August 31, 2010

BY ELECTRONIC DELIVERY

Donald Berwick, MD
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 Outpatient Prospective Payment System and CY 2011 Payment Rates [CMS-1504-P]

Dear Administrator Berwick:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS) and calendar year (CY) 2011 payment rates, published in the Federal Register on August 3, 2010 (the "Proposed Rule").[1] BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

As the representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO understands that appropriate reimbursement based on an accurate payment methodology is essential to protecting beneficiary access to care and encouraging continued investment in innovation. We are pleased that CMS proposes to reimburse all separately payable

[1] 75 Fed. Reg. 46170 (August 3, 2010).

drugs and biologicals[2] at average sales price (ASP) plus six percent in 2011 and that the agency has recognized and addressed some of the problems with its rate-setting methodology for drugs and biologicals. We continue to be concerned, however, about problems in CMS's methodology that continue to create instability in reimbursement for separately payable drugs and biologicals.

For 2011, CMS proposes to apply the methodology it used in 2010 to establish payment for separately payable drugs without pass-through status under the hospital OPPS. Under this approach, CMS first applies its standard methodology of comparing costs derived from claims data for separately payable and packaged therapies to the ASPs for those drugs. This methodology produces an estimated total payment for separately payable drugs of ASP plus zero percent.[3] The estimated aggregate cost for packaged drugs with Healthcare Common Procedure Coding System (HCPCS) codes and ASPs is ASP plus 283 percent, and the estimated aggregate cost for both separately payable and packaged drugs is ASP plus 14 percent.[4] Because CMS acknowledges that ASP plus zero percent "may not be sufficient" and ASP plus 283 percent "may overstate the combined acquisition and pharmacy overhead cost of packaged drugs and biologicals," CMS again proposes to reallocate $200 million in overhead costs from packaged drugs, including $150 million from packaged drugs reported with HCPCS codes and $50 million from uncoded packaged drugs.[5] This reallocation produces a payment rate of ASP plus six percent for separately payable drugs.[6] CMS notes that in prior years, the payment rate calculated as a percent of ASP declined by at least one percentage point when the agency updated the ASP data, claims data, and cost report data for the final rule, and therefore the proposed methodology could result in a rate lower than ASP plus six percent in the final rule.[7]

In order to preserve hospitals' ability to provide high quality drug and biological therapies to Medicare beneficiaries, BIO urges CMS pay no less than ASP plus six percent for separately payable drugs and biologicals administered under the OPPS and to implement a more stable methodology for establishing payment rates for separately payable drugs and biologicals. Our comments also

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[2] Excluding vaccines and blood products.
[3] 75 Fed. Reg. at 46275.
[4] Id.
[5] Id.
[6] Id. at 46276.
[7] Id.

address pass-through status for implantable biologicals, payment for blood clotting factors, and proposed revisions to physician supervision affecting drug administration services.

In short, we recommend that CMS:

- Pay no less than ASP plus six percent for separately payable drugs and biologicals administered in the OPPS.
- Implement a more stable reimbursement methodology for separately payable drugs and biologicals, including:
    - Use of an ASP file that is better aligned with its claims and cost report data to determine the ASP + X% for drugs in the final rule for 2011;
    - Reallocation of a larger portion of pharmacy overhead costs from packaged to separately payable drugs and biologicals;
    - Removal of data from hospitals that participate in the 340B program from CMS's rate-setting calculations for drugs and biologicals.
- Make separate payment for all drugs and biologicals with HCPCS codes as it does in the physician office setting or alternatively, not increase the packaging threshold for these therapies. If any drugs remain packaged, CMS should *require* hospitals to bill for them using HCPCS codes and revenue code 636.
- Comply with the statute and Congressional intent by reinstating separate payment for contrast agents and diagnostic radiopharmaceuticals.
- Consider implantable biologicals approved under biologics license applications (BLA) for pass-through status as drugs or biologicals, or, if CMS does not implement this recommendation, revise its regulation to clarify that a biological will be evaluated as a device for pass-through status only if it is solely surgically implanted according to its Food and Drug Administration (FDA)-approved indication.
- Reimburse blood clotting factors at least ASP plus six percent.
- Continue to pay for therapeutic radiopharmaceuticals based on ASP data if submitted by the manufacturer.
- Waive the coinsurance and deductible for vaccines and their administration as well as for other preventative services as proposed.
- Implement the proposed expansion of measures for CY 2012, CY 2013, and CY 2014 for the Hospital Outpatient Quality Reporting Program (HOP QDRP).

These comments are discussed in detail below.

I. CMS should pay no less than ASP plus six percent for separately payable drugs and biologicals administered in the OPPS and implement a more stable reimbursement methodology for separately payable drugs and biologicals. [Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status]

A. CMS should establish a final payment rate of no less than ASP plus six percent for separately payable drugs and biologicals administered in the OPPS.

BIO has urged in past comments that CMS should reimburse the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status at no less than ASP plus six percent. At its August 2010 meeting, the APC Panel also recommended that CMS reimburse separately payable drugs at no less than ASP plus six percent. We are pleased that CMS proposes to set payment for acquisition and overhead costs of all separately payable drugs and biologicals[8] at ASP plus six percent in CY 2011.

Reimbursement at no less than ASP plus six percent for separately payable drugs and biologicals administered in the OPPS would ensure that hospitals are reimbursed appropriately for the acquisition costs of drugs and biologicals. It also is consistent with the Medicare statute and Congressional intent. The Social Security Act (SSA) requires Medicare to reimburse specified covered outpatient drugs (SCODs) at the "average acquisition cost for the drug for the year," as determined by the Secretary using survey data.[9] If acquisition cost data are not available, the payment shall be set at the average price for the drug established under section 1842(o), 1847A, or 1847B (e.g., ASP plus six percent or the rates determined under the Competitive Acquisition Program).[10] Although we believe that ASP plus six percent would be a reasonable payment for acquisition cost, we believe it is inconsistent with both the language and the intent of the statute to use aggregate costs derived from charges as a proxy for average acquisition cost and

[8] Excluding vaccines and blood products.
[9] SSA § 1833(t)(14)(A)(iii)(I).
[10] SSA § 1833(t)(14)(A)(iii)(II).

pharmacy service and handling costs for each drug when CMS's current methodology for calculating those costs is severely flawed and does not even approximate acquisition cost alone—much less acquisition *and* handling costs – unless CMS transfers a substantial amount of overhead from packaged drugs to separately payable drugs. Congress enacted these provisions because it disagreed with CMS's use of claims data to set payment rates for these drug and biological therapies. The statute requires CMS to use either an accurate methodology to determine average acquisition cost for each drug or the rates established under sections 1842(o), 1847A, or 1847B. Accordingly, we urge CMS to pay at least ASP plus six percent for separately payable drugs and biologicals administered in the OPPS.

