



# G-2

# Compliance Report



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For Hospitals, Laboratories and Physician Practices

## “Pod” Labs Could Violate Anti-Kickback Law

**P**roposed pathology services joint-venture arrangements—so-called “pod” or “condo” labs—could violate the anti-kickback statute and thus subject pathology companies to administrative sanctions, the Health and Human Services Office of Inspector General (HHS OIG) said in an advisory opinion released December 17 (No. 04-17).

A pathology laboratory proposed entering a series of contracts with urology, gastroenterology, and dermatology physician groups to operate pathology laboratories for each group in an off-site location. The path company would furnish all necessary management and administra-

tive services, equipment leasing, premises subleasing, technical, professional, and supervisory pathology services, and, if requested, billing services for each physician group to operate its own “pod” lab.

The pathology company would enter into four contracts with each physician group: a management agreement, which includes equipment leasing and, if requested, billing services; a sub-lease agreement; a technical personnel agreement; and a pathology services agreement for the part-time services of a pathologist for the provision of all professional and supervisory services necessary to operate the “pod” lab.

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## Lab Proposal On Free Services A Bad Idea

**A** clinical laboratory that proposes to provide free employee services, equipment, and supplies to dialysis facilities could subject itself to sanctions and penalties under the anti-kickback statute, says the Health and Human Services Office of Inspector General (HHS OIG) in an advisory opinion issued November 24.

The lab in question provides testing services to dialysis patients pursuant to service contracts with dialysis facilities. It provides both composite rate tests, which are included in the composite rate that Medicare pays the dialysis facilities and are not separately billable, and noncomposite rate tests, which are separately billable.

Under the proposed arrangement, the lab would provide the services of lab assistants who would prepare specimens for delivery to the lab. The arrangement would have been for services related only to specimen preparation – such as centrifuging, sorting, packing, and shipping. In addition, the lab said it would provide all equipment and supplies needed to prepare specimens for testing at no cost to the dialysis facilities.

In opinion No. 04-16, the OIG noted that lab test preparation services are included in the Medicare composite rate payments received by dialysis facilities, regardless of whether the preparation services are for a composite rate test or a ➔ p. 9



Thomas Bartrum, Esq.

**"Pod" Labs, from p. 1**

Under the management agreement, the physician group will pay the requestor: 1) a flat, monthly fee, which will include the fee for the pathologist's services; 2) a per-specimen fee; and 3) if applicable, a fee for billing and collection services equal to 5% of the total net pod lab revenue. The monthly fee will be set at an amount that takes into consideration historical utilization data.

The pathology company would operate five independent and self-contained path labs within a single building. Each lab would have its own equipment and have separate contracts with the pathology company. While the pathologists and technical laboratory personnel will rotate among the "pod" labs, they would only provide services on behalf of one physician group's "pod" lab while located in that group's subleased space and would only use that physician group's leased equipment.

**OIG Analysis**

In its opinion, the OIG says it has longstanding concerns about certain joint-venture arrangements, especially between those in a position to refer business, such as physicians, and those furnishing items or services for which Medicare or Medicaid pays. It cites a 1989 Special Fraud Alert on joint-venture arrangements and a Special Advisory Bulletin on contractual joint ventures issued in 2003.

According to the OIG, the proposed arrangement presents a number of elements specifically listed as problematic in the Special Advisory Bulletin. For one, the physician group would be expanding into a related line of business that is dependent upon referrals from the physician group. Despite language indicating otherwise in the management agreement, the physician group would not actually participate in the operation of the path or "pod" lab but would contract out substantially all path lab operations, including the professional services necessary to provide the pathology services.

"On the whole, the physician group would commit almost nothing in the way of financial, capital, or human resources to the path lab, and accordingly, would assume no or very little real business risk," the OIG writes.

Based on the facts, the OIG says it cannot rule out the possibility that the pathology lab com-

pany "may be offering the physician groups impermissible remuneration by giving them the opportunity to obtain the difference between the reimbursement received by the physician groups from the federal healthcare programs and the fees paid by the physician groups to the requestor."

If the purpose of the arrangement were to provide remuneration to the physician groups in turn for referrals to the pathology labs or the requestor's affiliated labs, then the anti-kickback statute would be violated, concludes the OIG, which says it expresses no opinion regarding the legality of the proposed arrangement under the Stark Law.

The attorney who represented the pathology company requesting the OIG opinion tells *G-2 Compliance Report* that his client was approached by several physician groups who were interested in pursuing condo lab arrangements. Although the model worked from a Stark Law perspective, the client had concerns about uncertainties under the anti-kickback statute. When it became apparent that the OIG would not issue a favorable advisory opinion, the lab decided to proceed to seek a negative opinion out of concern about the proliferation of "pod" or "condo" labs.

"Although we were hoping that the opinion would be more broadly written," says Thomas Bartrum, a shareholder with Baker Donelson Bearman Caldwell & Berkowitz, P.C. (Nashville, TN) "we do believe there are several broad statements that should give concern to parties that are looking at developing this model."

