G2 INTELLIGENCE

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High Court Voids Prometheus Patents on Test Methods

The case has been closely followed by the biotechnology and diagnostics industries for its impact on the growing field of personalized medicine, which tailors treatment and therapy to an individual's genetic makeup.

In a unanimous decision released March 20, the U.S. Supreme Court invalidated two patents held by Prometheus Laboratories (San Diego) on test methods used to determine the proper dosage of thiopurine for patients with gastrointestinal and nongastrointestinal autoimmune diseases like Crohn's disease, based on the rate at which each patient metabolizes the drug.

Prometheus, a unit of Switzerland-based Nestle S.A., was the exclusive licensee of the patents for a blood test that covers methods of administering the drug and measuring the drug's metabolites in the red blood cells.

The company sued Mayo Collaborative Services in 2004 after Mayo created its own test for determining thiopurine dosage, which Prometheus said infringed on its patents, though the Mayo test had different optimal thresholds for adjusting the dosage.

In its decision the high court ruled that the Prometheus patents were unpatentable because they merely describe the laws of nature and "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity."

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INSIDE *NIR*

Bill Would Spare Pathologists From EHR Penalties

Bipartisan legislation has been introduced in the House that would prevent pathologists from being penalized for failing to participate in the meaningful-use (MU) program that offers incentive payments to physicians and hospitals for the adoption of electronic health records (EHR).

Under current law, pathologists who fail to participate would be subject to reduced Medicare and Medicaid payment rates, beginning Jan. 1, 2015.

Under the MU program run by the Centers for Medicare and Medicaid Services (CMS), pathologists, though eligible as physicians for the incentive payments, are effectively barred from participating because the MU criteria, designed for primary care, involve performance measures that do not apply to pathology.

Under H.R. 4066, pathologists identified with a Medicare enrollment specialty code of 22 (pathology practice) or 69 (independent laboratory) would escape MU-related payment reductions. However, the bill would not open the door to obtaining EHR incentive payments.

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High Court Voids Prometheus Patents, *from p. 1*

This reverses federal circuit court decisions against Mayo and upholding that the disputed claims were patent-eligible. The way is now clear for Mayo Collaborative Services, a subsidiary of the Mayo Clinic, to introduce a competing diagnostic test. Mayo had previously used the Prometheus test before developing its own, the move that triggered the lawsuit.

> *"The [Prometheus test method] claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities." U.S. Supreme Court decision in* Mayo Collaborative Services v. Prometheus Laboratories Inc.*, U.S., No. 10-1150, 3/20/12.*

In writing for the court, Justice Stephen Breyer noted that natural laws, natural phenomena, and abstract ideas are not eligible for a patent under the current statute. "The question before us is whether the [Prometheus] method claims do significantly more than simply describe natural relations. To put the matter more precisely, do the patent claims add enough to their statements of correlations to allow the processes they describe to qualify as patent-eligible processes that apply to natural laws. We believe the answer to this question is no."

The court found that the steps of the claims at issue failed to "add enough" to the "inventive concept" of the Prometheus patents—the correlations between metabolite levels and effectiveness of the drug. While not defining "enough," the court indicated that the concept must be found in the application, not in the law of nature.

While test developers generally supported Prometheus, most groups representing health care providers supported Mayo, saying such patents threatened to limit care to patients.

Myriad Genetics, which backed Prometheus, is fighting a challenge to its patents related to the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer. Myriad in January filed a brief with the Supreme Court in opposition to a petition seeking review in a case challenging its patents. In light of the *Prometheus* ruling, it's possible the high court will send the *Myriad* case back to the federal circuit court for reconsideration.

Bill Would Spare Pathologists, *from p. 1*

The bill, the Health Information Technology Reform Act, is sponsored by Reps. Tom Price (R-Ga.) and Ron Kind (D-Wis.), both members of the Ways and Means Committee. It is supported by the College of American Pathologists (CAP), the American Society for Clinical Pathology, and the American Clinical Laboratory Association (ACLA).

