G2 INTELLIGENCE

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Lab Coalition to Senators: Block Medicare Test Fee Cuts

The president's proposal would add a 1.75 percent cut to the Medicare Part B clinical laboratory fee schedule every year through 2023.

The Clinical Laboratory Coalition is urging key senators on the Finance Committee to reject a proposed 14 percent cut in Medicare lab fee schedule rates over 10 years. The proposal is contained in the president's budget request to Congress for fiscal year 2014, which begins this Oct. 1. It calls for reducing test reimbursement by an additional $9.46 billion over 10 years.

In an April 16 letter to Finance Committee chairman Sen. Max Baucus (D-Mont.) and the ranking minority member, Orrin Hatch (R-Utah), the coalition argued that "such reductions gravely threaten laboratory providers' ability to serve their communities, provide access to Medicare lab services, and be a vital partner in supporting health care providers in delivering appropriate, cost-effective, and high-quality health care services to the Medicare population."

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INSIDE *NIR*

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Medicare Contractors Revise MoPath Pricing

Several Medicare Administrative Contractors (MACs) in the last two weeks have increased pricing for eight molecular pathology codes that industry sources said were initially priced significantly below cost.

Palmetto GBA, the MAC for California, Nevada, Hawaii, and the U.S. Pacific territories, was the first to announce that it was increasing pricing for the codes, which include BRAF, KRAS, EGFR, CYP2C9, CYP2C19, CYP2D6, JAK2, and F5. Cigna Government Services and National Heritage Insurance Corp. soon followed. The revised pricing is based largely on information submitted by the California Clinical Laboratory Association, which had argued that the initial MAC payment rates were too low for labs to continue performing some critical molecular diagnostic tests.

The pricing increase ranged from 9 percent for CPT code 81275 (KRAS) to 189 percent for CPT 81226 (CYP2D6).

National Government Services also updated fees in mid-April, but they matched the original pricing released by Palmetto, according to Kyle Fetter, assistant vice president, molecular diagnostics services, XIFIN Inc., which helped coordinate the lab data submitted to Palmetto. "This would appear to be a timing issue, and we still expect

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Clinical laboratory testing represents only about 1.6 percent ($8.9 billion) of all Medicare spending and accounts for 70 percent of clinical decisionmaking, the letter pointed out. Yet it has been subject to significant freezes in payments and cuts over the last two decades. Since 2010, Medicare lab spending has been repeatedly cut as follows:

- ❑ 1.75 percent every year for five years (2010-2015);
- ❑ A productivity adjustment every year through the Affordable Care Act (ACA);
- ❑ A 2 percent rebasing of lab test fees as required by the Middle Class Tax Relief and Job Creation Act of 2012; and
- ❑ Another 2 percent in FY 2013 through sequestration.

Signatories to the Lab Coalition Letter

- American Clinical Laboratory Association
- American Medical Technologists
- American Society for Clinical Laboratory Science
- American Society for Clinical Pathology
- American Society for Microbiology
- Clinical Laboratory Management Association
- College of American Pathologists
- Laboratory Corporation of America Holdings
- National Independent Laboratory Association
- Novartis
- Quest Diagnostics
- Roche Diagnostics

"Adding in the President's budget proposal, the price of an average test on the clinical lab fee schedule in 2010 would be cut by 29 percent by 2023," the coalition said. "The proposal would more than double the annual cuts imposed by the ACA, the 2012 rebasing, and sequestration. "For clinical labs, especially those serving rural communities or nursing home populations, 60 percent or more of their patient base consists of Medicare beneficiaries. A significant number of small and midsize independent clinical labs operate on very low margins, with profit margins that do not exceed 3 percent. Additional cuts are not an option if they are to retain their ability to serve Medicare beneficiaries."

High Court Hears Challenge to Human Gene Patents

Can human genes be patented as intellectual property or are they products of nature that cannot be patented under current law?

That is the fundamental question in the case, *Association for Molecular Pathology et al. v. Myriad Genetics Inc. et al.*, on which the U.S. Supreme Court heard oral arguments for slightly more than an hour on April 15, with a decision expected in June when the court's current term ends.