For instance, Bartrum says he likes the broad language used by the OIG noting that an indication of the parties' intent upon entering into these types of arrangements is that specialists are soliciting these types of deals from both laboratories and pathologists. "Where in the past physicians sent their specimens to labs without any thought of generating revenue, today, physicians are looking at whether revenue can be generated from their ancillary referrals," he says.

In addition, Bartrum notes, the OIG acknowledges that although these arrangements may work on paper, the model raises practical concerns under the Stark Law that the Centers

Don't miss *G-2 Report's* February 10 audioconference: "Putting 'Pod' Labs Under The Microscope: Which Way Are The Feds Heading?" For more information or to register, go to [www.g2reports.com](http://www.g2reports.com)

for Medicare & Medicaid Services (CMS) will need to address. “We are trying to get further guidance from CMS as to whether the condo lab model stretches the intended use of the location requirement of the in-office ancillary services exception,” says Bartrum.

## Resources

- ❖ Thomas Bartrum: 615-726-5720
- ❖ OIG advisory opinion 04-17: [www.oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0417.pdf](http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0417.pdf) ▲

## Feds Launch Investigation Into PTH Testing

**T**he U.S. Department of Justice and the U.S. Attorney’s Office for the Eastern District of New York apparently have launched an investigation into tests used to determine parathyroid hormone (PTH) levels.

Over the past several months, the agencies have issued subpoenas to a number of laboratories and dialysis companies seeking documents related to PTH testing and vitamin D therapies. Patients with kidney disease typically have their PTH levels monitored to see if they need more vitamin D. A low vitamin D level can lead to bone pain and fractures.

PTH testing is ordered by physicians, who then decide if additional vitamin D is necessary. According to Larry Buckelew, president and CEO of Gambro Healthcare, about 75% of Gambro’s patients need the extra vitamin D.

Among the companies that have received subpoenas since late October: Quest Diagnostics, Inc. (Teterboro, NJ) and its test kit manufac-

turing subsidiary, Nichols Institute Diagnostics (NID); Gambro Healthcare (Lakewood, CO); Renal Care Group (Nashville, TN); DaVita Inc. (El Segundo, CA); Bone Care International (Middleton, WI); Abbott Laboratories Inc. (Abbott Park, IL); and Fresenius Medical Care (Bad Homburg, Germany).

PTH testing represents a small segment of revenues for most of the companies. Buckelew says PTH testing accounts for only about 1% of the company’s U.S. revenue and about a half-percent of its revenue globally. Vitamin D therapy brings in between 5% and 6% of the company’s revenue in the United States and 3% of its revenue globally.

According to Quest, revenues from sales of NID’s PTH test kits and related testing are estimated to be less than 1% of consolidated revenues.

All the companies that have received subpoenas say they are cooperating fully with the government’s investigation. ▲

## CMS Clarifies Policy On Lab Billing For TC Of Path Services

**I**ndependent clinical laboratories can continue to bill carriers for the technical component (TC) of physician pathology services furnished to patients of a covered hospital during 2005 and 2006, the Centers for Medicare & Medicaid Services (CMS) clarifies in transmittal 382, issued Nov. 26, 2004.

The Benefits Improvement & Protection Act of 2000 included a “grandfather” provision that allowed independent labs to continue billing Medicare directly for the TC of pathology services to hospital inpatients and outpatients through 2002 as long as those arrangements were in place with a hospital on or before July 22, 1999. CMS later administratively

extended this provision for services furnished in 2003 and 2004. Section 732 of the Medicare Modernization Act further extended this provision (Section 542 of BIPA) for services furnished during 2005 and 2006.

Section 542 of BIPA was implemented through Transmittal AB-01-47, issued on March 22, 2001. This transmittal was renumbered and reissued in December 2002 and remained in effect for 2003, but when it was incorporated into the Internet Only Manual in October 2003, it was not completely accurate. The intent of Transmittal 382, says CMS, is to clarify the existing policy. The transmittal is available at [http://www.cms.hhs.gov/manuals/pm\\_trans/R382CP.pdf](http://www.cms.hhs.gov/manuals/pm_trans/R382CP.pdf). ▲

## Dialysis Co. To Pay \$350 Million In Fraud Settlement

*DaVita Inc. (El Segundo, CA) said December 7 that it has entered into a definitive agreement to acquire Gambro Healthcare for approximately \$3.05 billion. DaVita's announcement contained no reference to Gambro's settlement with the Justice Department.*

**G**ambro Healthcare US Inc. (Lake-wood, CO), one of the country's largest providers of kidney-dialysis services, will pay more than \$350 million in criminal fines and civil penalties to settle allegations of healthcare fraud in the Medicare and Medicaid programs, U.S. Attorney for the Eastern District of Missouri James Martin announced December 2.

Under the settlement, Gambro will pay \$310.5 million to resolve civil liabilities stemming from alleged kickbacks paid to physicians, false statements made to procure payment for unnecessary tests and services, and payments made to Gambro Supply, which Martin called "a sham durable medical equipment company." The settlement also requires Gambro to allocate \$15 million to resolve potential liability for the conduct resolve under the federal agreement pursuant to a preliminary understanding reached with representatives of various state Medicaid programs. In addition, Gambro Healthcare has entered into a comprehensive Corporate Integrity Agreement.

