


**MEMORANDUM**

**To:** Julie Birkofer  
**From:** Stuart Langbein   
**Date:** December 26, 2013  
**Re:** Reimbursement Primer

Below please find an updated primer regarding reimbursement for products manufactured by Plasma Protein Therapeutics Association (“PPTA”) member companies. The most pertinent payment methodologies and programs are addressed separately.

**I. Inpatient Hospital Payment for PPTA Therapies under Medicare Part A**

In 1983, Congress established the inpatient prospective payment system (“IPPS”) to pay hospitals for inpatient hospital services furnished to Medicare beneficiaries. Under IPPS, providers receive a single payment amount for each type of case on a per-discharge basis. The Medicare payment amount is based on a patient classification scheme that assigns each patient to a Medicare severity diagnosis-related group (“MS-DRG”) composed of cases that theoretically are clinically coherent and that require similar resources. Patient assignment is made at discharge and each patient is assigned to only one MS-DRG. Currently, there are 751 active MS-DRGs. <sup>1/</sup>

The use of MS-DRGs began in fiscal year 2008, in an attempt to better account for patient severity of illness within IPPS. Prior to the move to the MS-DRG scheme, patients with different severity of illness were paid at the same rate, despite the significant difference in hospital resources used to treat the patients. The introduction of severity weighted MS-DRGs was to more accurately recognize the severity of the illness involved and lead to fewer variations in payments under each MS-DRG.

The Medicare payment allowed under each MS-DRG is intended to cover the necessary costs of the average patient in the MS-DRG. Each MS-DRG is assigned a numerical “weight” based on the resource consumption associated with that MS-DRG relative to the average case at the average hospital. MS-DRGs of higher weight correspond with more complex illnesses or procedures that are associated with higher treatment costs. Since 1988, the Centers

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<sup>1/</sup> See 78 Fed. Reg. 50495, 50412 (Aug. 19, 2013).

for Medicare and Medicaid Services (“CMS”) has adjusted these weights annually based on charge data for Medicare discharges.

The payment amount for an individual discharge is determined by multiplying the MS-DRG weight by a standardized per-case payment amount. The applicable standardized amount depends upon the pertinent hospital wage index and whether the hospital reports certain quality data (in which case it is a “full update” hospital with a higher standardized amount than if such data are not provided). The resulting number then is used, along with a variety of other factors to account for regional variations in labor costs, indirect medical education expenses, and costs for hospitals that care for a disproportionate share of poor patients, to calculate the amount of payment to be made in each case.

Additional payment amounts may be made for qualifying new technology services approved by CMS. To receive the additional payment, it must be demonstrated to CMS that (1) the technology is new; (2) the technology is a substantial clinical improvement compared to existing technologies; and (3) the technology satisfies a cost threshold. 2/ When the cost of a discharge involving a qualifying new technology exceeds the full MS-DRG payment, Medicare will make an add-on payment equal to the lesser of (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare’s payment) or (2) 50 percent of the difference between the full MS-DRG payment and the hospital’s estimated cost for the case. 3/ Not many services have qualified for additional payments since this mechanism was first implemented by CMS in federal fiscal year 2003 (i.e., discharges on or after October 1, 2002 and before October 1, 2003), but Kcentra<sup>®</sup>, a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by a Vitamin K antagonist, qualifies for an add-on payment in 2014, except when used to treat Medicare beneficiaries with hemophilia. 4/ The maximum add-on payment for a case of Kcentra is \$1,587.50. 5/

A number of years ago, CMS implemented a new policy pursuant to which Medicare will not pay hospitals the increased reimbursement associated with a higher paying MS-DRG for a case in which one of the hospital acquired conditions (“HAC”) identified by CMS was not present on admission. 6/ The statute requires the Secretary of Health and Human Services (“Secretary”) to identify HACs that are: (a) high cost or high volume or both, (b) result

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2/ 42 C.F.R. § 412.87.

3/ See 78 Fed. Reg. at 50571.

4/ *Id.* at 50575, 50579. When Kcentra is used to treat Medicare beneficiaries with hemophilia, it is paid separately as a blood clotting factor (discussed below), instead of being paid the new technology add-on payment.

5/ *Id.* at 50579.

6/ This policy implements a statutory change enacted in 2006. 42 U.S.C. § 1395ww(d)(4)(D) (as added by section 5001(c) of the Deficit Reduction Act of 2005 (“DRA”).

in the assignment of a case to a MS-DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the identified HACs is acquired or occurs during hospitalization. Currently, CMS has identified a total of 11 HACs. <sup>7/</sup> None of the HACs appear to involve cases in which plasma-based or recombinant biological therapies are part of the treatment.

Except for blood clotting factors used for patients with hemophilia as discussed below or products qualifying for a new technology add-on, there is no separate payment under IPPS for PPTA member plasma-based and recombinant biological therapies used in the treatment of hospital inpatients. Instead, as with other costs, hospitals mostly must absorb the costs of these therapies within the pertinent IPPS payment.

