BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Leslie Norwalk, 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 2008 Rates (CMS-1533-P)

Dear Acting Administrator Norwalk:

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 2008 rates, published in the Federal Register on May 3, 2007 (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 1,000 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 continues the efforts it began last year to improve payment accuracy by better recognizing severity of illness and basing the relative weights on costs rather than charges. BIO strongly supports this objective because accurate payments are essential to ensuring that hospitals can provide advanced care, including biological therapies, to their patients and to promoting continued development of new technologies. We are pleased that the proposed Medicare Severity Diagnosis Related Groups (MS-DRGs) appear to recognize the

1 72 Fed. Reg. 24680 (May 3, 2007).

cost of services that use complex technologies, as well as the severity of the patient's condition. At the same time, we believe that there is room for improvement in this system, and we make the following recommendations to help CMS make the inpatient PPS even better.

We ask CMS to implement the proposed MS-DRGs over a three-year period so that hospitals can adjust to the substantial changes in total reimbursement that are likely to occur under the new system. We urge CMS to act on the recommendations included in the recent study of the effect of charge compression on relative weights for drugs, biological products, and other technologies by making an adjustment to the cost-to-charge ratio for drugs and biological products. We also are concerned that the proposed -2.4 percent adjustment for improvements in coding and documentation will deprive hospitals of necessary funds during a difficult transition period, and we urge CMS not to implement such a reduction until it has more data about the actual effect of new DRGs on hospitals' case-mix indices. We ask CMS to ensure that the payment provisions regarding hospital-acquired conditions do not restrict access to necessary treatments or impede hospitals' ability to adopt new technologies. We also recommend that CMS implement the hospital quality measure regarding surgical resection of at least 12 nodes in patients with colon cancer because this measure will encourage better care for cancer patients, including more effective use of drugs and biological therapies. Finally, we are concerned that the proposed modifications to the DRGs will make it even more difficult for new technologies to qualify for add-on payments. We cannot help but view the small number of applications for new technology add-on payments as evidence that this system is not working to protect access to advanced therapies, and we recommend that CMS reconsider how it applies the criteria for determining whether a technology qualifies for these payments. These comments are discussed in more detail below.

I. CMS Should Finalize DRG Revisions that Recognize Complexity in Addition to Severity of Illness and Implement these DRGs over a Three-Year Period ("DRG Reform and Proposed MS-DRGs," "DRGs: Cochlear Implants," "DRGs: Spinal Procedures," "DRGs: Endoscopy")

CMS uses the term MS-DRGs to describe the revisions it proposes to make "to better recognize severity of illness and resource use based on case

complexity."[2] BIO agrees that the DRGs should be designed to recognize not only the severity of the patient's condition, but also the cost and complexity of the care provided to the patient, and we are pleased to see examples of DRG reassignments based on this principle in the Proposed Rule. For example, CMS proposes to place several procedures that involve the use of advanced technologies, such as cochlear implants and spinal devices, into higher severity DRGs.[3] We also are glad to see that the proposed DRGs build off CMS' past efforts to recognize the higher costs and greater complexity for patients who receive biological therapies. For example, CMS proposes to continue to recognize the use of thrombolytic agents, such as tPA, in DRG assignment for patients with acute ischemic stroke.[4] We agree that procedures using innovative and complex drugs, biologicals, and devices should be placed into higher severity DRGs or assigned to the appropriate higher level MS-DRG (e.g., acute ischemic stroke with thrombolytic agent) so that their use is reimbursed appropriately, and we recommend that CMS finalize these proposals.

