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Court Orders Halt to Medicare Lab Competitive Bidding Demo

Join us Thursday, May 8, for a special audio conference on the ramifications of this important legal decision, featuring Patric Hooper, lead counsel for the labs in the lawsuit, and Alan Mertz, ACLA president. The session will run from 2:00 – 3:30 p.m. (Eastern). Sign up at www.g2reports.com

A federal court issued a preliminary injunction Apr. 8 that blocks the Centers for Medicare & Medicaid Services from moving ahead with the lab competitive bidding demonstration in San Diego County until further notice.

The ruling is the latest development in the lawsuit filed Jan. 29 by three labs—Sharp Healthcare, Scripps Clinic, and Internist Laboratory—in the San Diego-Carlsbad-San Marcos metro area, the first site to be selected for the congressionally mandated project. The court issued its injunction after hearing oral arguments in the case on Apr. 8. For details on what the judge concluded, see the *Focus*, pp. 4-6.

Lab industry groups long opposed to the demo hailed the court's decision, noting that it further strengthens their arguments to Congress that the project will severely damage small business labs and the patients they serve and should be repealed. Legislation for repeal is pending in the House (H.R. 3453, with 40 bipartisan co-sponsors) and in the Senate (S. 2099, with eight bipartisan co-sponsors).

House Approves Overhaul of CLIA Cytology Proficiency Testing

The House on Apr. 8 approved by voice vote a bipartisan bill that would revamp the CLIA program for proficiency testing in gynecologic cytology, a measure backed by a coalition of more than 60 organizations, including national and state pathology groups.

The bill, H.R. 1237, would terminate the current CLIA cytology PT program in force nationwide since the start of 2005 and replace it with a continuing medical education alternative to assure patient health and safety in Pap testing.

Under the bill, the clinical laboratory is required to ensure that all individuals who screen and interpret cytological preparations participate annually in an approved CME program that provides each participant with gynecologic cytologic samples designed to improve locator, recognition, and interpretive skills. Further, the lab would be required to maintain a record of program results.

An identical bill is pending in the Senate, S. 2510, and the 60-plus member Cytology Proficiency Improvement Coalition is lobbying to build support for it on both sides of the aisle. *Continued on p. 2*

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CLIA Cytology PT, *from p. 1*

The College of American Pathology and members of the coalition say the current CLIA PT program is outdated, based on rules written in 1992, and does not reflect changes in cytology science and practice since. The House and Senate bills offer a better approach, CAP argues, "by challenging screening and interpretation skills in a constructive learning environment and, over time, keeping pace with advances in science and technology."

Meantime, cytology PT testing continues under the current CLIA program. CAP and the American Society for Clinical Pathology are the two nationally approved PT providers. The Maryland health department runs an approved program for specimens of state residents.

CLIA Cytology Program Shows Gains in PT Pass Rates

While the CLIA program for proficiency testing in gynecologic cytology is highly controversial (*related story, p. 1*), it has registered major gains in the passing scores of pathologists and cytotechnologists since nationwide enforcement began in 2005, according to the Centers for Medicare & Medicaid Services.

Cytology PT Stats

Comparison of PT Performance

2005	91% passed
2006	95% passed
2007	96% passed

2005—Final Initial Test (10 slides/2 hrs)

	Pass	*%*
CT	6,083	93%
Path w/o CT	312	67%
Path w CT	5,242	90%
Total tested: 12,831	11,654	91%

2006—Final Initial Test (10 slides/2 hrs)

	Pass	*%*
CT	6,085	95%
Path w/o CT	372	83%
Path w CT	5,437	95%
Total tested: 12,752	11,894	95%

2007—Preliminary Initial Test (10 slides/2 hrs)

	Pass	*%*
CT	6,052	97%
Path w/o CT	387	89%
Path w CT	5,544	97%
Total tested: 12,435	11,983	96%

Source: CMS presentation to CLIAC.

The pass rate has risen from 91 percent in 2005 to 96 percent in 2007, CMS pointed out in a briefing of the Clinical Laboratory Improvement Advisory Committee (CLIAC) in February.

The improved performance is "consistent with the Maryland state cytology PT experience over time," Judy Yost, the top CLIA official at CMS, told *NIR*. However, one category that still has above-average failure rates "causes us concern and justifies the need for continued testing." The category includes pathologists who don't use a cytotechnologist. The failure rates here are much higher than those of the total population tested, she observed.

