G2 INTELLIGENCE

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ACLU Renews Challenge to Myriad's Gene Patents

At press time, an ACLU spokesperson told NIR, *"We have not yet had a response" from the high court on the request for gene patents review.*

The American Civil Liberties Union (ACLU) and the Public Patent Foundation announced Sept. 25 that they have asked the U.S. Supreme Court to invalidate patents held by Myriad Genetics on two genes associated with hereditary breast and ovarian cancer.

The lawsuit against Myriad and the University of Utah Research Foundation (Salt Lake City) charges that the patents on the BRCA1 and BRCA2 genes are illegal and restrict both scientific research and patients' access to medical care by giving the company the exclusive right to perform tests on these genes and set the terms and the pricing for the work.

A federal district court previously had invalidated the patents, but a federal appeals court subsequently upheld Myriad's claim. In March of this year, however, the Supreme Court ordered the appellate panel to reconsider its ruling in light of the high court's decision in a related patent case, *Mayo v. Prometheus*. In August, the appeals court, divided 2-1, ruled for the second time in Myriad's favor, saying that its patents involve DNA isolates markedly different from the DNA that exists in the body's chromosomes.

"In our view, the court of appeals did not fully consider or correctly

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Next Stop for CLIA PT Referral Legislation: Lame-Duck Session to Begin in November

Legislation giving the Centers for Medicare and Medicaid Services (CMS) leeway in enforcing sanctions on clinical laboratories for violating proficiency testing (PT) referral rules was favorably reported by a key Senate health panel but not in time for floor action.

The bipartisan bill, S. 3391, the TEST Act—sponsored by Sens. John Boozman (R-Ark.), Amy Klobuchar (D-Minn.), and Jeanne Shaheen (D-N.H.)—cleared the Health, Education, Labor, and Pensions Committee on Sept. 19. But two days later the Senate adjourned until after the November elections.

The measure is expected to be taken up when the Senate convenes for the congressional lame-duck session, scheduled to begin Nov. 13. The House has already passed a bipartisan companion bill, H.R. 6118 *(NIR 12, 17/Sept. 20, p. 1).*

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ACLU Renews Challenge to Gene Patents, *from p. 1*
apply the Supreme Court's most recent and relevant patent law decisions," said Chris Hansen, staff attorney with the ACLU Speech, Privacy, and Technology Project. "DNA occurs naturally in the human body and cannot be patented by a single company that can then use its patents to limit scientific research and the free exchange of ideas."

ACLU argues that "under well-established law, patents cannot be obtained on either laws of nature or products of nature. For example, neither the law of gravity nor minerals, like iron, can be patented. The lawsuit contends that patents on human genes violate this core principle of patent law and the Constitution."

Daniel B. Ravicher, executive director of the Public Patent Foundation and co-counsel in the lawsuit, said, "The patenting of human genes, even in isolated form, has the effect of giving ownership over human genes to corporations, allowing them to decide who is allowed to know what they have inside their own body."

The challenge to Myriad's patents, which began in 2009, is backed by researchers, genetic counselors, patients, breast cancer and women's health groups, and medical professional associations representing 150,000 geneticists, pathologists, and laboratory professionals, ACLU notes. Among them are the Association for Molecular Pathology, the American Society for Clinical Pathology, and the College of American Pathologists.

The petition for Supreme Court review is posted at *www.aclu.org/womens-rights/brca-petition-writ-certiorari.*

Loss of One CLIA Certificate Ricochets to Three Other Labs

A recent ruling on revocation of certification under the Clinical Laboratory Improvement Amendments (CLIA) illustrates the need to consider the collateral consequences, particularly on labs with the same owner or operator, in determining whether to challenge the sanctions, notes attorney Robert E. Mazer with Ober/Kaler in Baltimore.

Mazer summarized the stakes involved in an e-mail to *NIR*. "In a Department Appeals Board (DAB) proceeding, a lab that received a notice of CLIA sanctions did not file an administrative appeal; instead it sent a letter to the Centers for Medicare and Medicaid Services (CMS) asking it to reconsider and to permit the lab to perform waived testing at least. After the appeal period expired, CMS revoked the lab's CLIA certificate.

