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San Diego Labs to Press On to Stop Medicare Bidding Demo

The labs serve the San Diego-Carlsbad-San Marcos metro area, the first of two sites to be selected by the Centers for Medicare & Medicaid Services for the controversial pilot project.

Though a federal court has denied a motion by three San Diego-area clinical laboratories to halt Medicare's competitive bidding demonstration prior to the February 15 deadline to submit bids, the labs have until the end of this month to show cause why their lawsuit against the project should not be dismissed.

Attorney Patric Hooper, with Hooper, Lundy & Bookman (Los Angeles), which is representing the labs, said in a statement that in addition to presenting further arguments to the court, he will ask for a preliminary injunction to stop the demo prior to April 11 when the winning labs are to be announced.

The court gave the labs—Sharp Healthcare, Scripps Health, and Internist Laboratory of Oceanside—until February 29 to respond to jurisdictional issues raised by the government. Meantime, the demo will proceed as planned, with Medicare to begin paying winning bidders for 303 demo lab tests under a competitively bid fee schedule as of July 1. Medicare will pay nothing to losing labs for these tests during the three-year run of the project.

For more on the lawsuit, plus separate moves on Capitol Hill to block the demo, see the *Focus*, pp. 4-5.

Pathology, Lab Priorities Riding on New Medicare Bill

Pathologists and clinical laboratories have a lot at stake in the outcome of new Medicare legislation that is expected to move in Congress during the first half of this year. At this point, this appears to be the most promising vehicle for enactment of some of their key legislative priorities left over from last year.

These include a physician fee fix, the "grandfather" protection for independent labs, repeal of the lab bidding demo, and an overhaul of the CLIA cytology proficiency testing program (*NIR, 29, 7/Jan 28 '08, pp. 4-6*).

The Senate Finance Committee is working on a new Medicare bill that is expected to be ready for markup in April, according to staff for chairman Max Baucus (D-MT). The House has already passed its Medicare payment and policy provisions, including a physician fee fix and an extension of the "grandfather" protection (*NIR, 29, 1/Oct 8 '07, p. 6*).

For pathologists, a prime goal is to prevent a looming 10.1% Medicare fee cut July 1 and to secure a fee increase instead, while joining with other physician groups to lobby for

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New Medicare Bill, *from p. 1*

replacement of the SGR (Sustainable Growth Rate) system used to update physician fees each year. Physician groups fault the SGR for triggering negative updates throughout the decade, and the Centers for Medicare & Medicaid Services has acknowledged that deeper cuts are ahead unless the SGR is changed.

Congress blocked the 10.1% cut scheduled for January 1, 2008 under the SGR formula and approved a 0.5% increase through June 30. The six-month reprieve was a compromise after Senate and House negotiators failed to agree on a longer-term Medicare fix, arguing back and forth over whether it should be for one or two years, and how to pay for it with offsets elsewhere in the budget. The House last year approved a 0.5% fee increase for 2008 and 2009, at an estimated cost of $20 billion over five years. It also replaced the SGR formula with a new system of expenditure targets for six categories of physician services.

Another top priority for pathology organizations and for clinical lab groups is preservation of the "grandfather" protection that allows eligible independent labs to bill Medicare Part B for the technical component of anatomic pathology services to hospital patients. The protection applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to eliminate such billings, saying that TC pathology payment is included in the hospital's DRG payment under Part A and labs should seek reimbursement from the hospital.

The protection expired December 31, 2007, but Congress granted a six-month extension, through June 30 of this year. The House has approved a two-year extension, through 2009. Pending in both the House and the Senate are bills that would extend the "grandfather" provision permanently:

- ❑ H.R. 1105, the Physician Pathology Services Continuity Act of 2007. *Introduced*: February 15, 2007. *Lead sponsor*: John Tanner (D-TN). *Co-sponsors*: 13. *Latest action*: Referred to the Subcommittee on Health.
- ❑ S. 458, the Physician Pathology Services Continuity Act of 2007. *Introduced*: January 31, 2007. *Lead sponsor*: Sen. Blanche Lincoln (AR). *Co-sponsors*: 8. *Latest action*: Referred to the Finance Committee.

