G2 Compliance Report

G2 INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

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Inside this issue

Palmetto addressing MolDx concerns; no implementation delay expected 1

OIG: Lab-doc practice arrangement might violate anti-kickback statute 1

High court takes on patent eligibility of diagnostic tests; ruling will have widespread implications 3

Preparing your lab for 2012 coding and policy changes: see *Perspectives* 5

DOJ intervenes in suit accusing Texas lab of misrepresenting Medicare mileage claims 9

Virginia's malpractice damages cap applies to genetic testing laboratory, court says 10

News in brief 12

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Palmetto Addressing MolDx Concerns; No Implementation Delay Expected

Palmetto GBA is working to address some of the concerns raised by the lab industry over its new coverage and payment program for molecular diagnostics tests, but the Medicare contractor has no plans to delay the March 1, 2012, implementation date for the program, dubbed MolDx.

Mike Barlow, vice president and program manager for Palmetto's J1 jurisdiction, tells G2 Intelligence that he has met with several "major" labs to discuss their concerns and is in the process of modifying the program to address some of the issues raised. For example, Palmetto will eliminate or make optional some of the information requested from labs as part of the application process to receive a Z-Code™ from McKesson.

One of the concerns raised by the American Clinical Laboratory Association (ACLA) was that the application required labs "to submit more than 32 separate pieces of information, far more than would be necessary for the mere assignment of a code." ACLA also complained

Continued on page 2

OIG: Lab-Doc Practice Arrangement Might Violate Anti-Kickback Statute

An arrangement in which a company would furnish allergy laboratory services to a physicians' office could violate the anti-kickback statute and be subject to administrative penalties, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion (No. 11-17) posted Nov. 23.

The proposed arrangement could result in civil monetary penalties under Section 1128(a)(7) of the Social Security Act, OIG said. It could also result in exclusion from federal health care programs under Section 1128(b)(7) of the act, as that section relates to the federal anti-kickback statute.

The requestor, a laboratory services management company whose name OIG redacted, proposed to provide lab services to a physicians' practice. The company would enter into exclusive contracts with physicians to operate an allergy testing laboratory on the physicians' behalf. The lab management company would provide the lab personnel and the tech-

Continued on page 9

Palmetto Addressing MolDx Concerns, *from page 1*

that the MolDx program would force labs to provide valuable commercial information to McKesson, a third-party-vendor, and that McKesson "could use and profit from the information in its other private business arrangements."

Barlow counters that the instructions accompanying the Z-Code application specifically tells labs not to provide any proprietary information. For example, in the field for "Test Information—Contributing Components," the instructions state "Do not include intellectual property."

"We are only asking for things that are already available publicly," says Barlow. "It's information that could be found in the scientific literature or on [labs'] Web sites or in their marketing materials." More detailed information is needed for the technology assessment panel, but that will not be shared with McKesson or any other third party, he says.

Willing to Work With Labs

Palmetto decided to use the Z-Code process because it was already in use and was recognized by other payers, explains Barlow. "We didn't see any reason to reinvent the wheel," he says. It also allows Palmetto to automate the approval system. Without the Z-Code, Palmetto will need to request additional information from a lab every time it receives a claim and then make a manual determination of whether the test is covered or not. "I believe the Z-Code process is the most efficient way of doing this," says Barlow. "I will work with labs on what information they think they need to provide."

> ***"We are only asking for things that are already available publicly. It's information that could be found in the scientific literature or on [labs'] Web sites or in their marketing materials."***
>
> ***– Mike Barlow, Vice President and Program Manager Palmetto***

Responding to criticism that Palmetto is proceeding with this program even as the Centers for Medicare and Medicaid Services (CMS) is developing a payment system for molecular diagnostic tests using new CPT codes developed by the American Medical Association (AMA), Barlow tells G2 Intelligence that MolDx can work in tandem with whatever system CMS announces. If a test has a specific code and payment assigned by CMS, it will no longer need a separate Z-Code. However, Barlow notes, the new AMA codes do not address all MDx tests. For those without a code and a payment assignment, MolDx would continue to apply.