In other PT program developments, Yost noted, "We have a proposed rule in clearance [to revise the current PT rules] reflecting the recommendations of CLIAC and soliciting comments. In labs that have numerous PT failures, we may conduct an on-site review to confirm compliance with the remaining CLIA quality standards. In cytology, the test result has a direct impact on patient health and safety, so it is our responsibility to ensure quality testing utilizing whatever authority and mechanisms that are available to us."

Preliminary Injunction Granted in Pathology Anti-Markup Lawsuit

A federal court on Mar. 31 ordered a preliminary injunction barring the Centers for Medicare & Medicaid Services from enforcing anti-markup rules that apply to anatomic pathology diagnostic services furnished in a centralized building, as

defined in the Stark physician self-referral law. The court said the injunction is in force "until trial on the merits of the case or further notice."

The U.S. District Court for the District of Columbia ordered the injunction in a lawsuit filed by Atlantic Urological Associates *et al.* and Uropath, LLC, against the Health & Human Services Secretary.

The urology plaintiffs charge that enforcing the rules would prohibit them from billing for the amount allowed under the Medicare physician fee schedule and require them to bill at a loss. They also argue that the rules violate public notice and comment requirements of the Administrative Procedures Act and are contrary to the Stark law.

But the court did allow the College of American Pathologists to file arguments supporting enforcement of the rules as a way to curb "pod lab" arrangements whereby certain physician specialties seek to increase Medicare revenue from pathology services they order but do not perform in their office practice. CAP contends these arrangements do not comply with the intent of the Stark exception for in-office ancillary services and can lead to overutilization.

Judge Rosemary M. Collyer said she was not ready to rule on the merits of the case and, to allow time to consider them, directed CMS not to apply the anti-markup provisions to the anatomic pathology services in question at least through the end of April. CMS had earlier agreed, in the wake of the filing of the lawsuit, to halt enforcement through the end of March. The ruling prevents CMS from recouping payments for any such services billed in violation of the provisions until further order, noted the American Society for Clinical Pathology.

Eliminating pod labs by drying up their profitability was a main goal of the anti-markup provisions in the final 2008 Medicare physician fee schedule rule published last November, CMS has acknowledged. The agency imposed the provisions on the professional and technical components of diagnostic tests payable under the physician fee schedule. But on Jan. 3, CMS revised its position, announcing that it would delay for one year, until Jan. 1, 2009, the applicability of the curbs to diagnostic tests, except:

- with respect to the technical component of a purchased diagnostic test and
- with respect to any anatomic pathology service furnished in a space that is utilized 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.

The delay, CMS said, provides time to consider concerns raised by the American Medical Association and other physician groups that the anti-markup prohibitions could disrupt many diagnostic testing arrangements currently in place and thus impede beneficiary access to needed care. CMS noted in particular that the definition of "office of the billing physician or other supplier" may not be clear and could have "unintended consequences."

However, CMS did not delay application of the anti-markup rules to the technical component of any purchased diagnostic test. This prohibition has been long-standing, the agency noted, and has been incorporated in the expanded and revised rules.

focus on: Competitive Bidding

Court Grants Preliminary Injunction Halting Lab Bidding Demo

Three clinical laboratories in the San Diego area that are suing to stop the Medicare competitive bidding demonstration in their locale won an important victory on Apr. 8 when a federal court granted their request for a preliminary injunction to bar the project from going forward until further notice.

Judge Thomas J. Whelan, of the U.S. District Court for the Southern District of California in San Diego, enjoined Health & Human Services Secretary Michael Leavitt, and his agent, the Centers for Medicare & Medicaid Services, from:

—Announcing winners in the bidding process. CMS required bid submissions by Feb. 15 and had planned to disclose the winning labs on Apr. 11 and begin the demo on July 1. Losing labs could not bill Medicare Part B for demo tests for fee-for-service beneficiaries during the three-year run of the project.

—Otherwise implementing or carrying out the project in the demo area.

— Disclosing any information in the bid applications submitted.

