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Medicare Urged To Require Test Results With Lab Claims

The American Clinical Laboratory Association and several physician and payer groups on March 3 called on Senate Finance Committee chairman Charles Grassley (R-IA) to wait until standards are in place before acting on this recommendation, due to its administrative burden and cost

The Medicare Payment Advisory Commission, which reports independently to Congress, has recommended that Medicare require clinical laboratories to report patients' test results with the claims they submit. The results would be used in assessing the quality of care that physicians furnish, MedPAC said in its annual report on Medicare payment policy, released March 1. Eventually, the panel noted, results would help support the kind of quality incentive payments to doctors that MedPAC has urged Congress to establish.

The test results data would have to adhere to a standard format and vocabulary, such as the LOINC (Logical Observations: Identifiers, Names, Codes) standards that the Federal Government has adopted and many clinical laboratories already use, MedPAC said, suggesting "a two- or three-year transition before using [the data] to pay for performance might be prudent. But adoption and implementation of standards must begin now."

The recommendation was MedPAC's most controversial, with two of its 17 members voting against it. All the other ➔ p. 2

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CLIAAC Wants New Look At Cytology PT

The Clinical Laboratory Improvement Advisory Committee (CLIAAC) has recommended that the government revise proficiency testing requirements for gynecologic cytology that are spelled out in the 1992 CLIA rules. When Congress enacted CLIA (the Clinical Laboratory Improvement Amendments) in 1988, one of the main aims was to crack down on widely publicized "Pap mills" and assure quality testing for cervical or vaginal cancer.

The College of American Pathologists and the American Society for Clinical Pathology have long objected that the requirements represent outdated technologies and clinical practice. CLIAAC member Dina Mody, MD, director of cytopathology at Methodist Hospital in Houston, TX, said the distinction between low-grade and high-grade no longer has clinical significance because both findings generate the same treatment response. "People will fail the test not because they're morons, but because it's a bad test. It's 1960s practice."

Cytology PT is a major lab concern now that the government will begin enforcing the CLIA standards this year. For more on other issues tackled by CLIAAC, see the *Focus* in this issue, pp. 4-6. 🏛️

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Medicare Urged To Require Test Results, from p. 1

recommendations in the panel's 2005 report were unanimous, save for a health system member's "no" votes on recommendations to set inpatient and outpatient prospective payments 0.4% below market basket.

MedPAC acknowledged that requiring test results with lab claims would "result in some increased burden for those who conduct lab tests," but did not suggest paying extra for the data. Private health plans, however, have grown interested, of late, in paying as much as 10% more for clinical data they can use in disease management programs (*National Intelligence Report*, 25, 15/May 24, '04, p. 4).

To avoid creating a new data stream, MedPAC called for including the test results, which it calls "laboratory values," on new or existing fields on lab claim forms or as attachments to the forms. With attachments, it would be easier to include the in-depth information, including text, required to describe some test results, the panel said.

Current Medicare Payment Systems

What MedPAC Recommends

- Hospital inpatient PPS: Market basket minus 0.4%.
- Outpatient PPS: Market basket minus 0.4%.
- Outpatient dialysis: Market basket minus 0.4%.
- Skilled nursing facility PPS: No update.
- Home health PPS: No update.
- Physician fee schedule: Market basket less a 0.8% productivity allowance
- Lab fee schedule: Not addressed. Currently frozen at 2003 levels thru 2008.

MedPAC did acknowledge concerns voiced by lab and physician groups that it would be difficult to blend information from clinical and payment systems and to design claim form fields to capture the variety of results reported, including textual and panel test results. Also, it would take time to redesign systems to fully conform to standards such as LOINC.

MedPAC envisions phasing in federally mandated standards that are based on industry consensus standards, as with the HIPAA standards

governing electronic transactions and code sets. For example, CMS could require LOINC for coding lab data and HL7 for sending it. MedPAC suggests "a phased approach could allow additional time for smaller labs to comply."

MedPAC advised initially setting aside 1% to 2% of physician payments to be distributed as quality bonuses. "As our ability to measure quality improves, this amount should increase significantly." Perhaps recognizing that Congress may be tempted to divert the set-aside to other uses such as debt reduction, the commission stressed that it "intends for all of the withheld dollars to be distributed." 🏛️

Pathology Societies Rev Up To Compete In Cytology PT

Since the Centers for Medicare & Medicaid Services late last year approved MIME (the Indianapolis-based Midwest Institute for Medical Education) as the first-ever national provider of CLIA proficiency testing for gynecologic cytology, the two leading pathology professional societies have been accelerating efforts to get into the action, but the earliest they are likely to do so is next year.

