OPPS Payment Methodology and 340B Program Interactions

October 8, 2008

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Payment Accuracy in OPPS

- Hospital acquisition cost for each drug is very difficult to measure through surveys
- CMS' current estimation methodology is inaccurate because of the interaction with the 340B program, charge compression and the packaging threshold
- CMS has the ability to achieve payment accuracy with no burden to hospitals
- Simple solution is to equalize payment between the physician and HOPD settings and set payments for drug acquisition at ASP+6%, with an adjustment for pharmacy services, as directed by statute

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Public Comments on OPPS

- American Hospital Association
  - *"...ASP plus 4 percent **is inadequate to cover acquisition cost**, let alone pharmacy services and handling. A growing body of evidence shows that CMS' methodology for calculating payment for separately paid drugs is not adequately addressing problems in the claims data and is **contrary to the statute**, yet CMS proposes no immediate corrections."*
  - *"We are concerned that CMS' proposed payment rate for separately covered outpatient drugs, at average sales price (ASP) plus 4 percent, does **not adequately represent the acquisition cost** of outpatient drugs and their related overhead costs, as Congress intended. **CMS' payment methodology** has been shown in a number of recent analyses to **contain serious flaws**, which lead us to conclude that this methodology should be revised."*
- Association of Community Cancer Centers
  - *A survey of members "...indicates that this **rate is not adequate to cover drug acquisition costs,** let alone the substantial costs for pharmacy services and overhead....For each drug, 56 to 80 percent of respondents reported that their acquisition costs are equal to or greater than the proposed reimbursement amounts."*
- Premier healthcare alliance
  - *"...CMS must default to the rates permitted in the statute, which is ASP plus 6 in the absence of current survey data. We also remind CMS that claims data **do not satisfy the statutory requirement** to use survey data."*
  - *"We believe that CMS is not complying with the statutory requirement as the last GAO survey was conducted in 2004, meaning that separately payable drugs should be paid at ASP plus 6 percent of rates under the CAP....We believe there is a **fundamental flaw in CMS' calculation** of the payment for separately payable drugs under the OPPS."*

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

More Public Comments on OPPS

- American Society of Health-System Pharmacists
  - *"Reimbursement of separately-payable drugs at ASP plus four percent is **insufficient to cover pharmacy costs**, in particular the costs of managing medications."*
- Federation of American Hospitals
  - *"...lowering payment for nonpass-through drugs and biologicals under OPPS to ASP+4% further erodes and **directly contradicts CMS's stated goal** 'to get rid of inadvertent incentives that favor ones setting over another.'"*
- Association of American Medical Colleges
  - *"Given the new insights regarding the current cost methodology, it is **clear that the proposed payment for separately payable drugs is too low** and should not be implemented. While ASP plus 6 percent may not represent the full costs of these drugs, we believe it is an acceptable rate, at least for now."*
- MedPAC
  - *"There is a problem that stems from CMS's use of the same cost-to-charge ratio (CCR) to estimate the cost of all drugs furnished by a hospital. Hospitals have stated that they tend to mark-up charges for low-cost drugs by a greater proportion than they mark-up high-cost drugs. This implies that hospitals reallocate overhead costs from high-cost drugs. This also implies that the actual CCR for high-cost drugs is higher than that for low-cost drugs, creating a case of charge compression. Consequently, the costs of high-cost drugs are underestimated, including their overhead costs. Because separately paid drugs tend to fall in the high-cost category, CMS underestimates their costs, which **results in hospitals being underpaid for these drugs**."*

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

OPPS Basics

- Two types of drugs and biologicals under the OPPS:
  - "Packaged" drugs: Those that cost less than $60 per day (the "packaging threshold"). Payments for these drugs are bundled into the related procedure payment.
  - "Separately Payable" drugs: Those drugs that are not packaged. These drugs and biologicals receive a separate payment from the procedure payment. Currently, this rate is ASP+5%
- ASP+5% is designed to include **both** the acquisition cost of the drug or biological, as well as the pharmacy services and handling costs associated with that therapy.

