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LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

December 2018

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G2 INTELLIGENCE **Upcoming Events**

Lab Leadership Summits

Billing & Collections Summit 2019: *Improve Your Lab's Billing and Collections Procedures & Increase Your Cash Flow and Revenue*

March 28, 2019, Orlando, FL
www.lableadershipsummits.com

HIPPA Compliance:
The Pitfalls of PHI De-Identification & How to Avoid Them

In 2016, the Australian government released medical billing records of 2.9 million people. They tried to protect patient privacy by removing names and other identifying data. But it didn't work. Shortly after the data was released, a University of Melbourne research team was able to easily "re-identify" people, without decryption, simply by comparing the released dataset to other publicly available information, such as medical procedures and year of birth.

While it happened on the opposite side of the globe, the Australia case is directly relevant to US labs to the extent it demonstrates the weaknesses of de-identification and how relying on it can cause privacy breaches that violate HIPAA and, more importantly, jeopardize the lab's relationships with healthcare partners and patients.

Continued on page 2

Compliance Perspectives:
Avoid Kickback Liability by Steering Clear of MD Processing Fees

Editor's Note

Two months ago, we talked about paying referring physicians a fee for collecting and processing blood, urine, tissue and other specimens. (G2 Compliance Advisor, Oct. 9, 2018, p. 1). While acknowledging the kickback implications of such arrangements, we also suggested that labs can navigate those risks. We heard from several persons, including GCA users and leading attorneys, who disagreed with our take and urged us to reconsider it. And that's what we did. Conclusion: While technically right about the law, our original piece also offered the wrong practical advice. So, now we are revising it (along with the Model Processing Fee Policy that accompanied it).

Kickback Red Flags

The federal *Anti-kickback Statute* (AKS) and *Stark Law* ban labs from offering or paying anything of value to physicians

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The Pitfalls of PHI De-Identification & How to Avoid Them , *from page 1*

Lab Obligations under HIPAA

HIPAA limits the collection, use and disclosure of personal health information to specific purposes such as:

- Coordinating information about care and treatment;
- Providing information to patients' family, significant others or friends who are directly involved in their treatment;
- Assessing the quality of care provided by the doctor or healthcare facility;
- Furnishing information requested by law enforcement or other government and public agencies for prescribed purposes.

HIPAA doesn't protect all health information, only personally identifiable information, i.e., information that directly or indirectly reveals the person's identity. HIPAA provides two ways for labs to "de-identify" information before sharing it for uses such as research:

1. The "Expert Determination" method in which a statistician or other person with appropriate training verifies that enough identifiers have been removed that the risk of identification of the individual is very small; or
2. The "Safe Harbor" method that requires removal of 18 specified identifiers.

The Risks of Re-Identification

Currently, the risks of re-identification are minimal for labs fully complying with HIPAA regulations, says **Adam Greene**, partner with Davis Wright Tremaine. Labs without systems that are fully complaint with HIPPA, however, have greater re-identification risks, says **David Gee**, also a partner with Davis Wright Tremaine. For example, if data is used internally and a lab substitutes "common sense lay definitions" to de-identify instead of complying with HIPAA rules, it may be subjecting itself to potential liability.

But as big data evolves, risks may increase because re-identification of patients from de-identified data using other publicly available information will get easier. This is particularly true of the HIPAA De-Identification Safe Harbor which doesn't apply even if a lab strips out all 18 identifiers to the extent it has "knowledge" that someone can re-identify patients from the data, says attorney **Kate Stewart** of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. Labs may need to ensure that data is de-identified under the Safe Harbor can't be combined with other data sets to re-identify patients, she says, and frequently reevaluate those findings.

LCA

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Takeaway: How to Protect Yourself

The ability to mine big data and combine it with other data sets is constantly evolving. Labs must be constantly aware that what may have been adequate to de-identify patients in the past may not work today. Steps labs can take to minimize re-identification risk:

- Making sure security and privacy officers are well trained, experienced and know how to get whatever help or guidance they need;
- Continually re-evaluating the processes in place to de-identify data;
- Relying on the Expert Determination method instead the Safe Harbor method to remove the re-identification knowledge risks;
- When relying on the Expert Determination method, getting the data recertified as frequently as necessary to maintain the right to disclose, e.g., every three years.

