WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 26th Year of Publication

Vol. 26, No. 2, October 25, 2004

'To Guarantee Universal Healthcare Coverage, Require It'

Ted Halstead, president and CEO of the New America Foundation, and a keynote speaker at Lab Institute 2004

Mandatory self-insurance is the most promising solution to the Nation's healthcare crisis, policy expert Ted Halstead told the 600+ participants at Lab Institute 2004, sponsored by Washington G-2 Reports on Sept. 29-Oct. 2 in Arlington, VA. Halstead, who heads the New America Foundation, a Washington-based think tank, said that similar to having auto insurance, individuals should be required to purchase basic health insurance, with public subsidies available to those who can't afford the full cost.

This approach not only would make coverage universal and fully portable across life for all Americans, but also would rely on private insurers to compete for consumers. The risk pool would be broadened by bringing in many millions of the uninsured below age 35, thus helping drive down costs for basic medical care.

In Halstead's view, the plans backed by the presidential candidates are flawed. He likes the focus in President Bush's plan on consumer choice, but criticized the plan as too miserly. Sen. Kerry's plan, while more ambitious and fair, he said, is too expensive and too complex and only props up failed structures in the current system. For more on other challenges posed at Lab Institute, see the *Focus*, pp. 3-6.

INSIDE NIR

CPT 2005 Approves Genetic Test Modifiers

CPT 2005, the American Medical Association's just-published compendium of codes for medical services, establishes new numeric-alpha modifiers for genetic tests as well as new coding schemes for certain flow cytometry and surgical pathology exams, among a host of other changes to lab and pathology coding.

The coding changes will take effect on Jan. 1, 2005—and in a break with the past—Medicare will no longer give providers 90 days (from Jan. 1-Mar. 31) to incorporate the changes. As of Jan. 1, providers should bill only active codes. The grace period has been eliminated under HIPAA electronic transaction and code set requirements.

CPT 2005 contains a new Appendix I, listing new modifiers that "should be used" when reporting molecular laboratory procedures for genetic tests performed beginning Jan. 1. The first digit of each modifier is a numeric code relating to one of 10 disease categories. The second is a capital letter denoting gene type, with the letter "Z" reserved for gene types "not otherwise specified." ➥ *p. 2*

For an expert interpretation of the 2005 CPT lab and pathology coding changes, plus tips on achieving a glitch-free switch, don't miss our Nov. 18 audioconference with coding expert Diana Voorhees. To register or get more information, visit our Website, www.g2reports.com*, or call 800-401-5937, ext. 2*

Genetic Test Modifiers, *from p. 1*

When coders use the procedure-specific molecular pathology codes 83890-83912, AMA instructs them to use the appropriate genetic-test modifier to specify the probe type or condition tested for molecular diagnostic procedures that are performed for infectious diseases, oncology, hematology, neurology, or inherited disorders. Similarly, AMA says appropriate genetic-test modifiers should be added when using cytogenetic study codes (88230-88299) for oncologic or inherited disorders.

The disease category codes for genetic tests are:

- ❑ 0 Neoplasia (solid tumor)
- ❑ 2 Neoplasia (lymphoid/hematopoetic)
- ❑ 3 Non-neoplastic hematology/coagulation
- ❑ 4 Histocompatibility/blood typing
- ❑ 5 Neurologic/non-neoplastic
- ❑ 6 Muscular, non-neoplastic
- ❑ 7 Metabolic, other
- ❑ 8 Metabolic, transport
- ❑ 9 Metabolic-pharmacogenetics
- ❑ 9 Dysmorphology

CPT 2005 does not explain why it skips a "1" modifier or why two categories share the "9" modifier. Modifiers for some of the better-known genetic disorders include: 0A for BRCA1 (hereditary breast/ovarian cancer); 3A for Factor V (Leiden, others) (Hypercoagulable state); and 8A CTFT (Cystic fibrosis). The complete list appears on pages 438-439 of *CPT 2005*.