With approval of MIME's program, CMS has said that this year it will begin to enforce the cytology PT requirements established under CLIA (the Clinical Labora-



For 2005, CLIA requirements for cytology proficiency testing can be satisfied only by enrolling in MIME's approved program. The enrollment deadline is June 30. But MIME is offering a 10% discount to those who sign up by March 31

tory Improvement Amendments). That means MIME is the only game in town in 2005 for anyone who reads Pap smears in the U.S. (outside of Maryland, that is, which has had a CMS-approved program since 1994).

The College of American Pathologists, which runs a continuing education program called CAP PAP, applied last December for CMS approval to furnish CLIA cytology PT in 2006. Last month, the American Society for Clinical Pathology, which runs the ASCP STAR continuing education program, followed suit. Also last month, CAP said it would expand its 2005 CAP PAP program with a 10-slide mock PT exam, starting this summer. It will also offer the mock exam in conjunction with the College's annual meeting this September 10-12 in Chicago, IL.

In recent public forums to get the lab industry up-to-speed on the cytology PT change, MIME has taken a great deal of flak, which many attribute to its competitors. "Proficiency testing is a potentially lucrative venture," said one source. "CAP probably is unhappy that MIME beat them to the punch." As ASCP complained in a December 7 letter to Thomas Hamilton, director of Medicare's Survey & Certification Group, ASCP STAR is losing some customers who, knowing they now must enroll with MIME, "have determined it is better not to participate and this is hurting our nonprofit endeavor."

Under MIME's program, as many as 4,000 facilities that are CLIA-certified for gynecologic cytology testing would have to pay a \$1,500 annual fee, plus \$75 to test each individual who reads Pap smears, or risk losing their ability to perform such testing. 🏠

Florida Withdraws Medicaid Lab Competition

Critics worry that the Florida initiative, if it gets off the ground, could become a model for other state Medicaid programs and even for Medicare, which is now working to design a Part B lab competitive bidding demonstration

The Florida Agency for Health Care Administration has pulled back its invitation to negotiate a winner-take-all capitated contract to provide independent laboratory services to Medicaid recipients throughout the state.

The agency announced the move, without comment, on February 18, following a challenge from the American Clinical Laboratory Association and protests by its two largest members, Quest Diagnostics and LabCorp.

The groups had contended that the contract, if awarded, would deny Medicaid recipients their right under federal law to get testing done by any qualified lab and would violate state Medicaid requirements for "delivery of quality healthcare."

If the state awards no contract by April 1, however, a provision in this year's funding measure would automatically cut lab fees under Florida Medicaid by 10%, at least until July 1, when the state's next fiscal year begins. ACLA is preparing to lobby the state legislature, after it convenes March 8, to prevent the fee cut. Florida Medicaid now pays labs via a fee schedule that is about 70% below Medicare rates.

Withdrawal of the invitation to negotiate (AHCA ITN 0508, issued December 13, 2004) does not necessarily signify the end of Florida's attempt to initiate a Medicaid bidding competition for independent lab services. The effort has been stymied for close to a year, however, by various lab challenges (*NIR*, 26, 6/Jan 10, '05, p. 5; 25, 14/May 10, '04, p. 2; 25, 13/Apr 19, '04, p. 3). 🏠



focus: CLIA Regulatory Oversight

'Hot-Button' Issues Dominate CLIAC Agenda

With the government and the healthcare industry increasingly pushing to base payments for patient care on quality, and the clinical laboratory sector pushing to assure quality in testing performance and in new diagnostic testing technologies coming to market, the Clinical Laboratory Improvement Advisory Committee (CLIAC) tackled a host of key related topics at its most recent meeting, on February 16-17 in Atlanta, GA. CLIAC is the government's top advisory panel on the CLIA lab oversight program (*see box below*).

Where's The FDA On CLIA Waivers?

The Food & Drug Administration drew fire from the committee for a delay in publishing revamped guidance on CLIA waived test criteria. The agency does not expect to issue guidance until this summer at the earliest, said Jean Cooper, sitting in for her boss, Steven Gutman, MD, director of FDA's Office of In Vitro Diagnostic Device Evaluation & Safety. Gutman is an ex officio member of CLIAC, representing the FDA.

