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LDTs: FDA Does an End Run on Regulatory Proposal Lab Industry Helped Create

A couple of years ago, the lab industry played an active role in the drafting of the *Diagnostic Accuracy and Innovation Act* (DAIA), a bill designed to establish a new regulatory regime for laboratory developed tests (LDTs). But last month, without consulting anybody, the FDA sent a 59-page Technical Assistance document (TA) to a pair of US Congressional Representatives (Larry Bucshon, R-Ind. and Diana DeGette D-Colo.) pretty much re-writing the DAIA. Predictably, the industry was none too pleased and roundly condemned the TA proposal. (See the box on page 3 for more on the industry reaction).

Here's a rundown of the situation.

Background: How FDA Clears Lab Tests

New diagnostics currently come to market via two FDA regulatory pathways:

- In vitro diagnostics are approved or cleared before coming to market and must prove clinical evidence of validity;
- LDTs undergo no pre-market regulatory review.

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Medicare Reimbursement: How CMS Price Transparency Proposal Could Hurt Labs & Patient Relations

Last April, CMS issued a proposed rule to make Medicare rates more transparent. While designed to "empower patients and reduce administrative burden," the proposed changes would literally come at a price for labs, hospitals and other diagnostics providers.

What CMS Is Proposing

The proposed rule deals specifically with Medicare Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) policies and rates. Under current rules, hospitals must either make publicly available a list of their standard charges, or their policies for allowing the public to view a

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LDTs: FDA Does an End Run on Regulatory Proposal Lab Industry Helped Create, *from page 1*

Critics contend that LDTs are often inaccurate and unreliable. And because they're not subject to adverse event reporting, there's no way to determine if patients are harmed. The DAIA was intended to resolve these issues by creating a new category of tests called in vitro clinical tests (IVCTs).

FDA Tinkers in the Name of 'Public Health'

But now the FDA is apparently unhappy with the DAIA it helped to create. We're all for creating streamlined paths to market for IVCTs, and getting rid of over-regulation that thwarts innovation, notes the agency in the opening of its August TA. However, it continues, safeguarding public health must be a priority. And to serve it, the FDA says it needs authority to request raw data and take corrective action against test developers which the current DAIA doesn't provide. In particular, the agency wants to make clear it has the power to remove tests that put public health at risk from the market.

FDA's 5 Proposed DAIA Changes

Among the notable differences between the current DAIA and the FDA's new TA proposal:

1. Definition of IVCTs

The DAIA defines IVCTs as a laboratory test protocol or finished product, which is used in disease detection, screening, prediction, and monitoring, and for selecting treatment based on analysis of human samples. The TA definition would also consider test platforms and software used for these same purposes to be IVCTs. The FDA doesn't specifically mention "finished product," "laboratory test protocol" or "laboratory-developed test" in its IVCT definition.

2. Risk Categories

The DAIA establishes a process for determining whether a test is low-risk, moderate-risk or high risk, and outlines regulatory requirements consistent with a test's risk level. The TA defines high and low risk tests but leaves out moderate-risk.

3. Timelines

The DAIA contains strict review timelines. Should the FDA fail to meet the deadlines, test would be automatically approved. The TA version of the bill contains no timelines for review.

4. Regulation of IVCTs

The DAIA would create a new center for IVCTs within the FDA. The

Backing for the FDA Proposal

While the lab industry hates it, the FDA approach does have its backers. On Aug. 20, the Pew Charitable Trusts submitted its own comments regarding the FDA's TA (Pew Comments). After outlining criteria that policymakers should consider, Pew came out in favor of the FDA's TA's oversight regime approach stating that it "would establish regulatory requirements based on a test's risk" while providing broad exemptions to maximize access. Pew also applauded the FDA's approach to gathering and reviewing information on exempted tests to ensure public health.

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TA proposes the creation of collaborative communities of private and public stakeholders who advise the FDA on mitigating measures and performance standards for IVCTs.

5. Raw Data

The TA makes explicit that raw data should be submitted for high-risk, cross-referenced, or first-of-a-kind tests, and that the U.S. Department of Health and Human Services secretary can request raw data for any other test.

