

The Impact of the Final 2009 CMS Hospital Outpatient Department Rule

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Summary:

This report focuses on changes to Medicare outpatient payment policies under the Centers for Medicare & Medicaid Services' (CMS) outpatient prospective payment system (OPPS). Its purpose is to urge pharmacy administrative teams to maintain a focus on regulation compliance, communicate in one voice and send one message, and integrate charging as a part of medication use. The impact on pharmacy is that the reimbursement for products covered under Medicare Part B has been decreased to Average Sales Price (ASP) plus 4%. The rate decrease is transitional, and could go even lower in 2010. The average wholesale price (AWP), a figure published in privately owned compendia that is

not defined by federal law or regulation and is usually not based on actual sales prices, bears little resemblance to the prices incurred by pharmacies and has mostly disappeared. Additional changes to intravenous immune globulin (IVIG) and medication administration reimbursement should play a major role in the discussions between pharmacy and the administrative team as they develop their financial strategy for 2009.

On October 30, 2008, CMS released its final rule establishing Medicare payment and policy changes for services for 2009. The final hospital OPPS rule, a segment of Medicare Part B, took effect on January 1, 2009, and applies to hospital outpatient departments (see Table 1 for a product listing). The final rule also includes payment rates for ambulatory surgical centers (ASCs), which are in the second year of a 4 year transition to a revised ASC payment system. Payment rates are calculated as the sum of 50% of the rate determined under the 2007 ASC payment rule and 50% of the rate determined under the new methodology. Additionally, to qualify for payment, the drug must be administered immediately before, during, or after an ASC procedure approved for payment.

The OPPS rule does not apply to Medicare Part D (see Table 2) or outpatient prescription drugs or self-administered drugs used at home, although this segment of Medicare coverage also had extensive changes for 2009. It also does not apply to inpatient services, which are governed by the inpatient prospective payment system, a segment of Medicare Part A coverage that operates on a fiscal year beginning October 1. CMS has also released the final rule changes for payment for physician services.

As part of the stakeholder group preparing comments for the Ambulatory Payment Classification (APC) Panel assisting CMS, the American Society of Health-System Pharmacists (ASHP) played an active role in com-

Table 1. Drugs Covered By Medicare Part B

- Injectables furnished incident to a physician's service and not usually self-administered.
- Drugs administered via a nebulizer or pump furnished by Medicare.
- Immunosuppressive drugs for organ transplants.
- Hemophilia blood clotting factors.
- Certain oral anticancer treatments.
- Oral antiemetics.
- Pneumococcal, influenza, and hepatitis B vaccines.
- Erythropoietin-like drugs administered by properly trained home dialysis patients.
- Iron dextran, vitamin D injections, and erythropoietin-like drugs administered by facilities specializing in the care of ESRD patients.
- Osteoporosis drugs.

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menting on the proposed OPPTS regulations once they were published and urging changes when they were in the best interest of the membership. The stakeholders, including ASHP, continued to emphasize that the 2008 rate was inadequate to cover acquisition costs, let alone pharmacy services and handling costs, and that CMS failed to pay appropriately for pharmacy services. ASHP, along with the other stakeholders, presented a growing body of evidence to show that CMS’s methodology for calculating payment for separately paid drugs under OPPTS is deeply flawed and contrary to the statute. CMS did not propose any immediate corrections.

The 2009 payment policies that now are in effect have a significant impact on the clinical and financial operations of hospitals and health systems, and it is crucial that ASHP members are able to discuss the strategic impact of these changes with the Chief Executive Office (CEO), Chief Financial Officer (CFO) and Chief Marketing Office (CMO) of their institutions. Within OPPTS there are two separate sections that address reimbursement of medications and their administration. Pharmaceuticals and biologicals themselves may be reimbursed in one of four different ways, as shown in Table 3, and injectable medication administration may be reimbursed as well. The pharmacy typically is responsible for overseeing the appropriate acquisition, preparation, and dispensing of the medications used in the outpatient and ambulatory surgery arenas, while the nursing staff assumes responsibility for administration and documentation of the products in a manner conducive to reimbursement. It is only when both of these

Table 2. Drugs Covered By Medicare Part D

- Generally a prescription drug that is prescribed and dispensed for self—administration.
- Biological products.
- Insulin
- Medical supplies associated with insulin injection e.g., syringes, needles, alcohol swabs, and gauze).
- Certain vaccines not covered under Medicare Part A or B.

departments work hand-in-hand with the billing or charge capture teams that the total available reimbursable amounts are likely to actually be collected by the facility.