CLIAC chairman David Sundwall, MD, noted that a year ago the committee had given the FDA a broad industry consensus on how to craft the waived test criteria. "I remember Steve Gutman using the analogy of you're passing the ball, so Steve can run with it. It looks like you stumbled, or at least haven't run," Sundwall said. "It should be out for public comment by now."

As broadly defined in the CLIA statute, waived testing involves simple lab exams that (1) are cleared by the FDA for home use, (2) employ methodologies that are so simple and accurate as to render the likelihood of erroneous test results negligible, or (3) pose no reasonable risk of harm to the patient if performed incorrectly. But the criteria to use when granting waived status to a product became controversial

when the FDA took over the CLIA categorization function from the Centers for Disease Control & Prevention and began waiving an ever-expanding number of analyte-specific devices. A major flashpoint over the criteria came when the FDA, pressed by the White House and top HHS echelons, waived a rapid HIV-1 test, citing public health needs, despite objections from CDC and CLIAC (*see box, p. 5*).

"The waiver guidance is a problem for us," Cooper acknowledged, "because we don't have it done and it introduces a lot of uncertainty. We do want to get this out to the public." One source said the snag involves continuing disagreement between the FDA

CLIAC At A Glance

- ❑ Established under the CLIA statute (Clinical Laboratory Improvement Amendments of 1988).
- ❑ Provides scientific and technical advice to HHS agencies on lab regulatory standards, technological advances, and their impact on medical and lab practice.
- ❑ Consists of 20 members, including the chair. Members are selected by the HHS Secretary and serve for overlapping terms of up to four years. The panel also consists of three voting ex officio members from CMS, FDA, and CDC, as well as a non-voting liaison representative from the Advanced Medical Technology Association.
- ❑ Meetings of the parent committee are held at least twice yearly (with additional meetings as needed). Meetings are open to the public.
- ❑ Management and support services are provided by CDC.

and the CDC, particularly over which scenarios for waived test usage to consider. FDA wants to look strictly at intended use; CDC wants to also consider likely misuse, this source said.

Quality In Waived Testing Still Problematic

In its 2004 sample survey of CLIA-waived labs, the Centers for Medicare & Medicaid Services found that many still had some quality issues. CMS visited 1,742 labs and issued 860 letters of compliance, 719 letters of recommendation, and 42 statements of deficiency. Overall performance was slightly better than for the 1,575 waived labs surveyed the year before. CMS found that 20% of the waived labs surveyed in

2004 were not performing quality control, 11% were not following the test manufacturer's instructions (some because they lost them, others because they didn't understand them), and 4% were testing beyond the scope of their waiver certificate.

Judy Yost, the top CLIA official at CMS and its ex officio representative on CLIAC, told the panel that two of the labs were placing patients in "immediate jeopardy." Committee member Cyril "Kim" Hetsko, MD, FACP, said this is an "order of magnitude" improvement over previous findings, but still unacceptable, as it may represent 166 cases of immediate jeopardy every year throughout the nation's 100,000 CLIA-waived labs.

Yost noted that it does help when CMS or state agencies instruct waived labs on how to improve quality. When CMS checked up on labs it had previously surveyed, the agency found they were following the new procedures it had

showed them. CMS continues to find that in states with lab licensure laws, CLIA-waived labs "perform outstandingly," Yost said.

CLIAC agreed to prepare an article on quality control problems at CLIA-waived labs, along with recommendations to address them. CLIAC will base the article on findings from the CMS sample surveys, along with the results of a CLIAC workgroup on good laboratory practices for waived testing. The article is expected to appear this fall in the CDC's *Morbidity & Mortality Weekly Report*.

The committee agreed to develop a comprehensive, high-level document on waived lab quality control, from which it would draw the *MMWR* article, a brief digest of highlights written at the seventh-grade level, a top 10 list of recommendations, and perhaps other products as well. Some committee members expressed hope that other organizations would spread copies of the report, as many did when CMS published the CLIA regulations and when CDC issued its universal precautions for healthcare workers.

Speaking Up For Rapid HIV Waiver Benefits

New CLIAC board member Patrick Keenan, MD, has personal experience with how the rapid HIV-1 waived test has increased access to testing among hard-to-reach or ignored at-risk populations. Keenan, a family physician with North Memorial Clinic in Minneapolis, MN, noted, "Some of these waived testing sites in the pipeline for the future are really designed to be done on street corners by non-laboratorians and, hang onto your hats, they're also designed to be done by consumers at home. I think we need to take that into account.