FDA Pre-Certification

Another notable difference between the DAIA and TA is the latter's proposed framework for pre-market approval, provisional approval and pre-certification of tests, with a substantial portion of tests being exempt from pre-market review and other requirements.

Basic outline: The FDA scheme would:

1. Exempt manual, public health surveillance, law enforcement and investigational tests from notification, pre-market review, adverse event reporting, quality systems and labeling requirements.
2. Require low volume test developers to report adverse events and include labeling.
3. Require grandfathered tests to notify FDA and report adverse events.
4. Exempt tests for rare diseases from pre-market review but subject them to other requirements.
5. Require pre-market review of high-risk tests, and subject them to labeling, quality systems, adverse event reporting and notification requirements.
6. Provisionally approve tests that use breakthrough technology or address an unmet need, allowing developers to bring them to market on an expedited time frame and remain on the market as long as they complete and submit post-market studies within the specified time frame.
7. Establish "mitigating measures," where, by following FDA requirements, test developers can limit the risk for patient harm from an erroneous result.
8. Allow test developers to apply for pre-certification for groups of IVCTs using a single technology or test method, and have other elements in common. After achieving pre-certification, developers could launch new tests that fall in that group without having to garner pre-market review.

6 Things the Lab Industry Hates about the FDA Proposal

Almost immediately after the FDA issued the TA, the ACLA wrote a response letter raising 6 objections to the proposal:

1. The FDA lacks the legal authority to regulate LDTs;
2. IVCTs should be subject to their own regulatory framework separate from medical devices;
3. The transition provision could subject IVCTs to regulation "immediately after enactment";
4. The agency could use the grandfathering provision "to 'claw back' grandfathered tests at its discretion without basis in meaningful standards";
5. Eliminating the moderate-risk category for IVCTs will create confusion and lead to more tests being classified as high risk; and
6. The definitions of "analytical validity" and "clinical validity" give the FDA "unprecedented discretion in determining whether an IVCT is analytically or clinically valid."

Health Insurance Market: Two Recent Changes & Their Impact on Labs

Amid all the talk of sweeping reform of the health insurance marketplace, the smaller, interim changes get overlooked despite their direct impact on labs and other providers. Two such changes took place last month.

In August, CMS awarded $8.6 million in grant funding to 30 states and the District of Columbia to help state insurance regulators strengthen their respective health insurance markets. These grants are part of a larger initiative, $250 million designated for State Rate Review Grants, provided by the Patient Protection and Affordable Care Act (PPACA), intended to improve the process for how states review proposed health insurance rates.

According to CMS, states can use the allocated funds during the next 24 months for a variety of planning and implementation objectives related to the selected market reforms and consumer protections, including but not limited to implementing or enhancing policy form review, hiring or contracting with a clinician to review formularies, developing actuarial and economic analyses, and performing market scans of the respective state's health insurance market to improve and expand the number of coverage options.

What the funding suggests: The PPACA, also known as the Affordable Care Act (ACA) and Obamacare, is far from dead.

Why it matters: Patient health insurance coverage, although always subject to change, is unlikely to face widespread disruption. The phrase about "performing market scans of the respective state's health insurance market to improve and expand the number of coverage options" is especially telling.

Short-Term, Limited-Duration Health Insurance Expanded

Separately, the Internal Revenue Service (IRS), Employee Benefits Security Administration, and Department of Health and Human Services (HHS) last month issued a final rule that expands the availability short-term, limited-duration health insurance, from a maximum of three months to a maximum of three years.

The rule, which takes effect Oct. 2, 2018, is in response to an executive order signed by President Trump in 2017, entitled "Promoting Healthcare Choice and Competition Across the United States."

What the insurance covers: Short-term health insurance is not "qualifying insurance," and as such does not have to meet the minimum requirements or "essential health benefits" of the ACA. One of these minimum requirements is laboratory services.

Although many short-term health insurance plans include laboratory services, not all plans are equal. What's more, short-term insurance does not generally cover pre-existing conditions.

