



# G-2

# Compliance

# Report



Vol. IX, No. 10, Nov.-Dec. 2007

## For Hospitals, Laboratories and Physician Practices

Kimberly Scott, Senior Editor,  
kscott@ioma.com

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### San Diego Selected as First Competitive Bidding Site

**D**espite widespread opposition to the test, the Centers for Medicare & Medicaid Services (CMS) has selected the San Diego-Carlsbad-San Marcos, California, metropolitan area as the first of two locations for a competitive bidding demonstration for clinical laboratory services provided to fee-for-service Medicare beneficiaries.

The demonstration, mandated by the Medicare Modernization Act of 2003, is designed to determine whether competitive bidding can be used to provide laboratory services under Medicare Part B at fees below current Medicare payment rates.

CMS says it will hold a bidder's conference on Oct. 31, 2007, in the San Diego-Carlsbad-San Marcos area to help labs there understand how the project will be implemented. Bidders will be

required to submit a bid price for each Health Care Procedure Coding System (HCPCS) code in the demonstration test menu.

Bidding laboratories will be asked to identify demonstration tests that they do not perform and will be asked to explain their plans for responding to requests for those tests (for example, subcontracting and referrals). Bidding labs will also have to provide information on ownership, location of affiliated laboratories and specimen collection sites, CLIA certification, laboratory finances, and quality.

The demonstration will last for three years in each demonstration site or competitive bid area (CBA). CMS has said it anticipates selecting multiple "winners" in each CBA and expects to announce winners sometime this winter, *Cont. on p. 2*

### OIG Issues Work Plan for 2008

**M**edicare payments to physicians, including those for services provided at institutions in which doctors have a financial interest, will be the subject of a number of audits and evaluations in the coming year, according to the Department of Health and Human Services Office of Inspector General's fiscal year 2008 work plan, published October 1.

Among such reviews will be

a look at Part B payments to physicians for diagnostic X-rays in hospital emergency departments, in particular because of growing concerns about the cost and utilization of diagnostic imaging services.

The OIG also said it would review financial arrangements under which magnetic resonance imaging (MRI) services are provided pursuant to the Medicare *Cont. on p. 9*

**First Competitive Bidding Site**, from page 1 with the actual demonstration to begin in spring 2008.

Industry reaction to CMS's announcement was swift. Alan Mertz, president of the American Clinical Laboratory Association (ACLA), said that for Medicare beneficiaries, the demonstration is "more trick, than treat, as they will find access to high-quality laboratory services compromised." ACLA and other groups representing clinical laboratories have long opposed the demonstration, saying it will result in less access, lower quality, and less competition.

CMS officials told lawmakers recently that it anticipated 10 to 13 labs would be required bidders in each CBA, although ACLA estimates there may be about 50 independent and hospital outreach labs that meet the definition of a required bidder in the San Diego area. Required bidders are defined as those organizations that expect to supply at least \$100,000 annually in demonstration tests to Medicare beneficiaries residing in the CBA during any year of the demonstration. Required bidders that bid and win will be paid under one demonstration fee schedule for services provided to beneficiaries residing in the CBA for the duration of the demonstration.

Nonrequired bidders are defined as laboratories that are not exempt from the demonstration but have the option of participating in the bidding process. Nonrequired bidders that do not bid, as well as those that bid and win, will be paid under the demonstration fee schedule for the duration of the demonstration. Nonrequired bidders that choose to bid and *do not win will not* receive payment for services provided to beneficiaries residing in the CBA during the demo.

#### **CMS Modifies Project Design**

CMS has made a few changes to the project design since it held an Open Door Forum on July 16. Linda Lebovic, project officer, described those changes October

11 during Washington G-2 Report's 25th annual Lab Institute, held in Arlington, Virginia. Among the more recent changes:

**1**Laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services in the competitive bidding area will not be required to bid but will be paid at the demonstration fee schedule for demonstration tests otherwise paid under the Part B Clinical Laboratory Fee Schedule.

**2**A nonwinning laboratory may serve as a reference laboratory to laboratories participating in the demonstration. However, they would not be allowed to bill Medicare directly for demonstration tests performed for Medicare fee-for-service beneficiaries residing in the competitive bid area.

