G2 INTELLIGENCE

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 35th Year of Publication

Vol. 14, Iss. 2, January 23, 2014

INSIDE *NIR*

www.G2Intelligence.com

Tricare Stops Covering Molecular Pathology Tests

Tricare, which provides medical services for military families and retirees, has stopped reimbursing clinical laboratories for more than 100 molecular pathology tests, saying that new CPT codes for these tests have provided greater transparency into what it has been paying for and that it believes many of the tests it previously paid for should not be covered.

According to a report in *Stars and Stripes*, the Defense Health Agency says the new codes allow the agency to "identify specific laboratory tests that 1) have not been approved or cleared by the Food and Drug Administration and/or 2) failed to meet Tricare criteria for coverage."

Among the tests that are no longer covered is a genetic test to determine if a woman who is pregnant carries a marker for cystic fibrosis, which would increase the chance of the baby having the disease.

In a Jan. 9 letter to the assistant secretary of defense for health affairs, the Military Coalition, a consortium of military and veterans organization representing more than 5.5 million members plus their families and survivors, said the lack of Tricare reimbursement for these laboratory tests creates two standards of care for uniformed service members, retirees, and their families.

Continued on p. 5

CAP Urges Cigna to Rescind New Policy on PC Payment For Clinical Pathology Services

The College of American Pathologists (CAP) is urging Cigna to rescind a nationwide policy under which it would stop paying for the professional component (PC) of clinical pathology (CP) services beginning March 10.

In a Jan. 10 letter to Cigna, CAP President Gene Herbek disagreed with Cigna's position that the updated policy is consistent with Centers for Medicare and Medicaid Services (CMS) practices for billing the PC of CP services. CAP also underscored recent court decisions that have sided with pathologists in cases involving the PC of pathology services.

"The PC of CP services under Cigna's new policy for which reimbursement will be discontinued are services that are critical to the diagnosis and treatment of patients, particularly in a delivery system reliant upon increased coordination, integration, and population management," said Herbek in the letter.

Continued on p. 2

CAP Urges Cigna to Rescind New Policy on PC Payment, *from p. 1*

According to CAP, Cigna asserted its decision to deny payment for the services during a routine policy review. As part of a larger claim-processing software implementation, Cigna will no longer pay claims submitted with modifier -26 when billed with laboratory and other codes. Cigna says this policy is consistent with CMS practices.

CAP disputes that this change matches CMS guidelines. The college also noted that court rulings have made clear that pathologists through the PC of CP services provide "valuable and compensable medical services." The 1995 federal case, *Central States v. Pathology Laboratories of Arkansas*, rejected an insurer's argument that pathologists do not provide services to hospital patients.

"The court also underscored pathologists being present or on call 24 hours and intervening to ensure a test is done right, recheck a surprising result, or interpret ambiguous data in support of its ruling in their favor on payment for their PC of CP services," Herbek noted in the letter.

Long-Running Dispute

There has been a long-running dispute over whether PC billing is a reasonable mechanism for compensating pathologists for their time and expertise in directing laboratories. Some patients and insurers object to such billing, arguing that it is inappropriate for a pathologist to bill a patient for a test if the pathologist has not personally performed the procedure or reviewed the results.

Pathologists have long billed private patients and private insurance companies for the PC of CP services. The American Medical Association, which develops and publishes all CPT codes, states that pathologists may bill for the PC of CP services using the -26 modifier.

Takeaway: Cigna's decision to stop reimbursing the PC of clinical pathology services is at odds with long-standing policies and legal rulings.

Specialists Weigh In on SGR Reform

An organization of specialists told the bipartisan congressional leadership Jan. 21 that although it is encouraged about progress on replacing the Medicare physician payment formula, none of the proposals encapsulates all the principles that should be part of a new system.

A replacement for the sustainable growth rate (SGR) formula "should base physician reimbursements on the actual cost of providing care and allow physicians to make investments in meaningful and relevant care delivery models that aim to improve quality and efficiency and foster patient access to the physician of their choice," according to a letter from the Alliance of Specialty Medicine.