Why it matters: From the standpoint of providers and patients, short-term insurance amounts to lesser coverage and is likely to affect reimbursement, and perhaps treatment decisions. From an IRS standpoint, short-term health insurance policyholders may owe an additional payment with their taxes.

Issues related to location: This is a federal rule, but individual state rules may differ. In Vermont, for example, extended short-term, limited-duration health insurance is not available. Anticipating federal action, Vermont signed into law Act 131, which among other things, mandates that short-term plans can only last for three months and cannot be renewed.

It is recommended that you check the laws in the states in which you do business in order to anticipate how this change may affect your facilities.

Dissolution: The Final Act of the Theranos Tragedy

Tragedy was a genre invented by the ancient Greeks to portray the fall of not just ordinary but great individuals. And while "Theranos" is not actually a Greek word (it's actually an amalgamation of the words "therapy" and "diagnosis"), it at least sounds like the name of a Sophocles tragedy. And now the final act has seemingly been written with word that the company once poised to disrupt the blood-testing business is dissolving.

The Theranos technology proved unreliable. In fact, Theranos often used analyzers from other companies to test consumer blood samples.

Theranos at its Peak

Just five years ago, Theranos was a Silicon Valley sensation with a valuation of over $9 billion. Venture capitalists, big-name shareholders, and the media embraced the company's approach and heralded its groundbreaking technology and founder Elizabeth Holmes, a Stanford University dropout who frequently wore black turtlenecks à la Steve Jobs.

At the center of its prominence and future prominence was its finger-stick blood test technology offering not only convenience but accuracy. Thanks to new technology, miniature tests using microscopic volumes would produce the same results as larger samples, Theranos claimed. It all turned out to be hype.

Faulty Technology

The Theranos technology proved unreliable. In fact, Theranos often used analyzers from other companies to test consumer blood samples.

What's more, Theranos modified some of those analyzers in ways that were not approved by the manufacturers or consistent with federal health agency guidelines. Because of the modifications, these test results were often inaccurate.

Financial Fallout

As a result of testing issues, an agreement with Walgreens, which had been the company's steppingstone to the consumer market unraveled. The drugstore chain sued the company for breach of contract and was awarded damages.

In April 2017, Theranos settled charges with CMS agreeing to a $30,000 fine and two-year Medicare exclusion.

Determined to carry on, Theranos refocused its business, shedding its CLIA lab testing and concentrating on technology. Layoffs followed. The company, which once reportedly employed 800, was down to fewer than 25 employees earlier this year.

Criminal Conduct Alleged

Things went from bad to worse. According to *The Wall Street Journal*, Holmes and her ex-boyfriend, Ramesh "Sunny" Balwani, who served as Theranos president and chief operating officer until he retired from the company in May 2016, have been indicted on nine counts of wire fraud and two counts of conspiracy to commit wire fraud.

If convicted of charges, which allege that they defrauded investors out of hundreds of millions of dollars, while also defrauding doctors and patients, Holmes and Balwani each faces up to 20 years in prison and a fine of $250,000, plus restitution to those found to have been defrauded—on each count.

Corporate Dissolution

Against this backdrop, it perhaps comes as no surprise that in an email to shareholders the company has now announced it has ceased operations and will formally dissolve.

Theranos indicates that before arriving at this decision, it pursued a sale. However, after reaching out to more than 80 potential buyers, no deal materialized.

The company owes at least $60 million to unsecured creditors, according to the email. As part of its dissolution, Theranos will distribute its remaining cash, estimated to be approximately $5 million, to unsecured creditors.

Case of the Month: Fraud or Legitimate Rural Hospital Lab Outreach Business?

A North Carolina lawsuit pitting one of the nation's largest health insurers and a national hospital management company raises novel legal issues that test the legal limits of provider contracts between insurers and hospital outreach labs.

What Happened

In February 2017, hospital management firm LifeBrite paid $400K to acquire a bankrupt rural outreach hospital in North Carolina. Part of the lure was the hospital's network status with Blue Cross Blue Shield North Carolina (BC). But within14 months, it all went terribly wrong. BC kicked LifeBrite out of its network after discovering what it saw as $11 million worth of fraudulent lab billings. LifeBrite sued the insurer for reneging on $15.5 million in lab reimbursement payments.