"Approximately a week later, CMS revoked the CLIA certificates of three other labs owned by the same individual who owned the lab that had had its CLIA certificate revoked. The original lab then attempted to challenge the revocation, but, according to the DAB, it was too late to do so."

How the Case Unfolded

In September 2010 a recertifcation survey was conducted at Kids Med (Delta Medical Branch) in Elsa, Texas, and based on the findings, CMS notified its owner-director, Dr. William A. Aviles, that the facility was not in substantial compliance with several CLIA conditions of participation. Accordingly, effective March 14, 2011, CMS would

suspend the lab's CLIA certificate and cancel its approval to receive Medicare payments. The lab had 60 days to request an administrative hearing; otherwise, CMS would revoke the certificate.

In a March 14, 2011, letter to CMS, Aviles acknowledged serious mistakes but asked to be allowed to at least continue providing waived tests. The agency turned him down on April 19 and again warned of automatic revocation on May 10 if he did not appeal. No hearing request was filed by the deadline, so the lab's certificate was revoked.

About a week later, CMS notified three other labs in the area served by Kids Med—Mid-Valley Pediatrics, Donna Medical Clinic, and Mercedes Children's Clinic—that Kids Med's certificate loss also meant their CLIA certification was revoked.

On Aug. 31, 2011, Kids Med filed with the DAB a request for hearing, arguing that Aviles's March 14 letter was a timely and complete appeal. As an alternative, there was good cause, the lab said, to allow it to file beyond the 60-day deadline. The next day, the three other labs filed nearly identical responses.

In further skirmishing, Kids Med maintained that the problems leading to the revocation were isolated and the fault of a single, new employee who was since reassigned. It also noted that because its certificate loss affected a total of four facilities, the impact on the community is disproportionately harmful.

In January 2012, administrative law judge (ALJ) Richard J. Smith granted a CMS motion to dismiss the case on grounds that the March 14, 2011, letter was not a hearing request and that by failing to exercise its appeal rights in a timely manner the lab failed to show good cause why its letter should be amended to meet appeal requirements or why the hearing request deadline should be extended. On Aug. 14, 2012, the DAB upheld the ALJ's decision.

Clinical Lab Services Under the OIG's Microscope in 2013

In its recently released work plan for fiscal year 2013 (which began this Oct. 1), the Office of Inspector General (OIG) at the U.S. Department of Health and Human Services says it will continue to scrutinize billing practices and payment rates for Medicare Part B clinical laboratory services.

The plan, posed at *www.oig.hhs.gov*, cites works in progress in three lab areas:

- *Billing characteristics and questionable billing in 2010:* This study will look into the growth in lab spending due to the increased volume of services ordered. In 2008, Medicare paid about $7 billion for lab services, a 92 percent increase from 1998.
- *Reasonableness of Medicare lab payment rates versus other payers:* The OIG will determine how the methods for setting Medicare payment rates for 20 lab tests, representing the most frequently ordered and most costly in terms of total dollars paid, vary from the rates of state Medicaid and the Federal Employee Health Benefits program.
- *Frequency screening for glycated hemoglobin A1C tests and appropriate payment:* Preliminary OIG work in two contractors showed variations in the frequency-screening procedures. Medicare does not consider it reasonable and necessary to perform the test more often than once every three months in a controlled diabetic patient unless documentation of medical necessity supports more frequent testing.

focus on: *Lab Payment Policy*

New Calls for Medicare Lab Competitive Bidding

Competitive bidding for Medicare Part B clinical laboratory services is again being touted in health policy circles as a money-saving reform that Medicare should adopt.

Research by RTI International (Research Triangle Park, N.C.) advocates this approach in a report released on the online *Medicare and Medicaid Research Review 2012: Volume 2, Number 2,* an information-sharing service of the Center for Strategic Planning at the Centers for Medicare and Medicaid Services (CMS).

