per day at this amount as well. We then believe CMS should create a separate pool of dollars to be allocated to pharmacy services and overhead using the difference between the estimated mean unit cost as calculated for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes (ASP plus 12.6 percent) and payment for acquisition cost (ASP plus six percent). This proposal is outlined in our comments to the final OPPS rule for 2008, available at http://bio.org/healthcare/medicare/20080128.pdf. We urge CMS to consider this solution and discuss any alternative approaches to addressing charge compression for drugs and biological therapies in the OPPS proposed rule for 2009. The agency should take action this year to resolve this critical flaw in its rate-setting methodology.

II. BIO Supports the Revision of the Titles of MS-DRGs 870-872 to Include "Severe Sepsis" (Proposed Changes to Specific MS-DRG Classifications)

BIO thanks CMS for proposing to revise the titles of MS-DRGs 870-872 to include "severe sepsis."[10] These MS-DRGs already include the most significant concentration of patients with severe sepsis, but their current titles do not reflect this fact. This change will help increase awareness of the significance of severe sepsis and will facilitate research into methods of improving care and outcomes for patients with this condition. We ask CMS to implement this proposal in the final rule.

III. New Technology (Proposed Add-On Payments for New Services and Technologies)

The new technology add-on payment provisions are intended to protect beneficiary access to innovative technologies by ensuring that hospitals are not penalized for adopting these treatment options in a timely manner. Whether the provisions achieve these goals depends on several factors, including the transparency and predictability of the application process and CMS's interpretation of the statutory and regulatory criteria a technology must meet to receive these payments.

CMS proposes to improve the application process by setting July 1 of each year as the deadline by which a new technology for which add-on payments

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10 73 Fed. Reg. at 23574.

are sought must receive approval from the FDA.[11] BIO supports the intent of this proposal because it will bring needed clarity to the new technology add-on application process by helping manufacturers determine when to submit their applications to better coincide with FDA approval of their therapies. This will save manufacturers the costs and effort of preparing applications for technologies that are not likely to be approved in time for CMS to grant add-on payments for the next fiscal year and will save the agency the effort of having to review those applications. Rather than specifying the July 1 date in the regulation, however, we ask that CMS outline the timeframe for FDA approval during the New Technology Town Hall meeting held each spring. Further, BIO asks that CMS accept FDA approvals up and until CMS must finalize that year's final rule, with a deadline no earlier than July 1. This approach will make the process more predictable and transparent, while also taking into account that applicants have little control over the approval timeframe and therefore create a more fair process. We ask CMS to use the discretion permitted by such a subregulatory process, as it has in other areas such as the Healthcare Common Procedure Coding System (HCPCS) application process, to allow for therapies that miss that year's date by short periods to be approved as new technologies.

In conjunction with this change, and to further establish predictability under this process, we urge CMS to reconsider its policy that a technology is eligible for add-on payments for two to three years from the date of FDA approval. Under CMS's proposed policy there will be at least a three-month lag (and often longer) between FDA approval and the time an approved new technology will be eligible for add-on payments. Because the purpose of the add-on payment policy is to help ensure full utilization of new technologies, it is likely that hospitals' utilization prior to the effective date of the add-on payment is not reflective of the optimal utilization of the new technology. In addition, because hospitals generally update their charge masters only once per year, it is unlikely that charges for the new technology would be reflected in the hospitals' charges before the technology begins to receive add-on payments. As a result, the direction of §1886(d)(5)(K)(ii)(II) of the Act to collect "data with respect to the costs of a new medical service or technology" for two to three years "beginning on the date on which an inpatient hospital code is issued with respect to the service or technology" is not fully realized. Therefore, a more appropriate (and predictable)

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11 Id.. at 23617.

policy would be for CMS to make add-on payments for not less than two to three full fiscal years from the later of the date of issuance of a code, as the statute directs, or the date of FDA approval. BIO believes that such a policy would be in keeping with the direction of the Social Security Act, even if CMS chose not to revisit its definition of "new" as discussed below. We urge CMS to include this policy in its final rule for FY 2009.

BIO remains concerned that CMS's narrow interpretation of the new technology add-on provisions prohibits worthy technologies from qualifying for add-on payments, thus potentially delaying patient access to these therapies. In prior years' comments, we have recommended that CMS revise its interpretation of the statute and regulations to better comply with their plain language and Congressional intent. For example, we have explained that CMS's statements 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 FDA[12] are contrary to both the statute and CMS' own regulations that refer to the date of issuance of an International Classification of Diseases – 9th Revision – Clinical Modification (ICD-9-CM) code, not the date of FDA approval, as the key date in determining whether a technology is "new."[13] We also have asked CMS to deem certain technologies to meet the substantial clinical improvement criteria. Specifically, we recommended that CMS deem the drugs and biologicals for which the FDA has granted fast track approval[14] or approval based on surrogate endpoints,[15] as well as devices that have been granted a humanitarian device exemption[16] or priority review[17] to represent substantial clinical improvements. Finally, we have recommended that CMS fully compensate hospitals for those few technologies that do meet the new technology add-on standards by paying on a cost basis, potentially ASP plus six percent for FDA approved drugs and biologicals and list price plus a percentage for devices. CMS has discussed these proposals in several final rules