Now BC is firing back in the form of a counterclaim accusing LifeBrite of using the hospital as a false billing "front" to "turn a trickle of legitimate monthly billing [for toxicology urine drug tests] averaging $37,400 into an $8.5 million fraudulent river of gold." The suit contends that LifeBrite billed BC at inflated rates for more than 500,000 urine toxicology tests at inflated rates, the "vast majority" of which were "conducted by an affiliated lab that had no relationship with BC, or any connection to the hospital's patients, the community or medical necessity," according to the counterclaim.

Outreach or Overreach?

This isn't your conventional fraud case. Neither side disputes that the tests were ordered or delivered. Nor does BC contend that LifeBrite tried to conceal what it was doing. The real question is whether LifeBrite had the right to bill for the tests given that they were performed by an outside lab for non-hospital, out of network patients.

BC argues that the "plain language" of the contract limits reimbursement to "tests performed by the hospital, at the hospital and for hospital patients."

LifeBrite says that BC is just trying to get out of the contract and doesn't understand its business model as a provider of "outsourced high complexity testing" to other hospitals, which it says is permitted by Medicare. BC may not like the lab outreach model but that isn't the basis for a fraud claim, according to LifeBrite. It also contends that the higher reimbursement rates charged to insurers that BC cites as false billing is a legitimate part of the operational appeal of a for-profit hospital to operate a critical-access rural hospital and keep it financially viable.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Texas Lab and Owner Get 15-Year Exclusion for Medicare Mileage Swindle

Case: What would *you* do if your bill for a $43 blood test included a $1,500 travel fee? The patient who actually received such a bill from Texas lab BestCare complained to the government. The subsequent investigation found evidence that BestCare billed Medicare for over $10 million in false mileage for miles not traveled by a technician. After refusing to toss the case without a trial, the court found the lab guilty of False Claims Act violations and fined it $30.5 million. And on Aug. 17, an Administrative Law Judge upheld the OIG's decision to exclude BestCare and its owner from all federal health programs for 15 years.

Significance: Under Medicare rules, labs can charge $1 per mile for transporting a specimen as long as a technician travels along. The lab committed two offenses:

- Billing travel mileage for specimens shipped on commercial airlines during flights in which no technician was present;
- Imposing a separate $1 per mile travel fee for each specimen transported collectively rather than prorating mileage among the individual specimens.

Aetna Sues Manager of Oklahoma Rural Hospital for Lab Test Ripoff

Case: People's Choice, a management firm specializing in turning around financially strapped hospitals, is being sued by Aetna for using an Oklahoma rural hospital client to carry out an elaborate lab billing fraud. In a bid to keep Newman Memorial Hospital afloat, People's Choice sent blood and urine samples to other labs and falsely claimed that Newman processed the tests, the suit contends. Aetna says that over a 16-month period, it lost $21.6 million on over 10,000 lab tests, in some cases paying $2,250 for tests it thought were done at Newman rather than the $120 it would have paid a larger lab to do the test. People's Choice denies the allegations and has already settled with Newman.

Significance: False billing of lab tests has been a perennial lightning rod for litigation. What's changing, however, is not the defendant but the plaintiff. What we're seeing is the plateau-ing of federal and state enforcement against labs accompanied by a steadily growing percentage of civil lawsuits by private parties, especially insurance companies. Because they charge premium rates, rural outreach hospitals are often at the center of these cases. Thus, the Aetna suit is the second major case pitting a private insurer against a hospital management company for alleged lab fraud we reported this month. (See page 7 to find out about Blue Cross North Carolina's suit against LifeBrite.)

Pennsylvania Hospital Settles Kickback Claims for $13.1 Million

Case: The year's most expensive kickback settlement to date began as a whistleblower lawsuit against Post Acute Medical, LLC (PAM) for falsely billing Medicare and Texas and Louisiana Medicaid for millions of dollars in medical services allegedly generated as a result of referrals from physicians and other providers on the Pennsylvania rehab hospital's dole. For his part in initiating the case, the whistleblower will pocket a tidy $2,345,670 share of the recovery.