Questions and hypothetical examples raised by the justices signaled a wariness on patents for isolated genomic DNA, but not necessarily on synthesized cDNA, noted Stephanie Murg, managing director at G2 Intelligence, who attended the hearing and spoke afterward during a webinar sponsored by Bloomberg, G2 Intelligence's parent company, and SCOTUSblog.

The patents under challenge are held by Myriad Genetics (Salt Lake City) on BRCA1 and BRCA2 genes and their mutations that are associated with hereditary predisposition to breast and ovarian cancer. Myriad has the exclusive right to perform diagnostic testing on these genes, license the testing to others, and threaten litigation against any unlicensed use.

Seeking to invalidate these patents are a host of plaintiffs spearheaded by the American Civil Liberties Union (ACLU) and the Public Patent Foundation on behalf of researchers, genetic counselors, patients, breast cancer and women's health groups, and medical professional associations representing 150,000 geneticists, pathologists, and laboratory professionals. They argue that the patents give Myriad a monopoly over the terms and costs of testing and researching these genes and bar patients who get the potential lifesaving test from obtaining a second opinion from another provider.

The plaintiffs contend that Myriad did not invent the genes themselves. "Where they start and stop, what they do, what they are made of, and what happens when they go wrong are all decisions made by nature, not by Myriad," Christopher Hansen of the ACLU said in his opening argument.

Myriad's attorney, Gregory Castanias of Jones Day, countered that a federal appeals court has twice declared the patents valid under Section 101 of the U.S. Patent Act, ruling that they involve DNA isolates "markedly different" in molecular composition from the DNA that naturally exists in chromosomes in the body.

Several justices, including Sonia Sotomayor and Ruth Bader Ginsberg, indicated they did not think that the process of isolating and removing human genes should be patented, while others such as Elena Kagan and Samuel Alito raised concerns about the impact a broad ruling could have on companies that invest in such research.

Emphasizing the need to tread carefully, Justice Stephen Breyer noted that patent law often involves "uneasy compromises." The U.S. Patent and Trademark Office has granted patents on at least 4,000 human genes to companies, universities, and others that have discovered and decoded them.

As Murg pointed out, the justices appeared to lean toward a more amenable option presented by Solicitor General Donald B. Verrilli Jr., who presented the Obama administration as an amicus but did not support either side. He made a distinction between genomic DNA and cDNA, which is synthesized from an mRNA template and thus is not a product of nature. "While isolated genomic DNA falls on the ineligible side, we do think cDNA is patent-eligible."

If the court were to adopt that approach, which neither the plaintiffs nor Myriad accept, Murg noted, some of Myriad's patents, concerning synthetic molecules called cDNA, could survive, although the parties disagree on that point as well.

In subsequent questioning, during which Stephen Breyer reiterated the court's "nervous[ness] about tying up laws of nature," the justices seemed inclined to agree with Verrilli and later queried Hansen on the value of striking down patents on genomic DNA yet upholding patents on cDNA.

"That's among the key questions facing the clinical lab and diagnostics industries, as they ponder the implications of a world in which the more sweeping, first-generation gene patents of Myriad and other companies are declared invalid while those constructed narrowly, such as those covering cDNA, are upheld," Murg concluded. "Given the relative rarity of the former type of patents and their rapidly approaching expiration dates (the first of Myriad's BRCA patents expires in 2014, BRCA2 in 2015), the significant outcome may be in the area of diagnostic genome sequencing. While this technology has rapidly entered the clinical laboratory, the incorporation of genome, exome, and transcriptome sequencing into medical practice has been slowed by the specter of patent infringement."

focus on: Clinical Lab Regulation

CLIA PT Changes Get 'Thumbs Up,' but With Caveats

Proposals that would modify rules under the Clinical Laboratory Improvement Amendments (CLIA) that govern the referral of proficiency testing (PT) samples won support from leading clinical laboratory and pathology organizations, though many sought clarification on specific provisions, in particular, the narrow one-time-only exception for intentional referrals.

The proposals were published in the Feb. 7 *Federal Register* in a broader rulemaking on regulatory provisions to promote program efficiency, transparency, and burden reduction. The comment deadline was April 8.

How Significant Are the Changes?

