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BY ELECTRONIC DELIVERY

Charlene Frizzera, Acting 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-1414-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates)

Dear Acting Administrator Frizzera:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) final rule regarding revisions to the hospital outpatient prospective payment system (OPPS) and 2010 payment rates, published in the Federal Register on July 20, 2009 (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 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

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 recognizes some of the flaws in its current rate-setting methodology for drugs and biologicals and strives to fix them in the

[1] 74 Fed. Reg. 35232 (July 20, 2009).

Proposed Rule. Specifically, CMS acknowledges that "the current method of converting billed charges to costs has the potential to 'compress' the calculated costs to some degree."[2] CMS also recognizes that it does not have average sales price (ASP) "information specifically for [drug and biological] sales to hospitals,"[3] but its calculated estimated acquisition and pharmacy overhead costs of ASP minus two percent for separately payable drugs might be too low and ASP plus 247 percent for packaged drugs might be too high.[4]

In the Proposed Rule for 2010, CMS proposes to reallocate $150 million of the pharmacy overhead cost attributed to packaged drugs to separately payable drugs to "more appropriately distribute pharmacy overhead cost among packaged and separately payable drugs and biologicals" than either paying for separately payable drugs at ASP minus two percent or implementing the stakeholder proposal.[5] As a result of this reallocation, the proposed payment rate for acquisition and pharmacy overhead costs of separately payable drugs is ASP plus four percent, the same rate in effect for 2009. CMS chose to propose this approach instead of the proposal put forward by BIO and other pharmacy stakeholders and recommended by the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel).

BIO appreciates CMS's recognition that its longstanding methodology fails to produce appropriate payment rates. Although we agree with the general approach to reallocating costs applied in the Proposed Rule, we believe that as long as CMS lacks data on hospitals' average acquisition cost, it should reimburse the acquisition cost of separately payable drugs and biologicals at ASP plus six percent, the rate applicable in physician's offices, plus make an adjustment for pharmacy services and handling. We also are concerned that CMS does not propose to implement the APC Panel's recommendation, suggested by the pharmacy stakeholders, to exclude data from hospitals that participate in the 340B program from its rate-setting calculations for drugs if the agency did not adopt the stakeholder proposal.[6]

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[2] Id. at 35327.
[3] Id.
[4] Id. at 35328.
[5] Id.
[6] Id. at 35332.

Our comments also address the proposed changes to pass-through status for implantable biologicals, the proposed changes to the eligibility period for pass-through status for drugs and biologicals, payment for blood clotting factors, payment for therapeutic radiopharmaceuticals, proposed revisions to physician supervision affecting drug administration services, and CMS's proposal not to expand the hospital-acquired condition payment policy to hospital outpatient departments (HOPDs).

In short, we recommend that CMS:

- discontinue using its flawed standard methodology to estimate the costs of separately payable drugs and biologicals and pay no less than ASP plus six percent for the acquisition cost of drugs and biologicals administered in HOPDs;
- reallocate, at a minimum, the highest amount of costs within the range the agency deemed appropriate in the Proposed Rule (specifically $198 million rather than $150 million) because CMS has not included over half the costs of packaged drugs in its analysis in the Proposed Rule;
- in any scenario, use an ASP file that is better aligned with the claims and cost report data used to estimate the ASP plus percentage for drugs;
- if CMS does not discontinue use of its standard methodology, remove data from hospitals that participate in the 340B program from its rate-setting calculations for drugs and biologicals;
- ultimately pay for the acquisition cost of separately payable drugs and biologicals at ASP plus six percent, package payment for packaged drugs at ASP plus 100 percent, calculate the pharmacy overhead pool, and then allocate the pool to reimburse for the pharmacy services of separately payable drugs and biologicals;
- make separate payment for all drugs and biologicals with Health Care Common Procedure Coding System (HCPCS) codes or alternatively, not increase the packaging threshold for these therapies;
- comply with the statute and Congressional intent by reinstating separate payment for contrast agents and diagnostic radiopharmaceuticals;

- continue to consider implantable biologicals approved under biologics license applications (BLA) for pass-through status as drugs or biologicals;
- not implement the proposed changes to the eligibility period for pass-through status for drugs and biologicals;
- reimburse blood clotting factors at least ASP plus six percent;
- implement the proposal to pay for therapeutic radiopharmaceuticals based on ASP data if submitted by the manufacturer;
- implement the proposed change to the supervision requirements to allow certain nonphysician practitioners to directly supervise hospital outpatient therapeutic services; and
- refrain from expanding its hospital-acquired conditions (HAC) payment policy until it has garnered additional experience with the payment mechanism in the inpatient setting, has resolved issues regarding causation in the outpatient setting, and has obtained comments on the proposal in its entirety.

These comments are discussed in detail below.

I. CMS should pay no less than ASP plus six percent for the acquisition cost of drugs and biologicals administered in HOPDs and reallocate a larger portion of the pharmacy overhead costs associated with packaged drugs to the separately payable drugs. [Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status]

A. Per the APC Panel's recommendation, CMS should discontinue using its current flawed methodology and pay no less than ASP plus six percent for the acquisition cost of drugs and biologicals administered in HOPDs.

For 2010, CMS proposes to continue to reimburse the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status at ASP plus four percent.[7] Although we commend CMS for proposing to reallocate some of the pharmacy overhead costs associated with packaged drugs to separately payable drugs – increasing the proposed payment rate

[7] Id.

from ASP minus two percent, as calculated using CMS's current methodology, to the proposed ASP plus four percent – we remain concerned that CMS does not have the data necessary to ensure that its proposed reimbursement rates equal hospitals' average acquisition cost. In the absence of this information, we urge CMS to pay no less than ASP plus six percent for separately payable drugs and biologicals, as Congress intended in the Social Security Act (SSA), [8] and as recommended at the most recent meeting of the APC Panel.[9]

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. Payment at ASP plus six percent is supported by our prior analysis of mean unit costs for non-340B hospitals yet is less than estimated cost for all drugs with HCPCS codes and ASP information of ASP plus 13 percent as calculated by CMS.[10] Moreover, unlike CMS's current methodology, reimbursement for acquisition cost at ASP plus six percent is consistent with the Medicare statute. The 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.[11] 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 6 percent or the rates determined under the Competitive Acquisition Program (CAP)).[12]

Since the Government Accountability Office (GAO) concluded its survey of acquisition cost in 2004, neither GAO nor CMS has conducted the subsequent periodic surveys and therefore CMS does not have the data necessary to set payment at average acquisition cost. We appreciate that these surveys are difficult to conduct and generally have supported the use of ASP plus six percent as a proxy for acquisition cost instead of asking the agency to incur the administrative and financial burden of conducting additional surveys. We continue to believe that ASP plus six percent would be a reasonable payment for acquisition cost. We

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[8] SSA § 1833(t)(14)(A)(iii)(I).
[9] APC Panel Recommendations, August 5-6, 2009, available at: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.
[10] 74 Fed. Reg. at 35327.
[11] SSA § 1833(t)(14)(A)(iii)(I).
[12] SSA § 1833(t)(14)(A)(iii)(II).

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 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.

Despite acknowledging in the Proposed Rule the impacts of charge compression, CMS continues to use its standard methodology in an attempt to determine the costs for separately payable drugs. However, because the resulting estimate is below what CMS believes is the acquisition cost for separately payable drugs, it effectively discards the results of its analysis. We recommend that CMS discontinue using its standard methodology of reducing charges to cost to estimate costs of separately payable drugs. The result of the methodology distorts and complicates CMS's proposed methodology.

For example, CMS states one of its fundamental assumptions is that acquisition cost of separately payable drugs is not less than 100 percent of ASP. Meanwhile, the standard methodology produces an estimate for the total costs of these drugs equal to 98 percent of ASP, causing CMS to essentially override the results in its proposed methodology. This inconsistency, combined with the ongoing criticisms of its standard methodology, should be enough reason for CMS to discontinue its use.