Medicare Part A pays hospitals an additional amount to supplement the MS-DRG payment for the costs of administering blood clotting factors to Medicare beneficiaries with hemophilia who are admitted for inpatient hospital stays. <sup>8/</sup> The separate payment was originally adopted by Congress as part of the Omnibus Budget Reconciliation Act of 1989 (“OBRA ’89”) in response to concern about growing hospital costs for treating beneficiaries with hemophilia. While the original pass-through provision expired in 1994, the Balanced Budget Act of 1997 (“BBA”) permanently reinstated the provision effective October 1, 1997. Historically, the separate payment rates were based on the average wholesale price (“AWP”) of drugs in each category of factor. Effective for discharges occurring on or after October 1, 2005, the separate payment rates are set at the average sales price (“ASP”) plus 6% for the product, updated quarterly, and an additional amount as a furnishing fee. <sup>9/</sup> This fee and ASP are discussed in Section II below.

## **II. Coverage and Payment for PPTA Therapies under Medicare Part B**

Medicare traditionally has addressed the issue of coverage and payment for items and services separately, requiring first that the item or service meet the requirements for coverage under the program, and then, once coverage has been established, making a determination as to reimbursement. In general, Medicare does not cover a drug unless it has been approved by the federal Food and Drug Administration (“FDA”), is included in any of the specified compendia, cannot be self-administered, is furnished incident to a physician’s

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<sup>7/</sup> 78 Fed. Reg. at 50524. The current list of HACs is available at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired\\_Conditions.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html).

<sup>8/</sup> 42 U.S.C. § 1395ww(a)(4). Additional guidance on separate payment to hospitals for blood clotting factors furnished to hospital inpatients is available in the Medicare Claims Processing Manual, Ch. 3, § 20.7.3.

<sup>9/</sup> 70 Fed. Reg. 47278, 47506 (Aug. 12, 2005).

service, 10/ and is reasonable and necessary for the diagnosis or treatment of the illness for which it is administered. 11/ Once coverage is established under these criteria, Medicare reimbursement for a drug depends largely on the setting in which the drug is administered.

When discussing FDA approval, it is important to distinguish between (1) a drug that has not been approved for marketing by the FDA; (2) a drug that has been approved for marketing by the FDA for a specific use and is furnished for that use; and (3) a drug that has been approved for marketing by the FDA for a specific use, but is furnished for a use other than the one for which it is approved by the FDA, commonly known as an “off-label use.” CMS’s general position is that it will not pay for a drug that has not received FDA approval for some use. If a drug has received FDA approval for a specific use, Medicare generally will pay for the drug when it is furnished for the approved use. When a drug is used for an off-label use, with the exception of certain anti-cancer drugs, the Medicare contractor has discretion to make payment for the drug taking into consideration the major drug compendia, authoritative medical literature, and accepted standards of medical practice. 12/ Currently, the following compendia are the ones recognized as authoritative for purposes of off-label coverage for drugs used in an anti-cancer chemotherapeutic regimen:

- American Hospital Formulary Service-Drug Information;
- National Comprehensive Cancer Network Drugs and Biologics Compendium;
- Thomson Micromedex DrugDex; and
- Clinical Pharmacology. 13/

Although the agency has not explicitly indicated as such, it seems reasonable to believe that the above compendia would be considered “major drug compendia” for purposes of off-label coverage of drugs not used in an anti-cancer chemotherapeutic regimen.

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10/ Incident to a physician’s service means that it must be administered by a physician or auxiliary personnel employed by the physician, represent a cost for the physician, and be included in the physician’s bill. Medicare Benefit Policy Manual (“MBPM”), Chapter 15, § 50.3. In other words, a service or supply is considered “incident to” a physician’s service when it is of a type that is commonly furnished in a physician’s office under the direct personal supervision of a physician. Except for blood clotting factors (which the statute allows to be covered when self-administered), intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (covered pursuant to a statutory mandate), and subcutaneous immune globulin (covered in connection with an item of durable medical equipment), PPTA member products are not covered under Medicare Part B when self-administered by the patient.

11/ MBPM, Chapter 15, § 50.

12/ MBPM, Chapter 15, §§ 50-50.4.3. For drugs used in an anti-cancer chemotherapeutic regimen, Medicare contractors cannot deny coverage because the use is off-label if the use is supported by (and not listed as not indicated) certain compendia. *Id.* at § 50.4.5.

13/ *Id.*

A. Payment for PPTA Therapies Administered in a Physician's Office

Historically, payment for drugs administered in a physician's office was based on the lower of actual charge on the Medicare claim or 95 percent of the drug's AWP, as determined by the Medicare carriers. 14/ This payment methodology remained in effect until the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 ("MMA"). This law revised the payment rate for some member products in 2004 to 85% of the April 1, 2003 AWP, while blood clotting factors continued to be paid at 95% of AWP in 2004. That change, however, was just a transition to the ASP + 6% payment methodology that commenced in 2005. Under this methodology, manufacturers report ASP information to CMS by National Drug Code ("NDC") on a quarterly basis. CMS compiles this information by Healthcare Common Procedure Coding System ("HCPCS") code 15/ and then computes a weighted average sales price for each HCPCS code. The applicable payment amount is 106% of ASP, as determined quarterly by CMS. 16/ The payment rates are announced on the CMS website at the site identified *supra* at n.16. The statute provides a mechanism for reducing ASP rates if the Office of the Inspector General ("OIG") determines the ASP rate for a product exceeds the widely available market price ("WAMP") by more than a threshold set by CMS (now 5%). Although the OIG has issued reports studying the WAMP of certain drugs, CMS has not adjusted any payment rates as a result. 17/

Beginning on April 1, 2013, Medicare payments for all items and services, including drugs and biologicals, have been reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, Pub. L. No. 112-25 ("BCA"), as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240 ("ATRA"). The BCA requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs, because Congress failed to enact legislation by January 15, 2012, to reduce federal deficits by \$1.2 trillion over ten years. The BCA caps the

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14/ 42 U.S.C. § 1395u(o)(1) (as added by § 4556 of the Balanced Budget Act of 1997); 42 C.F.R. § 405.517.

