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Court Tosses Out Pathology Anti-Markup Lawsuit

The urology plaintiffs challenged anti-markup rules for the professional and nonpurchased technical components of anatomic pathology services, not the payment limit that has applied to the purchased TC of diagnostic tests in effect since 1992.

Pathology and clinical laboratory opponents of "pod lab" business arrangements scored a win May 5 when a federal district court granted the government's motion to dismiss a lawsuit filed by several urology groups to stop Medicare from applying new anti-markup rules to anatomic pathology services.

Under the rules at issue, Medicare would prohibit, as of Jan. 1, 2008, any markup of the professional and technical component of anatomic pathology services provided in a "centralized building" that does not qualify as the "same building" under the in-office ancillary services exception to the Stark physician self-referral law.

Citing the plaintiffs' lack of standing and its own jurisdiction over the case, the court said the plaintiffs must challenge the rules through administrative channels before seeking relief in federal court.

In dismissing the lawsuit, the court vacated the preliminary injunction it granted March 31, blocking the Centers for Medicare & Medicaid Services from implementing the rules while further arguments were heard (*NIR, 29, 12/Apr 14 '08, p. 2*). *Continued on p. 2*

President to Sign Genetic Discrimination Ban

While a signing ceremony had yet to be scheduled at press time, the White House said the President will soon sign into law legislation prohibiting employers and health insurers from discriminating against patients based on their genetic information and test results. The measure cleared Congress May 1, capping a 13-year effort to get such a bill to the President's desk.

This comes on the heels of his April 24 signing of legislation offering new federal support to state and local newborn screening programs and promoting development of federal guidelines on the genetic conditions for which newborns and children who have or are at risk for heritable disorders in all states should receive.

On the regulatory front, a top federal advisory panel has recommended remedies that the Health & Human Services Secretary should employ to fill gaps in oversight of genetic testing, including Food & Drug Administration regulation of all lab tests, not just lab-developed tests, and expansion of CLIA proficiency testing in the marketplace and training of lab inspectors in testing for congenital, genetic, and metabolic disorders.

For more on these latest developments, see the *Focus*, pp. 4-6.

INSIDE *NIR*

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Pathology Anti-Markup Lawsuit, *from p. 1*

The plaintiffs include three physician groups—Atlantic Urological Associates, P.A., Urology Center of Alabama, P.C., and Urology Care Inc.—plus Uropath, LLC, a pathology lab management company, and several individuals involved in these businesses. They filed suit on Jan. 25 of this year, contending that enforcing the anti-markup rules would bar them from billing for the amount allowed under the Medicare physician fee schedule and require them to bill at a loss, forcing them out of business. The plaintiffs also contended that CMS failed to follow public notice and comment requirements under the Administrative Procedures Act and acted contrary to the Stark exception.

The Court's Findings

In dismissing the lawsuit, Judge Rosemary M. Collyer, of the U.S. District Court for the District of Columbia, noted that CMS has been "publicly concerned since at least 2004 about a growing tendency of physician groups to utilize 'pod' labs for lab work, miles from the physicians' offices, and then to claim that doctors in both locations are 'sharing a practice' for purposes of billing Medicare."

The College of American Pathologists, the American Society for Clinical Pathology, and the American Clinical Laboratory Association have long raised concerns that pod labs violate the intent of the Stark exception and lead to overutilization, Judge Collyer noted, citing an argument in the amicus brief that the College filed with the court in support of the government's position: "The principal reason for pod labs is financial. Pods provide the referring urologists a financial stake in pathology services that [they] order for their patients. Referring physicians seek such a financial arrangement so they can earn additional income from the work that results from their referrals. The CMS final rule is a reasonable attempt to remove from anatomic pathology the referring physician's profit motive that can corrupt medical decisions."