Our efforts to replicate CMS's methodology, described in the attached analysis from the Moran Company, produced estimated costs for individual separately paid drugs ranging from ASP minus seven percent to ASP plus 1643 percent, and costs for packaged drugs ranging from ASP minus 92 percent to ASP plus 6755 percent. 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 the acquisition cost of separately payable drugs and biologicals administered in HOPDs.

In addition to this legal requirement, there are other reasons why hospitals should be compensated no less than ASP plus six percent for separately payable drugs. One reason is parity between physicians' offices and HOPDs. Congress

recognized that, absent data to the contrary, it is inequitable to pay hospitals less than physicians for purchasing, handling, and preparing drugs and biologicals, and this inequity could unduly influence the site of care where these therapies are delivered. Another reason justifying at least the physician rate is that HOPDs may actually not be the highest volume provider of the most costly and complex drugs in the community, even though they may serve as a provider of last resort for some patients. For each of these reasons, and to comply with statute, CMS should reimburse separately payable drugs and biologicals at no less than ASP plus six percent.

B. CMS Should Reallocate, at a Minimum, One Half of the Pharmacy Overhead Costs (or $198 million) Associated with Packaged Drugs to the Separately Payable Drugs and Biologicals Because It Has Not Included Over Half the Costs of Packaged Drugs in Its Analysis in the Proposed Rule.

CMS proposes to reallocate $150 million of the $395 million in pharmacy overhead costs attributed to packaged drugs to separately payable drugs.[13] BIO believes that the $395 million pool is a low estimate for pharmacy overhead because it is based solely on drugs and biologicals with HCPCS codes that have ASPs. As a result, the overhead pool is inaccurate due to missing data that accounts for a significant portion of overhead costs. BIO requests that beginning in 2010, at a minimum, CMS allocate half of the $395 million overhead pool, representing the top end of CMS's range, to separately payable drugs. CMS chose the $150 million amount because it represented a "middle ground" between its current methodology and the methodology recommended by the APC Panel and the pharmacy stakeholder group.[14] This figure represents between one-third and one-half of the total overhead associated with packaged drugs and biologicals with HCPCS and ASPs, and CMS concludes that it is appropriate based on the results of analyses of two methods of allocating pharmacy overhead to drugs and biologicals by categories of overhead.

CMS's analysis, based on categories recommended by the Medicare Payment Advisory Commission (MedPAC), produced an allocation of $165

[13] 74 Fed. Reg. at 35328.
[14] Id.

million to separately payable drugs.[15] The analysis based on the pharmacy stakeholder proposal produced a reallocation of $153 million and later $157 million when CMS used revised pharmacy services assignments.[16] Under both analyses, CMS estimates that the cost of separately payable drugs, after rounding, is ASP plus four percent.[17] Unfortunately, we have not been able to replicate this analysis as the agency has not made its overhead assignments public. To the extent CMS continues to rely on this analysis for its payment methodology for drugs and biologicals in the future, we encourage the agency to release this information.

In any event, we believe that a reallocation of more than $150 million is essential to pay more appropriately for separately payable drugs and biologicals. CMS estimated the total pool of pharmacy overhead associated with packaged drugs to be $395 million. This estimate is low because it is based solely on drugs and biologicals with HCPCS codes and ASPs. It excludes a large number of drugs that do not have HCPCS codes or ASPs, but account for a significant portion of overhead costs. The attached analysis by Christopher Hogan, of Direct Research, LLC, found that packaged drugs and biologicals billed without HCPCS codes are subject to the same markup as packaged ones with HCPCS codes. Therefore, CMS reasonably could assume that these drugs and biologicals have the same ratio of estimated cost to ASP as the packaged drugs and biologicals billed without HCPCS codes and include them in its calculation of the overhead pool.[18] Our analysis, assuming the same proportion of overhead costs to total costs for drugs and biologicals not separately identified on the claims or without ASPs, estimates the additional overhead at $557 million. In order to appropriately allocate overhead costs for all OPPS drugs and biologicals, CMS's methodology must account for these additional packaged costs. At a minimum, for 2010, CMS should allocate the high end of the parameters it identified in the Proposed Rule (one-half of the $395 million) to account for them.

Our discussions with hospitals along with a review of claims data indicates that CMS does not have a true estimation of the total costs associated with all drugs with HCPCS codes due to the wide variation in provider billing practices. We found that 41 percent of hospitals have no cost data in CMS's claims data file

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[15] Id. at 35331.
[16] Id.
[17] Id.
[18] See Memorandum from Christopher Hogan, Direct Research, LLC, to Steve Phillips, Johnson and Johnson, Aug. 27, 2009, Attachment C.

where line items were reported with revenue code 250, the standard revenue code used by many hospitals to report packaged drugs, and a HCPCS code. We believe this is due to the wide variation in hospital billing practices. For example, some hospitals may have reported their packaged drugs with revenue code 250 and the associated charges and units and no HCPCS codes as HCPCS codes are not required to be reported for packaged drugs. Other hospitals may have reported their packaged drugs and the associated HCPCS codes using revenue code 250, but the actual HCPCS codes may not have printed on the claim due to provider billing systems. In other cases, hospitals have indicated that they have been instructed by their Medicare contractors that they are not permitted to report HCPCS coded drugs using revenue code 250. In this instance, the hospital may remove the HCPCS codes from the claim and then resubmit it to the contractor. In all of these cases, CMS would not have the cost information associated with packaged drugs with HCPCS codes. Other hospitals have moved the reporting of their packaged drugs with HCPCS codes from revenue code 250 to revenue code 636. In these cases the HCPCS codes print on the bill, and CMS will have the cost information from all hospitals that report in this manner. CMS also has cost data for packaged drugs with HCPCS codes from hospitals that have changed their billing systems to allow HCPCS codes to print on the bill when reported with revenue code 250.

The wide variation in hospital reporting of HCPCS coded packaged drugs, permitted by CMS, results in the agency not having all of the charge data associated with HCPCS coded packaged drugs that it then uses to estimate the pharmacy handling cost pool. Hospitals are reporting their packaged drugs with HCPCS codes correctly to CMS because the agency's guidance gives hospitals flexibility to use whatever revenue codes most appropriately reflect internal accounting of revenues and expenses. Similarly, CMS has given its contractors flexibility in implementing edits and other measures that they deem appropriate, though CMS historically has indicated that contractors should not edit for HCPCS and revenue code combinations unless specified by CMS. [19]

Although CMS permits flexibility in reporting packaged services, including packaged drugs and biologicals, the agency does not account for how this flexibility leads to variation in how hospitals may be reporting their packaged

[19] See, e.g., Claims Processing Manual, ch. 17, sec. 70 ("On claims to FIs the drug is identified by the appropriate HCPCS code for the drug administered and billed under revenue code 0636 unless specific instruction states otherwise."); we understand that some contractors have instructed hospitals to report packaged drugs with revenue code 250 and no HCPCS codes.

drugs with HCPCS codes and how this leads to an underestimation of the pharmacy overhead pool. To ensure that CMS has the data it needs to calculate accurate estimates of the total acquisition and overhead costs of drugs in the future, the agency should instruct hospitals to report all HCPCS-coded drugs with revenue code 636 and explain to hospitals why following this instruction and submitting HCPCS codes for packaged drugs will help produce more accurate payment rates. This also is consistent with the National Uniform Billing Committee's (NUBC) guidance on the issue.

In the meantime, CMS should include the charges associated with packaged drugs and biologicals reported without HCPCS codes in its calculations. As shown in the table below, Christopher Hogan analyzed data from 3,476 hospitals and found only 252 hospitals where packaged drugs and biologicals identified with HCPCS codes accounted for more than 81 percent of all packaged drug charges. At the other end of the scale, packaged drugs and biologicals billed with HCPCS codes accounted for less than 10 percent of their packaged drug charges in 336 hospitals. Although the percentage of packaged drugs and biologicals identified with HCPCS codes varies by hospital, the packaged therapies' share of total non-drug charges was relatively constant across hospitals. There is a direct substitution between packaged drugs and biologicals identified with HCPCS codes and without HCPCS codes, yet total charges for packaged drugs and biologicals were a roughly constant five percent of total non-drug hospital charges. Therefore, even though some hospitals report a relatively low percentage of their charges for packaged drugs and biologicals with HCPCS codes, CMS should be aware that a significant portion of these hospitals' charges likely were reported without HCPCS codes and should be included in the calculation of CMS's total pharmacy overhead pool. As discussed above, CMS reasonably can assume that these drugs and biologicals are subject to the same markup as packaged drugs and biologicals reported with HCPCS codes.

