G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

House Bill Would Increase Fraud Funding, Mandate Compliance Plans

The $1 trillion health care reform bill unveiled July 14 by House Democrats would increase funding for the Medicare integrity program and require most providers to adopt compliance programs among other measures aimed at curbing fraud, waste, and abuse in federal health programs.

The anti-fraud provisions in the America's Affordable Health Choices Act of 2009 (H.R. 3200) seek to deliver on promises by lawmakers and the Obama administration to be more aggressive in fighting wasteful and inappropriate spending in the Medicare and Medicaid programs.

The crux of the health care reform bill—crafted by the House committees on Ways and Means, Energy and Commerce, and Education and Labor—is to expand and improve health care coverage by creating a public health care plan option, providing subsidies for low-income individuals to obtain coverage, requiring everyone to have insurance and for employers to offer it, and making sweeping changes to Medicare.

The bill would be funded largely by new taxes on wealthy Americans and cuts in Medicare spending.

H.R. 3200 was approved July 17 by the Committee on Ways and Means by a vote of 23-18 and by the Committee on Education and

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Lab Operators Sentenced to Prison for Anti-Kickback Violation

A federal court in New Jersey has sentenced two men to 15-month prison terms for tax evasion and conspiracy to violate the anti-kickback statute by paying physicians to refer blood testing work to the defendants' laboratory (*United States v. Niaz*).

Asim Niaz and Taquir Khan, who operated Nu-Tek Diagnostic Laboratories in Langhorne, Pa., also were ordered by Judge Anne E. Thompson of U.S. District Court for the District of New Jersey to pay fines of $10,000 each.

Both men pleaded guilty in March 2008 to charges of income tax evasion and conspiring with each other to pay kickbacks to doctors for referral of lab work to Nu-Tek, the Justice Department said in a news release.

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Kimberly Scott, Senior Editor,
kscott@ioma.com

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Anti-Kickback Violation, *from page 1*

In 2008, a Trenton, N.J., medical group practice and three of its doctors were sentenced to probation after pleading guilty to federal charges filed against them in connection with the case. Mercerville Medical Associates (MMA) was sentenced to two years' probation and a $15,000 fine for obstructing the federal investigation into the alleged kickbacks.

MMA physicians Louis Tsarouhas, Giacomo Mangiaracina, and Brian Shaffer were sentenced to three years' probation for failing to report and pay federal income taxes on the cash payments they received in 2002 from Khan and Niaz in return for referring blood testing work to Nu-Tek, the Justice Department said.

The 2002 payments totaled $86,000 for Tsarouhas, $61,000 for Mangiaracina, and $66,000 for Shaffer, according to the charging documents.

New Jersey Blue Cross Plan Sues Lab, Alleges Fraud

Horizon Blue Cross Blue Shield of New Jersey has filed a civil suit in New Jersey Superior Court against a diagnostic laboratory that allegedly submitted more than $14 million in fraudulent health insurance claims to Horizon between 2005 and June 2009 (*Horizon Blue Cross Blue Shield of New Jersey v. Biodiagnostic Laboratory Services LLC*).

The six-count complaint was filed June 25 in Camden County Superior Court against Biodiagnostic Laboratory Services LLC (BLS), a clinical diagnostic laboratory in Parsippany, N.J., that is not part of Horizon's participating provider network.

The laboratory's three co-owners and its medical director also are named as defendants, along with unnamed individuals and businesses that participated in the alleged fraud whose identities are unknown to Horizon.

The complaint alleges violations of the New Jersey Insurance Fraud Prevention Act (IFPA) and common law claims for fraud, negligent misrepresentation, and tortious interference. According to the complaint, BLS and its principals submitted false and inflated health insurance claims that misrepresented and overstated the charges for services rendered by more than $14 million.

The laboratory allegedly submitted multiple claims for the same, incidental, and unnecessary services during a single patient visit by representing that the services were performed independently, by changing the diagnosis for which the test was ordered, and by failing to disclose that the tests were part of a single procedure, according to the complaint.