BIO also believes that the MS-DRGs should recognize that a patient's treatment may be very complex and resource intensive even though his or her disease severity is relatively low. Medicare must provide appropriate reimbursement for these cases, as well as for the cases in which the patient's condition is more severe. For example, patients who receive High-Dose-Interleukin 2 (HD-IL2) for metastatic renal cell cancer or melanoma may have relatively low severity of illness, yet require a very complex therapy. Under the proposed MS-DRG system, 88 percent of admissions for HD-IL2 for the treatment of metastatic renal cell cancer and melanoma would see a payment reduction of 32 percent to 65 percent. Cases assigned to the lower-paying DRGs would be reimbursed $8,500 to $14,000 less than the average $20,000 cost of a course of treatment with HD-IL2. These cases also would continue to be assigned to DRGs with acute leukemia and high-dose chemotherapy, even though HD-IL2 is an immunotherapy that is very different from chemotherapy and requires much stricter nursing protocols to prevent or manage complications that may develop. Unless CMS appropriately accounts for the complexity of care provided to these patients, hospitals will not be able to afford to provide this important, potentially life-saving treatment.

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2 Id. at 24691.
3 See, e.g., Id. at 24729 and 24734.
4 Id. at 24961

The DRG assignment for HD-IL2, similar to that of several other procedures using advanced technologies, was intended to be a temporary method of establishing appropriate payment for an innovative therapy. BIO appreciates CMS' past efforts to address these payment issues, but we believe that the implementation of new DRGs is a perfect opportunity for CMS to create permanent, appropriate DRGs for these procedures. Rather than carrying these stop-gap measures forward into the new MS-DRGs, we urge CMS to create new DRGs for therapies, such as HD-IL2, that are different from the base DRGs to which they currently are assigned. We ask CMS to evaluate the DRG assignments of cases using HD-IL2 and other procedures involving complex technologies to verify that they are assigned appropriately. When a technology is clinically different and requires different resource utilization from the other cases assigned to its current base DRG, CMS should create new, clinically coherent DRGs for that technology.

To ensure that the costs of new technologies are considered in making DRG assignments, we recommend that CMS use external data to place technologies appropriately until Medicare data are available. Advanced treatment options should not linger in underpaid DRGs for years until Medicare data can be collected. For example, in response to comments that the agency should reassign therapeutic endoscopic procedures to another DRG, CMS notes that it does not have sufficient supporting data for such a reassignment because new codes were created for those procedures in October 2006.[5] Rather than assigning these procedures to a DRG in which they may not be reimbursed adequately, CMS should accept external data that would help identify the costs of these procedures.

We also support the agency's efforts to review the complications and comorbidities (CC) list to ensure that conditions are included on that list if they lead to substantially increased hospital resource use, including a need for "expensive and technologically complex services."[6] CMS proposes to make significant revisions to the CC list and to create a list of major CCs (MCCs) that will be used to divide the proposed MS-DRGs into different levels of severity. If these changes are implemented, many diagnosis codes that currently affect DRG assignment would no longer be designated as CCs. We urge CMS to exercise caution in finalizing these lists to ensure that diagnosis codes are categorized appropriately and that the final lists include no mistakes. The proposed CC list at

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5 Id. at 24735.
6 Id. at 24698.

Table 6K, for example, does not include codes V85.35 (body mass index 35.0-35.9, adult), V85.36 (body mass index 36.0-36.9, adult), V85.37 (body mass index 37.0-37.9, adult), V85.38 (body mass index 38.0-38.9, adult), and V85.39 (body mass index 39.0-39.9, adult) as CCs, although CMS notes earlier in the rule that these codes, indicating body mass index greater than 35, would be considered CCs.[7]

We also are pleased that the MS-DRGs appear to accurately capture the severity of illness for patients with hemophilia and end-stage renal disease. Including these conditions on the MCC list[8] will help to ensure that hospitals are appropriately reimbursed for the costs of treating these complex conditions.

We also support CMS' proposal to place the MS-DRGs in the public domain so that all users will have free access to them.[9] BIO recommends that CMS implement this proposal.