Events Leading Up to the Court Ruling

Oct. 17, 2007	CMS picks the San Diego-Carlsbad-San Marcos metro area as the first site for the Medicare lab bidding demonstration.
In November	CMS issues a series of Frequently Asked Questions as part of the final bidders package. The agency interprets the face-to-face exception in the statute to exclude only "testing performed by physician office labs or by hospital labs for their own patients." CMS follows up with a bidders conference in San Diego in early December.
Jan. 29, 2008	Three labs in the demo site go to federal court to stop the project, alleging that it will, as designed, cause irreparable harm to their business and their patients. They ask the court to require the government to follow public notice and comment requirements of the Administrative Procedures Act.
Feb. 4	The lab plaintiffs seek a temporary restraining order to block the demo before the Feb. 15 deadline for submitting bids.
Feb. 14	The court denies the request, citing serious jurisdictional issues raised by the HHS Secretary, and says it is premature to gauge irreparable harm since winners and losers had yet to be announced.
Mar. 10	The labs seek a preliminary injunction to halt the demo before Apr. 11, the date when CMS plans to disclose the winning bidders.
Apr. 4	The court rules that it has jurisdiction over the case and the labs' claims are ripe for judicial review.
Apr. 8	The court hears arguments from both sides, then grants the injunction relief that the labs sought.

The ruling came in the lawsuit filed Jan. 29 by Sharp Healthcare, Scripps Clinic, and Internist Laboratory and follows the Apr. 4 decision by the court that it had jurisdiction to handle the case. The lead counsel for the plaintiffs, Patric Hooper, with Hooper, Lundy & Bookman in Los Angeles, told *NIR* that the court's action is "pleasing for the plaintiffs, the industry as a whole, and beneficiaries. If the government wants to go forward, it will have to be through a rulemaking. Or the government could disagree with the court and try to appeal." At press time, a CMS spokesperson said only that the agency was disappointed and had tried to develop the demo in line with congressional intent and provider input.

The lab demo, required by Congress in the Medicare Modernization Act of 2003, is intended to see if competitive bidding can be used to pay for independent lab services at rates below the current Part B lab fee schedule.

This is the first time a court has enjoined a Medicare demo project for failing to follow federal rulemaking requirements, said Patric Hooper, lead attorney for the San Diego-area labs.

The Demo Design

In his ruling granting the preliminary injunction, Judge Whelan noted that the statute requires CMS to conduct a bidding demo for services that would otherwise be payable under the Medicare Part B lab fee schedule. The law excluded Pap smears and colorectal cancer screening, as well as tests performed by entities that have a face-to-face encounter with the beneficiary being tested.

Under the bidding process, labs had to submit bids for 303 demo tests and for the collection and handling of patient specimens. Labs had to bid on each of the tests even if they do not provide the specific test. In the bidder's package, CMS limited the exception for face-to-face encounters to "testing performed by physician office labs and by hospital labs for their own patients."

Court Agreed With Key Challenges

While Judge Whelan did not accept all the arguments advanced by the lab plaintiffs, he did find that they had a likelihood of success on the merits of several of their main complaints. He agreed that the project, as currently designed, threatens irreparable harm to their business and their patients that could not be compensated by monetary damages. He further faulted CMS for failing to follow the Administrative Procedures Act (APA) in developing the demo, misreading congressional intent on the face-to-face exception, and expanding the scope of the demo to encompass not only specific tests, but also specimen handling and collection.

The finding that the labs would likely succeed on the merits of their major challenges "should make CMS take pause about going ahead," Mark Birenbaum, head of the American Association of Bioanalysts/National Independent Laboratory Association, told *NIR*. For example, he noted, the judge concluded that CMS went beyond what the statute specifies by including specimen collection and handling in the demo bidding process. "Even if CMS dropped this bidding requirement and decided to go ahead, would labs then have to re-do their bids?"

Birenbaum also was encouraged by the judge's finding regarding the face-to-face exception. If upheld, a lot of labs would be exempt, he said. Whelan ruled that Congress was unambiguous in legislating that the demo did not cover testing furnished as a result of a face-to-face encounter with the beneficiary. Although Internist Laboratory has such encounters, the Secretary's interpretation (and limitation) of the exception nonetheless required the lab to bid, Whelan noted. "The statute is clear on the exception. Nor has the Secretary once asserted that the statute, or more precisely the term, is in any way ambiguous, nor does the Secretary point to any legislative history suggesting that Congress did not mean what it said with regard to the exception."

