G2 INTELLIGENCE

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INSIDE *NIR*

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Congress Extends Sequester for One Year, Applies Funds to Physician Payment Reform

The House and Senate have approved legislation that would extend for one year the across-the-board cuts in certain discretionary government programs, known as the sequester, and apply $2.4 billion toward overhauling the Medicare payment system for physicians. President Obama is expected to sign the measure.

The bill, S. 25, reverses a $6 billion cut to military pensions that was included in the two-year budget agreement that cleared Congress in December 2013. The measure covers the cost by extending for one year the discretionary funding cuts—known as the sequester—for Medicare providers.

About $2.4 billion in additional savings generated by the provider cuts would be applied to a future increase in Medicare physician payments. The extra funds might be used as part of a comprehensive overhaul of the Medicare physician payment system or for an extension of the

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DaVita Will Pay $389 Million to Settle Kickback Charges

DaVita HealthCare Partners will pay $389 million in a settlement of federal investigations into the dialysis company's relationships with physicians.

The Denver-based company has agreed to a "framework for a global resolution" of 2010 and 2011 investigations by the U.S. attorney for the District of Colorado, it said in a Form 8-K filed with the Securities and Exchange Commission Feb. 11.

A federal grand jury investigation is probing allegations DaVita paid kickbacks to doctors to guarantee an ongoing stream of dialysis patients. The settlement remains subject to negotiation of specific terms, which the company believes will be finalized in the coming months, it said.

In addition to a payment of about $389 million, the settlement will require the company to enter into a corporate integrity agreement, appoint an independent compliance monitor, and impose certain other business restrictions related to a subset of the company's joint venture agreements.

"We have agreed to unwind a limited subset of joint ventures that were created through partial divestiture to nephrologists, and agreed not to

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Congress Extends Sequester for One Year, *from p. 1*

current physician pay rates after March 31, when the rates are scheduled for a cut of about 24 percent.

The $2.4 billion in "doc fix" funding included in S. 25 comes as efforts are under way in the House and Senate to repeal and replace the Medicare physician payment system. Medicare's sustainable growth rate (SGR) formula each year calls for deep cuts in physician pay that are routinely canceled by Congress with a so-called doc fix.

To eliminate the need for regular doc fixes, House and Senate committees Feb. 6 announced agreement on legislation (H.R. 4015, S. 2000) that would repeal the SGR formula and replace it over several years with new physician payment models that would provide physicians with financial incentives to meet newly established quality guidelines.

March 31 Deadline

The deadline for Congress to pass either the overhaul legislation or another short-term doc fix is March 31, when the current Medicare physician pay rates are scheduled to be cut by about 24 percent under the SGR formula.

The two-year Bipartisan Budget Act of 2013 (H. J. Res. 59), which was signed into law Dec. 26, extended the higher-level Medicare reimbursement rates to March 31 to allow lawmakers time to come to agreement on replacement legislation.

Although members of the committees working on the legislation have agreed to the policies included in the legislation, they have yet to specify the funding cuts or new revenue that would provide offsets to help pay for the cost of implementing the SGR overhaul. The Congressional Budget Office has estimated the legislation would cost $128 billion over 10 years.

Another potential complication in moving forward is the recent confirmation of Sen. Max Baucus (D-Mont.), chairman of the Senate Finance Committee, to be U.S. ambassador to China.

Baucus has been a principal advocate of SGR reform, along with the leaders of the House Ways and Means and Energy and Commerce committees, which worked with the Finance Committee on the bipartisan legislation.

Takeaway: Lawmakers have a little over a month to agree on an SGR overhaul or they will have to extend the "doc fix" again. G2

CMS, CAP Publish FAQs on Patient Access Rule

Both the Centers for Medicare and Medicaid Services (CMS) and the College of American Pathologists (CAP) have published frequently asked questions (FAQs) addressing the Feb. 6 final rule requiring clinical laboratories to provide test results directly to patients upon request.

The FAQs address the compliance date for the rule (Oct. 6, 2014), changes to the Clinical Laboratory Improvement Amendments and the Health Insurance Portability and Accountability Act (HIPAA) and their effect on state laws, and who is authorized to have access to an individual's sensitive laboratory test reports.

CMS notes that the only persons other than the individual who have a right to access test reports directly from a HIPAA-covered laboratory are those persons who are

designated by the individual as a "personal representative." This typically means someone who has authority under law to make health care decisions for the individual. Such authority is generally determined under state law.