Gambro Supply Corp. has agreed to: plead guilty to criminal felony charges, admit to execution of a healthcare fraud scheme, pay a \$25 million fine, and be permanently excluded from the Medicare program.

Except for the plea regarding Gambro Supply, Gambro Healthcare denies the government's allegations, according to the settlement agreement. The agreement is the

largest fraud settlement reached by the United States Attorney's Office for the Eastern District of Missouri and one of the largest healthcare fraud settlements for the Department of Justice. In 2000, Gambro Healthcare and two of its subsidiaries, Gambro Healthcare Laboratory Services and Dialysis Holdings Laboratory Services Inc., paid more than \$53 million to settle allegations of healthcare fraud.

### Whistleblower Case

The settlement grew out of a whistleblower lawsuit filed in 2001 by Gambro's former chief medical officer, Steven Bander, M.D. As part of his duties, Dr. Bander oversaw medical and nursing services at Gambro's outpatient dialysis centers across the United States. Dr. Bander will receive a portion of the settlement.

The civil settlement resolves allegations that Gambro Healthcare:

- ❖ Provided home dialysis patients equipment and supplies through a "shell" durable medical equipment company, Gambro Supply, in violation of Medicare regulations. By billing in this manner, Gambro Healthcare received a higher rate of reimbursement than it would have received if it had directly submitted the claims for payment, the government alleged. Also, emergency home dialysis supplies were not provided as billed by Gambro, officials charged.
- ❖ Engaged in "hard coding" of diagnostic codes on submitted claims. This practice resulted in the submission of false statements and bills being submitted for ancillary medications and services that were not medically necessary (bone density studies, nerve conduction studies, electrocardiograms, carnitor, epogen, vitamin D, and iron).
- ❖ Hired and compensated physicians as medical directors for their dialysis clinics based on the number and volume of anticipated patient referrals to Gambro clinics and with remuneration, which in many cases exceeded fair market value. This practice violated the anti-kickback statute.
- ❖ Paid its joint-venture physician partners illegal remuneration to either refer or retain their patients at Gambro clinics. 🏠

### Bush Picks EPA Chief To Head HHS

**P**resident Bush has tapped Environment Protection Agency chief Michael Leavitt to be secretary of the Department of Health and Human Services, succeeding Tommy Thompson, who recently resigned.

Bush announced his selection December 13, surprising many in the healthcare industry, who had expected Mark McClellan, M.D., the administrator of the Centers for Medicare & Medicaid Services, to be picked for the position. Bush reportedly was reluctant to pull Dr. McClellan away from his role in overseeing the new Medicare prescription drug law, which takes full effect in 2006.

Leavitt served as Utah's governor for 11 years before Bush appointed him to lead the EPA last year. As a three-term governor, he chaired the National Governors Association. He is married, a father of five, and a devout Mormon.

# COMPLIANCE PERSPECTIVES

## Transfusion Medicine Coding & Reimbursement 2005: We Can Squeeze Blood From a Turnip



*William B. Lockwood, Ph.D., M.D., is chair of the American Association of Blood Banks (AABB) Coding and Reimbursement Committee; associate clinical professor of the University of Louisville Department of Pathology & Laboratory Medicine; and director of Transfusion Services and Tissue/Bone Banks for the University of Louisville Hospital and Norton-Kosair Children's Hospitals Louisville, Kentucky.*

**T**ransfusion medicine services provided by blood centers, blood banks, and transfusion services consist of physician procedures and services, laboratory and outpatient services, blood component manufacturing/storage/dispensing, tissue/bone bank services, and cellular therapy. Clinical laboratories have long had experience with the Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS Level I) for billing tests under the routine sections of chemistry, hematology, microbiology, and others. The hospital transfusion services were comfortable in billing for the blood typing, antibody screen/identification, crossmatching, etc., under the CPT system.

In the past, the blood supplier submitted blood component processing fee charges to the hospital, and the supplier was paid for these components. The patient was charged for usual testing performed by the transfusion services for the blood component, but not for the blood. It was the practice in some blood centers to give “credits” on blood charges if the patient, family, or friends provided a “replacement” donation for the number of units received by the patient. However, in the last 10 years several changes occurred that required a review and revision of transfusion service billing practices:

**1** Hospital laboratories were no longer a “revenue” center, but a cost center to the hospital budget;

**2** Blood charges to the hospital from the supplier began to escalate in order to account for the additional infectious disease testing and stricter regulatory oversight by the Food and Drug Administration (FDA) and other agencies;

**3** The Diagnosis Related Group (DRG)/inpatient prospective payment system (IPPS) for Medicare inpatient beneficiaries

was implemented, followed in August 2000 by the hospital outpatient prospective payment system (HOPPS), which resulted in decreased reimbursement for blood-related services;

**4** Private payers began to emulate Medicare in their reimbursement policies; and

**5** Fraud and abuse in billing charges were filed against several laboratory providers. These changes required those in the blood industry to become actively involved in learning about proper coding and billing practices for their unique services.

