



August 21, 2006

BY ELECTRONIC DELIVERY

Mark McClellan, 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: CMS-1512-PN (Medicare Program; Five-Year Review of Work
Relative Value Units Under the Physician Fee Schedule and
Proposed Changes to the Practice Expense Methodology)**

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed notice regarding the five-year review of work relative value units (RVUs) and proposed changes to the practice expense methodology under the physician fee schedule, published in the Federal Register on June 29, 2006 (the "Proposed Notice").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

¹ 71 Fed. Reg. 37170 (June 29, 2006).

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.

Representing an industry that is devoted to discovering new treatments and ensuring patient access to them, BIO urges CMS to protect beneficiary access to important drug and biological therapies by ensuring that physicians are appropriately reimbursed for all of the services associated with providing these therapies. Patients' access to biological therapies is dependent not only on adequate reimbursement for the therapies themselves but also for the unique costs of handling, administering, and preparing them. We recommend that CMS take the following steps to establish appropriate payments for drug administration services in 2007:

- CMS must not change the RVUs for drug administration services until it can ensure that beneficiary access to care will be protected;
- CMS must not implement the proposed changes to RVUs for administration of radioimmunotherapies;
- CMS should establish RVUs for the codes for prolonged physician services; and
- CMS should not implement the proposed changes to the practice expense RVUs for diabetes self-management training.

I. CMS Must Not Change the RVUs for Drug Administration Services until It Can Ensure that Beneficiary Access to Care Will be Protected

BIO is concerned that the proposed changes to the work and practice expense RVUs for drug administration services will harm beneficiary access to care, contrary to Congress's intent when it passed section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). When Congress created reimbursement based on average sales price (ASP) for physician-administered drugs and biological products, it also recognized that Medicare payments for drug administration services would need to be adjusted at the same time to ensure that physicians could continue to provide critical therapies. Section 303 required the Secretary to take several steps to establish more appropriate payments for drug administration services. First, the Act required the Secretary to set work RVUs for certain drug administration services equal to the work RVUs for a level 1 office visit for an established patient.² Second, the Act required the Secretary to use survey data submitted by medical specialty societies to set practice

² Social Security Act (SSA) § 1848(c)(2)(H)(iv).

expense RVUs.³ Third, the Act required the Secretary to evaluate existing drug administration codes to “ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption” and to establish RVUs for any new codes.⁴ Finally, the Act created a two-year transition adjustment that increased payments for drug administration services by 32 percent in 2004 and by 3 percent in 2005.⁵ Congress intended that all of these requirements would improve the appropriateness of Medicare’s payments to physicians for drug administration services.

BIO has been pleased by CMS’ efforts to implement the MMA’s requirements in a manner that recognized the need to protect beneficiary access to drug and biological therapies. We are greatly concerned, however, that the proposed RVUs for drug administration services will produce significant payment cuts that undermine the protections CMS has implemented in the past two years. Although CMS estimates that the impact of the work and practice expense RVU changes on hematologists and oncologists will be a 3 percent increase in allowed charges in 2007 and a 2 percent increase in 2010,⁶ we believe this projection is overly optimistic. CMS’ proposed practice expense RVUs for many of these services will fall by approximately 2 to 8 percent in 2007 and 4 to 33 percent when the new practice expense RVUs are fully implemented in 2010. If the budget neutrality adjuster is implemented as proposed, the work RVUs will fall by approximately 10 percent.⁷ When the effect of the expected cuts in the conversion factor and the end of the oncology demonstration project are factored in, many physicians will experience a real and substantial cut in Medicare payments for drug administration services.

BIO urges CMS not to implement any cuts to reimbursement for drug administration services until it has confirmed that beneficiary access to quality health care will not be harmed by the changes. In particular, CMS should postpone any cuts at least until it has received both of the Medicare Payment Advisory Commission’s (MedPAC) reports on the MMA’s payment changes. The MMA requires the Medicare Payment Advisory Commission (MedPAC) to conduct two studies on the effect of the MMA’s payment changes on the quality of care furnished to beneficiaries and the adequacy of reimbursement.⁸ MedPAC issued

³ SSA § 1848(c)(2)(H) and (I).

⁴ SSA § 1848(c)(2)(J).

⁵ MMA § 303(a)(3).

⁶ 71 Fed. Reg. at 37255.

⁷ *Id.* at 37241.