Addressing concerns about labs giving individuals test results without the individual having the benefit of health care provider interpretation, CMS says it expects that individuals will continue to obtain their test reports and the interpretation of those reports from their health care provider. "The rule does not require laboratories to interpret test results," says CMS. "Laboratories can refer an individual back to their health care provider for this information."

Some labs have asked whether they would have to have an electronic health record (EHR) system, patient portal, or be a part of a health information exchange (HIE) to meet this new requirement for patient access to test results. CMS clarifies that a lab does not need to have an EHR system, patient portal, or be part of an HIE. "However, we would anticipate that as EHRs, portals, and HIEs become more commonplace, laboratories will develop processes to handle patient requests via these systems," says CMS.

Additional questions addressed in the CAP FAQs include:

What format do the results need to be in?

The Privacy Rule requires a covered entity such as a clinical laboratory to provide the individual with a copy of the requested information in the form and format requested by the individual, if a copy in that form or format is "readily producible." If not, the copy must be either a readable hard copy or in another form or format as agreed by the covered entity and the individual. If an individual declines to accept any of the electronic formats that are readily producible by the HIPAA-covered laboratory, the laboratory must provide a hard copy.

How do laboratories authenticate patients and their personal representatives' identity?

The commentary to the final rule states: " . . . a HIPAA-covered laboratory could verify a person's authority by asking for documentation of a health care power of attorney, or general power or durable power of attorney, that includes the power to make health care decisions, proof of legal guardianship, or, in the case of a parent, information that establishes the relationship of the person to the minor individual. A HIPAA-covered laboratory may also contact the treating provider to inquire whether the treating provider can provide documentation of the person's status as a personal representative of the individual."

Takeaway: There are many details in the final patient access rule that labs need to become familiar with. G2 Intelligence and the American Clinical Laboratory Association are sponsoring a webinar March 25 to address many of the most pressing issues.

DaVita Will Pay $389 Million to Settle Kickback Charges, *from p. 1*
enter into this type of partial divestiture joint venture with nephrologists in the future," the company said in the Form 8-K.

In August 2011, DaVita learned from the U.S. attorney it was the focus of an investigation concerning its physician relationships, the company said. According to the *Denver Post*, DaVita CEO Kent Thiry said that federal attorneys had "taken the position that some or all of our joint ventures do not comply with the anti-kickback statute."

As of Dec. 31, DaVita provided dialysis services to about 168,000 patients at 2,147 outpatient dialysis centers throughout the world.

Despite the $389 million settlement, DaVita still projects it will make robust profits. The company expects to generate $1.73 billion to $1.86 billion in operating cash this year. DaVita reported $212 million in net income for the fourth quarter of 2013 and $633 million for the year, both up over 2012.

Takeaway: DaVita will pay $389 million and unwind joint ventures to settle charges the agreements violate the anti-kickback law.

Kentucky Physicians, Lab to Pay $15.75 Million To Settle FCA Charges

Owners of 12 opiate addiction treatment centers and a clinical laboratory in Kentucky will repay the government $15.75 million to resolve False Claims Act allegations.

Drs. Bryan Wood and Robin Peavler—who own SelfRefind, a chain of addiction recovery clinics, and PremierTox LLC, a clinical laboratory that performs urine testing—agreed to settle civil allegations that they fraudulently billed federal health care programs for medically unnecessary and excessive tests, the Department of Justice (DOJ) said Feb. 10.

Wood and Peavler were accused of violating the False Claims Act by submitting claims to Medicare and Kentucky's Medicaid program for urine tests that were medically unnecessary and more expensive than the actual tests performed, the DOJ said, adding that under federal law, health care programs reimburse health care providers only for services deemed medically necessary.

The government alleged that after Wood and Peavler became owners of PremierTox, they began automatically referring all drug screens completed at SelfRefind clinics to the lab for additional comprehensive urine drug screening tests that were frequently unnecessary and often more expensive than suitable alternative tests.

In addition to violating the False Claims Act, the doctors were accused of violating the Stark law, the DOJ said, which forbids a laboratory from billing Medicare and Medicaid for certain services referred by physicians who have a financial relationship with that laboratory.

Prior to becoming part owners of PremierTox, SelfRefind didn't automatically refer urine samples for additional confirmation testing to outside laboratories, the gov-

ernment said, adding the clinic started to require all patients to submit to regular urine drug screening, as often as every two weeks.

The government alleged PremierTox submitted false claims that misidentified the class of drug that was tested for and received a higher financial reimbursement than necessary.

According to the settlement agreement, when the doctors referred urine samples to PremierTox in December 2010, the lab didn't have the equipment necessary to test the large volume of samples sent to it by SelfRefind.