15/ A crosswalk showing which NDCs are grouped to which HCPCS codes is available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2014ASPFiles.html>.

16/ Under the statute, single source drugs are paid at the lesser of 106% of ASP or 106% of wholesale acquisition cost ("WAC"), while the rates for multiple source drugs are set at 106% of ASP. 42 U.S.C. § 1395w-3a(b)(1). Since WAC is usually higher than ASP, rates for single source drugs are almost always set at 106% of ASP. For new drugs, however, until ASP information can be reported and used by CMS (typically 2 quarters), payment is set at 106% of WAC.

17/ The ASP payment methodology applies to plasma-based and recombinant analog therapies covered under Medicare's "incident to" a physician service benefit category. The statute, however, specifies that infusion drugs that are furnished through an item of durable medical equipment ("DME") are paid at 95% of AWP as of October 1, 2003 (or the first available AWP thereafter) until the product is paid under a DME competitive bidding program. 42 U.S.C. § 1395u(o)(1)(D). Since subcutaneous immune globulin is covered as a DME infusion drug and there are no drugs included in the currently implemented DME competitive bidding program, it is reimbursed at 95% of the first available AWP.



cuts to Medicare payments or items and services at 2%, and requires the cuts to be implemented on the first day of the first month following the issuance of a sequestration order. The Medicare cuts took effect April 1, 2013. Pursuant to a budget deal enacted by Congress that the President is expected to sign, sequestration would be extended for two years – to 2023.

The MMA also added a statutory mandate starting in 2005 to pay a “furnishing fee” for items and services associated with the furnishing of blood clotting factor. The initial amount of this fee was left to CMS’s discretion, but after that, the initial amount is increased by the consumer price index (“CPI”) for medical care. <sup>18/</sup> CMS set the fee at \$0.14 per unit in 2005 and has updated the fee annually since then, with the rate of \$0.192 per unit effective January 1, 2014. <sup>19/</sup>

In addition to reimbursement for the drug itself, Medicare Part B also reimburses the physician for his or her professional services in administering the therapy. The payment rates for these drug administration services are determined under the physician fee schedule based on the pertinent codes billed for the service. For the most part, physicians bill for drug administration services using the appropriate Current Procedural Terminology (“CPT”) code. <sup>20/</sup> In 2005, however, CMS directed physicians to bill using certain alphanumeric HCPCS codes to address changes to the CPT drug administration codes that were ultimately made effective January 1, 2006. These changes were needed to implement revisions to drug administration payments mandated by the MMA. The revisions increased payments for drug administration services, while payments for the drug products decreased. Since 2006, physicians have been billing for drug administration services using the CPT code, with the payment rates determined under Medicare’s physician fee schedule. These payment rates also are subject to sequestration.

**B. Payment for PPTA Therapies Administered in a Hospital Outpatient Department**

Historically, drugs administered in a hospital outpatient department (“HOPD”) were reimbursed under Part B of the Medicare program based on their “reasonable cost.” The Medicare statute defines reasonable cost as the cost actually incurred, excluding any part of incurred cost found unnecessary in the efficient delivery of needed health services. <sup>21/</sup> In practice, reimbursement was determined through the Medicare cost report, with no specifically assigned amounts for individual products. Indeed, HOPDs did not have to bill drugs by HCPCS code to receive payment for drugs under the reasonable cost methodology.

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<sup>18/</sup> 42 U.S.C. § 1395u(o)(5).

<sup>19/</sup> See <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/ClotFactorFurnishFee.html>.

<sup>20/</sup> “CPT” is a registered trademark of the American Medical Association.

<sup>21/</sup> 42 U.S.C. § 1395x(v)(1)(A).

Effective August 1, 2000, HOPDs began being paid by Medicare under the hospital outpatient prospective payment system (“OPPS”). Under this system, hospitals have to bill for drugs using HCPCS codes in order to be paid for them. Through December 31, 2002, most drugs, including PPTA member therapies, were paid at 95% of AWP. 22/ In 2003, payment rates were set using the OPPS median cost methodology under which rates for other items and services had been determined since 2000, with a dampening mechanism to mitigate decreases in payment rates. As a result of statutory changes in the MMA, OPPS rates for most drugs in 2004 and 2005, including PPTA member therapies, were determined using the OPPS median cost methodology with certain payment ceilings and floors based on the AWP in effect on May 1, 2003. As such, during 2004, PPTA member therapies were reimbursed at 88% of the May 1, 2003 AWP and, during 2005, they were reimbursed at 83% of that AWP. Beginning in 2006, CMS began paying for most drugs under OPPS at ASP + 6%, with the rates updated quarterly. 23/