In a move to tie hospital outpatient reimbursement rates to quality reporting, a differentiation in inflation rates took effect January 1, 2009. Hospitals reporting seven outpatient quality measures in 2009 will receive a 3.6% inflation update, while eligible hospitals not submitting data will receive only a 1.6% update. This trend will continue in future years, as the CMS final rule has adopted four new quality measures for measuring efficiency that will determine 2010 rates.

Fiscal Intermediaries

For the purposes of Medicare reimbursement, the United States is divided into several geographical regions, and each region is

Table 3. Reimbursement of Drugs and Biologicals under OPPTS 2009

New drugs not yet assigned unique Healthcare Common Procedure Coding System (HCPCS) code	New pass-through drugs	Specified covered outpatient drugs costing >\$60/day or separately payable drugs	Lower-cost packaged products costing <\$60/day
No change from 2008		ASP +4%	No change from 2008
95% of AWP	ASP +6% Competitive Acquisition Program (CAP) program discontinued	CMS pays separately for antiemetic drugs regardless of cost	No separate reimbursement, bundled into procedure
Use code C9399, unclassified drugs, or biologicals	Payment based on Wholesale Acquisition Cost (WAC) + 6% until enough ASP data gathered		

assigned a fiscal intermediary (FI). It is the FI that actually receives billings from the hospitals and outpatient clinics and submits them to CMS for payment. It is critical that hospitals know who their FI is and what peculiarities may affect their region. Not all FIs make the same coverage decisions.

The fact that a drug, device, procedure, or service has a Healthcare Common Procedure Coding System (HCPCS) code and a payment rate under OPSS does not imply coverage by Medicare. The code and payment rate indicate only how the product, procedure, or service may be reimbursed if it is covered by Medicare. Coding is the language used to describe what was done and what was used. It is the operational link between coverage and payment. However, any payor at any time can assess what was done and make the decision not to pay for it.

FIs determine whether all program requirements for coverage are met, such as whether it is reasonable and necessary to treat the beneficiary's condition and whether the drug is eligible for from payment for that condition. Each FI has a toll-free number that can be found on the CMS web site (www.cms.hhs.gov/medlearn/tollnums.asp). *MLN Matters* is a series of national articles designed to inform the physician, provider, and supplier community about the latest changes to the Medicare program (commonly referred to as change requests). CMS releases updates and software to the FIs quarterly, as well as provider education articles that are available shortly after a Change Request is issued. Sample articles are available on the CMS web site at <http://www.cms.hhs.gov/MLNMattersArticles>. The CMS web site is updated daily with articles that are developed to accompany recently released or changed Medicare program instructions.

Table 4. Definition of ASP

ASP: Average selling price of manufacturer's sales of all U.S. purchases for each National Drug Code (NDC) for one calendar quarter, divided by total number of units sold in that quarter.

Excludes nominal pricing and Medicaid's "best price."
Includes volume and prompt pay discounts, free goods, chargebacks, and rebates.

CMS abandoned AWP and adopted ASP in October 2005.

Payment for Separately Payable Drugs and Biologicals

Based on hospitals' Calendar Year (CY) 2007 claims and most recent cost report data, CMS has calculated hospitals' average costs for drugs and biologicals (including both drug acquisition and pharmacy overhead costs) to be equivalent to ASP plus 2%. (See Table 4 for a definition of ASP and see Table 5 for definitions of other terms pertinent to reimbursement). However, in CY 2009 CMS will pay for separately payable drugs and biologicals at the manufacturer's ASP plus 4%, which is a reduction from the 2008 rate of ASP plus 5%. Payment for these same products administered in a physician's office remains at ASP plus 6% as this payment model is determined by the Medicare Prescription Drug Improvement and Modernization Act of 2003, while the hospital outpatient arena is subject to OPSS rulings.

CMS rejected calls by ASHP and various other stakeholders to reimburse all separately paid drugs at a rate of at least ASP plus 6% and to make additional payments for pharmacy services. CMS contends that its proposed rates appropriately reflect both drug acquisition and pharmacy service costs.

Additionally, it is important to focus on the actual calculation of ASP. Midway through 2008, this calculation changed, which could prove to be a detriment to some ASHP members depending on their facility size and purchasing strategy. Section 112 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 (MMSEA) altered the calculation used to compute payment under the ASP methodology for many Part B-covered drugs and established a special payment rule for certain inhalation drugs administered through a piece of durable medical equipment. MMSEA requires CMS to apply an alternative volume weighting computation to its calculation of ASP-based payment amounts. These changes went into effect on April 1, 2008, and this revised methodology for the calculation of ASP remains in Medicare's regulatory language for 2009 as well.

