
September 16, 2005

***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-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates) – NonPass-Throughs; Orphan Drugs; Vaccines; and Drug Administration**

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 revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on July 25, 2005 (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

1 70 Fed. Reg. 42673 (July 25, 2005).

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 supports CMS' ongoing efforts to address patients, providers, and manufacturers' concerns about access to quality care under the OPPS. After years of meeting with CMS, submitting comments, and testifying before the Advisory Panel on Ambulatory Payment Classification (APC) Groups (APC Panel), we are pleased to see that the agency has made significant progress in addressing many of our concerns in the Proposed Rule. In particular, we support CMS' plan to reimburse most separately paid drugs and biologicals without pass-through status at 106 percent of average sales price (ASP).[2] We also support the agency's proposal to allow market forces to determine appropriate payment for two biological therapies that CMS previously linked using the "equitable adjustment" authority.[3]

We remain concerned; however, that reimbursement at 106 percent of ASP may not be adequate to protect patient access to certain types of drugs and biologicals. We urge CMS to take the following steps to ensure that hospital outpatient departments will continue to be able to provide innovative drug and biological therapies:

- monitor patient access to drugs and biologicals, particularly for intravenous immune globulin (IVIG) and drugs and biologicals used to treat rare disorders and, and increase rates as necessary to ensure that Medicare beneficiaries retain access to critical therapies;
- implement the APC Panel's recommendation to evaluate all drugs and biologicals during the transition to reimbursement at ASP plus 6 percent to monitor "precipitous" drops in reimbursement rates that could harm access to these therapies;
- clearly and explicitly state that infusion drugs administered through an item of durable medical equipment (DME) will be reimbursed at 95 percent of their average wholesale price (AWP);
- accept and consider industry data regarding pharmacy handling and service costs, develop rates that more accurately reflect pharmacy overhead costs, and apply those rates both to packaged and separately paid drugs and biologicals to help ensure access to them;

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2 Id. at 42726.
3 Id. at 42727.

- delay implementation of the pharmacy handling service codes until January 1, 2007, as recommended by the APC Panel, and continue to refine the codes and develop instructions for their use;
- implement the APC Advisory Panel's recommendation to reimburse FluMist®, the intranasal influenza vaccine, using the reasonable cost methodology applied to all other influenza vaccines and to reimburse its administration on par with administration of other influenza vaccines;
- monitor access to drug and biological therapies in hospital outpatient settings and adjust administration rates as needed to protect access to care;
- instruct hospital outpatient departments to continue to bill multiple "initial" drug administration codes as they have done in the past and pay them for additional hours; and
- provide clear and timely guidance on the use of the new drug administration codes, particularly for administration of substances such as monoclonal antibody agents and other biological response modifiers that should be billed as chemotherapy administration.

We discuss these recommendations in more detail below.

## I. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status – NonPass-Throughs; Orphans

### A. Payment for Drugs and Biologicals

BIO supports CMS' proposal to reimburse most separately paid drugs and biologicals without pass-through status, including the specified covered outpatient drugs, at 106 percent of ASP. We also believe it is important to reimburse hospital outpatient departments at least as much as physician offices and freestanding end stage renal disease facilities for the acquisition and administration of drugs and biologicals. Hospital outpatient departments are a critical part of the cancer care infrastructure. They often serve patients who are difficult to treat because they have complications and comorbidities or a history of infusion reactions. Hospitals also offer a safety net for Medicare and Medicaid patients and the uninsured. Because hospital outpatient departments frequently are involved in clinical trials, they tend to be early adopters of new drugs and biologicals and assist patients who need cutting-edge treatments. Indeed, certain drug and biological treatments, only are available in hospital

outpatient departments because they require special equipment and handling. Hospitals are more heavily regulated than physician offices and must meet stringent accreditation requirements. For all these reasons, it is critical that hospitals be reimbursed at least as much as physician offices for drugs and biologicals and their administration.

The 106 percent of ASP reimbursement methodology has the advantage of being based on data CMS already collects routinely and updates quarterly, offering greater administrative simplicity for CMS and assurance for hospitals that rates will reflect market conditions. In addition, we believe that using the same rate-setting methodology for most separately paid drugs and biologicals will simplify the OPPS and eliminate disparities between similarly situated therapies. We greatly appreciate this reasonable, straightforward proposal, and we urge CMS to implement it in the final rule.