Fraction of Packaged Drug Charges That is for Identified Drugs, Versus Packaged Drug Charges as a Percent of OPPS Charges, by Hospital[20]				
		Packaged Drug Charges as % of All Non-Drug Charges by Hospital		
Packaged identified drug charges as % of all packaged drug charges	**Hospitals**	**Total, All Packaged Drugs**	**Packaged Unidentified Drugs**	**Packaged Identified Drugs**
Total	3,476	5.0%	2.4%	2.6%
0%	113	4.0%	4.0%	0.0%
1-10%	223	5.0%	4.8%	0.3%
11-20%	248	5.8%	4.9%	0.9%
21-30%	348	5.3%	3.9%	1.4%
31-40%	415	5.5%	3.6%	1.9%
41-50%	501	5.1%	2.8%	2.3%
51-60%	543	5.1%	2.3%	2.8%
61-70%	468	4.8%	1.7%	3.1%
71-80%	365	4.6%	1.2%	3.4%
81-90%	163	5.0%	0.8%	4.2%
91-100%	89	4.4%	0.3%	4.2%
Source: Analysis of OPPS 2010 Proposed Rule file. Hospitals with less than $1000 in drug charges were excluded.				

CMS's estimated $395 million pool of overhead costs is only 12.7 percent of its total estimated costs of drugs and biologicals. Surveys indicate that pharmacy overhead should be at least 25 percent of total pharmacy costs, so CMS's estimate is only about half of what it should be. Because the total overhead pool likely is larger than what CMS estimated, a larger portion of it – if not all of it - should be allocated to separately payable drugs.

C. In Any Scenario, 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 2010

[20] See Memorandum from Christopher Hogan, Direct Research, LLC, to Steve Phillips, Johnson and Johnson, Aug. 27, 2009, Attachment C.

Our analysis also found that CMS underestimates the costs of separately payable drugs because it compares costs derived from 2008 claims data and 2007 cost reports to ASP data from the fourth quarter of 2008 (the April 2009 ASP file). This comparison fails to recognize increases in drug costs from the time hospitals purchased drugs in 2007 and 2008 to the time the drug sales were reported to CMS in early 2009. When we compared CMS's estimated costs from the claims data to ASP data from the first quarter of 2008 (the July 2008 ASP file), we calculated a payment rate for separately payable drugs of ASP plus zero percent, as opposed to the CMS calculation of ASP minus two percent, before correcting for charge compression. We ask CMS to 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 2010. CMS should continue to update payment rates quarterly using the current ASP file.

D. If CMS Does Not Discontinue Its Standard Methodology, It Should Remove Data from Hospitals that Participate in the 340B Program from Rate-Setting Calculations for Drugs and Biologicals

CMS decided not to implement the APC Panel's recommendation to exclude data from hospitals that participate in the 340B program from its rate-setting calculations if it did not implement the stakeholder proposal. As we explained in our comments on prior years' 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. 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, under CMS's standard methodology, 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 340B hospitals are excluded from the data, we calculate that the mean unit cost would rise from ASP minus two percent to ASP plus three percent.

Including sales at 340B prices significantly reduces CMS's estimated mean unit cost of separately payable drugs. The distorting effects of including data from 340B hospitals would be even greater if pending legislative proposals to allow significantly more hospitals to participate in the 340B program are implemented. 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.

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. As detailed in the attachment, the 340B program aims to improve access to care for poor and uninsured patients by allowing certain hospitals and other entities that serve those patients to purchase drugs at deep discounts. Congress intended for the savings from these discounts "to enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[21] The Health Resources and Services Administration (HRSA) that administers the 340B program has said that participating entities may use the savings achieved from participation in the program to "invest in more services for patients."[22]

Establishing a separate, lower reimbursement rate for these hospitals would be contrary to Congressional intent for participating hospitals to use savings under the 340B program to support their mission. These hospitals play a critical role in ensuring that all Americans have access to health care. Medicare should not impede these hospitals' efforts by reducing their reimbursement. Instead, CMS should focus its efforts on correcting the significant flaws in its rate-setting methodology for drugs and biologicals once and for all by paying no less than ASP plus six percent for therapies administered in the OPPS and increasing the allocation of overhead costs from packaged to separately payable drugs to ensure that pharmacy service costs are reimbursed adequately.

E. Ultimately, CMS Should Pay for the Acquisition Cost of Separately Payable Drugs and Biologicals at ASP Plus Six Percent, Package Payment for Packaged Drugs at ASP Plus 100 Percent, Calculate the

[21] H.R. Rep. No. 102-384, pt. 2, at 12 (1992)
[22] Elizabeth M. Duke, HRSA Administrator, Remarks to the Primary Health Care All-Grantee Meeting, June 22, 2005, http://newsroom.hrsa.gov/speeches/2005/BPHC-June.htm.

Pharmacy Overhead Pool, and Then Allocate the Pool to Reimburse for the Pharmacy Services of Separately Payable Drugs and Biologicals.

As illustrated by the issues discussed above and the attached analysis from the Moran Company, CMS's methodology is largely arbitrary and is highly sensitive to small changes in the agency's assumptions. CMS has many options to improve its proposed methodology to meet our shared goal of creating an accurate payment methodology that is administratively simple for CMS and for hospitals; however, the agency has asked us to offer specific recommendations. To this end, we propose the following approach to payment for drugs, biologicals, and pharmacy overhead costs:

1. Reimburse the acquisition cost of separately payable drugs at no less than ASP plus six percent. As discussed above, this rate is consistent with both the APC Panel's recommendations and the statute's requirements for reimbursement in the absence of acquisition cost survey data.

2. Package payment for drugs that are not separately payable at ASP plus 100 percent. CMS assumes that "packaged drugs and biologicals, as a group, typically have an aggregate absolute pharmacy overhead cost (direct and indirect) that exceeds the acquisition cost of the packaged drugs and biologicals."[23] We generally believe that ASP plus 100 percent would be sufficient reimbursement, on average, for the acquisition and overhead cost of these usually low-cost drugs given the agency's proposed packaging threshold of $65.

3. Calculate a pool of pharmacy overhead using CMS's proposed methodology, including the costs of drugs and biologicals that are not separately identified on the claims and making the other changes we recommended above.

4. Allocate the pharmacy overhead pool to separately paid drugs as reimbursement for pharmacy services and handling. CMS can allocate this pool in whatever administratively simple manner it chooses, such as adding it as a percentage of ASP, making a flat payment per separately payable drug administered, or making payment based on the three tiers of pharmacy services as recommended previously in the stakeholder proposal. We are not suggesting that

[23] 74 Fed. Reg. at 35329.

the pharmacy services payment be unbundled from the payment for the drug or biological administered. Rather, the pharmacy services payment would be packaged and automatically would be made with the drug or biological payment.

We believe this approach would be more stable, predictable, and accurate than CMS's current or proposed methods and also would be administratively simple for CMS and hospitals. We urge CMS to implement it.

F. CMS Should Make Separate Payment for All Drugs and Biologicals with HCPCS Codes or Alternatively, Not Increase the Packaging Threshold for These Therapies.

For 2010, CMS proposes to increase packaging threshold to $65 and to continue to package payment for all diagnostic radiopharmaceuticals and contrast agents.[24] CMS also proposes to subject 5-HT3 anti-emetics to this threshold, reversing a policy that has been in place since 2005.[25] BIO believes that CMS should make 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" [26] rather than serving themselves as the therapeutic modality. 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.[27]

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

[24] Id. at 35319.
[25] Id. at 35320-21.
[26] Id. at 35324.
[27] SSA § 1833(t)(14)(B).

services.[28] 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[29] 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.