In the same vein, 23 health policy veterans from academia and political circles, writing on containing health care spending in the Aug. 1 *New England Journal of Medicine*, urged Medicare "to expand competitive bidding to lab services, radiologic diagnostic services, medical devices, and all other commodities," citing a 42 percent savings achieved by using this method to pay for wheelchairs.

Congress has given a cold shoulder to the idea in the past, but should lawmakers warm up to it as part of a budget-cutting spree, the lab industry is poised to fight against it.

Congress once embraced the idea, then later cast it aside. In 2003 it authorized a three-year Medicare pilot program to see if competitive bidding could be used to pay for independent lab services at rates below the Part B lab fee schedule without sacrificing quality and access. In 2008, under intense lobbying from the lab industry, Congress repealed this authority, blocking the July 1 launch of the first demonstration in the San Diego area.

In Washington policy circles, however, ideas once discarded have a way of being put back on the table, and in the current budget-cutting climate, lawmakers could be tempted to take another look at lab competitive bidding in further Medicare reforms.

Is Current Payment Policy Outdated?

Yes, RTI International asserts in the introduction to its analysis of the national market for Medicare clinical lab testing and its implications for payment reform along competitive bidding lines.

The Part B lab fee schedule, designed in the 1980s, is based on lab charges from 1984 and has not kept up technology, market, and regulatory changes. Payment is made via 56 local fee schedules and labs are paid the lesser of the actual charge, the local amount, or the national fee cap (set at 74 percent of the national median). "With 84 percent of payments at the cap, the lab testing market faces what is essentially a national fee schedule," RTI notes.

Is the Market Ripe for Bidding?

Yes, the RTI report concludes. RTI itself is no stranger to the competitive bidding arena. CMS tapped the think tank to design the Medicare multiple-winners demonstration that was ready for launch in 2008 until blocked by court action and ultimately killed by Congress.

Now, RTI is again boosting the idea in its analysis of the national Medicare lab testing, based primarily on two 5 percent sample data files from 2006. In that year, Medicare paid almost $6.7 billion to physicians and facilities that billed nearly 650 million laboratory test codes on behalf of fee-for-service beneficiaries. Payments for independent lab and hospital outreach services constituted just under half (46.6 percent) of the total paid for all test codes on the lab fee schedule, including waived tests and routine venipuncture.

The independent laboratory market is highly concentrated, the study found, dominated by two companies—Quest Diagnostics and Laboratory Corporation of America. The hospital outreach market is less so. Two subgroups of Medicare beneficiaries, those with end-stage renal disease (ESRD) and those residing in nursing homes, are each served in separate lab markets.

The greatest potential for competition is in nonpatient testing, as both local and national independent labs vie with hospital outreach labs for referrals from physicians. Nonpatient testing is defined as that performed by independent and hospital labs for Medicare beneficiaries who are not registered as inpatients or outpatients of the hospital. Beneficiaries treated in the past as outpatients may still be considered nonpatients. Though largely paid the same Medicare fee when billing the same test code, the labs can compete for physician business on elements other than price such as providing accurate and reliable test results, quick turnaround times, and low rates of rejected or lost specimens.

Test Menu for Bidding

There are more than 1,000 test codes on the Medicare lab fee schedule, but test volume and spending are concentrated in a relatively small number of Healthcare Common Procedural Coding System (HCPCS) codes. Therefore, RTI says, "a bidding competition for only the top 100 or top 200 codes would encompass most of the market." The top 100 HCPCS codes account for about 90 percent of total Medicare Part B expenditures. More than half of the volume is contained in just the 10 most frequently billed. The top 200 codes cover 97.5 percent of volume. Hematology and chemistry test panels are among the most common codes and account for a large share of volume and expenditures.

National and Local Bidding Choices

Quest and LabCorp each have a significant share of the Medicare lab testing market and each serves large numbers of Medicare beneficiaries in all parts of the country, RTI notes. "This suggests that CMS could consider holding a bidding competition among Quest, LabCorp, and any other organizations that could qualify as 'national Medicare laboratories' qualified to provide services nationally. The primary advantage is they would have an incentive to bid aggressively, because their entire national Medicare business would be at stake. Also, a single nationwide competition could achieve substantial economies in the bidding and contracting process."