However, the bills being considered in the Senate and House fail to fully capture "the principles that the Alliance believes are critical to physician payment reform," the letter said.

Congressional Activity

Committees in both chambers are working on legislation (S. 1871, H.R. 2810) that would permanently replace the SGR.

In December, the Senate Finance and House Ways and Means committees approved similar measures. In July, the House Energy and Commerce Committee approved its own SGR overhaul proposal.

A two-year budget agreement (H. J. Res. 59) that cleared Congress in December provided for an extension of Medicare reimbursement rates through March 31.

Although slightly different in the details, the three committee proposals would replace the SGR with a new payment system that attempts to better align Medicare provider payments with medical outcomes.

Critical Principles

Among the essential elements of an agreement, according to the alliance, which represents about a dozen specialty societies, are:

- ❑ **Positive updates:** Repeal of the SGR should include a minimum five-year period of stability during which base payments to physicians capture the "true cost" of treating patients. This should include positive financial incentives for higher quality, more efficient care rather than arbitrary penalties and withholds.
- ❑ **Recognition of multiple payment and delivery models, including fee-for-service:** Physicians should be given the opportunity to participate in a range of delivery and payment models that are meaningful to their practices and patient populations, including fee-for-service.
- ❑ **Physician-led quality improvement:** The medical profession and its clinical subject matter experts must determine the most appropriate and clinically relevant quality improvement strategies for their practice types and patient populations.
- ❑ **Reward for personal improvement:** A reformed payment system shouldn't create winners and losers based on arbitrary performance benchmarks that pit physicians against each other, but instead should encourage personal growth.
- ❑ **Legal protections for adherence to clinical guidelines and quality improvement program requirements:** New standards of care created by quality improvement programs shouldn't be used in medical liability suits.
- ❑ **Repeal of the Independent Payment Advisory Board:** Significant health care decisions shouldn't be made by unelected, unaccountable individuals with little or no clinical expertise.
- ❑ **Private contracting:** Physician payment reform must allow for voluntary private contracting between physicians and Medicare beneficiaries.

Takeaway: SGR reform should base physician reimbursements on the actual cost of providing care, says an organization of physician specialists. G2

Lawsuit by Man Erroneously Told He Had HIV Allowed to Go Forward

A diagnostics laboratory company and a staffing agency that provides employees to it must answer various claims asserted against them by a man erroneously told that he had HIV and herpes, a federal district court said Jan. 17 (*Drew v. Quest Diagnostics*, N.D. Ala., No. 5-13-cv-629).

The U.S. District Court for the Northern District of Alabama partially denied motions by Quest Diagnostics and Aerotek Inc. to dismiss claims asserted by plaintiffs Kenneth and Elizabeth Drew. The court said the Alabama Medical Liability Act

(AMLA), which applies in actions brought against health care providers based on a breach of the standard of care, didn't provide an exclusive remedy for the plaintiffs, who complained that the companies' negligence resulted in emotional harm and lost wages.

The court refused to dismiss claims related to the defendants' alleged negligence; negligent hiring, supervision, training, and retention; medical negligence; and invasion of privacy. It dismissed claims for negligence per se, outrage, and res ipsa loquitur.

Sample Not Labeled

In 2011, Kenneth Drew had a blood sample taken during a routine physical examination required by his military employer. The sample was drawn at Quest's Huntsville, Ala., location by a technician employed by Aerotek. The sample either wasn't labeled or was labeled improperly by the employee.

The test results were sent to Drew's physician, who subsequently told him that he had tested positive for HIV and herpes. Drew was required to tell his employer about the test results. The results were false.

Drew claimed in his complaint that his marriage suffered as a result of the defendants' negligence in handling his blood sample. Both Drew and his wife suffered extreme emotional distress, mental anguish, and embarrassment, and they lost time from work to attend medical appointments. Their complaint contained numerous causes of action, ranging from medical negligence to defamation.