The President's budget request for fiscal 2009 is silent on both the physician fee fix and the "grandfather" protection, leaving it to Congress to decide these issues, including how to pay for them. The White House has warned, however, that it opposes any further reductions in spending for the fast-growing Medicare Advantage (MA) program that offers beneficiaries a range of coverage options such as HMOs, PPOs, and private fee-for-service plans. In 2007, about 20% of Medicare's 45.5 million beneficiaries were enrolled in an MA plan, according to CMS.

The President last year threatened to veto any Medicare legislation that would cut into Medicare Advantage, and in the final compromise, lawmakers made a small reduction in the managed care stabilization fund. The House had approved a reduction of MA payments to 100% of traditional Part B fee-for-service rates. The Medicare Payment Advisory Committee has told Congress that MA plans get 12% higher pay rates on average than traditional Medicare, though health plan groups dispute this and deny they are overpaid.

Meantime, the President's FY 2009 budget proposes major payment freezes next year and future reductions for hospitals and other institutional providers in traditional Medicare, but only a slight reduction of roughly $1 billion for Medicare Advantage (*NIR, 29, 8/Feb 11 '08, pp. 3-6*).

And ominously for all providers, including labs, the budget proposes a 0.4% cut in their payments when general fund revenues exceed 45% of program spending. The cut would increase each year by 0.4% until general revenue funding is brought back to 45%. Health & Human Services Secretary Michael Leavitt told a February 13 hearing of the House Ways & Means Committee that he will submit a trigger proposal this month with additional provisions to slow Medicare's growth rate and to promote changes in the program through electronic medical records, emphasis on quality, and greater transparency for consumers on medical costs.

Though the trigger provision, written into the Medicare Modernization Act of 2003, requires the President to propose, and Congress to quickly consider, spending cuts, lawmakers are not obliged to follow the recommendations. Given the current political climate, they are not likely to. Democratic health leaders and some Republicans have already said that proposals for sweeping Medicare provider payment cuts are "dead on arrival." House Democrats have faulted the Bush administration for trying to "privatize" Medicare by targeting massive cuts to providers while leaving managed care payments mostly untouched.

The ICD-10 Is Back!

The President's budget request for fiscal 2009, released earlier this month, has revived the initiative to switch the Medicare program from the ICD-9 coding system to ICD-10 and proposes new spending of $40.3 million for the transition to be completed by 2011.

The switch will be a major undertaking for the Centers for Medicare & Medicaid Services, the budget notes, including revision of instruction manuals, claims processing systems, medical software, and analyses. To implement ICD-10, current HIPAA transactions must first be upgraded from version 2010 to 5010, which accommodates increased space for the ICD-10 code sets.

To finance the transition, the President seeks:
- ❑ $17.9 million for ICD-10 implementation, planning, and pilot testing.
- ❑ $15.6 million for ICD-10 systems changes.
- ❑ $6.8 million for upgrading to Version 5010.

In defense of the turnover to ICD-10, CMS says the ICD-9 code set does not provide detailed information about a patient's diagnosis or the procedure or test that a provider orders, making it necessary to conduct a detailed medical review to see if a claim was paid improperly. The ICD-10 code set is much more specific, CMS says, making it easier to determine if a claim was appropriately billed.

Nor does ICD-9 provide the specificity needed for value-based purchasing, according to CMS. Such a purchasing program considers both quality and cost of care over an appropriate period of time. ICD-10 provides very specific data about a patient's diagnosis and the procedures performed. "As a result, payers can ascertain if additional services were performed due to provider error and if cost savings can be achieved by refusing to pay for provider errors," CMS says. *Continued on p. 7*

Major Differences Between ICD-9 & ICD-10

	ICD-9	*ICD-10*
Diagnosis Codes		
# of Characters	3-5 Alphanumeric	5-7 Alphanumeric
# of Codes	15,000	120,000
Procedure Codes		
# of Characters	3-4 Numeric	7 Alphanumeric
# of Codes	4,000	200,000 – 450,000

focus on: Competitive Bidding

Labs Wage Legal, Legislative Battle Against Medicare Demo

While three San Diego-area clinical laboratories press ahead with their lawsuit to stop the Medicare competitive bidding demonstration from being launched in their locale, the 10 national lab and pathology groups participating in the Clinical Laboratory Coalition back the effort and continue to lobby Congress to enact bipartisan legislation pending in the House and the Senate to repeal the demo.