### Coding And Billing

Coding and billing practices in blood/tissue bank services are really no different than other laboratory sections. Follow the ABCs for compliance: maintain **accountability** by always doing the right thing (know the rules), perform accurate **billing** so you get reimbursed for doing the right thing (bill for every blood-related activity performed), and ensure **compliance** in billing so you know the right thing is done (perform regular audits).

In addition, you must:

- ❖ Use the correct four-digit revenue code (code to designate location where service was performed: 038X series for in-house collected blood components; 039X series for blood components received from a supplier; 030X laboratory series for CPT/HCPCS Level I transfusion medicine services; 0250 or 0636 for derivatives; and 0278, 0811, 0812, 0814 or revenue code specific for tissue implant surgery);
- ❖ Use the exact CPT/HCPCS Level I transfusion medicine code(s) for *all* technical procedures performed linked to a blood component regardless of transfusion status;
- ❖ Use the appropriate HCPCS Level II alphanumeric code for blood components

- and derivatives (J, P, Q);
- ❖ Designate the correct quantity of blood components/derivative “units” *actually* transfused;
  - ❖ Identify the number of tests performed on the blood component ordered for a patient regardless of transfusion status;
  - ❖ Use the blood component transfusion code (CPT 36430) once per-day, per-patient receiving blood component transfusion(s);
  - ❖ Use correct *International Classification of Disease, Ninth Edition, Clinical Modification* (ICD-9-CM) procedure and diagnosis codes for IPPS billing (procedure codes for inpatients receiving transfusion medicine procedures include 41.0, 99.0, 99.00-99.09); and
  - ❖ Review/revise the facility chargemaster (CDM) at least semi-annually to reflect changes in the Centers for Medicare & Medicaid Services (CMS) coding requirements.

Wastage and other administrative costs are attributed to hospital overhead and cannot be billed. Mark-ups are allowed and should be used to accommodate such transfusion medicine costs (typical hospital mark-ups for blood components average 2-3X supplier charges). This also allows for spreading the cost-loss of untransfused autologous red blood cells (if the component was not given to the patient, do not bill the patient a “P” code but only the codes for the technical services performed on the component such as typing, crossmatching, etc.). Autologous blood also includes intraoperative collections and may be performed by the hospital transfusion service. Various blood component collection codes (appropriate P code and CPT 86891) should be billed for these procedures.

To prevent unintended billing errors, hospital transfusion services should perform blood and blood component billing compliance audits monthly. Review of UB-92 claims forms for correct service days, codes, descriptors, and charges can determine underbilled, overbilled, or uncredited patient charges and assist in determining the cause of such discrepancies (hospital coders, laboratory/hospital information systems, CDM errors).

#### Changes Between 2003-2004

CMS released several revised HOPPS codes on Nov. 1, 2003, for transfusion medicine

services:

- ❖ All blood component C-codes were converted to P-codes (P9051-P9060);
- ❖ The P9011 code for splitting (aliquoting) blood components was given a “K” status indicator, allowing for reimbursement in 2004 for this activity (use P9011 for the “blood component” aliquoted *and* CPT 86985 to capture the technical services needed to split the unit such as bags, syringes, and sterile connections); and
- ❖ National Correct Coding Initiative (NCCI) edits for comprehensive/component and mutually exclusive blood-related codes were revised to allow for the use of CCI modifiers where appropriate (*e.g.*, you cannot bill a patient receiving an irradiated blood component for inventory waste management who did not medically require an irradiated component – use modifier 1);

Also, CMS had proposed an 11% reduction in reimbursement for HOPPS blood-related services in 2004, but payments were frozen at the 2003 rates. As CMS reimbursement rates are based on historical claim charge databases, it is imperative for the blood community to accurately code for all transfusion medicine services to ensure that realistic reimbursement is received in the future. Only 47% of hospitals reported separate costs and charges in the two cost centers specific for blood on their CY 2003 annual cost reports.

#### Changes for 2005

On Aug. 16, 2004, CMS issued a proposed rule for CY 2005 HOPPS in which payment for blood and blood components/derivatives would continue to be paid separately using the ambulatory payment classification (APC) codes. As payment for transfusion medicine services is based on the APC category, a proposal was made to allocate each blood component/derivative to a separate APC (rather than have several “comparable” components assigned to an APC). Such a change would allow for more reasonable reimbursement for these blood components. The proposed rule also reduced significantly (by an average of 14%, but some components were to be reduced up to 48%) the reimbursement for “low-volume” blood components (defined by CMS as less than 1,000 components billed per year, with plasma frozen between eight