Prior to April 1, 2008, manufacturers' ASP data for smaller and larger package sizes were treated the same in CMS's calculation of payment amounts; (i.e., the ASP for one vial was treated the same as the ASP for a box of 10 vials). Beginning April 1, 2008, the ASP for larger package sizes has a greater impact on the payment amount and the ASP for smaller package sizes has less (i.e., the ASP for a box of 10 vials is given

10 times the weight of a single vial). Smaller facilities purchasing smaller package sizes of product at premium pricing could be negatively affected by this change.

Peculiarities of Coding

A peculiarity of coding is that often the HCPCS billing units assigned to each product are not the same as the vial sizes. To ensure correct reimbursement, the charge description master (CDM) must be adjusted accordingly or a crosswalk created. The HCPCS billing unit is completely different from the quantity required for Medicaid. If a facility is servicing both Medicare and Medicaid patients, two separate crosswalks will need to be constructed to accurately reflect the actual amount of drug administered to each of the two categories of patients.

Packaging Threshold for Drugs and Biologicals

Under the OPPS, CMS “packages” or bundles payment for many drugs and biologicals in the payment for the associ-

ated procedure. Separate payment for a drug is made only if the per diem cost is greater than the packaging threshold. For 2009, the OPPS drug packaging threshold is \$60. Oral and injectable 5HT₃ antiemetics will continue to be exempt from the packaging rule and reimbursed separately in 2009. Except for these drugs, CMS will not make any separate payment for drugs and biologicals with estimated per diem costs less than \$60. This packaging rule also applies to diagnostic radiopharmaceuticals and contrast agents. Payment for those drugs not granted separately payable pass-through status will continue to be packaged.

For the pharmacy department, this payment policy means that the product is reimbursed as part of a package of fees and services paid to another hospital department or physician service. The hospital needs to recognize the pharmacy component of this payment and at a minimum, transfer the cost of the product itself to the pharmacy department. This may take some degree of negotiation on the part of pharmacy services and the charge capture team, billing department, or financial section of the C Suite.

Pass-Through Payment for Drugs and Biologicals

CMS provides transitional pass-through payments for certain new technology items and services, including drugs, biologicals, and radiopharmaceuticals. Section 1833(t)(6) of the Social Security Act provides for temporary additional payments, referred to as transitional pass-through payments, for at least 2 but no more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and other categories of medical devices. New technology services that are not eligible for transitional pass-through payments and for which there is a lack of sufficient data to appropriately assign them to a clinical APC group, belong to special APC groups based on costs (new technology APCs). These new technology APCs are designated by cost bands that allow for the appropriate and consistent payment for designated new procedures that are not yet reflected in claims data. Similar to pass-through payments, an assignment to a new technology APC is temporary; that is, a new procedure is retained within a new technology APC until sufficient data is acquired to assign it to a clinically appropriate APC group.

CMS will continue to pay for pass-through drugs and biologicals at ASP plus 6% in CY 2009, which is equivalent to the rate these drugs and biologicals would receive in the

Table 5. Review of Charging Fundamentals

- ICD-9 codes are used by hospitals to designate disease types.
- Current Procedural Terminology (CPT) codes:
 - are used by physicians to describe procedures they perform;
 - are determined by the American Medical Association (AMA); and
 - may include payment for all products used during the procedure.
- HCPCS codes are used for products and may or may not be reimbursed
- Diagnosis-related groups (DRGs) apply to inpatients and to Medicare patients only.
- APCs apply to outpatients and to Medicare patients only.
- DRG and APC methodology is often used as a template for other insurance reimbursement.
- Medicare Part B covers drugs administered in an outpatient setting (see Table 1).
- Medicare Part D covers drugs that are considered self-administered.

Table 6. Drug Administration Services

- Use of local anesthesia
- Starting an intravenous line (IV)
- Providing access to an IV catheter, or port
- Use of routine tubing, syringes and supplies
- Preparation of drugs
- Flushing at completion
- Administration of Hydration fluid

physician’s office. However, a significant number of products lost their pass-through status this year See TABLE 23. Drugs And Biologicals For Which Pass-Through Status Expires December 31, 2008 at <http://www.ashp.org/DocLibrary/Advocacy/GAD/HOPPSTable23.pdf>. Appropriate budgeting will be required for these products which no longer will be separately paid for by CMS.

Payment for Drug Administration Services

Due to a significant restructuring in payment for drug administration services, it behooves pharmacies to closely examine the way charging mechanisms for these services are handled within the outpatient arena. Nursing and billing departments should be doing their part to ensure the financial

stability of the pharmacy department. If not, it is the pharmacy’s responsibility to step up and address the problem.