Bio
BIOTECHNOLOGY INDUSTRY ORGANIZATION

CMS Solution for Methodology Flaws

- CMS is attempting to measure acquisition cost plus pharmacy handling costs in aggregate
- CMS proposes to divide the "Drugs Charged to Patients" cost center into two cost centers
- Proposal requires hospitals to use HCPCS codes for all drugs in the inpatient setting
- The data produced by these changes likely will not merit the investment of significant time and effort by CMS and hospitals to implement these changes
  - Changes would have no effect on drug payments for at least two years and *would do nothing to improve payment accuracy in the meantime*
  - These changes would require significant changes in hospitals' practices and would impose substantial administrative burdens
  - To collect accurate data, CMS would have to provide explicit instructions on how to comply with the changes

CMS has the power to correct payment inaccuracies in 2009 without imposing new administrative burdens on hospitals

Bio
BIOTECHNOLOGY INDUSTRY ORGANIZATION

Overview of the 340B Program

- Administered by the Health Resources and Services Administration (HRSA)
- Allows certain health care providers to obtain access to below-Medicaid-level net drug prices
- There are more than 800 hospitals (and 1600 individual sites) receiving 340B pricing which accounts for 35% of the OPPS drug cost volume
- Only applies drugs/biologicals used in the outpatient setting
- Congressional actions have expanded 340B eligibility substantially since 2005

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

340B Pricing

- The 340B price is a "ceiling price"
- 340B prices are proprietary and therefore not published publicly. On average, 340B drugs and biologicals cost 20 to 40 percent below AWP
- The 340B price is calculated by subtracting the Medicaid rebate amount from AMP
  - Rebate amount is at greater of 15.1% of AMP or AMP minus best price
  - Rebate also includes inflation penalty where prices outpace inflation
- 340B participants are subject to "double dipping," transfer and resale prohibitions
- *Congress does not treat 340B prices as commercial 'rebates'*

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

OPPS and the 340B program

- CMS calculates mean unit costs using data from all hospitals, INCLUDING utilization from the 340B program
- 340B program sales are excluded from ASP; not considered 'rebates'
- As a result, CMS underestimates the aggregate costs of drugs for most hospitals, and the ASP-based rate that CMS produces by comparing aggregate costs to ASP is too low
- Inappropriate to blend prices: Apples and Oranges
- 340B program intended to help serve patients, not be punitive to ineligible hospitals

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Results of 340B Analysis

- Using 2007 hospital claims, 340B hospitals:
  - Share of drug costs increased to 35% from 34%
  - Drug costs averaged 8% to 9% below other hospitals' costs
- 340B discounts reduce CMS's findings of OPPS drug costs, on average, by 3.6%
- 340B hospitals identified in the CMS data file by cross-referencing the HRSA database
- When the 340B hospitals are excluded from CMS's analysis, the mean unit cost rises to ASP + 7.6% from ASP + 4%

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

340B Impact Analysis

Markup of Cost over ASP (the X in Cost = ASP +X%), by Hospital 340B status			
	All Hospitals	**Non-340B**	**340B**
Mathematically correct: Using CCR across all drugs	12.5%	16.0%	7.40%
CMS Methodology: Using CCR on separately-paid only	4.0%	7.6%	-1.10%
340B impact on average cost	**-3.6%**		
Note: 2009 File Analysis (2007 claims)			

Setting reimbursement for separately paid drugs and biologicals at ASP+6% in CY2009 is below estimated costs of 340B-participating hospitals

Bio
BIOTECHNOLOGY INDUSTRY ORGANIZATION

Acquisition Cost: BIO Concerns with Methodology

- Statutory language and Congressional intent
- Unrealistic to survey hospitals for acquisition cost
- Inclusion of 340B hospitals when calculating estimated charges
- Currently does not compensate for charge compression
- Lack of an appropriate adjustment for pharmacy services and handling
- CMS has a policy for packaging drugs into APCs. CMS does not have a policy for allocating drug costs between packaged and separately paid drugs

