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CMS Pulls The Plug On CLIA Genetic Testing Rule

The agency instead will strengthen its oversight of genetic testing labs under current CLIA rules, including new guidance for inspections, technical training of inspectors, and provider education aids.

Work to establish CLIA specialty requirements for genetic testing has been percolating inside the Health & Human Services bureaucracy for several years. Tentative release dates for a proposed rule have even been published in updates of the HHS semiannual regulatory agenda.

Now, however, the rulemaking effort has been scrapped, federal officials told the Clinical Laboratory Improvement Advisory Committee at its recent meeting in Atlanta. There is no sufficient rationale to impose special CLIA rules on genetic testing at this time, they said, nor is it clear how such rules could address related sensitive issues, including counseling, informed consent, confidentiality, and liability.

Instead of pursuing further regulation, the Centers for Medicare & Medicaid Services will beef up its oversight of genetic testing labs under existing CLIA rules, Judy Yost, the top CLIA official at CMS, told *NIR*. Genetic testing is already subject to high-complexity testing requirements, the most stringent level of CLIA regulation, she also noted. ➥ *p. 2*

Physician Fee Fix Left For Later

Physician groups that have been lobbying hard to prevent a 5.1% cut in Medicare payments for physician services next year will have to redouble their efforts in the "lame-duck" session of Congress scheduled for mid-November. Without congressional intervention, the cut is set to begin January 1, 2007.

Congress recessed at the end of September without taking any action on the impending pay cut. Lawmakers are likely to grant at least a zero update or a modest increase when the issue comes up in the lame-duck session, according to Capitol Hill watchers. But it's unclear how the issue would be impacted if Democrats gain control of at least the House.

Before lawmakers left town, physician lobbies rejected several plans put forth at the eleventh hour by Senate and House health leaders. One was a $6 billion plan floated by the Senate Finance Committee, which would have granted a 0.5% physician fee increase in 2007 and an additional 1.5% for doctors who report quality measures. Also rejected were plans with similar updates plus new performance bonuses that were offered by Ways & Means and Energy & Commerce health leaders. ➥ *p. 6*

INSIDE *NIR*

CLIA Genetic Testing Rule, *from p. 1*

Drafts for a proposed CLIA rule specific to genetic testing have been circulating for some time around the three HHS agencies that share jurisdiction over CLIA: CMS, the lead agency for standards and oversight; the Centers for Disease Control & Prevention, which advises on scientific and technical matters; and the Food & Drug Administration, which handles premarket review and CLIA test categorization. But according to lab industry sources, the draft rulemaking encountered a lot of "push-back" over questions of validation authority and controversial social issues.

CMS decided against moving forward with a rulemaking for several reasons, Yost said:

- ❑ It would not resolve the problem that these tests are not currently FDA-approved and, therefore, not necessarily clinically validated.
- ❑ CMS has no data indicating any more problems in genetic testing labs than in other labs.
- ❑ There is no (or very little) proficiency testing for genetic test products at this time.
- ❑ Since the genetic testing field is evolving so rapidly, it would be impossible to write prescriptive standards that would not become quickly outdated.
- ❑ CMS does not have staff available to facilitate clearance of special genetic testing requirements, given higher-priority regulations in development throughout the agency.

In lieu of more regulation, CMS will rely on current CLIA rules and provide specific guidance to lab inspectors to help assess compliance for genetic tests, along with technical training from subject matter experts on current technologies, Yost said. The agency also will develop educational guidance for genetic testing labs. In these efforts, CMS plans to tap the expertise of CLIA-approved accreditation organizations, some of which already have molecular diagnostics standards, she noted. Further, CMS will work with CDC and FDA on complex analytical test validations and development of PT alternatives as well as continuing oversight of genetic testing labs.

While CMS has pulled back from further genetic testing regulation, FDA moved ahead last month to tighten its rules for lab tests developed in-house and require premarket review for certain types of "home-brew" tests that are gene- or protein-based and combine assays and algorithms to produce results tailored to a specific patient. Examples of these tests, which FDA calls In Vitro Diagnostic Multivariate Index Assays, include proprietary tests to diagnose and guide treatment for breast and other cancers, cardiovascular disease, and Alzheimer's disease (*NIR, 27, 22/Sep 25 '06, pp. 4-5*).