The lab bidding demo, required by the Medicare Modernization Act of 2003, is intended to see if competitive bidding can be used to pay for Part B lab services at rates below the current fee schedule. The first of two sites picked for the pilot is the San Diego-Carlsbad-San Marcos metropolitan area.

Legal Skirmishes

While the San Diego labs lost the first round of arguments in the lawsuit, they have until February 29 to answer government objections. The government then has until March 14 to respond. Attorneys for the labs say they will ask the court for a preliminary injunction to stop the project before the April 11 deadline when winning labs are to be announced.

The lawsuit was filed January 29 in the U.S. District Court for the Southern District of California. The plaintiffs—Sharp HealthCare, Scripps Health, and Internist Laboratory of Oceanside—are represented by Hooper, Lundy & Bookman in Los Angeles. The labs seek an immediate halt to the demo, citing irreparable harm to their business and to thousands of Medicare fee-for-service beneficiaries. Rather than creating competition, the labs contend, the demo will result in fewer labs, less competition, and diminished patient access to care. The suit also seeks to require the government to follow public notice and comment on the demo in accord with the Administrative Procedures Act.

Meantime, the demo goes ahead as designed, with a July 1 start date in the San Diego area. It affects independent lab services payable under Part B, including hospital and physician office outreach work. Bids must be submitted on 303 demo tests that do not involve a face-to-face encounter with the beneficiary (excluding Pap smears, colorectal cancer screening, and new tests added to the lab fee schedule during the project).

In his first ruling on the case, Judge Thomas Whelan on February 14 denied the plaintiffs' motion for a temporary restraining order to halt the project prior to the February 15 deadline for submission of bids. But he gave the labs until the end of this month to file papers addressing jurisdictional issues raised by the court in response to objections filed by the government.

Whelan noted that the assertion of irreparable harm is premature since winning and losing labs have yet to be determined: "Plaintiffs' alleged injury is speculative since, according to their motion, the loss of business will only occur, *if at all* [sic], after they lose the bidding competition. This does not support granting a TRO two months before the injury might occur." He said that "courts have consistently found that a loss of at least 30% of a plaintiff's business constitutes irreparable harm, but such a finding generally occurs after the plaintiff's participation in the government program is suspended or terminated, thereby eliminating any concern that the alleged harm is speculative."

The best chance to get Congress to repeal the demo's statutory authority, according to the current thinking of lab and pathology groups, is to attach the pending repeal bills to broader Medicare legislation on this year's congressional calendar.

Internist Laboratory, a family-owned business with eight employees, says it will lose 65% of its business if not selected as a winner. Sharp and Scripps say patient care will be significantly disrupted if they don't win. In addition to layoffs, they may have to stop or significantly decrease lab services to non-hospital patients.

Judge Whelan further questioned whether the lawsuit met the standard of "the likelihood of prevailing on the merits." He pointed to the government's argument that the court lacks jurisdiction in the case and the lawsuit should be dismissed for the plaintiffs' failure to exhaust administrative remedies.

The government says plaintiffs may obtain review under the following scenario: "In order to bring their claims to a court, plaintiffs would have to proceed through the bidding process. Once the winners are selected, plaintiffs would then (whether they win or lose) be in a position to submit claims for lab tests to Medicare. If they are dissatisfied with the reimbursement they receive, they may then present their claim to CMS and pursue an administrative remedy—both prerequisites to judicial review … Once the Secretary renders a decision, plaintiffs may then seek judicial review," but not via the Administrative Procedures Act.

Patric Hooper, an attorney for the labs, said, "The court has given the labs additional time to address these arguments in light of the fact that they were not previously given that opportunity due to the lateness of the government's briefing. I am not particularly surprised, given the representations made by the government at the 11th hour."