B. CMS should use an ASP file that is better aligned with its claims and cost report data to determine the ASP + X% for drugs in the final rule for 2011.

BIO supports the proposed payment of ASP plus six percent, but we continue to be concerned about the instability of CMS's rate-setting methodology. As CMS acknowledges in the Proposed Rule, the methodology could produce a final payment amount for 2011 that is less than ASP plus six percent when CMS uses updated ASP, claims, and cost report data in its calculations.[11] In recent years, CMS's methodology caused a reduction of at least one percentage point from the proposed rule to the final rule.[12] Our analysis has found that this disparity is attributable to CMS's methodology, not changes in hospital acquisition cost relative to ASP. Specifically, CMS's methodology compares costs derived from two year-old claims data and cost reports that are at least two years old and current year ASP data. In the Proposed Rule, CMS uses data from the April 2010 ASP file in this comparison, and, consistent with prior years' practice, it plans to use data from the July 2010 ASP file in the final rule. As a result, the ASPs used for the final comparison will reflect sales reported to CMS in the first quarter of 2010, although the charge and cost data reflect drugs purchased in 2008 and 2009. When we compared CMS's estimated costs from the claims data to ASP data from the first quarter of 2009 (the July 2009 ASP file), we calculated a payment rate for separately payable drugs of ASP plus one percent, as opposed to the CMS

[11] 75 Fed. Reg. at 46276.
[12] Id.

calculation of ASP plus zero percent.[13] When the reallocation of $200 million in overhead is included in the comparison, we calculated a payment rate of ASP plus eight percent.[14] This result more accurately reflects hospitals' true acquisition costs. We recommend that CMS use an ASP file that is better aligned with its claims and cost report data to determine the percentage over ASP for reimbursement of drugs in the final rule for 2011. CMS should continue to update payment rates quarterly using the current ASP file. With regard to the agency's suggestion that using a different quarter of ASP data would require an adjustment to its cost to charge ratios (CCR), we do not believe such an adjustment is appropriate. The CMS methodology for setting payment rates for separately paid drugs and biologicals establishes a ratio between ASP and hospital costs. To be most accurate, the quarter of ASP used for this calculation should be the quarter closest in time to the cost data that is being used for comparison.

C. CMS should reallocate a larger portion of the pharmacy overhead costs from packaged to separately payable drugs and biologicals.

For CY 2011, CMS proposes to reallocate a total of $200 million of the pharmacy overhead cost attributed to packaged drugs and biologicals to separately payable ones – $150 million from coded packaged drugs and biologicals with an ASP and $50 million from those that are uncoded and packaged – just as it did in 2010. BIO commends CMS for proposing to make this reallocation for CY 2011, but we continue to be concerned that the amount of the reallocation is not sufficient.

In 2010, CMS reallocated $150 million of the $444 million in pharmacy overhead costs attributed to coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals and $50 million of the $656 million in uncoded drug costs to separately payable drugs. This reallocation represented 24 percent of total costs of coded packaged drugs and eight percent of uncoded packaged drugs.[15] The proposed reallocation for CY 2011 represents the almost exactly the same percentage of costs: 25 percent of coded packaged drug costs and eight percent of uncoded packaged drug costs. We believe CMS proposes to

[13] The Moran Company, Results of Various Analyses of Drug and Biological Reimbursement in the CMS Proposed Rule for the Calendar Year 2011 Outpatient Prospective Payment System (OPPS), August 30, 2010, at 4 (attached).
[14] Id.
[15] 74 Fed. Reg. 60315, 60512 (Nov. 20, 2009).

reallocate an insufficient amount of overhead from uncoded packaged drugs. We see no basis to assume that uncoded drugs have overhead costs, as a share of total costs, that are less than one third as much as the overhead costs of coded drugs, particularly because lower cost uncoded drugs tend to be marked up more than coded higher cost ones. CMS should apply the same assumptions to uncoded packaged drugs as it applies to coded packaged drugs.

In the Proposed Rule, CMS says it was not persuaded by the stakeholders' analysis that coded and uncoded packaged drugs are subject to the same mark-up. CMS explains that it is skeptical that coded drugs are the same as uncoded drugs and are subject to the same overhead costs because its analysis found that uncoded packaged drugs tend to be reported with surgical services, while coded packaged drugs tend to be reported with medical services.

We continue to believe that these drugs are similar and are subject to a similar proportion of overhead charges. Contrary to CMS's belief that coded and uncoded drugs are different products, the attached analysis by The Moran Company found significant overlap between packaged drugs reported with medical procedures and those reported with surgical procedures. To get a clearer view of packaged drugs, The Moran Company looked at claims from a group of "expert coder" hospitals in which coded drugs made up 85 percent or more of packaged drug costs. Of 174 coded packaged drugs, 100 were reported by these hospitals with both kinds of procedures. This indicates that many drugs packaged into payment for surgical procedures often are used with medical procedures, as well. The Moran Company also found that the differential between the cost of uncoded drugs on medical and surgical claims has been declining since 2006 as hospitals increasingly report codes for packaged drugs. With this trend in mind, the results from the "expert coder" hospitals likely reflect the upper bound for coding of packaged drugs. If all hospitals reported codes for packaged drugs whenever possible, CMS likely would see that many of the drugs used in surgical procedures also are used in medical procedures, and thus, CMS should reallocate the same amount of overhead from coded and uncoded packaged drugs to separately payable drugs.

Moreover, regardless of differences in use of some packaged drugs, CMS should recognize that hospitals apply the same charge-setting principles to all drugs. As CMS is aware, hospitals apply larger mark ups to lower cost drugs than to higher cost drugs. This is true for all lower cost drugs, not just those reported

with HCPCS codes. This practice is the reason that CMS's standard methodology for estimating the costs of drugs tends to overestimate the costs of lower-cost, packaged drugs and underestimate the costs of higher-cost, separately payable drugs.[16] The effects of charge compression are the same for any two drugs of similar cost, meaning that the amount of overhead included in the charge for an uncoded packaged drug is similar to the amount of overhead for a similarly priced coded packaged drug. In fact, the proportion of overhead included in charges for uncoded packaged drugs may be higher than that included in charges for coded packaged drugs due to CMS's packaging policies. CMS packages payment for contrast agents and diagnostic radiopharmaceuticals regardless of cost. These products often are reported with HCPCS codes and likely are subject the same mark-up as comparably priced separately payable drugs. As a result, the aggregate pool of overhead attached to coded packaged drugs may be smaller as a percent of aggregate ASPs than the pool of overhead attached to uncoded drugs. For these reasons, CMS should reallocate at least 25 percent of the total cost of uncoded packaged drugs, the same proportion it reallocates from coded packaged drugs, to separately payable drugs.