Quest and Aerotek moved to dismiss the complaint or for judgment on the pleadings. As an initial matter, they argued that AMLA provided the plaintiffs' exclusive remedy for claims resulting from the alleged negligence of a health care provider. Plaintiffs alleging damages arising out of a breach of a medical standard of care have a right to assert only a single cause of action under AMLA, the defendants said.

The court disagreed, citing *Collins v. Ashurst*, 821 So. 2d 173 (Ala. 2001). There, a patient sued her physician for removing the wrong ovary. She alleged three causes of action: medical malpractice, assault and battery, and trespass. The trial court dismissed the last two, saying that AMLA governed all actions between a patient and a physician.

The Alabama Supreme Court reversed, saying that the law itself "recognizes the possibility that more than one type of action may be brought under that act." The law "provides the applicable standard of care that governs all actions against health-care providers specified in the act; it does not contain language that would lead to the conclusion that the only available cause of action, in contract or in tort, is medical malpractice," the supreme court said. Based on that decision, the federal district court concluded that "AMLA was not intended to pre-empt all other claims."

The court dismissed several other claims, including those for outrage, negligence per se, and res ipsa loquitur. The plaintiffs wouldn't be able to recover for outrage, even assuming Alabama law recognized it as a separate tort, because the defendants' alleged conduct wasn't sufficiently outrageous, it said. The court noted that Alabama courts have allowed for recovery of emotional damages only in limited circumstances, and the plaintiffs' circumstances weren't among those considered outrageous.

Takeaway: State liability acts do not necessarily protect health care providers from having multiple claims brought against them. G2

Tricare Stops Covering Molecular Pathology Tests, *from p. 1*

"Beneficiaries who receive their health care at a [military treatment facility (MTF)] are covered for MoPath laboratory tests while beneficiaries who access care in the civilian provider network are denied coverage of these valuable tests," writes the coalition. "In short, Tricare beneficiaries without access to the MTF are relegated to second-class health care. This is troubling on multiple levels."

According to Julie Khani, vice president of the American Clinical Laboratory Association, beneficiaries haven't complained yet because labs had been continuing to perform tests ordered by physicians. To date, she said, labs have provided about $10 million worth of free tests to Tricare users. "That's obviously unsustainable," she told *Stars and Stripes*.

Takeaway: Tricare's decision to stop reimbursing for many molecular pathology tests administered in the civilian provider network creates two levels of care for military personnel and their families. G2

Justice Department Sets Record in Fraud Recoveries

The Department of Justice (DOJ) received $3.8 billion in settlements and judgments from civil cases involving fraud against the government in the fiscal year ending Sept. 30, 2013, according to Assistant Attorney General for the Civil Division Stuart F. Delery.

As in previous years, the DOJ said, the largest recoveries related to health care fraud, which reached $2.6 billion. Procurement fraud (related primarily to defense contracts) accounted for another $890 million—a record in that area.

The total $3.8 billion amount is the second largest annual recovery of its type in history and brings total recoveries under the False Claims Act (FCA) since January 2009 to $17 billion, the DOJ said.

The DOJ's fiscal 2013 efforts recovered more than $3 billion for the fourth year in a row and are surpassed only by last year's nearly $5 billion in recoveries.

The number of FCA qui tam suits filed in fiscal year 2013 rose to 752—100 more than the record set the previous fiscal year. Recoveries in qui tam cases during fiscal year 2013 totaled $2.9 billion, with whistleblowers recovering $345 million.

The DOJ noted that some of the largest recoveries this past fiscal year involved allegations of fraud and false claims in the pharmaceutical and medical device industries.

Of the $2.6 billion in federal health care fraud recoveries, $1.8 billion were from alleged false claims for drugs and medical devices under federally insured health programs that, in addition to Medicare and Medicaid, include Tricare, which provides benefits for military personnel and their families, veterans' health care programs, and the Federal Employees Health Benefits Program.

The department recovered an additional $443 million for state Medicaid programs.