Flow Cytometry Changes

Next year's coding update makes a major change in cytopathology coding, establishing per-marker coding for flow cytometry. CPT is deleting 88180 (Flow cytometry; each cell surface, cytoplasmic or nuclear marker) and adding five new flow cytometry codes:

- ❑ 88184, Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only, first marker
- ❑ 88185, each additional marker (List separately in addition to code for first marker)
- ❑ 88187, Flow cytometry, interpretation, 2 to 8 markers
- ❑ 88188, 9 to 15 markers
- ❑ 88189, 16 or more markers

Surgical Pathology Changes

In this coding section, there are five new and revised codes to distinguish between certain computer-assisted and manual services:

- ❑ 88360 (new), Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quant. or semiquant., each antibody; manual
- ❑ 88361 (revised), Same as previous code, but using computer-assisted technology
- ❑ 88365 (revised), In situ hybridization (eg FISH), each probe
- ❑ 88367 (new), Morphometric analysis, in situ hybridization (quant. or semiquant.), each probe; using computer-assisted technology
- ❑ 88368 (new), Same as previous code but manual

Other Lab-Related Changes

CPT 2005 includes 11 new CPT lab codes, which Medicare proposes to reimburse via the Part B lab fee schedule (*National Intelligence Report, 25, 22/Sept. 27, '04, p. 1*). The CPT update adds the terms "breath test" and "(eg, C-13)" to the descriptor for 83013, Heliobacter pylori; breath test analysis for urease activity, non-radioactive isotope (eg, C-13). Descriptors are also revised for 83014, drug administration; 84165, protein; and 85045, reticulocytes.

focus on: Lab Institute 2004

FRAMING the BIG PICTURE

Tech Trends

Quality

Pricing

Payment

On Sept. 29-Oct. 2, some 600+ clinical laboratory and pathology participants came together at Lab Institute 2004—sponsored by Washington G-2 Reports in Arlington, VA—around the theme, *Framing the Big Picture*, for a hard look at the impact of government policy reforms, market pricing pressures, test quality concerns, and new diagnostic technologies on their industry.

More Pressure on Medicare Spending

For Medicare spending, it's tough times ahead, speakers warned, pointing to mounting cost pressures from the burgeoning federal budget deficit, the financial strain of baby-boomer retirement starting at the end of the decade, and financing needed for the prescription drug benefit established by last year's Medicare Modernization Act.

The Act approved billions in tax breaks and other subsidies to help managed care plans and pharmaceutical companies compete in the Medicare market, boosted Medicare payments to certain hospitals, and endorsed a 1.5% hike this year and next in Part B physician fees. Labs got a different deal. Their Part B fees were frozen over five years (through 2008) in lieu of the return of a 20% co-pay. The Act added coverage of a screening benefit for heart disease and diabetes, starting in 2005, but how generous that will be is up to the Centers for Medicare & Medicaid Services.

Federal red ink, to flow for some time to come, will keep clinical labs and other healthcare providers on the defensive. Institute speakers with Capitol Hill experience predicted that regardless of who wins the November elections, the incoming 109th Congress will be pressed to cut domestic spending, and Medicare payment reductions aren't off the table. The lab co-pay, defeated last year, isn't dead and buried, the speakers cautioned—with its promise of some $18 billion in savings, it could get a second look. Competitive bidding is also moving ahead, as Medicare gets to work, at congressional insistence, on a design for a competitive bidding demonstration for Part B independent lab services. For pathologists, a big concern is whether lawmakers will fix the Medicare physician fee schedule to avert a cut projected for 2006.

Costs & Quality

Cutting costs while still achieving high-quality services has become even more crucial for clinical labs. Quality has been found compromised in widely publicized incidents—including two in Baltimore, one involving the Maryland General Hospital lab and the other, Reference Pathology Services (*NIR, 25, 21/Sept. 13, '04, p. 1; 25, 16/Jun 7, '04, pp. 4-6*). Quality concerns have also been raised in point-of-care testing by the proliferation of CLIA-waived devices.

Meantime, the genetic revolution is raising the stakes. More sophisticated and more expensive tests are expected to reach the market soon and could become available to a broad array of personnel with varying technical and on-the-job skills. And Medicare is now linking payments to performance, starting this fiscal year with inpatient hospital care. Could labs and other providers be next?

Among private payers, there is growing interest in using information from clinical diagnostic testing to pay test-ordering physicians for performance, as well as identifying high-risk patients for intensive disease management programs. Jeff Danilo, who heads Jeff Danilo Healthcare Consulting (Doylestown, PA), called the Institute audience's attention to the role that labs could play in helping health insurers pay doctors for performance. Aetna Excel, he said, awards 12 specialties for performance, based partly on lab data showing, for example, that diabetes patients got timely HbA1c tests. David Nichols, founder of Nichols Management Group (York Harbor, ME), suggested that labs might need to upgrade their information-technology capability to participate in such pay-for-performance programs.