We believe it is critical for CMS to continue to analyze this issue and to reallocate a more appropriate amount of overhead from uncoded, packaged drugs and biologicals to separately payable drugs and biologicals in 2011 and beyond.

D. CMS should remove data from hospitals that participate in the 340B program from its rate-setting calculations for drugs and biologicals.

BIO, other stakeholders, and the APC Panel have recommended in recent years that CMS exclude data from hospitals that participate in the 340B program from its rate-setting calculations if it did not implement the stakeholders' proposal to establish appropriate payment for the acquisition and overhead costs of drugs and biologicals.[17] CMS has not accepted this recommendation. As we have explained in our comments on prior proposed rules, CMS's cost estimates do not reflect the actual costs of acquiring and preparing drugs and biologicals at most hospitals because CMS calculates mean unit costs using data from all hospitals, including hospitals that purchase drugs and biologicals under the 340B program.

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[16] 75 Fed. Reg. at 46276.

[17] APC Panel Recommendations, February 18-19, 2009, available at: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.

Sales under the 340B program are excluded from the ASP calculation, however. Thus, CMS is mixing apples with oranges in its rate-setting calculations for these therapies.

Approximately one-third of all billed drugs and biologicals (by cost) under the OPPS are provided by 340B hospitals. Although the discounts are designed to help the 340B hospitals better serve their patients, including drugs purchased at 340B prices in the OPPS payment rate calculations could harm access to care at non-340B hospitals by significantly reducing the estimated mean unit cost of separately payable drugs. If these hospitals are excluded from the data, we calculate that the mean unit cost would increase about five percent of ASP.

Including sales at 340B prices significantly reduces CMS's estimated mean unit cost of separately payable drugs. Before any reallocation of overhead, excluding sales at 340B prices from CMS's calculation would increase the estimated mean unit cost for separately payable drugs from ASP plus zero to ASP plus two percent.[18] The distorting effects of including data from 340B hospitals are likely to be even greater now that more hospitals are eligible to participate in the 340B program. Because the 340B program was not intended to harm access to care for patients of other hospitals, we believe that these hospitals should be excluded from CMS's rate-setting calculations for drugs and biologicals. As we have commented in the past, if CMS excludes data from the 340B hospitals, BIO strongly believes that CMS should continue to establish a single payment rate for all hospitals, including 340B hospitals.

II. CMS should make separate payment for all drugs and biologicals with HCPCS codes or alternatively, not increase the packaging threshold for these therapies. If any drugs and biologicals remain packaged, CMS should *require* hospitals to bill for them using HCPCS codes and revenue code 636.

For 2011, CMS proposes to increase the packaging threshold to $70, after setting it at $65 in 2010,[19] and to continue to package payment for all diagnostic radiopharmaceuticals and contrast agents. BIO believes that CMS should make

[18] The Moran Company, Results of Various Analyses of Drug and Biological Reimbursement in the CMS Proposed Rule for the Calendar Year 2011 Outpatient Prospective Payment System (OPPS), August 30, 2010, at 5 (attached).
[19] 74 Fed. Reg. at 60487.

separate payment for all drugs and biologicals with HCPCS codes in the OPPS just as it does for these therapies when they are administered in a physician office. CMS continues to assert that that diagnostic radiopharmaceuticals and contrast agents can be treated differently from other SCODs because the statutory packaging threshold has expired and the agency believes that these drugs "function effectively as supplies that enable the provision of an independent service."[20] These assertions ignore the clear language of the statute and Congressional intent. The statute defines a SCOD as a "covered outpatient drug for which a separate ambulatory payment classification group (APC) has been established" and that is a radiopharmaceutical or a drug or biological for which pass-through payments were made on or before December 31, 2002.[21]

We note first that the statute does not distinguish between drugs and biologicals that serve as a therapeutic modality and those that are used with other services.[22] CMS has no authority to reclassify a drug or biological as a supply simply to avoid payment as a SCOD. Second, Congress did not intend for CMS to circumvent the statutory payment provisions for SCODS by establishing high packaging thresholds or packaging entire classes of therapies. To do so would render the statute's explicit payment instructions meaningless. When Congress enacted this definition, it established a packaging threshold of $50 per administration for drugs administered in 2005 and 2006[23] because it objected to the $150 packaging threshold that was in effect in 2003. Congress intended for CMS to establish a low packaging threshold for all drugs and biological products, and the absence of a statutory requirement regarding the packaging threshold after 2006 should not be interpreted as support for widespread packaging.

BIO believes that separate payment should be made for every drug or biological with a HCPCS code just as it is made in the physician office. At a minimum, packaging should not be expanded beyond current levels. To the extent that drugs and biologicals continue to be packaged, CMS should *require* hospitals to bill for them using HCPCS codes and revenue code 636. We support the APC Panel's recommendation that CMS require hospitals to report all drugs with a HCPCS code using revenue code 636, regardless of payment status. Although we appreciate that it has been CMS's longstanding policy to refrain from instructing

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[20] Id. at 60496.
[21] SSA § 1833(t)(14)(B).
[22] Id.
[23] SSA § 1833(t)(16)(B).

hospitals on the appropriate codes to use, the agency now is required to measure drug utilization to calculate the pharmaceutical tax under the Patient Protection and Affordable Care Act (ACA). Requiring hospitals to bill for drugs and biologicals using HCPCS codes and revenue code 636 not only will help CMS meet this new requirement, but it will provide CMS with better data for future rate-setting. We ask CMS to implement this requirement for 2011.

III. Biologicals approved under BLAs should be eligible for pass-through drug status [Pass-Through Payments for Implantable Biologicals]

CMS proposes to continue to use the device pass-through evaluation process and payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) that are newly approved for pass-through status beginning on or after January 1, 2010.[24] BIO continues to be opposed to this policy. Some implantable biologicals meet the SSA's definition of "biological"[25] even though they are approved by the FDA as devices. As CMS explained in the final rule for 2010, it believes these products "function as implantable devices," thus should be subject to the same reimbursement policies as devices.[26] CMS also notes that biological and non-biological implantable devices share payment methodologies during their non-pass-through periods, have "overlapping and sometimes identical clinical uses," and "similar regulation by the FDA as devices."[27] CMS believes that "the most consistent pass-through payment policy for these different types of items that are surgically inserted or implanted and that may sometimes substitute for one another is to evaluate all such devices, both biological and nonbiological, only under the device pass-through process."[28] To implement this policy, CMS revised the pass-through regulations at 42 C.F.R. §§ 419.64 to exclude implantable biologicals from

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[24] 75 Fed. Reg. at 46285.
[25] SSA § 1861(t)(1) ("The term 'drugs' and the term 'biologicals', except for purposes of subsection (m)(5) and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.").
[26] 74 Fed. Reg. at 60496.
[27] Id. at 60474.
[28] Id.

consideration for drug and biological pass-through payment beginning on January 1, 2010.

