January 9, 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-1501-FC (Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) final rule with comment period regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal

Register on November 10, 2005 (the "Final 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 healthcare, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new therapies and ensuring patient access to them, BIO supports CMS' ongoing efforts to address patients, providers, and manufacturers' concerns about access to quality care under the OPPS. This Final Rule implements many payment provisions that we believe will help protect beneficiary access to drugs and biologicals. We support CMS' decisions to reimburse vaccines at reasonable cost, apply a $50 per administration threshold for separately-paid drugs and biologicals as required by the statute, make separate payment for all 5HT3 anti-emetic therapies even if they do not meet the packaging threshold, and allow market forces to determine appropriate payment for two biological therapies that CMS previously linked using the "equitable adjustment" authority. We also approve of the agency's implementation of most of the new drug administration Current Procedural Terminology® (CPT) codes under the OPPS.

BIO supports CMS' decision to reimburse most separately paid drugs, biologicals, and radiopharmaceuticals without pass-through status, including the specified covered outpatient drugs, at 106 percent of average sales price (ASP). We are disappointed, though, that CMS did not implement its proposal to make an additional payment for pharmacy handling costs. We also are concerned that the add-on payment for the pre-administration-related services associated with infusions of intravenous immune globulin (IVIG) will not be sufficient to ensure access to this therapy. Finally, we appreciate CMS' recent guidance regarding use of the new drug administration CPT codes but continue to be concerned about the payment rates for these services because they are set using two-year old data that lacks the granularity necessary to set appropriate rates. We also ask CMS to clarify that administration of IVIG should be billed using the chemotherapy infusion codes and to allow separate payment for infusions of hydration and non-chemotherapy drugs during the same visit. Most important, we ask

---

1 70 Fed. Reg. 68515 (November 10, 2005).

CMS to monitor access to drug and biological therapies in hospital outpatient departments and adjust rates as necessary to protect patient access to care. We discuss these issues in more detail below.

I. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

A. Payment for Drugs and Biologicals and Pharmacy Handling Costs

In the Final Rule, CMS explains that its data "indicate that payment for drugs and biologicals and pharmacy overhead at a combined ASP plus 6 percent rate would serve as the best proxy for the combined acquisition and overhead costs of each of these products."2 We disagree with this conclusion. Although we generally believe that ASP+6% is a reasonable proxy for hospitals' average acquisition cost, we are concerned that it may not reflect the substantial costs associated with safely furnishing advanced therapies.

As the Medicare Payment Advisory Commission reported in June 2005, pharmacy handling costs are significant, making up 25-28 percent of hospital pharmacies' direct costs, with drug acquisition costs accounting for the remaining 75-72 percent.3 These costs include salaries and benefits for the pharmacists and pharmacy technicians, as well as the supplies and equipment that are essential to patient safety and high quality care. Pharmacy professionals not only prepare drugs and biologicals for administration, but they also consult with physicians about the appropriate selection, dosage, and administration of drugs; perform quality assurance measures to verify that therapies are correctly prepared; and safely dispose of any unused medications. These safety measures are particularly important for preparing complex biologicals because many of these therapies must be stored and prepared under carefully controlled conditions to protect them from changes caused by changes in temperature and light. Without these quality and safety protections, errors involving these therapies are likely to occur.

---

2 Id. at 68642.

3 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

We are deeply concerned that CMS' decision to not make an additional payment for pharmacy handling costs will threaten hospitals' ability to continue to provide drugs and biologicals safely. Hospitals currently use reimbursement for drugs and biologicals to support these services, but as Medicare's reimbursement for most separately paid drugs drops to ASP plus 6 percent, hospitals will have less income to fund pharmacy salaries and benefits. Because their services are not separately reimbursed, hospitals could choose to reduce the number of pharmacists and pharmacy technicians they employ to make up for revenue shortfalls. As a result, pharmacies could be pressured to prepare more therapies in less time, and the number of medication errors could increase.

We urge CMS to reconsider this decision and to implement an additional payment for hospitals' pharmacy service and handling costs. We recommend that CMS work with hospitals to accurately measure the costs of providing these services and to develop an appropriate mechanism for capturing these significant costs. An appropriate payment mechanism must be developed for them, both now and in the future.

B. Payment for IVIG

BIO also remains concerned that ASP plus 6 percent may not be adequate to protect patient access to certain types of drugs and biologicals. IVIG is one of these therapies. As CMS discussed in the Final Rule, many providers have reported difficulty in acquiring enough of the various brands of IVIG to meet their patients' needs.[4] In response to these comments, CMS created an add-on payment of $75 for the pre-administration-related services associated with infusion of IVIG.[5] We appreciate CMS' effort to protect access to IVIG, but we are concerned that this payment is not adequate to compensate hospitals for all of the costs associated with acquiring this important therapy. We recommend that CMS work with providers and the manufacturers of IVIG to identify the costs that remain uncompensated and to do what is necessary to ensure patient access to this critical therapy.

We also recommend that CMS create a unique Healthcare Common Procedure Coding System (HCPCS) code for each brand name IVIG product. Currently, there are only two HCPCS codes for IVIG, even though

---

4 70 Fed. Reg. at 68648.
5 Id. at 68649.

the products are not interchangeable. As a result, the ASP calculation methodology reflects the prices of all brands of IVIG, not the specific brand that is best suited for a particular beneficiary. We believe that Medicare reimbursement for one brand of IVIG should not be based on another brand that is used for different indications and may be inappropriate for the patient. Creating unique HCPCS codes for each brand would help to protect beneficiary access by ensuring that Medicare's reimbursement is appropriate for each brand. This step also would help CMS better track the supply of each brand in the marketplace.