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12 72 Fed. Reg. at 24771.
13 Social Security Act § 1886(d)(5)(K)(ii)(II) and (III); 42 C.F.R. § 412.87(b)(2).
14 A drug designated under section 506 of the Federal Food, Drug, and Cosmetic Act.
15 A biological approved under 21 C.F.R. 601.41 or a drug approved under 21 C.F.R. 314.510.
16 A device for which an exemption is granted under section 520(m) of the Federal Food, Drug, and Cosmetic Act.
17 A device for which priority review is granted under section 515(d)(5) of the Federal Food, Drug, and Cosmetic Act.

but has not agreed to implement them. We ask the agency to reconsider its position and adopt these recommendations, however.

Finally, in some instances, existing therapies have new FDA-approved indications or new therapies are appropriately captured under existing ICD-9-CM codes. We request that CMS provide clear guidance and greater transparency as to how a determination of "new" will be made when these technologies meet the substantial clinical improvement and cost thresholds of the new technology provision.

IV. CMS Should Continue to Develop and Implement Process-Based Quality Measures and Should Work Toward the Creation and Use of Outcomes-Based Measures (Reporting of Hospital Quality Data for Annual Hospital Payment Update)

BIO applauds CMS for its ongoing efforts to "transform the Medicare program from a passive payer to an active purchaser of higher quality, more efficient health care."[18] We particularly are impressed by the thoughtful, careful manner in which CMS has worked with the provider community to promote the development of consensus-based measures for use in the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. This program already addresses a broad range of conditions, and we support its continued use or expansion to include the following measures in 2009:

- Anti-Platelet Medication at Discharge;
- SCIP Infection 4: Cardiac Surgery Patients with Controlled 6 AM Postoperative Serum Glucose;
- SCIP-VTE-1: Venous Thromboembolism (VTE) Prophylaxis Ordered for Surgery Patients;
- SCIP-VTE-2: VTE Prophylaxis Within 24 Hours Pre/Post Surgery; and
- STK-1 DVT Prophylaxis.[19]

We also support implementation of VTE-1 through VTE-8 which were recently endorsed by the National Quality Forum (NQF).[20] For 2011 and subsequent years,

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18 73 Fed. Reg. at 23642.
19 Id. at 23649-51.
20 Id. at 23650.

we support implementation of the hospital inpatient cancer care measure, Surgical Resection Includes at Least 12 Nodes.21

We also support inclusion in the RHQDAPU of additional measures for 2011 and beyond, particularly NQF's Serious Reportable Events in Healthcare ("never events") related to medication errors and contaminated drugs or biologicals. CMS should encourage the NQF to develop consensus-based standards that recognize the medication error or contamination itself, rather than focusing solely on the outcome of death or disability resulting from the error. CMS also should encourage the NQF to develop consensus-based standards on coordination of care. As CMS develops and implements quality measures for various sites of care, it should take advantage of the opportunity to address lapses in quality that occur during the transition from one care setting to another. For example, when moving from a hospital to a skilled nursing facility or the patient's own home, failure to coordinate care may lead to poor communication among health care practitioners and the patient, lack of adequate follow-up care, medication errors, and other risks to patient safety. Appropriate standards would help to ensure that Medicare beneficiaries receive the right care for the right person, every time.

We also recognize that as the consensus-based guidelines are updated to reflect evolving standards of care, the measures will need to be updated as well. For example, the guidelines regarding provision of anti-platelet therapy for patients with coronary artery disease have been updated to include the use of clopidogrel bisulfate and aspirin.22 The Physician Quality Reporting Initiative measures reflect the current guidelines, but the RHQDAPU measures do not. The measures should be revised to reflect the current guidelines and to be consistent across settings.

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21 Id. at 23652.

22 E. Braunwald et al., American College of Cardiology (ACC), American Heart Association (AHA), Committee on the Management of Patients with Unstable Angina. *ACC/AHA 2002 guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction – summary article: a report of the American College of Cardiology/American Heart Association task force on practice guidelines* (Committee on the Management of Patients with Unstable Angina). J Am Coll Cardiol, 40: 1266-74 (2002); E. Antman et al., *ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction – executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines* (Writing Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction). Circulation, 110(5): 588-636 (2004).

CMS recognizes that "neither scientific advances nor consensus building entity standard updates are linked to the timing of regulatory actions," and the agency proposes to use a subregulatory process to implement updates.[23] We support this idea, and to ensure that these revisions occur in a clear and predictable manner, we recommend that CMS include in its process steps to notify the public, solicit comments on the update, and obtain an assessment of the impact of the revision by an oversight committee that includes hospital clinicians.