Although 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. Moreover, we believe that all 5-HT3 anti-emetics should be separately payable in order to preserve beneficiary access to them.

II. Biologicals Approved under BLAs Should Continue to be Eligible for Pass-Through Drug Status [Pass-Through Payments for Implantable Biologicals]

CMS proposes that implantable biologicals no longer would be eligible to submit drug and biological pass-through applications and to receive pass-through payment at ASP plus six percent.[30] Some implantable biologicals meet the SSA's definition of "biological"[31] even though they are approved by the Food and Drug Administration (FDA) as devices. CMS believes these products "function as implantable devices," thus should be subject to the same reimbursement policies as

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[28] Id.
[29] Id. § 1833(t)(16)(B).
[30] 74 Fed. Reg. at 35313.
[31] 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.")

devices.[32] 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."[33] 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."[34] To implement this policy, CMS proposes to revise the pass-through regulations at 42 C.F.R. §§ 419.64 to exclude implantable biologicals from consideration for drug and biological pass-through payment in the future.

We believe 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 specified covered outpatient drugs that previously had pass-through status, it intended for biologicals approved under BLAs to be reimbursed under the specific statutory provisions for drugs.[35] 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 underlined language to CMS's proposed regulatory language at 42 CFR § 419.64(a)(4):

> (iii) A biological <u>approved under a biologics license application or a drug</u>.
> (iv) A biological <u>not approved under a biologics license application</u> 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.

In addition, the word "nonimplantable" should be struck from CMS's proposed language for 42 CFR § 419.64(c)(3).

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[32] 74 Fed. Reg. at 35312.
[33] <u>Id.</u> at 35313.
[34] <u>Id.</u>
[35] <u>See</u> Conference Report, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, H. Rep. No. 108-391, at 679.

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.

III. CMS Should Not Implement the Proposed Change to the Definition of the Pass-Through Eligibility Period for New Drugs and Biologicals [Definition of Pass-Through Payment Eligibility Period for New Drugs and Biologicals]

BIO is greatly concerned that CMS's proposal to revise the regulations governing the eligibility period for pass-through status for new drugs and biologicals will harm access to innovative treatments and create an unpredictable reimbursement environment for new therapies. Currently, the regulation indicates that the pass-through payment eligibility period for "new" drugs and biologicals begins on "the date that CMS makes its first pass-through payment for the drug or biological."[36] CMS believes this regulation is inconsistent with the statute that specifies that the pass-through period of two to three years for "new" drugs and biologicals begins on the first date on which payment is made under Part B for the drug or biological as an outpatient hospital service.[37] We believe the current regulation is consistent with Congressional intent to protect access to new drug and biological therapies and should not be changed.

CMS proposes to change the dates on which pass-through eligibility begins and ends. Under the proposed change to the regulations, the pass-through payment eligibility period for a drug or biological would begin on the date on which payment first is made for a drug or biological as an outpatient hospital service under Part B.[38] CMS also proposes to use the date of first sale for a drug or biological in the U.S. following FDA approval as a proxy for the date of first payment under Part B.[39] In addition, pass-through status would expire on a quarterly basis, rather than the current annual basis.[40] CMS recognizes that under the proposed policy, "the pass-through payment eligibility period may begin well before application is made for pass-through payment for the drug or nonimplantable biological and pass-through status is approved," and this change

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[36] 42 C.F.R. § 419.64(c)(2).
[37] SSA § 1833(t)(6)(C)(i)(II).
[38] 74 Fed. Reg. at 35314-15.
[39] Id. at 35315.
[40] Id. at 35316.

"could have the effect of a shorter period of pass-through payment for some drugs and biologicals than would be the case under our current policy."[41]

BIO believes that CMS's proposal is contrary to statute and Congressional intent and is deeply concerned that the proposed changes that would shorten the period of eligibility for pass-through status would also harm patient access to new therapies. CMS notes that the pass-through eligibility period and pass-through payment period currently are the same, but would be different under the Proposed Rule. The statute establishes a single "limited period of payment," not an eligibility period that is different from the payment period. In addition, the "limited period of payment" does not include the period between the date of first sale of a drug or biological and the approval of an application for pass-through payment or issuance of a code for that new drug or biological. Congress established a specific payment methodology for the initial period during which new drugs and biologicals do not yet have HCPCS codes, therefore the period of pass-through payments begins after a pass-through application is approved and a new code is issued. CMS's current regulation recognizes that the period of payment begins on "the date that CMS makes its first pass-through payment for the drug or biological."[42] The current regulation is consistent with statute, and the proposed policy should not be implemented.

BIO believes that by shortening the period of pass-through eligibility, these changes would fail to protect timely beneficiary access to new therapies. Congress implemented the pass-through provisions because it was concerned that the OPPS could deny patients access to needed care and fail to keep up with changes in technology.[43] Rather than implementing the pass-through provisions with the goal of protecting access to care, CMS assumes that beneficiaries already have access to innovative technologies even without the benefit of pass-through payments. CMS anticipates that Medicare beneficiaries are "among the first" to use these new drugs and biologicals and assumes that Medicare beneficiaries have access to these therapies soon after launch.[44] We believe these assumptions are not correct. First, some therapies are used primarily in populations not covered by Medicare, such as patients under age 65. As a result, Medicare beneficiaries are not "among the first" to use these drugs and biologicals. Second, Medicare beneficiaries do not always

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[41] Id.
[42] 42 CFR § 419.64(c)(2).
[43] Conference Report, Balanced Budget Refinement Act of 1999, H.R. Rep. No. 106-479, at 867.
[44] 74 Fed. Reg. at 35313.

have access to therapies soon after the date of first sale. There may be a delay between the date of first sale and the date the first claim for the therapy is submitted to Medicare due to disruptions in manufacturing or distribution, for example.

The date of first sale thus would not be an appropriate proxy for the date on which Medicare begins to collect data on these drugs. We urge CMS to continue to use the date on which pass-through payment is first made as the beginning date of eligibility for pass-through status and to continue to have pass-through payments expire on an annual basis.

IV. CMS Should Reimburse Blood Clotting Factors At Least ASP Plus Six Percent. [Proposed Payment for Blood Clotting Factors]

CMS proposes to continue to pay for blood clotting factors at ASP plus four percent, consistent with the proposed rates for other separately paid drugs and biologicals without pass-through status.[45] We believe this rate is inappropriate for the same reasons that it is inappropriate for other drugs and biologicals, as discussed above. Accordingly, we urge CMS to pay at least ASP plus six percent for clotting factors in order to ensure beneficiary access to them.

V. CMS Should Implement Its Proposal to Pay for Therapeutic Radiopharmaceuticals Based on ASP Data If Submitted by the Manufacturer. [Proposed Payment for Therapeutic Radiopharmaceuticals]

For 2010, CMS proposes "to allow manufacturers to submit ASP information for any separately payable radiopharmaceutical in order for therapeutic radiopharmaceuticals to be paid based on ASP."[46] CMS would not compel manufacturers to submit ASP information, and if this information is not submitted, payment instead would be based on CY 2008 mean unit cost data derived from hospital claims. BIO agrees that using ASP data provides an opportunity to improve payment accuracy for therapeutic radiopharmaceuticals. We urge CMS to finalize this proposal accordingly. However, CMS specifies that "ASP data submitted would need to be provided for a patient-specific dose, or patient-ready

[45] Id. at 35333.
[46] Id. at 35334.

form, of the therapeutic radiopharmaceutical in order to properly calculate the ASP amount for a given HCPCS code."[47] Because many therapies have unique radiolabeling and distribution processes, individual manufacturers should have the opportunity to meet with CMS to ensure compliance with ASP reporting for a patient-ready dose. BIO requests guidance from CMS, as well as open dialogue with individual manufacturers, on what is necessary on an individual manufacturer basis, to accurately report a reasonable "patient-ready ASP."