Finally, we note that CMS' impact analysis indicates that the proposed changes will have a significant financial impact on certain types of hospitals, particularly rural hospitals and small hospitals. To allow hospitals time to adjust to these changes, we recommend that CMS implement the MS-DRGs over a three-year period. In 2008, the DRG weights would be a blend of one-thirds MS-DRG weight and two-thirds 2007 DRG weight. In 2009, the blend would be two-thirds MS-DRG weights and one-thirds 2007 DRG weights, and in 2010, the weights would be based entirely on the MS-DRGs.

II. CMS Should Adjust DRG Weights to Account for Charge Compression ("DRGs: Relative Weight Calculations")

In 2006, CMS asked RTI to study the effects of charge compression in calculating DRG relative weights. BIO long has been concerned about charge compression because it produces inaccurate payment rates for advanced technologies, including drugs and biological therapies, and we were pleased that CMS recognized the importance of this issue and commissioned the study. In the Proposed Rule, CMS summarizes RTI's findings, including its conclusion that intravenous solutions have a much higher markup and lower cost-to-charge ratio

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7 Id. at 24698.
8 Id. at 24988, 24993.
9 Id. at 24707.

(CCR) than therapeutic drugs.[10] This finding means that application of a single CCR to drugs and IV solutions produces relative weights for more costly drugs and biological products that are too low and weights for inexpensive solutions that are too high. We believe that the costs of all drugs and IV solutions should be accurately reflected in the payment system. In the short term, RTI recommends that CMS apply an adjustment to the CCR for drugs to estimate the effect of separating relatively low cost IV solutions from other drugs. CMS does not propose to implement any of RTI's recommendations for 2008, however. Although we understand that CMS has not been able to analyze the effect of implementing this adjustment with the proposed MS-DRGs, we agree with CMS' conclusion that RTI's recommendations "show significant promise in the short term" for addressing stakeholders' concerns about the cost-based weights.[11] RTI's suggested adjustment to the CCR for drugs could help improve the accuracy of payments for DRGs in which the administration of a drug or biological is the primary service. Therefore, BIO recommends that CMS implement an adjustment in 2008 and subsequently analyze and report on the effects of this adjustment on MS-DRGs. These steps would help to ensure that the new DRGs are assigned appropriate relative weights that account for the true costs of the technologies provided to patients and would help to encourage manufacturers to develop innovative products for Medicare patients.

In the long term, as CMS considers how to update cost reports,[12] we ask the agency to provide clear guidance to hospitals about how to report costs and charges for IV solutions and other drugs and biological products. CMS will not be able to calculate accurate costs for these products unless hospitals have clear and consistent guidance regarding how they report their costs and charges for these therapies. For example, the CCR would be inaccurate if some hospitals placed only saline, dextrose 5 percent in water (D5W), and similar IV solutions in this category, but others included relatively lower cost drugs and biologicals along with the relatively low-cost IV solutions. This guidance should specify which drugs and biologicals should be reported as IV solutions and which should be reported under other categories. We recommend that CMS instruct hospitals to report only the IV solutions subject to the highest markups as IV solutions.

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10 Id. at 24714.
11 Id. at 24715.
12 Id. at 24716.

III. CMS Should Not Reduce Payments to Account for Improved Documentation and Coding Without More Data ("DRG Reform and Proposed MS-DRGs")

As we note above, CMS proposes to make widespread changes to the CC lists and to DRG assignments. These changes will require hospitals to implement significant changes to their coding procedures and payment software. Although hospitals often need time install and verify that these changes are working correctly, CMS appears to assume that these changes will have an immediate effect on hospitals' case-mix indices (CMIs). CMS proposes to reduce the standardized amounts by 2.4 percent in each of 2008 and 2009 to offset increased CMIs due to improved coding and documentation.[13] CMS also proposes to make an adjustment in 2010 and 2011 based on data gathered during 2008 and 2009. BIO believes that implementing this payment reduction in the midst of other substantial changes to the inpatient PPS could deprive hospitals of necessary funds during a difficult transition period. We recommend that CMS not implement any adjustment until it has data confirming that CMIs have increased and that any adjustment be phased in over several years.