⁸ MMA § 303(a)(5).

the first of these reports, focused on oncology drugs and services, in January 2006. Based on the limited data available for analysis, MedPAC found that the “payment changes did not affect beneficiary access to chemotherapy services,”⁹ but also reported that some practices were sending beneficiaries without supplemental insurance to hospital outpatient departments for care.¹⁰

The effects of the MMA’s payment changes on beneficiary access to care are not yet fully understood. In its January 2006 report, MedPAC noted that its ability to analyze the impact of the MMA’s changes was limited because the changes had not been fully implemented yet and because claims data were available for only part of 2005.¹¹ For example, during the time under review, physicians received transitional adjustment payments as required by the MMA, as well as payment for participation in the demonstration to evaluate the effect of chemotherapy on patients’ levels of fatigue, nausea, and pain. In 2006, CMS made no transition payments, and the agency began a new demonstration project. MedPAC’s second report, due in January 2007, should describe the effect of current payments on access to care, but the full effect will not be known until later, when complete claims data for 2006 are available. Because physician payments for drug administration services are critical to protecting beneficiary access to care, BIO urges CMS to postpone any cuts in payment until it can confirm that the new rates will allow physicians to continue to provide vital drug and biological therapies to Medicare beneficiaries.

II. CMS Must Not Implement The Proposed Changes To RVUs For Administration Of Radioimmunotherapies

BIO also is concerned about the proposed changes to the RVUs for administration of therapeutic doses of radioimmunotherapies. For 2007, CMS proposes to reduce the practice expense RVUs for code 79403 (Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion) from 5.17 to 4.61, a reduction of 10 percent. If the new practice expense RVUs are fully implemented in 2010, the RVUs for this service would drop by 43 percent to 2.92. We believe this change would harm beneficiary access to radioimmunotherapies such as Zevalin and Bexxar in freestanding centers, and we urge CMS to reconsider this change.

⁹ Medicare Payment Advisory Commission, Effects of Medicare Payment Changes on Oncology Services, Jan. 2006, at vii, 23.

¹⁰ *Id.* at 12.

¹¹ *Id.* at 4.

III. CMS Should Establish RVUs for the Codes For Prolonged Physician Services

In the press release on the Proposed Notice, Administrator Mark McClellan states, “We expect that improved payments for evaluation and management services will result in better outcomes, because physicians will get financial support for giving patients the help they need to manage illnesses more effectively.”¹² BIO agrees that physicians should receive financial support for providing quality care. To this end, we recommend that Medicare make separate payment for codes 99258 (Prolonged evaluation and management service) and 99359 (Prolonged evaluation and management service, each additional 30 minutes). These codes are used to describe prolonged service not involving face-to-face care that is beyond the usual service.¹³ They describe activities central to providing advanced drug and biological therapies, such as developing treatment plans for patients receiving chemotherapy, reviewing extensive patient records and tests, and communicating with other professionals or the patient and his or her family. Medicare currently considers these services to be bundled into evaluation and management codes, but the work and practice expense inputs associated with these services are not represented by other codes. We recommend that CMS make separate payment for these codes to support physicians’ ability to provide quality care to Medicare beneficiaries.

IV. CMS Should Not Implement the Proposed Changes to the Practice Expense RVUs for Diabetes Self-Management Training

Finally, we recommend that CMS not implement the proposed changes to the practice expense RVUs for diabetes self-management training (DSMT). DSMT services help the millions of Medicare beneficiaries with diabetes manage their condition to prevent or reduce the severity of diabetes-related complications.¹⁴ Under the proposed new practice expense methodology, the RVUs for these services will decrease significantly over the next few years. In 2007, the RVUs for G0108 (DSMT per individual) will fall by 7 percent, and the RVUs for G0109 (DSMT group session) will drop by 8 percent. If the new RVUs are fully implemented in 2010, G0108 will decrease 28 percent and G0109 will fall

¹² CMS Press Release, CMS Announces Proposed Changes To Physician Fee Schedule Methodology, June 21, 2006,

<http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1887>.

¹³ Current Procedural Terminology 2006, at 29.

¹⁴ Diabetes Self-Management Training, <http://www.cms.hhs.gov/DiabetesSelfManagement/>.

by 34 percent. These codes have no work RVUs to offset the effect of the practice expense methodology changes, leading to steep declines in payment. We are concerned that these rates will not allow physicians to continue to provide these important services, denying Medicare beneficiaries the opportunity to learn how to improve their health. We urge CMS to reconsider the proposed changes to the practice expense RVUs for DSMT.

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BIO appreciates the opportunity to comment on the important issues raised in the Proposed Notice. We look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies by ensuring that physicians are appropriately reimbursed for all of the services associated with providing these therapies. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact me at 202-312-9273 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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