Two firms could be sufficient to ensure that Medicare receives a competitive price for laboratory tests, resulting in reduced program spending, RTI said. "With the exception of a few esoteric tests, a specific lab test is a homogenous test or product across laboratories."

Quest and LabCorp have successfully competed for exclusive lab contracts with large private insurers, the study noted. In 2007 United Healthcare, with 25 million

members, signed a 10-year contract with LabCorp that extended through 2018, while Aetna, with 17.5 million members, signed one with Quest. United and Aetna, combined, cover more lives than Medicare fee-for-service with approximately 36 million in 2010. "These national private insurers have already shown that exclusive contracting (i.e., competitive bidding) for lab services works on a national level, and it can therefore work for Medicare."

CMS could also sponsor bidding competitions in local areas for local or regional independent labs and hospitals and integrated delivery systems. These organizations could compete against each other, but not against the national labs if a national bidding competition were held. Or only local or regional bidding competitions could be held, including national labs, to serve that area.

Medicare Subpopulations

ESRD beneficiaries are served mainly by national laboratories associated with dialysis firms and by lab companies that cater almost exclusively to this population. Spectra, DaVita, and eight other labs account for over 93 percent of Medicare payments for lab tests for this population. In 2011, prospective payment was introduced for ESRD patients, including lab services associated with dialysis sessions. "To the extent that other lab tests (for example, for comorbid conditions) continue to be billed through Medicare fee-for-service, it may be possible to include them as part of competitive bidding," RTI suggests, either in a general or a separate bidding competition.

Bidding is problematic, however, in the market serving nursing home and homebound beneficiaries. In many areas of the country, there are only one or a small number of independent lab providers that cater to this market. CMS would have to ensure there are enough willing bidders. "Alternatively, nursing home and homebound beneficiaries could be excluded from the bidding competition, but their tests could be paid under the competitively-determined fee schedule."

RTI Conclusion and Objections

Medicare lab competitive bidding "has the potential to not only lower Medicare expenditures, but to change clinical laboratory market structure. For example, [it] could reduce prices paid by Medicare for lab tests to the marginal costs of large national labs that can take advantage of economies of scale and perform some tests at lower costs than smaller establishments. In this case, smaller labs such as those in the physician office may minimize losses by outsourcing their testing to an independent or hospital lab instead of providing those tests themselves."

The Clinical Laboratory Coalition, whose members include clinical lab and pathology advocacy organizations, has long and successfully opposed the introduction of lab competitive bidding under Medicare. One fundamental objection is the notion that lab testing can be treated as a commodity. Unlike a wheelchair or a walker that can be mass-produced, it is a complex medical service requiring technical skills and professional interpretation that are crucial in guiding a physician's decisions on treatment and therapy.

Competitive bidding also would devastate the niche markets serving nursing home and homebound beneficiaries, critics contend. National and regional labs have shunned these markets, leaving only small local testing facilities to serve these populations. These local labs depend on Medicare revenue to survive.

Next Stop for CLIA PT Referral Legislation, *from p. 1*
Currently, CMS takes a strict interpretation that the Clinical Laboratory Improvement Amendments (CLIA) require the agency to revoke a lab's certificate for one year and bar its owner and operator from running another lab for two years for intentional PT referrals for a test that the lab is certified to perform.

H.R. 6118 and S. 3391 would give CMS flexibility to consider sanctions on a case-by-case basis. The agency could substitute intermediate sanctions for PT referral violations instead of the two-year prohibition against ownership or operation that would otherwise apply and would make the one-year certificate revocation for the lab optional rather than mandatory.

Legislative relief is especially needed, say pathology and clinical lab groups, pointing to a growing number of labs across the country that have been sanctioned for inadvertent PT referrals.