The FDA's stance makes it all the more imperative to recognize CLIA as the appropriate vehicle for assuring the quality of genetic testing, Alan Mertz, president of the American Clinical Laboratory Association, told *NIR*. While some requirements could be tightened, CLIA has done a relatively good job in assuring safety nationwide, he said. ACLA is concerned that adding more requirements could stifle innovation and deny patients access to quality care. The Association also says an overly broad regulatory definition of genetic testing could sweep in many tests which have some genetic component but not necessarily an inherited one, including routine cholesterol or glucose checks, basic blood counts, and DNA-based tests for non-inheritable abnormalities.

What Could Election Upset Mean For Healthcare Legislation?

Polls at press time show the Democrats have a good shot at the 15-seat net gain they need to recapture the House and could even pick up more seats.

When Congress assembles for a "lame-duck" session in mid-November, it will have on its plate not only "must-pass" items like tax and spending bills, but also the Medicare physician fee fix and other legislation affecting pathologists and clinical laboratories. And given recent polls and scandals, there is speculation about what impact the midterm elections would have on healthcare legislation, especially if Democrats gain control of the House at least.

One obvious outcome would be a change in the leadership of key House health committees. On Ways & Means, the chairman's post would pass to Charles Rangel (NY) and the health subcommittee chairman's slot would go to Fortney "Pete" Stark (CA), replacing Nancy Johnson (R-CT). At Energy & Commerce, John Dingell (MI) would take the chair from Joe Barton (TX), while it's unclear which Democrat would replace health subcommittee chairman Nathan Deal (GA). The ranking Democrat, Sherrod Brown (OH), is seeking a Senate seat.

Stark, however, doesn't think anything too much will happen on the healthcare agenda even if the Democrats capture the House. In remarks on September 28 at Lab Institute 2006, sponsored by Washington G-2 Reports/IOMA in Arlington, VA, Stark said there would likely be a stalemate since the President has the veto power and the Democrats would not have enough votes to ensure an override.

On the issue of universal healthcare coverage, Stark advised the Institute audience not to expect this at the federal level. He thinks universal coverage will come, drip-by-drip, from the bottom up as states increasingly step in to assure coverage of the uninsured. An estimated 46 million Americans are without health insurance coverage.

Asked by G-2 editor Kim Scott what his position on lab competitive bidding would be if he became chairman of the Ways & Means health panel, Stark said this issue would be considered, adding that he doesn't think bidding is a good way to go about saving Medicare money.

House Bill Would Replace CLIA Cytology PT Program

Legislation introduced in the House shortly before Congress recessed at the end of September would replace the existing cytology proficiency testing program under CLIA (the Clinical Laboratory Improvement Amendments) with an alternative that does away with annual PT of pathologists and laboratory professionals who do Pap smear screening and diagnosis.

The bill instead would require annual continuing medical education that provides opportunities for improving screening and interpretation skills. The College of American Pathologists, which is spearheading the lobbying campaign for the legislation, says this approach is modeled on that used by the Food & Drug Administration to assure mammography quality. CAP is opposed to the existing CLIA cytology PT program, saying it is based on outdated science and clinical practice and needs a fundamental overhaul.

On the regulatory front meantime, the Centers for Medicare & Medicaid Services recently told the Clinical Laboratory Improvement Advisory Committee that a proposal for revised CLIA cytology PT rules will not be ready until at least February

2007. As a result, PT testing next year will continue under the current rules. There are two nationally approved PT providers: the College of American Pathologists and the American Society for Clinical Pathology. The Maryland health department runs an approved program for specimens of state residents.

At a CLIAC meeting earlier this year, CMS committed itself to revamping the existing PT rules, including addressing such issues as the frequency of testing, scoring, penalties, and diagnostic categories. CMS and CDC formed a workgroup to consider changes in the regulation as well as a timeline for public comment. CMS agreed to revisit the PT rules not long after the House passed a bill to suspend the current program until certain changes were considered (*NIR, 27, 6/Jan 9 '06, p. 3).* CMS said that while revisions were in the works, it would use PT to emphasize improvement vs. punitive sanctions (*NIR, 27, 8/Feb 6 '06, pp. 4-5*). The current rules were written in 1992, but CMS only began nationwide enforcement in January 2005.