At the Centers for Disease Control & Prevention, a "best practices" lab quality initiative is advancing, reported Toby Merlin, MD, associate director for lab medicine in the agency's lab systems division. CDC has reached agreement with the National Quality Forum to help with business and legal planning for a new public-private partnership, dubbed the Institute for Quality in Laboratory Medicine. The standards that could emerge could, some in the audience noted, become a template for policy reforms linking lab payment to recognized quality measures.

Access & Quality

The Food & Drug Administration is poised to issue draft criteria for CLIA-waived testing, said Steve Gutman, MD, MBA, in his remarks at the Institute. Gutman is director of the FDA Office of In Vitro Diagnostic Device Evaluation & Safety (Rockville, MD). FDA hopes to finish drafting a Level 1 proposed guidance for internal review within weeks, he said. The goal is to win departmental approval in time to release the guidance later this year or early in 2005. Based on comments, FDA would then issue a final guidance and begin a formal rulemaking process.

Gutman previewed the key features of work thus far:

- ❑ *What's not new:* the basic criteria for test simplicity; CLIA labeling requirements; and the CDC requirement for flex or stress studies.
- ❑ *What's a little new:* the term "untrained user" will focus on the intended user population such as a nurse, a physician's assistant, a medical secretary, or a physician working in a multi-tasking setting.
- ❑ *What's gone:* rigorous post-market surveillance of waived-test vendors (instead, FDA intends to expand its own pilot active surveillance program, MEDSUN); requirements for reference methods and materials; quality control requirements where federal agencies use "empiric judgment" to set QC frequency in the absence of real data.
- ❑ *What's new:*
  - —Instead of requirements for reference methods and materials, FDA will default to a European system, ISO 17511, that relies on traceability to a calibration method.
  - —A stronger emphasis on risk analysis and fail-safe or failure alert mechanisms.
  - —More focus on performance. Studies for quantitative tests would be at three or more sites, with three or more operators and 100 or more samples per site, and would take place over, say, 20 working days instead of just one or two focus group sessions.

The Next "Big Bang"

The sequencing of the human genome and the accelerating pace of molecular diagnostics have created the potential for a new era of "personalized medicine," based on ge-

nomic profiling. Cancer treatment is in the forefront of this trend. Randy Scott, PhD, co-founder, chairman, and CEO of Genomic Health (Redwood City, CA), described a new molecular diagnostic test his company developed that is well positioned for what he expects will be "a major shift in the valuation of therapeutics vs. diagnostics."

Genomic Health's first test, which won CLIA approval in January, quantifies the likelihood of recurrence of a type of breast cancer that accounts for more than 50% of all cases. It is designed to help a breast cancer patient and her physician decide in the two weeks after surgery whether chemotherapy is warranted. Scott said that, while under current guidelines, 89% of women with this type of breast cancer undergo chemotherapy at a total cost of $1.5 billion, only 4% actually benefit from it. With chemotherapy costing $15,000 per patient or more, his company's Oncotype Dx test would save money if it cost less than $7,500. So at $3,460—the asking price—it's a bargain. That said, Scott told the Institute audience, "We set out this year with the top three goals of our company being reimbursement, reimbursement, and reimbursement."

"Genomics and biotechnology as a whole are almost exactly where the computer industry was in the mid-1970s, meaning we're just at the dawn of the personal computer, or the equivalent in healthcare," Scott said. The exponential growth that Intel founder Gordon Moore had predicted for computing power and that Metcalf's Law predicted for the utility of networks such as the World Wide Web will apply to medical practice, now that the human genome has been decoded, he said. Though initial progress has been slow, he expects it to quicken.

Panelists in the concluding Institute session (from left): Robert Moran, interim executive VP, Clinical Laboratory Management Assn.; Paul Pomerantz, executive director, American Society of Plastic Surgeons; Elissa Passiment, executive VP, American Society for Clinical Laboratory Science; Dennis Weissman, founder, Washington G-2 Reports, panel chair; Nicki Norris, executive VP, College of American Pathologists; Richard Flaherty, executive VP, American Assn. for Clinical Chemistry; Mark Birenbaum, executive director, American Assn. of Bioanalysts

Lab Interests Meet Market Realities

In the Lab Institute wrap-up session on Oct. 2, top association executives representing leading laboratory and pathology groups tackled the current and future role—and relevancy—of professional organizations in helping members meet changing practice demands while capitalizing on emerging market opportunities.