Further, BIO requests that CMS provide a transition period of at least six months in 2010, for those manufacturers unable to report on an ASP basis, using the continuation of therapeutic radiopharmaceutical reimbursement at the methodology established by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) at charges-reduced-to-cost. CMS should provide a reasonable amount of time for manufacturers to implement potentially significant changes to current business models or price reporting mechanisms. Providing an appropriate transition period will ensure that therapies are not under-reimbursed during this time and that patient access is not at risk.

VI. CMS Should Implement Its Proposal to Allow Certain Nonphysician Practitioners to Supervise Hospital Outpatient Therapeutic Services. [Physician Supervision]

CMS proposes to allow "nonphysician practitioners, specifically physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives," to "directly supervise all hospital outpatient therapeutic services that they may perform themselves in accordance with their State law and scope of practice and hospital-granted privileges, provided that they continue to meet all additional requirements, including any collaboration or supervision requirements as specified in the regulation."[48] CMS also proposes "to make clear that Medicare Part B payment may be made for hospital outpatient services and supplies furnished incident to the services of a physician, clinical psychologist, nurse practitioner, physician assistant, clinical nurse specialist, or certified nurse-midwife service."[49]

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[47] Id.
[48] Id. at 35365.
[49] Id. at 35366.

We agree that it is appropriate to make payment for services provided incident to the services of these practitioners and to allow them to supervise others, and we applaud CMS for proposing these changes. The proposed changes will help hospitals provide critical drug administration services safely and cost-effectively, particularly in rural areas and areas with physician shortages. We urge CMS to implement the proposed changes in the final rule.

VII. CMS Should Not Expand the HAC Payment Provision to Hospital Outpatient Departments at this Time. [Healthcare Associated Conditions]

For 2010, CMS does not propose to expand the principles behind the HAC payment provision to the OPPS.[50] CMS recognizes that "there are many operational challenges to such an expansion" at this time.[51] BIO agrees with this conclusion. We support CMS's efforts to encourage hospitals to improve the quality of care provided to Medicare beneficiaries, but we also believe it would be premature to implement a HAC payment mechanism in the hospital outpatient setting before the payment policy is tested in the inpatient setting. In particular, BIO is concerned that using the approach in the outpatient setting would raise serious issues because HOPDs see patients only on an occasional and limited basis. In contrast, inpatient facilities have continuous control over a patient, thus making it more likely that a hospital can employ guidelines to prevent a secondary infection or other condition from developing.

In the case of HOPDs, causation is more difficult to determine when a patient develops a secondary infection or condition. In cases where a patient acquires an infection or other condition at home or in the community, it would be unfair for the outpatient department to be penalized by receiving a lower payment. Although extending the HAC to infections in the HOPD is not appropriate, there are instances that may be appropriate for inclusion in the outpatient setting. Specifically, the "never event" related to death or serious disability due to medication errors likely could be implemented in both the inpatient and outpatient settings. We also note that CMS was directed to create an outpatient quality measure for reporting medication errors in the Tax Relief and Health Care Act of

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[50] Id. at 35407.
[51] Id.

2006.[52] As the HAC payment policy is improved in terms of present on arrival coding and other refinements, it may be possible for CMS to develop an approach that would be fair to employ in the outpatient setting. Until such time, CMS should refrain from considering expansion of the HAC policy to HOPDs.

VIII. Conclusion

BIO thanks CMS for this opportunity to comment on the OPPS Proposed Rule for 2010. 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. The agency has made great strides in recognizing the flaws in its current rate-setting methodology for separately payable drugs and biologicals and proposing some corrections for them. We urge CMS to continue to refine its methodology as we have suggested in order to ensure the accuracy and stability that will preserve beneficiary access to these important therapies in the future. Namely, we believe it is critical for CMS to pay at least ASP plus six percent for the acquisition cost for separately payable drugs and biologicals and to make a reasonable adjustment for pharmacy services and handling.

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
Director, Reimbursement &
Economic Policy

Attachments

[52] SSA § 1833(t)(17)(C).

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 (e.g. Migrant Health Centers, Healthy Schools/Healthy Communities, Health Care for the Homeless)
- Certain Community Health Centers
- Certain Federal grantees (e.g. black lung clinics, comprehensive hemophilia diagnostic treatment centers)
- Ryan White CARE Assist entities
- State-operated AIDS Drug Assistance Programs (ADAPs)
- Urban Indian Health Centers
- Family Planning Clinics

There are currently 14,078 registered providers with access to the 340B discount and more than 800 hospitals receiving 340B pricing accounting for 35% of the drug cost volume in the Medicare hospital outpatient (OPPS) setting. HHS projects that the number of registered providers will grow to 15,747 within two years (under existing law).

- Manufacturers are required to participate in the 340B program in order to have their drugs/biologicals covered by Medicaid.
- The 340B price is a deeply discounted rate. It is calculated as the Average Manufacturer Price (AMP) minus the Medicaid rebate.
- 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 340 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 26, 2009)

TO: Pharmacy Stakeholders

FROM: Gregory Watson, Clare Mamerow and Kevin Kirby

SUBJECT: Results of Various Analyses of Drug and Biological Reimbursement in the CMS Proposed Rule for the Calendar Year 2010 Outpatient Prospective Payment System (OPPS)

In order to better inform the comments of a number of pharmacy stakeholders on the Centers for Medicare and Medicaid Services' (CMS) proposed rule "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 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 replicated CMS' pharmacy stakeholder analysis and modeled a number of potential variations. To do so, we assigned weights to each drug, based on the complexity of pharmacy services needed to prepare the drug for patients and determined the ASP plus percentages for separately paid and packaged drugs.

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 2008 manufacturer ASP reports would provide payments ranging from ASP -2% (no overhead allocation) to ASP + 14% (allocation of the entire $395 million in the CMS overhead pool).

- We also found that the choice of the first 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.
- Finally, using our replication of the CMS analysis that attempted to determine a pharmacy overhead allocation based on the pharmacy stakeholder weights, we modeled the impact of various policy alternatives on ASP based payment rates and found at least three scenarios that resulted in payment rates for separately paid drugs greater than ASP + 6%.
- 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.

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 + 4% 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 222 HCPCS separately paid drugs with ASPs, ranging from ASP - 7% to ASP + 1643%, and 278 HCPCS coded packaged drugs with ASPs, ranging from ASP -92% to ASP + 6755%.
- 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 $576 million; and
    - Drugs and biologicals with HCPCS codes, but no ASPs represented $207 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 + 31%.
- As the table below describes, changes to the amount of overhead used can have a material impact on the ASP + X% calculation.

$65/DAY PACKAGING THRESHOLD				
	$65/Day Packaging Threshold	$65/Day Packaging Threshold and $150 Million	$65/Day Packaging Threshold and $197.5 Million	$65/Day Packaging Threshold and $395 Million
Separately paid				
ASP +X%	**-2%**	**4%**	**6%**	**14%**
OPPS Total	$ 2,499,119,135.06	$ 2,649,119,135.06	$ 2,696,619,135.06	$ 2,894,119,135.06
Drugs Included	222	222	222	222
Packaged				
ASP +X%	**252%**	**156%**	**126%**	**0%**
OPPS Total	$552,520,474.83	$402,520,474.83	$ 355,020,474.83	$157,520,474.83
Drugs Included	278	278	278	278
Combined				
ASP +X%	**13%**	**13%**	**13%**	**13%**
OPPS Total	$3,051,639,609.89	$3,051,639,609.89	$3,051,639,609.89	$3,051,639,609.89
Drugs Included	500	500	500	500

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 2008 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 + 0, as opposed to the CMS calculation of ASP - 2%.
  - Adding the $150 million overhead calculation to this calculation resulted in a payment rate of ASP + 5%.
  - Allocation $197.5 million (one half of $395 million) would result in a payment rate of ASP + 7%.
  - Allocating the full $395 million overhead pool would result in a rate of ASP + 15%.