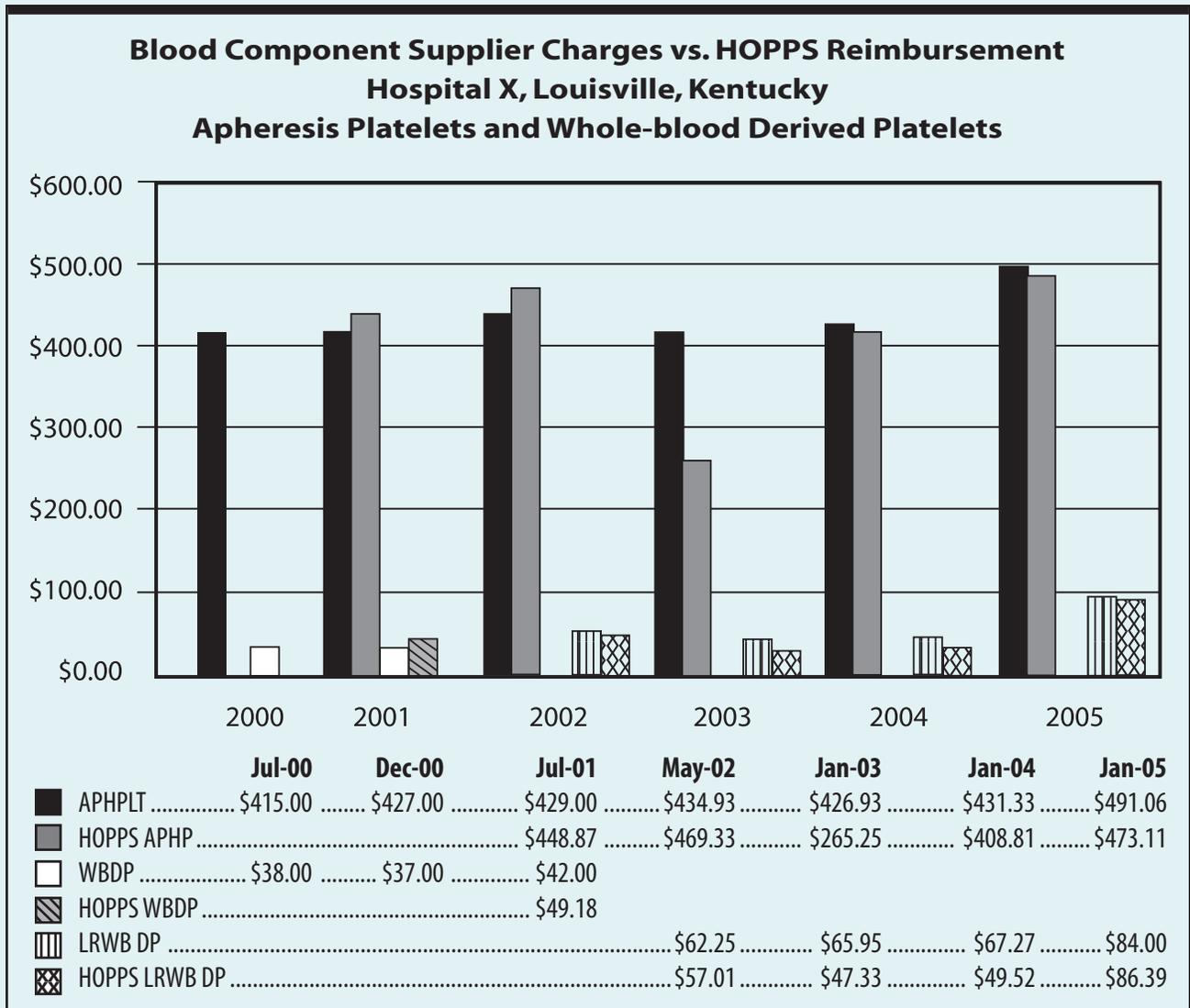
to 24 hours the most affected in this category). CMS received many comments on this proposed rule indicating that the hospital charge-to-cost reports (CCR) used to adjust claim charges to cost for blood were too low, which resulted in underestimation of the true costs for blood. Also, low-volume blood claims represented a small sample size, and those commenting requested review of these components.

As a result of the comments CMS received, the final HOPPS released on Nov. 15, 2004, improved the accuracy of payments made for blood and blood components. CMS will use a new method for calculating appropriate blood payment rates and increase the low-volume plasma component payment by using a 50/50 blend of the median costs used for payment in 2004 and the medians developed for 2005. These changes resulted in an

average overall increase in blood reimbursement of 20% beginning Jan. 1, 2005.

It's clear that for one of the author's hospitals, charges for the most utilized blood components (leukoreduced red blood cells/LRRBC and apheresis platelets/APHPLT) have steadily increased during the last few years and showed an average of 10% to 15% increase from 2004 to 2005. This hospital converted to 100% leukoreduced whole-blood derived platelets (WBDP) in 2002.

The chart below compares the blood supplier's charges for platelet components with the HOPPS reimbursements. Reimbursement has trended upward but still does not cover the costs to the hospital for these components. This gap would have been much greater had it not been for the efforts of various industry organizations (AABB, Ameri-



can Red Cross/ARC, America's Blood Centers/ABC, College of American Pathologists/CAP, American Society for Hematology/ASH, AdvaMed, and others) to educate CMS on the impact reduced reimbursement would have on the industry and patient care. The addition of many new blood and blood component HCPCS Level II codes since 2000 has allowed for more accurate billing of transfusion medicine services and improved reimbursement levels.