Risk of Irreparable Injury Real, Not Speculative

Whelan ruled that the project, as currently being implemented, will result in substantial economic harm if allowed to proceed. CMS had argued that the alleged injury is speculative because there is a possibility the plaintiffs will win. But the judge said the Apr. 11 date for announcing winning labs is a critical event—"the plaintiffs will, if not selected as winners, lose their ability to provide lab services to Part B patients and thus suffer irreparable harm." Citing previous court cases, he said, "They need not wait for the axe to fall."

Whelan disagreed with the government's contention that the plaintiffs did not establish that their alleged injuries are irreparable. Internist Laboratory, an 18-year-old community lab with 10 employees, told the court that if not selected as a winner, it

would lose 65 percent of its business, well above the loss of at least 30 percent that previous courts have determined to constitute irreparable harm, and be forced out of business. All of the Medicare patients it serves reside in the demo area and they would suffer too. "Internist is the only independent lab that performs blood draws and testing in the Oceanside-San Marcos-Vista-Carlsbad area and it is regularly referred special-needs patients whose medical or physical conditions make blood drawing difficult," the judge noted.

Similarly, Whelan said, the impact on "Sharp's and Scripps' integrated medical networks, and the attendant adverse consequences to patients, constitute harm that cannot be adequately compensated by an award of monetary damages." Sharp operates 13 labs that provide outreach services throughout San Diego, serving thousands of patients (a significant portion of them Medicare beneficiaries) and employing hundreds of people. Sharp said that if it did not win, it would have to close some blood draw sites and scale back a big part of the outreach lab. It also would have to make costly operational changes to the medical recordkeeping system and would have to shift some lab staff to non-revenue generating administrative work.

Scripps Clinic Medical Laboratories includes three testing labs and seven patient service centers throughout San Diego, also serving thousands of patients and employing hundreds of workers. If it did not win, it would lose a minimum of $1.9 million in revenue, triggering a reduction in services and employee layoffs. Also, it would have to establish procedures to determine which patients' lab tests must be performed by a different (winning) lab and how to deal with those tests.

The court ruled that the Secretary violated notice and comment requirements of the APA when developing certain demo project rules to the detriment of the plaintiffs. CMS did not assert that the APA did not apply, but said it believed it had provided sufficient avenues for provider and public input. But Whelan said this amounted to random presentations at industry and professional meetings between the fall of 2004 and 2007. As an example, the judge noted that in the final bidders package CMS held that non-winning labs, despite being not able to bill Medicare directly, could not legally refuse services to a beneficiary based on payment. Then, after the labs filed suit against the demo, CMS changed its position—non-winning labs did not have to provide these services to beneficiaries. "Thus, the evidence suggests that the failure to abide by the APA notice requirements was not harmless," Whelan said. This ruling only confirms that the labs were correct in their original complaint, Birenbaum told *NIR*.

Alan Mertz, president of the American Clinical Laboratory Association, said in a statement, "The judge was crystal clear in finding that both labs and patients could be hurt … and the court's findings bolster the case for congressional repeal of the project."

Some Challenges Not Likely to Succeed

Falling into this category are some of the complaints in the lawsuit. The labs challenged the CMS requirement that labs serving nursing home and ESRD beneficiaries exclusively must accept test prices set under the demo project. The labs also contended that CMS' use of Medicare claims paid data to determine and project test volume demand violates the APA. Based on the present record, both assertions appear to involve the Secretary's discretion in establishing payment amounts and the bidding structure for the demo, Whelan concluded. "Thus, these two areas are not subject to judicial review."

ACLA to CMS: 'Rethink Policy on New Panel Code'

The American Clinical Laboratory Association has asked the Centers for Medicare & Medicaid Services to change its coverage and payment policy for the new CPT code 80047, Basic metabolic panel (ionized calcium). In a Mar. 14 letter to CMS, ACLA also said the panel should not be considered an ESRD composite rate test.

CMS has announced that as of July 1, it will classify ionized calcium (CPT 82330) as an automated multichannel chemistry (AMCC) test for payment purposes when performed as part of 80047 and crosswalk the new panel to 80048 (an 8-test automated panel, currently paid by most carriers at a maximum of $11.83). Since Jan. 1, Medicare has paid for 80047 at the sum of a 7-test panel plus the ionized calcium, or a maximum of $30.51 under local fee schedules.

