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BY ELECTRONIC DELIVERY

Mark McClellan, M.D., Ph.D., 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 2007 Rates (CMS-
1488-P)**

Dear Administrator McClellan:

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 2007 rates, published in the Federal Register on April 25, 2006 (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

¹ 71 Fed. Reg. 23995 (April 25, 2006).

development of health-care, agricultural, industrial and environmental biotechnology products.

To achieve a goal of making payments to hospitals more fair and accurate, the Proposed Rule would implement the “first significant revision of the inpatient PPS since its implementation in 1983.”² Although CMS refers to these changes as “refinements” of the DRG system,³ they are far more substantial than the changes typically discussed in an annual proposed rule. CMS proposes to implement two significant changes to the payment methodology for acute hospital inpatient services: hospital-specific relative value cost center (HSRVcc) weights and severity-adjusted diagnosis related groups (DRGs). Both of these changes involve entirely new methodologies for analyzing hospitals’ cost and charge data and assigning services to DRGs and will have considerable impact on payments for many inpatient services.

BIO shares CMS’s goal of assuring beneficiary access to services in the most appropriate setting,⁴ and we agree that improving the accuracy of Medicare payment systems will help to achieve this goal. BIO has long argued that appropriate payments are critical to protecting patient access to advanced drug and biological products and to promoting continued innovation. In our comments on prior inpatient PPS proposed rules, we have expressed concern that payments under the inpatient PPS were not adequate to ensure that hospitals can provide new technologies to patients. We are hopeful that CMS’ attempts to make inpatient PPS rates more accurately reflect the costs of providing care also will include the costs of providing advanced drug and biological therapies.

Although we agree, in principle, with CMS’ efforts to make the inpatient PPS more accurate, we are concerned that neither the agency nor independent evaluators have had the time to evaluate whether the Proposed Rule’s methodologies are more accurate than the current system. We sincerely appreciate the Herculean efforts made by CMS’ staff to complete the new methodology in the Proposed Rule in record time. By CMS’ own admission, however, the agency was hard-pressed to complete this proposal for publication this spring and did not have time to confirm fully the accuracy of its methodology or its calculations. In the limited weeks since CMS released the Medicare Provider Analysis and Review File (MedPAR) data upon which the Proposed Rule is based, we are aware of

² CMS, Medicare Proposes Payment and Policy Changes for Acute Care Hospital Services to Inpatients, April 12, 2006, <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1833>.

³ See, e.g., 71 Fed. Reg. at 23996.

⁴ CMS, Medicare Proposes Payment and Policy Changes for Acute Care Hospital Services to Inpatients, April 12, 2006, <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1833>.

independent evaluations that have attempted to replicate CMS' results. In the course of these replications, questions about CMS' methodology have come to light. It is not clear from the Proposed Rule exactly how CMS applied this methodology to reach the published results. These changes should not be adopted in the inpatient setting until CMS explains its methodology in more detail, the agency and its stakeholders have had the opportunity to analyze the changes more fully, and CMS has responded to stakeholders' input. This explanation and analysis cannot be completed during this comment period or before the final rule is published.

BIO believes that the proposed changes are too significant and too untested to be implemented in 2007. We urge CMS to delay implementation by at least one year to allow the agency and stakeholders more time to assess, refine, and validate these proposals and update claims processing systems. We also recommend that CMS implement a refined DRG weight methodology (rather than the proposed HSRVcc method) and severity-adjusted DRGs at the same time, as recommended by the Medicare Payment Advisory Commission (MedPAC), to minimize distortions in the payment system. Severity-adjusted DRGs should be modified to recognize technologies that represent increased complexity, but not necessarily greater severity of illness. Finally, we urge CMS to reconsider its analysis of applications for new technology add-on payments in light of any methodological changes the agency adopts to ensure that access to innovative therapies is not disrupted during this transition to a new system.

I. CMS should delay implementation of the revised DRG weight methodology for at least one year

BIO recommends that CMS delay implementation of a refined DRG weight methodology for at least one year to allow the agency and stakeholders time to evaluate the proposed methodology, confirm the accuracy of CMS' calculations, and allow hospitals time to adjust to any changes in payment rates. CMS estimates that its entirely new methodology for calculating the HSRVcc weights would reduce the total weights for surgical services by 5.7 percent and increase the weights for medical services by 6 percent,⁵ but the effect on individual DRGs can be much larger, ranging from cuts of over 30 percent to increases of more than 80 percent.