BIO believes that biologicals approved by the FDA under a BLA should continue to be eligible for pass-through payment as drugs, regardless of whether they are implanted. When Congress implemented the current payment system for SCODs that previously had pass-through status, it intended for biologicals approved under BLAs to be reimbursed under the specific statutory provisions for drugs.[29] Therefore, it is only logical that Congress would have intended for these BLA-approved therapies to be reimbursed as pass-through drugs as well. Our recommended change thus is consistent with both Congressional intent to reimburse biologicals approved under BLAs under the methodologies for drugs and biologicals and CMS's goal of treating products approved as devices similarly. Therefore, we urge CMS to add the bold, italicized language to CMS's proposed regulatory language at 42 CFR § 419.64(a)(4):

> (iii) A biological ***approved under a biologics license application or a drug***.
> (iv) A biological ***not approved under a biologics license application*** that is surgically implanted or inserted into the body, for which pass-through payment as a biological is made on or before December 31, 2009.

Our revisions would allow biological therapies approved under BLAs to continue to be considered for drug pass-through status and be paid separately at ASP plus six percent as Congress intended.

If CMS does not implement our recommendation and continues to evaluate implantable biologicals for pass-through status as devices, we urge CMS to clarify that it will apply the device pass-through criteria only to biologicals if they are solely surgically implanted according to their FDA-approved indications. The current regulation leaves unclear how CMS would evaluate the eligibility for pass-through status of a biological that has multiple indications, including surgically implanted indications and non-surgically implanted indications. Evaluating an implantable biological as a device only if the biological is solely surgically implanted is consistent with CMS's own description of its policy, its application of the policy to date, and its billing instructions to hospitals for biological products

[29] See Conference Report, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, H. Rep. No. 108-391, at 679.

that do not always function as devices. In the final rule for 2010 and the proposed rule for 2011, CMS describes the current approach as applying to "implantable biologicals that are *always* surgically inserted or implanted (through a surgical incision or a natural orifice)."[30] CMS also refers to its instructions to hospitals to not bill separately for biologicals that *sometimes* can be used as implantable devices when used as such.[31] Under these instructions, hospital can bill separately for these biologicals when they are not used as implantable devices. In addition, the products that CMS has treated as implantable biologicals for determination of separate payment upon expiration of pass-through status have been products that are solely surgically implanted according to their FDA-approved indications.[32] To make the regulation text consistent with CMS's policy and practices, we recommend that CMS revise the regulation to refer to "a biological that is not always surgically implanted or inserted into the body."

IV. CMS should reimburse blood clotting factors at no less than ASP plus six percent. [Proposed Payment for Blood Clotting Factors]

CMS proposes to continue to pay for blood clotting factors at ASP plus six percent, consistent with the proposed rates for other separately paid drugs and biologicals without pass-through status.[33] We support this proposal, and consistent with our recommendation for other drugs and biologicals, we urge CMS to pay no less than ASP plus six percent for clotting factors in order to ensure beneficiary access to them.

V. CMS should continue to pay for therapeutic radiopharmaceuticals based on ASP data if submitted by the manufacturer. [Proposed Payment for Therapeutic Radiopharmaceuticals]

For 2011, CMS proposes to continue to reimburse all nonpass-through, separately payable therapeutic radiopharmaceuticals at the same rate as nonpass-through drugs and biologicals (ASP plus six percent) based on ASP information, if available, for a "patient ready" dose and updated on a quarterly basis for products for which manufacturers report ASP data.[34] If ASP data are not available, CMS

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[30] 74 Fed. Reg. at 60532; 75 Fed. Reg. at 46284 (emphasis added).
[31] 75 Fed. Reg. at 46272 (emphasis added).
[32] 74 Fed. Reg. 60472, 60496.
[33] 75 Fed. Reg. at 46280.
[34] Id.

proposes to use CY 2009 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals.[35] BIO agrees that using ASP data provides an opportunity to improve payment accuracy for therapeutic radiopharmaceuticals, and we support continued reimbursement based on reported ASPs.

VI. CMS should waive the coinsurance and deductible for vaccines and their administration as well as for other preventative services as proposed. [Coinsurance and Deductible for Preventative Services]

In the Proposed Rule, CMS states that vaccines and their administration meet the statutory requirements for waiver of the deductible and coinsurance under Medicare as required by section 4104 of the ACA.[36] BIO believes this is consistent with Congressional intent to preserve beneficiary access to preventive services, and thanks CMS for explicitly implementing these provisions in the OPPS. Waiving the coinsurance and deductible for vaccines and their administration will encourage Medicare beneficiaries to receive appropriate immunizations. Vaccines are a simple, safe, and cost-effective method of preventing negative health outcomes and mitigating the need for hospitalizations or other more costly treatments. We also support this waiver applying to all settings where these immunization services could be furnished. Pharmacists, particularly retail pharmacists, have played a critical role in providing seniors with convenient access to needed vaccinations. BIO also applauds the waiver of the coinsurance and deductible for other preventative services, including bone mass measurement tests and certain screening tests for colorectal and breast cancer. These are important changes that likely will improve beneficiaries' health outcomes.

BIO is concerned, however, that by limiting the waiver to only those vaccines covered under Medicare Part B that are recommended by the United States Preventive Services Task Force (USPSTF), a significant obstacle to proper immunization of at-risk seniors remains. As CMS notes, the USPSTF ceased to make recommendations with regard to vaccines and vaccine administration after 1996, to avoid conflicting with the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP).[37] Those ACIP-recommended vaccines that are covered under Medicare Part D and not subject to the waiver will continue to present cost barriers for beneficiaries. Several of these

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[35] Id.
[36] 75 Fed. Reg. at 46311.
[37] Id.

vaccines are designed to prevent diseases that are particularly onerous for seniors, such as shingles (herpes zoster). Others are significant for those with certain underlying illnesses, such as hepatitis A for those with chronic liver disease. Recognizing these potential obstacles, in section 4204(e) of ACA, Congress obligated the Government Accountability Office (GAO) to conduct a study on the ability of Medicare beneficiaries to access routinely recommended vaccines that are covered under Medicare Part D, including "any barriers" to such access. BIO is very concerned that failing to provide a mechanism to reduce beneficiaries' financial barriers to access for the rest of the ACIP-recommended vaccines means that many will not take advantage of those preventive services even when they are included as part of the patient's personalized prevention services plan. We ask CMS to work with us and Congress to ensure Medicare beneficiaries have access to these important, cost-effective vaccines.