The CLIA program, housed in the Centers for Medicare and Medicaid Services (CMS) gets greater flexibility in determining the scope and severity of penalties for a clinical lab that sends PT samples to an outside laboratory for analysis.

CLIA officials previously adopted a strict interpretation of the term "intentional referrals," stating that when a lab for any reason refers a PT sample to another lab for analysis for testing that it is certified to perform, they had no choice but to impose the harshest sanctions: revocation of the lab's CLIA certification and its approval to receive Medicare and Medicaid payment for one year as well as barring the lab's owner and operator from owning or operating another lab for two years from the date of revocation.

Now they agree that the changes would "prevent confusion on the part of labs, reduce the risk of noncompliance, and establish policies under which certain PT referrals would not generally be subject to revocation of a CLIA certificate or a two-year prohibition on laboratory ownership or operation that may be applied to an owner and an operator when a CLIA certificate is revoked."

The proposals emphasize that PT samples are never to be referred to another laboratory. "The requirement to treat PT samples in the same manner as patient specimens does not mean that it is acceptable to refer PT samples to another laboratory for testing even if that is the standard operating procedure for patient specimens—a PT sample must never be sent to another laboratory under any circumstances." But since there are cases where this does occur, the agency would explicitly note that this requirement applies only up to the point where the PT sample leaves the lab.

The carve-out for referrals deemed improper and subject to intermediate sanctions, but not intentional and thus subject to revocation, would apply when it is not a repeat referral, when it is a reflex or confirmatory test, and when the referral is in accord with the lab's written and legally accurate standard operating procedures. The expectation is that labs will ensure that improper referrals are addressed and eliminated, CMS said, "or we will find that future referrals are intentional. The carve-out is meant to be a one-time exception."

Separately, Congress last year passed the Taking Essential Steps in Testing (TEST) Act (Public Law 112-202) which gave CMS discretion in using its enforcement

authority to consider penalties on a case-by-case basis for breaches of the PT referral rules. CMS may make the CLIA certificate revocation optional rather than mandatory and may levy intermediate sanctions instead of the two-year prohibition against lab ownership or operation that would otherwise apply.

Comments on the Changes

COLA, a physician-directed organizations which accredits labs under CLIA, supported the proposals and the TEST Act, noting in particular that they "emphasize an educational rather than a punitive approach toward correcting the behavior of those who improperly refer PT samples."

The American Association for Clinical Chemistry (AACC) also backed the proposed changes, pointing out that in recent years, a number of clinical labs have inadvertently sent a PT specimen to another lab for testing. "Frequently, this mistake is the result of laboratory personnel sending the specimen to an outside facility for reflex or confirmatory testing as specified in their standard operating procedures. According to CMS, nearly one-third of the 41 cases of PT referral errors during 2007-2011 were the result of this type of mistake."

But AACC argued that the one-time carve-out exception should be broadened so the agency has greater discretionary authority in deciding when to apply the alternative sanctions. "Inserting such language now would ensure that CMS didn't need to make future regulatory changes to address an unforeseen situation that may warrant lesser penalties."

The College of American Pathologists (CAP) expressed strong support for amending CLIA to give CMS discretion in prosecuting improper PT referral cases, saying this is "an important initial step in modernizing the PT referral regulations." But CAP requested more information on how and under what circumstances the exception for improper PT referrals will be applied given the different possible scenarios to accidentally occur or go undetected. CAP also asked whether the exception would cover the directors of labs that have referred PT specimens and meet the carve-out criteria, and whether the agency would share its guidance on enforcing the rule.

The American Clinical Laboratory Association (ACLA) believes that "CMS should implement the TEST act, which was targeted at the same issue, rather than engaging in multiple rulemakings on the same topic. The act was passed to give CLIA more discretion in responding to a lab's inadvertent or accidental violation of the PT referral rule. The proposals still severely limit when the agency can exercise this discretion." ACLA believes that CMS should develop a "facts and circumstances test" in the current rulemaking to ensure the appropriateness of the penalties it applies in response to unintentional violations.