"The molecular and genetic industry is so far ahead of where the coding process is right now," he says. "We need to have some way of knowing what we're paying for. If CMS sets a fee schedule amount for a specific code, then I don't need MolDx for those codes. But those codes only cover a narrow spectrum of what we're trying to address."

The AMA approved 101 new molecular diagnostic codes for inclusion in the CPT update for 2012. The codes are assigned to one of two categories covering more than 90 percent of the volume of current molecular pathology procedures. One category, Tier 1, includes 92 high-volume tests coded by specific analyte. Tier 2 includes nine low-volume tests coded by the level of resources required for their performance and interpretation. The new coding system does not address molecular microbiology tests or most cytogenetic assays.

CMS has not yet determined whether it will pay the 101 new codes on the basis of the clinical laboratory fee schedule or the physician fee schedule, or a combination of both. Many in the industry believe that payment will be set in 2012 for implementation in 2013. Currently, molecular diagnostic codes are paid through "code stacking." Payers contend this makes it difficult to know precisely what is being tested and what they are paying for.

> ***"Any coverage or payment determination that a contractor makes is appealable."***
>
> ***– Mike Barlow, Vice President and Program Manager Palmetto***

When asked about industry concerns that the MolDx circumvents the appeals process since labs could not submit claims that are not covered and thus would have no opportunity to get a denial, which is necessary for an appeal, Barlow says there is nothing in the program that would prevent a lab from submitting a test for payment by Palmetto and subsequently appealing if payment is denied.

Even if Palmetto publishes a coverage decision stating that a particular test is not covered, labs can still submit a claim for payment, get a denial, and go through the appeals process, explains Barlow. "Any coverage or payment determination that a contractor makes is appealable," he says.

Barlow also says Palmetto intends to address concerns over the licensing agreement required as part of the Z-Code process by making it more of a disclaimer, similar to that used by the AMA for use of its CPT codes.

MolDx Program Set to Launch in March

Under the MolDx program, which is set to launch March 1, labs will register their molecular diagnostic tests with Palmetto and submit test information and supporting evidence for a coverage determination. Subject matter experts in academia and industry will provide technical assessments.

Each lab must apply for a unique McKesson Z-Code that will be maintained in an automated registry. Palmetto will use the system to identify the billed tests, determine if evidence supports it as reasonable and necessary, and apply appropriate reimbursement. All labs that perform molecular diagnostic testing and bill Medicare in A/B MAC Jurisdiction 1 (J1) will be affected by the new program. This includes California, Nevada, Hawaii, and the Pacific Territories of Guam, American Samoa, and the Northern Marianas. G2

High Court Takes on Patent Eligibility of Diagnostic Tests; Ruling Will Have Widespread Implications

A case heard this week before the U.S. Supreme Court on patents for diagnostic medical tests is being closely watched as the ruling is expected to have widespread implications throughout the diagnostics industry.

At issue are patents on method for determining the proper dosage of thiopurine, a stomach medicine, based on the rate at which particular patients metabolize the drugs. Doctors can use the method, which involves testing blood for metabolites, to maximize the effectiveness and limit toxic side effects while treating Crohn's disease and other inflammatory bowel illnesses.

Prometheus Laboratories Inc. is the exclusive licensee of two patents on the method.

Prometheus is suing two units of Mayo Clinic, which at one time shipped patient samples to Prometheus and paid the company to perform the test. That relationship ended in 2004, when Mayo created its own test. Prometheus claims that Mayo's tests measuring the same metabolites infringe the patents.

Mayo challenged Prometheus's patents, but a lower court ruled that the patents were potentially valid because they involved the application of a law of nature, not the law itself. The case tests the longstanding principle that natural phenomena can't be patented.

While a ruling in the case will affect many different industries, its greatest impact is likely to be in the field of personalized medicine.