Significance: The key to the case is the details of the scheme, which the feds contend began when PAM first acquired the facilities in 2006. The complaint cites two kinds of financially suspect arrangements to induce referrals:

- Bribes disguised as medical director and other administrative fees paid under physician-services contracts; and
- "Reciprocal referral arrangements" under which PAM promised to refer patients to unaffiliated home health agencies and other providers on the understanding that the provider would refer its other patients to PAM facilities.

Florida Lab Owners Convicted for Role in Notorious Drug Distribution Scheme

Case: The two brothers who own a Palm Beach lab pleaded guilty to health care fraud for their role in the illegal drug distribution conspiracy carried out by notorious sober home operator Kenny Chatman. The brothers, who face up to 10 years in prison, paid kickbacks to rehab centers operated by Chapman for urine samples used to perform medically unnecessary drug tests that were subsequently billed to insurance companies at high rates. Their lab, Smart Lab, also faces charges carrying potential fines of up to $500K.

Significance: If you've never heard of him, Kenny Chatman has been described by Florida prosecutors as not the biggest illegal drug treatment provider in the state, only the most dangerous. Chatman locked up drug addicts that came to his sober home for help, taking their food stamps, and even forcing them into prostitution. Addicts with insurance were forced to produce three urine samples per week for testing. Several died of overdoses in the homes. And Chatman made millions in the process. Now that the kingpin is in jail for 27 years for health fraud, money laundering and sex trafficking, prosecutors have begun targeting his lieutenants.

Shareholders Sue Missouri Hospitals for Alleged Lab Billing Ripoff

Case: A new shareholder lawsuit targets the CEO and other individuals at a Missouri 10-hospital group called HMC Hospitals for allegedly running a $90 million lab billing fraud scheme out of the facilities. The suit claims that HMC hospitals submitted claims for lab work ostensibly performed for pain and detoxification clinics but that was actually done at other labs. By leveraging the hospitals' status as Medicare and Medicaid critical access rural hospitals, the schemers were able to command higher rates than the labs that actually performed the tests. Those other labs were then paid a portion of the reimbursement as a kickback.

Significance: This case is the most recent example of the growing role the private sector in targeting lab fraud. Of course, whistleblowers have long represented the private arm of the enforcement. But this is lawsuit is driven by corporate rather than regulatory concerns. The plaintiffs aren't whistleblowers acting as private attorneys general but as shareholders of the entity that owns the 10 HMC hospitals suing on behalf of themselves and the other shareholders.

California Lab, Owner Excluded 5 Years for Medicare Screening Test Billings

Case: Billing Medicare for screening exams is illegal. The latest providers to learn that lesson the hard way is Orange, California, independent diagnostic testing facility CHJ Diagnostics, which along with its owner, agreed to a five-year exclusion after OIG investigators discovered it submitted claims for nerve conduction studies considered to be screening exams under Medicare coverage rules.

Significance: Although it is not clear exactly what tests were involved, lab billing for Nuclear Stress Tests has become a more frequent target of federal investigators over the past two years. For more details, see "*Using Nuclear Stress Tests as Screening Procedure = Medical Necessity Violation*," *NIR*, Dec. 12, 2017.

How CMS Price Transparency Proposal Could Hurt Labs & Patient Relations, *from page 1*

list of those charges upon request. CMS is now proposing that hospitals be required to post those charges online. The idea is to make it easier for consumers to access relevant health care data so they can compare providers.

The Case for Transparency

Transparent pricing has been shown to be beneficial to not only patients but also providers. For example, a Johns Hopkins University study found that among six ambulatory surgical centers that posted their prices online:

- Five reported an increase of patient volume and revenue;
- Three reported a reduction in administrative burden; and
- Five reported an increase in patient satisfaction and engagement.

Lab Concerns

While most healthcare professionals would agree with the principals of transparency, there's also real concern about the potential costs and risks associated with the proposed rule. In addition to imposing new administrative burdens and restrictions on what labs can charge, providers cite two concerns to the unforeseen the proposal could have on patient relations and expectations.