CMS's Final Rule and Final Order

Eliminating pod labs by drying up their profitability was a main goal of the anti-markup provisions applicable to diagnostic tests that were published last November in the final 2008 Medicare physician fee schedule rule, CMS has acknowledged. For that reason, while under a final order issued Jan. 3, the agency delayed applying the anti-markup rules to most diagnostic tests for one year, until Jan. 1, 2009, it specifically excluded anatomic pathology from this reprieve. CMS defended the exclusion, saying "[these] arrangements precipitated our proposal to revise the anti-markup provisions and remain our core concern."

Under the final order, the one-year delay applies to diagnostic tests, except with respect to:

- ❑ The technical component of a purchased diagnostic test and
- ❑ Any anatomic pathology service furnished in a space that is used by the physician group practice as a centralized building, as defined by Stark, and that is not part of the same building as the office of the billing physician or other supplier.

Snapshot of a 'Pod Lab'

Under a typical pod lab arrangement, a physician specialty group aims to tap pathology referrals to increase revenue in a shrinking reimbursement environment.

The group rents or leases space off-site, often in a site remote from the group, and "outsources" the referrals to "pod labs" that operate under contract with a pathologist. Groups often have labs in a common location, and the pathologist rotates from lab to lab, rendering interpretations for a number of referring specialists.

These arrangements have proliferated among dermatology, gastroenterology, and urology groups that typically order a significant volume of patient biopsies.

CMS noted that the anti-markup ban on the technical component of a purchased diagnostic test has been long-standing and is merely incorporated in the expanded and revised rules.

Under the final order, payment for anatomic pathology performed at a site other than the office of the billing physician or other supplier is limited to the lesser of (1) the performing supplier's net charge to the billing physician or other supplier; (2) the billing physician or other supplier's actual charge; or (3) the fee schedule amount for the test that would be allowed if the performing supplier billed directly. "This approach," the judge noted, "basically omits Medicare payment of any overhead associated with the use of a lab owned by a physician group when the lab is not located in the group practice's offices."

The one-year delay for other diagnostic tests is needed, CMS said, to consider concerns raised by the American Medical Association and other physician groups that the anti-markup prohibitions could have "unintended consequences" and disrupt many diagnostic testing arrangements currently in place, especially in radiology, and thus harm beneficiary access to needed care.

OIG Cuts Providers Some Slack on Integrity Agreements

Billing errors or overpayments are not handled under the self-disclosure protocol and providers should submit these directly to their claims processing entity, such as the Medicare contractor, the OIG advises.

In welcome news to clinical laboratories and other providers who opt to resolve potential federal fraud issues by using the self-disclosure protocol, the HHS Office of Inspector General has announced that it generally will not require them to enter into a corporate integrity agreement.

The OIG says that it will recognize as "effective compliance measures" the following: a complete good-faith disclosure of the conduct in question, timely response to the OIG's requests for further information, and performance of an accurate audit.

The self-disclosure protocol, which the OIG introduced in 1998, offers guidance to health care providers who voluntarily disclose federal health care compliance issues that the provider believes potentially violate federal criminal, civil, or administrative laws for which exclusion or civil monetary penalties are authorized.

In an open letter to providers on April 15 spelling out the latest refinements to the protocol, Inspector General Daniel R. Levinson said that, to improve the process, the initial submission must contain:

- A complete description of the conduct being disclosed.
- A description of the provider's internal investigation or a commitment as to when it will be completed.
- An estimate of the damages to federal health care programs and how the figure was calculated (or a commitment as to when the estimate will be completed).
- A statement of the laws potentially violated by the conduct.

The above information must be included in addition to the basic information described in the self-disclosure protocol. Further, Levinson said, the provider must be in a position to complete the investigation and the damages assessment within three months after being accepted into the protocol.

Levinson pledged that his office will respond promptly to self-disclosures and give priority to resolving the issues raised. "To that end, we have streamlined our internal process for resolving these cases."

focus on: Genetic Testing

Latest Developments in Law and Regulatory Oversight

Genetic testing is back in the political spotlight again. On the legislative front, the President, at press time, is poised to sign into law a bill prohibiting genetic discrimination by employers and health insurers. This follows his approval late last month of a new law expanding federal support for newborn screening programs.

