Plasma Protein Therapeutics Association

August 31, 2010
Reference No.: FASC010028

Donald Berwick, M.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1504-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-1504-P (Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Proposed Changes to the Ambulatory Surgical Payment System and CY 2011 Payment Rates; Proposed Changes to Payments to Hospitals for Certain Inpatient Hospital Services and for Graduate Medical Education Costs; and Proposed Changes to Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations)

Dear Administrator Berwick:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed rule detailing proposed payment policies in the Hospital Outpatient Prospective Payment System ("OPPS") for Calendar Year ("CY") 2011 ("Proposed Rule").[1] PPTA represents human plasma collection centers, the manufacturers of lifesaving therapies derived from this human plasma, and some of the manufacturers that produce blood clotting factors using recombinant DNA technology. The therapies manufactured from human plasma by our members include albumin, alpha$_1$-protenaise inhibitor, also known as alpha$_1$-antitrypsin, blood clotting factors, and immune globulin. Collectively, these therapies – both plasma-derived and recombinant – are known as "plasma protein therapies." With the exception of albumin, plasma protein therapies are used to treat debilitating diseases and chronic medical conditions that affect small patient populations.

Our comments on the Proposed Rule are intended to ensure that all Medicare beneficiaries have full access to the complete range of lifesaving, Food and Drug Administration ("FDA") approved plasma protein therapies in the hospital outpatient

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

147 Old Solomons Island Road · Suite 100 · Annapolis, MD 21401 USA
tel: 202.789.3100 · 410.263.8296 · fax: 410.263.2298 · e-mail: ppta@pptaglobal.org · www.pptaglobal.org
PPTA Offices in Washington · Annapolis · Brussels · Tokyo

department setting. The agency's proposal to continue reimbursing hospitals for the "furnishing fee" for blood clotting factors facilitates patient access to these products and thus PPTA recommends that proposal be finalized. Likewise, in order to ensure continued access to separately payable, nonpass-through drugs and biologicals, which includes many plasma protein therapies, throughout 2011 in the hospital outpatient setting, PPTA urges CMS to pay for these products at least at average sales price ("ASP") plus 6 percent as proposed, which would put the payment rates for such products on par with the rates paid for pass-through drugs and biologicals in the hospital outpatient setting and all drugs and biologicals in the physician office setting. PPTA notes the agency's statement that that a certain methodology for determining payments for separately billable, nonpass-through drugs and biologicals has led to the ASP plus 6 percent proposal, but that subsequent data may lead to a different figure for the final rule under this methodology. For reasons discussed below, even if the additional data were to suggest a lower level than ASP plus 6 percent, there are sufficient flaws in the methodology that justify the payment level being at least at ASP plus 6 percent.

DISCUSSION

I. PPTA RECOMMENDS THAT CMS FINALIZE ITS DECISION TO MAINTAIN THE FURNISHING FEE FOR BLOOD CLOTTING FACTORS UNDER OPPS

In 2003, Congress amended the Medicare statute to establish a "furnishing fee" for blood clotting factors provided in the physician office setting beginning January 1, 2005.[2] Pursuant to statute, this fee is updated annually according to inflation for medical care.[3] The fee for CY 2010 is $0.170 per unit.[4]

Beginning in 2006, CMS determined that similar resources were required to furnish blood clotting factors "across all types of service settings."[5] As such, the agency concluded that, moving forward, "it is appropriate to adopt a methodology for paying for clotting factors under the OPPS that is consistent with the methodology applied in the physician office setting and the inpatient hospital setting."[6]

The agency has continued to pay the furnishing fee to hospital outpatient departments since 2006 and it proposes to do so again for CY 2011.[7] PPTA agrees that the agency should continue to pay the furnishing fee to hospital outpatient departments. Indeed, we believe this furnishing fee has been important in facilitating patient access to blood clotting factors in the hospital outpatient setting over the past

[2] Social Security Act ("SSA") § 1842(o)(5).
[3] SSA, § 1842(o)(5)(C).
[4] 75 Fed. Reg. at 46280.
[5] 70 Fed. Reg. 68516, 68661 (Nov. 10, 2005).
[6] *Id*.
[7] 75 Fed. Reg. at 46280.

few years. Thus, PPTA appreciates CMS' inclusion of the furnishing fee under OPPS to date and we urge CMS to finalize its proposal to continue to pay the furnishing fee for blood clotting factors administered in a hospital outpatient department in CY 2011.