Although we believe that all payment rates must be calculated accurately, these dramatic changes raise particular concerns about whether

⁵ 71 Fed. Reg. at 24020.

Medicare payment truly will reflect the resources involved in providing care. Independent review of the proposed methodology and CMS' calculations is critical to ensure that the new DRG weights are accurate. Given the sheer complexity of the calculations, however, few stakeholders have been able to perform a thorough review of effects of the changes in methodology. Additionally, because CMS' proposal includes significant changes to the methodology developed and tested by MedPAC, CMS cannot rely on MedPAC's analysis to argue that the actual proposed rule methodology results in more accurate payments. In order to ensure that the CMS receives the "comprehensive feedback from hospitals, suppliers, and other stakeholders that will help to refine and improve the final version of the rule,"⁶ we need more time to study the data and methodology and work with CMS to resolve our concerns. A delay of at least one year will allow both the public and the agency to evaluate and refine the proposal.

Based on stakeholders' limited review of the proposal, we have learned of serious unanswered questions regarding the methodology. For example, CMS calculates unweighted national geometric mean cost-to-charge ratios (CCRs),⁷ rather than CCRs weighted by hospital size. This methodology gives small hospitals' CCRs the same weight as large hospitals' CCRs, although large hospitals have more claims and are more likely to use advanced technologies that could possibly lead to higher CCRs. Because each hospital's CCR is given the same weight, this methodology creates distortions in payments to all hospitals and is likely to harm access to new technologies by failing to account for the true costs of providing care with innovative drugs, biologicals, and devices. We ask CMS to further explain its methodology and work with stakeholders to determine if it is the most accurate way to calculate weights. We also recommend that CMS present any revised weights to the public for independent verification.

Additionally, the proposed methodology assumes that hospitals allocate costs consistently to certain cost centers. In practice, however, many hospitals assign costs to their cost centers in non-standard ways and provide cross-walks with their cost reports. The assignments do not reflect the departments to which charges are assigned in the MedPAR data. The accuracy of the proposed methodology relies on a uniform mapping of costs and charges to cost centers. Delaying implementation of a refined DRG weight methodology by at least one year would allow CMS time to study the effects of non-standard cost mappings on the results.

⁶ CMS, Medicare Proposes Payment and Policy Changes for Acute Care Hospital Services to Inpatients, April 12, 2006, <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1833>.

⁷ 71 Fed. Reg. at 24010.

We also are concerned that the HSRVcc weight methodology relies on out-of-date data that do not include the costs of many newer treatment options. CMS used fiscal year 2003 cost report data and fiscal year 2005 MedPAR data to calculate the HSRVcc weights.⁸ This means that cost data from October 2002 will be used to set payments in effect five years later, in September 2007. CMS' efforts to clean the data and eliminate outliers may have removed many large hospitals' claims, which include advanced technologies, from the calculations. We recommend that CMS explain further how its methodology will ensure that all hospitals' costs are included in refined DRG weight methodology calculations.

Finally, we request a delay to allow hospitals enough time to make the budgetary and administrative adjustments necessitated by the new weights. CMS proposes to implement the HSRVcc weights for payment for services beginning October 1, 2006.⁹ This proposal would give hospitals and other stakeholders only the 60-day comment period to evaluate this methodology and only a few weeks after the final rule is published to plan for payment changes, adjust their budgets, and implement and test billing system revisions. This simply is not enough time for hospitals to adapt to these substantial changes to the Medicare inpatient payment system. A delay of at least one year will help to ensure that hospitals are prepared for them.

II. CMS should implement the severity of illness DRGs at the same time as the refined DRG weight methodology and should include a method of recognizing technologies that increase complexity of care (DRGs: Severity of Illness)

In addition to substantial changes to the DRG weights, CMS proposes to refine DRGs based on severity of illness in 2008 or earlier.¹⁰ BIO agrees with MedPAC's recommendation that any severity-based DRGs be implemented at the same time as a refined DRG weight methodology. In March 2005, MedPAC recommended four policy changes to make payments more accurate: (1) use hospital-specific relative value weights instead of charge-based weights; (2) use refined DRGs that account more completely for differences in severity of illness among patients; (3) use weights based on estimated costs of providing care instead of charges; and (4) account for differences in frequency of outliers across patient

⁸ Id. at 24008, 24045.