Medicare's Current Automated Test List

Albumin	82040
Alkaline Phosphatase	84075
ALT (SGPT)	84460
AST (SGOT)	84450
Bilirubin, total	82247
Bilirubin, direct	82248
Calcium	82310
Chloride	82435
Cholesterol	82465
CK, CPK	82550
CO2 (bicarbonate)	82374
Creatinine	82565
GGT	82977
Glucose	82947
LDH	83615
Phosphorus	84100
Potassium	84132
Protein, total	84155
Sodium	84295
Triglycerides	84478
Urea nitrogen (BUN)	84520
Uric acid	84550

Source: Medicare Claims Processing Manual 100-04.

ACLA says CMS has erred by including ionized calcium as an AMCC test. Under Medicare policy, AMCC tests are those performed on the same time on the same equipment using a single specimen, and the agency has codified a list of 22 tests that fit this definition (see box). Only the Abbott I-Stat point-of-care device can run 80047 as an 8-test panel, but it is designed as a bedside instrument and "is not intended for high sample volumes, such as those generated by dialysis facilities and sent to ESRD labs for testing," ACLA noted. The automated chemistry analyzers that most labs use are not capable of running the ionized calcium as an AMCC test and require a separate collection method and instrument.

CMS' plan to rank ionized calcium as an AMCC test further complicates claims processing and payment, ACLA argued. When performed as part of 80047, it would be paid as an 8-test panel; when done alone or with some other combination of AMCC tests, it would be paid separately. One solution put forth by ACLA is to pay for 80047 as an AMCC test only when done on the I-Stat device and billed with the QW modifier, denoting a waived test. In all other circumstances, the panel should be paid as a 7-test panel, plus the ionized calcium.

Treating the new panel as a composite rate test and billing it with the modifier CD or CE is not appropriate, ACLA continued. Ionized calcium has never been considered in the composite rate category and is not routinely used for dialysis patients.

Following up on this argument, ACLA said CMS erred in indicating it would consider the ionized calcium under the 50/50 rule. Under this rule, if half or more of the tests in an automated chemistry panel are included in the ESRD composite rate, then the entire panel is considered part of the composite rate and will not be paid separately.

OIG Changes the Payment Rules for Advisory Opinions

Advisory opinions on how the Stark physician self-referral ban or its numerous exceptions apply to a business deal are handled separately by the Centers for Medicare & Medicaid Services.

If you want advice from the HHS Office of Inspector General about kickback and other legal risks to your current or proposed business arrangement, you no longer must put down a $250 deposit. Instead, you will pay the costs of preparing an advisory opinion in one lump sum directly to the U.S. Treasury via electronic funds transfer—checks and money orders will no longer be accepted. Once the OIG gets confirmation of payment in full, you will get the opinion.

The OIG announced the changes in an interim final rule in the March 26 *Federal Register*, with an effective date of Apr. 25 (though the OIG said it is "implementing the changes immediately").

An advisory opinion is a legal opinion by the OIG to one or more requesting parties about how the OIG's fraud and abuse authorities apply to an existing or proposed business arrangement. It is legally binding only on the U.S. Department of Health & Human Services and the party requesting it. Any other person or entity cannot rely on it. Most requests are for advice about anti-kickback law or the safe harbor regulations, though the OIG may also advise on its exclusion authorities, as well as civil money and criminal penalties.

washington WATCH

Prospects for passage this year of prohibitions to protect Americans from genetic discrimination by employers and insurers depend on Senate action, now that the House has approved these prohibitions and sent them to the Senate as part of a broader measure, H.R. 1424.

The House bill, passed last month, incorporates provisions of H.R. 493—the Genetic Information Non-Discrimination Act (GINA)—that bars employers from using genetic information in decisions on hiring, firing, job placement, or promotion. It also prohibits group health plans and other health insurers in the group and individual market from using genetic information to deny coverage or set premium rates and from requiring individuals to undergo genetic testing.

The Senate companion GINA bill, S. 358, is ready for floor action. It was reported out of the HELP Committee on April 10, 2007.

The White House supports the genetic anti-discrimination provisions.

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