**3**Laboratories must bid on 303 HCPCS codes, which CMS says represents the top 99% of tests paid under the Part B Clinical Laboratory Fee Schedule based on volume and payment in 2006. CMS initially planned on requiring labs to bid on 358 codes.

#### **Repeal Effort Gains Momentum**

Despite CMS's selection of a competitive bidding area, the laboratory industry has not given up on efforts to win congressional repeal of the demonstration. In late September, three senators—Ken Salazar (D-CO), Pat Roberts (R-KS), and Maria Cantwell (D-WA) introduced a bill, S. 2099, to repeal the project. All three senators serve on the Senate Finance Committee, which has jurisdiction over Medicare and the competitive bidding demonstration.

Similar legislation, H.R. 3453, was introduced in the House August 4 by Small Business Committee Chairwoman Nydia Velazquez. That measure has since gained additional support, with the addition of four cosponsors: Reps. Diana DeGette (D-CO), Charles Boustany Jr. (R-LA), Bart Gordon (D-TN), and Jim Matheson (D-UT). 🏛️

## Payment Issues Top Medicare Agenda at Lab Institute

**P**ayment for pathologists and clinical laboratory services topped the Medicare policy agenda at Washington G-2 Report's Lab Institute 2007, held in Arlington, Virginia, October 10-13.

Debbie Curtis, chief of staff for Rep. Pete Stark (D-CA), told attendees that she expects Congress to block a planned physician fee cut for 2008 when it takes up a broad Medicare bill later this year.

The House has already approved a measure that would prevent a 10% cut in Medicare physician fees scheduled to take effect January 1 and grant a 0.5% increase in 2008 and 2009. The ball is now in the Senate's court, said Curtis.

One area of disagreement is how to pay for the fix, estimated to cost \$20 billion in 2008 and 2009. Stark thinks some of the savings required under congressional pay-as-you-go rules could be captured by cutting the 12% higher pay rate enjoyed by Medicare managed care plans, she noted. The House approved reducing plan payments to 100% of fee-for-service payments.

John Scott, vice president of the division of advocacy for the College of American Pathologists (CAP), emphasized the urgency of replacing the SGR (sustainable growth rate) formula used to calculate the physician fee update.

"Physicians face cuts of 12% in 2010, and by 2015, the current formula will cut payments by 37%," he said. "By comparison, if payments were tied to the Medicare Economic Index, payments would increase by 22%."

CAP also is lobbying to ensure that the "grandfather" protection for independent lab billings is included in final Medicare legislation this year, Scott said. The Centers for Medicare & Medicaid Services

(CMS) has proposed ending such billings as of Dec. 31, 2007. The House approved a two-year extension, through 2009. CAP and lab groups support bills that would make the protection permanent (S. 458 and H.R. 1105).

The "grandfather" exception applies to independent labs that billed Medicare separately for the technical component of pathology services provided to hospital inpatients and outpatients as of July 22, 1999 (the date when CMS first proposed to end this policy). The agency contends that Medicare pays for the technical component (TC) in the hospital's DRG payment, and labs should get reimbursed by the hospital, not Part B.

### Paying for Lab Services

The current system that Medicare uses to pay for lab services is outdated and needs to be changed, argued representatives from the Clinical Laboratory Management Association (CLMA), the American Society for Clinical Laboratory Science (ASCLS), and AdvaMed.

Although many in the lab industry agree that the system is outdated, a survey completed by Lab Institute participants prior to the conference reflected caution about switching from the current lab fee schedule. Roughly half of those responding said they would rather stick with the present payment method they know than risk getting an alternative that could turn out to be worse.

AdvaMed backs a bipartisan bill (H.R. 1321, introduced March 5) that would require a consensus-driven approach to determining fees for molecular diagnostics, starting with the gap-fill method, said Teresa Lee, vice president of payment and policy for AdvaMed. Relying on the crosswalk method is flawed, opponents argue, because the fee schedule lags behind new technologies and does not reward their value, raising barriers to innovation and beneficiary access.