⁹ Id. at 23996.

¹⁰ Id. at 23966.

categories.¹¹ MedPAC found that these four changes, taken together, have the best potential to make payments more accurate.¹² MedPAC recently reiterated this conclusion in comments on the Proposed Rule in which it explained that each recommendation “targets a specific source of distortion in the current payment rates. . . . Failure to adopt any of them would leave some payment distortions in place.”¹³ Implementing a refined DRG weight methodology without the severity-adjusted DRGs not only would allow potential payment distortions to continue, it could create additional instability in payment rates. We urge CMS to implement any changes to the inpatient PPS as smoothly as possible by implementing both the severity-adjusted DRGs and a refined DRG weight methodology, as revised with stakeholder input, at the same time.

As CMS continues to develop the severity-adjusted DRGs, BIO urges the agency to include in this system a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness. We agree with CMS’ conclusion that such a method is necessary.¹⁴ For many years, BIO has advocated for better recognition and more appropriate payment of advanced technology in the inpatient PPS. We are pleased that CMS recognizes that factoring complexity of care into the severity-adjusted DRGs would be one method of addressing this concern. BIO believes such an adjustment is particularly important in light of the fact that the five-year old cost data used to create the HSRVcc weights does not include many currently used therapies.

Complexity must be factored into DRG groupings to ensure that hospitals will be appropriately reimbursed for providing advanced treatments to all of their patients, regardless of the severity of the patient’s condition. For example, for fiscal year 2004, CMS made an important policy change to ensure that Proleukin (high-dose IL-2), a therapy for patients with metastatic renal cell cancer or malignant melanoma that is administered primarily in the inpatient setting, was appropriately reimbursed. This change was imperative to ensure that Medicare beneficiaries continued to have access to the therapy because the prior DRG assignment so dramatically under-reimbursed for the therapy that programs across the country were threatened. Now CMS’ proposed implementation of the severity-adjusted DRGs would reverse the agency’s prior policy decision. Specifically, although patients must be in relatively good health to receive Proleukin, and thus

¹¹ Medical Payment Advisory Commission, Report to the Congress: Physician-Owned Specialty Hospitals, March 2005, at 36.

¹² *Id.*, at 37.

¹³ Letter from Glenn M. Hackbarth, Chairman, MedPAC, to Mark McClellan, Administrator, CMS, April 19, 2006, at 4.

¹⁴ 71 Fed. Reg. at 24014.

would map to low severity DRGs in the new proposed system, the treatment itself is complex and requires careful management of its potentially severe side effects. Under the proposed severity-adjusted DRGs, these patients would map to CSA-DRG 736 (chemotherapy SOI 2) or CSA-DRG 737 (chemotherapy SOI 3). Because these DRGs were created without regard for the complexity of care, they fail to account for the costs of providing this therapy. As proposed, payment for treatment with Proleukin would fall from \$16,925 in 2006 (DRG 492) to \$5,187 (CSA-DRG 736) or \$13,529 (CSA-DRG 737), cuts of 69 percent and 20 percent, respectively. If these cuts are implemented, many hospitals may not be able to continue to provide Proleukin, the only possibility of long-term survival for patients with metastatic renal cell cancer or malignant melanoma.

BIO is also concerned that the proposed severity-adjusted DRGs would reverse the important policy change finalized last year to create DRG 559, Acute Ischemic Stroke with Use of a Thrombolytic Agent. This policy change allows hospitals to be reimbursed for the additional costs of caring for more complex stroke patients in need of thrombolytic therapy. As CMS stated in last year's final rule: "We agree... that there is an increased cost in caring for these [stroke tPA] patients including increased use of the intensive care unit, more diagnostic imaging studies, and laboratory and pharmacy resources. We also agree that-(1) the data indicate that patients receiving thrombolytic therapy have increased severity; and (2) reperfusion therapy is a good means to segregate these patients into a separate DRG." (Federal Register, Vol. 70, 47288, August 12, 2005.) However, the proposed severity-adjusted DRGs would essentially reverse this DRG change by assigning stroke patients receiving reperfusion therapy to CSA-DRGs 56-58 with other less severe stroke patients. Overall, we estimate that hospitals would experience a weighted-average 35 percent reduction for treating thrombolytic patients compared to FY 2006 if such a policy were finalized. We urge CMS to carefully examine the proposed severity-adjusted DRGs to ensure that these and other potential problems are addressed and allow for adequate public notice and comment on these changes during the FY 2008 regulatory process.