Avoid Kickback Liability by Steering Clear of MD Processing Fees , *from page 1*

to encourage or reward them for referring patients covered by Medicare, Medicaid and other federal health programs. So, any time a lab pays a fee to a referring physician, it raises a red flag.

This is especially true when the fee covers a specimen processing fee to a physician. One problem is that, historically, such services have been built into the physician's reimbursement, e.g., via inclusion in CPT E & M codes.

The OIG Pronouncements

The OIG addressed this issue in a 2005 Advisory Opinion (05-08) stating that a lab's proposal to pay physicians a $3 to $6 per patient fee for collecting blood specimens for Medicare patients to be tested by the lab would raise AKS concerns since it would confer "obvious benefits to the referring physicians."

If any doubt remained, the OIG removed it on June 25, 2014 by issuing Special Fraud Alert (SFA) declaring its AKS suspicions of "Specimen Processing Arrangements," i.e., those involving services such as collecting the blood specimens, centrifuging the specimens, maintaining the specimens at a particular temperature and packaging the specimens so they're not damaged during transport. The SFA, on which our original article was based, then lists specific characteristics that raise red flags, including when the processing fee:

- Exceeds fair market value;
- Is calculated on a per-specimen, per-test, per-patient or other method based on the value or volume of referrals;
- Covers services already paid for by a third party such as Medicare;

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- Covers services actually performed by someone placed in the office by the lab;
- Is made directly to the ordering physician rather than the group practice that employs him/her and actually bears the cost of collecting and processing the specimen; and
- Is offered on the condition that the physician order either a specified volume or type of test or test panel, especially if the panel includes duplicative tests.

On its face, the SFA leaves room for compliant arrangements, i.e., those structured to avoid the OIG red flags. But as a practical matter, crafting a compliant processing fee arrangement is just about impossible.

The Stark Issues

One problem with relying on the OIG pronouncements, notes Seattle healthcare attorney **David Gee**, is that they cover only the AKS and not the Stark issues. Explanation: To justify a processing fee under Stark, a lab would probably have to rely on the so called personal services exception. But to structure specimen collection as a personal fee would be extremely difficult, especially to the extent it couldn't be based on the volume or value of specimens processed, he explains. "Theoretically, you could set an hourly personal service fee, but that would be highly dubious."

The Cases

The view that processing fees can be structured as somehow avoiding the AKS and Stark obstacles is borne out by the few court cases that have addressed the issue.

The HDL Case

The 2015 Health Diagnostic Laboratory (HDL) case is the poster child for abusive processing fee arrangements. The case began when a whistleblower filed a qui tam lawsuit accusing HDL and its business associate Singulex of paying kickbacks to physicians in the form of processing fees of up to $10 to $17 per test in exchange for orders of medically unnecessary blood tests. HDL then compounded its liability by subsequently billing those ill-gotten tests to Medicare and TRICARE, thereby bringing the False Claims Act into play.

By the time the dust had cleared, HDL paid $47 million and Singulex $1.5 million to settle kickback and false claims charges. And in July 2018, the individual principles of both companies were convicted and fined another $114 million for their role in the scheme.

The Boston Heart Case

The more recent case of US ex rel. Riedel v. Boston Heart Diagnostics Corp. involved a lab's payment of packaging fees. While acknowledging that the $15 to $25 it paid physicians was well above the $3 Medicare draw fee, the lab contended it was fair market value. The fee wasn't a draw fee but a packaging fee covering the costs of not only collection

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but also processing and shipping specimens to its facility for testing, it argued.

But the court didn't buy it, finding that the fees in this case were structured just like the ones the OIG rejected in the 2005 Advisory Opinion mentioned above. It also found credence in the whistleblower's contention that the lab encouraged physicians to cover their tracks by breaking up their testing needs among multiple colluding labs. Result: The whistleblower would get a shot to prove his allegations at trial.

