WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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Vol. 10, Iss. 4, February 22, 2010

Congress Pushes the Envelope on Medicare Physician Fee Fix

Unless lawmakers act by March 1, a 21 percent cut in Part B physician fees takes effect.

The House and the Senate reconvened Feb. 22 following a week-long recess to face a March 1 deadline to block a cut of 21 percent in Medicare physician payments, but how and when Congress will tackle a fix is uncertain at press time, leaving providers increasingly on edge.

Congress earlier this year blocked the cut scheduled for Jan. 1, 2010 under the Sustainable Growth Rate (SGR) formula and froze physician fees at their 2009 levels through Feb. 28.

A draft jobs bill unveiled by the Senate Finance Committee earlier this month included a provision to extend the freeze for seven more months, through Sept. 30.

But majority leader Harry Reid (D-Nev.) decided to strip it of all provisions not focused on jobs, including the physician fee freeze and other Medicare provisions affecting payments to hospitals, managed care plans, and ambulance services.

Reid's move left lawmakers scrambling to find a legislative vehicle to delay the cut before it is implemented and extend other Medicare provisions. *Continued on p. 2*

Gene Patent Lawsuit at a Crossroads

It is now up to a federal court judge to decide whether a landmark lawsuit challenging the patenting of human genes should go to trial, following oral arguments heard on motions for summary judgment in the case earlier this month in New York City.

Both the plaintiffs and the defendants asked U.S. District Judge Robert Sweet to rule in their favor without a trial. At issue are patents granted to Myriad Genetics and the University of Utah Research Foundation for BRCA1 and BRCA2 genes, which are indicators of hereditary disposition to breast and ovarian cancer.

The core of the case is whether the patent claims cover "products of nature" and "laws of nature" and are therefore invalid. The lawsuit, *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, was filed in May 2009 by the American Civil Liberties Union (ACLU) on behalf of an estimated 150,000 researchers, physicians, laboratory professionals, and patients.

The suit also alleged that the patents violate the First Amendment by giving exclusive control of the BRCA knowledge *Continued on p. 7*

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Medicare Physician Fee Fix, *from p. 1*

If Congress fails to act before March 1, it could try to enact a fee fix in a Medicare extenders bill in early March and have it be retroactive to March 1, so no cut would take effect. The Centers for Medicare and Medicaid Services also can legally hold claims for up to 15 days, which gives lawmakers some maneuver room.

The House has approved a fundamental change to the Medicare physician payment system, repealing the SGR and establishing a new update formula based on growth in the gross domestic product. The Senate reform bill makes no SGR changes but does block the 21 percent cut and grants a 0.5 percent increase for 2010 at a paid-for cost of an estimated $10.9 billion.

The House measure, passed in November 2009, approved a $210 billion permanent physician payment fix, but the Senate has not taken action on the bill. The costs of H.R. 3961 were not offset, raising concerns among some senators about its effects on the deficit. The Senate already rejected a bid to repeal the SGR because the bill did not specify how it would be paid for.

The American Medical Association, pathology groups, and other physician organizations, along with the AARP, the seniors' lobby, continue to urge lawmakers to repeal the SGR system, which has triggered ever-deeper cuts over the past decade and is poised to force even more in coming years. But the price tag is looming as a major stumbling block.

"As the Senate debates a way out of the Medicare morass that a 21 percent physician payment cut will create for seniors on March 1, it must address the problem head-on and permanently repeal this payment formula that will erode seniors' access to care and choice of physician," the AMA said in a statement.

"Kicking the can down the road with another short-term action increases the size of the cut and the cost of reform—and makes it very difficult for physicians to care for seniors and military families."

Medicare Extenders Bill Is Hoped-For Vehicle to Revive Pathology 'Grandfather' Protection

Clinical laboratory and pathology groups are looking to a Medicare extenders bill that Congress is expected to take up when it reconvenes Feb. 22 as a vehicle for extension of the "grandfather" protection for certain independent lab billings, which expired Dec. 31, 2009. The extension is critical, they say, to maintain quality testing and access to testing by Medicare beneficiaries, especially in rural areas.