This earlier quarter may match more appropriately with CMS claims data from 2008—and may be closer to the information reflected in the hospital cost reports underlying the 2008 claims data. The fourth quarter 2008 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 2008 ASP DATA (FIRST QUARTER 2008 MANUFACTURER REPORTS)				
	$65/Day Packaging Threshold	$65/Day Packaging Threshold and $150 Million	$65/Day Packaging Threshold and $197.5 Million	$65/Day Packaging Threshold and $395 Million
Separately paid				
ASP +X%	**0%**	**5%**	**7%**	**15%**
OPPS Total	$ 2,536,588,290.22	$ 2,686,588,290.22	$ 2,734,088,290.22	$ 2,931,588,290.22
Drugs Included	240	240	240	240
Packaged				
ASP +X%	**257%**	**160%**	**130%**	**2%**
OPPS Total	$ 552,625,928.71	$ 402,625,928.71	$ 355,125,928.71	$ 157,625,928.71
Drugs Included	285	285	285	285
Combined				
ASP +X%	**14%**	**14%**	**14%**	**14%**
OPPS Total	$3,089,214,218.93	$3,089,214,218.93	$3,089,214,218.93	$3,089,214,218.93
Drugs Included	525	525	525	525

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 CY2010 proposed rule rate-setting, we measured the impact that 340B data have on the calculation.[53]

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 + 3%.
  - Adding the $150 million overhead pool to this calculation would result in a payment rate of ASP + 12%.[54]

These findings are summarized in the table below.

340B HOSPITALS EXCLUDED

	$65/Day Packaging Threshold	$65/Day Packaging Threshold and $150 Million	$65/Day Packaging Threshold and $197.5 Million
Separately paid			
ASP +X%	**3%**	**12%**	**15%**
OPPS Total	$ 1,572,451,124.90	$ 1,722,451,124.90	$ 1,769,951,124.90
Drugs Included	221	221	221
Packaged			
ASP +X%	**246%**	**104%**	**59%**
OPPS Total	$ 366,128,082.23	$ 216,128,082.23	$ 168,628,082.23
Drugs Included	278	278	278
Combined			
ASP +X%	**18%**	**18%**	**18%**
OPPS Total	$1,938,579,207.12	$1,938,579,207.12	$1,938,579,207.12
Drugs Included	499	499	499

Note: 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. We have removed the higher overhead allocations that would exceed the packaged drug payment pool entirely with the 340B hospitals excluded.

As shown in the table below, combining removal of 340B data with the use of first quarter 2008 ASP amounts results in payment rates ranging from ASP + 4% to ASP + 17%, depending on the choice of overhead allocation. We have removed the higher overhead allocations that would exceed the packaged drug payment pool entirely with the 340B hospitals excluded.

[53] We performed the 340B analysis twice. In the body of this memo we provide the results of the first 340B analysis, using a list of hospitals designed to approximate 340B participation that could be linked to Medicare claims. We found comparable results when we performed the analysis again with a list of 340B participating hospitals given to us by a member of the pharmacy stakeholder group. Please see Addendum A for those results.

[54] 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 JULY 2008 ASP DATA (FIRST QUARTER 2008 MANUFACTURER REPORTS)			
	$65/Day Packaging Threshold	$65/Day Packaging Threshold and $150 Million	$65/Day Packaging Threshold and $197.5 Million
Separately paid			
ASP +X%	**4%**	**13%**	**17%**
OPPS Total	$ 1,598,909,443.79	$ 1,748,909,443.79	$ 1,796,409,443.79
Drugs Included	240	240	240
Packaged			
ASP +X%	**253%**	**109%**	**63%**
OPPS Total	$ 366,207,578.10	$ 216,207,578.10	$ 168,707,578.10
Drugs Included	285	285	285
Combined			
ASP +X%	**19%**	**19%**	**19%**
OPPS Total	$1,965,117,021.89	$1,965,117,021.89	$1,965,117,021.89
Drugs Included	525	525	525
Note: 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. We have removed the higher overhead allocations that would exceed the packaged drug payment pool entirely with the 340B hospitals excluded.			

Variations on the CMS Analysis Using the Pharmacy Stakeholder Weights

The Pharmacy Stakeholders' Group asked us to replicate the CMS analysis allocating pharmacy overhead based on the weights supplied by that group, along with other potential variations on that analysis. As described in more detail in the methodology section that follows, we used the overhead assignments provided to us by the pharmacy stakeholders, since the assignments used by CMS are not public.[55]

Replicating CMS' analysis of the pharmacy stakeholders' drug overhead analysis as closely as possible, we also calculated ASP + 4%. We also modeled three different overhead methodologies and found that they all produced higher ASP plus percentages for separately paid drugs, while maintaining an overall ASP + 13% for separately paid and packaged drugs combined.

In the first alternative model, we first assigned all drugs a payment amount of ASP + 6%, summed those amounts and subtracted that sum from the actual OPPS payment amount to determine the overhead pool. We then used that pool to assign additional overhead payments to drugs based on whether their complexity rating was low, medium or high. At the end, we then calculated the effective ASP plus percentage based on the inclusion of the pharmacy overhead payments.

In the second alternative model, we first assigned all separately paid drugs at ASP + 6% and all packaged drugs at ASP + 100%, determined the overhead pool, and allocated the pool based on each drugs' complexity. Finally, we calculated the effective ASP plus percentage based on the inclusion of the pharmacy overhead payments.

[55] We note that CMS staff were helpful in clarifying language in the proposed rule's preamble that had hindered our analysis in this area.

In the third alternative model, we determined the ASP + 6% for separately paid drugs and ASP + 100% for packaged drugs, determined the pool and allocated the pool only to separately paid drugs, and then computed the effective payment.

We would note that a variety of other values would be possible, depending on the overhead pool and allocation methodology chosen. Results of our analyses are in the table below.

OVERHEAD ANALYSES				
	Replication of CMS' Pharmacy Stakeholder Overhead Analysis	Using ASP+6% to Determine Pool, then Assign Overhead	Separately Paid at ASP+6%, Packaged at ASP+100%, then Assign Overhead	Separately paid at ASP+6%, then Assign Overhead. Packaged drugs limited to ASP+100%
Separately paid				
ASP +X%	**4%**	**8%**	**7%**	**8%**
Packaged				
ASP +X%	**153%**	**91%**	**120%**	**100%**
Combined				
ASP +X%	**13%**	**13%**	**13%**	**13%**

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 2008 claims data. We initially used the April 2009 ASP file, which corresponds to manufacturer reports from the fourth quarter of 2008, 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 but 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 2009 ASP file. Then, we assigned all lines to four different categories:

1. has a packaged revenue code (From Table 4 of the 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 that we calculated for packaged drugs based on our replication using CMS claims data (ASP + 251%). While this differs slightly from the CMS calculation of ASP + 247, we believe it is more appropriate to use our calculation to maintain the internal consistency of our analyses. 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 2008 manufacturer reports corresponding to the ASP payment rates in the physician office beginning July 1, 2008.

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.[56]

To replicate CMS' pharmacy stakeholder overhead analysis, we used pharmacy complexity weights provided to us by the pharmacy stakeholder group, since the CMS list is not public. Although the pharmacy stakeholder group provided us with different complexity ratings for packaged drugs, we assigned all packaged drugs to the low category in order to match CMS' results. We rolled up each drug to the days level. We summed up all the drug weights and divided that number into $345 million,[57] CMS' stated overhead pool. This resulted in a factor of $10.90. We multiplied that factor by the weights provided by CMS – 1 for low complexity drugs, 2.67 for medium complexity drugs and 5.5 for high complexity drugs, resulting in overhead payments of $10.90 for low, $29.10 for medium and $59.95 for high complexity drugs. We multiplied the payment amounts by the days available to determine the ASP cost plus overhead amount. Then we divided this amount by the ASP amount to calculate the ASP plus percentage.

Results

More detailed results of some of our analyses are presented in the tables that follow.

[56] 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.

[57] This is the pool remaining CMS subtracted $50 million from the initial $395 million pool to ensure that separately paid drugs started at a payment rate no less than ASP (ASP + 0) instead of ASP -2.

