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LABORATORY INDUSTRY REPORT®

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Vol. 13, Iss. 12, June 20, 2013

HIGHLIGHTS

OIG Recommends Medicare Payment Cuts

A new report by the Health and Human Services Office of Inspector General (OIG) concludes that the Medicare program could save nearly $1 billion a year by instituting double-digit payment cuts for laboratory services.

It's a recommendation that labs—battered by other payment reductions and the sequestration in recent years—have hardly found heartening. Medicare is the largest payer for laboratories, and any further cuts from the program would be felt acutely.

Instead, representatives from the laboratory sector will be surveying their options and likely will lobby Congress to ensure lawmakers do not adopt the report's recommendations.

The OIG scrutinized lab payments for 20 different high-volume fee-for-service tests conducted on behalf of 50 state Medicaid programs and three federal employee health benefit plans. It concluded that Medicare paid between 18 percent and 30 percent more for tests than other payers. Were its payment methodology more in line with the other payers, it would save about $910 million a year, according to

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The *Myriad* Supreme Court Decision: A Win-Win-Win?

Good for labs? Good for patients? Good for providers? It was the rarest kind of decision from the U.S. Supreme Court—a unanimous one. The 9-0 opinion announced on June 14 was penned by one of its most conservative jurists in favor of a case argued by the American Civil Liberties Union—at a time when consensus in Washington is rare as a humidity-free July.

Yet the decision barring Myriad Genetics from patenting unaltered genetic material appears not to have a winner and a loser—just winners, according to most of the interested parties.

The laboratory industry says the ruling will promote more laboratory-developed genetic tests and create more options for patients.

"We believe the High Court today removed a significant barrier to innovation in molecular pathology testing," said Roger D. Klein, M.D., professional relations committee chair for the Association for Molecular Pathology, which was the primary plaintiff in the case.

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■ **The Myriad Supreme Court Decision: A Win-Win-Win?**, *from page 1*

"And we look forward to future advancements in clinical diagnostics and therapeutics that will accrue to the benefit of our patients and our field."

Indeed, at least three labs announced they would offer BRCA testing immediately, one of them at a discount approximately 75 percent of what Myriad charges to detect a genetic predisposition for breast cancer.

Nevertheless, Myriad is also pleased that the decision, penned by Associate Justice Clarence Thomas, will permit the Salt Lake City-based company to retain patents on complementary DNA (cDNA)—material that has been modified for laboratory tests.

"We believe the court appropriately upheld our claims on cDNA and underscored the patent eligibility of our method claims, ensuring strong intellectual property protection for our BRACAnalysis test moving forward," said Peter D. Meldrum, Myriad's chief executive officer.

And patients are also expected to benefit.

"The Supreme Court decision invalidating Myriad Genetics' patents on BRCA1 and BRCA2 is a huge victory for patients," said Debra Leonard, M.D., chair of the personalized health care committee for the College of American Pathologists. "It will allow women to receive life saving, state-of-the-art genetic tests without being forced to trust one provider or one laboratory performing a single test to secure a diagnosis or inform treatment."

Yet the investment market was a little less sanguine about the outcome. Initially Myriad stock was up after the Supreme Court announcement, but then it quickly plunged, losing nearly 14 percent of its value in trading the day the opinion was announced.

The losses came not long after Bank of America downgraded Myriad from buy to neutral and also cut its outlook for its share price.

Analysts noted that Myriad will soon be competing with other labs that will offer similar tests, including Bio-Reference Labs, Quest Diagnostics, and Ambry Genetics, a company affiliated with the University of Washington.

An affiliate company of Gene by Gene, the Houston-based lab that has been focused on low-cost genetic testing, announced within a couple of hours of the Supreme Court decision that it will offer a BRCA 1 and 2 test for $995—compared to the $3,000 to $4,000 Myriad charges. Bennett Greenspan, Gene by Gene's CEO, noted in a statement that competition is crucial to keeping prices down.

"The noise around competition is a continued overhang on the [Myriad] stock and probably will not be resolved into at least the calendar fourth quarter," said Amanda Murphy, an analyst with William Blair & Co.

But Murphy expressed some doubt that other labs will be able to quickly enter the BRCA market: "The IP landscape is far from clear. Myriad retains 23 patents and still has almost 500 claims around the BRCA1/2 testing franchise," she said.

Murphy also noted that Myriad has a huge database of genetic mutations—16,000 versus the mere 1,000 in the public domain.

GeneDX, a Bio-Reference subsidiary, announced it would offer a 27-gene panel for breast and ovarian cancers. It did not disclose pricing.