While the agency had proposed paying for drugs and biologicals at less than ASP + 6% for 2006 and 2007, it was not until 2008 that CMS finalized a lower payment rate for separately payable drugs and biologicals under OPPS – ASP + 5%. For 2008 through 2012, CMS decided that it would continue to tie payments for drugs to ASP, but that it would base the ASP percentage on mean costs for drugs, determined based on HOPD claims data. The led to payment rates at ASP + 4% or ASP + 5% during these years. For 2013, CMS indicated that due to limitation of hospital claims and cost data on drugs and biologicals, among other things, it was reverting to a “statutory default,” i.e., paying the same rate in the hospital outpatient department setting that it pays physicians by statute. 24/ Thus for 2013, CMS adopted an OPPS payment rate of ASP + 6% for drugs and biologicals, including PPTA member therapies. 25/ For 2014, CMS will continue to use an OPPS payment rate of ASP + 6% for these drugs and biologicals. 26/

Each year, CMS also updates the packaging threshold – the dollar figure for which if a drug’s per day cost is below, the product will not be paid separately. CMS uses the Producer Price Index for Prescription Drugs for the update and that results in a packaging threshold of \$90 for 2014 (up from \$80). 27/ While CMS had proposed not to pay separately for J7191 (Factor viii (antihemophilic factor (porcine)), per IU) because of a lack of data to use for the packaging threshold, the agency received additional claims data from the proposed rule to the

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22/ In 2002, however, PPTA member therapies had their 95% of AWP payment rates reduced in the last three quarters of that year.

23/ 70 Fed. Reg. 68515, 68661 (Nov. 10, 2005) (setting 2006 rates); 71 Fed. Reg. 67960, 68091 (Nov. 24, 2006) (setting 2007 rates).

24/ 77 Fed. Reg. 68209, 68386 (Nov. 15, 2012).

25/ *Id.* at 68389.

26/ 78 Fed. Reg. 74826, 75028 (Dec. 10, 2013).

27/ *Id.* at 75021-22.

final rule to determine that the cost per day of the product exceeds the \$90 threshold. As such, it will be paid separately at ASP +6% in 2014.28/

CMS also establishes separate payment rates for drug administration services under OPPTS. For 2014, CMS proposed to package all CPT add-on codes, including drug-administration add-on codes such as CPT code 96366 (for second and subsequent hours on intravenous infusions), meaning that there would no longer be separate payment for such add-on codes. In the final rule, CMS indicated that given the wide variety of different drug treatment protocols for various diseases, the agency needs to study further the impact of packaging drug administration add-on codes. As a result, the agency is not packaging drug administration add-on codes for 2014 but indicated that it may explore other payment options in the future. 29/ Note that CMS also continues to pay a furnishing fee for clotting factors furnished in the hospital outpatient setting in 2014. 30/

In 2014, the following plasma protein therapies qualify for “pass-through” status, which ensures payments at ASP+6% for 2-3 years: Bivigam (C9130, injection, immune globulin (Bivigam), 500 mg), Kcentra (C9132, prothrombin complex concentrate (human), Kcentra, per i.u. of Factor IX activity), and Rixubis (C9133, factor ix (antihemophilic factor, recombinant, Rixubis, per i.u.). Pass-through status for the following two plasma protein therapies will expire at the end of 2013, though the products will continue to be paid at ASP + 6%: Flebogamma (J1572, injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg) and Factor VIII Human (J7180, injection, factor xiii (antihemophilic factor, human) 1 i.u.). 31/

The Medicare payments for PPTA member therapies and the service of administering them under OPPTS are subject to sequestration, as discussed in Section II(A) above.

### **III. Federal Government Pricing Programs Affecting PPTA Products**

Over the past decade, the Federal statutory and regulatory requirements regarding a company’s price reporting obligations have steadily increased. This part of the Primer summarizes some of the statutory and regulatory obligations.

#### **A. Medicaid Rebate Program**

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28/ *Id.* at 75022.

29/ *Id.* at 74945.

30/ *Id.* at 75029.

31/ *Id.* at 75011, 75014.



In order for federal funds to be available for the payment of a manufacturer's drugs under any State Medicaid program or Medicare Part B, a drug manufacturer must enter into a Medicaid Drug Rebate Agreement with the Secretary to provide rebates, as discussed below. These rebates are intended to provide states, which are large reimbursers of outpatient prescription drugs under Medicaid, with the ability to obtain a discount that is tied to the best commercial price at which a manufacturer sells such drugs. Under the Medicaid Drug Rebate Program, manufacturers must pay quarterly rebates based on the number of units of their product reimbursed by each state's Medicaid program. 32/ Each state will send an invoice to the manufacturer showing the number of units reimbursed (by NDC) approximately sixty days after the end of each calendar quarter. The statute requires states to collect rebates on single source physician administered drugs and to collect NDCs for the 20 multiple source physician administered drugs with the highest dollar volume in Medicaid, as determined by the Secretary, for the purposes of collecting rebates on both of these types of drugs. 33/ The payments are due to be received by each state 30 days after the manufacturer receives the state's invoice. 34/ Interest accrues (at the 13-week Treasury-bill rate) for each day that the payment is late. 35/

The rebate due for each drug is the number of units multiplied by the per-unit rebate amount. The per-unit rebate amount for a single source drug has two components: the "basic rebate" and a consumer price index ("CPI")-based "additional rebate." 36/ Effective January 1, 2010, the maximum per-unit rebate amount for a single source and innovator multiple source drug is 100 percent of the average manufacturer price ("AMP") of the drug. 37/ The *basic rebate* is the greater of (1) 23.1 percent of AMP (17.1 percent of AMP for certain clotting factors and pediatric drugs) 38/ or (2) AMP minus best price ("BP"). 39/

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32/ The rebate requirement historically applied only to utilization reimbursed under a Medicaid fee-for-service program; however, drugs paid for under Medicaid capitated managed care arrangements became eligible for federal rebates as of March 23, 2010. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 ("PPACA") § 2501(c); 42 U.S.C. § 1396r-8(j)(1).