Unbundling Alleged

BLS also unbundled services performed as part of a test panel to get higher reimbursements, according to the complaint. The insurer also alleged that BLS paid physicians through facility-use agreements and service agreements to encourage them to refer patients to BLS. Under those agreements, BLS allegedly paid above-market rates to physicians to rent space in their facilities or to compensate them for drawing blood or collecting samples.

The laboratory submitted claims to Horizon for amounts that "vastly exceeded" the amounts in the schedule of fees for services that it provided to referring medical providers in violation of the New Jersey Clinical Laboratory Improvement Act, according to the complaint.

Horizon said BLS waived patients' out-of-network coinsurance and deductibles but included the waived amounts in claims submitted to Horizon, according to the complaint. As a result, Horizon said it paid BLS more than $10 million in charges for services that should have been charged to patients.

The insurer argued that by waiving the out-of-pocket costs patients are supposed to pay when they obtain services out of network BLS diverts patients from participating providers, undermines the insurer's ability to control costs, interferes with and circumvents the terms of the health benefits plan, and promotes the proliferation of unnecessary services.

Horizon made the same argument in lawsuits filed in state court in May against two New Jersey hospitals over their policy of waiving the coinsurance, deductibles, and other out-of pocket expenses patients normally pay when they obtain services from nonparticipating providers.

Horizon is seeking a court order barring BLS from waiving member liability for coinsurance, deductibles, and other out-of-pocket costs, and prohibiting it from paying referral fees. The insurer also is seeking compensatory and punitive damages, treble damages under the state IFPA, and attorneys' fees.

BLS declined to comment on the lawsuit.

The complaint Horizon filed is available at *www.horizon-bcbsnj.com/SiteGen/Uploads/Public/horizon_bcbsnj/pdf/news_room/newsroom_complaint_062509.pdf*.

Miami Doc Sentenced to Prison Over Blood Scam

A Miami physician was sentenced June 29 to more than eight years in prison for participating in a $10 million Medicare billing scheme in which blood samples were manipulated to make it appear HIV infusion treatments were medically necessary, authorities announced.

In addition to the 97-month prison term, the U.S. District Court for the Southern District of Florida ordered defendant Roberto Rodriguez to pay more than $9 million in restitution to Medicare, acting U.S. Attorney Jeffrey H. Sloman and other officials said in a written statement.

In March, Rodriguez pleaded guilty to conspiracy to commit health care fraud, admitting he was a co-owner of and practicing physician at Midway Medical Center Inc., a Miami clinic that purported to specialize in drug-infusion treatment of HIV patients. He also admitted that he routinely billed Medicare for services that were medically unnecessary and often never provided, the statement said.

Rodriguez was among a number of co-defendants sentenced for roles at Midway and other clinics, including Alexis Dagnesses, a chemist who manipulated blood samples drawn from patients so resulting laboratory reports would make it appear they had low blood platelet counts.

Midway was not the only clinic where Rodriguez purported to treat HIV patients with injection and infusion therapies, the statement said, noting he admitted that, between October 2003 and February 2005, he engaged in similar activity as medical director and practicing physician for five other Miami-area HIV infusion clinics.

A final defendant, physician Carmen Lourdes Del Cueto, is scheduled for sentencing Sept. 11, the statement said.

COMPLIANCE PERSPECTIVES

Compliance in Billing Transfusion Medicine 2009

William B. Lockwood, Ph.D., M.D., is a clinical professor in the Department of Pathology & Laboratory Medicine and director of transfusion services & tissue/bone banks at the University of Louisville Hospital & Norton-Kosair Children's Hospitals in Louisville, Ky. Dr. Lockwood is also a member of the American Association of Blood Banks Coding & Reimbursement Committee.

Correct billing practices for transfusion medicine services continue to pose uncertainty for many facilities that code blood components and transfusion medicine services, including apheresis and cellular therapy. Although a few changes have occurred since the review of this area in 2007, much of the confusion in billing compliance remains with the most common transfusion medicine codes.