Many of these settlements involved allegations that pharmaceutical manufacturers improperly promoted their drugs for uses not approved by the Food and Drug Administration (FDA)—or "off-label" marketing. For example, drug manufacturer Abbott Laboratories Inc. paid $1.5 billion to resolve allegations that it illegally promoted the drug Depakote to treat agitation and aggression in elderly dementia

patients and schizophrenia when neither of these uses was approved as safe and effective by the FDA.

The DOJ also said it settled allegations relating to the manufacture and distribution of adulterated drugs. For example, it said generic drug manufacturer Ranbaxy USA Inc. paid $505 million to settle allegations of false claims to federal and state health care programs for adulterated drugs distributed from its facilities in India. That settlement included $237 million in federal civil claims, $118 million in state civil claims, and $150 million in criminal fines and forfeitures.

In another major pharmaceutical case, biotech giant Amgen Inc. paid the government $762 million, including $598.5 million in FCA recoveries, to settle allegations that included its illegal promotion of Aranesp, a drug used to treat anemia, in doses not approved by the FDA and for off-label use to treat non-anemia-related conditions.

Tuomey Case

The DOJ noted that the Civil Division's Consumer Protection Branch, together with U.S. attorneys across the country, obtained 16 criminal convictions and more than $1.3 billion in criminal fines, forfeitures, and disgorgement under the Federal Food, Drug and Cosmetic Act (FDCA). The FDCA protects the health and safety of the public by ensuring, among other things, that drugs intended for use in humans are safe and effective for their intended uses and that the labeling of such drugs bears true, complete, and accurate information.

In other areas of health care fraud, the DOJ obtained a $237 million judgment against South Carolina-based Tuomey Healthcare System Inc., after a four-week trial, for violating the Stark law and the FCA. The Stark law prohibits hospitals from submitting claims to Medicare for patients referred to the hospital by physicians who have a prohibited financial relationship with the hospital. Tuomey's appeal of the $237 million judgment is pending. If the judgment is affirmed on appeal, it will be the largest judgment in the history of the Stark law.

The department also recovered $26.3 million in a settlement with Steven J. Wasserman, a dermatologist practicing in Florida, to resolve allegations that he entered into an illegal kickback arrangement with Tampa Pathology Laboratory that resulted in increased claims to Medicare. Tampa Pathology Laboratory previously paid the government $950,000 for its role in the alleged scheme. The $26.3 million settlement is one of the largest with an individual in the history of the FCA.

Takeaway: Record fraud recoveries by the federal government in recent years are likely to lead to an even more difficult enforcement climate for health care providers.

Physician Must Signal Intent to Order Diagnostic Tests For Medicare Reimbursement

The denial of more than 150 Medicare reimbursement claims for audiology testing services was affirmed in a Jan. 10 federal district court ruling that held such services are only reimbursable when a treating physician has clearly requested the service beforehand (*Doctors Testing Ctr., LLC II v. Sebelius*, 2014 BL 6527, E.D. Ark., No. 4:11-cv-00857-KGB).

The U.S. District Court for the Eastern District of Arkansas granted summary judgment to the Department of Health and Human Services on an appeal from a Medi-

care Appeals Council's (MAC) decision to deny reimbursement of all of plaintiff Doctors Testing Center LLC II's (DTC) claims.

Judge Kristine G. Baker said in her decision that Medicare regulations require diagnostic tests of the type provided by the DTC to be requested by a physician prior to the performance of the test in order to be reimbursable. Baker said it was clear from the record that DTC's technicians, not physicians, ordered the tests in the claims at issue and affirmed the MAC's decision.

Partial Claim Victory Reversed

The DTC's appeal centered on claims for diagnostic audiological testing services performed on Medicare beneficiaries in 2007. The DTC technicians ordered the tests for Medicare beneficiaries. The claims were denied reimbursement by a prepayment auditor in January 2008 and again later by a qualified independent contractor.

An administrative law judge (ALJ) eventually ruled that 68 claims were reimbursable and denied the remaining claims. The MAC overturned the ALJ's decision and ruled that none of the DTC's claims was reimbursable because records showed that the tests weren't ordered by a physician and therefore weren't "reasonable and necessary" under 42 C.F.R. §410.32(a).