33/ 42 U.S.C. § 1396r-8(a)(7).

34/ 42 U.S.C. § 1396r-8(b)(1)(A).

35/ See Interest Calculation for Late Rebate Payments, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html>.

36/ 42 U.S.C. § 1396r-8(c)(1)-(2).

37/ PPACA § 2501(e); 42 U.S.C. § 1396r-8(e).

38/ 42 U.S.C. § 1396r-8(c)(1)(B). Clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Social Security Act are eligible for the minimum rebate of 17.1 percent. Otherwise, only drugs approved exclusively for pediatric indications are eligible for the 17.1 percent rebate percentage. The standard that CMS has established for determining which drugs are approved exclusively for pediatric indications is available at: <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/BCFandPedGuidance.pdf>.

39/ *Id.* at § 1396r-8(c)(1)(A)(ii).

Through the third quarter 2010, AMP is defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. **40/** Effective the fourth quarter 2010, AMP is defined as the average price paid to the manufacturer for the product by (1) wholesalers for products distributed to retail community pharmacies, and (2) retail community pharmacies that purchase drugs directly from the manufacturer. This revised AMP definition, which applies to typical retail pharmacy products, excludes payments received from, and rebates or discounts provided to, pharmacy benefit managers (“PBMs”), managed care organizations (“MCOs”), health maintenance organizations (“HMOs”), insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy. **41/** *With respect to an “inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy,”* however, payments received from, and rebates or discounts provided to, PBMs, MCOs, HMOs, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy are not excluded from AMP. **42/** BP is defined as the lowest price available from the manufacturer to any purchaser, provider, or third party payer in the same quarter that the AMP is calculated, excluding sales to specified state and federal entities. **43/**

The *additional rebate* is the full dollar amount by which the AMP in a particular quarter exceeds the AMP during the first calendar quarter that the product was marketed, as adjusted for inflation. **44/** The AMP for the first full calendar quarter that the drug is marketed establishes the product’s “baseline AMP.” The baseline AMP is significant because all future rebates are calculated based upon the price differential between the baseline AMP, adjusted for inflation, and the company’s current AMP.

Beginning the first quarter 2010, there is an alternative formula for the additional rebate for new formulations of certain drugs. **45/** This new alternative formula for the additional rebate applies only to “a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.” **46/** The term line extension “means,

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**40/** *Id.* at § 1396r-8(k)(1)(A); Medicaid Rebate Agreement at § I(a).

**41/** PPACA § 2503(a)(2)(B); Health Care Education and Reconciliation Act of 2010, Pub. L. No. 111-152 (“HCERA”) § 1101(c); Education, Jobs and Medicaid Assistance Act, Pub. L. No. 111-226 (“EJMA”) § 202; 42 U.S.C. § 1396r-8(k)(1).

**42/** 42 U.S.C. § 1396r-8(k)(1).

**43/** *Id.* at § 1396r-8(c)(1)(C)(i), (k)(1); Medicaid Rebate Agreement at § I(a) and (d).

**44/** 42 U.S.C. § 1396r-8(c)(2).

**45/** HCERA § 1206(a), 42 U.S.C. § 1396r-8(c)(2)(C).

**46/** *Id.*

with respect to a drug, a new formulation of the drug, such as an extended release formulation.” CMS defines the alternative additional rebate calculation for new formulations of existing drugs as the *greater* of (1) the total unit rebate amount (not just the additional rebate) for the new formulation, or (2) the highest additional rebate for any strength of the original product (as a percentage of the original drug’s AMP) multiplied by the AMP of the new formulation. 47/

The Medicaid statute requires manufacturers to report AMP data no later than 30 days after the end of each month and each calendar quarter. For single source and innovator multiple source drugs, manufacturers must also report BP no later than 30 days after the end of each calendar quarter. 48/

#### B. Public Health Service Pricing

Section 602 of the Veterans Health Care Act of 1992 amended the Medicaid rebate statute to also require participation in the Public Health Service (“PHS”) Drug Pricing Program as a condition of Medicaid and Medicare Part B coverage for the manufacturer’s covered outpatient drugs. 49/ The PHS Drug Pricing Program is administered through the Office of Pharmacy Affairs (“OPA”) within the Health Resources and Services Administration (“HRSA”) of the Department of Health and Human Services (“HHS”).