Because the court will consider the most fundamental question in patent law—what can be patented—the ruling "will or could have shock waves across all industries."

– Erika Amer
Washington lawyer

"The important and developing industry of personalized medicine would be seriously jeopardized if such substantial and innovative contributions to science and medicine were denied patent protection at the doorway of the Patent Act," said Myriad Genetics in a court filing. Myriad and Novartis AG are backing Prometheus.

But the American Medical Association, which is backing Mayo, says the opposite is true. "Patents on scientific observation threaten to stifle innovation, including the development of personalized medicine," the AMA said in a court filing.

More than two dozen legal briefs were filed in support of both Mayo and Prometheus. Mayo has the support of Verizon Communications Inc., Hewlett-Packard Co., LabCorp, and AARP. Prometheus has backing from trade groups for the drug and biotechnology industries.

"The claims have to do with diagnostic methods, but it has the potential to touch industries we don't know about," said Erika Amer, a Washington lawyer who filed a brief asking the court not to restrict software and computer patents, according to Bloomberg *Businessweek*. Because the court will consider the most fundamental question in patent law—what can be patented—the ruling "will or could have shock waves across all industries," said Amer.

Influenced by *Bilski*

This case is the second at the Supreme Court since 2010 concerning what types of inventions are eligible for legal protection. In July 2010, the high court declared that the machine or transformation test (MoT) was a valuable tool in determining patent eligibility but not the only tool (*Bilski* v. *Kappos*). A day after the *Bilski* ruling, the Supreme Court granted certiorari in the *Prometheus* case and remanded the case to the Federal Circuit for reconsideration in light of the *Bilski* decision.

On remand, a reconstituted Federal Circuit panel Dec. 17, 2010, again upheld the patentability of the disputed claims. The court used the MoT test as an investigative tool, as the high court had allowed in *Bilski*, and again held that the claims asserted passed the transformation prong of the test. The court did not end its analysis there, though, as it further concluded that the asserted claims did not preempt all uses of the correlations between the results of the diagnostic tests and the toxicity and efficacy of the drug dosage, that the testing steps were not mere data gathering, and that a final "warning" step requiring no physical action by a physician did not negate patent eligibility. Mayo on March 17, 2011, filed a certiorari petition with the Supreme Court, and the court agreed June 20 to hear the case.

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COMPLIANCE PERSPECTIVES

Preparing Your Lab for 2012 Coding and Policy Changes

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It's that time of year . . . again. Laboratories are brushing up on regulatory changes that affect coding and policy changes for 2012. This process should include a thorough review of the lab charge masters and any required edits necessary to be compliant.

To provide you with details on the 2012 CPT® changes, Rick Oliver, compliance director, McKesson Revenue Management Solutions, and Donna Beasley, national director, McKesson Revenue Builder© for Labs, have prepared this summary of new, deleted, and revised codes issued by the American Medical Association (AMA)[1]. Any updated Healthcare Common Procedure Coding System codes by the Centers for Medicare and Medicaid Services (CMS) are not currently available as they have, to date, not yet been published by CMS for 2012.

Molecular Diagnostics—Still a Question Mark

The major changes in CPT®-2012 compared to CPT®-2011 are the development of new molecular pathology codes designated as Tier 1 and Tier 2 codes. Publication in CPT®-2012 of the new Tier 1 and Tier 2 molecular pathology codes may be a moot point as CMS has stated it will *not* recognize any of these new codes for 2012 because they were not introduced to CMS in time for the agency to price them. Therefore, coding for molecular diagnostic testing must continue to use the "stacking codes" (83890-83914) for at least calendar year 2012. CMS stated it will review the new codes and determine if it will implement and price them in the 2013 calendar year. Private insurers likely will follow Medicare's lead in these regards, but that too is uncertain at the moment. Providers will need to watch carrier bulletins and notices to determine whether they will recognize and pay on the new molecular codes or continue to require the old "stacking codes" for molecular diagnostic testing.