#### **Changes in Cellular Therapy**

With the increasing utilization of hematopoietic stem cell and cord blood components in bone marrow transplant programs, the blood bank or transfusion service participation in these programs has also increased. Cell collection, processing, storage, and distribution may be performed in part or in toto by these facilities. CPT codes 38204-38242 should be used as appropriate for the services/procedures performed. Several of these codes have been added or revised since 2000.

#### **Changes in Therapeutic Apheresis**

Many blood centers and transfusion services provide therapeutic apheresis services for hospitals. Since 2000, several new codes were added and packaged in APCs based on charge data available to CMS during this period (CPT 36511-36522). A major change for 2005 is the movement of CPT 36515 (therapeutic apheresis with extracorporeal immunoadsorption and plasma reinfusion) from APC 0112 (Apheresis, Photopheresis, and Plasmapheresis), which pays \$2,127, to APC 0111 (Blood Product Exchange), which pays \$725. ASH and AABB will continue to work with CMS to reverse this change in APC allocation.

#### **Changes in IPPS for 2005**

In the inpatient setting, blood and blood components are not reimbursed separately, but are part of the inclusive DRG payment for each hospital stay based on procedure and diagnosis codes. On Aug. 11, 2004, CMS published the final rule for IPPS reimbursement effective FY 2005 (Oct. 1, 2004), which increased the overall DRG payments by 5.8%. The agency also introduced the concept of linking "quality services" in patient care to reimbursement. Those hospitals participating by submitting specified quality data to CMS may see an increase of 3.3% in full market basket reimbursement.

The blood industry is collaborating to procure accurate national median cost data for blood and blood component collection, processing, testing, storing and distribution. Only with such information will CMS be able to accurately determine market basket costs used in determining reimbursement rates.

#### **Changes for the Medicare Beneficiary**

Under previous payment systems, beneficiary coinsurance was set at 20% of the hospital's charges, which were often significantly higher than the Medicare payment rate. The HOPPS final rule reduces the maximum coinsurance rate for outpatient services to 45% of the total payment to the hospital. This cap will be gradually reduced in future years until all services have a coinsurance rate of 20%. This should also enhance reimbursement to the hospital by decreasing the write-offs for non-payment of coinsurance.

#### **Future Initiatives**

AABB and industry partners have made progress in advising CMS about deficiencies and inaccuracies in transfusion medicine coding and reimbursement, and important changes have been made, particularly in the HOPPS rules. Work continues by these agencies to make the HCPC coding system more user-friendly, both in the IPPS and HOPPS, by proposals to: streamline coding activities; allow for current/future technologies, such as electronic crossmatching, volume reduction and pathogen inactivated blood components; acquire accurate and current cost data associated with blood manufacturing, testing, storing, preparing, and issuing; and transfuse safe blood components to our patients.

Can we squeeze blood from this turnip? Yes, if we all work as a team to develop improved coding and reimbursement policies and regulatory processes for blood/tissue components, derivatives, and related clinical activities, which are unambiguous in the interest of providing the highest quality transfusion medicine treatment modalities to those in need of our services.

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**Lab Proposal On Free Services**, *from p. 1*

noncomposite rate test. Medicare does not make separate payments for administrative tasks associated with laboratory tests, such as collecting, preparing, and handling specimens.

**Discounted Services**

In the opinion, the OIG noted that its position on the provision of free or below-market goods or services to actual or potential referral sources is longstanding and clear: Such arrangements are suspect and may violate the anti-kickback statute, depending on the circumstances. Specifically, the OIG referred to a 1994 Special Fraud Alert, “Arrangement for the Provision of Clinical Laboratory Services” (59 Fed. Reg. 65372).

“The Special Fraud Alert explained that when a laboratory offers or gives an item or service for free or less than fair market value to a referral source, an inference arises that the item or service is offered to induce the referral of business,” the OIG said.

“Also, with respect to laboratory pricing at dialysis facilities, the Special Fraud Alert identified suspect ‘swapping’ arrangements where a laboratory offers discounts to a dialysis facility for composite rate tests payable out of the facility’s pocket, in exchange for referrals of all or most of a dialysis facility’s noncomposite rate tests billable by the laboratory directly to Medicare or other federal healthcare programs. For the reasons set forth below, the proposed arrangement has all the hallmarks of the disfavored arrangements described in the Special Fraud Alert.”

**I**n the provision of the lab assistant, along with all the necessary testing supplies, to the dialysis facilities at no cost would be a tangible benefit to the dialysis facilities, according to the OIG. It is likely that most, if not all, of the services provided by the lab assistants would substitute for services currently provided by the dialysis facilities at their own expense and for which they would be receiving reimbursement through their composite rate payments. Thus, there would be a financial benefit to the dialysis facilities—the receipt of free services and supplies for which the dialysis facilities would otherwise be obligated to incur costs.

In these circumstances, an inference arises that the free services and supplies are intended to influence the dialysis facilities’ selection of a laboratory, the OIG says. By capturing referral streams from the dialysis facilities, the lab would likely be able to generate substantial revenue, because dialysis patients typically need lifetime laboratory testing services associated with their receipt of dialysis services. Further, the OIG notes that it discerns no safeguards to rebut the inference that the free goods and services would be intended to induce referrals or to reduce the risk that the arrangement is designed to induce referrals.