II. CMS MUST NOT SET THE PAYMENT LEVEL FOR SEPARATELY PAYABLE, NONPASS-THROUGH DRUGS AND BIOLOGICALS AT ANY LESS THAN ASP PLUS 6 PERCENT.

A. Payment at ASP Plus 6 Percent Ensures Patient Access to Products Such as Plasma Protein Therapies

For CY 2011[8] CMS proposes to pay for the acquisition and pharmacy overhead costs of separately payable non-pass-through drugs and biologicals, which include most plasma protein therapies, at ASP plus 6 percent, PPTA supports the proposed payment level for CY 2011 and believes by setting payment rates at no less than ASP plus 6 percent, CMS will help ensure at this time that hospital outpatient departments remain a viable option for beneficiaries to receive therapies like alpha$_1$-antitrypsin, blood clotting factors, and intravenous immune globulin (IVIG).

Adequate Medicare reimbursement is imperative for the preservation of patient access to plasma protein therapies in the hospital outpatient setting. Both the U.S. Department of Health and Human Services ("HHS")[9] and the Immune Deficiency Foundation ("IDF")[10] issued reports in 2007 that concluded insufficient reimbursement was a leading factor in the difficulties patients faced in accessing IVIG. At that time, reimbursement differences resulted in patient migration from the physician office to the hospital outpatient department.[11] We believed then and continue to believe that it is imperative that Medicare beneficiaries be able to obtain IVIG (and other plasma protein) therapies best suited for their individual needs in the most appropriate site of service, and thus hospital outpatient departments must remain a viable option for beneficiaries

---

[8] 75 Fed. Reg. at 46276.

[9] *See* ASPE Report, *supra* note 3 at 4-22 (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites); *see* OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERVS., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007) [hereinafter "OIG Report"], at 15 (concluding that a significant percentage of sales of IVIG to hospitals and physicians were at prices at or above the Medicare payment rate for the third quarter of 2006).

[10] *See* IMMUNE DEFICIENCY FOUNDATION, ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMAGLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 17 (2006) (revealing that a significant majority of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

[11] *See, e.g.*, Ricardo Alonso-Zaldivar, *Crucial But Costly Treatment Is Drying Up With Funding: Thousands Of Elderly Patients Who Need Intravenous Antibodies Are Hurt By Medicare Cutbacks - More Pain Could Be On The Way,* L.A. TIMES, February 28, 2006, at A8 (illustrating the challenges, including shifts in sites of service, patients must overcome to receive IVIG therapies because of the Medicare reimbursement cuts).

to receive IVIG. Thus, we applaud the proposal to pay hospital outpatient departments at ASP plus 6 percent, just as these products are reimbursed in physicians' offices, yet we remain concerned that finalizing a payment level lower than ASP plus 6 percent would cause reimbursement to impede patient access to plasma protein therapies. Just as CMS has correctly decided to pay the same furnishing fee for blood clotting factors in physician offices and hospital outpatient departments to avoid a financial advantage for one setting over another, so too should CMS set payments at no less than ASP plus 6 percent in hospital outpatient departments. By matching payment levels in both settings, the choice of setting would be driven by clinical, not financial considerations, as it should be.

According to the Proposed Rule, CMS would use the same methodology that it used in setting the current rates for separately payable, nonpass-through drugs and biologicals. Specifically, for CY 2010, the agency applied its standard drug payment methodology to these products to determine an ASP equivalent (ASP minus 2 percent) and redistributed $200 million in cost from packaged drugs and biologicals for a payment rate of ASP plus 4 percent.[12] CMS proposes to use the same methodology for determining payment rates for these products for CY 2011 and again would redistribute $200 million in packaged drug costs. However, the application of the standard drug payment methodology to CY 2009 claims data for separately payable, nonpass-through drugs and biologicals produces a higher ASP equivalent (ASP plus 0 percent) and thus a higher proposed rate, ASP plus 6 percent, for CY 2011 than is in place for CY 2010. In discussing this proposal, CMS notes that it will reassess the applicable ASP equivalent based on the additional CY 2009 claims that become available and that, based on past history, that could result in a decrease in the ASP equivalent and the pertinent payment rate for CY 2011.[13] In PPTA's view, payment at any level less than ASP plus 6 percent for CY 2011 may impede patient access to important products, such as plasma protein therapies, and be based on a flawed methodology and would be arbitrary and capricious.

