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FDA Holds Forum on Lab-Developed Test Oversight

"Although FDA has decided to exercise its authority over laboratory-developed tests, we have not made any decisions about how to exercise that authority," said Jeffrey E. Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health, in his opening statement. "That's what this two-day meeting is about."

The Food and Drug Administration (FDA) last month announced that it is reconsidering the way it regulates laboratory-developed tests (LDTs). This month the agency convened a public meeting for comments on how changes in oversight policy should proceed.

At the July 19-20 forum in Hyattsville, Md., FDA officials got an earful of suggestions, concerns, and frustrations from approximately 700 stakeholders, including laboratory professionals, clinicians, and industry representatives. The officials also got the chance to brief the public on the issues that have prompted the FDA to take a new look at its regulatory stance on LDTs. These are in vitro diagnostics that are manufactured by and offered in the same laboratory.

The agenda ranged from public presentations to panel discussions on patient and clinical considerations concerning LDT oversight, clinical laboratory challenges, direct-to-consumer testing, and education and outreach.

LDTs include some genetic tests as well as others used to prevent, diagnose, and treat patients with a wide range of cancers,

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Code Changes on the 2011 Lab Fee Schedule: What Should the Pay Rates Be?

The Centers for Medicare and Medicaid Services (CMS) has begun the annual fee-setting process, required by law, for coding additions and other changes to next year's Medicare lab fee schedule, which takes effect Jan. 1.

CMS launched the process at a July 22 public meeting at its Baltimore headquarters, inviting public advice on setting payment rates for:

- ❑ 11 new CPT codes in drug testing, chemistry, hematology and coagulation, immunology, transfusion medicine, and microbiology.
- ❑ Five HCPCS G codes that CMS has established internally.
- ❑ Four contested CPT codes on the current fee schedule. CMS wants input on requests it has received to reconsider its payment decisions for these codes.

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cardiovascular and neurological disease, Alzheimer's, and many other serious health conditions.

FDA Concerns

The FDA's move on oversight of LDTs comes in the wake of a bid last May by Pathway Genomics to sell its genetic tests directly to consumers through the Walgreens national chain of pharmacies. The FDA blocked that plan, saying the tests are subject to premarket review. The case also drew the agency's attention, and ultimately that of a congressional committee, to other genetic testing companies making online direct-to-consumer (DTC) sales. The controversy further prompted the FDA to reconsider how it handles the broader field of LDTs.

Next steps: The FDA said it will review comments from the July meeting, as well as those submitted to the docket by Aug. 15, and develop, for further public comment, a draft oversight framework for lab-developed tests. Such a framework would likely be phased in over time, based on the level of risk associated with the test.

Currently, labs performing LDTs are regulated under standards different from the premarket review required of test kit manufacturers. But the labs are subject to the highest quality standards under the Clinical Laboratory Improvement Amendments (CLIA).

Courtney Harper, Ph.D., of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), described the current regulatory strategy as bifurcated, with commercially distributed tests and LDTs taking divergent paths to market. Meantime, biopharmaceutical giant Genentech and AdvaMed, the medical device industry lobby, have filed petitions with the FDA to end the separate treatment.

The proportion of tests taking the LDT route, which does not require FDA review, has climbed in the past 10 to 15 years, Harper said, and the volume and variety of LDTs has grown exponentially. The self-determined nature of LDT status is also problematic, she said. "An LDT is not always lab-developed."

Commercially offering LDTs through a CLIA-certified laboratory created specifically for that purpose is now frequently used as a mechanism for market entry, allowing novel tests to reach the national market without going through the FDA. "We see LDT being used more and more as a loophole," said Elizabeth Mansfield, Ph.D., director for personalized medicine at OIVD. "Preliminary medical data is being packaged as medical information."

FDA representatives conceded they have no clear idea of the scope of the LDT market they are seeking to regulate and suggested that efforts to learn who is offering what tests would be coordinated with the National Institutes of Health, which recently announced its plan to develop a genetic testing registry. "There are thousands of LDTs out there. Most have been offered safely and efficaciously for many years," said Gail Vance, M.D., representing the College of American Pathologists (CAP). "If I were the FDA, I would start by gathering data. Get to know the universe—CAP, CLIA. It's going to take a considerable amount of effort to bridge the CLIA and FDA worlds."