"Pathologists would welcome an opportunity to be included in the EHR Meaningful Use program," said CAP President Stanley M. Robboy, M.D., FCAP. "However, the program focuses on office-based primary care practices. To meet some of the requirements, physicians must ensure that the EHR for each patient contains their vital signs, medical allergies, smoking status, as well as their communication preferences. It also requires the systems to generate e-prescriptions, update immunization registries, and support drug interaction checks. There is no way for pathologists to participate."

ACLA President Alan Mertz noted in a March 14 letter to Price, "Because pathologists rarely have face-to-face encounters with patients, they are not in a position to

meet many of the required MU criteria. Further, unlike other physician specialties, medical records of pathologists are already generated, transmitted, received, and stored in integrated laboratory information systems. Transitioning to another, less efficient records system just to avoid penalties under a legislative mandate would be wasteful and counterproductive."

"Penalizing pathologists for their failure to adopt standards that do not apply to their clinical setting appears to be an oversight that will lead to bad public policy."
—ACLA President Alan Mertz

The MU program was authorized by the American Recovery and Reinvestment Act of 2009. Reporting requirements were established by the Office of the National Coordinator for Health Information Technology.

While CMS has taken the position that pathologists meet the definition of "eligible professionals" within the meaning of the law and that the agency lacks the authority to correct it, CMS has invited comments on granting exceptions to those who meet certain criteria but lack face-to-face or telemedicine interaction with patients, lack follow-up with patients, and lack control over a certified EHR at their practice locations.

According to CMS's proposed Stage 2 MU rule, one option would be a two-year payment adjustment, the other would provide the exception but not for more than five years. G2

CMS Again Extends Version 5010 Compliance Deadline

No enforcement action will be initiated for an additional three months, through June 30, against any entity that is required to comply with updated Version 5010 and other electronic transaction standards under the Health Insurance Portability and Accountability Act (HIPAA), the Centers for Medicare and Medicaid Services (CMS) announced March 15.

The standards are:

- ASC X12 Version 5010, which allows more functionality for transactions such as eligibility requests and claims status. It also is a prerequisite for using the International Classification of Diseases, 10th Edition (ICD-10), diagnosis and procedural code sets.
- NCPDP Telecom D.0 (NCPDP D.0), which addresses certain pharmacy industry needs.
- NCPDP Medicaid Subrogation 3.0 (NCPDP 3.0), which allows state Medicaid programs to recoup payment for pharmacy services in cases where a third-party payer has primary financial responsibility. (For small health plans, the deadline to comply with this standard is Jan. 1, 2013).

Second Deadline Extension

The March 15 announcement marks the second 90-day grace period that CMS has granted to give HIPAA-covered entities time to adopt the above standards. The previous grace period ran from Jan. 1 of this year (the effective date of the updated standards) through March 31 (*NIR 11, 22/Dec., p. 2*).

Noncompliance could result in disruptions in claims processing and reimbursement. Links to a Version 5010 Testing Readiness Fact Sheet and other information on the above are available at www.cms.gov/ICD10.

In announcing the latest delay in enforcement action, CMS noted that covered entities are making steady progress. The Medicare fee-for-service program reports successful receipt and processing of more than 70 percent of all Part A claims and more than 90 percent of all Part B claims in the Version 5010 format. Commercial plans report similar numbers, the agency said. State Medicaid programs show progress as well, CMS said, and some have made the full transition to Version 5010.

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focus on: Clinical Lab Regulation

CLIA Update: What's on the Agenda for 2012?

This year marks the 20th anniversary of the national regulatory program established under the Clinical Laboratory Improvement Amendments (CLIA). CLIA certification and compliance are required to legally perform testing on human specimens for disease diagnosis, prevention, treatment, and monitoring or for the purpose of assessing health or impairment. This also is a prerequisite for receiving Medicare and Medicaid payment for covered lab services.

Key works in progress in the program this year were discussed by Judy Yost, the top CLIA official at the Centers for Medicare and Medicaid Services (CMS), during a March 7 webinar sponsored by G2Intelligence.