The latest high-profile case involves Ohio State University's Wexner Medical Center. CMS proposed to revoke its CLIA certificate for prohibited PT referrals, though Wexner self-reported six incidents, saying these were accidental and corrective action has been taken. The center is appealing, putting the proposed sanctions on hold *(NIR 12, 16/Sept. 6, pp. 4-5)*.

CMS Announces New Waived Tests, Billing Codes

The Oct. 1, 2012, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes 11 more devices, the latest approved by the Food and Drug Administration (FDA) for this category. New waived tests are approved on a flow basis and are valid as soon as approved. Prior to payment approval, claims are checked for waived testing certification.

The update, plus a complete list of CLIA waived devices, can be found in Change Request 7868, at www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2496CP.pdf.

Below are the latest tests approved by the FDA as waived under CLIA.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
G0434QW	March 14, 2012	Wondfo Oxycodone Urine Test {Dip card format}
G0434QW	March 14, 2012	Wondfo Oxycodone Urine Test {Cup format}
87880QW	March 23, 2012	McKesson Strep A Test—Dipstick
87880QW	March 23, 2012	McKesson Strep A Test—Twist
86318QW	April 3, 2012	McKesson H. pylori Test (Whole Blood)
87804QW	April 20, 2012	Sofia Analyzer and Influenza A+B FIA (for use[] with nasal swabs and nasopharyngeal swabs)
85610QW	May 8, 2012	AlereINRatio®2 PT/INR Home Monitoring System {Prescription Home Use}
83986QW	May 8, 2012	Dale Medical Products Inc. RightLevel pH
83986QW	May 8, 2012	Dale Medical Products Inc. RightSpot pH
G0434QW	May 22, 2012	Chemtron Biotech Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests
G0434QW	May 22, 2012	Chemtron Biotech Inc. Chemtrue Single/Multi-Panel Drug Screen Dip Card Testst Number: 7868

Your Medicare contractor is not required to search its files to either retract payment or retroactively pay claims; however, it should adjust claims you bring to its attention.

Noridian to Handle Medicare Workload for Jurisdiction E

Noridian Administrative Services (Fargo, N.D.) has been awarded the contract to handle Medicare Part A and Part B fee-for-service claims in Jurisdiction E, previously called Jurisdiction 1 and serviced by Palmetto GBA (Columbia, S.C.). The "cost plus award fee" contract has an estimated value of $345.2 million and a maximum duration of five years.

The transfer of the Medicare workload from Palmetto to Noridian will occur over the next several months and is expected to go smoothly with few disruptions, the Centers for Medicare and Medicaid Services said.

Jurisdiction E covers California, Nevada, and Hawaii, as well as the U.S. territories of American Samoa, Guam, and the Northern Mariana Islands. It includes more than 3.5 million Medicare fee-for-service beneficiaries and serves approximately 500 Medicare hospitals and 86,500 physicians. This jurisdiction comprises approximately 8.9 percent of the national Medicare A and B fee-for-service claims volume.

With the newly awarded contract, Noridian has a lock on Medicare A and B business on the West Coast and in key states along the Rocky Mountains. Since 2011, the company has handled this combined workload for 10 states consolidated in Jurisdiction F: Alaska, Washington, Oregon, Idaho, Montana, Wyoming, Utah, Arizona, North Dakota, and South Dakota.

Upcoming G2 Events

Webinar (2 p.m. - 3:30 p.m. Eastern)

Nov. 15

The Final Word on MDx Coding and Payment: What Will CMS's Decision Portend for the Future of Molecular Diagnostics?

Featured Speakers:
Peter Kazon, Esq., Alston & Bird
Bruce Quinn, M.D., Health Policy Specialist, Foley Hoag
Diana Voorhees, M.A., CLS, MT, SH, CLCP President, DV & Associates

Conferences

Nov. 14

Lab Leaders Summit
Union League Club of New York
New York City
www.lableaderssummit.com

Nov. 15

Laboratory Investment Forum
Give and Take in the Laboratory Market: Political and Market Forces Shaping the Investment Climate
Bloomberg Tower
New York City
www.labinvestmentforum.com

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