VII. CMS Should implement the proposed expansion of measures for CY 2012, CY 2013, and CY 2014 for the HOP QDRP [Reporting Quality Data for Annual Payment Rate Updates]

In the Proposed Rule, CMS proposes to expand the list of quality measures to be reported by hospital outpatient departments. We believe that the expansion of HOP QDRP and the resulting payment decrease associated with non-reporting support CMS's mission to improve the quality of care for Medicare beneficiaries. The expansion of HOP QDRP also provides consistency compared to other Medicare programs and sites of services. CMS should implement appropriate, nationally-endorsed quality measures in the outpatient setting, for FY 2011, 2012, and 2013 reporting, for FY 2012, 2013, and 2014 payment determinations.

For example, the CY 2013 proposed provision "ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival" aligns well with quality measures reported under the Medicare Hospital Inpatient Prospective Payment System (IPPS). Under IPPS for FY 2011, CMS includes a measure related to stroke and describes several measures in consideration for future years,[38] but currently there are none reported in the hospital outpatient department. Many stroke patients present with signs and symptoms to emergency departments (ED) and are then admitted. For these patients, quality care should begin in the ED. We thank CMS

[38] 75 Fed. Reg. 50041, 50188, 50204-05 (August 16, 2010).

for aligning quality across relevant sites of care. This quality measure is clearly needed. Median time from ED arrival to CT scan is 1.1 hours, putting many patients beyond the time that they can receive the standard of care.[39] This measure may be able to reduce health disparities as well: African Americans are much more likely to die of a stroke, because they are much less likely to receive the standard of care in treatment.[40]

We also commend CMS on its consideration of quality measures for future payment updates that ascertain whether or not patients have received preventive vaccinations such as the influenza and pneumococcal vaccines.[41] In an effort to ensure that patients who respond "no" to questions about whether they have received these vaccinations receive appropriate follow up care, we recommend that measures be tested and considered for future inclusion that capture this information. For example, a future measure might state: For patients who respond that they have not received a pneumococcal vaccination, was the vaccination given or was the patient directed to a pharmacy or other facility for vaccination (yes, no).

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[39] Dexter L. Morris; Wayne Rosamond; Kenneth Madden; Carol Schultz, Scott Hamilton. Prehospital and Emergency Department Delays After Acute Stroke. Stroke 2000;31:2585-2590.

[40] S. Claiborne Johnston, Lawrence H. Fung, Leslie A. Gillum, Wade S. Smith, Lawrence M. Brass, Judith H. Lichtman, Andrew N. Brown and David Z. Wang. Utilization of Intravenous Tissue-Type Plasminogen Activator for Ischemic Stroke at Academic Medical Centers : The Influence of Ethnicity Editorial Comment: It Is Time to Implement Stroke Practice Improvement Programs and Prevent the Racial Disparity in Stroke Care. Stroke 2001;32;1061-1068.

[41] 75 Fed. Reg. at 46374.

Conclusion

BIO thanks CMS for this opportunity to comment on the OPPS Proposed Rule for 2011. We look forward to continuing to work with the agency to ensure that hospitals are reimbursed appropriately for the costs of acquiring, preparing, and administering drug and biological therapies. We urge CMS to reimburse separately payable drugs and biologicals at no less than ASP plus six percent and make additional refinements to its methodology to produce the stable and accurate payment rates that are needed to preserve beneficiary access to these important therapies in the future.

Please contact Laurel Todd at (202) 962-9220 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel Todd
Managing Director,
Reimbursement and Health Policy

Attachments

- Attachment A: Background on the 340B Program
- Attachment B: The Moran Company Memorandum dated August 30, 2010

Attachment A

Background on the 340B Program

In 1992, Congress created the 340B Drug Pricing Program which is a federally administered program that allows certain qualified entities "covered entities" within the health care safety-net to purchase outpatient drugs and biologicals at or below a defined discount price. The 340B program was intended by Congress to assist covered entities in serving the pharmaceutical needs of uninsured patients and other vulnerable populations.

Eligible covered entities include:

- Certain public and non-profit Disproportionate Share Hospitals
- Federally Qualified Health Centers (FQHCs) and FQHC-like entities
- Certain Community Health Centers
- Certain Federal grantees such as Health Care for the Homeless, Migrant Health and Public Housing Primary Care Programs
- Certain entities receiving grants under the Ryan White CARE Act
- State-operated AIDS Drug Assistance Programs (ADAPs)
- Urban Indian Health Centers
- Family Planning Clinics

Effective January 1, 2010, the ACA amended the 340B statutory definition of a covered entity to include certain qualifying children's hospitals as well as free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. There are currently more than 14,700 registered providers with access to the 340B discount. This number is expected to increase as newly eligible hospitals begin enrolling in the program in August 2010.

- Manufacturers are required to participate in the 340B program in order to have federal funds available to pay for their drugs/biologicals under Medicaid.
- The 340B price is a deeply discounted rate. It is calculated as the Average Manufacturer Price (AMP) minus the Medicaid rebate. Drugs with an orphan designation under section 526 of the Federal Food, Drug, and Cosmetic Act are exempt from the ceiling price requirement as to those new covered entity types added by the ACA.
- 340B pricing applies to drugs and biologicals in the hospital outpatient setting only. However, nothing prevents individual entities from negotiating

340B or lower prices for their inpatient products or from negotiating additional concessions for outpatient products below the 340B ceiling price.

- 340B entities are permitted to dispense drugs and biologicals acquired at the 340B price to any of their patients in the outpatient setting, regardless of insurance status, including patients enrolled in Medicare Part D. Thus, although 340B covered entities purchase drugs at heavily discounted prices, they receive reimbursement based on the patient's insurance plan. In these instances it is the covered entity, not the patient, which benefits from any differential between the 340B price and the insurance reimbursement rate for the drug or biological.
- 340B participating entities are prohibited by statute from dispensing 340B-priced drugs and biologicals to Medicaid patients if the State Medicaid program will be requesting a rebate for the same drug or biological.
- Participating entities are also prohibited from reselling or otherwise transferring drugs and biologicals purchased at the 340B prices to individuals who are not patients of the participating entity or who are receiving care in the inpatient setting.
- The definition of "a patient of a covered entity" is the subject of only limited guidance from the Health Resources and Services Administration (HRSA), which administers the 340B Program, and there are instances where 340B medications have been re-sold and/or distributed to non-340B patients, a troubling practice known as "diversion."

1655 FORT MYER DRIVE, SUITE 1250 ARLINGTON, VA 22209 (703) 841-8400 FAX (703) 465-9969

Attachment B

Memorandum (August 30, 2010)

TO: Laurel Todd, BIO

FROM: Kevin Kirby, Marla Kugel, Clare Mamerow and Gregory Watson

SUBJECT: Results of Various Analyses of Drug and Biological Reimbursement in the CMS Proposed Rule for the Calendar Year 2011 Outpatient Prospective Payment System (OPPS)

In order to better inform BIO's comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates," we have conducted a series of analyses of the CMS proposed payment methodology for separately paid drugs and biologicals.