Many of the questions asked by facilities concern how to bill for red blood cell (RBC) antigen tests, blood components that are not transfused to the intended recipient, diagnostic versus nondiagnostic transfusion services, and charges from a blood supplier. These and other transfusion services will be highlighted in this review. As transfusion medicine firms do not intentionally commit "fraud and abuse" in billing patient services, incorrect billing practices could create regulatory headaches and minimize reimbursement.

Coding Changes for Hospital Outpatient Transfusion Services

The Centers for Medicare and Medicaid Services (CMS) in March 2005 published Transmittal 496 as a means to clarify the intended use of certain codes in transfusion medicine for their hospital outpatient beneficiaries. Other third-party insurance companies adopted these rules and no subsequent updates have been published.

Billing for Blood Processing Versus Blood Product Costs

Many billing facilities remain perplexed by the terminology of "blood processing" and "blood." Transmittal 496 instructed providers of blood components to use the alpha-numeric HCPCS Level II codes on form UB-04 (formerly UB-92 for hospital services) and UB-1500 (physician services) for the blood component transfused, the number of units transfused, line item date of service and the Revenue Code 0390 if the provider "*did not purchase the blood*." This rule applied to most blood suppliers (all American Red Cross suppliers and a majority of the independent blood centers) and their client facilities as the charge to the facility was for processing and handling red blood cells, 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/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) 038X, plus the HCPCS codes with –BL modifier, processing/handling charge for the blood, number of units transfused, line item date of service, and the RC 0390. 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 regardless of the number or type of blood components

Much of the confusion in billing compliance remains with the most common transfusion medicine codes.

transfused in the 24-hour period. CMS Transmittal 1702 (March 13, 2009) again defined the billing of processing and blood charges.

Therefore, unless a facility receives blood from that rare supplier (the receiving facility should determine with certainty what their blood supplier red cell component charges are for) that includes a charge for the liquid blood itself, only billing RC 0390, the appropriate HCPCS code, the associated nondiagnostic transfusion services (patient blood typing, antibody screening, antibody ID, crossmatch, etc.) is correct billing compliance.

Billing for Autologous Blood and Directed Donor Blood

Transmittal 496 clarified the correct billing practice for autologous blood components including intra- and 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 0390, and the transfusion CPT charge (36430) 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).

As transfusion medicine firms do not intentionally commit "fraud and abuse" in billing patient services, incorrect billing practices could create regulatory headaches and minimize reimbursement.

If the autologous component was *not* transfused, the facility should bill CPT Level I HCPCS codes 86890 (pre-deposited autologous component) or 86891 (intra/post-operative autologous component), the number of units not transfused, RC 0390, 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 codes for directed donor components are currently not available.

Billing for a Split Unit of Blood

Based on Transmittal 496, many facilities were billing aliquoting (splitting) of blood components incorrectly. Billing of split units was again discussed in CMS Transmittal 1487 (April 8, 2008). 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 "3" 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 CPT code (36430) should be billed once per day per patient transfused.

Billing for Irradiation of Blood Components

Again, based on Transmittal 496, and clarified in CMS Transmittal 1487, 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 being transfused. If an irradiated component P code was not available, the facility could bill the appropriate nonirradiated component P code 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."

Billing for Frozen and Thawed Blood Components

Many transfusion facilities were not in compliance with CMS's intent as to billing of frozen and 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. CMS reimbursement for these frozen component P codes includes "thawing" and CPT 86927 (fresh frozen plasma, thawing, each unit) should *not* be billed.