Palmetto GBA, a Medicare administrator, recently announced that it is expanding the J1 Molecular Diagnostic Services Program (MolDx) to identify and establish coverage and reimbursement for molecular diagnostic tests. Under the expanded program, laboratory providers in Jurisdiction 1 (J1) which includes California, Nevada, Hawaii, and the U.S. Pacific Territories, will register molecular diagnostic tests to obtain a unique McKesson Z-Code™. As mentioned above, CMS will continue to recognize the use of stacking codes; however, labs in J1 will also need to include the Z-Code on claims submitted to CMS. Additionally, labs will also submit required clinical evidence via the McKesson Diagnostics Exchange™ Test Assessment Module in order to get a coverage determination. This program will affect all hospital, private, and reference laboratories that perform molecular diagnostic testing and bill Medicare in (J1). Again, carrier bulletin updates will be crucial to keep abreast of changes and application dates.

New Codes: Effective Jan. 1

The vast majority of new codes as stated previously involve the molecular pathology codes designated in Tier 1 or 2. The new CPT® codes will cover roughly

[1] *CPT is a registered trademark of the American Medical Association. The AMA is the owner of all copyright, trademark, and other rights to CPT® and its updates. CPT® codes, descriptions, and other data are copyright 1966, 1970, 1973, 1977, 1981, and 1983-2010 American Medical Association. All rights reserved.*

90 percent of the present molecular diagnostic pathology procedures and also have a structure designed to add new codes in the future. These changes do *not* affect molecular microbiology tests or most cytogenetic assays. These new codes will eventually replace the current molecular stacking codes (83890-83914) for those specifically defined analyte tests; however, the stacking codes will remain available to report tests in 2012 for those that have not been assigned analyte-specific or resource-level codes. Stacking codes will likely be retired in 2013. For laboratories and pathologists this very well may be the biggest change in code selection since the implementation of the anatomic pathology code set structure back in the early '90s.

The new codes assigned in a "Tier" setting will not be further discussed in detail in this article due to the nonpricing status and potential for nonuse until 2013.

Other new code changes include:

Immunology: 86386—Nuclear Matrix Protein 22 (NMP22), qualitative

(Ouchtertony diffusion, use 86331)

(Platelet antibodies, use 86022, 86023)

Microbiology: 87389—HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result

Delete Codes: Effective Jan. 1

There is no replacement code for these deleted codes; AMA refers you to 88104, 88106 codes for the 88107 code.

DELETED CODES	CODE DESCRIPTION
88107	Smears and simple filter preparation with interpretation
88318	Determinative histochemistry to identify chemical components (eg, copper, zinc)

Revised Codes: Effective Jan. 1

The descriptors and instructions for special stain codes 88312-88319 have been modified. The modified description by the AMA for special stain codes now advises that the unit of service for special stains is the "block" instead of the "stain," which coincides with the 2009 determination by CMS. The revised codes and parenthetical notes are indicated below; items in bold italic are new while "strikethrough" verbiage was deleted from the narrative.

REVISED CODES	CODE DESCRIPTION
38230	Bone marrow harvesting for transplantation; ***allogeneic***
86148	Parenthetical note after CPT® 86148—Anti-phosphatidylserine (phospholipid) antibody was updated to add: ***(For cell enumeration using immunologic selection and identification in fluid specimen [eg, circulating tumor cells in blood], see 0279T, 0280T)***
86294	Parenthetical note after CPT® 86294—Immunoassay for tumor antigen, qualitative or semiquantitative (eg, bladder tumor antigen) was updated to add: ***(For qualitative NMP22 protein, use 86386)***
86703	HIV-1 and HIV-2, single ~~assay~~ result ***(For HIV-1 antigen(s) with HIV-1 and HIV-2 antibodies, single result, use 87389)*** (When HIV ~~antibody~~ immunoassay [HIV testing 86701-86703 or 87389] is performed using a kit or transportable instrument that wholly or in part consists of a single use, disposable analytical chamber, service may be identified by adding modifier 92 to the usual code)
86822	Parenthetical note after CPT® 86822—lymphocyte culture, primed (PLC) was updated to read: ***(For HLA typing by molecular pathology techniques, see 81370-81383)***