The first set of these analyses used the CMS medians file to model the impact of potential changes to the CMS methodology—using potentially more appropriate Average Sales Price (ASP) data and different allocations of pharmacy overhead spending to calculate the percentage markup over ASP (ASP + X%). We also calculated hospital spending on drugs with HCPCS codes but no ASPs, and drugs without HCPCS codes to provide a sense of the relative contribution of these categories of drugs to the CMS reimbursement calculations for separately paid drugs and biologicals.

In our second set of analyses, we used The Moran Company's replication of the CMS rate-setting methodology for drugs and biologicals to model the impact of removing claims data for 340B hospitals from that methodology.

In our third set of analyses, we evaluated the CMS contention that uncoded packaged drugs tend to come from surgical, rather than medical procedures and we investigated whether there were ways to better compare uncoded versus coded drugs. In particular, we identified a sample of "expert coders" that had lower volume of uncoded drugs and compared the drugs and biologicals used in these hospitals for medical versus surgical procedures.

Highlights of Our Analysis

Based on our analyses, we have found that:

- Various allocations of pharmacy overhead dollars using the current CMS methodology based on fourth quarter 2009 manufacturer ASP reports would provide payments ranging from ASP + 0% (no overhead allocation) to ASP + 10% (allocation of $150 million from coded packaged drugs and $150 million from uncoded packaged drugs).

- We also found that the choice of quarter of ASP data used can result in a different ASP + X%.
- Similarly, excluding data from hospitals participating in the 340B program can have a material effect on the calculation.
- In our various analyses, we noted that the results of any ASP + X% were sensitive to even relatively minor changes in calculations, assumptions, or overhead allocation methodologies.
- Our analysis suggests that CMS is correct that higher numbers of uncoded drugs appear on surgical claims than medical claims, but this differential is shrinking over time as more drug and biological volume is coded.
- Moreover, based on an analysis of "expert coders" that had significantly reduced levels of uncoded drug and biological usage, we identified some overlap between the drugs and biologicals used in surgical versus medical procedures for these hospitals.

More details on our findings are described in the balance of this memorandum.

Findings from Our Replication of the CMS Proposed Rule Analysis

We began our analyses by using both the CMS drug medians file and the OPPS Limited Dataset (LDS) to replicate the CMS calculation of the ASP + 6% payment rate that is proposed for non-pass-through separately paid drugs and biologicals, along with various other relevant pieces of data.

Highlights of these findings include:

- Replicating CMS' proposed rule methodology without policy variation, we found that there were 234 HCPCS coded separately paid drugs with ASPs, ranging from ASP -100% to ASP + 1192%, and 284 HCPCS coded packaged drugs with ASPs, ranging from ASP -86% to ASP + 11,435%.
- While the CMS calculation is based on drugs with HCPCS codes and ASPs, we found that significant drug and biological spending in the OPPS fell outside this definition. Specifically:
    - Spending for drugs without HCPCS codes totaled $594 million; and
    - Drugs and biologicals with HCPCS codes, but no ASPs represented $191 million in spending.
- When all drugs—separately paid, packaged, HCPCS code but no ASP, and no HCPCS code—are included in the calculation, we calculate mean costs equivalent to ASP + 40%.
- As the table below describes, changes to the amount of overhead used can have a material impact on the ASP + X% calculation.

In the four tables that follow, only HCPCS coded drugs are included. Because CMS' proposed policy would remove $150 from coded packaged drugs and $50 million from uncoded packaged

drugs, we only removed $150 million from the packaged drug category. We assumed any additional overhead reallocation would be taken from uncoded packaged drugs.

$70/DAY PACKAGING THRESHOLD					
		$70/Day Packaging Threshold	$70/Day Packaging Threshold and $200 Million	$70/Day Packaging Threshold and $225 Million	$70/Day Packaging Threshold and $300 Million
Separately paid					
	ASP +X%	**0%**	**7%**	**8%**	**10%**
	OPPS Total	$ 2,844,867,947.30	$ 3,044,867,947.30	$ 3,069,867,947.30	$ 3,144,867,947.30
	Drugs Included	234	234	234	234
Packaged					
	ASP +X%	**264%**	**171%**	**171%**	**171%**
	OPPS Total	$590,897,302.44	$440,897,302.44	$ 440,897,302.44	$440,897,302.44
	Drugs Included	284	284	284	284
Combined					
	ASP +X%	**14%**	**14%**	**14%**	**14%**
	OPPS Total	$3,435,765,249.74	$3,435,765,249.74	$ 3,435,765,249.74	$3,435,765,249.74
	Drugs Included	518	518	518	518

The Impact of the ASP Reporting Period Chosen on the CMS Calculation

We also measured the effect on the CMS calculations of changing the quarter of ASP data used and found that:

- Using ASP data from the first quarter of 2009 instead of the fourth quarter has a material impact on the ASP + X calculation.
    - Without any additional allocation of overhead spending, using the first quarter ASP data, we calculate a payment rate for separately paid drugs of ASP + 1%, as opposed to the CMS calculation of ASP + 0%.
    - Adding the $200 million overhead calculation to this calculation resulted in a payment rate of ASP + 8%.
    - Allocating $225 million would result in a payment rate of ASP + 9%.
    - Allocating $300 million in overhead would result in a rate of ASP + 11%.

This earlier quarter may match more appropriately with CMS claims data from 2009—and may be closer to the information reflected in the hospital cost reports underlying the 2009 claims data. The fourth quarter 2009 data that CMS is using would be more likely to reflect price increases that would not yet be fully incorporated up in hospital claims data or cost reports.

These findings are detailed in the table below.

JULY 2009 ASP DATA (FIRST QUARTER 2009 MANUFACTURER REPORTS)					
		$70/Day Packaging Threshold	$70/Day Packaging Threshold and $200 Million	$70/Day Packaging Threshold and $225 Million	$70/Day Packaging Threshold and $300 Million
Separately paid					
	ASP +X%	**1%**	**8%**	**9%**	**11%**
	OPPS Total	$ 2,944,784,118.42	$ 3,144,784,118.42	$ 3,169,784,118.42	$ 3,244,784,118.42
	Drugs Included	237	237	237	237
Packaged					
	ASP +X%	**242%**	**156%**	**156%**	**156%**
	OPPS Total	$ 592,882,372.26	$ 442,882,372.26	$ 442,882,372.26	$ 442,882,372.26
	Drugs Included	290	290	290	290
Combined					
	ASP +X%	**15%**	**15%**	**15%**	**15%**
	OPPS Total	$3,537,666,490.68	$3,537,666,490.68	$3,537,666,490.68	$3,537,666,490.68
	Drugs Included	527	527	527	527

The Effect of Removing Data from 340B Hospitals

Various parties have argued that hospitals eligible to receive statutorily required discounts under section 340B of the Public Health Service Act should be removed from the CMS ASP + X% calculation as 340B sales are excluded from the calculation of ASP. Using the Medicare LDS data used in the CY2011 proposed rule rate-setting, we measured the impact that 340B data have on the calculation.