"I'm most familiar with the rapid HIV test, that's what I work with. The reason why it was waived was because of the failure of non-rapid testing. About 30% of clients never learned the test results. That translates every year to about 6,000 to 8,000 persons who have a positive test and never learn the results. To me, that is the definition of imminent jeopardy.

"In Minneapolis in the past few years, we've tested 3,000 persons at high risk for HIV. We've gone on-site to gay bars, chemical dependency programs, homeless shelters, drug courts, sex trade worker organizations, you name it. Over 99% of our clients have learned their test results, on average, within 28 minutes after their fingerstick.

"The persons doing this outreach have not been laboratorians. Their last jobs have included bus driver, bartender, clerical worker, printer, and they've done excellent work. We've diagnosed 15 persons with HIV. I think it's safe to say they wouldn't have accessed the testing establishment for a long time. Fourteen went on to anti-retroviral therapy."



CMS hopes to issue a proposed CLIA rule on genetic testing later this year, said top CLIA official Judy Yost. Work on the rule "has been overtaken by other events," she said

Equivalent QC Gets Another Look

Yost said that CMS is looking into improving on the controversial equivalent quality control policy the agency adopted in January 2003 as part of its final QC regulation. The idea of labs and test manufacturers putting systems in place to allow substantially reduced frequency of liquid controls was greeted with "mixed reviews," Yost said. "So, we have got to look at the future of where we need to go with quality control." Just two years after publication of the QC rule, technology already has begun to outgrow it, Yost commented. For example, the rule contains conflicting specialty-specific requirements that are a problem for new devices that include tests in multiple lab specialties in a single platform.

Yost called CLIAC's attention to a March 18 "QC for the Future" workshop on equivalent QC, which the Clinical & Laboratory Standards Institute (formerly NCCLS) will host in Baltimore, MD, to air the issues and work toward consensus. (For more information or to register, call CLSI at 610-688-0100 or visit <http://nccls.org>.)

CDC would like QC for non-waived testing to be a major topic at the CLIAC meeting scheduled for September 7-8, said the agency's Rhonda Whalen. Regulators will need to account for a great variety of test systems, some of which involve various types of built-in QC and other checks or balances. It may be that the manufacturer's instructions will have to identify these checks in greater detail. There may be a need for performance data templates that manufacturers would customize for their tests and labs would fill with data. Traditional QC and alternative QC schemes would have to co-exist, she noted. "It is complicated and very difficult to look at all the aspects because the technology is so diverse."

Getting A Firmer Grip On Accredited Lab Oversight

In response to widely reported lab quality lapses in Maryland, Yost reported that CMS, private accrediting organizations, the two CLIA-exempt states (Washington and New York), and others drafted a set of rapid-response criteria at their second meeting on improving CLIA accreditation oversight, held in Atlanta just before the CLIAC meeting. The groups first got together last November after disclosures of faulty HIV-1 testing and falsifying of records at the Maryland General Hospital lab in Baltimore (*NIR*, 26, 5/Dec 16, '04, p. 4).

The idea behind the rapid-response criteria is that if an oversight agency encounters a problem situation, it would immediately alert other involved agencies to devise a joint response, Yost said. The oversight agencies, she added, compared survey protocols to identify critical elements that all protocols should include.

The situation at Maryland General, where the College of American Pathologists accredited the lab without detecting the deficiencies, "was an isolated incident," Yost asserted. "This is not a pervasive problem ... it came about because the lab was willfully falsifying records. Not the best surveyor in the world was going to find it." That said, CMS and the other players are now addressing the gaps in communication among the oversight agencies, she noted.

Meanwhile, yet another overseer—the congressional General Accountability Office (formerly known as the General Accounting Office)—is getting involved. U.S. Rep. Elijah Cummings (D-MD), in whose district Maryland General is located, requested an audit of lab quality oversight and GAO began it at CMS on January 6. "I can tell you it's not a scanty overview. It's a deep and broad review of the entire program," Yost told CLIAC, covering every aspect of the CLIA regulatory program. 🏠



Providers Lagging On HIPAA Security Compliance

The final security rule requires HIPAA-covered entities, including any healthcare provider that transmits protected health information electronically, to prevent others from accessing such information while it is in electronic form

Despite the fast-approaching April deadline to comply with the final HIPAA security rule, a new survey discloses that many healthcare providers aren't ready to meet it. In a winter 2005 survey, released February 16, the Healthcare Information & Management Systems Society and Phoenix Health Systems found that only 18% of providers had achieved compliance—unchanged from six months earlier. Only 74% expect to comply by the deadline—down 13% from six months earlier.