Stalemate Emerges Over Expanded E-Health Safe Harbors

Compromise on legislation to promote wider use of health information technology (HIT) by hospitals, physicians, labs, and other providers has thus far eluded members of Congress and their staff, who have been meeting to iron out differences between versions passed by the House and the Senate. A big roadblock has emerged over whether the Stark safe harbors for physician self-referrals should be expanded, Jason DuBois, vice president of government relations for the American Clinical Laboratory Association, told *NIR*.

Proponents argue that expanded protections for HIT donations to physician referral sources are needed to advance the President's initiative to promote national use of e-health records by 2014. Democrats, fearing new opportunities for fraud, are reluctant to broaden the curbs on self-referrals of Medicare and Medicaid patients to facilities with which the physicians have a financial relationship, DuBois said.

The Senate bill (S. 1418) makes no safe harbor provisions. The House bill (H.R. 4157) would allow donations of HIT software and training to physicians by hospitals, group practices, prescription drug sponsors, Medicare Advantage plans, and other providers specified by the HHS Secretary. Unlike recently finalized HHS e-health anti-kickback and Stark safe harbor rules that take effect this October 16, the House bill contains no requirements that doctors pay 15% of donated HIT, allows hardware donations and is not limited to software, and does not mandate a "sunset" deadline for the safe harbors after 2013. The HHS rules also specifically recognize clinical labs as covered providers and allow HIT hardware and software donations for e-prescribing purposes.

Also awaiting reconciliation is a proposed transition from the ICD-9 diagnosis and procedure coding system to version 10. The Senate bill contains no such provision. H.R. 4157 includes a compromise on the all-payer transition. The switch to ICD-10 for billing and payment purposes, involving more than 120,000 codes, would be required as of October 1, 2010. The Ways & Means Committee had approved a 2009 deadline, while Energy & Commerce was silent on the issue. A broad coalition of healthcare providers, including ACLA, supports a deadline of no earlier than 2012, citing the complexity and costs involved.

CDC Calls For Routine HIV Screening Of Teens, Adults

Early diagnosis will help curb the spread of HIV infection and get those infected into life-extending therapy quickly. CDC estimates that 25% of the one million Americans infected with HIV do not know it.

HIV screening should be part of routine medical care for all patients ages 13 to 64, in all healthcare settings, regardless of risk or prevalence, the Centers for Disease Control & Prevention has recommended in newly revised guidelines. The screening should be voluntary, the agency emphasizes. The patient is to be notified that the testing will be performed, be educated about HIV infection and treatment, and given the option to decline the screening.

CDC also recommends:

- ❑ Consent for HIV screening should be incorporated in the general consent form for medical care. Separate written consent is not recommended.
- ❑ Persons at high risk for HIV infection should be tested at least once a year.
- ❑ Pre-test counseling is not required. While all patients should be educated about HIV infection and treatment, CDC says counseling should be focused on individuals who test positive.

The agency also is adding to its guidelines for HIV testing of pregnant women:

- ❑ Include HIV screening in the routine panel of prenatal screening tests for all pregnant women, unless the patient opts out.
- ❑ Repeat screening in the third trimester in certain jurisdictions with elevated rates of HIV infection among pregnant women.

The newly revised guidelines were published in the September 22 issue of CDC's *Morbidity & Mortality Weekly Report*. They replace CDC's 1993 guidance for hospital patients and update 2001 guidelines for pregnant women (*NIR, 27, 17/Jun 29 '06, p. 7*).

FDA Expands Access To Blood Lead Screening Test

The agency grants CLIA-waived status to a rapid point-of-care test made by ESA Biosciences.

In a move to broaden screening nationwide for blood lead levels, the Food & Drug Administration has granted CLIA-waived status to a rapid point-of-care test previously restricted to clinical laboratories performing CLIA moderate or high complexity testing.