REVISED CODES	CODE DESCRIPTION
88106	Parenthetical note after CPT® 88106—simple filter method with interpretation was updated to add: ***(Do not report 88106 in conjunction with 88104)*** ***(88107 has been deleted. To report smears and simple filter preparation, see 88104, 88106)***
88189	Parenthetical note after CPT® 88189—16 or more markers was updated to add: ***(For cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood), see 0279T, 0280T)***
88312	Special stains including interpretation and report; Group I for microorganisms (eg, ~~Gridley~~, acid fast, methenamine silver), ~~including interpretation and report, each~~ ***(Report one unit of 88312 for each special stain, on each surgical pathology block, cytologic specimen, or hematologic smear)***
88313	Group II, all other (eg, iron, trichrome), except **stain for microorganisms, stains for enzyme constituents, or** immunocytochemistry and immunoperoxidase ~~stains, including interpretation and report, each~~ ***(Report one unit of 88313 for each special stain, on each surgical pathology block, cytologic specimen, or hematologic smear)*** (For immunocytochemistry and ***immunohistochemistry***, ~~immunoperoxidase tissue studies~~ use 88342)
88314	Histochemical ***stain on frozen tissue block*** ~~staining with frozen section(s), including interpretation and report~~ (List separately in addition to code for primary procedure) (Use 88314 in conjunction with ***17311-17315***, 88302-88309, ***88331, 88332)*** (Do not report 88314 with 17311-17315 for routine frozen section stain [eg, hematoxylin and eosin, toluidine blue], performed during Mohs surgery. When a nonroutine histochemical stain on frozen tissue ***during Mohs surgery*** is utilized, report 88314 with modifier 59.) ***(Report one unit of 88314 for each special stain on each frozen surgical pathology block)*** ***(For a special stain performed on frozen tissue section material to identify enzyme constituents, use 88319)*** ***(88318 has been deleted)*** ***(For determinative histochemistry to identify chemical components, use 88313) enzyme constituents, use 88319)*** ***(88318 has been deleted)*** ***(For determinative histochemistry to identify chemical components, use 88313)*** ***(Report one unit of 88314 for each special stain on each frozen surgical pathology block)*** ***(For a special stain performed on frozen tissue section material to identify enzyme constituents, use 88319)*** ***(88318 has been deleted)*** ***(For determinative histochemistry to identify chemical components, use 88313)***
88319	Group III, for ~~Determinative histochemistry or cytochemistry to identify~~ enzyme constituents , ~~each~~ ***(For each stain on each surgical pathology block, cytologic specimen, or hematologic smear, use one unit of 88319)*** ***(For detection of enzyme constituents by immunohistochemical or immunocytochemical technique, use 88342)***
In Vivo Lab	Parenthetical note under the In Vivo (eg, Transcutaneous) Laboratory Procedures section was updated to add: ***(For transcutaneous oxyhemoglobin measurement in a lower extremity wound by near infrared spectroscopy, use 0286T)***

Clinical Laboratory Fee Schedule

In the CMS Physician Fee Schedule final rule with comments, CMS indicated a slight increase of payments to the laboratory. The net effect of the standard clinical laboratory fee calculations ended up with a 0.7 percent (rounded) increase in the fee schedule for 2012.

Physician Fee Schedule

While the Clinical Lab Fee Schedule (CLFS) had many fewer changes to consider, the vast majority of changes for 2012 affected the Physician Fee Schedule (PFS). On Nov. 1, 2011, CMS released the PFS final rule with comments that will update payment policies and payment rates for calendar year (CY) 2012. This final rule also includes changes to the Physician Quality Reporting System (PQRS), Electronic e-Prescribing (eRX), electronic health records (EHRs) and Clinical Lab Fee Schedule (CLFS) signature on requisition, among other items. The rule also includes CMS's initial attempt on a framework for a new value-based modifier for implementation in CY 2015; this rule is a result of a mandate in the Patient Protection and Affordable Care Act (ACA) of 2010.