Risk was also on the minds of the stakeholders. Would more FDA oversight stifle innovation by test developers, deprive patients and clinicians of the latest testing

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Lab Fee Update: Negative Outlook for 2011

Clinical laboratories can expect to see a cut in their Medicare reimbursement next year under a new formula to be used to calculate the annual update to the Part B lab fee schedule. This is the second year in a row that the update is headed into negative territory. This year's update cut, the first in the fee schedule's 25-year history, is minus 1.9 percent.

The new update formula, effective Jan. 1, 2011, is based on the consumer price index for all urban consumers (CPI-U), minus a multifactor productivity (MFP) adjustment. In addition, there is a percentage adjustment of 1.75 percent for each of years 2011 through 2015. Application of the MFP adjustment can never result in a negative update; however, the percentage adjustment can. The formula change was mandated by the health care reform law, the Patient Protection and Affordable Care Act (PPACA).

The CPI-U update applicable to the 2011 lab fee schedule is 1.1 percent, according to a July 16 release from the Bureau of Labor Statistics. For purposes of the fee schedule, the CPI-U is based on the figure for the 12-month period ended June 30 of the year preceding the update year.

What won't be known until later this year is the MFP adjustment. The Centers for Medicare and Medicaid Services (CMS) will announce this figure in the final 2011 physician fee schedule rule, typically published in October or November.

However, in the proposed physician fee schedule rule published in the July 13 *Federal Register*, CMS spelled out how it would apply the MFP adjustment. "If the CPI-U update factor is positive, it would be reduced by the MFP. However, if application of the MFP would result in a negative update, the update would be held to zero."

Currently, the MFP adjustment is estimated at 1.3 percent. Assuming it continues to hover at or around this mark, it would trigger a negative update when subtracted from the CPI-U increase of 1.1 percent. The update would thus be held to zero, but clinical labs would still have to absorb a percentage adjustment cut of 1.75 percent, as of Jan. 1, 2011.

MFP Adjustment

The PPACA statute defines the productivity adjustment as "equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, or other annual period)."

Multifactor productivity relates output to a combination of inputs used in the production of that output, such as labor and capital or capital, labor, energy, materials, and purchased business services (KLEMS). Capital includes equipment, structures, inventories, and land.

CMS is proposing to align the determination of the MFP adjustment with the CPI-U. "Since the CPI-U update factor is reduced by the MFP adjustment to determine the annual update for the lab fee schedule, we believe it is appropriate for the numbers associated with both parts of the calculation to be projected as of the same end date (in this case, June 30th of the year preceding the update year itself). In this way, changes in market conditions are aligned."

Pathology Takes a Hit in Final IT 'Meaningful Use' Rules

Starting in 2011, physicians and hospitals are eligible for Medicare or Medicaid financial incentives when they adopt and make "meaningful use" of certified electronic health record (EHR) technology.

The rules are scheduled to appear in the July 28 Federal Register. *The meaningful use final rule will be effective 60 days after publication, while the rule on standards and certification will be effective 30 days after publication.*

Two final rules were issued July 13 to implement the program. The meaningful use rule specifies the objectives that providers must meet in payment years 2011 and 2012 to qualify for incentive payments. The certification rule specifies the technical capabilities that EHR technology must have to be certified and to support providers in meeting meaningful use criteria.

But most pathologists are unlikely to qualify for the incentives, according to a preliminary analysis in the July 22 issue of *Statline* from the College of American Pathologists (CAP). "The rule requires reporting of quality measures that are largely outside the pathologists' practices."

The American Society for Clinical Pathology also raised similar concern in its comments on the proposed rule, saying the objectives focused on primary care, vital signs, immunizations, screenings, medications, and other clinical information to which the pathologist or laboratory would not likely have access.

The CMS rule affects direct incentive payments to pathologists in independent practice and hospital-based pathologists who practice primarily in ambulatory settings. But by law, hospital-based physicians who perform substantially all of their services in inpatient hospital and emergency care settings are not eligible for direct payments. They are considered covered under the hospital's incentive payment and must negotiate their share with the hospital.

Pathologists and other eligible professionals will have to meet 15 specific objectives, down from the 25 originally proposed. Hospitals will have to meet 14 requirements, down from the 23 proposed. They also will have a separate menu of objectives, five of which they can defer in 2011 and 2012.

Both CAP and the American Medical Association (AMA) are "currently analyzing the impact on their members, specifically how measures that do not fit a physician practice can or should be reported or 'credited,'" *Statline* noted, adding that the AMA and 95 state and specialty medical societies had been critical of the earlier proposed rule, cautioning that it was too aggressive and would prevent many physicians from participating.