Hooper said he is confident that additional briefs filed by the labs will give the court "a clear understanding of why immediate injunctive relief is necessary and why it is empowered to grant such relief." He noted that he recently overcame similar government arguments in another federal court case involving a CLIA dispute and Medicare payment for lab services (*NIR, 29, 8/Feb 11 '08, p. 7*).

Opposition Growing on Capitol Hill

Leaders of the House Committee on Small Business have weighed in on CMS's plans to proceed with the demo. In a February 13 letter, chairwoman Nydia M. Velazquez (D-NY) and ranking Republican Steve Chabot (OH) urged HHS Secretary Michael Leavitt to delay implementation until the committee can re-examine the project. They specifically asked him to postpone the deadline for submission of bids, noting that action on Medicare legislation this year "will provide an opportunity for a comprehensive review of the issues related to the demo's implementation."

Velazquez and Chabot went on to say, "The agency should revisit the appropriateness of instituting competitive bidding under Medicare **as currently designed** [sic] due to our concerns about a number of the demo's aspects, including the risk of small labs going out of business," compromising care for special populations they serve such as nursing home and home care patients.

The House Small Business Committee held a hearing on the demo issues on July 25, 2007, receiving comments from members of the Clinical Laboratory Coalition and from hundreds of small community labs. Velazquez subsequently introduced H.R. 3453 to repeal the demo. The bipartisan bill now has 34 co-sponsors, with the addition of Reps. Barney Frank (D-MA), Susan Davis (D-SD), and Timothy Walz (D-MN) since our previous coverage (*NIR, 29, 7/Jan 28 '08, p. 5*). A similar bipartisan bill is pending in the Senate (S. 2099), introduced September 26, 2007, with Ken Salazar (D-CO) as lead sponsor and six co-sponsors.

NPI News: CMS Clarifies Key Medicare Implementation Dates

Citing confusion among providers, the Centers for Medicare & Medicaid Services has issued a chart of critical dates between now and May 23 for Medicare fee-for-service (FFS) implementation of the National Provider Identifier (NPI). The chart illustrates expected claim results for different identifiers, or combinations thereof, submitted in the primary provider fields on the Medicare FFS 837P and the CMS-1500. When the chart indicates that claims will be paid, this would be only if no other errors (non-NPI) exist, CMS notes.

Before March 1: 837P and 1500 claims, primary provider fields		
Legacy Medicare Identifier	*NPI*	*Result*
X		Claim will be paid.
X	X	Claim will be paid as long as there is an NPI/legacy match on the NPI crosswalk (claim will be rejected if there is no match).
	X	Claim will be paid as long as there is an NPI/legacy match on the NPI crosswalk.
As of March 1: 837P and 1500 claims, primary provider fields		
Legacy Medicare Identifier	*NPI*	*Result*
X		Claim will be rejected.
X	X	Claim will be paid as long as there is an NPI/legacy match on the NPI crosswalk
	X	Claim will be paid as long as there is an NPI/legacy match on the NPI crosswalk.
As of May 23 and beyond: All providers, all transactions, both primary and secondary provider fields		
Legacy Medicare Identifier	*NPI*	*Result*
X		Claim/transaction will be rejected.
X	X	Claim/transaction will be rejected.
	X	Claim/transaction will be paid/processed as long as there is an NPI/legacy match on the NPI crosswalk.

ACLA to SACGHS: Clarify CMS, FDA Roles in Genetic Test Oversight

Contrary to the squabbling in the presidential primaries, words have meaning—and they have the power to steer both thought and action, as George Orwell drove home forcefully in *1984*. And that's the point of recent comments made by the American Clinical Laboratory Association to the HHS Secretary's Advisory Committee on Genetics, Health & Society (SACGHS).

The top federal advisory panel met February 12-13 to finalize its draft report and recommendations to Secretary Michael Leavitt on filling gaps in governmental and private oversight of genetic testing, including lab-developed tests or LDTs (*NIR, 29, 5/Dec 17 '07, pp. 3-6*). The final version is slated to go to Leavitt at the end of April and could be a springboard for further action by HHS and Congress.