Gene by Gene laboratory director Concetta Bormans noted that her company's test would be composed of a straight sequencing assay. The test would be on a buccal swab taken at a doctor's office and sent in for examination.

Bormans said the company expects a four-to-six week turnaround for testing. "But if we're deluged with a lot of tests, it could take longer," she said.

Quest, Hologic Align With Focus on Women's Health

In a bid to expand its role as a provider of women's health care services, Quest Diagnostics has entered into a strategic alliance with Hologic Inc.

Hologic, which is based in Bedford, Mass., focuses primarily on women's health, with diagnostics aimed at gynecological, skeletal, and breast health.

The joint alliance will last for five years and is nonexclusive. It will focus on broadening Quest's offerings of Hologic's APTIMA testing line, which focuses on sexually transmitted infections, including assays for the human papillomavirus, HPV genotyping, chlamydia, gonorrhea, and trichomonas vaginalis. The assays home in on overexpressed RNA that are linked to persistent HPV infections and the development of cervical cancer. The APTIMA tests are considered by the medical community to be more reliable than DNA-based testing for HPV infections.

The companies also will work on developing new test products, although no specifics were provided. Quest spokesperson Wendy Bost said the companies planned to set up joint research and development and marketing committees to "explore areas to better serve unmet diagnostic needs in women's health."

Rob Cascella, Hologic's chief executive officer, effused about the agreement in a statement. "This collaboration represents a potentially important new chapter in women's health diagnostics. Quest Diagnostics' strong capabilities in diagnostic information services and laboratory and interpretive consulting, when combined with Hologic's technical expertise and product excellence, holds the potential for us to develop new capabilities for serving unmet clinical needs for women."

Harmonic Diagnostic Partnership

Peter Francis, president of Clinical Laboratory Sales Training LLC in Woodstock, Md., considers the joint alliance a "harmonic diagnostic partnership," noting that the market is robust.

"In the continuing effort to treat disease early and reduce the death rate, demand for women's health testing should continue to rise—and the strategic vendor alliance between Quest Diagnostics and Hologic appears to be a positive one," he said.

Francis noted that Hologic's acquisition of Gen-Probe last year helped boosted its research and development capabilities and may have made it a more attractive partner for Quest. Gen-Probe helped Hologic in being able to better detect the herpes simplex virus and gave it solid chlamydia and gonorrhea assays, he said.

With Mobile Labs and Expanded EHRs, Pathology Practices Cater Directly to Patients

Call it the pathology of convenience. Two sizable providers have made changes to the way they deliver pathology services and results, with a focus on enhancing the speed and ease of delivery to patients.

Doctors Pathology Services, the Delaware-based pathology group that made headlines a decade ago when it introduced the Mobile Intraoperative Consultation Service (MICS), a mobile pathology laboratory operated by its own clinicians, began earlier this year to sell and lease such labs to other medical practices.

Doctors Pathology currently operates four of the labs, which serve providers in Delaware, Maryland, New Jersey, Pennsylvania, and the District of Columbia. They can provide basic pathology services such as sectioning, frozen sectioning, staining, grossing, and microscopic analysis.

It's not the only pathology practice delving into the possibilities of mobile care. Mid-Florida Pathology in Leesburg, Fla., recently began providing a mobile frozen sectioning service. It's so new that the lab's commercial director, Alexander Onushko, declined to comment for now.

Meanwhile, the Cleveland Clinic has just announced plans to greatly expand the data available to patients in its MyChart electronic health record that is available to patients online. The expansion includes full pathology reports and their textual interpretations—making the renowned hospital among the first in the nation to provide such records to patients electronically, according to Kandice Kottke-Marchant, M.D., chair of the Cleveland Clinic's Tomisch Pathology & Laboratory Medicine Institute.

Cleveland Clinic and Online Pathology Reports

Indeed, both Doctors Pathology and Cleveland Clinic officials say the reasons behind such decisions are to make both the health care decisionmaking and clinical processes easier for patients.

"By enhancing the connection between our patients and their clinicians, we will create new opportunities to use information to more fully engage our patients as active partners in their health and the decisions they make related to the care they receive," said C. Martin Harris, M.D., the Cleveland Clinic's chief information officer.

"The release of this type of information is important for patients. They often receive life-changing diagnoses," Kottke-Marchant observed. Most want copies of their records in order to receive second opinions or to further research their conditions.

The traditional process of obtaining such records is securing releases from the patient on paper, which may be particularly burdensome to them if their diagnosis is serious.