$65/DAY PACKAGING THRESHOLD

	$65/Day Packaging Threshold	$65/Day Packaging Threshold and $150 Million	$65/Day Packaging Threshold and $172.5 Million	$65/Day Packaging Threshold and $197.5 Million	$65/Day Packaging Threshold and $345 Million	$65/Day Packaging Threshold and $395 Million
Separately paid						
ASP +X%	**-2%**	**4%**	**5%**	**6%**	**12%**	**14%**
OPPS Total	$ 2,499,119,135.06	$ 2,649,119,135.06	$ 2,671,619,135.06	$ 2,696,619,135.06	$ 2,844,119,135.06	$ 2,894,119,135.06
Drugs Included	222	222	222	222	222	222
Packaged						
ASP +X%	**252%**	**156%**	**142%**	**126%**	**32%**	**0%**
OPPS Total	$552,520,474.83	$402,520,474.83	$ 380,020,474.83	$ 355,020,474.83	$ 207,520,474.83	$157,520,474.83
Drugs Included	278	278	278	278	278	278
Combined						
ASP +X%	**13%**	**13%**	**13%**	**13%**	**13%**	**13%**
OPPS Total	$3,051,639,609.89	$3,051,639,609.89	$3,051,639,609.89	$3,051,639,609.89	$3,051,639,609.89	$3,051,639,609.89
Drugs Included	500	500	500	500	500	500

JULY 2008 ASP DATA (FIRST QUARTER 2008 MANUFACTURER REPORTS)

	$65/Day Packaging Threshold	$65/Day Packaging Threshold and $150 Million	$65/Day Packaging Threshold and $172.5 Million	$65/Day Packaging Threshold and $197.5 Million	$65/Day Packaging Threshold and $345 Million	$65/Day Packaging Threshold and $395 Million
Separately paid						
ASP +X%	**0%**	**5%**	**6%**	**7%**	**13%**	**15%**
OPPS Total	$ 2,536,588,290.22	$ 2,686,588,290.22	$ 2,709,088,290.22	$ 2,734,088,290.22	$ 2,881,588,290.22	$ 2,931,588,290.22
Drugs Included	240	240	240	240	240	240
Packaged						
ASP +X%	**257%**	**160%**	**146%**	**130%**	**34%**	**2%**
OPPS Total	$ 552,625,928.71	$ 402,625,928.71	$ 380,125,928.71	$ 355,125,928.71	$ 207,625,928.71	$ 157,625,928.71
Drugs Included	285	285	285	285	285	285
Combined						
ASP +X%	**14%**	**14%**	**14%**	**14%**	**14%**	**14%**
OPPS Total	$3,089,214,218.93	$3,089,214,218.93	$3,089,214,218.93	$3,089,214,218.93	$3,089,214,218.93	$3,089,214,218.93
Drugs Included	525	525	525	525	525	525

340B HOSPITALS EXCLUDED

	$65/Day Packaging Threshold	$65/Day Packaging Threshold and $150 Million	$65/Day Packaging Threshold and $172.5 Million	$65/Day Packaging Threshold and $197.5 Million
Separately paid				
ASP +X%	**3%**	**12%**	**14%**	**15%**
OPPS Total	$ 1,572,451,124.90	$ 1,722,451,124.90	$ 1,744,951,124.90	$ 1,769,951,124.90
Drugs Included	221	221	221	221
Packaged				
ASP +X%	**246%**	**104%**	**83%**	**59%**
OPPS Total	$ 366,128,082.23	$ 216,128,082.23	$ 193,628,082.23	$ 168,628,082.23
Drugs Included	278	278	278	278
Combined				
ASP +X%	**18%**	**18%**	**18%**	**18%**
OPPS Total	$1,938,579,207.12	$1,938,579,207.12	$1,938,579,207.12	$1,938,579,207.12
Drugs Included	499	499	499	499

Note: 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. We have removed the higher overhead allocations that would exceed the packaged drug payment pool entirely with the 340B hospitals excluded.

340B HOSPITALS EXCLUDED JULY 2008 ASP DATA (FIRST QUARTER 2008 MANUFACTURER REPORTS)

	$65/Day Packaging Threshold	$65/Day Packaging Threshold and $150 Million	$65/Day Packaging Threshold and $172.5 Million	$65/Day Packaging Threshold and $197.5 Million
Separately paid				
ASP +X%	**4%**	**13%**	**15%**	**17%**
OPPS Total	$ 1,598,909,443.79	$ 1,748,909,443.79	$ 1,771,409,443.79	$ 1,796,409,443.79
Drugs Included	240	240	240	240
Packaged				
ASP +X%	**253%**	**109%**	**87%**	**63%**
OPPS Total	$ 366,207,578.10	$ 216,207,578.10	$ 193,707,578.10	$ 168,707,578.10
Drugs Included	285	285	285	285
Combined				
ASP +X%	**19%**	**19%**	**19%**	**19%**
OPPS Total	$1,965,117,021.89	$1,965,117,021.89	$1,965,117,021.89	$1,965,117,021.89
Drugs Included	525	525	525	525

Note: 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. We have removed the higher overhead allocations that would exceed the packaged drug payment pool entirely with the 340B hospitals excluded.

ADDENDUM A

A member of the pharmacy stakeholder group requested that we rerun our analysis of the effect of removing 340B hospitals from the ASP calculation using an alternative list of 340B providers. To conduct this analysis, we used a list of 340B providers given to us by the member as opposed to the list we had assembled. We found that there is about a $60 million difference in the total drugs included, but the ASP + X% calculations for separately paid and packaged drugs were identical. There is a difference of one percentage point on the combined ASP + X calculation.

340B HOSPITALS EXCLUDED			
		TMC Proxy 340B Hospital List	Analysis Using Alternative 340B Hospital List
Separately paid			
	ASP +X%	**2.5%**	**3.3%**
	OPPS Total	$ 1,572,451,124.90	$ 1,517,752,955.73
	Drugs Included	221	221
Packaged			
	ASP +X%	**246.0%**	**245.6%**
	OPPS Total	$ 366,128,082.23	$ 360,323,115.51
	Drugs Included	278	278
Combined			
	ASP +X%	**18.2%**	**19.4%**
	OPPS Total	$1,938,579,207.12	$ 1,878,076,071.24
	Drugs Included	499	499

Attachment C

Memorandum
To: Steve Phillips, Johnson and Johnson
From: Christopher Hogan, Direct Research, LLC
Subject: Separately identified and non-identified packaged OPPS drugs.
Date: 8/27/2009

This memo briefly examines packaged drug costs in the OPPS claims. Mainly, we ask whether or not the lines with packaged-unidentified drugs (pharmacy lines with no HCPCS codes) appear similar to the packaged-identified lines (pharmacy lines with HCPCS codes).

In this memo, I show that:

1) Hospitals' markup behavior appears similar for the two sets of drug lines. In the aggregate, the share of drug charges in packaged-unidentified and packaged-identified lines have roughly the same impact on overall hospital-wide markup on drugs.
2) There is a direct substitution between packaged-identified and packaged-unidentified drugs. We categorized hospitals based on the share of packaged drug charges that was for identified drugs, and demonstrated that, on average, the packaged-identified drug charges simply substitute one-for-one with the packaged-unidentified drug charges.

Background.

The OPPS claims have three types of drug lines: lines for separately paid drugs, lines for packaged drugs where the drug is identified, and lines for packaged drugs where the drug is not identified (typically, a blank HCPCS code in a drug revenue center).

It seems plausible that the drugs that are packaged but not identified have roughly the same mix as the ones that are packaged but identified. Probably, some hospitals simply do not separately identify the drugs when packaged. Your coalition provided some evidence of this, in terms of CMS FI requirements that HCPCS be blanked for the drug revenue centers that do not require separate identification of the drugs.

Last year, when I assumed that the packaged-unidentified drugs were similar to the packaged-identified drugs I could, for what I believe is the first time by any analyst, reconcile the claims data and the cost reports for drugs. That is, the estimated total overhead cost (cost of drugs above the ASP) calculated from claims, including the packaged non-identified drugs, was similar to the estimate obtained from cost report data. This required the assumption that the identified and unidentified packaged drugs had the

same average ratio of cost to ASP. (That could be measured from the identified drugs, and was then assumed for the unidentified drugs).