On the regulatory front, the HHS Secretary's Advisory Committee on Genetics, Health & Safety (SACGHS) has just released its final report on gaps in genetic testing oversight, including recommendations for expanded roles for the Food & Drug Administration and the Centers for Medicare & Medicaid Services.

Protecting Patients From Genetic Discrimination

The Genetic Information Non-Discrimination Act (GINA, H.R. 493 as amended) cleared Congress May 1. The American Clinical Laboratory Association was among the many industry groups that applauded the action. "Passage of this landmark legislation will go a long way to reassuring patients that their genetic testing information is confidential and protected against misuse," said ACLA president Alan Mertz. "Spectacular innovation in genetic testing is playing an increasingly critical role in transforming our health care system in the direction of 'personalized medicine.' This legislation removes a key obstacle to this much-heralded transformation."

The act bars employers from using genetic information in decisions on hiring, firing, job placement, or promotion. It prohibits group health plans and other health insurers in both the group and the individual market from using genetic information to deny coverage or set premium rates and from requiring individuals to undergo genetic testing. The prohibitions apply to employment agencies, labor unions, and Medicare supplemental policy plans as well.

Purchasing of genetic information is prohibited for underwriting purposes or for any individual prior to enrollment, but employers may purchase it for certain purposes, including when it is required to comply with certification rules under family and medical leave laws, when it is used for genetic monitoring of persons exposed to the risk of toxic substances in the workplace, and when the employer conducts forensic DNA analysis for law enforcement.

The act stipulates that any reference to the genetic information of an individual or family member includes a fetus and an embryo legally held by an individual or family member utilizing an assisted reproductive technology.

A majority of states have laws to protect the public from genetic discrimination, and they vary widely in approach, application, and level of protection. While the act establishes uniform national safeguards, it does not preempt state requirements.

Expanding Newborn Screening and Education

The Newborn Screening Saves Lives Act (P.L. 110-402, signed by the President on April 24) provides new funds to help states improve and expand their programs for newborns and children who have or are at risk for heritable disorders. The act

includes authority for the Health Resources & Services Administration to award grants for screening, counseling, or health care services as well as education and training in congenital, genetic, and metabolic disorders for health care professionals, laboratory personnel, parents, and families. For these purposes, $58.5 million is authorized in fiscal 2008.

In a report filed with the act, Congress noted that "since the early 1960s, when Robert Guthrie devised a screening test for phenylketonuria (PKU) using a newborn blood spot dried onto a filter paper card, more than 150 million infants have been screened for a number of genetic and congenital disorders … that, if left untreated, can cause disability, intellectual disabilities, serious illness, and even death. Except for hearing, screening tests are done using a few drops of blood from the newborn's heel, usually taken in the hospital 24 to 48 hours after birth. With the advent of the tandem mass spectrometer, it is now possible to detect more than 40 conditions and, for some conditions such as PKU, tandem mass spectrometry has been shown to reduce the false positive rate."

The act addresses lawmakers' concern about the lack of uniformity in state screening requirements. Some states screen for more than 40 conditions, some for as few as nine. Funding under the act should include incentives to states to screen for all 29 core treatable conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children, the congressional report said. "At present, only 15 states and the District of Columbia require infants to be screened for all 29 disorders … An estimated 1,000 of the 5,000 babies born every year in the United States with one of the 29 core conditions potentially go unscreened."

Citing the experience of Hurricanes Katrina and Rita, the act requires the Health & Human Services Secretary to develop a national contingency plan for newborn screening in the event of a public health emergency. This is essential because of the short time frame for detecting and treating congenital disorders, the report said, noting that more than 11,000 babies are born each day in this country. The national plan should address contingency measures for sample delivery, backup lab operations, and effective follow-up, including treatment, medications, and dietary interventions. The report recommended that the Centers for Disease Control & Prevention oversee development of the plan and conduct practice drills.

The CDC also is urged to continue work through its Environmental Health Laboratory to ensure the accuracy of newborn screening tests. This facility is the only comprehensive program in the world devoted to this purpose, the report noted. It provides training, consultation, proficiency testing, guidelines, and reference materials to state public health labs and other labs responsible for such screening.