Although BIO generally supports CMS' proposal, we also believe that ASP plus 6 percent may not be adequate to protect patient access to certain types of drugs and biologicals. Exceptions may be needed to protect access, especially for IVIG and drugs and biologicals used to treat rare disorders. We urge CMS monitor patient access and increase rates as necessary to ensure that Medicare beneficiaries retain access to critical therapies. We also ask CMS to implement the APC Panel's recommendation to monitor for "precipitous" drops in reimbursement rates during the transition to ASP-based payment. In the past, CMS has applied its dampening option to certain proposed payment rates that decreased by more than 15 percent.[4] We believe 15 percent is an appropriate threshold to apply in this situation as well.

In addition, BIO supports the agency's proposal to "permit market forces to determine the appropriate payment"[5] for two biological products that CMS previously has linked using its "equitable adjustment" authority. In order to allow a market-oriented, ASP-based payment system to work as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) intended, CMS should permit the system to function without arbitrary government interference. We urge CMS to implement this proposal in the final rule.

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4 67 Fed. Reg. 66718, 66769 (Nov. 1, 2002).
5 70 Fed. Reg. at 42727.

As required by the statute[6], CMS set the threshold for establishing separate APCs for drugs and biologicals at $50 per administration in 2006.[7] CMS also requests comments on the use of alternate packaging thresholds in 2007.[8] BIO encourages CMS to set the threshold for drugs and biologicals no higher than $50 in 2007 and beyond in order to maintain beneficiary access to appropriate drugs and biologicals. Indeed, to better protect patient access to critical therapies, CMS should continue to pay separately for all drugs and biologicals that were separately paid in the past, including all therapies that ever had pass-through status.

Finally, BIO supports CMS' proposal to pay separately for all 5HT3 anti-emetic therapies even if they do not meet the $50 packaging threshold.[9] We agree that this policy will help ensure Medicare beneficiaries have access to the particular anti-emetic that is most effective for them as determined by the beneficiary and his or her physician and ask that it be finalized accordingly.

### B. Payment for DME Infusion Drugs

The Proposed Rule makes no mention of how infusion drugs administered through an item of DME, such as drugs administered through an implantable or external infusion pump, will be reimbursed in the hospital outpatient setting in 2006. Although CMS does state that in 2006 payment for drugs and biologicals in the hospital outpatient setting will follow that of the physician office setting, CMS does not specifically state in either the physician fee schedule or OPPS proposed rules that this particular group of drugs that are not paid under the ASP reimbursement methodology will continue to be reimbursed at 95% of AWP. Therefore, we ask the agency to clearly and explicitly state that this category of drugs will continue to be reimbursed according to the statute.[10]

### C. Payment for Pharmacy Handling Costs

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6 Social Security Act § 1833(t)(16)(B).
7 70 Fed. Reg. at 42724.
8 Id.
9 Id.
10 Social Security Act § 1842(o)(1)(D)(i) and (ii) ("(i) Except as provided in clause (ii), in the case of infusion drugs furnished through an item of durable medical equipment covered under section 1861(n) on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003. (ii) In the case of such infusion drugs furnished in a competitive acquisition area under section 1847 on or after January 1, 2007, the amount provided under section 1847.").

BIO is pleased that CMS recognizes the need for additional payment to compensate hospitals for the service and handling costs associated with furnishing advanced therapies.[11] These costs are substantial and must be adequately reimbursed because they are so imperative to patient safety and high quality care. Studies cited in a recent MedPAC report found that these costs are significant.[12] We commend CMS for proposing an additional payment for these costs. CMS also should recognize that relatively low cost drugs and biologicals may have substantial handling costs and should implement the APC Panel's recommendation to apply the additional payments to packaged drugs and biologicals, as well as to separately paid therapies.