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Statutory Requirements

- By statute (SSA § 1833(t)(14)(A)), payment for SCODs without pass through status shall be equal to:
  - "the average acquisition cost for the drug for that year" as determined by GAO or CMS surveys of hospital acquisition cost; or
  - if hospital acquisition cost data are not available, the rates applicable in physicians' offices – ASP + 6% or the rates set under the Competitive Acquisition Program (CAP).
- CMS is authorized to adjust payments for these drugs to pay for overhead and pharmacy service and handling costs. (SSA § 1833(t)(14)(E))
- Congress enacted these requirements because it found that CMS' method of estimating costs from charges did not produce appropriate rates for drugs.
- Congress required the survey and allowed CMS to adjust OPPS rates for drugs because it recognized that hospitals' drug acquisition costs and pharmacy services and overhead could be greater than ASP + 6%.

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

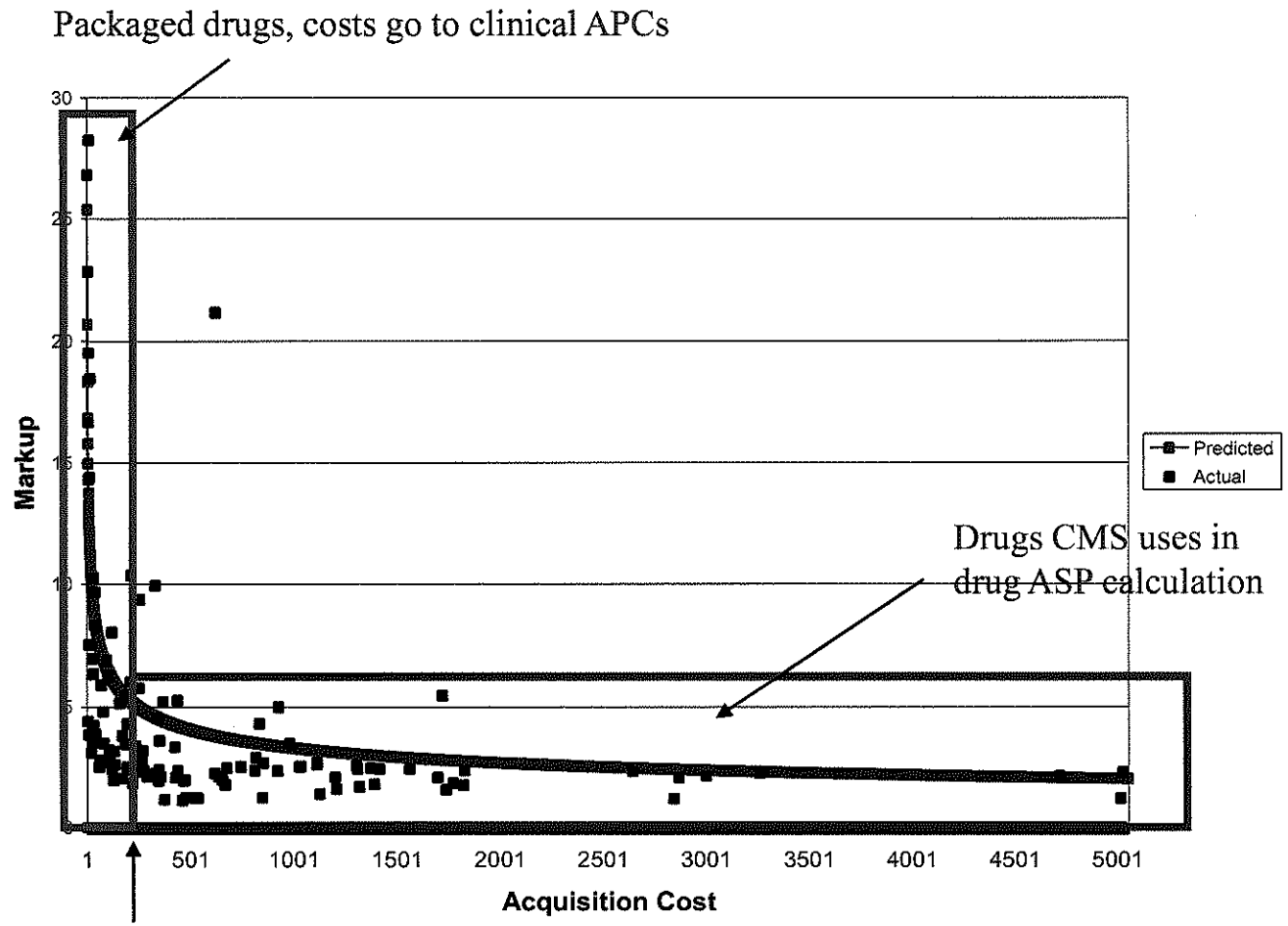
Statutory Compliance

- Neither the GAO nor CMS have conducted surveys of hospital acquisition cost since 2004
- Experience from survey in 2004 demonstrates that it is likely unrealistic to perform annual surveys of acquisition costs
- Although CMS claims that its methodology is the "best currently available proxy for average hospital acquisition cost and associated pharmacy overhead costs," several analyses show that CMS' methodology produces rates that do not represent hospital acquisition cost and pharmacy overhead
- The methodology is not a survey; it is an inaccurate extrapolation from claims data

Therefore payment for drug acquisition should be equal to that available in the physician office

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Charge compression: Pharmacy services are not evenly allocated



BIO BIOTECHNOLOGY INDUSTRY ORGANIZATION

Updated Pharmacy Overhead Analysis

- Updated analysis again shows disproportionate amount of pharmacy services and handling allocated to packaged drugs
  - Packaged Drugs: ASP – 85% to ASP + 8869%. Avg: ASP+315.46%
