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For more information, contact:

John T. Bentivoglio

202.626-5591

jbentivoglio@kslaw.com

David J. Bloch

202.661.7963

dbloch@kslaw.com

Laura E. Loeb

202.661.7836

lloeb@kslaw.com

Beverly Lorell

202.383.8937

blorell@kslaw.com

Josh T. O'Harra

202.626.5582

joharra@kslaw.com

M. Kay Scanlan

202.383.8935

kscanlan@kslaw.com

John D. Shakow

202.626.5523

jshakow@kslaw.com

Anna Weinstein

202.661.7973

aweinstein@kslaw.com

**King & Spalding
Washington, D.C.**

1700 Pennsylvania Avenue, NW
Suite 200

Washington, D.C. 20006

Phone: 202.737.0500

Fax: 202.626.3737

www.kslaw.com

CMS Releases Physician Fee Schedule Proposed Rule

Proposed Changes in Self-Referral Law, Approved Drug Compendia, Physician Payments for Recalled Devices, ASP Calculation, Physician Quality Measures

On July 2, 2008, the Centers for Medicare and Medicaid Services (CMS) released the proposed rule for 2008 physician payments and policies. The rule includes a number of changes of interest to manufacturers and providers with respect to the physician self-referral law, new approved drug compendia, payments for physician services involving recalled devices, the calculation of ASP, CAP, physician quality measures, payments for imaging and clinical lab services, among other proposed revisions.

A copy of the complete rule can be found at:
www.cms.hhs.gov/center/physician.asp.

It will be published in the July 12, 2007 *Federal Register*, and comments are due to CMS on or before August 31, 2007.

Overall Impact

CMS projects a 9.9% across the board reduction in Medicare physician payments as required by the sustainable growth rate (SGR) formula specified in the Medicare statute. Congress has intervened the past five years to avert the negative updates resulting from the SGR formula. We anticipate that there will be another last minute one- or two-year Congressional fix later this year, as this change has wide bipartisan support.

In addition, this proposed rule reflects continued changes to the practice expense (PE) relative value units (RVUs) for physician services. 2008 is the second year of a 4-year transition to the new practice expense methodology.



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Physician Self-Referral and Reassignment Provisions

In last year's proposed rule, CMS raised the possibility of refining the physician self-referral and reassignment provisions but declined to make any changes in the final rule. Once again, CMS raises the possibility that it might close some perceived loopholes in these areas. CMS is looking closely at so-called "Pod" labs and "per-click" arrangements and invites comments on these issues. Specifically, CMS is proposing that:

- The professional component (PC) of a purchased diagnostic test be subject to an anti-markup provision similar to that applied to a purchased technical component (TC);
- The anti-markup provision for the PC and TC apply to all arrangements not involving the reassignment of billing rights from a full-time employee of the billing entity;
- The performing physician's or supplier's net charge should be calculated exclusive of any charge that reflects the cost to the performing entity to lease space or equipment from the billing entity;
- The anti-markup provision should not apply to independent laboratories that have not ordered the technical component;
- A physician's space and equipment leases should not include "per click" payments for services to patients whom the physician refers to the leasing entity;
- Percentage compensation arrangements may be used only for personally performed physician services and must be based on revenues received directly from providing the physician services; and
- An entity that owns or controls another entity to which a physician refers patients must "stand in the shoes" of the entity it controls by having the same compensation arrangements as the owned entity.

CMS also invites comments on whether any changes are necessary to the in-office ancillary exception, such as whether the definition of "same building" should be revised or whether any services should *not* qualify for this exception. Further, CMS is interested in whether nonspecialist physicians should be able to use the in-office exception to refer patients for specialized services involving the use of equipment owned by the nonspecialist.

Possible New Compendia for Medically-Accepted Off-Label Uses

CMS is proposing a new process incorporating public notice and comment by which it could identify annually new compendia that Medicare contractors would use in determining medically accepted indications for off-label uses of anti-cancer drugs and biologicals. This new process also could be used to eliminate



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compendia from the list. The proposed process and criteria used to evaluate the compendia reflect recommendations from the Medicare Coverage Advisory Committee (MedCAC).