The extension has drawn bipartisan support, but it is entangled in health care reform legislation that has stalled since the election of Republican Scott Brown (Mass.), which deprived Senate Democrats of a filibuster-proof majority of 60 votes.

The grandfather protection allows independent clinical labs to bill Medicare directly for the technical component (TC) of pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999, the date when the Centers for Medicare and Medicaid Services (CMS) first proposed

eliminating separate billings. Congress has repeatedly blocked the agency from going ahead with this policy change.

The delay in reviving the protection has left qualified providers in suspense over whether they will get paid. CMS has advised them how to hold TC claims, but this was premised on the expectation that Congress would enact an extension as part of comprehensive health care reform legislation.

The House-passed reform bill approves an extension for two years; the Senate bill backs one year. If attached to a Medicare extenders bill, the extension is likely to be at least through the end of this year, according to industry sources.

CMS told providers "to hold, to the extent possible, claims for services furnished on or after Jan. 1, 2010. If legislation is enacted, claims submission for affected services may resume. Otherwise, claims submitted with dates of service on or after Jan. 1 will not be paid" (*NIR 10, 1/Jan. 11, p. 1*).

CMS has repeatedly sought to end "grandfathered" TC billings, contending that the TC is paid through the hospital's inpatient DRG and labs should seek reimbursement from the hospital, not the Part B program.

The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

Fate of Lab Date of Service Change in Doubt

The pilot project for reimbursing certain complex molecular diagnostic tests, included in the Senate health care reform bill, but not in the House-passed version, is not on the list of items for a Medicare extenders bill that the Senate is expected to consider soon, according to industry sources.

Authorization of the project stalled when the Senate reform bill got stopped in its tracks after the Democrats lost their 60-vote supermajority in the wake of the election of Scott Brown (R-Mass.), who has said he would vote to block the comprehensive reform bill from being considered on the floor.

The two-year project would allow hospital-based and independent clinical labs to bill Medicare directly for certain complex molecular diagnostic tests performed within 14 days of a beneficiary's discharge, beginning July 1, 2011.

The Health and Human Services Secretary is to set the payment rates for these tests (*NIR 09, 21/Nov. 23, p. 4*). The cost of the project could not exceed $100 million, to be drawn from the Medicare budget. The original Finance Committee version paid for the project by tapping the lab fee update.

Under current Medicare rules, if a lab performs testing on blood or tissue samples collected by a hospital for inpatients and outpatients within the 14-day period, it must be paid by the hospital through its inpatient DRG payment, rather than a direct payment from Part B.

focus on: Health Information Technology

CLIA Rules and the Current Stage of E-Health Records

With the federal initiative to promote adoption of health information technology (HIT), including electronic health records (EHRs), clinical laboratories face significant challenges in meshing their operations with a host of requirements, including system interoperability with trading partners and with health information exchanges, privacy and security standards, and rules for assuring the accuracy and reliability of patients' health data.

Labs will soon have newly clarified interpretive guidance on meeting standards for test ordering and reporting under CLIA (the Clinical Laboratory Improvement Amendments), top program official Judy Yost told the Clinical Laboratory Improvement Advisory Committee (CLIAC) this month.

CLIA standards apply to a large universe of clinical labs that must be certified by the program to legally perform testing for diagnostic and assessment purposes and to receive Medicare and Medicaid payment for covered tests (*see table*). Private accrediting programs approved as CLIA certifying bodies and state exempt programs must have standards equal to the federal rules and may have even more stringent requirements.

CLIA Lab Universe

Enrollment	***# Labs***	***# Physician Office Labs***
Labs registered (exempt/nonexempt)	214,875	110,025
Labs registered (nonexempt only)	208,560	109,521
By Certificate Type (nonexempt only)		
Waiver	134,778	59,790
Provider-Performed Microscopy	38,509	31,174
Compliance (CMS surveys)	19,178	12,517
Accreditation	16,095	6,040
CLIA Exempt States		***# Labs***
New York		3,103
Washington		3,212
Certificate of Accreditation by Organization (nonexempt only)		***# Labs****
COLA		7,057
College of American Pathologists		5,476
Joint Commission on Accreditation of Health Care Organizations		2,580
American Osteopathic Association		77
American Association of Blood Banks		203
American Society for Histocompatibility and Immunogenetics		125