BIO also commends CMS for its efforts to develop a more refined method for reimbursing hospitals for pharmacy service costs in the future. CMS proposes to instruct hospitals to report charges by using new C-codes for pharmacy handling services.[13] We generally support this proposal as a potential mechanism for capturing these costs and then establishing appropriate reimbursement for hospitals. We agree that CMS needs to begin collecting data on pharmacy service costs as soon as possible so it can set accurate rates in the future. As MedPAC reported, however, most hospitals do not currently charge for their handling costs, and no systematic, consensus based approach exists for measuring these costs.[14] Developing such an approach will require dedication of considerable time and effort, specifically educating hospitals on how to accurately use these new codes. We are concerned that there is insufficient time to properly instruct and educate hospitals and how and when to use these new codes. To ensure that these codes are used effectively, CMS should consult with hospital organizations on this issue and, after reviewing their feedback, consider delaying the implementation of the codes until January 1, 2007, as recommended by the APC Panel, and continue to refine the codes and develop instructions for their use.

## II. Vaccines

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11 Id. at 42730.
12 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.
13 70 Fed. Reg. at 42730.
14 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 143.

BIO supports CMS' proposal to continue to reimburse influenza and pneumococcal vaccines at reasonable cost.[15] 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. The same payment concerns also apply to FluMist®, the intranasal influenza vaccine, yet CMS proposes to classify FluMist® (90660) as status E, meaning that Medicare does not cover the code, does not recognize it, or does not provide separate payment for it. The only payment proposed for FluMist® is for its administration, and these codes (90473 and 90474) are packaged into APC 1491 with a payment rate of $5.00. This proposed rate is inadequate to cover a hospital's cost of the vaccine and the administration service and could impair hospitals' efforts to vaccinate against the flu next year. BIO urges CMS to implement the APC Panel's recommendation to reimburse FluMist® (90660) on a reasonable cost basis and to reimburse its administration on par with administration of other influenza vaccines by clarifying that hospitals should use procedure code G0008 to bill for the administration of FluMist®. CMS also should exempt FluMist® and its administration from coinsurance and deductible, similar to all other influenza vaccines.

## III. Drug Administration

BIO is pleased that CMS proposes to begin using the new Current Procedural Terminology (CPT®) codes for drug administration services. 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 services. In the meantime, rates for the new codes will be set using two-year old data that lack the granularity necessary to set appropriate 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. When similar concerns were raised in the physician office setting, CMS responded by revaluing payment for the administration codes and by establishing a demonstration project to pay oncologists to collect data on their patients' pain, fatigue, and nausea. CMS has not proposed any similar adjustments under the OPPS, however. We urge CMS to monitor

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15 70 Fed. Reg. at 42733.

access to drug and biological therapies in hospital outpatient settings and adjust rates as needed to protect access to care.

Although we support the use of the new CPT® codes, we are concerned that applying a certain coding guideline to them in the hospital outpatient setting could have a dramatic and unintended effect. Specifically, the coding guidelines for the new codes state:

> When administering multiple infusions, injections or combinations, only one "initial" service code should be reported, unless protocol requires that two separate IV sites must be used. The "initial" code that best describes the key or primary reason for the encounter should always be reported irrespective of the order in which the infusions or injections occur. If an injection or infusion is of a subsequent or concurrent nature, even if it is the first such service within that group of services, then a subsequent or concurrent code from the appropriate section should be reported (eg, the first IV push given subsequent to an initial one-hour infusion is reported using a subsequent IV push code).16

Because hospitals currently are not paid in the OPPS for additional hours, application of this guideline in the hospital outpatient setting could lead to dramatic under-reimbursement for drug administration services, potentially creating access issues for patients.

For example, before some types of chemotherapy are administered, it often is necessary to hydrate the patient. Currently, a hospital performing this service would report CPT codes 90780 and 96410 and receive full payment under APCs 0120 and 0117. Next year under the new coding guidelines, however, the hospital could bill only one "initial" code, and the additional hour would not be paid. Specifically, the hospital would bill the new CPT codes that will correspond to codes G0359, "Chemotherapy Administration, Intravenous Infusion Technique; up to one hour," and G0346, "Intravenous Infusion, Hydration; each additional hour." The new CPT code corresponding to code G0346 is a packaged service, however, and no separate payment would be

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16 American Medical Assocation, CPT 2006, available at http://www.ama-assn.org/ama1/pub/upload/mm/362/cpt2006drugadmin.doc .

made. Both services would continue to be reimbursed in a physician office though.