IV. CMS Must Ensure that the Provisions Regarding Hospital-Acquired Infections Do Not Restrict Access to Necessary Treatments or Impede Hospitals' Ability to Adopt New Technologies ("DRGs: Hospital-Acquired Conditions")

As CMS notes in the Proposed Rule, 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.[14] We support the goal of improving the quality of care patients receive in the hospitals, and we agree that hospitals should be encouraged to adopt procedures and technologies that will help prevent hospital-acquired infections. The Secretary is required to identify these infections using the following 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.[15]

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13 Id. at 24711.
14 Id. at 24716.
15 Social Security Act § 1886(d)(4)(D)(ii).

In the Proposed Rule, CMS requests comments on 13 conditions that might meet these criteria. Although BIO will not address any particular condition in detail, we urge the agency to take care in applying this section of the statute only to conditions that hospitals and physicians agree meet all three of these criteria. We are especially concerned about the third criterion. CMS must be sure that hospitals are not penalized for infections that originated outside the hospital or that are caused by factors beyond the hospital's control. Additionally, CMS must recognize that, even with the best infection control practices, some infections will occur anyway. Reducing payments for all cases in which those infections occur could harm hospitals' ability to purchase and provide advanced drugs and biologicals or invest in other infection control technologies. We ask that CMS implement Section 5001(c) in a manner that will ensure that hospitals can provide critical therapies for all infections.

BIO supports the goal of encouraging improvements in health care and reducing the number of preventable infections, but we also believe that hospitals must be reimbursed appropriately for providing the care patients need. We support CMS' proposal to implement Section 5001(c) only to cases in which the selected condition is the only MCC or CC on the claim.[16] This will help to ensure that hospitals continue to be reimbursed appropriately for treating complex or more severe cases in which the hospital-acquired condition is only one of several illnesses that must be treated.

V. CMS Must Protect Access to New Technologies in the Hospital Inpatient Setting ("New Technology")

BIO remains concerned about the extremely small number of technologies that qualify for new technology add-on payments and the declining number of applications submitted for these payments. This year, CMS proposes to discontinue add-on payments for the three technologies that received them in 2007.[17] CMS concludes that only one of these technologies, the X-STOP, still qualifies as "new," but then concludes that it no longer meets the cost threshold under the proposed MS-DRGs.[18] In addition, CMS received only one application for add-on payments in 2008. However, CMS is not convinced that the Wingspan® Stent System with Gateway™ PTA Balloon Catheter either meets the

16 72 Fed. Reg. at 24726.
17 Id. at 24773-74.
18 Id. at 24774.

cost threshold or that there is sufficient evidence that the device is a substantial clinical improvement.[19] CMS also questions the validity of the Medicare and non-Medicare data available regarding this technology, although the agency acknowledges that very little data are available because the procedure was not covered until October 2006. Unless CMS will accept external data, it appears that this new technology will not qualify for add-on payments during the limited period in which CMS will consider it to be new. This is not how Congress intended for this provision to work. BIO is concerned that CMS' narrow application of the criteria for add-on payments, combined with the proposed MS-DRGs, will prevent deserving technologies from receiving those payments and will discourage manufacturers from seeking these payments. As we have commented repeatedly in the past, BIO urges CMS to implement the new technology add-on payments in a manner that encourages continued innovation and access to advanced therapies.

BIO reiterates its request that CMS correct its narrow interpretation of the new technology add-on provisions. As we have explained in prior years' comments, CMS' 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 Food and Drug Administration (FDA)[20] is contrary to both the statute and CMS' own regulations. The statute clearly requires data collection and add-on payments beginning the "date on which an *inpatient hospital code* is issued with respect to the service or technology."[21] The regulation implementing this section acknowledges that an "inpatient hospital code" is an International Classification of Diseases – 9th Revision – Clinical Modification (ICD-9-CM) code and requires a medical service or technology to be considered new within two or 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).)"[22] Neither the statute nor the regulation refers to the date of FDA approval in determining whether a technology is "new." 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 new technologies and cuts short its opportunity to collect data on the technologies that receive add-on payments. BIO again urges CMS to protect beneficiaries' access to these technologies as Congress intended by using

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19 Id. at 24775-76.
20 Id. at 24771.
21 Social Security Act § 1886(d)(5)(K)(ii)(II) and (III) (emphasis added).
22 42 C.F.R. § 412.87(b)(2).

the issuance date of a new code, not the date of FDA approval, as the starting date for new technology status.

