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INSIDE THIS ISSUE

Compliance: How the Opioid Crackdown Is Affecting Lab Enforcement & Test Utilization

- ***103 in 1: Odds of dying in a motor vehicle crash***
- ***96 in 1: Odds of dying from an opioid overdose***

The alarming finding that a person is now more statistically likely to die of an opioid overdose than a motor vehicle crash comes from The National Safety Council (NSC). And it's only the latest reminder of how the opioid epidemic has transcended from a medical to a societal crisis. Of course, all of this is having more than a peripheral impact on medical labs.

The 2 Faces of the Epidemic

In 2017, the Trump administration declared the opioid crisis a public health emergency. In October 2018, new bipartisan legislation to deal with the problem was signed, including:

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Medicare Reimbursement: New Guidance on Date of Service Rules for Part B Billing of Hospital Outpatient Lab Tests

In 2018, new date-of-service rules took effect for billing and coding of outpatient lab tests under Medicare Part B, rather than as part of the Hospital Outpatient Prospective Payment System (HOPPS) bundled payment. On Jan. 24, CMS reissued guidance clarifying how providers should apply the new rules on their CMS-1500 and/or X12 837 Professional Claim forms. Here are the three key points you need to know if you bill outpatient lab tests under Part B.

General Date of Service Rule for Clinical Laboratory Services

The date of service for clinical lab services is generally the date the specimen is collected. If the specimen is collected over a period that spans two calendar dates, the date of service is the date the collection ended. However, the guidance notes three exceptions:

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- The STOP Act (aka, Synthetics Trafficking and Overdose Prevention Act of 2018) providing for tougher postal screening and tighter manifest controls at ports of entry to prevent opioids and illegal drug distribution; and

- The SUPPORT Act (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act) which includes new measures to crack down on opioid-related Medicare and Medicaid fraud and abuse.

Even as lawmakers and enforcement attempt to stem the flow of *illegal* opioids, the number of opioid users continues to grow because so many people get the drugs legally—at least initially. Accordingly, the crackdown on illegal drugs isn't enough to solve the opioid crisis; misuse of prescription opioids must also be addressed.

Misuse of Legal Prescription Opioids by the Numbers

- **130:** The number of people who die of opioid overdoses in the U.S. each day;
- **$78.5 Billion:** The Centers for Disease Control and Prevention (CDC) estimates of the total "economic burden" of prescription opioid misuse in the U.S. per year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.
- **21 to 29:** The approximate percentage of patients prescribed opioids for chronic pain and who misuse them;
- **8 to 12:** The approximate percentage of patients prescribed opioids for chronic pain and who develop an opioid use disorder;
- **4 to 6:** The approximate percentage of patients who misuse opioids who transition to heroin;
- **80:** The approximate percentage of people who use heroin that got there by misusing prescription opioids.

Source: National Institutes of Health (NIH) data

Impact on Labs—Enforcement

In terms of Medicare fraud and abuse enforcement, the opioid epidemic has had a mixed impact on labs. The prioritization of opioid-related activities has diverted resources previously utilized to combat financial fraud; however, it has had the exact opposite effect on labs that provide

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urine drug testing services for physicians who prescribe opioid medications, particularly those who own the labs to which tests are referred. (See, *LCA*, Feb. 19, 2018, for more details on how opioid enforcement is affecting labs.)

Impact on Labs—Test Utilization

Lab testing capable of detecting the use/misuse of opioids is utilized by employers for employment and pre-employment screening, as well as by insurers and physicians to monitor the effects of legally prescribed opioids. However, according to Lab Tests Online, a program of the American Association for Clinical Chemistry (AACC), these tests don't distinguish between opiates that come from natural sources (e.g., heroin and morphine) and semi-synthetic and synthetic opioids (e.g., oxycodone, hydrocodone, and fentanyl).

While this may actually turn out to be advantageous given the overlap in usage, a new approach is needed. With this in mind, AACC recommends that drug testing become more widespread. In addition to typical testing (work-related, court ordered, and treatment-related), it recommends that people get tested:

- When prescribed opioids for long-term (chronic) pain; and
- When a person has signs and symptoms suggesting drug intoxication or overdose.