Finally, the act reauthorizes and expands the role of the Advisory Committee on Heritable Disorders in Newborns and Children, establishes an Interagency Coordinating Committee on Newborn and Child Screening, and creates an Internet-based information clearinghouse to provide information about newborn and child screen-

Regulatory Status of Currently Available Genetic Tests

More than 1,100 genetic tests are currently offered in 1,167 clinical labs, according to data submitted voluntarily to Genetests.org.

The FDA has cleared or approved several dozen genetic tests to date—*e.g.*, tests for Leiden factor, cystic fibrosis, UGT1A1, CYP450 2D6 and 2C19, breast cancer prognosis gene expression tests, bladder cancer fluorescence in situ hybridization (FISH), prenatal aneuploidy FISH, and HER2 FISH. This number refers to molecular genetic tests; when biochemical assays for genetic conditions (mainly newborn screening) are added, the figure approaches 100.

According to a 2003 survey of U.S. molecular diagnostics labs, testing for inherited diseases was the second largest testing activity, representing 15 percent of the total volume. Of the labs surveyed, 85 percent reported using at least one lab-developed test.

Source: Final SACGHS Report, *U.S. System of Oversight of Genetic Testing*, April 2008.

ing for heritable disorders. It also directs the National Institutes of Health to carry out research on new screening technologies and disease management strategies for conditions that can be detected through screening, but for which no treatment is yet available.

Expanding FDA, CMS Roles in Genetic Test Oversight

Meantime, SACGHS has released its final report to HHS Secretary Michael Leavitt on genetic testing oversight in response to his directive to identify gaps in current public and private systems and recommend steps to address the shortfalls. Leavitt called for the report to help advance his Personalized Medicine Initiative, launched in March 2007 and aimed at injecting into clinical practice new testing technologies that tailor treatment and therapy to the individual's unique genetic characteristics. The draft was circulated for comment last year (*NIR, 29, 5/Dec 17 '07, pp. 3-6*).

Though the final report examined government and private oversight systems, its recommendations concentrated on steps that HHS agencies should take to beef up regulatory requirements. With regard to the FDA, SACGHS said that, to address the gap related to clinical utility, the agency should address all lab tests, including lab-developed tests (LDTs), in a manner that takes advantage of its current experience in evaluating lab tests.

In doing so, the panel recommended that HHS convene a multistakeholder public and private sector group to determine the criteria for risk stratification and a process for systematically applying these criteria. The group should consider new and existing regulatory models and data sources and should explicitly address and eliminate duplicative oversight procedures, SACGHS said. To facilitate the review process, the panel called for establishment of a mandatory genetic test registry.

For clinical lab and pathology interests, the FDA recommendation is the most controversial. David Mongillo, ACLA's vice president for policy and medical affairs, told *NIR* that "ACLA [and the agency] have shared goals—to make tests fully available to revolutionize clinical practice in terms of prevention, early diagnosis, treatment, and therapy. We do have a caution and a concern over the notion that LDTs should be regulated by the FDA." In comments on the draft report, ACLA and the College of American Pathologists said that CMS' CLIA program should have the lead oversight role, in particular over LDTs, while a significant consultative role should be carved out for the FDA.

However, the final report does not slam the door on further discussion of the issue, Mongillo noted. Citing the call for convening a multistakeholder group, he said the recommendation is broad enough to be interpreted as providing an opportunity to get the FDA to take a slower approach, guided by input from industry and consumer groups and various regulatory models and methods.

To address gaps related to analytical validity, SACGHS recommended that CMS require proficiency testing for an expanded list of regulated analytes. For tests without PT products, labs should use alternative assessment methods, as required under current CLIA rules. The agency also was advised to develop training for inspectors of genetic testing labs. To pay for these initiatives, the CLIA program should be exempt from hiring constraints imposed by or on HHS, the panel said.

SACGHS also urged HHS to address clinical decision support systems by supporting efforts to improve the education and training of health care practitioners, lab personnel, public health workers, patients, and consumers.