Proposed 2010 Payments for Blood Procedures

HCPCS	Description	2009 Final APC	2010 Proposed APC	2009 Final Payment Rate	2010 Proposed Payment Rate	$ Change	% Change
36430	Blood transfusion service	0110	0110	$221.59	$226.60	$5.01	2.26%
36440	Bl push transfuse, 2 yr or <	0110	0110	221.59	226.60	5.01	2.26
36450	Bl exchange/transfuse, nb	0110	0110	221.59	226.60	5.01	2.26
36455	Bl exchange/transfuse non-nb	0110	0110	221.59	226.60	5.01	2.26
36511	Apheresis wbc	0111	0111	759.70	818.57	58.87	7.75
36512	Apheresis rbc	0111	0111	759.70	818.57	58.87	7.75
36513	Apheresis platelets	0111	0111	759.70	818.57	58.87	7.75
36514	Apheresis plasma	0111	0111	759.70	818.57	58.87	7.75
36515	Apheresis, adsorp/reinfuse	0112	0112	2,033.73	2,119.73	86.00	4.23
36516	Apheresis, selective	0112	0112	2,033.73	2,119.73	86.00	4.23
36522	Photopheresis	0112	0112	2,033.73	2,119.73	86.00	4.23
38206	Harvest auto stem cells	0111	0111	759.70	818.57	58.87	7.75
38207	Cryopreserve stem cells	0110	0110	221.59	226.60	5.01	2.26
38208	Thaw preserved stem cells	0110	0110	221.59	226.60	5.01	2.26
38209	Wash harvest stem cells	0110	0110	221.59	226.60	5.01	2.26
38210	T-cell depletion of harvest	0393	0393	400.19	409.25	9.06	2.26
38211	Tumor cell deplete of harvst	0393	0393	400.19	409.25	9.06	2.26
38212	Rbc depletion of harvest	0393	0393	400.19	409.25	9.06	2.26
38213	Platelet deplete of harvest	0393	0393	400.19	409.25	9.06	2.26
38214	Volume deplete of harvest	0393	0393	400.19	409.25	9.06	2.26
38215	Harvest stem cell concentrte	0393	0393	400.19	409.25	9.06	2.26
38220	Bone marrow aspiration	0003	0003	208.26	211.31	3.05	1.46
38221	Bone marrow biopsy	0003	0003	208.26	211.31	3.05	1.46
38230	Bone marrow collection	0112	0112	2,033.73	2,119.73	86.00	4.23
38241	Bone marrow/stem transplant	0112	0112	2,033.73	2,119.73	86.00	4.23
88184	Flowcytometry/ tc, 1 marker	0433	0433	16.50	16.64	0.14	0.85
88185	Flowcytometry/tc, add-on	0433	0433	16.50	16.64	0.14	0.85
88187	Flowcytometry/read, 2-8	0342	0342	10.06	10.68	0.62	6.16
88188	Flowcytometry/read, 9-15	0343	0343	34.55	35.70	1.15	3.33
88189	Flowcytometry/read, 16 & >	0343	0343	32.75	35.70	2.95	9.01
99363	Anticoag mgmt, init			Code Not Recognized By OPPS			
99364	Anticoag mgmt, subseq			Code Not Recognized By OPPS			
G0364	Bone marrow aspirate & biopsy	0340	0340	42.69	45.06	2.37	5.55
G0267	Bone marrow or psc harvest					N/A	N/A

Billing for Unused Blood

Other than autologous blood that is not transfused, transfusion facilities may not bill CMS (or other payers) for *unused* blood components. Facilities should report these charges for Medicare beneficiaries under cost centers for blood on the Hospital Outpatient Prospective Payment System (HOPPS) provider's Medicare Cost-to-Charge 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).

Many transfusion services remain confused as to whether they are allowed to "markup" blood charges from their supplier. This confusion results from language found in some blood suppliers' contract many years ago that prohibited increasing the charge to the patient over what the supplier was charging the facility. Medicare (and other payers) has no regulations on what a facility may "charge" a beneficiary for services as long as the services were "medically necessary and reasonable."

Billing for Red Cell Antigen Testing

Confusion still exists in how to use the CPT codes 86903 (Blood typing: antigen screening for compatible blood unit using reagent serum, per unit screened), 86904 (Blood typing: antigen screening for compatible unit using patient serum, per unit screened), and 86905 (Blood typing: RBC antigens, other than ABO or Rh (D), each). The CPT description for code 86903 instructs to bill for each unit screened. Therefore, the facility can bill for all units tested to find the antigen negative units. However, if a single unit is tested for multiple antigens, 86903 may be billed only once. However, if several blood units are screened and only one unit is transfused, it would be appropriate to bill 86903 times the total number of blood units screened. The same process would be used for 86904. Only when typing patient red cells for antigens (phenotyping) could a facility bill for each antigen typed using 86905.