CAP and ASCP have previously urged that pathologists be exempt from the EHR functionality measures and the clinical care measures. Given the reliance of other physicians on pathology and laboratory information, pathologists and labs providing information electronically to their clients should be deemed as meeting reporting requirements. But CMS denied the exemption request, CAP noted.

Dollars at Stake

According to the final rule's economic analysis, incentive payments under Medicare and

The College of American Pathologists has previously expressed concern that the definition of meaningful use does not recognize the differences among physician specialties and subspecialties and does not accommodate those not engaged in core functionalities for e-prescribing, information exchange to coordinate care, or reporting clinical measures.

Medicaid EHR programs from 2011 to 2019 will range from $9.7 billion to $27.4 billion.

The financial incentives were approved as part of the economic stimulus package, the American Recovery and Reinvestment Act of 2009 (Public Law 111-5), in a bid to jump-start public and private collaboration leading to a nationwide system of electronic health records that will achieve health, quality, and efficiency goals.

According to a CMS fact sheet, "Eligible professionals can receive as much as $44,000 over a five-year period through Medicare. For Medicaid, eligible professionals can receive as much as $63,750 over six years." Those who sign on early gain the most. If the first payment year is 2011 or 2012, the bonus is $18,000. Otherwise, it is $15,000 for the first payment year. Medicare EHR incentive payments will begin in mid-May 2011, CMS said.

While the incentive program is voluntary, there are penalties for eligible professionals who do not participate and fail to meet meaningful use requirements. Their Medicare reimbursement will be reduced by 1 percent beginning in 2015 and in subsequent years by up to 5 percent.

Three-Stage Phase-In

Instead of the "all or nothing" approach found in the proposed rule for meaningful use, the final rule divides the objectives for Stage 1 into a "core" group of required objectives (15 for eligible professionals and 14 for eligible hospitals) and additional optional objectives, from which providers can choose five to defer in 2011 or 2012 to Stage 2.

Final Rules for E-Health Record Incentive Program

HHS Office for Civil Rights: Rule announced July 8 to expand privacy protections under the Health Insurance Portability and Accountability Act (HIPAA) to ensure EHR acceptance and use.

HHS Office of the National Coordinator (ONC) for HIT: Rule published June 24 to establish a process through which organizations can be approved as certifying entities to which vendors may submit their EHR systems for review and certification.

ONC: Rule announced July 13 governing technical standards that must be met in the certification process.

CMS: Rule announced July 13 setting requirements for achieving meaningful use in clinical settings and qualifying for incentive payments based on this meaningful use.

Meaningful use criteria will be phased in over the next several years in three stages.

- ❑ Stage 1: Collect electronic health data in coded formats and rport health information usable to track key clinical conditions.
- ❑ Stage 2: Implement structured data exchange and continuous quality improvement in coordinated care.
- ❑ Stage 3: Improve oucomes by providing advanced decision support and tracking of population health priorities. CMS said that it will raise the bar in requirements for Stages 2 and 3 in future rule making, "establishing graduated criteria for demonstrating meaningful use consis tent with anticipated developments in technology and providers' capabilities."

Code Changes on the 2011 Lab Fee Schedule, *from p. 1*

Two methods are used to set rates on the lab fee schedule: crosswalk or gap-fill. The crosswalk method matches a new test code to a similar existing code and pays at that code's rate (the lower of the local fee schedule amount or the national fee cap).

The comment period on the lab codes ends Sept. 24. A summary of CMS's preliminary payment determinations and all comments received by Aug. 6 will be posted on its Web site (cms.hhs.gov/ClinicalLabFeeSched) in early September. Final determinations will be posted in October, CMS said.

The gap-fill method is used when there is no comparable existing test. In this case, local contractors set the fee for the first year, based on local pricing patterns such as charges for the test, routine discounts, resources needed for the test, and what other payers pay. CMS then taps these local amounts to set a fee cap for following years.

New CPT Lab Codes

These test codes (*last two digits to be finalized*) were developed and are copyrighted by the American Medical Association.

Drug Testing

- ❑ **801XX**, Drug screen, qualitative; multiple drug classes other than chro matographic method, each procedure (this CPT code takes the place of the HCPCS code G0430)

Chemistry

- ❑ **829XX**, Gastric acid analysis, includes pH if performed, each specimen
- ❑ **838XX**, Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity
- ❑ **841XX,** Placental alpha microglobulin-1 (PAMG-1), cervicovaginal secretion, qualitative

Hematology and Coagulation

- ❑ **855XX**, Phospholipid neutralization; hexagonal phospholipid

Immunology

- ❑ **864XX**, Tuberculosis test, cell mediated immunity antigen response measure ment; enumeration of gamma interferon-producing T-cells in cell suspension

Transfusion Medicine

- ❑ **869XX**, Blood typing; antigen testing of donor blood using reagent serum, each antigen test

Microbiology

- ❑ **875XX1**, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, reverse transcription and amplified probe technique, each type or sub type
- ❑ **875XX2**, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, reverse transcription and amplified probe technique, first two types or subtypes
- ❑ **875XX3**, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, multiplex reverse transcription and amplified probe technique, each additional influenza virus type or subtype beyond two

(List separately in addition to code for primary procedure)

- ❑ **879XX**, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion)

HCPCS G Codes

- ❑ **GXXX1**, Drug screen, other than chromatographic; any number of drug classes, per specimen
- ❑ **G9143**, Pharmacogenomic testing for Warfarin response
- ❑ **G0432**, Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening. Short descriptor: EIA HIV-1/HIV-2 screen
- ❑ **G0433**, Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening. Short descriptor: ELISA HIV-1/HIV-2 screen
- ❑ **G0435**, Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening. Short descriptor: Oral HIV-1/HIV-2 screen

Requests for Reconsideration

The agency also has received requests to reconsider the pricing already set for the following codes (amounts below are the current national cap):

- ❑ **84145**, Procalcitonin (PCT). $27.76.
- ❑ **84431**, Thromboxane metabolite(s), including thromboxane if performed. $18.54.
- ❑ **86352**, Cellular function assay involving stimulation (e.g., mitogen or antigen) and detection of biomarker (e.g., ATP). $97.30.
- ❑ **G0430**, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure. $20.83.
- ❑ **G0431**, Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class. $19.72.

Interest Rate Up for Medicare Overpayments, Underpayments

Effective July 21, 2010, the rate of interest that Medicare will pay you for claims that are underpaid, or collect from you for claims that are overpaid, has risen to 11 percent. This is up from 10.875 percent in effect from April 23 through July 20 and down from the rate of 11.25 percent in effect from Jan. 25 to April 22 of this year. The highest rate in the past decade was in early 2001, 14.125 percent, but for most of the years since, the rate has hovered between 11 percent and 12 percent.

Medicare regulations provide for assessing interest at the higher of the current value of funds rate (1 percent for calendar year 2010) or the private consumer rate fixed by the Treasury. Upon notification from the Treasury of the new private consumer rate at 11 percent, the Centers for Medicare and Medicaid Services announced the quarterly update to the Medicare interest rate in Change Request 6654 (July 14, 2010).

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technologies, burden the small clinical labs for which the LDT designation was originally designed, and overtax the limited resources of the FDA?

There was a widespread call for the FDA to undertake in-depth research on many fronts, including how clinicians and patients are using LDTs and how they understand the result, before proceeding with draft LDT guidance. "We have to go forward in a very measured way, identify gaps, and fully understand what's at stake," said Alan Mertz, president of the American Clinical Laboratory Association (ACLA), who also called for a broad grandfather exception for existing, established tests. "Labs are labs, not manufacturers. We are a service provider."

Also prominent in the discussions were collaborative roles in LDT oversight. CAP and ACLA have favored CMS in the lead under CLIA, with the FDA in a consultative role. A collaborative solution was also favored by Judy Yost, director of laboratory services at CMS and head of the CLIA program. "A public-private partnership is probably a good way to go. We clearly offer the resources of CMS and CLIA to assist in this process." The FDA said it is considering using CLIA inspectors for the LDT inspection process.

• Upcoming G-2 Events •

Webinar

Aug. 17
Medicare Changes on the Horizon: Assessing the Potential Impact on Labs, Pathologists, and Imaging Providers
2 – 3:30 p.m. (Eastern)

Conferences

Oct. 13
Lab Leaders Summit
Come for the Summit and Stay for Lab Institute
Crystal Gateway Marriott
Arlington, Va.

Oct. 13-15
28th Annual Lab Institute
Making Change Work for You
Crystal Gateway Marriott
Arlington, Va.

Dec. 8-10
Laboratory Sales and Marketing 2010
The Venetian Las Vegas
Las Vegas

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