*"It's better for us to go to Congress with lab payment alternatives than to have them come from CMS or Congress"*  
—Jeffrey Boothe

Medicare lab fees were established in 1984, based on 1983 charge data. When considered in light of fee limits subsequently enacted by Congress, the fee schedule is out of date, Lee said.

AdvaMed favors a demonstration to test a new payment scheme for molecular diagnostics. It would reflect value in patient care management, resource use, stakeholder involvement, administrative efficiency, and overall cost savings, Lee said, and would have no geographic or site-of-service limits.

In arguing against the current lab fee schedule, Jeffrey Boothe, an attorney with Holland & Knight LLP and legal counsel to CLMA, emphasized that it reflects only data from independent labs and is based on 1983 prevailing charge data and on technologies in use at the time. Since then, there has been an almost complete shift to automation for many tests, and some that were esoteric in 1983 (like TSH) are now routine, he said. Moreover, the Consumer Price Index used to update the fee schedule is based on general, not

lab-specific cost factors.

CMS can't change the lab fee schedule administratively, Boothe noted, and urged the audience to support CLMA-ASCLS efforts to get Congress to legislate a change. The groups are working to get bills introduced in the House and Senate to build on H.R. 1321 by requiring a negotiated rule-making process to set Medicare fees for new tests. Congress has used this process several times before to resolve thorny Medicare issues, such as to establish uniform national coverage policies for frequently ordered lab tests and to revise fees for ambulance services.

"It's better for us to go to Congress with lab payment alternatives than to have them come from CMS or Congress," Boothe said. "The status quo is no longer acceptable. Costs to providers have increased, and fees have not been updated to reflect this. The lab industry has experienced real reductions in reimbursement since 1994, and the fee schedule pays less today than five years ago and doesn't reflect the marketplace." 🏛️

### Washington G-2 Reports Expands Web Site: [www.g2reports.com](http://www.g2reports.com)

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# COMPLIANCE PERSPECTIVES

## Compliance in Billing Transfusion Medicine 2007



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

**T**ransfusion medicine services have continued to expand over the past five years to include new blood components, increased use of cellular therapy procedures, advances in technology for perioperative autologous blood collection and administration, and molecular diagnostic testing. Coding and billing requirements have had to keep pace with these patient services. Payment for transfusion medicine activities, both inpatient and out-of-hospital, have lagged behind the actual costs and charges. Without correct billing of blood components, blood derivatives, transfusion medicine services, and cellular therapy activities, facilities will continue to see reduced payments by government and private payers.

There are many groups in the blood industry that have come together to collect data on inpatient and out-of-hospital patient blood costs, as well as actual transfusion medicine processes and procedures, to present to the Centers for Medicare and Medicaid Services (CMS) for review. The groups represent the major "stakeholders" in transfusion medicine and include the AABB, America's Blood Centers (ABC), American Red Cross (ARC), College of American Pathologists (CAP), American Society for Clinical Pathology (ASCP), American Society of Hematology (ASH), American Society for Apheresis (ASFA), and Advanced Medical Technology Association (AdvaMed). Such unity in purpose to "educate" CMS on the field of transfusion medicine has produced improvements both in the language of codes available for use by providers and reimbursement levels for blood-related services.

### **Coding Changes for Transfusion Services**

In 1997 there were a total of 35 Current Procedural Terminology (CPT) codes (Level I Healthcare Common Procedural Coding System-HCPCS) available for use in identifying transfusion services provided to patients. These codes are for services such as blood typing, screening for unexpected antibodies, antibody identification, crossmatches, and other services. There were no codes available for the blood product(s) being transfused to the patient, and, therefore, no means of billing for the cost of the component(s). From 1997 to 1999, the groups mentioned above had discussions with CMS to develop such codes.

With the publication by CMS of the Hospital Outpatient Prospective Payment System (HOPPS) in 2000, HCPCS Level II codes (21 P codes for blood components) were made available. Continued communication with CMS allowed for the addition of new HCPCS codes, and today there are 37 Level I and 55 Level II blood-related codes. Included in the CPT codes were new codes for volume reduction of blood or blood products (CPT 86960) and electronic crossmatch (CPT 86923).