The list of covered entities that are participating in the PHS Drug Pricing Program changes each quarter and can be found at <http://opanet.hrsa.gov/OPA/CESearch.aspx>. Most relevant to PPTA is the inclusion of any comprehensive hemophilia treatment center receiving a grant under 42 U.S.C. § 701(a)(2). Sales at any price to a PHS covered entity (i.e., regardless if at the PHS discounted price or not) for drugs used in the outpatient setting, as well as sales at any price to disproportionate share hospital covered entities for drugs used in the inpatient setting, are excludable from the calculations of AMP and BP (for Medicaid) and ASP (for Medicare). 50/

Under this program, a manufacturer is obligated to charge covered entities no more than the “PHS ceiling price.” 51/ The PHS ceiling price is equal to the AMP minus the

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47/ The CMS guidance on the calculation of the additional rebate for line extensions is reproduced on the CMS website, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html>. This also is consistent with the rebate formula included in the proposed rule published by CMS in February 2012 to implement the changes to the Medicaid Rebate Program by PPACA. See 77 Fed. Reg. 5318, 5364 (Feb. 2, 2012) (proposed 42 C.F.R. § 447.509(a)(1)-(4)). A final rule currently is expected in May 2014.

48/ 42 U.S.C. § 1396r-8(b)(3).

49/ *Id.* at § 256b, 1396r-8(a)(5)(A).

50/ See 42 U.S.C. § 1395w-3a(c)(2) and 42 C.F.R. § 414.804(a)(4)(i) (ASP); 72 Fed. Reg. at 39,241 (July 17, 2007) (formerly codified at 42 C.F.R. § 447.504(h)(1); withdrawn by 75 Fed. Reg. 69,591 (Nov. 15, 2010)) (AMP); and 42 U.S.C. § 1396r-8(c)(1)(C)(i)(1) and 42 C.F.R. § 447.505(d)(1) (BP).

51/ 42 U.S.C. § 256b(a)(1).

Medicaid unit rebate amount for the quarter that is two quarters prior to the quarter for which the PHS ceiling price is being calculated. 52/ If the manufacturer plans to sell its product directly to end-users, the PHS ceiling price is the maximum that can be charged to the participating covered entities on the PHS list. If the manufacturer plans to distribute its product through commercial wholesalers, the PHS price is implemented through a wholesaler chargeback mechanism in the same way that other group purchasing contracts are implemented. The manufacturer notifies wholesalers each quarter of the PHS price and verifies the list of entities that are authorized to purchase at that price. The wholesaler fills the eligible orders at the PHS price and issues a “chargeback” to the manufacturer for the difference between the price at which the manufacturer sold the product to the wholesaler and the (lower) PHS ceiling price that it charged the covered entities.

In 2010, the PPACA added four additional covered entity types to the PHS Drug Pricing Program: critical access hospitals, certain freestanding cancer hospitals, rural referral centers, and sole community hospitals. 53/ These new covered entity types were added to the PHS Drug Pricing Program on a more limited basis than the existing categories of covered entities. As noted above, under the PHS statute, only “covered outpatient drugs” are subject to the discounted price requirement, and the PPACA amended the statutory definition of that term to exclude orphan drugs for purposes of the four new covered entity types. 54/ HRSA issued a final regulation implementing the statutory provision in July 2013. 55/ That regulation became effective on October 1, 2013. It interprets the statutory exception narrowly, to refer to the orphan indication alone, rather than the drug as a whole, such that the four new covered entity types are still able to access the PHS discounted price on orphan drugs so long as the entity uses the drug for a non-orphan indication. All covered entities, including children’s hospitals, other than the four new covered entity types, are entitled to the PHS discounted price on orphan drugs regardless whether used for the orphan indication or for a non-orphan indication.

The PHS Pricing Program is implemented through an agreement between the Secretary and each participating manufacturer. 56/ The PPACA amended the PHS statute to direct that each agreement include provisions to require manufacturers to submit PHS ceiling prices to the Secretary on a quarterly basis. 57/ The agreements also must now provide that a

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52/ *Id.* at § 256b(b).

53/ PPACA § 7101, 42 U.S.C. § 256b(a)(4)(M)-(O). Children’s hospitals were also included in the legislation adding these new entity types to the PHS Drug Pricing Program but had previously been made eligible for PHS pricing through an amendment to the Medicaid drug rebate statute. *See* 74 Fed. Reg. 45206 (Sept. 1, 2009).

54/ 42 U.S.C. § 256b(e). An orphan drug is defined as a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition. *Id.*; 42 C.F.R. § 10.3.

55/ 78 Fed. Reg. 44,016 (July 23, 2013), codified at 42 C.F.R. § 10. A lawsuit brought by the Pharmaceutical Research and Manufacturers of America (“PhRMA”) against HHS challenging the final regulation is ongoing.

56/ 42 U.S.C. § 256b(a)(1) .

57/ PPACA § 7102(b), 42 U.S.C. § 256b(a)(1).

participating manufacturer offer each covered entity covered outpatient drugs for purchase at or below the ceiling price if the drug is made available to any other purchaser at any price, known as the “must offer” requirement. <sup>58/</sup> The Secretary has not yet issued a revised agreement containing these new provisions, but OPA issued a Program Notice in May 2012, Release No. 2011-1.1, regarding the “must offer” requirement. <sup>59/</sup> Within Release No. 2011-1.1, OPA indicated that its previous guidelines regarding discrimination in the PHS Drug Pricing Program, released in 1994, also require manufacturers to comply with the “must offer” requirement added by the PPACA, without regard to whether OPA revises the agreement between the manufacturer and the Secretary. Release 2011-1.1 also provides guidelines for the development of a product allocation plan where product availability is insufficient to satisfy market demand, including demand from PHS covered entities.