The methodology, terminology, and payment amounts all are changing for this category of drug administration services, and a thorough review of the codes in use and the methods of documentation is necessary in order to prevent inappropriate and lost charges. This type of payment also includes the preparation of products as shown in Table 6.

In previous years, CMS used six different levels of codes to capture the variety of different drug administration services used in outpatient and infusion clinics. CMS is restructuring the drug administration APCs from a six-level to a five-level structure for CY 2009 to more closely align payment with hospital claims data. This structure assigns the current procedural terminology (CPT) codes for drug administration into five levels. These levels are consistent with observed differences in hospital resource costs, both across levels and within each level. Hospitals will continue to report CPT codes for drug administration services, and the five-level APC structure will continue to pay hospitals separately for each additional hour of infusion, in addition to the initial hour payment. Although a few examples are shown in Table 7, the entire chart should be pulled and examined at the facility level to determine which codes are appropriate for which procedures and what the reimbursement for each will be for 2009.

Table 7. Comparison of 2008 and 2009 Drug Administration Rates

CPT Code	Description	2008	2009	%Change
90772	Non-chemotherapy SC/IM injection	\$25	\$25	0%
90774	Non-chemotherapy IV push, single/initial drug	\$51	\$37	-27%
90765	Non-chemotherapy IV infusion, first hour	\$115	\$127	10%
90766	Non-chemotherapy infusion, additional hour	\$25	\$25	0%
96413	Chemotherapy IV infusion, first hour	\$149	\$191	28%
96415	Chemotherapy IV infusion, additional hour	\$51	\$37	-27%
96409	Chemotherapy IV push, first/initial drug	\$105	\$127	21%

Preadministration Services for IVIG Products

Effective January 1, 2009, CMS followed through with its proposal to discontinue the payment for preadministration services for IVIG infusion, since according to the agency, the intravenous immunoglobulin market is more stable than it was a few years ago. This discontinuation of payment applies both to physicians who administer IVIG in their offices and to hospital outpatient departments. The preadministration payment for hospital outpatient departments will instead be packaged with the payment for IVIG administration. According to CMS, the preadministration payment was a temporary add-on fee put in place to help providers locate product and schedule patients, and it was in place longer than CMS had originally intended it to be.

Pharmacies should be prepared for a possible influx of patients who have been denied access to IVIG infusions in physician offices and who revert to the hospital infusion clinic for their therapy. A 2007 Office of Inspector General (OIG) report stated that 61% of the physicians who responded to their survey had sent patients to hospitals for IVIG treatment because of their inability to acquire adequate amounts of IVIG or problems with Medicare payment.

Code Changes for Antihemophilic Factor Products

Effective January 1, 2009, hospitals must use code J7186 when billing Medicare for inpatients' use of a product containing antihemophilic factor with von Willebrand factor complex. Code Q4096, signifying use of von Willebrand factor complex with ristocetin cofactor products other than Humate-P, will not be recognized in 2009.

Medicare Part B Vaccines

CMS has published quick reference information on billing Medicare for influenza, pneumococcal, and hepatitis B vaccines that are administered to beneficiaries with Medicare Part B coverage.

Off-Label Use and Compendia

A dilemma often arises when the literature supports treating a patient with an off-label indication. The fact that the medication is prescribed for an off-label use may be sufficient grounds for an FI to deny payment. Patient and billing

assistance programs offered by several pharmaceutical companies may be helpful in providing support in attempting to have these denials overturned. Officially accepted compendia can be used to support the decision to administer a medication for an off-label use. Pharmacies should. **Pharmacists should be aware of which compendia are officially accepted by CMS and when additional compendia have been added to support a claim of appropriateness of use.** Additional compendia are discussed in the CMS Manual (Pub. 100-02, Medicare Benefit Policy, Transmittal 96, Change Request 6191, October 24, 2008). CMS recognizes the following as authoritative compendia and lists them in the CMS Manual (Pub. 100-02, Medicare Benefit Policy, chapter 15, section 50.4.5) for use in the determination of a "medically-accepted indication" of drugs and biologicals used off-label in an anticancer chemotherapeutic regimen:

- *American Hospital Formulary Service-Drug Information (AHFS-DI)*
- *National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium*
- *Thomson Micromedex DrugDex*
- *Clinical Pharmacology*

Strategies for Financial Survival

To prepare a strategy for financial survival in 2009, the following action steps require immediate attention:

1. Meet with the nursing (outpatient clinic and ambulatory surgery) and the charge capture team to determine charge description master and procedural changes needed for 2009.
2. Determine the impact of the 1% reduction in reimbursement for Medicare Part B reimbursable medications (a loss of \$10,000 for each \$1 million spent).
3. Determine the impact of the loss of the IVIG preadministration fee, not only to the facility but to the physician's office, and the likelihood that the hospital will receive additional patients seeking therapy.
4. Determine the impact of the loss of pass-through payment on the 15 drugs listed.
5. Meet with the financial team to determine the strategy for coping with these changes.