The FDA says that waived status will make the test available to more than 115,000 certified point-of-care contacts throughout the country, including healthcare clinics, mobile health units, and schools, and will allow children and adults to be tested and treated for lead poisoning much easier and faster.

The test—the LeadCare II Blood Lead Test System made by ESA Biosciences (Chelmsford, MA), a subsidiary of Magellan Biosciences—is used to detect harmful levels of lead, using a finger stick or venous whole blood sample It is performed while the patient is present, with results in as little as three minutes. The rapid result means a second sample for further testing can be obtained quickly if needed, reducing the need for a follow-up visit. The test is payable under CPT 83655 on the Medicare lab fee schedule, currently capped at $16.91.

More than 300,000 children under age six each year have blood levels that exceed 10 milligrams per deciliter, the threshold used to indicate lead poisoning, reports the Centers for Disease Control & Prevention. Blood levels above that number need to be confirmed by another laboratory method. Lead poisoning in children has been linked to learning disabilities and developmental delays.

Congress has repeatedly blocked a Medicare physician fee cut and granted an increase, though one year it let the cut go through and restored the funding retroactively.

Physician Fee Fix, *from p. 1*

Physician groups said none of the plans addresses even deeper fee cuts after 2007 under the SGR (sustainable growth rate) formula used to calculate fee updates. Without a fix to the SGR, says the College of American Pathologists, physician payments are scheduled to be cut by 37% over the next nine years, "on top of the 20% reduction in aggregate pay rates since 2001." Physician groups also questioned whether the plans provided sufficient funding to hike physician fees and also grant higher reimbursement for reporting quality measures.

Congress is not inclined to tackle replacing the SGR formula for now, but in the short term, a multi-year fix is being considered vs. revisiting the physician fee issue every year to prevent cuts. One option is a three-year fix with a zero or modest update and quality reporting measures at an estimated cost of $20-$30 billion.

How to fund a physician fee update is of great concern because lawmakers could find the money by cutting pay rates for other healthcare providers. Replacing the SGR-based system would cost $218 billion over 10 years, the Congressional Budget Office estimates.

CAP Urges Congress To Protect Pathology TC Billings

In the November "lame-duck" session of Congress, one big priority for the College of American Pathologists—and the American Clinical Laboratory Association as well—is passage of legislation to continue the "grandfather" protection for certain pathology technical component billings.

The protection, which expires at the end of this year, allows independent clinical labs to be paid by Medicare for the TC of pathology services to hospital inpatients and outpatients. The Centers for Medicare & Medicaid Services has proposed not to revive it. CMS regards the TC as paid under the hospital's DRG reimbursement and says labs should seek payment from the hospital instead.

CAP-backed legislation to make the protection permanent has been introduced in both the House (H.R. 6030) and the Senate (S. 3609). The protection applies to hospitals that used an independent lab for pathology TC services as of July 22, 1999, the date when CMS first proposed eliminating these hospital/lab business arrangements. Congress has intervened a number of times—most recently in the 2003 Medicare reform law—to block CMS's plan.

Under current policy, the "grandfather" protection applies to the hospital, not the lab. So, hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. Medicare also has defined the TC of pathology services to include not only anatomic services, but also cytopathology and surgical pathology (CMS Transmittal AB-01-47).

About 95% of 4,773 PPS hospitals and critical access hospitals outsourced some TC pathology services to labs that received direct payment for those services in 2001, according to the latest data from the Government Accountability Office. By eliminating direct payment, Medicare would have saved $42 million in 2001, the GAO estimated, while beneficiary cost-sharing for inpatient and outpatient services would have been cut by $2 million.

Award Recipients Honored At Lab Institute 2006

Renown educator and researcher **Michael Laposata**, MD, PhD, is the recipient of Washington G-2 Reports' **2006 Laboratory Public Service National Leadership Award**. The award, sponsored by Kellison & Co., was presented September 28 at Lab Institute 2006 in Arlington, VA.