### C. FSS Contracts and VHCA Federal Ceiling Price

Section 603 of the Veterans Health Care Act of 1992 (“VHCA”) established a program administered by the Department of Veterans Affairs (“VA”), under which manufacturers must provide discounted prices on innovator drugs and biologicals purchased off of Federal Supply Schedule (“FSS”) and “depot” contracts by the VA, the Department of Defense (“DoD”), the PHS (including the Indian Health Service), and the Coast Guard. Under the program, manufacturers are required to enter into negotiations to make their products available for procurement on an FSS contract with the VA.

**Basic FSS Requirements:** The FSS program is a government contracting program under the authority of the General Services Administration (“GSA”). However, GSA has delegated authority to VA for the negotiation and administration of FSS contracts for medical goods and services, including pharmaceuticals. Although negotiated and administered by the VA, FSS contracts can be accessed by all government agencies (as well as various other statutorily authorized FSS users, such as D.C. General Hospital). Under government procurement regulations, the FSS price is negotiated by the manufacturer and the contracting officer assigned by the VA’s National Acquisition Center. The negotiating objective of the government is to obtain the most favored customer (“MFC”) price (and terms) that the manufacturer makes available, but VA policy allows FSS awarded pricing to be set at a level that is “fair and reasonable” – i.e., that is akin to pricing extended to customers that are considered comparable to the FSS purchasers. As discussed below, however, FSS contract prices often are significantly below commercial prices given application of the Federal Ceiling Prices established per VHCA Section 603. The procurement regulations impose comprehensive disclosure and

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<sup>58/</sup> *Id.*

<sup>59/</sup> “Clarification of Non-Discrimination Policy,” 340B Drug Pricing Program Notice, Release No. 2011-1.1, available <http://www.hrsa.gov/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf>. Release No. 2011-1.1 replaces a prior Policy Release on this same subject, 2011-1, issued in November 2011. The earlier Policy Release 2011-1 is available at <http://www.hrsa.gov/opa/programrequirements/policyreleases/nondiscriminationclarification112111.pdf>.



reporting obligations on the manufacturer with significant penalties for inaccuracies and/or noncompliance.

**VHCA Pricing:** The discounted price offered to VA, DoD, PHS, and the Coast Guard under the VHCA is called the Federal Ceiling Price (“FCP”). The FCP is equal to the annual “non-Federal Average Manufacturer Price” (“non-FAMP”) minus 24 percent and minus a CPI-U-based penalty known as the “additional discount.” 60/ The non-FAMP is the weighted average price charged by the manufacturer for product distributed through domestic wholesalers to commercial customers. Excluded from the non-FAMP are: (1) federal sales through wholesalers under FSS and other federal contracts; (2) Tricare retail pharmacy utilization (units dispensed by Tricare network retail pharmacies to eligible DoD Tricare beneficiaries, see below 61/); and (3) product sold to PHS covered entities through wholesalers at the PHS ceiling price, 62/ discussed above. Essentially, the non-FAMP is the price the manufacturer charges wholesalers less any discounts allowed for prompt payment, any other discounts or stocking incentives provided to or through wholesalers, and less any manufacturer chargebacks to wholesalers on sales to non-federal customers. Manufacturers are required to report quarterly non-FAMPs to the Secretary of Veterans Affairs 30 days after the end of each quarter, 63/ and an annual non-FAMP for the 12-month period that ends with the third quarter. Note that the VA has permitted manufacturers to report their quarterly non-FAMPs up to 45 days after the end of the quarter and the official date for annual non-FAMP filings is November 15. The VA uses the non-FAMPs reported on November 15 to establish the FCPs for the following year.

Manufacturers are obligated to extend the FCP only to the VA, DoD, PHS, and the Coast Guard. The “other government agencies” that are eligible to procure pharmaceuticals through the FSS are not entitled under the VHCA to access the FCP. They are entitled only to the price that the manufacturer makes available as a result of the negotiation with the VA, although each manufacturer may voluntarily offer FCP-based pricing to all FSS purchasers.

Like the PHS ceiling price discussed above, FSS pricing in many cases is provided via chargeback relationships with certain commercial wholesalers. Sales to the VA, DoD, PHS, and the Coast Guard typically are transacted through wholesalers that are the

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60/ 38 U.S.C. § 8126(a)(2); 38 U.S.C. § 8126(c).

61/ Dear Manufacturer Letter (Oct. 16, 2009).

62/ Sales to PHS covered entities at “sub-ceiling prices,” *i.e.*, at prices below the PHS ceiling price, also are considered (and excluded as) federal sales if the sub-ceiling prices have been negotiated with the PHS pharmaceutical prime vendor. *See* Dear Manufacturer Letter (Oct. 19, 2001); Dear Manufacturer Letter (Oct. 19, 2010). However, any sub-ceiling sales not negotiated through the prime vendor must be included in the non-FAMP calculation as commercial sales. *See id.*

63/ 38 U.S.C. § 8126(e)(1).

government's contracted "prime vendors." Finally, the VA collects an "Industrial Funding Fee" from manufacturers to cover the costs of administering its FSS contracts. 64/