Additional Resources

Although they are too voluminous to publish here, it is important to access various tables in the final rule which provide valuable information and actual reimbursement rates. These include:

- TABLE 24.—Drugs And Biologicals With Pass-Through Status In CY 2009, <http://www.ashp.org/DocLibrary/Advocacy/GAD/HOPPSTable24.pdf>
- TABLE 26.—Anti-Emetics Exempted From CY 2009 OPPS Drug Packaging Threshold, <http://www.ashp.org/DocLibrary/Advocacy/GAD/HOPPSTable26.pdf>
- TABLE 27.—Drugs And Biologicals Proposed As Packaged But With Final Per Day Costs Above \$60, For Which Separate Payment Will Be Made In CY 2009, <http://www.ashp.org/DocLibrary/Advocacy/GAD/HOPPSTable27.pdf>
- TABLE 31.—HCPCS Codes Unrecognized In CY 2007 Or Cy 2008, Associated Recognized HCPCS Codes, And Status Indicators For CY 2009, <http://www.ashp.org/DocLibrary/Advocacy/GAD/HOPPSTable31.pdf>
- TABLE 34.—CY 2009 Drug Administration APCs, <http://www.ashp.org/DocLibrary/Advocacy/GAD/HOPPSTable34.pdf>
- ADDENDUM B.—Final OPPS Payment By HCPCS Code For CY2009, <http://www.ashp.org/images/AddB.pdf>
- ADDENDUM BB.—Final ASC Covered Ancillary Services Integral To Covered Surgical Procedures For CY 2009 (Including Ancillary Services For Which Payment Is Packaged), <http://www.ashp.org/DocLibrary/Advocacy/GAD/HOPPSAddBB.pdf>
- ADDENDUM D1.—Final OPPS Payment Status Indicators For CY 2009, <http://www.ashp.org/DocLibrary/Advocacy/GAD/HOPPSAddD1.pdf>

Appendix 1. Level II HCPCS Codes Implemented in April and June 2008:

CY 2008 HCPCS Code	CY 2009 HCPCS Code	CY 2009 Long Descriptor	Final CY 2009 ASC Payment Indicator
C9241	J1267	Injection, doripenem, 10 mg	K2
Q4096	J7186	Injection, antihemophilic factor viii/von willebrand factor complex (human), per factor viii i.u.	K2
Q4097	J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg	K2
Q4098	J1750	Injection, iron dextran, 50 mg	K2
C9242	J1453	Injection, fosaprepitant, 1 mg	K2

Appendix 2. CMS Billing Procedure on Uncoded New Drugs

Hospitals now receive 95% of Average Wholesale Price (AWP) on newly approved drugs and biologicals used in an outpatient setting that have not yet been assigned a product-specific Healthcare Common Procedure Coding System (HCPCS) code. Previously, there was no payment for these products until a specific billing code had been approved. To successfully obtain reimbursement for these products, the following steps should be followed:

- Use unclassified drug or biological **HCPCS code C9399**.
- Contact the group purchasing organization to determine pricing, contract status, and other negotiated terms.
- Contact the manufacturer for information on patient assistance programs, reimbursement programs, or assistance that outlines the steps for documentation required for reimbursement.
- Assign a charge description master (CDM) number and a price (billing departments should accept changes at least weekly).
- Link the CDM number to the CMS billing code for new drugs.
- Stay aware of assignment of a designated code to replace this temporary non-specific code. (Unfortunately, no easy-to-use recap is available, just the quarterly CMS Web site updates).
- Submissions to CMS using the wrong code will be rejected by the fiscal intermediary.
- If used in an outpatient setting, ensure that the code assigned matches the billing units being reimbursed. Consider using a crosswalk to automatically correct for this discrepancy.
- Activate the drug in the pharmacy computer drug master file and link it to the CDM number (Do not forget to change miscellaneous codes for actual and designated codes as soon as they are assigned).
- Contact the pharmacy computer vendor if new drug data is not provided on a timely basis
- Avoid miscellaneous CDM numbers and drug entries created "in-house". CMS is highly unlikely to reimburse if these numbers and entries are used.