

August 31, 2009
Reference No.: FASC09044

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; Proposed Changes to the Ambulatory Surgical Payment System and CY 2010 Payment Rates)

Dear Administrator Frizzera:

The Alpha-1 Association, Alpha-1 Foundation, Guillain-Barre Syndrome (GBS)/Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Foundation International, Hemophilia Federation of America and Immune Deficiency Foundation as ‘stakeholders’ within the community of patients who rely upon lifesaving plasma derived and recombinant analog therapies and ASD Healthcare and the Plasma Protein Therapeutics Association (“PPTA”) appreciate 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”) 2010 (“Proposed Rule”).¹ We are deeply committed to the health and safety of the patients we serve, and these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration (“FDA”) approved, plasma-based and their recombinant analog therapies (“plasma protein therapies”) in the hospital outpatient department setting.

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 department setting. Certainly, the agency’s proposals to continue reimbursing hospitals for the “furnishing fee” for blood clotting factors facilitates patient access to these products and WE recommends that proposal be finalized. While we acknowledge the agency’s proposal to continue to pay for separately billable, non-pass-through drugs (which includes most plasma protein therapies) at average sales price (ASP) plus 4 percent, We believe that payment rates at that level are insufficient to ensure that the

¹ 74 Fed. Reg. 35232 (July 20, 2009).

vulnerable patients that depend on plasma protein therapies have access to them in the hospital outpatient setting. We urge CMS to pay for these therapies at least at ASP plus 6 percent, which would put those payment rates on par with the rates paid for pass-through drugs in the hospital outpatient setting and all drugs in the physician office setting.

DISCUSSION

I. STAKEHOLDERS APPLAUD CMS FOR ITS DECISION TO MAINTAIN THE FURNISHING FEE FOR BLOOD CLOTTING FACTORS UNDER THE OPSS

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 2009 is \$0.164 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 OPSS 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 2010.⁷ We agree 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 few years. Thus, we appreciate CMS’ inclusion of the furnishing fee under OPSS 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 2010.

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

² Social Security Act (“SSA”) § 1842(o)(5).

³ SSA, § 1842(o)(5)(C).

⁴ See 74 Fed. Reg. at 35333.

⁵ See 74 Fed. Reg. at 35333 (proposing to continue the policy of paying the furnishing fee); 70 Fed. Reg. 68516, 68661 (Nov. 10, 2005) (establishing the policy of paying the furnishing fee to hospital outpatient departments).

⁶ *Id.*

⁷ See 74 Fed. Reg. at 35333 (proposing to continue the policy of paying the furnishing fee).

Adequate Medicare reimbursement is imperative for the preservation of patient access to plasma protein therapies in the hospital outpatient setting. CMS, however, 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 4 percent for CY 2010.⁸ Thus, we believe that Medicare beneficiaries should be able to obtain drugs and biologicals, especially plasma protein therapies, best suited for their individual needs in the most appropriate site of service. Hospital outpatient departments must remain a viable option for beneficiaries to be able to receive therapies like alpha₁-antitrypsin, blood clotting factors, and intravenous immune globulin (IVIG). While the proposed payment level is the same as the current payment level, stakeholders believe that ASP plus 4 percent does not reimburse hospitals sufficiently for plasma protein therapies to ensure that beneficiaries will be able to access such products in this setting. Moreover, we believe that the Proposed Rule and the past few OPPS final rules reveal a goal-oriented approach to determining the payment levels for separately payable drugs and the time has come to move back to the established and congressionally sanctioned ASP plus 6 percent payment methodology for all separately payable drugs under OPPS. ASP plus 6 percent is the level that the Advisory Panel on Ambulatory Payment Classification Groups recommended on two separate occasions this year, both in February and August of this year. PPTA encourages CMS to adhere to the recommendations of the APC advisory panel and the spirit of the congressional statute.

CMS believes that payment at ASP plus 4 percent would provide for accurate payments for the acquisition pharmacy overhead costs for separately payable drugs and biologicals.⁹ The agency reached the ASP plus 4 percent figure by applying its “standard drug payment methodology” to these products (yielding a payment level of ASP minus 2 percent) and reallocating \$150 million in cost from packaged drugs and biologicals (which is between one-third and one half of the \$395 million of pharmacy overhead costs for packaged products) to yield ASP plus 4 percent.¹⁰ The agency arrived at ASP plus 4 percent using a methodology that is inherently flawed and strikingly arbitrary. CMS should eschew the annual attempts to contort data it has to arrive at a payment level it deems appropriate in favor of a congressionally sanctioned, and now well-established payment methodology which would not incentivize the provision of drugs and biologicals in one setting versus another – ASP plus 6 percent. This is the level that the Advisory Panel on Ambulatory Payment Classification Groups recommended, both in February and August of this year.¹¹ While we believe this is the appropriate policy for all separately payable drugs and biologicals, we note that given

⁸ See 74 Fed. Reg. at 35331.

⁹ 74 Fed. Reg. at 35328-29.

¹⁰ 74 Fed. Reg. at 35327-28.

¹¹ 74 Fed. Reg. at 35326 (noting the February recommendation); The recommendation of the Ambulatory Payment Classification Panel on August 16, 2009 has not yet been published in the Federal Register.

the vulnerabilities of the patients using plasma protein therapies, there is a basis for paying only plasma protein therapies at ASP plus 6 percent.