“With the deadline only weeks away, these numbers are cause for concern,” said Joyce Sensmeier, HIMSS director of professional services. “The continuing lack of compliance may be compromising the overall HIPAA objectives and jeopardizing the ability to maintain privacy of protected health information.”

The security standards, effective April 21, are part of a series of rules promulgated in accord with HIPAA (the Health Insurance Portability & Accountability Act of 1996) to facilitate electronic data exchange. Related rules already in effect apply to privacy, the employer identifier, and electronic transactions and code sets.

The HIMSS/Phoenix Health Systems survey found the toughest HIPAA security standards for providers to implement were:

- Audit controls (55%)
- Risk management/risk analysis (49%)
- Information system activity review (48%)
- Data backup/disaster recovery/emergency mode operation plan (39%)

The American Hospital Association reported even graver findings at a January 27 federal advisory committee meeting. Of 475 organizations surveyed in an AHA conference call, only 9.3% were compliant. Most were in the planning stages. AHA's Roslyne Schulman suggested that many may be suffering from “HIPAA burnout.” 🏠

◆ QUESTION of the M·O·N·T·H

We follow the new American Diabetes Association guidelines for diagnosing diabetes by performing two tests: fasting glucose, CPT 82947, followed two hours later by the glucose challenge test, CPT 82950. Will we be reimbursed for both if we bill them together under Medicare's new diabetes screening benefit?

No, according to Marcel Salive of the Centers for Medicare & Medicaid Services' coverage group. The ADA guidelines apply to diagnostic testing, performed, for example, when a patient presents with signs and symptoms of diabetes. The screening benefit covers any one of three tests annually for Medicare beneficiaries with certain diabetes risk factors (*NIR*, 26, 6/Jan 10, '05, p. 2), and every six months for those previously diagnosed with pre-diabetes (defined as a fasting glucose level of 100-125 mg/dL or a two-hour post-glucose challenge of 140-199 mg/dL).

As a practical matter, it would be most appropriate for those with diabetes risk factors, but no pre-diabetes, to take the fasting glucose test, CPT 82947, Salive said. The glucose challenge test, CPT 82950, might be particularly relevant for a beneficiary whose fasting glucose was somewhat elevated the previous year. The third option—CPT 82951, glucose tolerance test (GTT)—would be best for those deemed most likely to have pre-diabetes, Salive suggested. 🏠



Legislative Update

LAB OVERSIGHT: Rep. Elijah Cummings (D-MD) on February 9 re-introduced the Clinical Laboratory Compliance Improvement Act (H.R. 686), which he had first proposed last year in the wake of lab quality failures at Baltimore’s Maryland General Hospital, which is in his district. The bill protects whistleblowers, requires unannounced inspections by accrediting bodies, and calls for better coordination among federal, state, and private lab regulatory bodies.

BAN ON GENETIC DISCRIMINATION: In our last issue, we reported that the Senate unanimously passed a bill (S. 306) barring employers and insurers from discriminating against individuals with a genetic predisposition to disease. Armed with this victory as well as White House support, proponents are talking with senior House Republicans about sponsoring a House version. Democratic Rep. Louise Slaughter (NY) sponsored a similar measure last year, but the three GOP-controlled committees to which it was referred never acted on it. Health insurers have long opposed such legislation, which has been kicked around for eight years, but this is changing. America’s Health Insurance Plans, in a February 22 letter to key House committee heads, expressed support for the Senate bill. Employer groups still oppose it.

LAB REIMBURSEMENT: Sen. Ben Nelson (D-NE) on February 1 introduced the Critical Access to Clinical Lab Services Act (S. 236), which would let critical access hospitals get cost-based Medicare payment for lab tests on specimens they obtained off-site. 🏠

Conference Countdown

Time’s running out, so act now and sign up for our 2005 Outreach Conference, ***Building Profitability in a Competitive Outreach Market.***

When: March 31-April 1.

Where: Renaissance Concourse Hotel, Atlanta, GA.

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