Dr. Laposata

Board-certified in clinical pathology, Dr. Laposata is director and chief of the division of clinical laboratories at Massachusetts General Hospital in Boston and is a professor of pathology at Harvard Medical School. He was cited by an independent selection committee for scientific and educational leadership in pathology and laboratory medicine nationally and internationally. Noted achievements include promotion of interpretive rounds and consultative services for pathologists in clinical practice and the identification of novel methods for detecting recent alcohol intake, possible mechanisms for alcohol-induced tissue damage, the relation between alcohol and decreased thrombosis. More recently, his work has extended into advances in cystic fibrosis.

Dr. Laposata also frequently sees patients with clotting and bleeding disorders. He is an internationally recognized expert in hemostasis, has published well over 100 peer-reviewed articles, and has served several pathology professional societies in a variety of capacities.

Arikpo Onda

Arikpo Onda, currently at the blood center at Rush University Medical Center in Chicago, is this year's recipient of the **Dennis Weissman/Washington G-2 Reports' Scholarship Award for Excellence in the Clinical Laboratory Sciences**, also presented at Lab Institute 2006.

Selected for demonstrated leadership potential and excellence in the clinical laboratory sciences curriculum, she is vice president of the CLS student club at Rush University and has been active in motivating classmates and organizing events. She has just begun her tenure as the student forum chairperson for the American Society for Clinical Laboratory Science-Illinois.

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Code Change For Fecal Occult Blood Screening

Effective January 1, 2007, the Medicare program will retire HCPCS code G0107 for fecal occult blood screening and replace it for billing and payment purposes with CPT 82270—Blood, occult, by peroxidase activity (e.g., Guaiac) qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (*i.e.*, patient was provided three cards or single triple card for consecutive collection).

The change applies to claims with dates of service January 1, 2007 and later. Claims with dates of service December 31, 2006 and earlier should use G0107 (CMS Change Request 5292, September 22, 2006).

Fecal occult blood screening is part of the Part B colorectal cancer screening benefit, which also includes flexible sigmoidoscopy (G0104), colonoscopy (G0105 and G0121), and barium enemas (G0106 and G0120).

Norwalk Named As Acting Head Of CMS

No change is expected in the agency's priorities, including continuing implementation of the Part D drug benefit and the push for Medicare pay-for-performance programs to reward physicians who report quality measures.

Leslie V. Norwalk, deputy administrator of the Centers for Medicare & Medicaid Services, has been selected as acting head of the agency, Health & Human Services Secretary Michael Leavitt has announced. Norwalk will take over the post October 15, when administrator Mark McClellan, MD, PhD, departs. McClellan announced his resignation early last month (*NIR, 27, 21/Sep 11 '06, p. 2).*

Norwalk has held top posts at CMS over the past five years, coming to the agency as a counselor to former administrator Thomas A. Scully, who later picked her to take on the responsibilities of deputy administrator and chief operating officer. McClellan promoted her to deputy administrator in January 2004. Before joining the Bush administration, Norwalk practiced law in the Washington office of Epstein Becker & Green, PC, advising clients on health policy issues.

As acting deputy administrator, Norwalk has selected Herb B. Kuhn, who for the past two years has served as director of the CMS Center for Medicare Management, which handles provider reimbursement policy. Kuhn is a former corporate vice president for advocacy at Premier Inc., a nonprofit hospital alliance.

washington WATCH

HHS Secretary Michael Leavitt has named **Robert Kolodner**, an official at the Veterans Affairs Department, to serve as interim national coordinator for health information technology, in charge of the Bush administration's campaign for widespread adoption of electronic health records in healthcare. He succeeds the first coordinator, David Brailer, who held the job for two years before moving on last spring.

At the VA, Kolodner was chief informatics officer and involved with development and oversight of MyHealtheVet and VistA, the VA's e-health records system for patients and clinicians, respectively.

On Capitol Hill meantime, the President's nomination of **Andrew von Eschenbach** to head the Food & Drug Administration cleared the Senate HELP Committee without objection on September 20. Von Eschenbach has been acting FDA commissioner for the past year. Confirmation by the full Senate could be contentious since some Senators want to grill him about the agency's stance on drug importation and birth control devices.

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