Clearly, this result was not intended and could have dramatic consequences for drug administration services in hospital outpatient departments. BIO suggests two solutions to this problem. First, hospital outpatient departments should be instructed to ignore this specific guidance and continue to bill multiple "initial" codes and they have done in the past. Second, CMS should establish payment rates for additional hours beginning in 2006, using any claims data available from 2004 and 2005. We urge CMS to implement a solution to this problem in the final rule.

We also recommend that CMS assist hospitals' adoption of the new codes by providing clear guidance on their use. When the codes were introduced in physician offices, CMS provided guidance on their use before they became effective. We ask CMS to publish similar guidance in the final rule, through transmittals and Medlearn Matters articles, and on the CMS website to help hospitals learn to use the new codes appropriately. In particular, we recommend that the guidance include a clear explanation that the administration of substances such as monoclonal antibody agents and other biological response modifiers should be billed as chemotherapy administration.[17] The crosswalk table in the final rule and the titles of the chemotherapy administration APCs should be updated to reflect these changes. Our revised draft of Table 27, attached to this letter, shows the correct crosswalk from the CY 2005 CPT codes to the expected CY 2006 CPT codes, identified by their descriptions and 2005 G-codes.

## IV. Conclusion

Once again, BIO commends CMS for making important improvements to the OPPS this year. We appreciate 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 life-improving drug therapies. We

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[17] CMS Transmittal 129, Change Request 3631 (Dec. 10, 2004) states, "Under the new codes, chemotherapy administration codes apply to parenteral administration of non-radionuclide anti-neoplastic drugs and also to anti-neoplastic agents provided for the treatment of noncancer diagnoses (e.g., cyclophosphamide for autoimmune conditions), or to substances such as monoclonal antibody agents and other biologic response modifiers." This same guidance should be included in the preamble of the final rule and be transmitted to hospitals and contractors.

hope CMS will incorporate our suggestions in the final rule. Please contact Jayson Slotnik at 202-962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

James C. Greenwood
President and CEO
Biotechnology Industry Organization

## Proposed Crosswalk from Expected CY 2006 Drug Administration CPT Codes to Drug Administration APCs [adapted from CMS Table 27]

| 2005 CPT® Code | 2005 HCPCS G Code | Current CPT® Description (abbreviated) | CY 2006 Proposed Status Indicator | APC | Maximum APC Units per OCE | |
|---|---|---|---|---|---|---|
| | | | | | Without 59 18 | With 59 [1] |
| | | **Hydration infusion:** | | | | |
| 90780 | G0345 | IV infusion, hydration, up to 1 hour | S | 0120 | 1 | 4 |
| 90781 | G0346* | Each additional hour, up to 8 hours | N | --- | 0 | 0 |
| | | **Therapeutic/diagnostic infusion & injection:** | | | | |
| 90780 | G0347 | IV infusion, for therapy/diagnosis, initial, up to 1 hr | S | 0120 | 1 | 4 |
| 90781 | G0348* | Each additional hour, up to 8 hours | N | --- | 0 | 0 |
| N/A | G0349* | Additional sequential infusion, up to 1 hour | N | --- | 0 | 0 |
| N/A | G0350* | Concurrent infusion | N | --- | 0 | 0 |
| 90782 | G0351 | Therapeutic or diagnostic injection | X | 0353 | n/a | n/a |
| | | **Chemotherapy & complex biologic infusion & injection:** | | | | |
| 96410 *90780*19/ | G0359 | IV infusion technique; up to 1 hour, single or initial substance/drug | S | 0117 | 1 | 2 |
| 96412 *90781* | G0360* | Each additional hour, 1 to 8 hours | N | --- | 0 | 0 |
| N/A | G0362* | Each add sequential infusion, up to 1 hour | N | --- | 0 | 0 |
| 96414 | G0361 | Initiation of prolonged chemotherapy infusion | S | 0117 | 1 | 2 |
| 96400 | G0355 | Chemo administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic | S | 0116 | 1 | 2 |
| 96400 | G0356 | Chemo administration, subcutaneous or intramuscular; hormonal anti-neoplastic | S | 0116 | 1 | 2 |
| | | **IV Push Technique:** | | | | |
| 90784 | G0353 | IV push, single/initial substance/drug, non-chemo | X | 0359 | n/a | n/a |
| 90784 | G0354* | Each add sequential IV push, non-chemo | X | 0359 | n/a | n/a |
| 96408 | G0357 | IV push, single or initial substance/drug, chemo | S | 0116 | 1 | 2 |
| 96408 | G0358* | IV push, each additional substance/drug, chemo | S | 0116 | 1 | 2 |
| | | **Other related new codes:** | | | | |
| N/A | G0363 | Irrigation of implanted venous access device for drug delivery systems | N | --- | 0 | 0 |