**2**The free services and supplies may be viewed as a price reduction or discount on the lab’s composite rate tests, says the OIG. There is a risk that the lab would be offering a functional “discount” to the dialysis facilities in exchange for the referral of noncomposite rate tests to the lab. In fact, the circumstances surrounding the proposed arrangement suggest that a nexus may exist between the free services and supplies and referrals of other federal healthcare program business. Both parties have obvious motives for agreeing to swap nonmonetary “discounts” on composite rate business for referrals of noncomposite rate business: the dialysis facilities to maximize expense recoupment under the composite rate systems and the lab to secure lucrative business in a highly competitive market.

Any evaluation to determine whether the effect of such a “discount” would result in swapping is more difficult where the discount is nonmonetary, according to the opinion. Thus, in this case, there is greater risk that the arrangement as a whole could involve a nexus between the composite rate business and the noncomposite rate business. In connection with items or services provided to the dialysis facilities, the presence of such a “discount” arrangement is particularly suspect under the anti-kickback statute.

**Resource**

Advisory opinion No. 04-16 is available at [www.oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0416.pdf](http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0416.pdf) 🏠

## MedPAC May Recommend Eliminating Whole-Hospital Exception From Stark Law

**T**he Medicare Payment Advisory Commission (MedPAC) may propose that Congress eliminate the whole-hospital exception from the physician self-referral law, commonly known as the Stark law, in an effort to prevent doctors from billing Medicare for referrals to their own hospitals.

The draft recommendation was one of many discussed at the group's December 9 meeting in Washington, DC. The recommendation also would call for grandfathering in existing specialty hospitals.

The Stark law broadly prohibits doctors from referring patients to facilities in which they have an ownership interest. However, the whole-hospital exception permits such referrals if doctors are invested in the whole hospital, rather than a specific department or practice area. Currently, the whole-hospital exception allows doctors to bill Medicare for referrals they make to specialty hospitals in which they have ownership interest.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) imposed an 18-month moratorium on physician referrals to certain doctor-owned specialty hospitals so that Congress would have an opportunity to review the financial impact of these hospitals on community hospitals with which they compete. The moratorium expires in June 2005.

Another recommendation would permit gainsharing arrangements between doctors and hospitals. MedPAC staff said such arrangements would allow doctors and hospitals to share the savings from cost-reduction efforts

and encourage physicians and hospitals to cooperate in efficient, quality care delivery. Gainsharing typically involves hospitals paying doctors to cut healthcare costs by reducing or limiting services to Medicare patients.

MedPAC staff members acknowledged, however, that the Department of Health and Human Services Office of Inspector General prohibits hospitals from paying physicians to reduce care to beneficiaries. Specifically, such activity is banned by the civil monetary penalties law.

### DRG Overhaul

The commission may also recommend that Congress make major changes to the way Medicare reimburses hospitals by overhauling the diagnosis-related group (DRG) system. Currently, the DRG system generally reimburses hospitals based on fixed amounts for specific diagnoses, regardless of severity. The draft recommendations from MedPAC include changes that would allow the DRG system to account for severity and diminish incentives for physician owners to choose patients based on profitability.

Among specific policy changes called for in the draft recommendations were refining broad DRG definitions and adjusting relative values used to account for the hospital resources typically used by patients in individual DRGs. The MedPAC staff noted that the DRG-related recommendations could create administrative difficulties for the Centers for Medicare & Medicaid Services, but otherwise would be budget-neutral.

### Resource

MedPAC: [www.medpac.gov](http://www.medpac.gov) 🏠

## Lab NCD Changes Take Effect January 1

**T**he Centers for Medicare & Medicaid Services (CMS) on November 26 announced several changes to the lab national coverage determination (NCD) software that will be included in the January 2005 release:

**I**n accordance with coding analysis published July 26, 2004 (<http://cms.hhs.gov/mcd/viewdecisionmemo.asp?id=127>), CMS is deleting ICD-9-CM code V72.82 from the list of codes covered by Medicare for the urine culture and serum iron studies NCD. Cover-

*The draft recommendations are expected to undergo changes before MedPAC's final report to Congress, due in March 2005.*

age for this code will terminate for services furnished on or after Jan. 1, 2005.

**2**In accordance with the coding analysis published July 27, 2004 (<http://cms.hhs.gov/mcd/viewdecisionmemo.asp?id=132>), the agency is adding code V10.41, personal history of malignant neoplasm, cervix uteri, and V10.42, personal history of malignant neoplasm, other parts of the uterus, to the list of codes covered by Medicare for the tumor antigen by immunoassay CA-125 NCD. Coverage for these codes will begin for services furnished on or after Jan. 1, 2005.

**3**In accordance with the coding analysis published July 28, 2004 (<http://cms.hhs.gov/mcd/viewdecisionmemo.asp?id=131>), CMS is removing diagnosis code V43.60, unspecified joint replaced by other means, from the list of covered codes for the prothrombin time (PT) test NCD. Coverage for this code will terminate for services furnished on or after Jan. 1, 2005.