The availability of such records is not instantaneous. After about two months of deliberation with a small team of colleagues that included anatomic pathologists, cytopathologists, and others, Kottke-Marchant and her colleagues decided that a 20-business-day delay before posting such records was appropriate. Such a policy is intended to be helpful to the patients.

"We felt it would give them ample time to meet for the physician and allow for any ancillary studies, such as cytogenetics and molecular testing, to be performed," she said. Physicians still have the option of manually releasing records earlier than that time frame, according to Kottke-Marchant.

"The release of this type of information is important for patients. They often receive life-changing diagnoses."
—Kandice Kottke-Marchant, M.D., Cleveland Clinic

The result, she says, is that patients will not only be provided with more convenience by being able to access their results electronically, but such access should also encourage better dialogue with caregivers.

"They will have a report they can discuss with their physician, which could [prompt them] to raise additional questions," noted Kottke-Marchant. "It helps with engagement."

Reduced Costs and Greater Visibility

Doctors Pathology created a new entity, MIX Management, to sell its MICS laboratories. It has already sold one of its mobile labs to a New York-area Mohs surgeon, according to V. Raman Sukumar, M.D., the practice's medical director. A major New York teaching hospital upstate and another interested party are likely to purchase or lease vehicles later this year, Sukumar said.

Despite a price tag that begins at $200,000 and can approach $300,000, it is actually significantly less expensive for a MICS to diagnose patients than the traditional physician-referral-to-hospital model, according to Sukumar.

He noted that if a patient undergoes similar procedures in a hospital, they likely not only have to pony up copayments and deductibles for in-hospital providers such as a radiologist, but hospital facility fees as well. Such fees have been mushrooming in recent years and can now run well into the three-figures and can sometimes exceed $1,000.

"Generally the hospital costs run 132 percent of Medicare. We run at 80 percent of Medicare," Sukumar said. He added that a hospital visit can almost double the out-of-pocket expenses for a typical patient versus the mobile lab.

Practice costs are also lower for clinicians. Sukumar noted that the first buyer of the mobile lab, the New York-area Mohs surgeon, plans to oper-

ate almost exclusively from the vehicle, avoiding the cost of running a traditional histology lab from the most expensive real estate in the United States.

"The guy who bought it said 'I am just going to go full-time with it and not doing anything else. I can take around and provide services to 10 different dermatology groups,'" Sukumar said.

Utilizing a mobile lab can also be seen as a way to enhance patient engagement. Although Sukumar admits up front that selling the mobile lab is intended to make money for his pathology group, employing such a vehicle greatly enhances convenience for patients. They can undergo a biopsy at their primary care physician's office—while the mobile lab is parked nearby—and receive the results as soon as that day and often within 48 hours. That compares to three weeks or more under the traditional care model.

"If you do one frozen section a day, and one fine needle aspiration a week, it pays for itself. The rest is gravy."
—V. Raman Sukumar, M.D., Doctors Pathology Group

To Sukumar, that is eminently preferable to a patient being referred by their physician to the hospital and spending hours shuttled around undergoing a biopsy before finally having the samples sent to the pathologist.

Given the push for accountable care organizations and other cost-efficient structures, a mobile laboratory is a great way for pathologists to remain cost competitive while creating greater patient satisfaction, according to Sukumar.

"Part of pay-for-performance and performance-based review is the patient being happy," he said.

Moreover, by getting pathologists away from their notoriously reclusive way of practicing medicine, a mobile lab can help create a networking structure that will eventually lead to enhancing their revenue streams.

"The mobile service is 10 percent of our revenues, but it's the conduit to everything we do," Sukumar said.

The mobile labs operate from Mercedes Sprinter buses that retail for about $50,000. The vehicles are modified and outfitted by a firm that specializes in such work (Sukumar declined to identify the company). Along with the lab equipment, the buses contain an appropriate air conditioning and ventilation system for such work, as well as convenience items such as refrigerators and microwave ovens.

Lab prices start at $200,000, but can reach $299,000 if the buses are equipped to provide fine needle aspiration ultrasound. However, a 60-month lease option is available through an arrangement with PNC Bank. Payments are in the neighborhood of $5,000 a month, according to Sukumar.

"If you do one frozen section a day, and one fine needle aspiration a week, it pays for itself," he said. "The rest is gravy."

■ **OIG Recommends Medicare Payment Cuts,** *from page 1*

the report. Given that Medicare paid $8.2 billion for lab tests in fiscal 2010, that represents a reduction of 11 percent.