Revised Quality Control Guidelines

In a 2003 final rule to streamline and simplify quality systems requirements for testing categorized by the Food and Drug Administration (FDA) as moderate and high complexity, CMS allowed laboratories performing such testing to reduce the frequency and workload associated with equivalent quality control (QC). Facing sharp criticism on the risk this posed to patients, CMS partnered with the Clinical and Laboratory Standards Institute (CLSI) to develop new guidance on alternative QC.

CMS is now revising QC guidelines, Yost said, to incorporate risk management principles used in manufacturing and other industries and contained in CLSI guidance, called EP-23, which was published in October 2011. Under EP-23, labs should consider what could go wrong in their operations and take into account a host of factors—specific device capabilities (control processes engineered by the manufacturer into the device or instrument), package-insert recommendations, literature about the test, the laboratory setting, operator experience, how the test will be utilized in medical care, and local quality regulations.

EP-23 provides labs greater flexibility in customizing the design of their QC plans to their environments, Yost said. CMS interpretive guidelines will permit individualized QC plans for each laboratory and each existing and new test (excluding pathology), based on patient population, environment, clinical use, and test system. The revised guidelines won't necessarily decrease the amount of QC required, but it will be "the right QC," she said.

Personnel Qualifications and Competency

Problems in this area have led CMS to focus on documentation of personnel qualifications and competency assessment, Yost noted. Among the problems cited: individuals downloading qualifications from the Web and using them fraudulently to obtain CLIA certificates and bill Medicare

CLIA Enrollment

Total Laboratories	229,815
Total Nonexempt	222,899
• Compliance	19,387
• Accredited*	15,697
• Waived	150,256
• Provider Performed Microscopy	37,559
Total Exempt	6,802
• New York (excludes physician office labs)	3,469
• Washington	3,447

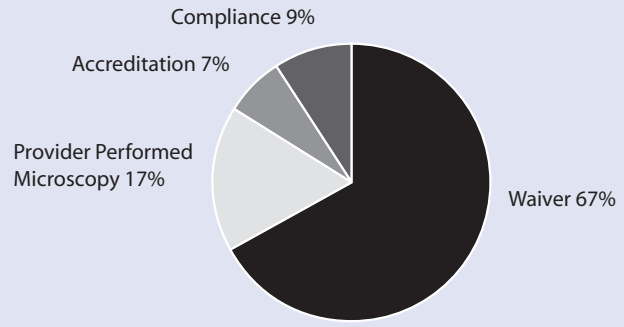
*Approved programs are run by the American Association of Blood Banks, American Osteopathic Association, COLA, College of American Pathologists, Joint Commission, and American Society for Histocompatibility and Immunogenetics.

Source: CMS database, January 2012

for millions of dollars; offshore operations upgrading degrees for a fee; diploma mills offering "quickie" degrees; and labs with multiple, consecutive proficiency testing (PT) failures employing testing personnel with falsified credentials, requiring a review of all the lab's testing results.

"There is great risk to patients if an individual in a regulated position is identified as unqualified and testing quality issues are also found," she said. "If an individual doesn't meet education, training, or experience requirements or fulfill related responsibilities, the lab is cited for a condition-level deficiency." Failure to address such a deficiency exposes the lab to a host of sanctions, ranging from a plan for corrective action to limitation, suspension, or revocation of its CLIA certificate.

CLIA Labs by Certificate Type



Source: CMS database, January 2012

Under CLIA rules, laboratory directors must satisfy the most stringent qualifications due to their overall responsibility for lab operations and testing quality but are not subject to competency assessment. This, however, is required for all technical, supervisory, and testing personnel based on their regulatory responsibilities and must be documented by a qualified individual (a technical or general supervisor or technical consultant). Lab directors should evaluate pathologists as technical supervisors.

Competency for all tests performed must include:

- ❑ Direct observation of routine patient test performance, including a patient's preparation, if applicable, specimen handling, processing, and testing;
- ❑ Monitoring the recording and reporting of test results;
- ❑ Review of intermediate test results or worksheets, QC records, PT results, and preventive maintenance records;
- ❑ Direct observation of instrument maintenance and function checks;
- ❑ Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples; and
- ❑ Assessment of problem-solving skills.