*Data represent labs whose membership with the accreditation organization has been confirmed. Some labs are accredited by more than one organization.
Source: CMS CLIA database, October 2009

In remarks at CLIAC's Feb. 9-10 meeting, Yost, who is director of the division of laboratory services at the Centers for Medicare and Medicaid Services (CMS), said the guidance will contain expanded information and regulatory interpretations for test ordering and result reporting applicable to the present state of EHRs under the current CLIA rules.

CLIA regulations and interpretive guidelines are quite specific about a clinical laboratory's responsibility for reporting test results accurately and reliably, she noted and presented clarifications of certain misperceptions.

Recap of the Rules for Test Ordering and Result Reporting

❑ §493.1105 Standard: Retention Requirements (a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least two years after reporting.

❑ §493.1241 Standard: Test request

- (a) The laboratory must have a written or electronic request for patient testing from an authorized person.

❑ §493.1241 Standard: Test request

- (c) The laboratory must ensure the test requisition solicits:

—(c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life-threatening laboratory results or panic or alert values.

—(c)(2) The patient's name or unique patient identifier.

—(c)(3) The sex and age or date of birth of the patient.

—(c)(4) The test(s) to be performed.

—(c)(5) The source of the specimen, when appropriate.

—(c)(6) The date and, if appropriate, time of specimen collection.

—(c)(7) For Pap smears, the patient's last menstrual period and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

—(c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

❑ §493.1291 Standard: Test report

- (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:

— (a)(1) Results reported from calculated data.

— (a)(2) Results and patient-specific data electronically reported to network or interfaced systems.

— (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite, or point-of-care testing locations.

❑ §493.1291 Standard: Test report

- (f) Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.
- (k) when errors in the reported patient test results are detected, the laboratory must:

—(k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.

—(k)(2) Issue corrected reports promptly to the authorized person(s) ordering the test and, if applicable, the individual using the test results.

Misperceptions and Clarifications

Misperception: Test results must be retrieved and saved in the identical format as the original report.
Clarification: No specific format is required, but all required elements must be transmitted accurately and reliably.

Misperception: CLIA doesn't permit test results to go directly to a health information exchange.
Clarification: With the authorized person's order on the test request, they can.

Misperception: The lab's responsibility is met when the first entity receives the results.
Clarification: The lab is responsible for getting the results to the authorized person who ordered the test.

Misperception: CLIA requires both a paper and electronic copy of results.
Clarification: No, CLIA only specifies one copy and doesn't require a certain method of saving or transmitting.

Misperception: CLIA requires visual verification of results transmission to the authorized person.
Clarification: CLIA doesn't specify the mechanism or frequency to check transmission.

Misperception: If all interface software is the same, it only needs to be verified once.
Clarification: ALL interfaces and all locations must be checked.

Misperception: CLIA should compile the list of LOINC codes and standard terminology and oversee the accuracy of the EHR vendor's transmissions.
Clarification: CLIA is user-fee funded and doesn't have the authority to oversee these entities, but the government supports use of standard terminology and coding.

ACLA Comments

In its statement to CLIAC, the American Clinical Laboratory Association (ACLA) highlighted areas where it said changes in CLIA rules and interpretive guidelines would improve the exchange of electronic laboratory data.

- ❑ While CLIA does not currently specify the manner in which interface verification must occur, there is as yet no automated verification method, so as a practical matter, visual verification is required to ensure compliance. A results interface should be deemed verified if results are sent to an EHR certified under requirements established by the Health and Human Services Secretary.
- ❑ The lab's responsibility for the test result report should end once it is provided to the destination intended by the clinical lab transmitting the result or to an intermediary contractually obligated to send the results to the intended destination. The lab should not responsible for later modifications made by the physician or other third parties.
- ❑ CMS should amend the definition of "authorized person" to include not only a person authorized under state law to receive the test results, but also the authorized person's agent and other legitimate recipients of the results.