D. Tricare Retail Pharmacy Program

The DoD Tricare health system contains a pharmacy benefit that includes the ability to fill prescriptions at commercial retail pharmacies. For prescriptions filled at retail pharmacies participating in the Tricare network (including certain specialty pharmacies), DoD reimburses the pharmacies the difference between a commercial price and applicable beneficiary co-pays. Section 703 of the National Defense Authorization Act for Fiscal Year 2008 ("NDAA"), which was enacted in January 2008, 65/ provides that "[w]ith respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008, the Tricare retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards of such section 8126." 66/

DoD regulations implementing Section 703 create a rebate program, under which VHCA covered drug manufacturers pay quarterly rebates to DoD equal to the difference between a product's (NDC-11) annual non-FAMP and corresponding FCP multiplied by the total utilization of that product (*i.e.*, the totality of retail network dispensings to eligible Tricare beneficiaries rounded down to the closest NDC-11 package size unit). 67/ The program is implemented by way of a written agreement between the Defense Health Agency (formerly, Tricare Management Activity) and the manufacturer, under which the manufacturer agrees "to honor the pricing standards" of Section 703 in order for the manufacturer's covered drugs to be included on the DoD Uniform Formulary without being subject to a preauthorization requirement at network pharmacies. 68/ Thus, although they do not involve actual sales by a manufacturer to DoD, the implementing regulations treat prescriptions filled by Tricare beneficiaries through commercial channels as "sales" by the manufacturer to DoD that are capped by FCPs.

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64/ In prior years, the Industrial Funding Fee ("IFF") was equal to 0.5% of the manufacturer's FSS sales for the quarter. Effective January 1, 2007, the IFF was reduced to 0.25%. Beginning April 1, 2008, the IFF was raised back to 0.5%.

65/ Pub. L. No. 110-181, § 703, 122 Stat. at 188 (codified at 10 U.S.C. § 1074g(f)).

66/ *Id.* § 703(b).

67/ The regulations were issued pursuant to two final rules, *see* 74 Fed. Reg. 11279 (Mar. 17, 2009) and 75 Fed. Reg. 63383 (Oct. 15, 2010), which have been challenged by the Coalition for Common Sense in Government Procurement ("the Coalition"). The U.S. District Court for the District of Columbia entered summary judgment for the Government. The Coalition appealed that decision to the U.S. Court of Appeals for the District of Columbia Circuit. Oral argument was held on October 17, 2012.

68/ *Id.* § 199.21(q)(2). *See also id.* § 199.21(k) (preauthorization provisions).

#### **IV. Medicaid Reimbursement for PPTA Products**

Reimbursement for covered blood clotting factors and other covered PPTA therapies used by Medicaid-eligible patients is dictated by the same rules that govern reimbursement for other covered drugs under a particular state's Medicaid program. For PPTA therapies that are either self-administered by a Medicaid-eligible patient or, in most states, used in a hospital outpatient setting, a reimbursement claim is submitted by the dispensing pharmacist and the individual state pays for the drug dispensed in accordance with the particular drug reimbursement level it has set. With certain notable exceptions, including California's adoption of its own drug coding system, Medicaid reimbursement is drug specific and based upon NDC (as opposed to the HCPCS code system discussed above).

Historically, Medicaid reimbursement has been 10 to 15 percent off of the AWP of the specific drug, or the wholesale acquisition cost plus 10 percent, although differing reimbursement mechanisms (e.g., ASP-based reimbursement) have been used. For many reasons, State approaches to Medicaid pharmacy reimbursement are in a period of transition. AWP-based reimbursement is not likely to be as prevalent in the coming years because the primary publisher of AWP data, First DataBank, ceased publishing AWP in September 2011. As suggested alternatives, CMS has initiated a project aimed at surveying and compiling information related to pharmacies' actual acquisition costs for drugs, known as the National Average Drug Acquisition Cost ("NADAC"), as well as pharmacies' prices to different categories of customers, known as the National Average Retail Price ("NARP"). CMS has released its draft methodologies for developing these pricing metrics and began to make draft results of its surveys to date available on its website in October 2012. On November 27, 2013, CMS announced that it was finalizing its NADAC methodology and began posting final NADAC files that same day. <sup>69/</sup> It is unclear at this point whether and the extent to which such data will be available for the products sold by PPTA members. It is also unclear whether states will move in large numbers toward NADAC- or NARP-based pharmacy reimbursement. It also is possible that states will adopt other forms of familiar or unfamiliar reimbursement methodologies – perhaps grounded in ASP or AMP – in lieu of AWP-based reimbursement.

PPTA therapies used in outpatient hospital settings and those that are self-administered are subject to Medicaid rebates. At the end of 2008, CMS issued two final rules affecting the Medicaid program that permit states greater flexibility in structuring the standard Medicaid benefit package and implementing cost sharing for certain drugs for Medicaid beneficiaries depending on income level. <sup>70/</sup> It is not clear how or whether any state would do so for PPTA-member products, but the implementation at the state level should be monitored.

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<sup>69/</sup> Information regarding this initiative is available on the CMS website at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html>.

<sup>70/</sup> See 73 Fed. Reg. 73694 (Dec. 3, 2008) (addressing cost sharing); 73 Fed. Reg. 71828 (Nov. 25, 2008) (addressing flexibility in structuring benefit package).

For PPTA therapies used by Medicaid-eligible patients in a hospital inpatient setting, payment usually is tied to a bundled payment for services and is based on the hospital payment rules and rates of the particular state. PPTA therapies reimbursed through a bundled payment are not subject to the Medicaid rebates.

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