Medically Unlikely Edits (MUE)

MUEs have been implemented by CMS to identify common billing errors of multiple procedures being performed on a Medicare beneficiary (Level I codes) on the same day of service. A *maximum* number of units of service per patient per day have now been published through the CMS. Although the published MUEs are not a complete list (only those codes allowed three times or less per day are published), facilities should review these quarterly to determine compliance. The use of modifier -59 may be cautiously used for justified multiple same-day services. The MUEs are used for all clinical laboratory tests, not just for transfusion medicine. The blood industry is given the opportunity to review each MUE proposal and provide comments prior to final implementation of the edits. The blood industry organizations will continue to review such edits for "unbelievable" proposals and request changes where appropriate.

Coding for Apheresis/Cell Therapy Services

After much discussion with CMS by the interested cell therapy organizations, CMS has made changes to recognize and reimburse CPT 38206-38215. Although the payment rates have been increased, they are still in most instances far below the cost of the procedures. Apheresis services continue to be billed using CPT 36511-36522.

Reimbursement for Transfusion Medicine Services

Reimbursement by CMS for transfusion medicine services has, and continues, to underpay providers for these lifesaving services. CMS used hospital reporting of charge data for 2008 claims to set the proposed 2010 reimbursement rates (*Federal*

Reimbursement by CMS for transfusion medicine services has, and continues, to underpay providers for these lifesaving services.

Register, July 20, 2009). Utilizing overall hospital cost-to-charge ratios (CCR), proposed blood payment rates for 2010 were set at the adjusted median costs calculated using a simulated blood CCR for each hospital reporting a blood cost center. The proposed payment rates show an increase for the most *high-volume* blood components and transfusion medicine services (see charts).

Hospital inpatient reimbursement for blood services continues to be paid on a diagnosis related groups (DRG) basis. Use of specific CPT and HCPCS codes are not required on the UB-04 claim form. It is imperative for facilities, however, to include with other billed principle diagnoses and procedures (ICD-9-CM codes) proper procedure codes and revenue codes related to blood components and transfusion services. This will provide CMS (and other payers) adequate information for establishing future DRG reimbursement for procedures utilizing transfusion medicine services.

Do you know if you are billing transfusion services correctly? If the facility is receiving rejected claims for these services, then probably you are not in compliance. Even if you are not seeing returned claims, good compliance in billing practice dictates that audits be conducted frequently to ensure that errors are not being made unintentionally. Although computer technology has helped in billing health care claims, it is only as good as the human programmers and their knowledge. In the words of Alexander Pope: "Trust not yourself, but your defects to know. Make use of every friend and every foe."

Dr. Lockwood can be reached at the University of Louisville Hospital, Transfusion Services, 530 S. Jackson St., Louisville, KY 40202. Phone: 502-852-5857. E-mail: wblock01@gwise.louisville.edu.