Instead of narrowly defining the precise circumstances in which it will determine that a PT referral is "not intentional," CMS should set forth in regulations the factors it will consider when making such a determination, ACLA said, "including, but not limited to the accuracy and adequacy of a lab's written standard operating procedures; the degree of automation in the lab's work flow; the training and experience level of the person(s) referring the PT sample; the incidence of PT referrals from the lab in the past five years; and other relevant factors. Only if CMS determines that a PT referral was made willfully or in reckless disregard of CLIA and its implementing regulations, or that a laboratory has not made sincere and credible efforts to rectify inadequacies in its written manuals and in its training, should it resort to the harsh penalty of certificate revocation."

Medicare Contractors Revise MoPath Pricing, *from p. 1*

to see Medicare contractors come into line with Palmetto's new pricing," he wrote in a blog posting at *www.xifin.com*. "While it's heartening to see these prices trending upward, even these updated prices are below where they need to be."

REVISED MOPATH PRICING

CPT CODE, TEST	PALMETTO (INITIAL)	PALMETTO (REVISED)	CHANGE (PALMETTO)	NHIC	CGS
81210, BRAF	$57.51	$97.45	+69%	$55.01	$97.45
81275, KRAS	$225.88	$246.40	+9%	$208.62	$246.40
81235, EGFR	$116.25	$225.00	+94%	$116.25	$225.00
81227, CYP2C9	$96.78	$169.50	+75%	—	$169.50
81225, CYP2C19	$135.26	$319.12	+136%	$135.26	$319.12
81226, CYP2D6	$147.50	$426.43	+189%	—	$426.43
81270, JAK2	$72.81	$82.88	+14%	$72.81	$82.88
81241, F5	$68.64	$78.39	+14%	$60.41	$78.39

Sources: G2 from XIFIN, Piper Jaffray, and NHIC. CPT codes © American Medical Association.

Purchasers of G2 Intelligence's new report, Medicare's New Payment System for Molecular Tests: Coding Methodology, Reimbursement Strategies, Rates Update*, will receive an update in early May containing all 2013 pricing by MACs. A second update, to be published later this year, will include final MAC pricing. The report is available for $795. To order, visit* www.G2Intelligence.com/MDxPaymentGuide.

Analysts from Piper Jaffray note that with two MACs following Palmetto's lead, it has cemented its place as the leader in the field. Sustained lobbying pressure by industry groups is having an effect on pricing, the analysts add. "We continue to believe this will culminate in 2014 MolDx codes (Tier 1) being higher than their 2013 counterparts," they wrote in an April 19 industry note.

Whistleblower Case Over Lab Discounts Dismissed

A federal appeals court has thrown out a whistleblower's complaint that a lab discount arrangement paid improper kickbacks to physicians for referrals to the hospital.

In the case of *United States ex rel. Nunnally v. West Calcasieu Cameron Hospital*, the U.S. Court of Appeals for the Fifth Circuit ruled that the qui tam relator did not provide specifics sufficient to meet the requirements of the federal False Claims Act (FCA). The decision upheld a Louisiana lower court's dismissal of the complaint on similar grounds.

An FCA complaint must allege specific indicia of a fraudulent scheme to collect payment from the government, even if the details of each false claim are unknown.

Dent T. Nunnally stated that the hospital was charging reduced lab test fees to physicians who referred the work to the hospital but would charge Medicare patients much more than patients not on Medicare for the same tests. These referrals, he said, were improper, violated the anti-kickback law, and thus constituted false claims.

The appeals court said his complaint failed to show how physicians were induced into referring patients to the hospital, located in Sulphur, La., or how the hospital provided improper kickback payments to the referring physicians. Further, the court said he failed to allege with any particularity that the defendant certified compliance with the anti-kickback law, nor did he identify any specific Medicare claims submitted to the government for payment.

The court said that FCA pleading standards are "context specific and flexible" but still need to "set forth 'the who, what, when, where, and how' of the alleged fraud." An FCA complaint need not provide specific details of "each false claim" the court said, but still "requires the relator to provide other reliable indications of fraud and to plead a level of detail that demonstrates that an alleged scheme likely resulted in bills submitted for government payment."

The court said Nunnally failed this pleading standard. His allegations regarding "verbal agreements" between physicians and the hospital for improper referrals were "conclusory . . . without a shred of detail or particularity." While he provided an example of the hospital charging physicians $3.60 for a particular blood test, while charging Medicare $10.60 for the same test, the court said this did not show how physicians were given kickbacks for referrals, and no other details of any agreement, or referral payments, were provided.