**4**In order to accommodate the new cardiovascular and diabetes screening benefits that were added to Medicare by the Medicare Modernization Act of 2003 (MMA), CMS is removing the following codes from the list of ICD-9-CM codes not covered by Medicare: V77.1, V81.0, V81.1, and V81.2.

**5**In order to implement the new cardiovascular screening benefit that was added to Medicare by the MMA, the agency is subdividing the lipid NCD edit into two parts. It is adding codes V81.0, V81.1, and V81.2 to the list of codes covered by Medicare for CPT codes 80061, 82465, 83718, and 84478. The covered codes list for the remaining CPT codes in the lipid NCD (83715, 83716, and 83721) remain unchanged.

**6**In order to implement the new diabetes screening benefit that was added to Medicare by the MMA, CMS is dividing the blood glucose NCD into two parts. Diagnosis code V77.1 is added to the list of codes covered by Medicare for CPT code 92947. The covered codes for the remaining CPT codes in the blood glucose NCD (82948 and 82962) remain unchanged.

#### Resource

Transmittal 380: [http://www.cms.hhs.gov/manuals/pm\\_trans/R380CP.pdf](http://www.cms.hhs.gov/manuals/pm_trans/R380CP.pdf) 🏠



#### Payment for Referred Lab AMCC Tests

**E**ffective April 1, 2005, carriers must calculate the amount payable for each locality in which a test or panel is performed when one or more automated multi-channel chemistry (AMCC) test/panel is referred to another laboratory for processing, according to Transmittal 372, issued by the Centers for Medicare & Medicaid Services November 19.

Lab tests covered under Medicare may be billed either individually or as an organ/disease panel. The carrier/intermediary must group together the individual tests when billed separately, or as components of any organ/disease panels, and consider the price of all the related AMCC tests performed on the same day by the same physician/supplier, for a particular beneficiary. (Medicare covers 22 AMCC tests, when reasonable and necessary).

Under current payment guidelines for laboratory AMCC tests/panels, contractors do not distinguish between tests/panels that were performed by the billing laboratory and tests/panels that were referred to another laboratory and billed by the referring independent laboratory when calculating the amounts payable.

However, beginning April 1, 2005, carriers will have to calculate the amount payable for each locality in which a test or panel is performed when one or more AMCC test/panel is referred to another lab for processing. Transmittal 372, available online at [http://www.cms.hhs.gov/manuals/pm\\_trans/R372CP.pdf](http://www.cms.hhs.gov/manuals/pm_trans/R372CP.pdf), details the process that carriers should use in calculating the payment amounts. 🏠

**OIG Claims \$30 Billion In Savings:** The Department of Health and Human Services Office of Inspector General (HHS OIG) claims it saved American taxpayers almost \$30 billion in fiscal 2004: \$27.3 billion in implemented recommendations and other actions to put funds to better use; \$754.2 million in audit receivables; \$8.3 million in additional audit recoveries; and \$1.9 billion in investigative receivables. The OIG reported exclusions of 3,293 individuals or entities for fraud or abuse of federal healthcare programs; convictions of 533 individuals or entities; and 268 civil actions. The OIG Semiannual Report to Congress is available at <http://oig.hhs.gov/publications/docs/semiannual/2004/SemiannualFall04.pdf>.

**TAP Payouts Exceed \$1 Billion:** Drug company TAP Pharmaceutical Products Inc. will pay \$150 million to settle allegations that it illegally marketed and artificially inflated the price of its cancer drug, Lupron, according to an attorney representing health insurers and consumers who alleged they were overcharged for the drug. A final hearing on the settlement will be held in April 2005. The latest settlement, which resolves several civil lawsuits brought against TAP by consumers and insurers since 2001, means that the company will have paid more than \$1 billion to resolve

charges related to Lupron marketing practices.

**OIG Seeks Safe Harbor Suggestions:** The Department of Health and Human Services OIG is asking the healthcare industry for recommendations on developing new or modifying existing anti-kickback safe harbors and creating new special fraud alerts, according to a December 10 *Federal Register* notice. The OIG is required by the Health Insurance Portability and Accountability Act of 1996 to solicit such proposals annually. Comments must be submitted to the OIG no later than 5 p.m. on February 8. For more information, contact Joel Schaer, OIG regulations officer, 202-619-0089.

**Hospital Faculty Reaches PATH Settlement:** In one of the last settlements of its kind in an almost decade-long inquiry by the U.S. Department of Health and Human Services into billing practices at medical teaching hospitals, 20 faculty practice corporations affiliated with Loma Linda University Hospital in Southern California November 29 paid \$2.2 million to settle allegations that they submitted false claims to Medicare during four years in the 1990s. The investigation of the Loma Linda faculty practice groups, part of the nationwide Physicians at Teaching Hospital (PATH) initiative begun by the HHS OIG in 1995, covered all billings by the group between June 30, 1992, and June 30, 1996, and was self-conducted by the Loma Linda faculty groups. 🏠

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