The lab put the samples into frozen storage for several months before performing the prescribed tests, which by that time were medically unnecessary for the treatment of the patients.

Nevertheless, the government said, PremierTox submitted claims seeking reimbursement for the tests.

Corporate Integrity Agreement

Under the settlement, PremierTox has agreed to enter into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General.

The agreement obligates PremierTox to undertake substantial internal compliance reforms and commit to a third-party review of its claims to federal health care programs for the next five years.

Kentucky is also a party to the agreement and will receive about $2.74 million, the state's share of the government's recovery of Medicaid funds.

Takeaway: Two physicians and a clinical laboratory are settling charges they referred and performed unnecessary urine testing in violation of the False Claims Act.

Court Dismisses Antitrust Claims Against Quest—Again

A federal district court Feb. 6 again dismissed all state and federal antitrust law claims asserted by specialty laboratories that alleged a conspiracy between Quest Diagnostics and several large health insurers designed to drive them out of business in California (*Rheumatology Diagnostics Lab., Inc. v. Aetna, Inc.*, 2014 BL 32470, N.D. Cal., No. 3:12-cv-5847).

The U.S. District Court for the Northern District of California ruled that the independent labs could pursue certain claims under California's Unfair Practices Act and Unfair Competition Law but that all remaining antitrust law claims had to be dismissed. Those claims were subject to dismissal because the laboratories failed to allege adequately either an agreement between Quest and the insurance defendants or specific facts showing that Quest's network agreements with insurers foreclosed competition in a substantial share of the relevant markets.

The decision largely tracked an October 2013 ruling in which the court reached the same conclusions with respect to the antitrust law claims asserted in the independent laboratories' first amended complaint. The second amended complaint didn't cure the defects identified in the earlier decision, so the antitrust claims were subject to dismissal with prejudice, the court said.

Violations Alleged

The court addressed claims brought by Rheumatology Diagnostics Laboratory Inc., Pacific Breast Pathology Medical Corp., Hunter Laboratories LLC, and Surgical Pathology Associates against Blue Shield of California Life and Health Insurance Co. (BSC), Blue Cross and Blue Shield Association (BCBSA), Aetna Inc., and Quest Diagnostics Inc. for allegedly conspiring to restrain trade and monopolize the markets for certain laboratory testing procedures, in violation of Sherman Act §1 and §2.

Specifically, they contended that the insurers and Quest violated the Sherman Act, California's Cartwright Act, California's Unfair Competition Law (UCL), and California's Unfair Practices Act through predatory pricing with health insurers and agreements with doctors that ran afoul of anti-kickback statutes.

The district court, in July 2013, dismissed the labs' initial complaint, concluding that they hadn't adequately pleaded the existence of any horizontal or vertical agreements in violation of any statute, that any relevant market was foreclosed, or that competition was adversely affected by any of the alleged misconduct. It further held that in the absence of any allegations of price or cost, the labs couldn't state a claim for intentional interference or a violation of the UCL. The plaintiffs responded by filing a first amended complaint, which the defendants again sought to dismiss.

When Judge William H. Orrick of the U.S. District Court for the Northern District of California found the amended complaint to be insufficient to resolve the court's previously identified concerns regarding the labs' antitrust law claims, the labs sought to amend their complaint a second time.

Pleading Inadequacies Remain

With respect to the antitrust law claims in the second amended complaint, the court found the pleading inadequacies remained.

The court began by holding that claims against BCBSA failed to allege that there was any agreement between Quest and the association concerning policy changes BCBSA initiated with respect to billing and payment under its Blue Card program. Although that program allows BCBS members served by an affiliated plan in one state to receive services while traveling in states served by other BCBS plans, the labs claimed a policy change made it more difficult for them to bill and get paid by out-of-state BCBS affiliates.

With respect to the renewed antitrust law claims asserted against BSC and Aetna, there was simply too little factual information in the second amended complaint to support the antitrust law allegations against them. Addressing the claims against Aetna, the court noted that because the independent labs did "not plead sufficient facts about the markets and their participants, or how the markets have changed due to the agreement," the court couldn't determine what effect the agreement had on competition.

Takeaway: Allegations of antitrust activity between Quest Diagnostics and insurers have been thrown out by a federal court, which says there are not enough facts to support the charges. G2

Cigna Adopts Genetic Counselor Exception

Cigna has added an exception to its national genetic testing payment policy that will allow for coverage of the services when provided by certain additional genetic counselors, according to the College of American Pathologists (CAP).