The transfusion services had a means for billing blood products and services, but confusion arose as to the proper use of certain codes. Several areas of uncertainty as to how to use codes for autologous blood, aliquoting (splitting) blood components, irradiated blood components, freezing/thawing blood components, and purchased versus nonpurchased blood and other miscellaneous procedures created a need for guidance from CMS on

proper billing of these items. Again, the blood industry discussed with CMS the appropriate use of these codes, and in March 2005, CMS published Transmittal 496 as a means to clarify their intended use of certain codes.

#### **Billing for Blood Processing Versus Blood Product Costs**

Transmittal 496 instructed providers of blood components to use the HCPCS Level II code(s) for the blood component transfused, the number of units transfused, line item date of service, and the Revenue Code 39X if the provider “did not purchase the blood” (using the revised UB-92 claims form, now called UB-04, effective May 23, 2007). This rule applied to most blood suppliers and their client facilities as the charge to the facility was for processing and handling, not a charge for the liquid blood itself.

For those rare facilities that still charged a fee for the liquid blood (usually under the supplier’s requirement of a “replacement fee”) and processing and handling charges, a different coding was required. The client facility must code the blood transfused using the appropriate HCPCS Level II code and add a modifier (-BL), the number of units transfused, charges for the blood, line item date of service, Revenue Code (RC) 38X, and, plus the HCPCS codes with -BL modifier, processing and handling charge for the blood, number of units transfused, line item date of service, and the RC 39X. The date of service was clarified to be the date the blood component was transfused. The transfusion charge (CPT 36430) may be billed once per day per patient transfused.

#### **Billing for Autologous Blood and Directed Donor Blood**

Transmittal 496 clarified the correct billing practice for autologous blood components including intra-and/or post-operative salvaged autologous blood. Providers should bill the appropriate HCPCS Level II code of the autologous blood component, the number of units transfused, the line item date of service,

RC 39X, and the transfusion charge if the blood was transfused. The date of service is the date of intended transfusion (not the date collected or date the component was received by the facility).

If the autologous component was not transfused, the facility should bill CPT Level I HCPCS codes 86890 (predeposited autologous component) or 86891 (intra/post-operative autologous component), the number of units not transfused, RC 39X, and the date of intended transfusion or outpatient discharge date.

For directed donor components, the facility should bill identical to routine allogeneic blood transfusions. Specific code(s) for directed donor components are not available.

#### **Billing for Split Unit of Blood**

Based on Transmittal 496, many facilities were billing aliquoting (splitting) of blood components incorrectly. CMS intended that HCPCS Level II code for splitting blood components (P9011) and Level I code (CPT 86985) be billed for each split except for what blood was remaining in the original container after splitting. If three splits were made from the original blood component and the remaining blood was also transfused, the facility should bill both the Level I and Level II codes with the quantity three as a line item. A second line item would be the Level II P code only for the blood transfused from the final container as it was not split. The usual transfusion code can be billed once per day per patient transfused.

#### **Billing for Irradiation of Blood Components**

Again, based on Transmittal 496, billing for irradiated blood components was probably being performed incorrectly by many facilities. CMS intended for the facility to bill the appropriate HCPCS Level II (P code) blood component descriptor, if one was available that described the component. If an irradiated P code was not available, the facility could bill the appropriate nonirradiated component P codes and an irradiation CPT code (86945).

There are many facilities that irradiate their own blood components rather than having the blood supplier irradiate before shipping. In these scenarios, the P code descriptor to bill should be chosen that reflects the final blood component transfused, if such a code is available. An additional billing of CPT 86945 would constitute "double billing." The blood groups are discussing with CMS this coding rule as it does not allow proper tracking of which facility actually performed the irradiation.

#### **Billing for Frozen and Thawed Blood Components**

Many transfusion facilities were not in compliance with CMS's intent as to billing of frozen/thawed components. Transmittal 496 clarified the proper billing procedure for these components. If a blood component had a P code descriptor that included freezing and thawing, then an additional line item with use of CPT 86931 (thawing) and/or CPT 86932 (freezing and thawing) should not be billed. Additional communication with CMS also clarified the issue of thawing fresh frozen plasma and cryoprecipitate. CMS reimbursement for these frozen component P codes includes "thawing" and CPT 86927 (fresh frozen plasma, thawing, each unit) should not be billed.