We found that:

- Removing 340B hospital data from the claims used to calculate the payment rates for separately paid drugs could have a significant impact.
    - Using the CMS methodology with no overhead allocation but removing 340B data, we calculate a payment rate of ASP + 2%.
    - Adding the $200 million overhead pool to this calculation would result in a payment rate of ASP + 15%— a larger increase because $200 million is a larger percentage of the overhead pool with the 340B volume removed.[1]

These findings are summarized in the table below.

[1] We note that CMS might choose to reduce the overhead amount used if claims from 340B hospitals were removed from its calculations, since the overhead pool would be reduced by the removal of those hospitals.

340B HOSPITALS EXCLUDED					
		$70/Day Packaging Threshold	$70/Day Packaging Threshold and $200 Million	$70/Day Packaging Threshold and $225 Million	$70/Day Packaging Threshold and $300 Million
Separately paid					
	ASP +X%	**2%**	**15%**	**16%**	**21%**
	OPPS Total	$ 1,692,902,898.16	$ 1,892,902,898.16	$ 1,917,902,898.16	$ 1,992,902,898.16
	Drugs Included	234	234	234	234
Packaged					
	ASP +X%	**255%**	**112%**	**112%**	**112%**
	OPPS Total	$ 374,146,454.84	$ 224,146,454.84	$ 224,146,454.84	$ 224,146,454.84
	Drugs Included	284	284	284	284
Combined					
	ASP +X%	**18%**	**18%**	**18%**	**18%**
	OPPS Total	$2,067,049,353.00	$2,067,049,353.00	$2,067,049,353.00	$2,067,049,353.00
	Drugs Included	518	518	518	518

As shown in the table below, combining removal of 340B data with the use of first quarter 2009 ASP amounts results in payment rates ranging from ASP + 4% to ASP + 22%, depending on the choice of overhead allocation.

340B HOSPITALS EXCLUDED JULY 2009 ASP DATA (FIRST QUARTER 2009 MANUFACTURER REPORTS)					
		$70/Day Packaging Threshold	$70/Day Packaging Threshold and $200 Million	$70/Day Packaging Threshold and $225 Million	$70/Day Packaging Threshold and $300 Million
Separately paid					
	ASP +X%	**4%**	**16%**	**17%**	**22%**
	OPPS Total	$ 1,748,859,201.68	$ 1,948,859,201.68	$ 1,973,859,201.68	$ 2,048,859,201.68
	Drugs Included	237	237	237	237
Packaged					
	ASP +X%	**234%**	**101%**	**101%**	**101%**
	OPPS Total	$ 375,345,964.39	$ 225,345,964.39	$ 225,345,964.39	$ 225,345,964.39
	Drugs Included	292	292	292	292
Combined					
	ASP +X%	**18%**	**18%**	**18%**	**18%**
	OPPS Total	$ 2,124,205,166.07	$ 2,124,205,166.07	$ 2,124,205,166.07	$ 2,124,205,166.07
	Drugs Included	529	529	529	529

Methodology

To perform the initial analysis we attempted to repeat CMS' calculation of mean unit cost compared to ASP on a volume weighted basis using separately payable drugs, packaged drugs, and both separately payable and packaged drugs. We used CMS' own published mean costs and unit volumes, which are based on 2009 claims data. We initially used the April 2010 ASP file, which corresponds to manufacturer reports from the fourth quarter of 2009, and we followed CMS' methodology of excluding drugs for which no ASP information was available. We also calculated the spending on drugs without HCPCS codes and drugs with HCPCS codes and no ASPs. To do so, from the claims file, we pulled every line with a pharmacy revenue code eligible for packaging (those revenue codes dealing with pharmacy) or a HCPCS drug code. For those lines that had HCPCS codes, we followed the standard CMS data cleaning methodology,

and we excluded any lines that did not have a status indicator of N, K or G. We merged the results with the April 2010 ASP file. Then, we assigned all lines to four different categories:

1. has a packaged revenue code (From Table 3 of the proposed rule: 0250, 0251, 0252, 0254, 0255, 0257, 0258, 0259, 0630, 0631, 0632, 0633) , but not HCPCS codes;
2. has a HCPCS code, but no ASP;
3. has a HCPCS code and ASP and is separately paid (status indicators K and G); or
4. has a HCPCS code and ASP and is packaged (status indicator N).

For those categories without ASPs we assumed they had the same ASP percentage CMS calculated for packaged drugs (ASP + 251%). We summed the categories to determine the drug spending for each category.

We also modeled the impact of using a different quarter of ASP data, namely, the first quarter of 2009 manufacturer reports corresponding to the ASP payment rates in the physician office beginning July 1, 2009.

To perform the claims-based analyses, in which we examine the effects of removing 340B data, we followed the CMS methodology for determination of drug mean cost. We extracted drug and biological charge and cost data from the OPPS rate-setting file. We then followed the data cleaning procedures to trim outlier cases, and then calculated: total units, total days, and mean cost per unit. We then validated our calculations with the CMS published results to verify our methodology. From there we were able to remove the claims for 340B hospitals and re-run the analyses to demonstrate the impact of 340B hospital data on the CMS calculation.[2]

[2] The Health Resources and Services Administration (HRSA) does not release a list of 340B participating hospitals that can be linked to Medicare claims data. We approximated this list using a list of hospitals with Disproportionate Share Hospital (DSH) adjustment percentages. From that list, we used not for profit hospitals with DSH adjustment percentages meeting the 340B eligibility requirement as the best proxy for 340B participating hospitals.

Packaged Drug Analysis

Initial Research into Coding Practices among Outpatient Hospital Facilities

We calculated the costs associated with pharmacy revenue codes 025X and 0636 by hospital and overall using 2009 claims data to look at outpatient billing patterns associated with packaged drugs. We found that almost no uncoded packaged drug cost is associated with revenue code 0636, which is not surprising considering this revenue code is not a packaged revenue code. Uncoded packaged drugs are billed to revenue codes in the 025X series and represent about 14 percent of all packaged drug costs. About 91 percent of the drug cost billed to 025X is for uncoded packaged drugs. The 025X series is a packaged revenue code, and thus coding is not as important for payment purposes.

Packaged Drugs Associated with Medical versus Surgical Procedures

According to sections in the OPPS proposed rule discussing drug overhead costs, CMS believes the products that account for coded packaged drug costs are not the same as the drugs and biologicals that comprise uncoded drug volume. As a result, the agency declined to assume that uncoded and coded packaged drugs and biologicals have similar overhead proportions. In making this finding, CMS relied particularly on evidence that a majority of uncoded packaged drug costs appear on surgical claims.