The Moral: Stay Away from Processing Fees

In our original, we suggested that processing fee arrangements can be structured to satisfy OIG criteria. Theoretically, this is true. But as a practical matter, it won't work. So, don't try it. A more legally sound alternative to help physicians manage the costs and hassles of specimen collection and processing (assuming your lab has the necessary resources):

- Establish a collection station near the offices of your physician clients; and/or
- Place a phlebotomist or staff member compensated by your lab at fair market value within their facilities.

TOOL Model Specimen Processing Fees Compliance Policy

Here's a Model Policy your lab can adapt to avoid specimen processing fee arrangements with referral sources:

XYZ LABORATORY POLICY ON SPECIMEN PROCESSING FEES

POLICY

Specimen Processing Fee Arrangements between XYZ Laboratories and its Referral Sources are not permissible under any situation, regardless of payor, the value of fees and/or how they are structured. Marketing, sales and other personnel that offer such arrangements to Referral Sources shall be subject to discipline up to and including termination.

DEFINITIONS

For purposes of this Policy:

- "Referral Source" means a physician or other person or entity that can order or influence or recommend the ordering of diagnostic tests to XYZ Laboratories for testing;
- "Specimen Processing Fee Arrangement" means one in which XYZ Laboratories pays a Referral Source a fee for collecting, processing or packaging blood, urine, tissue and other patient samples for testing, including but not limited to services such as collecting blood specimens, centrifuging specimens, maintaining specimens at a particular temperature and packaging the specimens so they are not damaged during transport.

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Medicare Reimbursement: CMS Provides Needed PAMA Relief—But Newly Covered Hospital Labs Must Report in 2019

The battle between CMS and the lab industry over Medicare Part B pricing for lab tests **could be on the road to resolution** notwithstanding the ACLA's recent court loss. **But even as the legal battle continues,** the final 2019 Clinical Laboratory Fee Schedule (CLFS) (Final Rule) **offers significant relief that may result in higher Medicare reimbursement rates for all labs. At the same time, it may also imperil the hospital labs that are now subject to pricing data reporting requirements but may not realize it.**

The "Applicable Laboratories" Controversy

The center of the controversy remains the overly narrow CMS definition of "applicable laboratories" that has the effect of excluding the pricing data of hospital outreach labs in calculating market rates for lab tests (see box below).

CMS Definition of Applicable Laboratory

An entity that's a laboratory (as defined in CLIA) that bills Medicare Part B under its own NPI and/or that gets more than 50% of its Medicare revenues during a data collection period from the CLFS and/or Physician Fee Schedule (PFS). Applicable labs must also meet a "low expenditure threshold," i.e., get at least $12.5K of Medicare CLFS revenues for clinical diagnostic lab tests that are not advanced diagnostic lab tests (ADLTs).

One major part of the problem is the current definition's reliance on NPI number which precludes hospital outreach labs that bill under the hospital NPI from counting as "applicable laboratories." In the Final Rule, the CMS acknowledges the problem and characterizes the arguments made by industry during the comment period to include more hospital outreach labs as "particularly compelling."

At the same time, the comments also reveal the agency's hand and the essence of its philosophical difference with industry. Simply stated, CMS does want more hospital representation but not too much more. Reasoning: By basing the definition on CLFS/PFS rather than inpatient and OPPS revenues, the intent of the PAMA legislation is to exclude hospital labs and "limit reporting primarily to independent laboratories and physician offices."

A Significant Concession

Notwithstanding its reservations, CMS included a significant change in the Final Rule by adopting an American Clinical Laboratory Association recommendation to treat hospital outreach labs that use the Form CMS-1450 14x TOB to bill for non-patient lab services as "applicable laboratories."

Result: Many hospital outreach labs that had been **prohibited** from

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providing commercial payor information to CMS are now *required* to provide this data. Robust reporting from hospital labs could positively impact future Medicare reimbursement rates for all labs.

No Time to Waste

This is a potential game changer that positively impacts Medicare reimbursements for all labs. The tricky aspect of the change is that it takes effect **in the next data collection and reporting periods** (Jan. 1, 2019 thru June 30, 2019, and Jan. 1, 2020 thru March 30, 2020, respectively).