#### **Billing for Unused Blood**

Other than autologous blood that is not transfused, transfusion facilities may not bill CMS for unused blood components. Facilities should report these lost charges for Medicare beneficiaries under cost centers for blood on the HOPPS provider's Medicare Cost Report. Other transfusion medicine services provided to the Medicare beneficiary in preparing the unused blood for transfusion (i.e., typing, antibody screening, antibody identification, crossmatching, etc.) may be billed using the appropriate CPT codes, quantity, charge, and line item date of service. Dates of service in these cases are the dates the service was provided (performed).

Hospital transfusion services are still confused as to whether they are allowed to

"mark-up" blood charges from their supplier. This confusion results from language found in some blood supplier's contract many years ago that prohibited increasing the charge to the patient over what the supplier was charging the facility. Medicare has no regulations on what a facility may "charge" a beneficiary for services as long as the services were "medically necessary and reasonable." The blood suppliers have since corrected their contracts, and hospital mark-ups are appropriate (such as to cover unused blood).

#### **Medically Unlikely Edits (MUEs)**

What originally was termed "Medically Unbelievable Edits" by CMS, MUEs have been implemented to identify common billing errors of multiple procedures being performed on a Medicare beneficiary (Level I codes). A maximum number of units of service per patient per day have been proposed through the CMS contracted company, Correct Coding Solutions, LLC, Carmel, Indiana. The MUEs have been released in phases, the most recent being Phase V MUEs in mid 2007. The blood industry was given the opportunity to review each MUE proposal and provide comments prior to final implementation. Several codes were identified where the maximum number of 1/day/patient was proposed (such as ABO and Rh typing). Comments were submitted to Correct Coding Solutions, LLC, as to the inappropriateness of the MUE for selected transfusion medicine codes. In all instances, the request for changes to a higher maximum was allowed. The blood industry organizations will continue to review such edits for "unbelievable" proposals and request changes where appropriate.

#### **Coding for Cellular Therapy Services**

The expanding cellular therapy services being provided to patients has also created a need to review and update current codes for these types of services. Cellular therapy services will usually entail a professional component and a technical component. Several codes for bone marrow/stem cell processing (CPT 38207-38215)

were established many years ago. However, CMS has not in the past recognized these codes for payment, but instead has used three "G" codes for reporting such services (G0265-G0267). The code for all cell depletion activities (G0267) was reimbursed under HOPPS APC payment rates substantially lower than the cost of providing these services. The other two

"G" codes were reimbursed under the clinical laboratory fee schedule.

Again, after much discussion with CMS by the interested cell therapy organizations, CMS has proposed for 2008 to recognize and reimburse CPT 38207-38215. Although the proposed payment rates have been increased, they are still in most instances far below the cost of the procedures.

**Table 1. Proposed Blood Component Reimbursement Rates for Hospital Outpatient Prospective Payment System (HOPPS), 2008 (percent change from 2007 rates are indicated)**