A copy of the full final rule with comments is available at *https://www.cms.gov/PhysicianFeeSched/*. Some particular points of interest in the full document:

1. The PFS rate conversion factor (CF) will be $24.6712 for CY 2012 down, from $33.9764 in CY 2011. This is a 27.4 percent cut from CY 2011. This CF will go into place Jan. 1, 2012, unless Congress steps in, once again, and averts the cut with legislation.

2. The termination of the "TC Grandfather Clause" will occur Dec. 31, 2011, unless Congress steps in to overrule this termination. If Congress does not step in, pathologists and labs that are performing the TC of any physician fee schedule tests on "hospital inpatients or outpatients" will no longer be able to bill for those services to the Part B carrier/MAC. They will have to bill back the hospital for their payments.

3. CMS finalized the proposed rule that "will retract the policy that was finalized in the Nov. 29, 2010, *Federal Register* and reinstate the prior policy that the signature of the requesting (ordering or treating) physician is not required on a requisition for Medicare purposes for a clinical diagnostic laboratory test paid under the CLFS." (*Federal Register*, June 30, 2011, pgs. 38,342-38,347). Requisitions are not required to be signed by that ordering physician or practitioner; however there must be a signed order in the patient's medical record at the ordering physician or practitioner's office.

4. Three new PQRS measures for pathology were finalized in addition to retaining the original two (measures 99 and 100) for CY 2012.

5. Final ruling on the three-day window rule for nondiagnostic tests performed by a hospital or wholly owned or directed facility of the hospital on patients that are admitted to that facility within 72 hours of the testing. CMS did not make any changes for the "diagnostic tests" performed in this time frame; they remain subject to the 72-hour rule as always.

Issue Unresolved

CMS did not address in the 2012 PFS rulemaking any language regarding the anatomic pathology self-referral arrangements, a growing concern for pathologists as physician specialists increasingly enter into business arrangements that take advantage of gaps in the anti-markup and self-referral rules. These gaps allow them to bill and be paid for anatomic pathology services actually furnished by physicians with no relationship to the ordering physician.

OIG: Lab-Doc Practice Arrangement, *from page 1*

nicians, and the physicians would bill federal health care programs and third-party payers for laboratory items and services provided under the proposed agreement.

In turn, physicians would pay the requestor a fee for items and services provided by the lab equal to 60 percent of the "physicians' gross collections from allergy testing and immunotherapy items and services," the opinion said. "According to [the requestor], this percentage fee is equal to fair market value."

No Safe Harbor

The OIG said the proposed arrangement would not qualify under anti-kickback safe harbor provisions that would protect it from prosecution and sanctions. To be eligible for safe harbor protection, the contract for payment must specify that the compensation be set in advance, the OIG said. It must not be determined in a way that takes into account the volume or value of business generated between the parties that is payable by a federal health care program.

"Instead, [r]equestor would receive a percentage of the [p]hysicians' gross collections from allergy testing and immunotherapy items and services," the OIG said. "Percentage compensation arrangements are inherently problematic under the anti-kickback statute, because they relate to the volume and value of business generated between the parties, rather than the fair market value of the services provided."

'Suspect' Marketing Activity

Additionally, the OIG voiced concern with the requestor reviewing patient files to assist the physicians in marketing allergy testing services to patients. This could be a suspect marketing activity, it said.

"We are concerned that this type of marketing activity could encourage [p]hysicians to order medically unnecessary tests that could pose a risk of patient harm," the OIG said. "The [p]roposed [a]rrangement's fee structure would create a risk of overutilization, because [r]equestor would engage in marketing activities by identifying patients the [p]hysicians could refer for allergy testing and would receive a percentage of revenues generated from such referrals."