Under the current Medicare statute, contractors *must* cover any off-label, anti-cancer use of a drug or biological, provided that the off-label, anti-cancer use is listed in an approved compendium. The statute lists three approved compendia: American Hospital Formulary Service-Drug Information (AHFS-DI); American Medical Association Drug Evaluations (AMA-DE) (no longer in publication); and United States Pharmacopoeia-Drug Information (USP-DI) (purchased by Thomson Micromedex). The statute gives the Secretary of the Department of Health and Human Services the authority to name additional compendia to this approved list for coverage under Part B. However, there is no similar authority under Part D.

Costs of Additional Physician Services Created by Device Recalls

Recently, there has been a recall of 73,000 implantable cardioverter-defibrillator (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) because of a faulty capacitor. This follows upon the recall of thousands of ICDs and pacemakers in CYs 2004 and 2005.

For outpatient hospital costs involving the replacement devices, for services furnished on or after January 1, 2007, CMS reduced the payments made to hospitals when the hospital receives a replacement device without cost or with full credit for the device. CMS also proposed a reduction in the Medicare payment for inpatient hospital services in the FY 2008 inpatient proposed rule (72 FR 26479) when hospitals use a recalled or replacement device at no cost or with partial credit.

There are also costs associated with physician monitoring of patients treated with recalled devices. Specifically, manufacturers of the devices that have been recalled typically recommend that patients with the recalled device consult with their physicians in each case and, in some cases, begin a routine of monthly evaluations. Therefore, CMS anticipates that not only could extra visits to physician offices or hospital outpatient departments be necessary, but additional diagnostic tests may also be needed to care for beneficiaries who have the recalled devices. Thus, even when immediate replacement of the device is not required, CMS is concerned that the potential costs to Medicare and to the beneficiary for these unforeseen extra services might be substantial and burdensome.

CMS is requesting comments on ways to identify the additional health care costs and Medicare expenditures associated with device recall actions and exploring what actions would be appropriate in the case of these additional monitoring and related expenses as they relate to both the hospital outpatient and physician payment systems.

Of note, CMS makes no mention of a possible Medicare Secondary Payer (MSP) issue. Arguably, there is an open question as to whether manufacturer offers to incur certain costs in a recall thereby render Medicare as the secondary payer and the manufacturer as the primary payer with respect to certain costs.



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Proposed Average Selling Price (ASP) Changes

The proposed rule addresses only one substantive aspect of manufacturer ASP calculation: treatment of bundled arrangements. In last year's final rule, CMS declined to establish a specific methodology for the treatment of bundled price concessions and instructed manufacturers to rely instead on their own reasonable assumptions.

CMS now proposes that manufacturers, beginning with the first quarter of 2008, "allocate the total value of all price concessions proportionately according to the dollar value of the units of each drug sold under a bundled arrangement." This is almost exactly the same construction as put forward in the Deficit Reduction Act of 2005 (DRA) implementation proposed rule (71 FR 77174 *et seq.*, December 22, 2006).

The definition of "bundled sale" or "arrangement" is equally similar to the language in the proposed Medicaid regulations, with one exception: two new examples of performance requirements giving rise to bundled arrangements ("purchasing patterns" and "prior purchases") are included in the proposed ASP regulation. This suggests a broader concept of a bundle than was articulated in 2006, one that looks backward as well as forward.

The choice of methodology suggests that CMS is attempting to avoid unnecessary computational complexity, and that it values consistency in the treatment of bundled arrangements between Medicare ASP and Medicaid AMP/BP. CMS is very reluctant, however, to speak to many of the outstanding questions regarding this proposed methodology until the previously filed AMP/BP comments are considered and the DRA implementation final rule is issued. In the meantime, CMS invites comment on the proposed treatment (specifically in the context of ASP and its impact on the estimation of lagged price concessions) and on the propriety of Medicare-Medicaid consistency generally.

Part B Drug and Biological Competitive Acquisition Program (CAP)

In this proposed rule, CMS addresses proposed CAP changes due to Section 108 in Division B of the Tax Relief and Health Care Act of 2006 (TRHCA), discusses comments submitted in response to its July 6, 2005 Interim Final Rule with Comment Period, and invites comment on other operational aspects of the CAP, with the intent to incorporate final CAP operational provisions in the upcoming physician fee schedule final rule.