Perspectives on the Ruling

In comments to *NIR*, attorney Robert E. Mazer with Ober/Kaler in Baltimore, said, "Although the decision was based on the lack of specificity in the complaint, the court indicated that charging physicians less than Medicare should not in itself result in violation of the federal anti-kickback statute. Generally, for a lab or hospital to violate the law, it must offer or pay 'remuneration' to a physician or other referral source. According to the court, the mere fact that the amount charged to the physician was less than the amount billed to Medicare did not indicate that the hospital had provided the physician with 'remuneration'.

"The court determined that the relator had not alleged that the hospital had expressly certified that it was in compliance with federal law, and stated that it had never recognized the theory of 'implied certification'. The court indicated that without such a certification, a violation of the anti-kickback law could not result in liability under the FCA.

"This is no longer the case. As a result of legislation enacted after the complaint was filed—the Affordable Care Act and the Health Care and Education Reconciliation Act of 2010—a violation of the anti-kickback law now constitutes a false or fraudulent claim under the FCA."

Tightening the Stark In-Office Services Exception

The president's budget request for fiscal year 2014 proposes to save $6.1 billion by excluding certain services, but not anatomic pathology, from the in-office ancillary services (IOAS) exception to the Stark physician self-referral law.

Alliance for Integrity in Medicare

- American Clinical Laboratory Association
- American College of Radiology
- American Physical Therapy Association
- American Society for Clinical Pathology
- American Society for Radiation Oncology
- Association for Quality Imaging
- College of American Pathologists
- Radiology Business Management Association

In response, the Alliance for Integrity in Medicare (AIM) advocates increased savings by removing anatomic pathology services from the exception. And it is urging Congress and the Centers for Medicare and Medicaid Services to remove anatomic pathology as well as other services from the IOAS exception.

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Tightening the Stark In-Office Services Exception, *from p. 7*

The budget recommends exclusion of radiation therapy, advanced imaging, and therapy services, except in cases where a practice meets "certain accountability standards, as defined by the secretary of the Department of Health and Human Services."

AIM said it has long supported restrictions on physician self-referral, "and we would strongly recommend adding anatomical pathology services to the proposed list of excluded services, as the same overutilization and patient care concerns exist."

Critics charge that the current IOAS exception is being exploited by physician specialists who have brought their pathology work in house, setting up their own histology labs for whose work the physicians can bill. "We believe this loophole results in increased spending, unnecessary utilization of medical services, and potentially compromised patient choice and care, thusly eroding the integrity of the Medicare program."

A Fond Adieu: Jim Curren, editor of *National Intelligence Report*, is retiring May 1 after nearly 34 years with G2 Intelligence (formerly Washington G-2 Reports). Jim helped launch G2 in 1979, along with Dennis Weissman, former publisher and current executive editor. Jim has served as editor of *NIR* during all of his tenure. Kimberly Scott, managing editor of G2, will take over as editor of the publication. We are grateful to Jim for his many years of service and wish him well in his future endeavors.

Upcoming G2 Events

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

May 9

Blood Management for the Lab: Collaboration for Better Patient Outcomes and Fewer Transfusions

Featured Speakers: **Nanci Fredrich, RN, BSN, MM,** Transfusion Safety & Blood Management Officer, Blood Center of Wisconsin; **Kathleen Puca, M.D., MT(ASCP)SBB**, Medical Director, Blood Center of Wisconsin; and **Sandy Holdcraft, RN, BSN**, Haemovigilance Specialist, Children's Medical Center, Dallas

Conferences

May 16

Lab Contracting Workshop: How to Master Changing Market Realities in Dealing with Payers

Westin Atlanta Airport
www.G2Intelligence.com/ContractingWorkshop

June 12-14

MDx Next 2013 Gaining Ground in Molecular Testing andGenomic Medicine

Westin Las Vegas Hotel Casino and Spa
www.mdxconference.com

Oct. 16-18

31st Annual Lab Institute

Hyatt Regency Crystal City
Arlington, Va.

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