The case against Myriad and the U.S. patent office marks the first time that a challenge to gene patenting has been heard in federal court.

Gene Patent Lawsuit, *from p. 1*

to patent holders, restricting scientific research, the development of new tests, and patients' access to medical care, including the right to a second opinion on test results.

Speaking for Myriad, Brian Poisssant said, "This is not a patent on information. This is a patent on a chemical composition." The U.S. Patent and Trademark Office has ruled that genes can be patented if they are "isolated from their natural state and purified." Myriad says its patents cover how to sequence the gene to identify its components, then map that sequence to look for mutations indicative of cancer.

The ACLU's Chris Hansen retorted that "isolating" a gene, no matter how difficult and ingenious, does not alter the structure of the DNA itself, and so what has been patented is indeed a product of nature. "Uncovering a law of nature—while deserving of praise for the time, ingenuity, and hard work that it takes—is not patentable. Einstein certainly deserved praise and awards for discovering $E = mc^2$, but he could not patent it."

Myriad said a decision to invalidate the patents would affect "thousands of biotechnology patents and effectively unravel the foundation of the entire biotechnology industry. Numerous therapeutic drugs and diagnostic tests in development would be jeopardized."

Judge Sweet's decision is expected in the next few months. It is likely to be appealed to a court in Washington, D.C., that specializes in patent law, according to legal sources following the case.

Senate Bill Clarifies EHR Bonuses for Hospital-Based Physicians

The draft jobs bill released earlier this month by the Senate Finance Committee aims to clarify a provision in last year's economic stimulus package that had been interpreted by the Department of Health and Human Services (HHS) as excluding all hospital-based physicians from being eligible for federal financial incentives to adopt health information technology.

The provision in the Hiring Incentives to Restore Employment (HIRE) Act would change the language in the Health Information Technology for Economic and Clinical Health (HITECH) Act to make clear that incentives for the meaningful use of electronic health records (EHRs) could be paid to all Medicare- and Medicaid-participating physicians except those working only in inpatient or emergency room settings.

This would allow pathologists and other physicians in hospital-affiliated group practices and hospital-owned ambulatory clinics to be eligible for incentive payments of as much as $44,000 for adopting EHRs.

While hospital groups favor the EHR clarification provision in the HIRE Act, the fate of the bill is not certain. One likely vehicle is a Medicare extenders bill that Congress is expected to take up soon.

The proposed "meaningful use" rule issued Dec. 30, 2009, by the Centers for Medicare and Medicaid Services interprets HITECH as excluding all hospital-based doctors from being eligible for incentives (*NIR 10, 2/Jan. 25, p. 3*). If the clarification were enacted, CMS would change the proposal to accord with the statute.

Illinois High Court Upholds Pathologist PC Billing for Lab Tests

The Illinois Supreme Court has denied a petition to review the recent decision of the Appellate Court of the Third Circuit of Illinois to allow professional component billing by pathologists in the *Martis v. Pekin Memorial Hospital* case.

The lawsuit was filed by a patient on behalf of himself and all others similarly situated against Pekin Memorial Hospital, Data Management Inc., and Peoria-Tazewell Pathology Group, stemming from laboratory tests his physician ordered in 2004. One month after the tests were performed, the patient received a bill from the hospital for $609 and a bill from the pathologist group for $73.30.

Although the form authorizing treatment, which the patient signed and which the court found to be an express contract, explicitly included the services provided by pathologists, the plaintiff alleged defendants double-billed for their services. The case also claimed the pathologists were unjustly enriched.

Two lower courts have already ruled professional component billing is not actionable. The Illinois Supreme Court's denial to hear the case brings this lawsuit to a conclusion.

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March 16

CLIA Compliance 2010: What's Next from CMS?
Featured faculty: Top CLIA official Judy Yost, MA, MT (ASCP)
Time: 2:00 p.m. – 3:30 p.m. (Eastern)

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Lab Outreach 2010: Building the Value Equation for Your Program
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 NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Telephone: (973) 718-4700. Fax: (973) 718-0595. Web site: www.g2reports.com. Order Line: (212) 629-3679.

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