HCPCS	Description	2007 Final Payment	2008 Proposed Payment	% Change
P9010	Whole blood for transfusion	\$131.98	\$282.63	114.15%
P9011	Blood split unit	137.22	135.26	-1.43
P9012	Cryoprecipitate each unit	48.59	43.59	-10.29
P9016	RBC leukocytes reduced	175.74	188.47	7.24
P9017	Plasma 1 donor frozen w/in 8 hr	70.21	69.44	-1.10
P9019	Platelets, each unit	58.95	69.00	17.05
P9020	Platelet rich plasma unit	209.29	342.31	63.56
P9021	Red blood cells unit	129.53	129.57	0.03
P9022	Washed red blood cells unit	211.03	268.10	27.04
P9023	Frozen plasma, pooled, sd	57.45	76.31	32.83
P9031	Platelets leukocytes reduced	95.08	109.60	15.27
P9032	Platelets, irradiated	129.57	132.11	1.96
P9033	Platelets leukoreduced irradiated	125.33	129.17	3.06
P9034	Platelets, pheresis	452.93	448.44	-0.99
P9035	Platelet pheres leukoreduced	488.74	509.25	4.20
P9036	Platelet pheresis irradiated	418.52	446.33	6.64
P9037	Platelet pheresis leukoreduced, irradiated	617.14	639.53	3.58
P9038	RBC irradiated	197.00	211.84	7.53
P9039	RBC deglycerolized	358.31	369.02	2.99
P9040	RBC leukoreduced irradiated	217.56	243.25	11.81
P9044	Cryoprecipitate reduced plasma	82.39	83.64	1.52
P9050	Granulocytes, pheresis unit	750.36	990.55	32.01
P9051	Blood, l/r, cmv-neg	156.70	152.00	-3.00
P9052	Platelets, hla-m, l/r, unit	671.62	616.33	-8.23
P9053	Plt, pher, l/r cmv-neg, irr	705.38	686.62	-2.66
P9054	Blood, l/r, froz/degly/wash	211.05	213.50	1.16
P9055	Plt, aph/pher, l/r, cmv-neg	396.81	496.26	25.06
P9056	Blood, l/r, irradiated	144.28	155.23	7.59
P9057	RBC, frz/deg/wsh, l/r, irr	496.21	412.06	-16.96
P9058	RBC, l/r, cmv-neg, irr	262.18	294.81	12.45
P9059	Plasma, frozen between 8-24 hr	76.77	79.34	3.35
P9060	Fresh frozen plasma donor retested	74.49	74.09	-0.54

#### Reimbursement for Transfusion Medicine Services

Reimbursement by CMS for transfusion medicine services has, and continues, to underpay providers for these life-saving services. CMS used hospital reporting of charge data for 2006 claims to set the proposed 2008 reimbursement rates. Utilizing overall hospital cost-to-charge ratios (CCR), proposed blood payment rates for 2008 were set at the adjusted median costs calculated using a simulated blood CCR for each hospital reporting a blood cost center. CMS, therefore, is not providing the transitional "floor" on payments that was provided in setting the 2007 rates. However, the proposed payment rates show an increase for the most high-volume blood components (Table 1).

As hospital transfusion services continue to become educated about the proper coding and billing practices for blood, blood derivatives, and cellular therapy services, claims forms submitted for CMS beneficiaries should better reflect actual costs/charges to provide such services. This will allow CMS to set future reimbursements at a more realistic level for both out-of-hospital patients and inpatient Diagnosis Related Groups (DRGs). Each member of a blood industry group should keep informed of the current billing guides and rules and inform their respective industry organizations of issues that need to be addressed with government and private payers. Remember that "the squeaky wheel gets the grease"!

*William B. Lockwood, Ph.D., M.D., can be reached at the University of Louisville Hospital, 530 S. Jackson St., Suite C1R06, Louisville, KY 40202. Phone: 502-852-5857. E-mail: wblock01@gwise.louisville.edu.* 

**OIG Issues Work Plan**, from page 1

Physician Fee Schedule. The work plan specifically noted that the OIG would look at the relationships among physicians, billing providers, and others who provide MRI services and whether those relationships impacted utilization rates.

*Other studies the OIG expects to undertake regarding physician services include a review of the appropriateness of Part B payments for certain, unspecified physician services and a look at the appropriateness of claims for Medicare services that some doctors billed as "incident to" their professional services.*

Independent diagnostic testing facilities (IDTFs) will be the subject of another review, in which the OIG will examine billing patterns in connection with provider and beneficiary profiles. The study follows a 2006 OIG review in which more than \$71 million in potentially improper Medicare payments to IDTFs were identified.

Also slated for fiscal year 2008 is a study of physicians' reassignment of Medicare benefits to other entities to determine the extent to which doctors reassign their billing rights and to what extent physicians are aware of reassignment requests made on their behalf.

The OIG said the review is in response to investigative findings that some fraudulent schemes seek to reassign physicians' Medicare billing rights without physicians' knowledge.

The OIG also will study the patient care and safety at physician-owned specialty hospitals, citing concerns among some lawmakers about the appropriateness of care and about staffing levels at such hospitals.

Other studies the OIG expects to undertake regarding physician services include a review of the appropriateness of Part B payments for certain, unspecified physician services and a look at the appropriateness of claims for Medicare services that some doctors billed as "incident to" their professional services.