In issuing the opinion, the OIG said it relied solely on the facts and information furnished by the laboratory services firm. Any definitive conclusion regarding anti-kickback violations, however, requires a determination of the parties' intent and is beyond the scope of the advisory opinion, OIG said.

Advisory opinion No. 11-17 is available online at *www.oig.hhs.gov.*

DOJ Intervenes in Suit Accusing Texas Lab Of Misrepresenting Medicare Mileage Claims

The Department of Justice has intervened in a whistleblower lawsuit alleging a Texas laboratory and its founder violated the False Claims Act by knowingly misrepresenting the distances traveled by its lab technicians to artificially increase reimbursement from Medicare for mileage-based technician travel allowance fees, prosecutors announced Nov. 22 (*United States ex rel. Drummond v. BestCare Laboratory Services LLC*).

In an intervenor's complaint filed in the U.S. District Court for the Southern District of Texas, the government charged that BestCare Laboratory Services LLC of Webster and its founder, Karim A. Maghareh, transported test specimens as air cargo from

nursing home customers in Austin, Dallas-Fort Worth, El Paso, San Antonio, and Waco to its laboratory near Houston.

BestCare claimed mileage for ground travel, however, as though its technicians drove the specimens one-way or round-trip to those cities and Houston, according to the complaint.

Relator Richard Drummond filed the whistleblower lawsuit originally in August 2008. Mark S. Armstrong, an attorney representing BestCare Laboratory in the lawsuit, said Drummond is BestCare's longtime competitor.

$24 Million in Claims

From 2004 through 2009, BestCare received more than $24 million from claims submitted to Medicare for mileage-based compensation for purported technician travel, the complaint stated.

"There's no question that health care providers are entitled to recover their reasonable costs for services they actually deliver, but we have zero patience for those who invent or inflate Medicare reimbursement claims," Assistant Attorney General Tony West said in a statement.

The complaint further alleges that Maghareh supervised BestCare's day-to-day operations and directed or authorized the false billing. The defendant allegedly withdrew substantial amounts from BestCare as salaries and distributions to himself and his wife and used BestCare's assets and profits for his and his wife's personal benefit.

Medicare pays labs certain fees, including the federal per-mile automobile mileage rate, for sending trained technicians to draw specimens from homebound or nursing home patients and to return the specimens to the lab for testing, the lawsuit said. Medicare rules require mileage claims for technician travel to be prorated by the number of patients serviced in a single trip.

The United States seeks to recover treble damages and civil penalties under the False Claims Act, plus unspecified compensatory and punitive damages for filing false claims with the intent to deceive, the complaint said. The government also said it is entitled to recover money paid to BestCare. G2

Virginia's Malpractice Damages Cap Applies To Genetic Testing Laboratory, Court Says

A federal district court Nov. 7 determined that Virginia's statutory cap on medical malpractice damages applies to an independent testing laboratory named as a defendant in a wrongful birth lawsuit (*Khadim v. Laboratory Corporation of America*).

The U.S. District Court for the Western District of Virginia found that defendant Laboratory Corporation of America (LabCorp) was a health care provider within the meaning of Virginia's Medical Malpractice Act (VMMA), Va. Code Section 8.01-581.1 et seq. Thus, it said in an opinion by Judge Norman K. Moon, LabCorp was entitled to summary judgment and that it could not be held liable for damages in excess of the statutory cap.

Genetic Condition Not Detected

Plaintiffs Seema Khadim and Sultan Zeb were both carriers of a gene that causes Cooley's anemia, an inherited life-threatening blood disorder. People with the disorder require

regular blood transfusions and extensive ongoing medical care. They often suffer excruciating pain following transfusions, and female sufferers often are rendered infertile.

When Khadim became pregnant, she and Zeb asked their doctor to test the fetus to determine whether it would be afflicted with Cooley's anemia. Because they had several family members with the condition, they decided they would terminate the pregnancy if the result was positive.