Promoting this message while the NIH educates the public about opioid use could lead to an increase in voluntary lab tests. At the same time, as more people seek treatment, tests in connection with treatment programs will likely increase.

Testing Factors and Methods

Still, testing for opioids is not without challenges. Numerous factors affect how quickly an opiate leaves the system. According to American Addiction Centers, these include:

- The individual's metabolism rate;
- Body mass and weight;
- Body fat content;
- Health of the liver and kidneys;
- Age;
- How often and how heavy opiate use is;
- Quality of the drug; and
- Amount of water in the body

What's more, not all opiates stay in the system for the same length of time. Add to this the fact that different tests are more effective than others for different opiates. For example, according to American Addiction Centers, "a saliva test will only be able to detect heroin for the first five hours after the

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last dose, while blood tests can detect it for about six hours after the last use. Urine tests are the most commonly used, and can detect heroin up to seven days after the last use. Hair follicle tests, however, can find heroin for up to 90 days."

Oxycodone, by contrast, can be detected in saliva for one to four days, in blood for up to 24 hours, in urine for three to four days, and in hair for up to 90 days.

Hair follicle tests offer the most accurate results as far as long-term drug use, but they can't detect recent use. Hair follicle tests are also more expensive than urine tests.

So, what is the answer?

Research suggests that more testing, including voluntary testing, that uses multiple detection methods could provide early and essential insight.

Enforcement Trends: Record Breaking Year for HIPAA Fines

The federal Office for Civil Rights (OCR) reports that 2018 was a record year for HIPAA enforcement, with 10 settlements and one judgment bringing in $28.7 million in fines, easily surpassing the old record of $23.5 million set in 2016. The highlight of 2018 HIPAA enforcement was the $16 million settlement with Anthem, the OCR's largest ever HIPAA settlement.

Here's the entire Top 10 settlements list.

1. Anthem, Inc.: $16 million
2. Fresenius Medical Care North America: $3.5 million
3. Cottage Health: $3 million
4. Massachusetts General Hospital: $515,000
5. Advanced Care Hospitalists: $500,000
6. Brigham & Women's Hospital: $384,000
7. Allergy Associates of Hartford (Conn.): $125,000
8. Pagosa Springs (Colo.) Medical Center: $111,400
9. Filefax(tie): $100,000
10. Boston Medical Center(tie): $100,000

The lone judgment the OCR obtained was for $4.348 million against MD Anderson Cancer Center in Houston.

FDA Watch: Latest Plan to Simplify 510(k) Premarket Review of New Tests

While everybody agrees that the FDA 510(k) premarket review pathway is antiquated and in desperate need of an overhaul. For several years, the FDA, Congress and lab industry have been working together on a solution. Now, after all the fits, starts and false hopes, real relief may actually be on the way. Here's a quick recap of the FDA's newly proposed plan.

The 510(k) Pathway

Device and diagnostic test manufacturers can use the 510(k) pathway to secure expedited approval for new products that they can show are substantially equivalent to products that were grandfathered in when Congress created the pathway back in 1976. The absurdity of using technology that's 40+-years-old as the standard for letting new products into the market is lost on nobody. There's a perception that we've gone too far in stretching what's "equivalent," and that new 510(k) approvals should be compared to the benefits and risks of modern technology, notes Philadelphia attorney Janice Hogan, who represents companies in the 510(k) process.

The New FDA Proposal

Of course, the FDA recognizes the problem and has taken steps to address it. In April 2018, the agency suggested that substantial equivalency of new products be evaluated based on objective performance criteria rather than predicate devices. Its November 2018 guidance advances that objective via establishment of an alternative 510(k) pathway (to be called the "Safety and Performance Based Pathway") that allows manufacturers of certain-well-understood device types to rely on objective safety and performance criteria to demonstrate substantial equivalence.

The proposal also calls for modernization via embarrassment, i.e., publication of manufacturers and products who rely on predicate technology over 10 years old.