* Add-on codes reflect incremental resources associated with administering an additional drug and must be billed in conjunction with an initial code. Initial codes are G0345, G0347, G0359, G0353, and G0357.
Note: G-codes are only for use in the physician office setting in CY 2005; new CPT code numbers not yet released.
18 "59" indicates modifier 59
19 Italics added per CMS previous explanation of G codes: "Infusions that were previously reported under CPT code 90780 (non-chemotherapy infusion, 1st hour) will be billed under one of three G-codes …. The first hour of a hydration infusion will be billed under G0345. The first hour of infusion of a non-chemotherapy drug other than hydration will be billed under G0347. The first hour of anti-neoplastic agents provided for treatment of non-cancer diagnoses or substances such as monoclonal antibody agents and other biologic response modifiers is billed under G0359."

# Proposed Crosswalk from Expected CY 2006 Drug Administration CPT Codes to Drug Administration APCs [adapted from CMS Table 27]

| 2005 CPT® Code | 2005 HCPCS Code | Current CPT® Description (abbreviated) | CY 2006 Proposed Status Indicator | APC | Maximum APC Units per OCE | |
|---|---|---|---|---|---|---|
| | | | | | Without 59 1 | With 59 [1] |
| | | **Non-Chemo Administration:** | | | | |
| 90783 | 90783 | Intra-arterial injection, therapeutic or diagnostic | X | 0359 | n/a | n/a |
| 90788* | 90788* | Intramuscular injection of antibiotic | X | 0359 | n/a | n/a |
| | | **Chemotherapy Administration:** | | | | |
| 96405 | 96405 | Intralesional, up to and including 7 lesions | S | 0116 | 1 | 2 |
| 96406 | 96406 | Intralesional, more than 7 lesions | S | 0116 | 1 | 2 |
| 96542 | 96542 | Chemotherapy injection subarachnoid intraventricular; sc reservoir | S | 0116 | 1 | 2 |
| 96549 | 96549 | Chemotherapy unspecified | S | 0116 | 1 | 2 |
| 96420 | 96420 | Chemotherapy, push technique, intra-arterial | S | 0116 | 1 | 2 |
| 96440 | 96440 | Chemotherapy, intracavitary; pleural cavity | S | 0116 | 1 | 2 |
| 96445 | 96445 | Chemotherapy, intracavitary; peritoneal cavity | S | 0116 | 1 | 2 |
| 96450 | 96450 | Chemotherapy, into CNS; intrathecal | S | 0116 | 1 | 2 |
| 96422 | 96422 | Chemotherapy, infusion method up to 1 hour | S | 0117 | 1 | 2 |
| 96423 | 96423 | Chemotherapy, infusion method add-on; each additional hour up to 8 hours | N | --- | 0 | 0 |
| 96425 | 96425 | Chemotherapy, infusion method; initiation of prolonged infusion more than 8 hours using portable implantable pump | S | 0117 | 1 | 2 |
| | | ***Other Related Codes*** | | | | |
| 96520 | 96520 | Portable pump refill & maintenance | T | 0125 | n/a | n/a |
| 96530 | 96530 | Portable pump refill & maintenance | T | 0125 | n/a | n/a |

*Source*: "Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates"; adapted from Table 27 per 70 Fed. Reg. 42738-9 (July 25, 2005)

* Code 90788 will be deleted as a CPT® code in 2006, but remains effective for 2005.

1 "59" indicates modifier 59

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**Key to Payment Status Indicators:**

S = Significant service, separately payable.
N = Packaged into APC rates.
X = Ancillary services.
T = Significant service, multiple reduction applies.