1. Damage Due to Disconnect between Quoted & Actual Charges

Standard charges are based on customary care and don't take into account emergency or acute situations. In other words, standard pricing assumes a best case scenario which doesn't always prove to be realistic. This puts labs in a ticklish position when actual patient charges end up being higher than the previously quoted prices. The potential result is damage to not only customer relations but the trust on which the patient relationship is based.

2. Demand for Medicare Payment Information

The standard charges referred to in the CMS proposal are provider charges only. They don't take into account what Medicare pays for the service. But if providers begin disclosing this information, patients may also expect and insist on receiving Medicare payment information as well.

Bottom Line

While transparency and patient empowerment are laudable objectives, the CMS proposal must, at a minimum, clearly define standard charges covered and consider the potential administrative burdens the change would place on providers as well as the expectations of patients.

Stark Relief: Comments Urge Change but Don't Expect Anything Too Dramatic

After decades of resistance, CMS is giving serious indications of its willingness to entertain changes to relieve the "undue regulatory impact and burden" imposed by the Stark Law. Back in June, CMS issued a Request for Information (RFI) requesting public comments and suggestions. (See *GCA*, July 16, 2018.) Comments closed on Aug. 24. And in its latest move, CMS issued a summary of the comments.

CMS needs to clarify and expand some of the existing exceptions for value-based payment.

Main Theme: Stark Is Out of Sync with Modern Health Care

One of the noteworthy things about the comments is who did not participate in the process, namely, consumer advocate groups who would likely oppose any significant changes to Stark. In their absence, the vast majority of comments came from industry and other groups determined to change Stark.

So, it's hardly surprising that comments overwhelmingly skewed in favor of revamping Stark to reflect current medical industry practices and allowing further modernization. Stark's intent of preventing inappropriate physician referrals remains valid, commentators acknowledged. But the law was adopted at a time when Medicare services were provided on a fee-for-service basis and health care was provided in distinct silos. Those conditions no longer pertain today. In addition, modern industry payment policies and reimbursement models currently address the referral risks that Stark was meant to prevent.

3 Things the Commentators Want

Among the more notable comments and suggestions:

1. New Value-Based Payment Exception

Create a new Stark exception for value-based payment methodologies that would allow hospitals to incentivize physicians for selecting the most efficient and effective care options by sharing a portion of any cost savings when overall costs of care are reduced.

2. Clarify & Expand Current Exceptions

CMS needs to clarify and expand some of the existing exceptions for value-based payment. For example, several commentators suggested expanding the personal services arrangement exception by removing limitations on its applicability to commercially insured patients.

3. Clarify Key Definitions

The comments cite a number of important Stark definitions that are extremely difficult to decipher—and thus comply with—that CMS needs to clarify or simply redefine, including:

- "fair market value";
- "financial relationship"; and
- "remuneration".

OIG Also Getting in on Kickback Relief

CMS isn't the only agency contemplating modernizing the health care kickback laws. On Aug. 28, the OIG published its own Request for Information seeking comments on how to modify or add new safe harbors to Stark's cousin, the Anti-Kickback Statute to "foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse." Deadline to comment: Oct. 26.

What Happens Next?

After comments, the next step after comments in the new rulemaking process is for CMS to propose new rules based on the comments. This is unlikely to happen quickly, notes Nashville health care attorney Bradley J. Sayles. And any new rulemaking that CMS does propose must be submitted for 60 days of public comment. Thus, even if CMS fast tracks the process, it'll take at least six months for permanent changes to be made. And even that seems overly optimistic. Sayles suggests a best-case scenario of one year.

Takeaway: Don't Get Too Excited

Sayles also throws cold water on the hopes for sweeping change. Real change can only happen legislatively, he contends. The best CMS can do is revamp definitions to remove ambiguities and create more certainty. It can also pitch new exceptions as it has in the past. But previous recommendations for Stark changes fell on deaf ears and Sayles says there's no guarantee the outcome would be any better this time around.