An amniotic fluid sample was sent to LabCorp for analysis. Initially, LabCorp reported that the fetus was only a carrier, but it asked for more information to make a complete analysis. After analyzing blood samples from both parents, LabCorp again reported that the baby would not be afflicted with the condition.

After the plaintiffs' daughter's birth, tests determined that she had Cooley's anemia. She had her first blood transfusion at 1 month.

Laboratory's Liability Alleged

Khadim and Zeb filed a lawsuit against LabCorp and others to recover damages for wrongful birth. They alleged that LabCorp negligently analyzed only part of the genetic test strip and that it knew or should have known that the parents would rely on its testing.

LabCorp moved for partial summary judgment to limit its damages liability. It maintained that it was a health care provider within the meaning of the VMMA and, therefore, the statute's damages cap applied in this case.

The VMMA defines "health care provider" as: "(i) a person, corporation, facility or institution licensed by this Commonwealth to provide health care or professional services …; (ii) a professional corporation, all of whose shareholders or members are so licensed; (iii) a partnership, all of whose partners are so licensed …; (vi) a corporation, partnership, limited liability company or any other entity, except a state-operated facility, which employs or engages a licensed health care provider and which primarily renders health care services; or (vii) a director, officer, employee, independent contractor, or agent of the persons or entities referenced herein, acting within the course and scope of his employment or engagement as related to health care or professional services."

"Health care," according to the VMMA, is "any act … or treatment performed or furnished, or which should have been performed or furnished, by any health care provider for, to, or on behalf of a patient during the patient's medical diagnosis, care, treatment or confinement."

The court found that LabCorp was covered by the VMMA because it was a corporation that employed or engaged Virginia-licensed health care providers and primarily rendered health care services. The company had provided evidence that at least two of the physicians employed at its North Carolina facility were licensed in Virginia, the court said.

Also, the court said, LabCorp was a health care provider within the VMMA because it was an independent contractor of a physician licensed in Virginia—Khadim's obstetrician. According to the court, the obstetrician employed LabCorp "to do a piece of work without restrictions as to the means to be employed." G2

News-At-A-Glance

NIST RELEASES HANDBOOK FOR LABS: The National Institute of Standards and Technology's National Voluntary Laboratory Accreditation Program (NVLAP) Nov. 29 announced the release of NIST Handbook 150-31, *Healthcare Information Technology Testing*. The handbook details the program-specific requirements for accrediting laboratories performing functional and conformance testing of electronic health record products to nationally recognized "meaningful use" requirements for health information technology products. NVLAP also released the program-specific application form associated with the Healthcare Information Technology Testing Laboratory Accreditation Program (HIT LAP). The program is scheduled to begin accepting applications Jan. 1, 2012. Additional information and future updates regarding the NVLAP HIT LAP can be found at *www.nist.gov/nvlap/hit-lap.cfm*. The handbook is available at *www.nist.gov/nvlap/upload/NIST-HB-150-31-2011.pdf*.

PAYMENT ERROR RATE DECLINING: The government's announcement in mid-November that it reduced the rate of paying improper Medicare claims by 1.5 percent in fiscal year 2011 may well result from a change in enforcement policy in which more claims are examined for fraud before they are paid. The National Health Care Anti-Fraud Association's executive director, Louis Saccoccio, said the drop is a result of increased government efforts to review Medicare claims before they are paid. Most claims are honored up front and then reviewed for fraud, known as the pay-and-chase model. A small percentage of claims are examined before they are paid. The Centers for Medicare and Medicaid Services changed the error rate calculation methodology in 2011 to include estimates of late documentation and the result of appeals and was based on a review of actual appeals results and submitted documentation for fiscal 2009 and 2010 claims. Some payments that were originally deemed improper were later found to be legitimate upon appeal, which led to the lowered error rate. The overall Medicare error rate dropped from 10.2 percent in fiscal 2010 to 8.6 percent in fiscal 2011, CMS announced Nov. 15. The fiscal year started Oct. 1, 2010, and ended Sept. 30, 2011.

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