In addition to changing its interpretation of the time period in which a technology is considered to be "new," we urge CMS to deem certain technologies to meet the substantial clinical improvement criteria. Specifically, we recommend that CMS deem the drugs and biologicals for which the FDA has granted fast track approval[23] or approval based on surrogate endpoints[24] to represent substantial clinical improvements. Likewise, CMS should deem a device to be a substantial clinical improvement if it has been granted a humanitarian device exemption[25] or priority review based on the fact that it represents breakthrough technologies, that offer significant advantages over existing approved alternatives, for which no alternatives exist, or the availability of which is in the best interests of the patients.[26]

We also urge CMS to revise the new technology add-on formula to better reflect true provider costs and provide payment equity across treatment settings. The current payment formula chosen by CMS does not adequately reimburse providers for use of the new service or technology. Currently, once a new service or technology has been granted new technology add on status, "Medicare pays a marginal cost factor of 50 percent for the costs of a new medical service or technology in excess of the full DRG payment. If the actual costs of a new medical service or technology case exceed the DRG payment by more than the 50-percent marginal cost factor of the new medical service or technology, Medicare payment is limited to the DRG payment plus 50 percent of the estimated costs of the new technology."[27]

This approach does not adequately compensate the hospitals for the new service, as in most cases they receive only half of the cost of the new technology. Given that so few technologies have met the new technology add-on standard set by CMS, it would make more sense for CMS to fully compensate hospitals for those few technologies that do meet the new technology add-on

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23 A drug designated under section 506 of the Federal Food, Drug, and Cosmetic Act.
24 A biological approved under 21 C.F.R. 601.41 or a drug approved under 21 C.F.R. 314.510.
25 A device for which an exemption is granted under section 520(m) of the Federal Food, Drug, and Cosmetic Act.
26 A device for which priority review is granted under section 515(d)(5) of the Federal Food, Drug, and Cosmetic Act.
27 42 C.F.R. 412.88.

standards. This could be accomplished by paying on a cost basis, potentially ASP+6 percent for FDA approved drugs and biologicals and list price plus a percentage for devices. The use of ASP+6% for drugs and biologicals or list price plus a percentage for devices as the payment formula would ensure that providers recoup their costs, Medicare pays a fair rate, and that payment is harmonized across treatment settings.

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.

VI. CMS Should Implement RHQDAPU Measure 13 – Surgical Resection Includes at Least 12 Nodes (ACOS-02) – Cancer – Colon ("Hospital Quality Data")

Finally, BIO would like to comment on the possible measures for the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program for FY 2009 and subsequent years. We recommend that CMS adopt measure 13, Surgical Resection Includes at Least 12 Nodes (ACOS-02) – Cancer – Colon.[28] BIO's members are committed to producing new therapies for cancer and other deadly conditions, and we support efforts to improve care for all patients with cancer. Colon cancer, the third most common cause of cancer deaths in the U.S., is just one of the conditions for which our members are working to develop therapies, and we were pleased that a quality measure for colon cancer treatment was included on the list of possible RHQDAPU measures. Encouraging hospitals to meet this quality measure could lead to better survival for patients with stage II and III colon cancer, and could help physicians determine the patients' prognosis and plan for treatment more effectively. We encourage CMS to include this measure for FY 2009 or sooner.

VII. 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

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[28] 72 Fed. Reg. at 24806.

beneficiaries' access to new and advanced therapies. Please contact John Siracusa at (202) 312-9281 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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