The DTC made four arguments in its appeal of the MAC's decision. The DTC argued that the MAC should have reviewed the ALJ's decision for errors of law only, instead of making its own findings of fact; should have remanded the case to the ALJ; erred in holding that a physician's signature is required for a diagnostic test to be reimbursable; and erred in finding that the tests at issue weren't later approved by a treating physician.

Physician Intent Required

The court rejected the DTC's arguments with regard to the ALJ findings. Baker said the MAC was limited to the ALJ's findings of fact only in deciding whether to review the appeal at all, but it was free to make its own finding of fact on the evidence once it decided to review the decision. In addition, Baker said remand to the ALJ was unnecessary because the MAC's decision was supported by substantial evidence.

The court also disagreed with the DTC's substantive arguments regarding the MAC's decision. The court said that the MAC's decision held that a physician must signal the intent to order the diagnostic test in question in order for it to be reimbursable. The MAC didn't hold that a physician's signature on an order prior to the test was required, according to the court, and that the DTC misinterpreted the MAC's ruling on the issue.

Baker said the MAC was correct in ruling that a physician's signature approving of a test after it was performed didn't satisfy §410.32(a).

Further, Baker said it was immaterial whether a treating physician accepted and used the results of the technician-ordered tests for treatment for purposes of reimbursement. Baker said that the patient records didn't refute the substantial evidence showing that the tests weren't ordered by a treating physician and therefore weren't reimbursable under Medicare.

Takeaway: Diagnostic tests must be ordered by a treating physician to be eligible for reimbursement under Medicare.

Enforcement Climate Likely to Get Tougher

Health care providers, including clinical and anatomic pathology laboratories, are likely to see increased enforcement efforts by Medicare and Medicaid program integrity contractors in 2014 and beyond.

Over the past few years, the Centers for Medicare and Medicaid Services (CMS) has expanded the ranks of program integrity contractors. Recovery Audit Contractors (RACs), for example, began operating exclusively in the Medicare fee-for-service program but have since expanded into Medicare Part C, Medicare Part D, and Medicaid. Because of record fraud recoveries, the federal government has continued to devote more money to its anti-fraud efforts.

But even as the government pours more resources into fraud fighting, some of the programs may be in for some changes. Karen Lovitch, an attorney with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (Washington, D.C.), says the RAC program will face increased scrutiny in 2014, in part due to a September 2013 report from the Department of Health and Human Services Office of Inspector General that was critical of CMS's oversight of the RAC program.

Current RACs

Region A	Performant Recovery
Region B	CGI Federal Inc.
Region C	Connolly Inc.
Region D	HealthDataInsights Inc.

Lovitch also noted that a bill was introduced in Congress in 2013 designed to improve the RAC process. The Medicare Audit Improvement Act of 2013 was introduced in May 2013 in both the House (H.R. 1250) and Senate (S. 1012) with the intention of improving the accuracy of RAC audits and increasing contractor transparency.

Another factor contributing to the overall turmoil within the RAC program is the expiration of all four RAC contracts. The contracts are due to expire in February, which means some RACs may be replaced, but CMS has said that as it continues the procurement process for the new RAC contracts, the current contracts will be extended several months. In particular, the active recovery auditing period will be extended through the awards and implementation phases of the new contracts.

James Sheehan, chief integrity officer and executive deputy commissioner for the New York City Human Resources Administration, said he expects to see some RAC expansion. He said CMS is committed to some changes in the program and will spend the next two years reviewing proposals and litigating protests.

RAC changes include moving from four RACs to five RACs and requiring RACs to support the appeals process through the level of administrative law judges.

 National Intelligence Report (ISSN 2332-1458) is published by G2 Intelligence, 24 Railroad Street, Keene NH 03431-3744 USA. Tel: 800-531-1026 or +1 603-357-8101. Fax: +1 603-357-8111. Web site: www.G2Intelligence.com.

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, President and Publisher.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 800-531-1026.