A. The Methodology CMS Utilizes in Proposing Payments at ASP Plus 4 Percent is Flawed

CMS has been using hospital claims data to set the payment level for separately payable drugs and biologicals in the OPSS since January 1, 2008. We believe that determining OPSS payment rates based on these data is inappropriate because of flaws in the data. Furthermore, this use of hospital claims data also fails to consider 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.”¹² For drugs, charge compression essentially undervalues high cost products and overvalues low cost products. This is especially problematic for separately payable drugs, 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.”¹³

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.¹⁴ 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 acknowledges “that the current method of converting billed charges to costs has the potential to ‘compress’ the calculated costs to some degree,”¹⁵ it makes no effort in its methodology to address the flaw caused by charge compression.

¹² 73 Fed. Reg. at 41429.

¹³ 73 Fed. Reg. at 41490.

¹⁴ 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.

¹⁵ 74 Fed. Reg. at 35327.

Moreover, CMS' policy of using hospitals claims data in setting OPSS payment rates for drugs and biologicals is flawed because of its inclusion of drugs 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.¹⁶

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,¹⁷ the BP calculation,¹⁸ and the ASP calculation.¹⁹ 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.²⁰ 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 OPSS, somehow the agency reaches 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.²¹ In essence, the agency's position is that it is acceptable to utilize information from a minority of OPSS hospitals that will distort the data used to set the payment levels for all other OPSS hospitals, which represent a significant majority of the OPSS 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 OPSS ratesetting. An April 2008 study of 2006 hospital claims data by Chris Hogan of Direct Research revealed that the inclusion of 340B hospitals

¹⁶ 42 U.S.C. § 256b (2007).

¹⁷ See 42 C.F.R. § 447.504(h)(1).

¹⁸ See SSA § 1927(c)(1)(C)(i)(I).

¹⁹ See 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).

²⁰ 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).

²¹ 74 Fed. Reg. at 35332.

reduces the estimated mean unit cost of separately covered outpatient drugs to ASP plus 3.4 percent.²² 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 would more appropriately be ASP plus 7.6 percent based on the 2007 claims data,²³ up from ASP plus 6.9 percent based on 2006 claims data.²⁴ Accordingly, the inclusion of the 340B hospitals' claims artificially lowers the payment level that CMS generates under its methodology. CMS must correct this flaw in its data.

Individually, the failure to address charge compression and the improper inclusion of 340B hospital claims in the OPSS 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. Thus, stakeholders respectfully urge CMS to restore OPSS reimbursement to ASP plus 6 percent.

B. The Methodology CMS Utilizes in Proposing Payments at ASP Plus 4 Percent is Arbitrary

We urge CMS to move to the well-established ASP plus 6 percent payment level in OPSS because the methodology that CMS uses in the Proposed Rule is 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.²⁵ This is the very same drug payment methodology that CMS used to set OPSS rates for CY 2003 and that Congress summarily rejected later that year through legislation mandating different ratesetting mechanisms under OPSS 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 without explanation represents arbitrary agency action.

²² See Memorandum from Chris Hogan, Direct Research, LL to Interested Parties 2 (April 15, 2008) [hereinafter "Hogan April Memo"] (Attachment A).

²³ See Memorandum from Chris Hogan, Direct Research, LLC to Interested Parties 2 (July 27, 2008) [hereinafter "Hogan July Memo"] (Attachment B), at 2.

²⁴ See Hogan April Memo, at 2.

²⁵ 74 Fed. Reg. at 35327.

- As the agency discusses moving dollars between acquisition cost and pharmacy overhead, it states “we currently have no way of assessing whether this current distribution of overhead costs to packaged drugs and biologicals is appropriate.”²⁶ Despite this lack of information, the agency makes this part of its ratesetting methodology.
- CMS states that some, but not all, of the \$395 million in overhead costs associated with packaged products “should, *at least for CY 2010*, be attributed to separately payable drugs and biologicals.”²⁷ The agency fails to explain why 2010 would be different from the current or a future year.
- In determining that the agency would reallocate \$150 million, 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.

In our view, particularly as it relates to plasma protein therapies, CMS should reimburse hospitals at ASP plus 6 percent 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 OPSS over the past few years has led to the use of flawed, arbitrary, and ever-changing mechanisms that fail to promote stability within OPSS. That needs to change and the use of ASP plus 6 percent as the payment level for all separately payable drugs and biologicals provides a rational and stable mechanism that CMS should utilize in CY 2010 and beyond.

CONCLUSION

We appreciate 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 OPSS for CY 2010 and urge the agency to finalize it with the pertinent update for CY 2010. We are, however, very concerned with the agency’s proposal to pay for separately payable, non-pass-through drugs to ASP plus 4 percent and believe the agency should set payment for these products at ASP plus 6 percent, for reasons noted above. Thank you for your attention to this very important matter.

Respectfully submitted,

Alpha-1 Association
Alpha-1 Foundation

²⁶ 74 Fed. Reg. at 35327.

²⁷ 74 Fed. Reg. at 35327 (emphasis added).

GBS/CIDP Foundation International
Hemophilia Federation of America
Immune Deficiency Foundation
ASD Healthcare
Plasma Protein Therapeutics Association