All recognized that the lab and pathology share of healthcare dollars is under assault and robust lobbying is crucial. The unity achieved by the Clinical Laboratory Coalition in defeating the lab co-pay last year was cited as one successful model for future collaboration. But panelists also noted the need to find ways to stem a long, steady decline in association membership and recruit new, younger blood.

"What keeps organizations apart is ego," said Paul Pomerantz, former executive director of the Clinical Laboratory Management Association and now head of the American Society of Plastic Surgeons. "There's a huge cost in maintaining separate, distinct infrastructures," which suggests joint initiatives can't accomplish as much as could a consolidation of lab groups. Mark Birenbaum, president of the American Association of Bioanalysts, disagreed, noting that the diversity of groups in the lab field reflects the varying legitimate interests of their members. Speaking from the audience, LabOne executive Wendell O'Neal, said, "We've got to get past those individual constituencies and get to a common point" and come together "in a way that serves the higher interests of the laboratory community."

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In a separate session, Debra Leonard, MD, PhD, of New York Presbyterian Hospital, Cornell Campus (New York City), noted that while molecular diagnostics "is the fastest growth area in lab medicine," the field faces continued difficulties in coding, high costs, and low reimbursement. Leonard is vice chair of lab medicine at the department of pathology & laboratory medicine. The 2005 update to CPT should clear up much of the coding confusion, she predicted (*related story in this issue, p. 1*).

Factors such as royalties, the high number of controls required for each test run, and the use of expensive commercial test kits drive costs up, Leonard said. But reimbursement remains generally low. For example, Medicare pays $59.20 for hepatitis C viral load testing, which costs labs on average $99.18. Thanks to advocacy by groups such as the Association for Molecular Pathology, Medicare set a $118.89 cap for HIV viral load testing, which involves the same procedure. Now the association is urging Medicare to lift the HCV cap, using its "inherent reasonableness" process.

Cost-Cutting Perils

On the surface, they looked just like typical community hospital laboratories, Kathy Murphy, PhD, of Park City Solutions noted in an Institute session. But inside there were major quality lapses. The consulting firm was called in to solve problems at a California hospital after a transfusion-related death and at the Maryland General Hospital lab after an investigation of a whistleblower's complaint. "Cost was a huge driver. It was all-consuming, all important for these two organizations," Murphy said.

The problems were manifold. Instead of demanding clinical excellence, the pathologists serving as medical directors appeared to be "disengaged." To save money, they paid as low as 25% below market and maintained vacancy rates as high as 30%. With the low pay, they had difficulty finding job applicants who could even pass the drug screen. Consequently, the staff were not up to the task at hand. People were promoted to management without the necessary training and development. "In both of these organizations we saw non-technical staff who were doing technical jobs … it's because they did not have technologists to do it."

Unfortunately, Murphy continued, regulatory inspections of these labs "did not show any real big problems—don't you think that's a problem?"

For the first 6-8 months of its work with the labs, Park City Solutions focused more on helping regulators re-examine lab policies and procedures than on tackling underlying operational issues, "an interesting comment on the state of the regulatory process in this country." To improve lab operations, the firm convinced each hospital to become the market's highest payer instead of its lowest one, and to add recruitment and retention bonuses.

Park City Solutions is relying on Rick Oulette, president and CEO of Management Decision Systems (Holden, MA), to help monitor and improve quality on a daily basis. Oulette warehouses data streamed from the lab information system to produce daily reports on performance factors, such as how well the labs met their promise to turn around stat orders in an hour and to report early morning results by 8 a.m. The aim is to accelerate error discovery and change, creating an environment where it's good to find and fix problems, Oulette said.

Regulatory Initiative Yields First New TDM Assay In A Decade

AACC members have been clamoring for such test kits so they can run their own therapeutic drug management procedures, instead of sending samples to reference labs for "home-brew" testing

Working together, representatives of clinical laboratories, test manufacturers, and the Food & Drug Administration have opened a door to more test kits for gene markers that help physicians set dosage levels for pharmaceuticals. The FDA has ended a 10-year drought of approvals of such kits, thanks to a regulatory drive by the American Association for Clinical Chemistry's Therapeutic Drug Management (TDM) Renaissance Committee.