B. The Methodology CMS Utilizes in Proposing Payments at ASP Plus X Percent is Flawed

For reasons discussed above, there are strong policy reasons for finalizing payment for separately payable, nonpass-through drugs and biologicals of at least ASP plus 6 percent for CY 2011. However, PPTA also believes that there are flaws in the CMS methodology that lead to the under-compensation of separately payable, nonpass-through drugs and biologicals. Addressing these flaws would result in more accurate payment rates.

[12] 75 Fed. Reg. at 46274.
[13] 75 Fed. Reg. at 46275-46276.

CMS has been using hospital claims data to set the payment level for separately payable drugs and biologicals in the OPPS since January 1, 2008. PPTA believes that determining OPPS payment rates based on these data is inappropriate because of flaws in the data, including one resulting from the impact that charge compression has on such data.

Charge compression is "the practice of applying a lower charge markup to higher-cost services and a higher charge markup to lower-cost services."[14] For drugs and biologicals, charge compression essentially undervalues high cost products and overvalues low cost products. This is especially problematic for separately payable drugs and biologicals, including all plasma protein therapies, because of their relatively high costs and lower pharmacy overhead charge by the hospital. The agency's own contractor, RTI International, confirmed what commenters have long told CMS about hospital charging practices:

> RTI determined that hospitals billing a greater percent of drug charges under revenue code 0636 (Drugs requiring detail coding) out of all revenue codes related to drugs had a significantly higher CCR for cost center 5600 (Drugs Charged to Patients). "These findings are consistent with the a priori expectation that providers tend to use lower markup rates on these relatively expensive items, as compared with the other items in their CCR group." [15]

In its final report, RTI stated that the impact of charge compression could be addressed by using regression-based cost-to-charge ratios, which would result in costs being roughly 17% higher.[16] Thus, CMS' reliance on data on drugs and biologicals that are biased because of charge compression causes the median costs of these products to be significantly understated. While the agency has acknowledged "that the established method of converting billed charges to costs has the potential to 'compress' the calculated costs to some degree,"[17] it makes no effort in its methodology to address the flaw caused by charge compression.

Moreover, CMS's policy of using hospitals claims data in setting OPPS payment rates for drugs and biologicals is flawed because of its inclusion of drugs and biologicals sold as part of the 340B Drug Pricing Program. This program requires a manufacturer to provide significant discounts on its covered outpatient drugs to certain federally funded grantees and other safety net health providers.[18]

---

[14] 73 Fed. Reg. 41416, 41429 (Jul. 18, 2008).
[15] 73 Fed. Reg. at 41490.
[16] RTI Final Report at p. 91, available at http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf.
[17] 75 Fed. Reg. at 46275.
[18] 42 U.S.C. § 256b (2007).

The mandatory price concessions to 340B covered entities, such as disproportionate share hospitals, can be large enough to inappropriately distort data. As a result, the sales to 340B covered entities are excluded from numerous drug pricing calculations made by CMS, such as the AMP calculation,[19] the BP calculation,[20] and the ASP calculation.[21] Likewise, when the Government Accountability Office ("GAO") conducted a study of drug purchase prices in hospital outpatient departments, it also excluded drugs purchased under the 340B program.[22] Thus, Congress, GAO, and the agency itself in other contexts, have clearly recognized that including prices to 340B entities would distort data inappropriately.

Yet, within OPPS, the agency continues to assert the conclusion that inclusion of data from 340B hospitals is warranted. The agency's explanation is that it is concerned about removing data from 340B hospitals while paying such hospitals at the same amount as non-340B hospitals.[23] In essence, the agency's position is that it is acceptable to utilize information from a minority of OPPS hospitals that will distort the data used to set the payment levels for all other OPPS hospitals, which represent a significant majority of the OPPS hospitals. The agency fails to explain why information from a limited number of hospitals should adversely affect a majority of the hospitals, particularly when in all other contexts; CMS recognizes the unrepresentative nature of the sales to 340B entities and excludes them from important payment related calculations.