Prior to implementation of the TRHCA, a CAP vendor could not receive payment until the prescription number contained on the vendor drug claim could be "matched" with a prescription number on a physician claim for drug administration in the Common Working File (CWF). Section 108 of the TRHCA requires that, effective April 1, 2007, payment for CAP drugs and biologicals be made upon receipt of a claim for a drug or biological supplied for administration to a beneficiary. The legislation also required CMS to establish a post-payment review process to ensure that payment is made only if the drug or biological had



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been administered to a beneficiary and authorized CMS to recoup any overpayments discovered through post-payment review.

A. The Post-Payment Review Process:

1. Uses statistical sampling to determine whether drugs were administered **and if they were medically necessary**;
2. The designated carrier will initially use the CMS claims processing system to look for a match between the CAP prescription order number on the participating CAP physician's claim and the prescription order number on the approved CAP vendor's claim to track drug administration;
3. The designated carrier will, if necessary, obtain documentation of administration from the CAP vendor and medical records from the CAP participating physician for claims identified for review;
4. If the medical record is not received within 30 days, the CAP vendor drug claim will be denied;
5. Local carrier medical review policies continue to govern CAP medical necessity determinations.

B. Additional Proposed Refinements:

1. The CAP vendor may collect beneficiary copayments and submit claims to supplemental insurers if it verifies with the participating physician's office that the drug was administered. If the CAP vendor later learns that the drug was not administered, it must (within two (2) weeks) refund any payment from the Designated Carrier, a beneficiary and/or supplemental insurer;
2. CMS proposes to refine the CAP appeals process to differentiate prepayment and post-payment review claim denials;
3. The set of exigent circumstances justifying withdrawal from the CAP would be expanded to permit physicians to opt out within 30 days of the election agreement upon a demonstration that remaining in CAP would be a significant burden;
4. CMS seeks comment on the feasibility of narrowing the restriction on transportation of CAP drugs, subject to State law and other applicable laws and regulations. This restriction proved burdensome for many physician practices, including those with limited-hours satellite offices;



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5. The Proposed Rule also seeks comments on potential alternatives to the CAP prescription order that would accurately track administration of specific doses of drugs; and
6. Although CMS does not intend to change its regulations on use of prefilled syringes this year, it seeks comments on whether allowing approved CAP vendors to repackage CAP drugs may be beneficial to beneficiaries, the program, and to the physicians who participate in it. Additionally, CMS is considering whether the CAP vendor should be permitted to supply bevacizumab repackaged in patient-specific doses to avoid wastage in connection with single-use vial purchase for patients with age-related macular degeneration.

Physician Quality Reporting Initiative (PQRI)

Beginning July 1, 2007, if physicians report certain quality measures on their Medicare claims forms, they will receive up to a 1.5% increase in payment for Medicare services from that beginning date through December 31, 2007. This program will continue in 2008 to provide practitioners with financial incentives to meet these standards and offers opportunities for manufacturers able to position their products to be used as a quality measure or as a way to assist physicians (or hospitals as they have their own quality measures) in meeting their quality standards. The same 2007 quality standards will be used for 2008, and others will be added.

The identified quality measures CMS proposes for the 2008 PQRI program will be made final as of the effective date of this final rule (late October or early November 2007). However, as was the case in 2007, the agency *may* make modifications or refinements, such as code additions, corrections, or revisions, to the detailed specifications for the 2008 measures through December 31, 2007.

During 2008, CMS will evaluate and test mechanisms for using registries to collect and report the data generated by physician use of the quality measures.

Imaging Provisions

Section 5102(b) of the DRA of 2005 required reductions in the Medicare payment of the technical component of imaging services provided in a physician office so that payment does not exceed the payment for the same service in a hospital outpatient department. CMS has made a determination of which CPT and alpha numeric HCPCS codes fall within the scope of “imaging services”, as defined by the DRA provision. As stated in the CY 2007 physician fee schedule final rule, in general, CMS believes that imaging services are “those that provide visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury.”