Proposed 2010 Payments for Blood Components

HCPCS	Description	2009 Final APC	2010 Proposed APC	2009 Final Payment Rate	2010 Proposed Payment Rate	% Change
P9010	Whole blood for transfusion	0950	0950	$230.40	$207.95	-9.74%
P9011	Blood split unit	0967	0967	31.12	91.05	192.58
P9012	Cryoprecipitate each unit	0952	0952	42.46	44.84	5.61
P9016	RBC leukocytes reduced	0954	0954	188.92	187.93	-0.52
P9017	Plasma 1 donor frz w/in 8 hr	9508	9508	76.73	75.28	-1.89
P9019	Platelets, each unit	0957	0957	73.25	66.20	-9.62
P9020	Platelet rich plasma unit	0958	0958	394.95	148.82	-62.32
P9021	Red blood cells unit	0959	0959	136.82	141.53	3.44
P9022	Washed red blood cells unit	0960	0960	261.64	270.09	3.23
P9023	Frozen plasma, pooled, sd	0949	0949	58.83	53.49	-9.08
P9031	Platelets leukocytes reduced	1013	1013	111.67	114.45	2.49
P9032	Platelets, irradiated	9500	9500	164.42	160.12	-2.62
P9033	Platelets leukoreduced irrad	0968	0968	128.19	126.00	-1.71
P9034	Platelets, pheresis	9507	9507	468.66	461.09	-1.62
P9035	Platelet pheres leukoreduced	9501	9501	514.82	519.79	0.97
P9036	Platelet pheresis irradiated	9502	9502	469.53	358.24	-23.70
P9037	Plate pheres leukoredu irrad	1019	1019	653.50	673.01	2.99
P9038	RBC irradiated	9505	9505	250.69	221.84	-11.51
P9039	RBC deglycerolized	9504	9504	341.43	330.90	-3.08
P9040	RBC leukoreduced irradiated	0969	0969	251.33	252.91	0.63
P9043	Plasma protein fract,5%,50ml	0956	0956	15.62	57.92	270.81
P9044	Cryoprecipitatereduced plasma	1009	1009	85.16	94.58	11.06
P9048	Plasmaprotein fract,5%,250ml	0966	0966	196.27	110.16	-43.87
P9050	Granulocytes, pheresis unit	9506	9506	1,669.99	48.64	-97.09
P9051	Blood, l/r, cmv-neg	1010	1010	144.13	146.73	1.80
P9052	Platelets, hla-m, l/r, unit	1011	1011	711.89	720.24	1.17
P9053	Plt, pher, l/r cmv-neg, irr	1020	1020	649.24	685.09	5.52
P9054	Blood, l/r, froz/degly/wash	1016	1016	101.68	97.80	-3.82
P9055	Plt, aph/pher, l/r, cmv-neg	1017	1017	480.41	408.02	-15.07
P9056	Blood, l/r, irradiated	1018	1018	226.31	194.91	-13.87
P9057	RBC, frz/deg/wsh, l/r, irrad	1021	1021	424.67	417.10	-1.78
P9058	RBC, l/r, cmv-neg, irrad	1022	1022	301.43	281.53	-6.60
P9059	Plasma, frz between 8-24hour	0955	0955	75.62	80.87	6.94
P9060	Fr frz plasma donor retested	9503	9503	64.25	61.57	-4.17

House Bill, *from page 1*

Labor by a vote of 26 to 22. The Committee on Energy and Commerce approved the bill July 31 by a vote of 31 to 28.

Anti-Fraud Efforts

For anti-fraud efforts, the proposed legislation would give an additional $100 million annually to the Health Care Fraud and Abuse Control (HCFAC) program and allow more access to those funds by the Centers for Medicare and Medicaid Services (CMS) for Medicare program integrity efforts.

CMS, the Department of Health and Human Services Office of Inspector General, Department of Justice, and Federal Bureau of Investigation already are slated to share $1.2 billion in mandatory funding from the HCFAC program in fiscal year 2010, and the White House requested in its FY 2010 budget an additional $300 million in discretionary funding for program integrity.

In addition to increased funding, the bill would give the secretary of health and human services the authority to identify areas of "significant risk," where enhanced oversight was needed to prevent fraud, waste, and abuse.

Among specific oversight enhancements lawmakers would mandate are new screening procedures for new Medicare providers, such as licensing checks, background checks, and unannounced pre-enrollment site inspections. The new secretarial authority also would allow for moratoriums on new provider enrollments in service areas at high risk for fraud.

Lawmakers also are seeking to require all providers and suppliers, except physicians, to adopt compliance programs. Under the measure, the HHS secretary would have the discretion either to disenroll a provider or supplier or impose civil monetary penalties for failing to adopt an anti-fraud plan.

Other program integrity measures in the bill would give providers no more than 12 months to submit Medicare claims and would require providers, suppliers, Medicare Advantage organizations, and Part D plans to report and repay any overpayments they identify within 60 days.

New Penalties

The health reform bill contains several new and increased penalties for a host of fraudulent activities, including establishing fines of $50,000 per violation for false statements on provider and supplier enrollment applications and for false statements in information submitted with claims.