There should be no mistake about the impact of the continued inclusion of sales to 340B hospitals in the OPPS ratesetting. An April 2008 study of 2006 hospital claims data by Chris Hogan of Direct Research revealed that the inclusion of 340B hospitals reduces the estimated mean unit cost of separately covered outpatient drugs to ASP plus 3.4 percent.[24] In July 2008, Hogan updated his study with analysis of 2007 hospital claims data, which revealed that number increased to ASP plus 4 percent. Hogan's analysis concludes that if CMS were to exclude 340B hospitals from its claims data analysis, the estimated mean unit cost of separately payable outpatient drugs

---

[19] 42 C.F.R. § 447.504(h)(1).
[20] SSA § 1927(c)(1)(C)(i)(I).
[21] SSA § 1847A(c)(2)(A) (2008) (exempting sales that are exempt from the calculation of BP, which statutorily excludes drugs sold at or below the 340B ceiling price under SSA § 1927(c)(1)(C)(i)(I)); 42 C.F.R. § 414.804(a)(4) (2007). *See also* MICHAEL O. LEAVITT, SECRETARY,HHS, REPORT ON SALES OF DRUGS AND BIOLOGICALS TO LARGE VOLUME PURCHASERS 3 (2006), *available at* http://www.cms.hhs.gov/reports/downloads/LVP_RTC_2_09_06.pdf (last visited August 1, 2008).
[22] *See* Letter from A. Bruce Steinwald, Dir., Health Care, Government Accountability Office ["GAO"] to Michael O. Leavitt, Secretary, HHS 8 (June 30, 2005) (demonstrating that GAO believes that including purchases at or below the 340B Drug Pricing Program ceiling price would provide an inaccurate average purchase price for a specified covered outpatient drug).
[23] 75 Fed. Reg. at 46279.
[24] *See* Memorandum from Chris Hogan, Direct Research, LL to Interested Parties 2 (April 15, 2008) [hereinafter "Hogan April Memo"] (Attachment A).

would more appropriately be ASP plus 7.6 percent based on the 2007 claims data,[25] up from ASP plus 6.9 percent based on 2006 claims data.[26] Accordingly, the inclusion of the 340B hospitals' claims artificially lowers the payment level that CMS generates under its methodology. PPTA urges CMS to correct this flaw in its ASP calculation.

Individually, the failure to address charge compression and the improper inclusion of 340B hospital claims in the OPPS data set represent significant flaws in the data CMS has used to propose ASP plus 4 percent as the 2010 payment level for separately payable drugs and biologicals. Collectively, these flaws convincingly demonstrate that the CMS methodology underlying the proposal is too flawed to utilize.

C. The Methodology CMS Utilizes is Arbitrary

PPTA urges CMS to move to the well-established ASP plus 6 percent payment level in OPPS because the methodology that CMS has been using appears arbitrary and goal-oriented rather than driven by a consistent mechanism. The arbitrary nature of the proposed methodology is evident in a number of places in the Proposed Rule:

- The agency indicates that its methodology employs the "standard drug payment methodology" by which it means using charges from hospital claims for drugs and adjusting them to costs to develop cost data.[27] This is the very same drug payment methodology that CMS used to set OPPS rates for CY 2003 and that Congress summarily rejected later that year through legislation mandating different ratesetting mechanisms under OPPS for drugs and biologicals in new SSA § 1833(t)(14). The reliance on this congressionally rejected mechanism as a source of appropriate data for determining rates for drugs and biologicals without explanation represents arbitrary agency action.
- As the agency discusses moving dollars between acquisition cost and pharmacy overhead, it recognizes that it has "no way of assessing whether this current distribution of overhead costs to packaged drugs and biologicals is appropriate."[28] Despite this lack of information, the agency makes this part of its ratesetting methodology.
- In determining that the agency would redistribute $150 million from the pharmacy overhead cost of code packaged drugs and biologicals, the agency arrived at that figure by computing one-third and one-half of the total pharmacy overhead cost and picking a number in the middle. The selection of this figure is plainly arbitrary.