In the CY 2008 proposed rule, the agency does not make any refinements to the definition, nor does it exclude any of the codes on the 2007 list of imaging services subject to the DRA hospital outpatient prospective payment (OPPS) cap provision. However, the agency proposes that certain ophthalmologic



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procedures meet the DRA definition of imaging procedures, but were not included in the original list of imaging services subject to the OPSS cap.

A complete list of codes that identify imaging services defined by the DRA OPSS cap provision was published in Addendum F of the CY 2007 PFS proposed rule (71 FR 49249 - 52).

Like last year and despite much speculation to the contrary, CMS did not propose any changes to the imaging equipment interest rate and utilization rate assumptions in the CY 2008 proposed rule. The rates could remain at 11% and 50% respectively. However, because the agency did address both issues in the proposed rule, and asks for public comment, it has latitude to make a change to either assumption in the final rule. Alternatively, Congress very well may include provisions in the upcoming Medicare legislation mandating that the agency move forward with reducing either (or both) assumption(s).

Proposed Provisions Related to Services Furnished by End-Stage Renal Disease (ESRD) Facilities

Section 623(f)(1) of the MMA directs the Secretary of Health and Human Services to submit a Report to Congress detailing a bundled prospective payment system (PPS) for services furnished by ESRD facilities to Medicare beneficiaries. CMS expects to release the long overdue Report later this summer. Without data from an expanded payment bundle demonstration that has yet to be implemented, there has been concern within the dialysis community that CMS does not have the necessary data to include EPO in an expanded payment bundle. However, CMS states in this CY 2008 proposed rule that a bundled PPS payment would include not only composite rate services, but also separately billable drugs such as EPO, as well as laboratory tests, and other separately billable items.

For CY 2008, CMS proposes the following updates to the composite rate payment system:

- A growth update to the drug add on adjustment to the composite rates; and
- An update to the wage adjustment to reflect the latest available wage data, and a revised budget neutrality adjustment.

Payment for Intravenous Immune Globulin (IVIG)

Based on concerns in 2006 about the availability of intravenous immune globulin (IVIG), a unique product derived from blood plasma, CMS created HCPCS code G0332, Preadministration related services for intravenous infusion of immunoglobulin, per infusion. The RVUs were based on the nonfacility PE RVUs for code G0319, which describes ESRD related services during the course of treatment.

The rationale for the PE valuation was that CMS believed that there were additional physician practice resources expended for IVIG preadministration-related services, particularly clinical labor, that were



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comparable to the PE for the ESRD management code. In 2007, CMS based the RVUs for G0332 on a blend of the PE RVUs for two ESRD codes, G0319 and G0318.

Despite concerns that the existence of the preadministration fee could “further distort the market and provide inappropriate incentives for IVIG utilization”, CMS proposes to continue payment for G0332 only through CY 2008 at the same level of PE RVUs as in CY 2007.

CMS requests that the OIG further study some of the issues raised in its April 2007 report on the IVIG marketplace titled, “Intravenous Immune Globulin: Medicare Payment and Availability” (OEI-03-05-00404). The OIG was unable to determine the underlying reasons that physicians have had problems accessing IVIG products.

Independent Diagnostic Testing Facilities (IDTFs)

CMS in its 2007 physician fee schedule rule established new standards for IDTFs. In the 2008 proposed rule, CMS is considering a number of revisions to these standards. A central proposed revision is that a supervising physician may oversee a maximum of three sites.

Clinical Laboratories

CMS is proposing a reconsideration process with respect to payments for new clinical diagnostic tests with new or substantially revised HCPCS codes assigned after January 1, 2008. Currently CMS uses one of two methods to establish payment for a new lab test. Either CMS sets the payment by crosswalking the new test to a comparable existing test or multiple existing tests or it instructs its contractors to utilize gapfilling where no comparable existing test is available. These methodologies have long injected an element of unpredictability, as contractors often crosswalk new tests to existing tests with similar function, yielding inadequate payment rates for new technologies and leaving manufacturers and testing facilities with no recourse at the contractor or CMS level. CMS proposes a process in which a payment value for a new code, established under either methodology, could be reconsidered in a transparent way.

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If you have questions or concerns relating to the CMS release of the proposed rule for the Physician Fee Schedule, please feel free to call or e-mail Laura Loeb at 202-661-7836 or lloeb@kslaw.com.

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