Cigna notified CAP that the exception would be published as part of Cigna's national policy on Feb. 15. Under the exception, a genetic counselor employed or contracted with a laboratory, which is also part of an integrated health system that routinely delivers health care services, may see patients and secure prior authorization for testing. Previously, these genetic counselors were not permitted to provide services nor secure authorizations for testing to be performed at their integrated delivery systems under Cigna's policy.

Effective Sept. 15, 2013, Cigna became the first U.S. health insurer to require genetic counseling and prior authorization nationwide before covering tests for hereditary breast and ovarian cancer, colon cancer, and a heart disorder, long QT syndrome.

Effective Sept. 15, 2013, Cigna became the first U.S. health insurer to require genetic counseling and prior authorization nationwide before covering tests for hereditary breast and ovarian cancer, colon cancer, and a heart disorder, long QT syndrome. The genetic counseling occurs either face-to-face or over the phone through a Florida firm. According to Cigna, this will prove individuals with the opportunity to become fully informed about these complex genetic tests.

According to CAP, Cigna says it will cover genetic testing as medically necessary when a recommendation for the services is confirmed by one of the following:

- ❑ An independent board-certified or board-eligible medical geneticist;
- ❑ An American Board of Medical Genetics or American Board of Genetic Counseling-certified genetic counselor not employed by a commercial genetic testing laboratory (genetic counselors are not excluded if they are employed by or contracted with a laboratory that is part of an integrated health system that routinely delivers health care services beyond just the laboratory test itself); or
- ❑ A genetic nurse credentialed as either a genetic clinical nurse or an advanced practice nurse in genetics by either the Genetic Nursing Credentialing Commission or the American Nurses Credentialing Center who is not employed by a commercial genetic testing laboratory (*genetic counselors are not excluded if they are employed by or contracted with a laboratory that is part of an integrated health system that routinely delivers health care services beyond just the laboratory test itself*).

Without the exception in the parentheses in the second bulleted item, genetic counselors who are part of these integrated health systems would not be able to provide the testing. A genetic counseling professional unaffiliated with the genetic testing laboratory performing the results must make the recommendations for testing by these systems.

Takeaway: Individuals insured by Cigna will be able to receive genetic testing services from counselors employed by or contracted with a lab that is part of an integrated health system.

ICD-10 Implementation May Be More Costly Than Thought

An updated report prepared for the American Medical Association (AMA) released Feb. 12 showed an increase in physician implementation costs for the upcoming transition to the International Classification of Diseases, 10th Revision (ICD-10) code set from the original 2008 report, in some cases by as much as five times.

The report, which was prepared by Nachimson Advisors LLC, said "costs to implement ICD-10 may be much higher than what was estimated in 2008, especially for physicians who must pay for upgrades to their electronic health records (EHR) and practice management systems (PMS)."

For example, the original report estimated small physician practices would incur ICD-10 implementation costs of $83,000, while the updated report said costs could range from $57,000 to $226,000.

For medium physician practices, estimated implementation costs changed from a fixed $285,000 in 2008 to between $213,000 and $824,000 in the updated report; for large physician practices, estimated costs changed from a fixed $2.7 million in 2008 to a range of between $2 million and $8 million in the updated report.

ICD-10 is a code set updating health care diagnoses and procedures from the currently used 13,000 codes in ICD-9 to 68,000 codes. All Health Insurance Portability and Accountability Act entities must transition to ICD-10 by Oct. 1, 2014.

The updated report said physician practices that have no costs associated with ICD-10 software upgrades will see implementation costs somewhere in the lower end of the report's estimates. However, the report said only one-third of practices are likely to have no software upgrade costs, and the majority will see cost increases.

"Specialty practices, because of their higher revenues and per hour rates, show the greatest costs, especially for productivity losses and payment disruption," the report said.

ICD-10 Delay Sought

In addition to releasing the updated cost report, AMA Feb. 12 sent a letter to Health and Human Services Secretary Kathleen Sebelius calling for a repeal of the ICD-10 code set. The letter said that transitioning to the ICD-10 code set would lead to heavy financial burdens for physicians as well as prevent them from making progress on other federal programs, including achieving meaningful use of electronic health records and meeting electronic prescribing standards.

Beyond repealing ICD-10, the AMA letter said that the Centers for Medicare and Medicaid Services (CMS) should conduct end-to-end ICD-10 testing for all physicians. If full testing isn't possible for all physicians, AMA said CMS should conduct end-to-end testing with a sample of 100 physician practices of all sizes.

Takeaway: Health care providers should be prepared to invest heavily in software upgrades as they prepare to transition to ICD-10 come Oct. 1, 2014.

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