The committee was established three years ago to encourage development of TDM kits, which had languished because test makers were unwilling to invest in research for these niche products, given the high cost and long lead time required for clinical trials and outcome studies needed for full pre-market approval.

One advantage of using kits is standardization, explains Paula Stonemetz, a member of the TDM Renaissance Committee and director of business development for Microgenics, the Fremont, CA, maker of the first TDM test kit to win FDA approval in a decade. She said there can be a 40% variation in results from "home-brew" tests. More importantly, kits promise rapid turnaround time—one day or even same-day, compared to 2-6 days for "home-brews."

AACC members surveyed in October 2002 said the TDM tests they most needed to offer, based on customer demand, were to monitor levels of (1) sirolimus, an immunosuppressant for transplant recipients; (2) gabapentin, an anti-epileptic; (3) lamotrigine, an anti-epileptic; (4) mycophenolic acid, an immunosuppressant metabolite of micophenolate mofetil; and (5) clozapine, an anti-psychotic for treating schizophrenia.

The TDM committee worked with FDA to establish a roundtable that included other industry groups—the American Medical Technologists, American Society for Clinical Laboratory Science, American Society for Clinical Pathology, and the College of American Pathologists. The committee also drafted several sets of assay-validation recommendations, which the roundtable later approved. The TDM Renaissance Committee held its final meeting July 26. Two days later, FDA's Office of In Vitro Diagnostics approved an application from Microgenics to reclassify its CEDIA sirolimus assay from a class III device (requiring premarket approval) to class II (special controls), using the committee's assay validation recommendations for sirolimus, as adopted by the TDM roundtable. FDA's approval appeared in the Sept. 30 *Federal Register*.

♦CODING A·D·V·I·S·O·R·Y

For years, Medicare has given us 90 days to install CPT coding changes approved for the year beginning Jan. 1. That gave us through Mar. 31 to update our lab's coding and billing systems. It was helpful too because the CPT update comes out in the last quarter of the year, so we didn't have to scramble to make all the changes. Now, I hear that grace period will no longer be granted. Why?

Medicare says this is necessary to comply with a requirement in the electronic transaction and code set rules under HIPAA (the Health Insurance Portability & Accountability Act). According to HIPAA, only active codes valid at the time a medical service, such as lab testing, is furnished should be billed. As of Jan. 1, 2005, Medicare will reimburse only active codes.

Pathology, Inpatient Lab Services On OIG's Study List

Next year, the HHS Office of Inspector General intends to review pathology services performed in physicians' offices, which account for more than $1 billion a year of Medicare spending, the agency said in its fiscal 2005 work plan. The work plan is issued annually and gives providers a snapshot of the OIG's priorities for investigation and enforcement.

The OIG will focus on relationships between physicians who furnish pathology services and outside pathology companies. Pathology and lab groups hope the OIG is heeding their call for scrutiny of flourishing new arrangements that allow physician specialty groups to profit from pathology services that they refer to off-site "pod labs" managed on their behalf (*NIR, 26, 1/Oct. 11, '04, p. 6; 25, 18/Jul 5, '04, pp. 4-6; 25, 17/Jun 21, '04, p. 1*).

In other areas, the OIG plans to:

- ❑ Assess compliance with CLIA proficiency testing requirements.
- ❑ See how much hospitals are billing Medicare for unallowable laboratory services for inpatients. An estimated $73 million of inpatient lab services were billed to Medicare in calendar 2001, a considerable increase over prior years.
- ❑ Make sure that states are paying no more than Medicare for laboratory and pathology services reimbursed under Medicaid. The OIG is concerned that at least one state continues to pay too much.

The work plan for 2005 is posted online at *oig.hhs.gov/publications/workplan.html#1*.

In Memoriam

A well-known and respected leader—a true Renaissance man with whom we worked over many years—**Bernard Statland**, MD, PhD, on Oct. 19 succumbed to a brain tumor. He lived in Rockville, MD, after obtaining a law degree from the University of Minnesota, and most recently was of counsel to Arent Fox (Washington, DC).

A board-certified clinical pathologist, Dr. Statland's career spanned some three decades in all sectors of the laboratory field—academic, commercial, and hospital—including serving as director of the Office of Device Evaluation at FDA's Center for Devices & Radiological Health.

For many years, he edited the "Tips for Technologists" column for *MLO* magazine. He also served on the board of the National Committee for Clinical Laboratory Standards.

Bernie was extraordinary in so many ways, we will miss him but always cherish his legacy.

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