In addition to increased funding, the bill would give the secretary of health and human services the authority to identify areas of "significant risk," where enhanced oversight is needed to prevent fraud, waste, and abuse.

Under the legislation, MA and Part D plans also would be subject to false claims penalties of up to three times the payment made to a plan based on false information. The bill calls for establishing new criteria for Part D and MA marketing violations, giving the HHS secretary and CMS greater discretion in imposing penalties on plans that violate marketing rules.

Further, the bill would clarify that exclusion of certain individuals and entities from the Medicare and Medicaid programs would mean exclusion from all federal health programs. The bill also calls for a $15,000 per-day penalty for delaying OIG access to information for audits, investigations, and evaluations.

Supreme Court Ruling Puts Lab Analysts in the Hot Seat

In a 5-4 decision, the U.S. Supreme Court ruled that analysts who create crime laboratory reports must be available to testify in court and be cross-examined on how they reached those results. Submission of the paperwork alone is not sufficient. Prosecutors can no longer rely on the crime lab report as prima-facie evidence of what they assert.

The ruling applies to testing for blood alcohol, narcotics, or any substance whose results are included in a crime laboratory report and to the qualifications and skills of personnel who produce the test results cited in the report.

The majority opinion, written by Justice Antonin Scalia, held that a criminal defendant has the right "to be confronted with the witnesses against him." Cross-examination of witnesses "is designed to weed out not only the fraudulent analyst, but the incompetent one as well." Serious deficiencies have been found in the forensic evidence used at criminal trials, he wrote, adding that "forensic evidence is not uniquely immune from the risk of manipulation."

Scalia dismissed dissenters' arguments that producing analysts in court would be burdensome and costly. "The confrontation clause may make the prosecution of criminals more burdensome, but that is equally true of the right to trial by jury and the privilege against self-incrimination."

The case, *Melendez-Diaz v. Massachusetts* (No. 07-591), arose when Luis E. Melendez-Diaz was convicted on cocaine trafficking charges. Part of the evidence against him was a lab report stating that bags of white powder said to have belonged to him contained cocaine. He objected, saying he had the right to confront the analyst about the report. The trial court disagreed, he was convicted, and the state appeals court affirmed the lower court ruling, rejecting his claim that the paperwork submission violated his right under the Sixth Amendment.

Justice Anthony M. Kennedy, writing for the dissenters, said the majority decision upends 90 years of settled law. Scientific evidence should be treated differently from statements from witnesses to a crime. He warned that the decision would subject the nation's criminal justice system to "a crushing burden" and that it means "guilty defendants will go free, on the most technical grounds."

"The defense bar today gains the formidable power to require the government to transport the analyst to the courtroom at the time of trial," Kennedy wrote. As an example, he cited the FBI's laboratory in Quantico, Va., which employs 500 and conducts more than a million scientific tests each year. "The court's decision means that before any of those million tests reaches a jury, at least one of the laboratory's analysts must board a plane, find his or her way to an unfamiliar courthouse, and sit there waiting to read aloud notes made months ago."

Court Upholds Denial of Payment for Lab Tests

A federal district court July 28 upheld the denial of Medicare reimbursement for blood glucose laboratory tests performed by three skilled nursing facilities (*Willowood of Great Barrington Inc. v. Sebelius*).

In so ruling, the U.S. District Court for the District of Massachusetts adopted a June 30 recommendation by Magistrate Judge Kenneth P. Neiman that the health and human services secretary's denial of reimbursement to three skilled nursing facilities (SNFs)—nonprofit affiliates of Berkshire Health Systems—for

the Medicare claims was not arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or contrary to law.

The court found that the tests, which were performed on the SNFs' patients, were not promptly reported to the patients' physicians and that the SNFs knew that prompt reporting of blood glucose testing to physicians was deemed necessary.

During October 2005, each attending physician for 12 patients issued a patient-specific order authorizing at least twice-daily blood glucose testing. No physician performed any part of the testing or was present for any single test, and the results were simply recorded on the patients' charts without the physician being notified, promptly or otherwise.