The final SACGHS report, U.S. System of Oversight of Genetic Testing, *is posted online at www4.od.nih.gov/oba/SACGHS.*

FDA Clears Glove Made From New Type of Latex

Use of gloves has long been part of the universal precautions to protect clinical lab personnel, phlebotomists, and other health care workers from exposure to blood-borne pathogens. But an estimated three percent to 22 percent of all health care workers are sensitized to traditional latex gloves made from the milky sap of a rubber tree containing a protein that may trigger allergic reactions from mild to severe, especially after prolonged and repeated contact.

Now there is an alternative for people sensitive to traditional latex, the Food & Drug Administration recently announced. It has cleared for marketing the first device made from a new form of natural rubber latex, guayule latex. The product is the Yulex Patient Examination Glove, made by the Yulex Corporation of Maricopa, Ariz. It is derived from the guayule bush, a desert plant native to the Southwestern United States. Available data show that people who are highly allergic to traditional latex do not react on first exposure to guayule latex proteins.

"This approval has the potential to make a significant difference to both the general public and the medical community at large," said Daniel Schultz, M.D., director of the FDA's Center for Devices & Radiological Health. "Gloves made from guayule latex may prove to be a safer alternative for some people with sensitivity to traditional latex. And yet they will not sacrifice the desirable properties of traditional latex, such as flexibility and strength."

A 1998 FDA rule requires that all medical devices containing latex carry a statement on the label warning about the risk of allergic reactions. Because there are no data on people's long-term experience with the Yulex glove, the product will carry a warning for now about the potential for allergic reactions.

NPI Update:
May 23 Is Medicare Deadline for NPI-Only Transactions

As of May 23, the Medicare fee-for-service program will accept/send transactions that use only the National Provider Identifier (NPI), and the Centers for Medicare & Medicaid Services is encouraging labs and other providers to make sure that they and their trading partners are ready for the change. CMS recommends the following steps to ensure a smooth transition:

- ❑ Step 1: Bill with Medicare legacy ID and the NPI. Once claims are successfully processed, move to Step 2.
- ❑ Step 2: Bill with NPI-only. Start with a small batch of claims. If, or when, the results are positive, begin sending a greater volume and move to Step 3. Billing with only the NPI also tests the ability to receive the NPI on 835 transactions.
- ❑ Test NPI-only on other HIPAA transactions. CMS will require use of the NPI on the 270/271, 276/277, and NCPDP transactions. Providers should begin testing use of the NPI on these transactions in small quantities prior to May 23. Also, be prepared to accept the NPI-only on the 835 remittance advices.

CMS will host a national NPI roundtable on May 14 (2:00 – 3:30 p.m., Eastern) to address questions from the Medicare provider community. For registration details and other NPI matters, go to www.cms.hhs.gov/NationalProvIdentStand

Maryland Enacts Pathology Direct Billing Law

In Missouri meanwhile, the state Senate approved direct billing legislation (S. 817) on April 24. The measure now goes to the House for consideration in committee.

Under a new law set to take effect Oct. 1, 2008, the state of Maryland will require direct billing for anatomic pathology services, with limited exceptions. Generally, a clinical laboratory or physician practice that performed the service must bill the patient or other responsible party for it directly. The lab or practice may bill for the service only if it performed or directly supervised the service and satisfied other stated requirements.

The law does allow some exceptions, including those that allow a lab to bill a hospital and that permit a lab to bill another lab that referred to it a test specimen for histologic processing or anatomic pathology consultation.

The law applies to any anatomic pathology service provided to a Maryland patient, even if provided by a lab, physician, or group practice in another state.

Maryland is the 14th state to enact a direct billing statute applicable to anatomic pathology. The others are Arizona, California, Massachusetts, Nevada, New Jersey, New York, Rhode Island, Louisiana, South Carolina, Tennessee, Iowa, Montana, and Kansas.

G-2 Conference Calendar

June 18-20:
Laboratory Outreach 2008, Winning With the Right Numbers
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