This year, I hoped to do two things:

First, show that packaged-identified and packaged non-identified drug costs behave similarly with respect to ASP and markup. That is, the packaged-identified drugs have a high markup over cost, whereas hospital markup for the (typically much more expensive) separately paid drugs is a much lower percentage.

Second, show that there appears to be substitution between packaged-identified and packaged-nonidentified costs. That is, if hospitals are not reporting the packaged-identified drugs, are they in fact reporting significant cost as packaged-nonidentified drugs, and vice-versa.

1 Analysis of drug markup

1.1 Methods

The question for this analysis is whether or not the packaged-nonidentified drugs appear to have the same markup over (actual) cost as the packaged-identified drugs. If so, then we have a good case for treating these two pools of costs the same in the calculation of the overall ratio of cost to ASP.

The analysis of drug markup followed our early analysis of charge compression for implantable devices. The idea is that the total markup for all drugs in the hospital should reflect the mix of drugs between high-markup (packaged) and low-markup (separately identified) drugs. All other things equal, a high share of drug costs in separately-identified (low-markup) drugs should result in a low overall hospital markup on drugs. The question is, how does the share of costs in packaged-unidentified drugs affect hospital average drug markup? If it has the same effect as the packaged-identified drugs, that than suggests that the overall markup on the packaged-unidentified and packaged-identified drugs is similar.

To test this, we took hospital-level cost-to-charge ratios for all drugs (essentially, the pharmacy CCR from the cost report). We used regression analysis to predict this overall drug CCR, based on the hospital's share of drugs in the three categories (packaged-unidentified, packaged-identified, and separately paid). We also included the overall outpatient CCR for all items other than drugs to control for the hospital's aggregate charging policy (i.e., the average markup policy for that hospital). The result is a single OLS regression, one observation per hospital, that looked like this:

Drug CCR = A*hospital OPD overall CCR +
B*share of drugs in packaged-unidentified lines +
C*share of drugs in packaged-identified lines +
D*share of drugs in separately-paid lines.

We want to see that coefficients B and C are similar, and that they are much lower than coefficient D. Incidentally, we would also like coefficient A to be somewhere near 1.0.

1.2 Results

Tables 1 and 2 show that the two categories of packaged drugs (non-identified and identified) show similar markup behavior. For both, the regression calculates low coefficients for both (Table 1), and these translate into low estimated cost-to-charge ratios for both (Table 2). If anything, the packaged-nonidentified drugs have, on average, a slightly lower CCR than the packaged-identified drugs. The regression estimate suggests a true average CCR for packaged-nonidentified drugs of 0.17; for packaged identified drugs of 0.19; and for separately paid drugs of 0.27.

Table 1: Hospital Drug CCR as a Function of Share of Drug Charges in Packaged-Nonidentified, Packaged-Identified, and Separately Payable Drugs

Variable	Parameter	Error	T-value	Pr > |t|
OPD CCR for all non-drug items	0.491	0.015	31.99	<.0001
% of drug charges, packaged-nonidentified	0.035	0.010	3.48	0.0005
% of drug charges, packaged-identified	0.064	0.011	5.67	<.0001
% of drug charges, separately paid drugs	0.138	0.006	23.01	<.0001

Notes: Predicted variable is hospital overall drug CCR. Observations are hospitals.
Source: Analysis of OPPS 2010 Proposed Rule file.

Table 2: Predicted Average CCR, Implied Markup and Actual Markup Over ASP

	Regression-Predicted CCR	Implied Markup over fully-loaded cost	Actual Markup Over ASP
If all drugs were packaged-nonidentified	0.17	5.86	Unknown
If all drugs were packaged-identified	0.20	5.00	12.0
If all drugs were separately paid	0.27	3.65	3.6

Notes: Regression-predicted CCR is based on the regression above, using average OPD CCR for all non-drug items, then setting the % of charges to 100% for each of the drug categories separately. Implied markup over cost = 1/CCR. Markup over ASP was separately measured from claims match to ASP data.
Source: Analysis of OPPS 2010 Proposed Rule file.

These are the regression-based estimates of the markup over full-loaded cost. For two of the three categories, we can compare them directly to markup over ASP. For the high-cost separately-paid drugs, the markup over (full-loaded) cost is nearly the same as the markup over ASP. For the packaged-identified drugs, however, the markup over (fully-loaded) cost is much smaller than the markup over ASP. We can only guess why that is, but our best guess would be the presence of some true per-prescription cost that is borne by the pharmacy department. This would raise the true, fully-loaded cost of the low-cost drugs significantly (relative to ASP) but would tend to have a negligible impact on the high-cost separately paid drugs.

All things considered, the regression-based evidence suggests that hospitals' markup for the packaged-unidentified drugs is, if anything, slightly higher than that of the packaged-identified drugs. Although we cannot know the ASP for the packaged-unidentified drugs, this strongly suggests that their markup over ASP would be similar to that of the packaged-identified drugs. It would therefore be reasonable to include them in an overall drug cost calculation assuming they have the same ratio of CMS-estimated "cost" (that is, deflated charges) to ASP as the packaged-identified drugs do.

2 Evidence of substitution.

It turned out to be both surprisingly difficult and surprisingly easy to demonstrate that the packaged-unidentified drugs are direct substitutes for the packaged-identified drugs. The main problem is that there is nothing concrete to which you can tie the drug charges. How much drug spending, of what type, should I expect to see in a hospital? That was a hard question, and one that I never answered satisfactorily.

Instead, demonstrating the tradeoff within packaged drugs turned out to be simple. First, find all packaged unidentified and packaged identified drugs. Second, categorize hospitals based on the share of all packaged drugs that was identified versus not. Finally, show that "total packaged drug spending" was constant regardless of the share that was identified and not identified. In this case, we did that by tabulating total packaged drug charges as a fraction of OPPS non-drug charges, by hospital, after sorting the hospitals based on the share of packaged drug charges that were for identified drugs.

The result is Table 3. Table 3 shows that packaged drugs constitute a roughly constant share of OPPS charges, independent of whether those packaged drugs are separately identified or consist mainly of blank HCPCS codes. That demonstrates the substitution. For example, there were 223 hospitals where packaged-identified drugs accounted for just 1 to 10 percent of packaged drug charges. In those hospitals, charges for all

packaged drugs amounted to 5 percent of total OPPS non-drug charges. By contrast, there were 163 hospitals where packaged-identified drugs accounted for 81 to 90 percent of all packaged drug charges. There, total packaged drugs charges *still* amounted to 5 percent of all OPPS non-drug charges. In short, when moving from hospitals where almost all the packaged drug lines were blank, to hospitals where almost all the packaged drug lines had HCPCS codes, there was no change in packaged drug charges as a fraction of the total.

Table 3: Fraction of Packaged Drug Charges That is for Identified Drugs, Versus Packaged Drug Charges as a Percent of OPPS Charges, by Hospital

		Packaged Drug Charges as % of All Non-Drug Charges by Hospital		
Packaged identified drug charges as % of all packaged drug charges	**Hospitals**	**Total, All Packaged Drugs**	**Packaged Unidentified Drugs**	**Packaged Identified Drugs**
Total	3,476	5.0%	2.4%	2.6%
0%	113	4.0%	4.0%	0.0%
1-10%	223	5.0%	4.8%	0.3%
11-20%	248	5.8%	4.9%	0.9%
21-30%	348	5.3%	3.9%	1.4%
31-40%	415	5.5%	3.6%	1.9%
41-50%	501	5.1%	2.8%	2.3%
51-60%	543	5.1%	2.3%	2.8%
61-70%	468	4.8%	1.7%	3.1%
71-80%	365	4.6%	1.2%	3.4%
81-90%	163	5.0%	0.8%	4.2%
91-100%	89	4.4%	0.3%	4.2%

Source: Analysis of OPPS 2010 Proposed Rule file. Hospitals with less than $1000 in drug charges were excluded.