**Medicare Rx Studies**

The OIG will continue in FY 2008 a strong focus on Medicare Part D issues, including a review of the Centers for Medicare & Medicaid Services' (CMS) oversight of Part B and Part D claims to avoid duplicate payments for drugs.

The OIG also plans to determine whether prescription drug plans

and Medicare Advantage plans with drug coverage have appropriately enrolled beneficiaries into medication therapy management programs and properly billed for such services.

Other Part D work will include a review of Part D data for aberrant claims and whether drug costs paid by beneficiaries during the catastrophic coverage phase were accurate.

The OIG further intends to review CMS's methodology for reviewing and approving bids from Part D plan sponsors and whether the process is adequate and whether the benefit of Part D negotiated drug prices and concessions are passed on to enrollees.

**Other Scheduled Work**

Other OIG work plans for FY 2008 include an evaluation of CMS's oversight of marketing and sales of Medicare Advantage plans, including the adequacy of sanctions against noncompliant plans.

The OIG also will review CMS's oversight of recovery audit contractors and whether they have met requirements for the Recovery Audit Contractor (RAC) program. Other contractor oversight reviews will include a look at whether CMS has adequately overseen the performance of Medicare and Medicaid Data Matching Project contractors.

The work plan is available at [www.oig.hhs.gov/publications/docs/workplan/2008/Work\\_Plan\\_FY\\_2008.pdf](http://www.oig.hhs.gov/publications/docs/workplan/2008/Work_Plan_FY_2008.pdf). 

## OIG Sets New Safe Harbor for Certain Health Centers

A final rule announced October 3 by the Department of Health and Human Services Office of Inspector General establishes safe harbor protection under the anti-kickback statute for certain financial arrangements involving federally qualified health centers.

In accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the rule sets forth a safe harbor to protect certain arrangements involving goods, items, services, donations, and loans provided by individuals and entities to certain health centers funded under section 330 of the Public Health Service Act. Under section 330, health centers are funded with federal Public Health Services (PHS) grants, but health centers often have opportunities to enter into arrangements with hospitals, care providers, and suppliers to improve patient care.

Consistent with their mission and the terms of their PHS grants, section 330 grant recipients serve predominantly low-income individuals, including some beneficiaries of the Medicare and Medicaid programs, the rule said. The final rule specified that health centers must serve a population that is medically underserved or a special medically underserved population comprised of migratory and seasonal agriculture workers, the homeless, and residents of public housing.

Under the final rule, payments to the health center must be medical, clinical, or relate directly to services provided by the health center as part of the scope of the health center's grant. A protected

arrangement must contribute to the ability of the health center to maintain or increase the availability of, or enhance the quality of, services provided to a medically underserved population.

The rule requires protected arrangements to be in accordance with a contract, lease, grant, loan, or other written agreement and signed by the parties. The document must cover all of the payment to be provided and the amount of the payment must be specified, not conditioned on the volume or value of federal healthcare program business generated between the parties, the final rule said.

In addition, the rule requires health centers to document the basis for their determination that the arrangements will yield the benefits of maintaining, increasing, and enhancing the quality of services provided. The health centers also must periodically re-evaluate the agreements to ensure ongoing compliance with the benefit standard, according to the rule.

### Referring Patients

Health centers must not be required to refer patients to a particular provider or supplier and must be free to refer patients to any provider or supplier, the final rule said. Further, donors offering to furnish goods, items, or services for health center patients must furnish them to all patients who clinically qualify for them, regardless of payer status or ability to pay.

The rule also requires health centers to provide effective notification to patients of their freedom to choose any willing provider or supplier and to disclose to patients, upon request, the existence and nature of the arrangement with the donor.

The safe harbor rule also made clear that a health center may require a donor entering into a protected arrangement to charge a referred health center patient the same rate it charges other persons not referred by the health center or furnish items or services to health center patients at a reduced rate. 

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## CMS Backs Off Changes to Clinical Trials Policy

Medicare's clinical trials policy will remain as stated in a memorandum issued in early July, the agency announced October 17, nixing a proposal to impose additional coverage standards that provider and device groups called burdensome.