---

[25] *See* Memorandum from Chris Hogan, Direct Research, LLC to Interested Parties 2 (July 27, 2008) [hereinafter "Hogan July Memo"] (Attachment B), at 2.
[26] *See* Hogan April Memo, at 2.
[27] 75 Fed. Reg. at 46275.
[28] 75 Fed. Reg. at 46274.

In PPTA's view, particularly as to plasma protein therapies, CMS should set payments rates to hospitals for non-pass through separately paid drugs and biologicals at a rate of at least ASP plus 6 percent for CY 2011 to ensure patient access to these products. Such a policy would set the rates based on a known methodology that is stable over time, with rules that are known to all interested entities. The agency's choice to use an alternative methodology in OPPS over the past few years has led to the use of flawed, arbitrary, and ever-changing mechanisms that fail to promote stability within OPPS. That needs to change and at the very least the use of ASP plus 6 percent as the payment level for all separately payable, nonpass-through drugs and biologicals provides a rational and stable mechanism that CMS should utilize in CY 2011.

III. CMS SHOULD ENSURE THAT ALL PASS-THROUGH DRUGS AND BIOLOGICALS FOR CY 2011 ARE INCLUDED IN ADDENDUM B

In its efforts to ensure that patients have continued access to plasma protein therapies, PPTA closely monitors the treatment of its member products in OPPS. Our review of the Proposed Rule identified what appears to be an inadvertent oversight regarding a number of products, one of which is a plasma protein therapy. We ask the agency to correct this error in the final rule to avoid any access problems related to these products in the hospital outpatient setting. In Table 21 of the Proposed Rule, CMS identifies 31 drugs and biologicals that it proposes will have pass-through status in 2011.[29] However, Addendum B in the Proposed Rule includes only 24 of these 31 pass-through drugs and biologicals. [30]

PPTA believes that the agency has correctly included 24 of the products in Addendum B and that the omission of the other 7 products is a simple oversight. We ask that the agency correct this oversight in the final rule because the absence of these products from Addendum B could cause hospitals or Medicare contractors to believe that the products are not reimbursed under OPPS, which clearly would not be the case if they were pass-through drugs and biologicals.

CONCLUSION

PPTA appreciates the opportunity to comment on the Proposed Rule. Again, we are especially grateful for your proposal to continue the blood clotting factor furnishing fee in the OPPS for CY 2011 and urge the agency to finalize it with the pertinent update for CY 2011. In addition, for the reasons discussed, we urge CMS to finalize the payment level for separately payable, non-pass-through drugs at no less than ASP plus 6 percent for CY 2011. Finally, PPTA asks that CMS ensure that all pass-through drugs

[29] 75 Fed. Reg. at 46260.
[30] The codes for the products in Table 21 that are not listed in Addendum B are: C9264, C9265, C9266, C9267, C9268, C9367, and Q2025.

and biologicals be included in Addendum B. Please contact either Jon McKnight or Jay Greissing at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer
Senior Vice President, PPTA North America

Memorandum

To: **Interested parties**
From: **Christopher Hogan, Direct Research, LLC**
Subject: **Update of 4/15/2008 memo on 340B hospitals and Medicare OPPS mean drug costs.**
Date: **7/27/2008**

This analysis uses the OPPS 2009 Proposed Rule file to estimate the impact of the Section 340B drug price discounts. It is an update of a prior analysis using last year's file. Results using the most recent file (2007 claims) are essentially identical to results from last year's file.

- The 340B hospitals' share of drug cost increased from 34 percent to 35 percent.
- The 340B hospitals' drug costs averaged 8 to 9 percent below other hospitals' costs.
- The 340B discounts reduce OPPS drug costs, on average, by about 3.5 percentage points (prior analysis) or 3.6 percentage points (current analysis).