The risk is that hospital outreach labs may not realize that they're now considered "applicable laboratories" who are required to report their pricing data. Applicable laboratories that fail to report could be subject to civil monetary penalties of up to $10,000 per day for each day they fail to report.

A Less Significant Concession

In addition to addressing the hospital labs situation, the Final Rule provides for more PAMA relief by excluding Part C Medicare Advantage payments from the denominator by which the CLFS/PFS numerator is divided. The Final Rule, in other words, makes it easier for labs with significant MA plan revenues to qualify as "applicable labs" under the majority of Medicare revenues threshold (see the shaded box above for the technical definition of "applicable laboratory).

While a step in the right direction, these changes aren't nearly as significant as the hospital outreach lab concessions, especially since they wouldn't kick in for another two years. "These modifications are insufficient because the changes outlined in the final PFS rule will not take effect until 2021. Regional and community clinical laboratories face an unsustainable 10% cut in less than two months, on January 1, 2019," according to an NILA and AAB statement.

Future Lab Reimbursement Issues Still on the Table

The Final Rule addresses but reserves for later determination issues affecting future Part B reimbursements for lab tests, including:

Weighted Median Pricing: Some industry groups have called for a "weighted median" formula for calculating Medicare reimbursements which would consider the percentage of hospital labs in relation to the total market. For example, if hospital labs make up 20% of the market, data from those facilities would be weighted to 20% of the final calculation.

Low Expenditure Threshold: Another big concern for the lab industry is CMS' proposal to reduce the "low expenditure threshold" for reporting private payor lab prices by 50%, from $12,500 to $6,250. Reducing the threshold wouldn't make a significant impact on PAMA pricing and could overburden small labs, industry experts argue.

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OIG Monthly Work Plan Review: November 2018

This month, there were six new Work Plan items, two of which have implications for at least some labs.

1. CDC's Oversight of the President's Emergency Plan for AIDS Relief Funds

Issue: Through the President's Emergency Plan for AIDS Relief (PEPFAR), the Centers for Disease Control and Prevention (CDC) has altered the course of the global acquired immunodeficiency syndrome (AIDS) epidemic, saving millions of lives, improving the lives of countless others, and preventing millions of infections around the world. CDC received more than $1.7 billion of fiscal year 2017 PEPFAR funds (about 97% of the funds received by HHS) to accelerate progress toward achieving an AIDS-free generation and create a lasting infrastructure that allows partner countries to respond to a range of health challenges and threats.

OIG Action: To date, OIG has conducted a series of PEPFAR audits at CDC in five countries in Africa, North America, and Asia. OIG's oversight of PEPFAR has helped CDC and other HHS staff learn important grant and program integrity lessons that apply to ongoing and future responses to infectious diseases. In previous audits of CDC offices in the United States and foreign countries, OIG identified noncompliance with policies, inadequate monitoring of grantees, and internal control weaknesses in the award of PEPFAR funds. OIG will now determine whether CDC has taken corrective action to ensure it has improved and implemented internal controls, including adhering to policies and procedures for awarding and monitoring PEPFAR funds.

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2. Grantees' Use of President's Emergency Plan for AIDS Relief Funds

Issue: In more than 60 countries, grantees of the CDC, such as ministries of health and other partners, work to control the spread of AIDS. In fiscal year 2017, CDC awarded more than $1.5 billion in PEPFAR funds to accelerate progress toward achieving an AIDS-free generation and create a lasting infrastructure that allows partner countries to respond to a range of health challenges and threats.

OIG Action: To date, OIG has conducted a series of PEPFAR audits of grantees in eight countries in Africa and Asia. OIG's PEPFAR oversight has helped grantees learn important grant and program integrity lessons that apply to ongoing and future responses to infectious diseases. In previous audits of foreign PEPFAR grantees, OIG identified unallowable expenditures and internal control weaknesses. OIG will now determine whether selected foreign and domestic grantees managed PEPFAR funds in accordance with award requirements.