Core CLIA Principles

- Regulation by test complexity, site-neutral
- Universal in scope
- Legal basis to perform laboratory operations
- Self-financed from user fees
- Alternative compliance avenues: private nonprofit accreditation programs and state CLIA-exempt programs

Tips for Competency Assessment

- ❑ Operator training prior to testing is critical and required.
- ❑ Competency records should match your lab's actual procedures that are performed by your personnel.
- ❑ When observing test performance, use the procedure manual or package insert to ensure the manual is current.
- ❑ Use competency assessment for quality assurance when confirming that tests ordered match the tests reported and charted results.
- ❑ Follow-up on QC corrective actions will demonstrate your problem-solving ability to CLIA surveyors.

While personnel performing pre- and post-analytic stages of the testing process and not in regulatory positions subject to competency assessment do not have to be reviewed and assessed, "it is good quality assurance," Yost noted.

Ensuring Quality in Waived Testing

Since the debut of the CLIA program in 1992, the number of tests categorized by the FDA as CLIA-waived has increased from eight to more than 100, Yost noted, and the number of labs with a certificate of waiver (CW) has grown from 20 percent to 67 percent of the nearly 230,000 laboratories that are CLIA-enrolled.

CMS's Top 10 Condition-Level Deficiencies

Citation	*% Labs Cited*
Lab director, moderate complexity, qualifications/ responsibilities	3.8%
Successful PT participation	3.0%
PT enrollment	1.7%
Analytic Systems (QC)	1.4%
Lab director, high complexity, qualifications/responsibilities	1.4%
Moderate-complexity testing personnel	1.2%
Technical consultant, qualifications/responsibilities	0.8%
Hematology	0.6%
High-complexity testing personnel	0.3%
General lab systems, preanalytic	0.3%

While waived testing takes advantage of technology advances to offer timely, efficient, and convenient care for patients, it also is the least regulated, requiring only that the user follow the test manufacturer's instructions. CW labs are only randomly inspected to ascertain CLIA compliance, in response to a complaint, or when the lab poses an immediate jeopardy to public health and safety.

In 1999, as the number of CW labs soared, CLIA launched a pilot project to look into quality issues. Of 100 visited, 50 percent had quality problems. The project since expanded into a national, ongoing effort. In 2006, of 1,947 labs initially visited, 69 percent were following the manufacturer's instructions. Of 414 labs revisited for not doing so, 353 or 85 percent improved upon revisit.

Currently, CMS visits a 2 percent sample of CW labs annually, with each responding to standard questions about its testing practices. Still, Yost said, data show continuing problems, including high staff turnover and personnel who lack formal lab education, have limited training in test performance and quality assurance, are not aware of "good laboratory practice" guidance, and comply partially with the manufacturer's QC instructions.

To address CW issues, one option for the long term would be for Congress to change the CLIA statute to enhance oversight. For now, CMS will continue its annual CW lab sampling indefinitely. It also will launch a new pilot project, "Ready, Set, Test!," with a new educational booklet developed by the Centers for Disease Control and Prevention (CDC) with CMS input. The booklet will be sent to a small sample of CW labs prior to a visit, and CMS will evaluate the performance of labs that received the booklet versus those that did not. If successful, the booklet will be shared with all CW labs as part of ongoing efforts to ensure quality testing in this large majority of CLIA-certified labs, Yost said.

Pending CLIA Regulations

CMS is analyzing comments received on the proposed rule, issued jointly with the CDC and the Office of Civil Rights, to grant patients access to their lab test results (*NIR 11, 17/Sept. 22, p. 1*). There is no firm timeline for finalizing it.

With regard to PT revisions, a plan with milestones and a timeline has been developed, including test selection, target values, grading criteria, PT programs, and PT referral. Such revisions would require a proposed rule with comment period and there is no firm estimated time of arrival, Yost said, but work continues to gather additional data for certain requirements such as grading criteria and target values.