ACLA urged SACGHS to amend "one particularly important recommendation that, if not carefully communicated to the Secretary, could have unintended consequences." In the recommendation, SACGHS affirms its support for the Food & Drug Administration's regulation of LDTs and the flexible risk-based approach the agency is taking to prioritize review of these tests.

Concerned that this could be interpreted to mean that FDA requirements should be applied to LDTs without interagency coordination, ACLA noted: "Though there are many similarities between FDA's and CLIA's quality validation, there are clear redundancies and duplications that, if not coordinated, harmonized, and streamlined will stifle innovations in this area. These include separate requirements for inspection, quality systems, reporting and labeling, and other rules for design control, corrective action, and prevention."

ACLA asked SACGHS to make clear that interagency coordination is the goal for LDT regulation. This is in line, ACLA said, with the "overarching" guidance in the SACGHS draft report to "enhance interagency coordination" and "promote public-private partnerships" to tackle knowledge gaps concerning clinical validity and utility. ACLA suggested the following revised wording: "*SACGHS supports an interagency role for FDA in CMS's regulation of LDTs (italics added)* and the flexible risk-based approach the agency is taking to prioritize LDTs, an approach that should be robust enough to accommodate new genetic testing technologies and methodologies."

The draft SACGHS report advised the FDA to take a "go slow," broader consultative approach to LDT oversight. ACLA and the College of American Pathologists contend that CMS' CLIA program should be the lead federal agency to oversee genetic testing services, while the FDA's role should be consultative.

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Moreover, CMS says it will run out of ICD-9 procedure codes sometime in FY 2009. Thus, providers will not be able to submit electronic claims as required by HIPAA for new procedures and payers. As the ICD-9 code set expires, it will be impossible to continue to be HIPAA-compliant, CMS notes.

Clinical labs and other providers "dodged the ICD-10 bullet" in 2006 when legislative proposals to mandate the switch from ICD-9 by 2009 failed to clear Congress (*NIR, 28, 4/Nov 20 '06, p. 5; 27, 16/Jun 12 '06, p. 1, 4-5*). CMS did indicate at the time, however, that it could require the switch administratively. And at press time, the agency reportedly is seeking regulatory clearance to soon publish a Notice of Proposed Rulemaking that would carry out the President's plan.

The International Classification of Diseases (ICD), version 10, was endorsed by the 43rd World Health Assembly in May 1990 and came into use in WHO member states beginning in 1994. All G-7 countries use it, except the U.S. The ICD system is the international standard diagnostic classification for all general epidemiological and many health management purposes. It is used to classify diseases and other health problems recorded on many types of health and vital records, including death certificates and hospital records. In addition to enabling the storage and retrieval of diagnostic information for clinical and epidemiological purposes, these records provide the basis for compilation of national mortality and morbidity statistics by WHO member states.

Legal Liability Safeguards Proposed for Reporting Medical Errors

The American Hospital Association welcomed the proposal: "We strongly support creation of PSOs as one of the most important tools to spur safer patient care. Hospitals have waited two years for this rule, and this is only a first step." Comments on the proposal are due April 14.

The HHS Agency for Healthcare Research & Quality released a proposed rule in the February 12 *Federal Register* that would establish patient safety organizations (PSOs) and procedures by which healthcare providers can voluntarily report medical errors to the PSOs without fearing legal liability. The PSOs will collect and analyze medical data that can be aggregated to uncover trends in patient treatment that would help lower the incidence of medical errors.

Breaches of confidentiality would be subject to civil monetary penalties of up to $20,000 per act, to be enforced by the HHS Office for Civil Rights, according to the proposed rule. Providers participating in the PSO effort also must comply with HIPAA privacy standards. PSOs were authorized by the Patient Safety & Quality Improvement Act, signed into law in July 2005.

HHS expects a "broad range of organizations" to seek PSO status, even though they will not be entitled to federal funding. Organizations that conduct regulatory oversight of healthcare providers, including accreditation or licensure, will not be eligible to become a PSO. HHS predicts that after the rule is finalized, some 100 PSOs could become operational within a few years.

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