Finally, although we support the current process-based measures, we believe they should be used only in the interim until outcome-based measures can be developed and implemented. Unlike process-based measures that require frequent review to ensure that they reflect evolving standards of care, outcomes-based measures would not lock in a particular treatment or technology as the standard. These measures would encourage hospitals to improve patient care while allowing hospitals to adopt new methods of preventing complications and improving treatment. Outcomes-based measures should be risk adjusted to avoid penalizing hospitals for variations in the patient populations they serve. We urge CMS to continue its leadership role in promoting quality improvement by initiating the development of these measures and a risk adjustment mechanism.

V. CMS Should Continue to Work with Stakeholders to Identify Conditions that are Suited to the Hospital-Acquired Condition Payment Provisions (Preventable Hospital-Acquired Conditions (HACs), Including Infections)

BIO strongly supports the goal of improving the quality of care patients receive in hospitals, and we agree that hospitals should be encouraged to adopt procedures and technologies that will help prevent hospital-acquired infections. Section 5001(c) of the Deficit Reduction Act of 2005 (Pub. Law No. 109-171) requires discharges in which certain hospital-acquired infections are present not be placed into higher paying DRGs as of October 1, 2008. BIO commends CMS for the progress it has made toward implementing this provision. CMS selected the initial set of HACs that would be subject to this payment provision in the FY 2008 final rule, and CMS now proposes to refine and expand the list of HACs.[24]

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23 73 Fed. Reg. at 23647.
24 Id. at 23552.

We are pleased that CMS has worked with the Centers for Disease Control and Prevention (CDC) and with stakeholders to identify and evaluate HACs that could be subject to this provision. This development process should help to ensure that the payment provisions apply only to HACs which CMS, CDC, and stakeholders agree meet all three of the statutory criteria:

1. the condition has high cost or high volume, or both;
2. the condition results in the assignment of a case to a DRG that has a higher payment when the code is present as a secondary diagnosis; and
3. the condition could reasonably have been prevented through the application of evidence-based guidelines.25

Compliance with the third criterion is particularly important to ensuring that hospitals are not penalized for conditions that occur for reasons beyond the hospital's control. Hospitals should not be penalized in situations where, despite best efforts and adherence to appropriate prevention techniques, adverse outcomes occur due to factors beyond the hospitals' reasonable control. For example, as CMS acknowledges, questions have been raised concerning the preventability of many infections (e.g. Ventilator Associated Pneumonia and Septicemia), and applying the statute where preventability is in question could result in punishing hospitals for the incidence of conditions they could not reasonably have prevented in a significant number of cases. In contrast, conditions for which there is consensus that preventability is obtainable in a high percentage of cases (e.g. Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE)) may be more appropriate HAC candidates, providing that hospitals will not be penalized in the small percentage of instances that could not be prevented, such as when the prophylaxis was contraindicated or when the DVT/PE was caused by a drug side effect or adverse event. One way CMS could ensure that hospitals are not penalized in these instances is to refine the codes to better distinguish between reasonably preventable and unpreventable conditions. We encourage CMS to work with hospitals and other stakeholders to explore revisions to coding and other options to identify cases in which HACs are reasonably preventable through the application of evidence-based guidelines. Overall, the HAC payment provision should be implemented in a manner that both encourages hospitals to adopt evidence-based practices to prevent harm to patients while

25 Social Security Act § 1886(d)(4)(D)(ii).

continuing to reimburse hospitals appropriately for providing essential care to patients.

BIO supports implementation of the proposed glycemic control events as a HAC.[26] Poor glycemic control clearly is prevalent during hospital stays; however, the types of extreme glucose derangement that CMS lists in the Proposed Rule clearly are reasonably preventable in the hospital setting. Indeed, the American Diabetes Association,[27] the American Association of Clinical Endocrinologists, and others have developed clear evidence-based guidelines that reasonably can prevent these clinical conditions. BIO urges CMS to add these glucose derangement conditions as HACs accordingly.

BIO also recognizes that many stakeholders disagree about whether some of the proposed conditions satisfy the statutory criteria to be subject to the HAC payment provision. As CMS notes in the Proposed Rule, some conditions currently lack appropriate codes or evidence-based guidelines for prevention. The HAC mechanism is just one of many tools the agency may choose to use to improve quality of care for Medicare beneficiaries. If a condition proves to be unsuited to the HAC provision, we recommend that CMS work with other agencies and stakeholders to develop alternate methods of promoting prevention and improvements in treatment. For example, some of these conditions could be addressed through quality measures under the RHQDAPU program.

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26 73 Fed. Reg. at 23554.

27 See http://care.diabetesjournals.org/cgi/content/full/30/suppl_1/S4#SEC22.

VI. Conclusion

BIO appreciates this opportunity to comment on our concerns about the Proposed Rule, and we look forward to working with CMS to protect Medicare beneficiaries' access to new and advanced therapies. Please contact Laurel Todd at 202-962-9220 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel Todd
Director, Reimbursement and
Economic Policy