  - Separately Paid: ASP -97% to ASP + 2077%. Avg: ASP+4.49%
  - Combined: Average is 13.02%

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Updated Packaging Threshold Analysis

- Hospitals clearly do not have a negative acquisition cost, much less if adjusted for pharmacy services.
- At what point is the threshold correct?

Packaging Threshold in relation to ASP markup

Packaging Threshold	ASP + %, 2007 analysis	ASP + % Using 4Q2007 ASP	ASP + % Using 1Q2008 ASP
$60	1.3	4.5	4.5
$100	-1.3	2.0	2.1
$150	-1.5	1.9	1.9
$200	-1.4	1.9	2.2
$300	-3.4	0.1	0.3
$500	-3.8	-3.6	-11.1
$1,000	-6.8	-3.9	-3.3

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Data Summary

- CMS has a policy for packaging drugs into APCs
- CMS does not have a policy for allocating pharmacy handling costs between packaged and separately paid drugs
- The current allocation of costs is whatever happens when hospital markups interact with the packaging threshold
- At high thresholds, CMS methods clearly underpay separately paid drugs
- No obvious nonzero threshold at which there is no longer underpayment of separately paid drugs
- Since CMS continues to package drugs, it needs an explicit policy to accurately account for pharmacy costs across drugs

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Broad Support for CMS Action

- Seven hospital associations are uniformly supportive of parity with physician offices at ASP+6%
- Inclusion of 340B data in estimated costs artificially depresses the ASP equivalent value, and is not in line with the Congressionally mandated definition of ASP that excludes sales under the 340B program
- Reducing hospital charges to cost using a single CCR for all drugs is not an accurate measure of average acquisition cost per drug, per year
- CMS has the ability to improve payment accuracy currently, without any added burden to hospitals
- Statute provides for acquisition cost payment at ASP+6% with adjustment for pharmacy services

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Questions?

Laurel Todd
Director, Reimbursement & Economic Policy
BIO
ltodd@bio.org
(202) 962-9220

BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION