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Laboratory-Developed Tests Back in the FDA Spotlight

The agency says it is time to reconsider its policy of enforcement discretion over these tests. "At this time, a risk-based application of oversight to these tests is the appropriate approach to achieve desired public health goals."

The Food and Drug Administration (FDA) will hold a public meeting July 19-20 in Rockville, Md., to obtain comments on how the agency can effectively regulate laboratory-developed tests (LDTs). These are in vitro diagnostics that are manufactured by and offered in the same laboratory. They include some genetic tests as well as others that may lead patients to make important medical decisions.

The public meeting comes on the heels of the FDA's recent crackdown on companies that market their genetic tests directly to consumers. On June 10 the agency notified five companies that their respective tests do not fall within the current LDT regulatory scheme but are medical devices subject to premarket review. In May, the agency squelched plans by Pathway Genomics to sell its personal genetic tests through Walgreens nationwide pharmacy chain (*NIR 10, 10/May 25, pp. 4-5*).

Expansion of FDA oversight of LDTs is a highly controversial issue pitting clinical laboratory and pathology groups against test manufacturers. But in scheduling the public meeting, the FDA has signaled that it wants to take a fresh look at how it regulates LDTs. For more on the issue, see the *Focus*, pp. 4-5.

Obama Signs Six-Month Increase for Medicare Physician Payments

President Obama June 25 signed into law legislation that provides a 2.2 percent update to fees paid under the Medicare Part B physician fee schedule retroactive from June 1 through Nov. 30, 2010.

The bill, the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, passed the House June 24 following Senate approval of the measure June 18.

The legislation cancels the 21 percent cut in Medicare physician fees that took effect June 1 when the congressionally mandated freeze keeping fees at their 2009 levels expired May 31.

The Centers for Medicare and Medicaid Services (CMS) had directed contractors to hold physician claims with a date of service on or after June 1 through June 17, anticipating congressional action by then.

But on June 18, with no legislative reprieve, CMS began processing

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INSIDE *NIR*

New Rules Interpret 'Grandfather' Provision for Health Plans

As reported in our previous issue, health plans had a lot riding on how the government would interpret a "grandfather" protection for them granted by the health care reform law. Plans in the group and individual markets that qualify are not required to provide a number of consumer protections, as of Sept. 23, 2010, including coverage of certain clinical laboratory, pathology, and other prevention services with no cost sharing (*NIR 10, 11/June 10, p. 2*).

The interpretation came in the June 17 *Federal Register*, where three federal departments—Health and Human Services, Labor, and Treasury—released interim final rules on what constitutes a grandfathered plan and how that status can be forfeited.

Under the Patient Protection and Affordable Care Act, plans existing on March 23, 2010, the day the law was enacted, are exempt from the full consumer protections that take effect Sept. 23, including coverage with no cost sharing of:

- ❑ Preventive services with an A or B rating from the U.S. Preventive Services Task Force (*NIR 10, 9/May 5, p. 5*).
- ❑ Recommended immunizations from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.
- ❑ Preventive care and screenings for infants, children, and adolescents as stipulated in guidelines supported by the Health Resources and Services Administration.

Changes Allowed, Not Allowed

Insurers and employers may make routine changes to copayments, deductibles, and contributions to employee premiums and retain grandfather status. These changes include cost adjustments to keep up with medical inflation, adding new benefits, modest adjustments to existing benefits, voluntarily adopting new consumer protections under the health care reform law, or making changes to comply with state or other federal laws.

Plans must fully disclose to enrollees and potential customers whether they are grandfathered, thus enabling consumers to understand the benefits of staying with a plan or switching to a new one. Premium changes are not taken into account when determining whether a plan is grandfathered.

Plans lose grandfather status if they make significant changes that reduce benefits or increase costs to consumers. They are then considered "new plans" and enrollees in plans that make such changes will gain new consumer protections, as of Sept. 23, including recommended clinical lab, pathology, and other prevention services with no cost sharing, access to ob/gyns and pediatricians without a referral by a separate primary care provider, and emergency care.

Case Examples of Changes Not Allowed

The rules provide some examples of how plans and coverage could forfeit grandfather status. Compared to their policies and coverage in effect on March 23, 2010, grandfathered plans *cannot:*

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Lab, Pathology Groups Seek Delay in July 6 PECOS Deadline

Clinical laboratory and pathology groups have registered strong objections with the Centers for Medicare and Medicaid Services (CMS) to a new requirement, effective July 6, 2010, that would adversely affect payment of claims for laboratory testing, imaging, and specialist services.

These claims would be denied when the ordering or referring physician is not enrolled in Medicare's Provider Enrollment, Chain, and Ownership System (PECOS) or has a valid opt-out record, and when the physician is not identified on the claim by his or her legal name and National Provider Identifier (that is, the NPI assigned by the National Plan and Provider Enumeration System as an Entity Type 1.

The deadline is one of a series of changes made by the health care reform law and intended to weed out fraudulent entities from legitimate health care providers and suppliers, making it harder for the former to bill federal health care programs.

The requirement is contained in an interim final rule, published in the *May 5 Federal Register* with a 60-day comment period, that implements changes made by the Patient Protection and Affordable Care Act (PPACA) to Medicare and Medicaid enrollment and reimbursement requirements.

The law requires that ordering or referring physicians of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and home health services be enrolled in Medicare by July 1, 2010. CMS added clinical laboratory, imaging, and specialty services, using its discretionary authority granted under PPACA. Affected providers must document orders/referrals for seven years. Failure to comply could lead to revocation of Medicare enrollment for up to a year (*NIR 10, 10/May 25, p. 2*).

Postponement Sought

The College of American Pathology (CAP), in its comments on the rule, urged CMS to "restrict the July 6 deadline to services named in the law, DMEPOS and home health, and permit physicians who order or refer for laboratory, imaging, and specialist services to enroll or re-enroll by Jan. 3, 2011." CAP said that "by implementing the discretionary provisions of PPACA on July 6, CMS is rescinding on very short notice its previous Jan. 3, 2011, deadline which is more realistic in terms of getting all these physicians enrolled in PECOS."

The American Clinical Laboratory Association, in its comments, urged CMS to exempt clinical laboratory services altogether from the interim final rule. "It is unfair to penalize laboratories because ordering or referring physicians are not enrolled in PECOS, a circumstance over which a lab has no control." It has no way to compel a physician to have an active enrollment record. However, "if these services are not to be exempt, CMS should implement the Jan. 3, 2011 deadline and continue to permit the billing lab to use its own NPI on claims until then."

Both ACLA and CAP question CMS's logistical ability to meet the July 6 deadline, having repeatedly delayed implementation of the PECOS database to tackle enrollment and outreach glitches. The agency expects to have it fully loaded by the end of the year, "including those who enroll solely to continue to order and refer." ACLA counters that from CMS's admission that PECOS will not be complete by July 6, "it is clear CMS is not in any position to implement the interim final rule for lab services [by then]."

focus on: Genetic Testing

FDA to Reconsider How It Regulates Lab-Developed Tests

Only days after notifying five manufacturers that their genetic tests marketed directly to consumers are not considered laboratory-developed tests (LDTs) but are medical devices subject to premarket review, the Food and Drug Administration (FDA) announced that it will convene a public meeting next month to air wider issues and proposals on how it should change the way it regulates LDTs.

The term laboratory-developed test refers to in vitro diagnostics that are manufactured by and offered in the same laboratory. They include some genetic tests as well as others used in screening or diagnostic services to prevent, diagnose, and treat patients with a wide range of cancers, cardiovascular and neurological disease, Alzheimer's, and many other serious health conditions.

The forum to be held July 19-20 in Rockville, Md., will feature an overview of the history and current regulatory status of LDTs, plus discussions on patient considerations, challenges for labs, direct-to-consumer (DTC) test marketing, and education and outreach. The FDA will review comments from the meeting and develop a draft oversight framework for public comment "with the goal of providing a level of predictability as quickly as possible." Such a framework would be phased in over time based on the level of risk of the test.

Expanded Regulation Controversial

FDA oversight of LDTs is a highly sensitive issue within the lab industry. The agency asserts that it has jurisdiction under the law to regulate all tests as medical devices, whether developed by clinical labs for in-house testing or by manufacturers for use in kits.

But the FDA has limited its regulation of LDTs thus far to analyte-specific reagents used in these tests and to a category of genetic tests known as In Vitro Diagnostic Multivariate Index Arrays which use a proprietary algorithm to generate a patient-specific result. Most LDTs thus far do not fall under FDA review but are regulated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA).

LDTs and diagnostic test kits are subject to different standards and uneven enforcement, the FDA has acknowledged. Seeking to level the playing field, biopharmaceutical giant Genentech and AdvaMed, lobbying for major medical device makers, have petitioned the agency to treat all LDTs the same as test kits, except for low-risk tests. The American Clinical Laboratory Association and the College of American Pathologists oppose this stance, arguing that further FDA regulation would stifle innovation and impede patient access to the latest technological advances. Moreover, they point out, LDTs are subject to the most stringent requirements under CLIA and these are sufficient to assure the test's validity and utility.

Why the New Scrutiny?

The FDA reopened the book on how it should regulate LDTs following the publicity surrounding Pathway Genomics' bid to go retail in May, selling its genetic tests through the Walgreens pharmacy chain. That plan is on hold. The House Energy and Commerce Committee jumped into the fray, seeking extensive documentation

from San Diego-based Pathway and two other California genetic test companies engaged in DTC sales *(NIR, 10, 10/May 25, pp. 1. 4-5).*

On June 10, the FDA sent warning letters to deCode Genetics, Illumina, 23andMe, Navigenics, and Knome about their DTC genetic tests. Navigenics, deCode Genetics, 23andMe, and Knome offer genetic screening. Illumina provides arrays to other companies for clinical diagnostic use. In the letters, Alberto Gutierrez, Ph.D., director of FDA's Office of In Vitro Diagnostic Device Evaluation and Safety, said the companies' respective tests are medical devices requiring premarket approval but the agency has not received the required information on their validity.

In an interview with Washington G-2 Reports, Gutierrez said letters seeking information have gone to more than the above five companies, and representatives have met with FDA officials to discuss their test offerings and related claims. "Some of the letters just sent refer to information gathered at those meetings," he said, "and how that led us to believe the tests were not LDTs."

While the LDT area is fairly fluid, he said, what is clear is that DTC tests do not fall within the agency's enforcement discretion. DTC testing is a separate category from LDTs, even though some DTC tests may be lab-developed, he continued. "When an LDT is marketed to the consumer, FDA clearance is required. When an LDT is sold to a physician, it is not at this point."

What Has Changed in FDA's Thinking?

The FDA has generally used its enforcement discretion for LDTs. Initially, the agency saw them as relatively simple, well-understood, low-risk tests that diagnosed rare diseases and conditions, and intended for use by physicians and pathologists in a single setting in patient care. But over the last 15 years, the nature of LDTs has changed dramatically, the FDA said. "These tests, which are becoming more complex and high risk, are playing an increasingly important role in clinical decisionmaking. As a result, LDTs not properly validated put patients at risk, such as for missed diagnosis, wrong diagnosis, and failure to receive appropriate treatment."

Genetic Tests Challenged by the FDA

Manufacturer	Device	Conditions Tested For and Claims
deCODE	deCODEme Complete Scan	Identifies 12 common genetic variants and interprets associated risk for breast cancer in women of European descent.
Illumina Inc.	Illumina® Infinium HumanHap550 array	Used by deCODE Genetics and 23andMe to provide genetic information to their customers, but is labeled "For Research Use Only."
Knome Inc., Cambridge, Mass.	KnomeCOMPLETE™	Genome browser software that explores the complete genome, with a component describing the genetic basis of specific disease traits or conditions.
Navigenics, Foster City, Calif.	Navigenics Health Compass	Provides personalized information on genetic predispositions for important health conditions and which medications are more likely to work best given the individual's genetic makeup, including warfarin and clopidogrel.
23andMe Inc., Mountain View, Calif.	23andMe Personal Genome Service™	Tells patients in advance how they will respond to certain medications, including warfarin and clopidogrel. Data generated from one feature of the service includes the single-nucleotide polymorphisms and disease risk. Recently the company has begun sales through Amazon.com.

Source: FDA letters to manufacturers, June 10

'Grandfather' Provision for Health Plans, *from p. 2*

- ❑ *Cut or reduce benefits.* For example, if a plan covers care for diseases such as diabetes, cystic fibrosis, or HIV/AIDS, it cannot eliminate this coverage.

- ❑ *Raise coinsurance charges*. Typically, coinsurance requires a patient to pay a fixed percent of a charge (for example, 20 percent of a hospital bill). Grandfathered plans cannot increase this percent.

- ❑ *Raise copayment charges.* Frequently, plans require patients to pay a fixed-dollar amount for doctor's office visits and other services. Compared with the copayments in effect on March 23, 2010, grandfathered plans will be able to increase copays for physician office visits and other services by no more than the greater of $5 (adjusted annually for medical inflation) or a percentage equal to medical inflation plus 15 percentage points. For example, if a plan raises its copayment from $30 to $50 over the next two years, it will lose grandfather status.

- ❑ *Raise deductibles.* These can only increase by a percentage equal to medical inflation plus 15 percentage points. In recent years, medical costs have risen an average of 4 percent to 5 percent so this formula would allow deductibles to go up, for example, by 19 percent to 20 percent between 2010 and 2011, or by 23 percent to 25 percent between 2010 and 2012. For a family with a $1,000 annual deductible, this would mean if they had a hike of $190 or $200 from 2010 to 2011, their plan could increase the deductible again by another $50 the following year.

- ❑ *Lower employer contributions*. Grandfathered plans cannot decrease the percent of premiums the employer pays by more than five percentage points (for example, decrease their own share and increase the workers' share of premium from 15 percent to 25 percent).

- ❑ *Add or tighten an annual limit on what the insurer pays.* To retain grandfather status, plans cannot tighten any annual dollar limit in place as of March 23, 2010. Moreover, plans that do not have an annual dollar limit cannot add a new one unless they are replacing a lifetime dollar limit with an annual dollar limit that is at least as high as the lifetime limit (which is more protective of high-cost enrollees).

- ❑ *Change insurance companies.* If an employer decides to buy insurance for its workers from a different insurance company, this new insurer will not be considered a grandfathered plan. This does not apply when employers who provide their own insurance to their workers switch plan administrators or to collective bargaining agreements.

The government can revoke grandfather status if a plan forces consumers to switch to another grandfathered plan that, compared to the current plan, has less benefits or higher cost sharing or if the plan is bought by or merges with another plan simply to avoid complying with the law.

Grandfathered Plans Not Exempt From Some Consumer Protections

While exempt from mandated preventive services and other consumer requirements, grandfathered plans must under insurance reforms that take effect Sept. 23, 2010:

– Provide dependent coverage for children until age 26

– Not use pre-existing condition exclusions for children this year (and everyone in 2014)

– Impose no lifetime insurance limits (but not annual limits)

– Not retroactively cancel coverage after a policyholder gets sick or makes an unintentional mistake on a policy application (called rescissions)

Small-group plans must spend at least 80 percent of premiums on medical expenses or improving the quality of care quality.