Regular Review

Although the results were available for the physicians to review at their next routine visits, there was no indication that any of the results were regularly reviewed by the physicians. The fiscal intermediary denied the SNFs' claims for reimbursement and the denials were upheld by a Medicare contractor.

An administrative law judge (ALJ) subsequently denied the SNFs' reimbursement claims and the Medicare Appeals Council upheld the ALJ's decision. The ALJ found that the test results were not promptly reported to the physicians and, therefore, the results were not used by the ordering physicians in such a way as to qualify for reimbursement.

On appeal, the SNFs not only sought to reverse the coverage decisions with respect to the testing performed on the 12 patients in October 2005, but also sought reimbursement for the denied claims for all of their similarly situated patients between Nov. 1, 2005, and Dec. 31, 2006.

The SNFs raised several arguments, including the argument that the controlling regulation, 42 C.F.R. §410.32(a), does not use the word "promptly" in connection with physician notification for diagnostic laboratory testing. Thus, the SNFs argued, the secretary's failure to reimburse the SNFs for not promptly notifying physicians was a direct violation of that regulation.

Rule Amplified

The court, however, found that the SNFs were not able to surmount the steep standard of review required for the appeal to succeed. The regulation was amplified by both Transmittal AB-00-108 and the Medicare program manuals, which provide that clinical laboratory services must be ordered and used promptly by the physician, the court found.

The court also rejected the SNFs' assertion that the ALJ failed to consider certain undisputed medical evidence, particularly the fact that the "promptness" requirement was actually met. The court found that there was no evidence that the patients' results were ever actually reported to or reviewed by a physician and the evidence wholly supported the ALJ's conclusion that the patients' test results were not promptly reported to their physicians.

The court also found no equal protection violation existed with regard to the SNFs' argument that the ALJ's decision discriminated against the SNFs because tests performed at outside laboratories would have been reimbursed despite the lack of prompt physician reporting. The court found that the SNFs ignored the fact that the operative regulation at issue in the ALJ's decision—§ 410.32(a)—applies to all diagnostic laboratory testing, whether the services are performed in an SNF or at an outside laboratory facility.

News-At-A-Glance

RED FLAG RULES DELAYED: The Federal Trade Commission (FTC) announced July 29 it will further delay enforcement of rules that require a broad range of entities to implement identity theft prevention programs, from Aug. 1 until Nov. 1, and will provide additional guidance for health care providers and other low-risk entities on compliance. Under the rules, financial institutions and creditors are required to develop prevention programs that identify relevant patterns, practices, and specific activities that are "red flags" for possible identity theft. The FTC has been accused of applying the rules to organizations that were not intended to be covered, including health care providers, and the agency already has delayed enforcement twice because of such concerns.

MEDICARE CLAIMS: Calling fraud a "serious financial drain" on the nation's health care system, the Government Accountability Office (GAO) said in a July 20 letter to a Senate panel that it had identified several weaknesses in how Medicare claims are reviewed, both before and after they are paid. The GAO letter was in response to follow-up questions after an April 22 hearing on improper payments in the Medicare and Medicaid programs. Among weaknesses in Medicare payments that GAO said it had found in previous work were limitations in the number of home health claims that were reviewed by Medicare contractors before they were paid.

FDA ENFORCEMENT: Food, medical device, and pharmaceutical manufacturers that violate Food and Drug Administration laws and regulations should expect swift and strong enforcement, Commissioner Margaret Hamburg said Aug. 6. Hamburg told members of the Food and Drug Law Institute that "companies must have a realistic expectation that if they are crossing the line, they will be caught." Hamburg said she was making changes within the agency to streamline enforcement of regulations, as well as ensure industry compliance with enforcement actions. In an effort to change the current approach to enforcement, Hamburg said, the agency will no longer send multiple warning letters to noncompliant companies before taking action. Sometimes, if there is a significant danger to public health, Hamburg said, the agency will take immediate action without a warning letter.

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Kimberly Scott, Senior Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Publisher; Joe Bremner, President.

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