Summary of Background and Methods

- The Section 340B program is a federally-administered program that allows certain health care providers to obtain access to Medicaid-level drug discounts.
- To estimate the effect of these discounts, I extracted a list of the current 340B hospitals from the DHHS HRSA website, http://opanet.hrsa.gov/opa/CE/CEExtract.aspx. Most hospitals were readily identified based on the CMS hospital ID embedded within HRSA's identifier. Others were matched to the CMS provider-of-services listing to obtain the hospital identifier necessary for use in analyzing the claims data. I identified a total of 802 Section 340B hospitals. These hospitals tended to be large, urban public hospitals.
- I processed the 2009 Proposed Rule file using CMS's methods to calculate mean cost per drug unit for each OPPS-paid drug. I calculated these separately for the 340B and non-340B hospitals. These mean unit costs were then used in the calculation of the markup of cost over ASP, that is, the X in the equation Cost = ASP + X%, again using the same methods as CMS.
- My overall estimate of ASP + X from the claims is slightly different from the CMS 2008 OPPS Final Rule calculation or 2009 Proposed Rule calculation. I re-based mine to match the CMS calculation when I included all hospitals in the calculation.

Summary of Prior and Current Results

The 340B share of all drug costs rose slightly, from 34 percent to 35 percent of OPPS file drug costs (Table 1).

Table 1: Cost Share and Average Cost Index, OPPS Drugs, by Hospital 340B Status

	All	Non-340B	340B
2008 File Analysis (2006 claims)			
Total cost ($billions)	$ 2.8	$ 1.8	$ 0.9
Percent of total cost	100%	66%	34%
2009 File Analysis (2007 claims)			
Total cost ($billions)	$ 3.1	$ 2.0	$ 1.1
Percent of total cost	100%	65%	35%

Source: Analysis of OPPS 2008 proposed rule file (CY 2006 claims) and OPPS 2009 Proposed Rule File (2007 claims)

The overall impact of 340B discounts on OPPS average drug costs increased from a 3.5 percentage point reduction to a 3.6 percentage point reduction (Table 2). That is the difference in costs that occurs when the 340B hospitals are excluded from the calculation of average costs. On this table, the first column replicates CMS's results, showing that cost is ASP plus 3.4 percent (last year) or ASP plus 4 percent (this year), for separately paid drugs. The second and third columns show the impact of separating the 340B hospitals from others. The difference between those two columns shows the net 340B discount. It appears to average between 8 and 9 percentage points. That is true whether the analysis looks at all drugs or only at the separately-paid drugs.

Table 2: Markup of Cost Over ASP (the X in Cost = ASP + X%), by Hospital 340B Status			
	All hospitals	**non-340B**	**340B**
2008 File Analysis (2006 claims)			
All Identified Drugs	13.0%	16.1%	8.8%
Separately-Paid Drugs Only	3.4%	6.9%	-1.7%
Memo: 340B impact on average cost	**-3.5%**		
2009 File Analysis (2007 claims)			
All Identified Drugs	12.5%	16.0%	7.4%
Separately-Paid Drugs Only	4.0%	7.6%	-1.1%
Memo: 340B impact on average cost	**-3.6%**		
Source: Analysis of OPPS 2008 proposed rule file (2006 claims) and CMS 2008 Final Rule drug medians, and October 2007 ASP files (prior year analysis); and OPPS 2009 Proposed rule, CMS 2009 proposed rule drug medians, and April 2008 ASP file (current year analysis).			

As was the case last year, the apparent drug discounts were far from uniform. The ratio of 340B to non-340B average cost varied across drugs. The table above captures only the weighted average effect of the discounts.

ATTACHMENT B

Memorandum

To: Interested parties
From: Christopher Hogan, Direct Research, LLC
Subject: Effect of 340B hospitals on Medicare OPPS mean drug costs.
Date: 4/15/2008

This brief memo summarizes an analysis of OPPS drug costs compared to Average Sales Price (ASP), including and excluding hospitals participating in the Section 340B drug discount program.

BACKGROUND

A good plain-language description of the Section 340B program may be found at this URL: http://pssc.aphanet.org/pdfs/340b_handbook.pdf. In a nutshell, 340B is a federally-administered program that allows certain health care providers to obtain access to Medicaid-level drug discounts.

This memo shows the effect of the 340B drug discounts on the average cost (charge times cost-to-charge ratio) for drugs billed under the Medicare OPPS.