In order to test this claim, we attempted to replicate the analysis CMS conducted looking at the differences between packaged drugs associated with medical versus surgical procedures. CMS determined that uncoded packaged drugs were more often associated with surgical procedures while coded packaged drugs were more often associated with medical procedures.

We found that when limited to only claims used in rate-setting, surgical procedures do indeed have a higher proportion of uncoded packaged drug costs, while medical procedures have a higher proportion of coded packaged drugs costs. However, this relationship was more dramatic in the previous years than it was in 2009 claims. See Tables 1-4. The yellow highlighted cells show the cost of uncoded packaged drugs found on surgical claims used in rate-setting as a percentage of total packaged drug costs associated with medical and surgical rate-setting claims.

Table 1. Packaged Drug Costs, 2009 Medical and Surgical Single Claims

2009	Cost		Percent	
	Medical	Surgical	Medical	Surgical
Coded Packaged Drug Cost	$ 103,325,728	$ 70,988,337	22%	15%
Uncoded Packaged Drug Cost	$ 91,803,423	$ 209,179,699	19%	44%

Table 2. Packaged Drug Costs, 2008 Medical and Surgical Single Claims

2008	Cost		Percent	
	Medical	Surgical	Medical	Surgical
Coded Packaged Drug Cost	$ 109,205,680	$ 60,535,522	23%	13%
Uncoded Packaged Drug Cost	$ 89,709,535	$ 206,208,028	19%	44%

Table 3. Packaged Drug Costs, 2007 Medical and Surgical Single Claims

2007	Cost		Percent	
	Medical	Surgical	Medical	Surgical
Coded Packaged Drug Cost	$ 64,677,589	$ 49,774,579	16%	12%
Uncoded Packaged Drug Cost	$ 89,515,118	$ 211,485,960	22%	51%

Table 4. Packaged Drug Costs, 2006 Medical and Surgical Single Claims

2006	Cost		Percent	
	Medical	Surgical	Medical	Surgical
Coded Packaged Drug Cost	$ 17,113,192	$ 41,909,268	5%	12%
Uncoded Packaged Drug Cost	$ 65,928,636	$ 215,922,324	19%	63%

The proportion of packaged drugs associated with surgical claims used in rate-setting has gone down from 76 percent in 2006 to 59 percent in 2009. The proportion of uncoded packaged drugs associated with all rate-setting claims for medical and surgical procedures has decreased from 83 percent in 2006 to 63 percent in 2009.

To determine whether the uncoded packaged drugs being used with surgical procedures were in fact similar to the mix of drugs associated with medical procedures, we identified hospital outpatient facilities determined to be "expert coders" – when coded packaged drug costs as a proportion of total packaged drug costs was greater than 85 percent. We also used two hospitals identified by one of the pharmacy stakeholders as potential targets for this analysis. In all, we used nine hospitals in this portion of the analysis. Again, coded packaged drug cost is still not evenly distributed among medical and surgical procedures. See Table 5.

Table 5. Packaged Drug Costs, 2009 Expert Coding Hospitals Only

2009	Cost		Percent	
	Medical	Surgical	Medical	Surgical
Coded Packaged Drug Cost	$ 2,673,582	$ 319,354	83%	10%
Uncoded Packaged Drug Cost	$ 75,960	$ 158,974	2%	5%
Total Packaged	$ 2,749,542	$ 478,328	85%	15%

When comparing the coded drugs associated with surgical claims and those associated with medical claims for "expert coder" hospitals, we find some overlap among the top 15 billed drugs and overall for medical versus surgical claims. Nineteen drugs appear on surgical claims but not medical, and fifty-four drugs appear on medical claims but not surgical. Please see the tab labeled *Top Drugs - Surgical vs Medical* in the Excel Workbook titled, "Packaged Drug Analysis - Surgical vs Medical Association 08202010_client" sent along with this memorandum for more details.

APC Analysis

The twenty 2011 APCs with the most packaged drug costs based on rate-setting claims only are shown in Table 6 below. The APCs with the highest packaged drug costs are cataract procedures, drug administration, lower GI endoscopy, and cardiac catheterization. Cataract procedures have a very high amount of uncoded packaged drug cost (about 90 percent). A complete list of APCs, their total packaged drug cost, and average packaged drug cost per claim is shown on the tab *APC Analysis* in the attached Excel Workbook.

Table 6. Packaged Drug Cost by 2011 Proposed APC

APC	Group_Title	SI	Payment Rate	Total Packaged Drug Costs	% Uncoded	Packaged Drug Cost per Claim*
0246	Cataract Procedures with IOL Insert	T	$1,691.57	$ 82,280,224	90%	$ 173.51
0440	Level V Drug Administration	S	$203.81	$ 59,031,294	26%	$ 106.75
0439	Level IV Drug Administration	S	$126.28	$ 42,858,907	45%	$ 42.21
0143	Lower GI Endoscopy	T	$636.29	$ 18,595,548	64%	$ 29.39
0080	Diagnostic Cardiac Catheterization	T	$2,719.58	$ 16,110,527	66%	$ 55.17
0207	Level III Nerve Injections	T	$527.05	$ 13,030,698	61%	$ 31.02
0141	Level I Upper GI Procedures	T	$606.29	$ 12,148,167	65%	$ 29.00
0131	Level II Laparoscopy	T	$3,279.42	$ 11,766,818	68%	$ 163.57
0377	Level II Cardiac Imaging	S	$768.38	$ 10,495,094	44%	$ 22.28
0436	Level I Drug Administration	S	$26.30	$ 9,339,416	38%	$ 2.92
0088	Thrombectomy	T	$2,854.35	$ 8,781,705	73%	$ 141.05
0154	Hernia/Hydrocele Procedures	T	$2,277.93	$ 7,797,303	69%	$ 117.17
0672	Level III Posterior Segment Eye Procedures	T	$2,774.88	$ 7,089,237	81%	$ 201.90
0272	Fluoroscopy	X	$85.14	$ 6,936,128	69%	$ 237.96
0162	Level III Cystourethroscopy and other Genitourinary Procedures	T	$1,803.60	$ 6,790,809	67%	$ 84.26
0279	Level II Angiography and Venography	S	$2,030.25	$ 6,203,291	68%	$ 130.77
0041	Level I Arthroscopy	T	$2,069.68	$ 6,049,862	69%	$ 106.20
0616	Level 5 Type A Emergency Visits	V	$340.57	$ 5,983,841	71%	$ 8.14
0624	Phlebotomy and Minor Vascular Access Device Procedures	X	$43.27	$ 5,419,493	37%	$ 27.18
0615	Level 4 Type A Emergency Visits	V	$229.03	$ 4,835,430	67%	$ 3.03

* Packaged drug cost per claim was calculated by dividing the total packaged drug cost by the number of single claims (natural and pseudo) for each APC reported by CMS.