C. Packaging Threshold for Separately-Paid Drugs and Biologicals

BIO supports CMS' decision to set the threshold for establishing separate APCs for drugs and biologicals at $50 per administration in 2006 as required by statute.[6] We believe this threshold will help to maintain beneficiary access to appropriate drugs and biologicals. We also support the decision to pay separately for all 5HT3 anti-emetic therapies even if they do not meet the $50 packaging threshold because it will protect beneficiaries' access to the particular anti-emetic that is most effective for them as determined by themselves and their physicians.

D. CMS' Decision to Not Apply an "Equitable Adjustment"

Finally, we support CMS' decision to not apply an "equitable adjustment" to certain biologicals.[7] Instead of linking payment for one biological to another, as CMS has done in the past, the Final Rule uses the ASP methodology, which is based on market prices, to determine rates for these therapies. Using the ASP-based rates for these therapies is consistent with Congress' intent, in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, to use market-based payment systems, not arbitrary government price setting. We thank CMS for implementing this proposal in the final rule.

II. Vaccines

---

6 Id. at 68637.
7 Id. at 68652.

BIO supports CMS' decision to continue to reimburse influenza and pneumococcal vaccines at reasonable cost.[8] We share CMS' concern for protecting beneficiary access to these important vaccines, and we agree that payment at reasonable cost helps to ensure that hospitals are adequately reimbursed for providing them. We also are pleased that CMS implemented the APC Panel's recommendation to reimburse FluMist®, the intranasal influenza vaccine, on a reasonable cost basis as well and to assign it to status indicator "L" (paid at reasonable cost; not subject to coinsurance or deductible). In addition, we appreciate CMS' clarification that "vaccine administration codes other than G0008 for administration of influenza virus vaccine are not exempted in the [Outpatient Code Editor] from charging beneficiary deductible and coinsurance and they should not be used to report these services which are exempt from copayment."[9] This clarification will ensure that Medicare beneficiaries can receive any appropriate influenza vaccine, including FluMist®, without liability for coinsurance and deductibles.

III. Drug Administration

BIO is pleased that CMS decided to implement 20 of the 33 new CPT codes for drug administration services.[10] Instead of recognizing the 13 new codes that require determinations of initial, sequential, and concurrent infusions or intravenous pushes, CMS created 6 new C-codes that describe these services.[11] These codes are a significant improvement over the old codes because they offer more specific descriptions of the types of services offered. As charge data are collected using these codes, CMS should be able to set more appropriate rates for these procedures in the future. BIO continues to be concerned that reimbursement for these services may not be appropriate because they are set using two-year old data that lack the granularity necessary to set rates for all the codes. These potentially inadequate rates, combined with the transition to ASP-based payment for almost all separately paid drugs and biologicals, raise concerns about hospitals' ability to provide essential therapies in outpatient departments. We urge CMS to monitor access to drug and biological therapies in hospital outpatient settings and adjust rates as needed to protect access to care.

---

8 Id. at 68670.
9 Id. at 68682.
10 Id. at 68679.
11 Id. at 68880.

We also appreciate the guidance recently issued by CMS on the use of the new codes in hospital outpatient departments,[12] and we ask CMS to make two additional clarifications. First, consistent with the CPT's guidance for the chemotherapy codes used in physician offices, the guidance explains that "hospitals are to report chemotherapy drug administration HCPCS codes when providing non-radionuclide anti-neoplastic drugs to treat cancer and when administering non-radionuclide anti-neoplastic drugs, anti-neoplastic agents, monoclonal antibody agents, and biologic response modifiers for treatment of noncancer diagnoses."[13] We appreciate this instruction and recommend that CMS clarify that it also applies to IVIG. IVIG is a biologic response modifier, and thus its administration should be billed using C8954, not C8950, the code for non-chemotherapy intravenous infusion for therapy or diagnosis.

Second, the guidance explains that hospitals may report a first hour for each different type of infusion provided when the infusions can be reported using differed codes and they meet the requirements for billing an hour of each type of infusion.[14] This would allow a hospital to report and be paid for both a hydration service and a chemotherapy service. Because CMS has assigned one code for both hydration infusions and non-chemotherapy infusions in hospital outpatient departments, however, a hospital would not be paid separately for both infusions. Instead, payment for the hydration service would be packaged into payment for the drug infusion. In physician offices, these services have different CPT codes and both services are separately reimbursed. We recommend that CMS also allow hospitals to be paid for administering both a hydration infusion and a non-chemotherapy infusion in the same visit.

VI. Conclusion

In conclusion, BIO commends CMS for making important improvements to the OPPS, and we urge the agency to continue to make patient access to quality care its primary focus as the OPPS is refined. We hope our suggestions will help CMS address these important issues in the final rule. Please contact Jayson Slotnik at 202-962-9200 if you have any

---

12 January 2006 Update of the Hospital Outpatient Prospective Payment System (OPPS) Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785, Change Request 4258, December 16, 2005.

13 Id. (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2.2).

14 Id. (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2).

questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

James C. Greenwood
President & CEO
Biotechnology Industry Organization