CMS Again Extends Deadline, *from p. 3*

During the grace period, however, the CMS Office of E-Health Standards and Services, which enforces compliance with HIPAA transactions and code sets, will investigate complaints for noncompliance. If requested by this office, covered entities that are the subject of complaints (known as "filed-against entities") must produce evidence of either compliance or a good-faith effort to become compliant during the 90-day period.

CMS Announces New Waived Tests, Billing Codes

The April 1, 2012, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes 13 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.

The Centers for Medicare and Medicaid Services cautions that when billing for the tests below, you must use the QW modifier so your local Medicare contractor can recognize the code as waived under CLIA. Prior to payment approval, claims are checked for waived testing certification.

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

CPT CODE	EFFECTIVE DATE	DESCRIPTION
82274QW, G0328QW	Sept. 8, 2004	Hemosure One-Step Fecal Occult Blood Test
81003QW	Oct. 28, 2009	Acon Mission U120 Urine Analyzer
G0434QW	May 5, 2011	Premier Integrity Solutions P/Tox Drug Screen Cup (OTC)
81003QW	June 2, 2011	BTNX Rapid Response U120 Urine Analyzer
G0434QW	July 7, 2011	Instant Technologies Inc. iCassette DX Drug Screen Test
G0434QW	July 19, 2011	Express Diagnostic Int'l Inc. DrugCheck Waive RT (Model 9308z)
80061QW, 82465QW, 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84450QW, 84460QW, 84478QW	Aug. 16, 2011	Alere Cholestech LDX (Whole Blood)
82055QW	Sept. 13, 2011	Acon Laboratories Inc. Mission Saliva Alcohol Test Strip
G0434QW	Sept. 13, 2011	Amedica Biotech Instant Test Cup
81003QW	Sept. 26, 2011	Immunostics Inc., Detector Uristrip+ Analyzer
82055QW	Oct. 4, 2011	Teco Diagnostics Saliva Alcohol Test
86386QW	Jan. 1, 2012	Alere NMP22 BladderChek Test (Prescription Home Use)
86386QW	Jan. 1, 2012	Alere NMP22 BladderChek Test (Professional Use)

For 2012, the new CPT code 86386 was developed for the Nuclear Matrix Protein 22 (NMP22), qualitative test. Therefore, the CPT code assigned to the Matritech Inc. NMP22® BladderCheck® Test for Professional and Prescription Home Use is changed to 86386QW with an effective date of Jan. 1, 2012.

The official instruction, including a complete list of waived tests, is found on the CMS Web site at www.cms.gov/transmittals/downloads/R2408CP.pdf.

Your carrier or Medicare Administrative Contractor is not required to search their files to either retract payment or retroactively pay claims; however, they should adjust claims you bring to their attention.

Upcoming G2 Webinars, LabCast Tailored to Your Business Needs

Webinars *(2 p.m. – 3:30 p.m. Eastern)*

March 27

Lab Cuts and Expiring TC Grandfather Policy: What the Middle Class Tax Relief and Job Creation Act of 2012 Means for Your Laboratory

Co-sponsor: American Clinical Laboratory Association

Featured speakers: Alan Mertz, president, ACLA; Jan Bowman, vice president for policy and regulatory affairs, ACLA; and Peter Kazon, Esq., Alton & Bird

April 10

How to Disaster-Proof Your Lab Business

Featured speaker: Gina Potenza, M.S., CBCP, business continuity and information technology consultant

LabCast – Complimentary
(1 p.m. – 2 p.m. Eastern)

March 28

3 Keys to Winning More Clients and Serving Them for Life: How to Optimize the Entire Client Lifecycle

Featured speaker: Ken Cemey, president, Know Error.

Sponsor speaker: Brad Bostic, CEO, hc1.com

Registration fee waived courtesy of hc1.com, a health care relationship management company

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— Empower clients with intelligence while becoming a valued strategic partner

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Las Vegas
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Oct. 10-12

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