METHODS

- A list of current 340B hospitals was extracted from the HRSA website: http://opanet.hrsa.gov/opa/CE/CEExtract.aspx
- There are more then 2000 lines in the listing, but many are multiple entities within a hospital (e.g., both a hospital OPD and a hospital-based home health agency).
- For about three-quarters of the hospitals, the 340B identification number is just the CMS hospital provider number plus a few additional characters. These were identified by extracting the provider number and verifying it by match to the CMS provider-of-services file.
- The remaining hospitals were matched to the CMS provider-of-services file by name, address, and ZIP. This gave a clear match for all but a handful (roughly 20) entries on the file.
- In total, 802 340B hospitals were identified by Medicare provider number.
- These provider numbers were used to flag the 340B hospitals on the 2008 OPPS proposed rule file (2006 claims).
- Drug lines on the 2008 OPPS proposed rule file (2006 claims) were extracted, trimmed, and averaged to yield average (mean) cost per unit, following the CMS methodology.
- The mean costs and units were calculated for all hospitals, then separately for the 340B and non-340B hospitals.
- These mean unit costs were then used in the calculation of the markup of cost over ASP, that is, the X in the equation Cost = ASP + X%, again using the same methods as CMS.
- Because this is based on the Proposed Rule file, my calculation of ASP + X from the claims was slightly different from the CMS 2008 OPPS Final Rule calculation. I re-

based mine to match the CMS calculation when I included all hospitals in the calculation.

RESULTS

I identified a total of 802 Section 340B hospitals. These hospitals tended to be large, urban public hospitals. All together, the Section 340B hospitals accounted for almost exactly one-third of all billed drugs (by cost) in the OPPS file (Table 1).

Table 1: Cost Share and Average Cost Index, OPPS Drugs, by Hospital 340B Status			
	All	**Non-340B**	**340B**
Total cost ($billions)	$ 2.8	$ 1.8	$ 0.9
Percent of total cost	100%	66%	34%
Source: Analysis of OPPS 2008 proposed rule file (CY 2006 claims)			

Inclusion of the 340B hospitals reduces the estimated markup of drug cost over ASP (Table 2). The first column replicated CMS's results, showing that cost is ASP plus 3.4 percent, on average, for separately paid drugs, for all hospitals. The second and third columns show the impact of separating the 340B hospitals from others. Excluding the 340B hospitals, the cost of the separately-paid drugs was ASP plus 6.9 percent. For the 340B hospitals alone, the cost of the separately-paid drugs was ASP minus 1.7 percent. Similar differences were found when all identified drugs (separately-paid and packaged) were included in the analysis.

Table 2: Markup of Cost Over ASP (the X in Cost = ASP + X%), by Hospital 340B Status			
	All hospitals	**non-340B**	**340B**
All Identified Drugs	13.0%	16.1%	8.8%
Separately-Paid Drugs Only	3.4%	6.9%	-1.7%
Source: Analysis of OPPS 2008 proposed rule file (2006 claims) and CMS 2008 Final Rule drug medians, and October 2007 ASP files.			

It is worth noting that the apparent drug discounts were far from uniform. The ratio of 340B to non-340B average cost varied across drugs. The table above captures only the weighted average effect of the discounts.

CONCLUSION

Section 340B uses the power of Federal law to grant certain providers access to Medicaid-like drug discounts. This is thought to serve a public purpose, as these discounts are restricted to hospitals serving a large volume of poor and uninsured patients.

The 340B discounts affect drug payments under the Medicare OPPS. The 340B providers appear to have drug costs that average about 8 percent below the costs of non-340B hospitals. Because the 340B hospitals account for about a third of OPPS drug costs, this reduces the average cost for all hospitals to roughly 3 to 3.5 percent below the cost for the non-340B hospitals.

This raises a potentially difficult policy issue for OPPS payment. The (indirect) Federal subsidy to the 340B hospitals, in the form of legally-mandated drug price reductions, results in payment below cost for the remaining unsubsidized (non-340B) hospitals. And, correspondingly, payment above cost for the 340B hospitals.

When the 340B program was passed, it was almost certainly not the intent of the Congress to inflict financial harm on the non-340B hospitals. Yet that seems to be a clear side-effect of the interaction of the 340B drug discounts with the OPPS rate calculation process. The 340B discounts reduce payments to non-340B hospitals, as CMS uses the average of all hospitals when calculating OPPS drug payments.