The Centers for Medicare & Medicaid Services' (CMS) decision to stick to its July 9 memorandum means that there is little change overall to the policy other than language modifications and clarifications of what Medicare will cover.

CMS said it ultimately decided not to change the July 9 memorandum after reviewing public comments and the enactment of the Food and Drug Administration Amendments Act of 2007 (Pub. L. No. 110-85) on September 27. According to CMS, the new law includes new requirements for registration of clinical trials and additional authority for other Department of Health and Human Services (HHS) agencies. CMS said it intends to review this new law and to work with other HHS components to avoid imposing duplicative or inconsistent obligations.

### Further Refinement Planned

"Making no change to the July 9, 2007, clinical trial policy national coverage determination enables Medicare beneficiaries to continue, as before, participation in clinical research studies with the support of Medicare," acting CMS Administrator Kerry Weems said in a statement. "The CMS will continue to work to further refine the policy, as appropriate, in order to ensure the quality and appropriateness of trials that enroll Medicare beneficiaries."

In announcing its decision, CMS said it believes any policy that covers costs associated with beneficiary participation in clinical research should meet two main objectives.

First, such a policy should ensure that Medicare beneficiaries are participat-

ing in high-quality studies that provide appropriate protections for the patients enrolled. This requires that the organization responsible for the studies adheres to appropriate and recognized standards.

Secondly, it should ensure that Medicare beneficiaries have access to clinical studies. This requires that Medicare approve coverage of specific trials prospectively, to ensure providers are confident of payment for services provided to Medicare beneficiaries.

### First Update

The July 9 memo marked the first national coverage determination update since Medicare adopted its clinical trials policy seven years ago. That memo modified language in the 2000 policy to clarify that Medicare would cover items or services if they would be covered outside of the clinical research trial and amended the policy to include CMS's Coverage with Evidence Development (CED) policy, which allows for coverage of items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a "reasonable and necessary" determination.

Less than two weeks after releasing that memorandum, CMS issued a proposal July 19 to require an approval process to determine if a study met those standards and to clarify the items and services that would be covered in approved trials. However, CMS said it received feedback in regard to the authority of CMS to establish standards and provide limitations to coverage within research studies.

Commenters said they found the proposed policy confusing, recommending instead that Medicare use a notice and comment rule making to provide a longer transition period for clinical trials to prepare for these changes. Medicare ultimately decided any changes to the July 9 memo would be "inappropriate" at this time. 🏠

*Details of the current coverage for clinical trials are available at [www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=210](http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=210).*

**Lab Lawsuit:** A Long Island woman who underwent a double mastectomy has filed a lawsuit against CBLPath lab in Rye Brook, New York. Darrie Eason told Hannah Storm on CBS's *The Early Show* that she had the mastectomy after lab results showed she had breast cancer. However, a state health department report said Eason's tissue sample was mislabeled at the lab. Eason, a single mother of a 15-year old, is seeking an undisclosed sum from CBLPath lab.

**CMS Rules on Excess Receipts Provision:** The Centers for Medicare & Medicaid Services (CMS) has ruled that a recruitment arrangement between a hospital and a physician, if amended to delete an excess receipts provision, would not satisfy the requirements of the recruitment exception to the Stark law physician self-referral prohibition. In an advisory opinion (CMS-AO-2007-1) posted on the Web October 5, CMS determined the excess receipts provision could not be deleted. "We do not believe that the parties should now be able to

amend the arrangement to provide for additional (or potentially additional) compensation to the physician," CMS said. "Because the physician has already relocated his medical practice, the additional compensation is not for the purpose of inducing relocation and may directly or indirectly reflect the volume or value of the recruited physician's actual or potential referrals." This is only the fifth advisory opinion that CMS has issued on a topic other than one related to specialty hospitals.

**Physician Compensation Gets Nod:** The Department of Health and Human Services Office of Inspector General (HHS OIG) has approved an arrangement between a not-for-profit medical center and physicians to compensate for emergency department on-call coverage. The proposed on-call payments to doctors also account for the uncompensated care physicians are expected to provide to uninsured and underinsured patients who come to the emergency department and for the follow-up care of patients subsequently admitted as inpatients, according to advisory opinion No. 07-10, released September 27. 🏠

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