Until CMS develops a method of recognizing complexity in the severity-adjusted DRG system and makes available for comment any criteria for determining how and when to recognize increased complexity in the structure of the DRG system, CMS should not implement the severity-adjusted DRGs.

III. As CMS implements the severity of illness DRGs and HSRVcc weights, it must protect access to innovative therapies (New Technology)

The biotechnology industry provides innovative and potentially life-saving technologies for Medicare beneficiaries. When new technologies come to market, however, inadequate payment can pose a barrier to their use. Under the current and proposed DRG payment systems, it may take two or three years for the increased costs associated with the use of new technologies to be reflected in DRG payment rates. New technology add-on payments can provide support to hospitals while ensuring access to the highest quality of care for Medicare beneficiaries. In order to preserve patient access to cutting-edge care, it is critical for CMS to use the add-on payment mechanism appropriately for qualified new technologies and services under the current payment methodology as well as in whatever new methodology is adopted in the future.

In the Proposed Rule, CMS discusses several technologies that have received or have applied for new technology add-on payments but does not describe how the changes to DRG weights and groupings will affect these payments.¹⁵ Because the regulations make new technology payments available only if the technology is inadequately paid under the DRG system,¹⁶ changes in the rates or definitions of DRGs would affect CMS' assessment of whether a technology is adequately reimbursed. CMS also acknowledges that a method of including complexity in the severity-adjusted DRGs would "interact with the existing statutory provisions for new technology add-on payments."¹⁷ Before CMS implements a refined DRG weight methodology and severity-adjusted DRGs, we ask the agency to examine the effect of these changes on new-technology add-on payments. In particular, we urge the agency to reconsider recent applicants for new technology add-on payments in light of any methodological changes CMS adopts in the inpatient PPS.

We also believe that implementation of the International Classification of Diseases, 10th Revision (ICD-10) coding system is a critical element of any effort to improve the accuracy of inpatient PPS reimbursement, especially for new technologies. This revised coding system offers more granularity than the ICD-9, allowing hospitals to describe their patients' conditions and the care provided in greater detail. As hospitals submit claims using these

¹⁵ *Id.* at 24068.

¹⁶ 42 C.F.R. § 412.87(b)(3).

¹⁷ 71 Fed. Reg. at 24014.

codes, CMS will be able to use this data to set more accurate payment rates. The ICD-10 also will improve CMS' ability to recognize new technologies and reimburse hospitals appropriately for their use. Unlike the ICD-9, which is running out of codes, the ICD-10 can be expanded to add new codes as new technologies and procedures are developed. BIO recommends that CMS adopt the ICD-10 as soon as possible to ensure that the inpatient PPS can continue to recognize new technologies and to help CMS set appropriate rates for all services.

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)¹⁸ 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."¹⁹ 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)."²⁰ 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 the issuance date of a new code, not the date of FDA approval, as the starting date for new technology status.

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.

¹⁸ *Id.* at 24068.

¹⁹ Social Security Act § 1886(d)(5)(K)(ii)(II) and (III) (emphasis added).

²⁰ 42 C.F.R. § 412.87(b)(2).

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.”²¹

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 standards. This could be accomplished by paying on a cost basis, which could be ASP+6% 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.

IV. 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. Toward this end, we urge CMS to delay implementation of the significant changes it has proposed in this rule for at least one year until we and other stakeholders have more time to assess, refine, and validate them. In addition, we recommend that CMS implement the refined DRG weight methodology and the severity-adjusted DRGs at the same time and find a way to modify these methodologies to pay more appropriately for advanced technologies, particularly those that increase complexity. Please contact

²¹ 70 Fed. Reg. 47342 (August 12,2005)

Jayson Slotnik at 202-312-9273 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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