Sources: National Association of Insurance Commissioners, Patient Protection and Affordable Care Act.

Impact of the Rules on the Market

According to government projections, most of the 133 million Americans with employer-sponsored health insurance through large employers will maintain the coverage they have today. Large employer-based plans already offer most of the comprehensive benefits and consumer protections that the health care reform law will provide to all Americans this year.

The roughly 42 million people insured through small businesses will likely transition from their current plan to one with the new protections over the next few years. Small plans tend to make substantial changes to cost sharing, employer contributions, and health insurance issuers more frequently than large plans. To help these businesses afford employee coverage, the law includes a tax credit for up to 35 percent of their premium contributions.

The 17 million people covered in the individual health insurance market, where switching of plans and substantial changes in coverage are common, will receive the new protections of PPACA sooner rather than later. Roughly 40 percent to two-thirds of people in individual policies normally change plans within a year.

Lab Entrepreneur Pat Lanza Receives AAB's Highest Honor

Pat Lanza

The American Association of Bioanalysts (AAB) has presented its highest honor, the Lucien Dean Hertert Memorial Award, to Pat Lanza of Long Island, N.Y., AAB administrator Mark S. Birenbaum, Ph.D., announced June 10. She received the award during AAB's 2010 annual meeting May 13-15 in Las Vegas.

Lanza began her laboratory career as a bench technologist, with a degree in medical technology from the State University of New York in Farmingdale. After six years on the bench, she shifted to lab sales. In 1986, she joined a small local lab named Sunrise Medical Laboratories in Valley Stream, N.Y.

Along with her partner, Larry Siedlick, she was able to grow Sunrise into the largest and fastest-growing privately held regional medical laboratory in the New York metropolitan area. She became a co-owner of Sunrise in 1993 and served as president and chief executive for new business development.

The award was established in 1981 in honor of the late Lucien D. Hertert, an AAB founding member and its first executive director (1956-1962). He is generally acknowledged to have coined the terms "bioanalyst" and "bioanalysis." The award is given to an individual who exemplifies the dedication, loyalty, and service that Hertert gave to his profession.

In 1997, she joined AAB as an "owner" member and quickly organized a group within AAB for senior laboratory executives that was reconstituted in 2006 as the National Independent Laboratory Association (NILA), with Lanza as chair. She was a leader in AAB lobbying that helped fend off a legislative proposal for a 20 percent Medicare lab copay as well as the implementation of the Medicare lab competitive bidding demonstration.

After Sunrise was sold to Sonic Healthcare (an Australian-based lab company) in 2007, Lanza assumed her current position as director of government affairs for Sonic Healthcare USA and consultant for Sonic's divisions in the United States and Australia, and she still serves as NILA's chair.

The short-term fix does not repeal the SGR formula that has triggered negative updates to Medicare physician fees for most of the past decade. An SGR cut is scheduled to return Dec. 1, 2010, when the current fix expires, unless Congress intervenes.

Medicare Physician Fees, *from p. 1*

the claims with the cut required under the Sustainable Growth Rate (SGR) formula used to update fees each year.

The agency now has directed Medicare contractors to discontinue processing claims at the negative update rates and to temporarily hold all claims for services rendered June 1, 2010, and later, until the new 2.2 percent update rates are tested and loaded into the contractors' claims processing systems. "Effective testing of the new 2.2 percent update will ensure that claims are correctly paid at the new rates. We expect to begin processing claims at the new rates no later than July 1, 2010."

Claims containing June 2010 dates of service which have been paid at the negative update rates will be reprocessed as soon as possible, CMS said. Physician payments under the Part B fee schedule are based on the lesser of the submitted charge on the claim or the fee schedule amount. Claims containing June dates of service that were submitted with charges greater than or equal to the new 2.2 percent update will be automatically reprocessed.

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