As a result, the OIG recommended that the Centers for Medicare and Medicaid Services (CMS) "seek legislation that would allow it to establish lower payment rates for lab tests and consider seeking legislation to institute co-payments and deductibles for lab tests."

Four Common Lab Tests If Repriced Under OIG proposal

CPT Code	Test	2011 Allowed Tests	2011 Allowed Medicare Amount	Potential Medicare Savings If Repriced	Percentage Savings to Medicare
80053	Comprehensive Metabolic Panel	27.4 million	$315.9 million	$130.6 million	41%
80061	Lipid Panel	20.6 million	$300.2 million	$126.0 million	42%
84443	TSH	14.8 million	$348.0 million	$140.1 million	40%
85025	Complete Blood Count	30.8 million	$333.4 million	$136.8 million	41%

Source: HHS Office of the Inspector General

Should CMS follow the OIG recommendations, it could put laboratories in enough of a financial bind to seriously reconsider their business models. "I am concerned that labs won't provide assays they can't make their costs on," said Jennifer L. Hunt, M.D., who is chair of the pathology department at the University of Arkansas. Hunt also serves as the president of the Association for Molecular Pathology.

The American Clinical Laboratory Association (ACLA) declined to immediately comment on the impact of the study, saying it was too soon to tell. However, ACLA raised questions regarding the OIG's methodology. It noted that there were 4,000 different price comparisons in the report, and in many circumstances Medicare was the lowest-priced payer.

"There is a tremendous variation in those prices," said ACLA President Alan Mertz. "There is an in-network component, and the question of whether there are there allowable charges on top of those rates, along with the actual amount the lab gets paid. There are all kinds of questions."

ACLA also noted that reimbursement reductions to labs have totaled more than 11 percent since 2010—including 5 percent this year alone. Moreover, labs "face double [that] amount of cuts already scheduled for the next nine years," according to an association statement.

Mertz said Congress should take those cuts "taken into consideration" regarding any deliberations it might make on the OIG's recommendations.

"We as an industry have to point this out to Congress. . . . [W]e need to educate them on that," Mertz said.

The report is available at *http://oig.hhs.gov/oei/reports/oei-07-11-00010.asp*.

INDUSTRY BUZZ

Bio-Reference Subsidiary Strikes Deal With Big Oncology Group

The fast-growing Bio-Reference Laboratories is continuing to consolidate its foothold in the Greater New York area by striking a development pact with one of the largest oncology medical groups in the region—a deal it says it wants to replicate elsewhere.

Bio-Reference subsidiary GenPath Oncology entered into a development agreement earlier this month with Regional Cancer Care Associates, a Newark, N.J.-based practice with 92 physicians and 230,000 oncology patients across New Jersey.

The two entities developed and opened a molecular lab on the grounds of John Theurer Cancer Center at Hackensack Regional Medical Center on June 3. The lab can perform up to 3,000 flow tests annually. Regional Cancer Care capitalized its construction, which cost about $750,000.

Additionally, the parties will develop a physician-owned immunophenotyping service for hematological malignancies. No timetable was available for when that service will commence or its projected volumes. GenPath will also perform a variety of esoteric tests for Regional Cancer Care, including OnkoMatch and GenArray, according to Bio-Reference spokesperson Karen Maurer.

The deal consolidates lab services for Regional Cancer Care, which previously sent its testing to a variety of labs in the area, according to Bryan Soltes, the group's vice president for marketing and business development. "Through this relationship, Regional Cancer is well positioned to offer the most innovative cancer diagnostics," said Edward J. Licitra, M.D., the medical group's chairman of the board.

Bio-Reference Chief Executive Officer Marc D. Grodman, M.D., suggested that such semiexclusive pacts are a reflection of the current health care business environment. "We recognize that providers are forming larger practices to meet the challenges of a changing market," Grodman said.

Meanwhile, the Elmwood Park, N.J.-based Regional Diagnostic is continuing to grow rapidly. For the second quarter of fiscal 2013, ending April 30, the company reported revenue of $176.5 million, up 17 percent from the year-ago quarter's revenue of $151.4 million. Net income was $11.3 million, up 22 percent from $9.3 million during the fiscal second quarter of 2012.

According to company officials, the lab is seeking similar deals in other parts of the country.

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202-637-9466

Association for Molecular Pathology
301-634-7939

Bio-Reference Laboratories
800-229-5227

Cleveland Clinic
216-445-8904

Doctors Pathology Services
302-677-0000

Mid-Florida Pathology
352-460-0292

Myriad Genetics
801-584-3600

Quest Diagnostics
800-222-0446

Regional Cancer Care Associates
201-996-3559

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