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You Make the Call: Incentivizing MDs to Order More Early Screening Tests

SITUATION

A Managed Care Organization (MCO) wants to pay providers incentives to increase early and periodic screenings, diagnostic and treatment (EPSDT) services to Medicaid patients. Payments are capitated, i.e., providers get a set per enrolled Medicaid patient amount regardless of services actually utilized. The MCO provides per-enrollee incentive payments to providers for meeting benchmarks based on increases in EPSDT services provided:

Incentive Amount	Incentive Trigger
$1 per patient	10% to 19% year-over-year increase in screenings
$2 per patient	20% to 29% year-over-year increase in screenings
$3 per patient	30% or higher year-over-year increase in screenings

The MCO would offer no incentives for recruiting new Medicaid beneficiaries nor participating in any of its other plans. It would also cover the payments out of its own pocket and doesn't pass them on to Medicaid.

QUESTION

Does the arrangement violate anti-kickback rules?

A. Yes because it incentivizes doctors to order more tests
B. No because it includes proper safeguards

ANSWER

B. According to a new OIG Advisory Opinion 18-11, this arrangement would, in fact, be acceptable.

EXPLANATION

The OIG said the proposed arrangement would fall under the Eligible Managed Care Organization (EMCO) safe harbor because:

- Payments would be based solely on the provision of Medicaid services to existing enrollees; and
- The arrangement wouldn't inappropriately increase or shift costs to federal health care programs.

The OIG also noted that the objective of increasing EPSDT tests is consistent with the strategy of the State Medicaid agency.

TAKEAWAY

While not technically binding (nor applicable to Stark Law), the new Advisory Opinion is significant to not just payors but also labs and other providers considering arrangements incentivizing utilization of EPTSD testing. Specifically, the OIG has now provided a blueprint on how to structure these arrangements to fall into the EMCO safe harbor. In the larger context, this opens the door to offering physicians incentives for modifying their normal ordering patterns for proactive and strategic public goals even if it results in higher test utilization.

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Labs IN COURT

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

New York Doctor Busted for Falsely Billing Medicaid for Lab Drug Tests

Case: The State claims that the physician billed for $939,000 worth of drug testing services that his lab didn't and couldn't actually provide. For example, instead of charging for a single test on a patient, he charged for 11 nonexistent tests. Other alleged offenses include performing medically unnecessary services and operating the lab without a director.

Significance: This case is typical of the current pattern of health care fraud enforcement—focus on drugs and drug testing and sweep in all related charges, in this case violating federal and state requirements that labs employ a director to oversee operations.

Abbott Settles TriCor Kickback & Off-Label Marketing Claims for $25 Million

Case: The case started when a sales rep accused Abbott Laboratories and AbbVie Inc. of paying kickbacks to induce or reward physicians for prescribing TriCor to patients with abnormal cholesterol levels. Improper inducements allegedly included gift baskets, gift cards and other items offered via sales reps as well as consulting and speaking fees. The whistleblower will collect a $6.5 million share of the settlement amount.

Significance: The suit wasn't just about kickbacks. The government also accused Abbott of marketing TriCor, a drug approved by the FDA to help patients raise their HDL and lower their LDL, in conjunction with diet, for off-label, i.e., non-approved uses including use:

- In treating, preventing or reducing cardiac health risks
- In combination with statin drugs
- As a first-line treatment for diabetes.

Provider Fined for Not Taking Compliance Measures Required by Its CIA

- In 2015, Pediatric Services of America (PSA) made the wrong kind of history by becoming the first provider to settle claims for violating the overpayment rules..

Case: Nearly 10 years ago, a new Affordable Care Act rule requiring labs and other providers to investigate their credit balances for potential Medicare overpayments took effect. In 2015, Pediatric Services of America (PSA) made the wrong kind of history by becoming the first provider to settle claims for violating the overpayment rules. In addition to a $6.88 million fine, PSA had to enter into a corporate integrity agreement (CIA) And now the OIG has fined PSA $22,500 for not meeting its compliance obligations under the CIA, specifically:

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- Not having its Chief Compliance Officer make a quarterly report directly to the Board of Directors in the first quarter of 2017.
- Not ensuring that the Compliance Committee met at least once a quarter during 2017.

Significance: The CIA is something like health care enforcement's version of the scarlet letter, a penalty whose legacy seems to continue perpetually after the transgression that prompted it. Providers that enter into a CIA as part of a settlement are compelled to take draconian compliance measures for a number of years and subject to review and pre-determined fines for not implementing those measures. The PSA case is the latest example of just how onerous the CIA can be.

Shareholders Sue Illumina for Stock Fraud

Case: A pair of investors brought a class action lawsuit accusing lab giant Illumina of artificially inflating stock prices by making "overwhelmingly positive statements" about its sales before releasing its earnings for the third quarter of 2016. Although Illumina did post 10% growth in Q3, its $607.1 revenues came in far short of both average Wall Street estimates ($628.1 million) and the firm's own guidance of $625 to $630 million. The investors claim that this was no accident and are suing on behalf of shareholders who bought Illumina stock between July 26, 2016 and Oct. 10, 2016.

Significance: The suit, the latest pitting a publicly traded lab against its own shareholders, contends that Illumina was pumping up expected sales while failing to disclose the serious flaws in its internal controls and forecasting processes. "Prior to and during the third quarter of fiscal 2016, Illumina had been experiencing a material decline in sales of its traditional HiSeq sequencing instrument," according to the complaint. "The decline in sales, which defendants would later refer to as a 'trend' that had been 'building' for some time and 'didn't show up suddenly' during the third quarter, went unnoticed during the forecasting process."

Clinic Owner Gets 36 Months in Jail for Medicare Test Ripoff

Case: It was sentencing day for the owner of three Houston area clinics convicted of falsely billing Medicare for $5.963 million in allergy tests, complex cystometrograms and anal/urinary muscle studies that either weren't ordered or not performed. The giveaway for investigators was that the clinic didn't even have the equipment to perform the billed for tests. In addition to 3 years in the pen, the owner has to repay the $2.760 million Medicare shelled out for the tests.

Significance: This was a particularly egregious case. As part of her plea bargain, the clinic owner admitted to ordering her business associate to create false patient records to support the test claims and hiring an unlicensed individual to pose as a qualified medical professional to assess patients without professional supervision.

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Surviving a Medicare Audit: Warn Lab Staffers Not to Lie to Auditors

As a lab compliance director, you understand the dangers of obstructing a Medicare audit. The problem is you staff may not. So, make it clear to any staffer that may come into contact with an auditor visiting your facility that lying to a Medicare auditor is a form of obstruction that can get them jailed.

A Cautionary Tale

To drive home your point about not lying to auditors, you might want to relate the sad story of the 73-year-old endocrinologist specializing in diabetes management who just learned that lesson the hard way.

The Medicare program integrity contractor was auditing his practice after his wife, who worked for an outside home health agency, became the subject of a Medicare fraud investigation. During the audit, the physician told the auditor that a third-party employer was renting office space. In fact, his wife would later admit after pleading guilty to health care fraud that she was actually using the space to improperly access patient data that was then used to generate referrals from the practice to the HHA without regard to medical necessity.

In addition to $118,831 in restitution, the doctor was sentenced to five months in jail followed by three years of supervised release.

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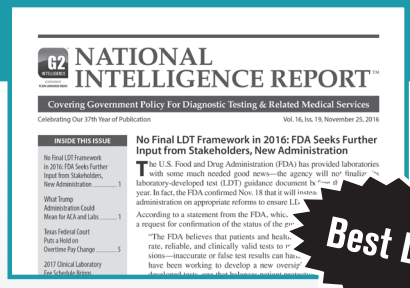
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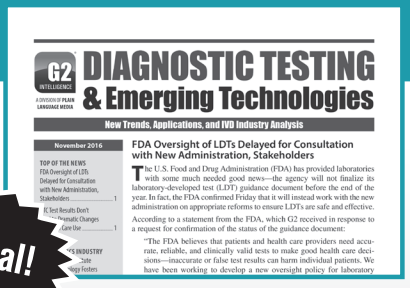
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