Impact on the Lab Industry

Hogan suggests that the new rules will have less impact on diagnostics than therapeutics given the former's current reliance on newer predicates. What's more, adds Hogan, 510(k) may become moot for diagnostics if some version of the Diagnostic Accuracy and Innovation Act (DAIA) (see *NIR*, Sept. 2018) is passed. That's because DAIA would establish a new pathway for diagnostic tests instead of continuing to include them in the definition of a medical device within the scope of the 510(k) process.

Although it has bi-partisan support, Hogan cautions that DAIA is far from being a done deal. And unless and until it passes, new diagnostics will still have to go through the 510(k) process reach the market.

Labs IN COURT

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

Texas Pathology Lab Settles EHR Consulting Kickback Claims for $63.5 Million

Case: In 2006, HHS implemented an AKS safe harbor and Stark exception letting non-physician providers pay up to 85% of physicians' costs to help them transition from paper records to EHR systems. But Inform Diagnostics (then known as Miraca Life Sciences Inc.) allegedly stretched the rules beyond the breaking point by offering physicians discounts on EHR consulting services in exchange for lab referrals, It even based individual discount amounts on the anticipated return on investment the particular physician's referrals would generate and offered the deal only to physicians it targeted as high-volume referral sources. Three different whistleblowers filed qui tam lawsuits and now Inform has agreed to settle the claims for $63.5 million, to be paid by its former parent, Japanese company Miraca Holdings Inc.

Significance: Under the False Claims Act first-to-file rule, the first whistleblower to file a lawsuit is the only one allowed to bring an FCA case arising out of a particular fraud scheme. But each of the three whistleblowers in this case (including the former Miraca Life Science Sr. Vice President of Commercial Operations, former dermapathologists and a company called LPF LLC) had legally distinct claims based on different factual information. Result: All three cases were allowed to proceed. And when the DOJ decided to intervene in each case, Inform/Miraca saw the writing on the wall and agreed to settle.

Mass. Pain Management MDs Jailed for Elaborate Drug Testing Conspiracy

Case: After pleading guilty to running "one of the most dangerous pain management practices in Massachusetts," a medical resident was sentenced to 75 months in jail, three years of supervised release and a $1,852,000 restitution payment. His physician co-conspirator was also sentenced to eight years in prison for health care fraud and money laundering. The defendants routinely dispensed large quantities of powerful narcotics to addicted patients out of the now-defunct New England Pain Management Associates clinic and billed Medicare and private payors for services not performed.

Significance: The details of the scheme were particularly sordid including falsification of patient encounter notes to make it look like patients received exams of up to 40 minutes and fabrication of urine drug test results with false dates when, in fact, samples weren't tested for up to three months after specimens were collected. The defendants also lied to investigators and provided forged documents in response to subpoenas.

Tennessee Pain Doctor Faces Jail for Opioid Abuses, Medicare Fraud

Case: The doctor is facing 45 charges, including 22 counts of illegal distribution of a controlled substance for routinely prescribing oxycodone and other Schedule II drugs without examining and diagnosing patients, including one Chronic Pain Syndrome patient who died as a result of ingesting "The Holy Trinity" of oxymorphone, Soma and alprazolam. According to the indictment, the doctor required Medicare beneficiaries to visit his office four to six times per month for the same services cash-paying patients only had to come in twice a month to receive. He also allegedly wrote 164 individual

prescriptions for over 12,000 Schedule II controlled substance pills the very day the State of Tennessee permanently revoked his Pain Management Certificate.

Significance: As is commonly the pattern in these opioid distribution scams, the doctor allegedly exacerbated his wrongdoings by engaging in Medicare fraud (13 counts) and money laundering (9 counts), including:

- Upcoding claims to indicate a higher level of service than actually provided;
- Billing for services that weren't medically necessary;
- Causing submission of claims for unlawful prescriptions to Medicare; and
- Diverting proceeds of the fraud.

Kentucky Pain Clinic Pays $127K to Settle Specimen Validity Test Billing Claims

Case: The Northern Kentucky Center for Pain Relief agreed to pay the OIG $126,799.90 to settle claims of billing Medicare for specimen validity testing (SVT). Explanation: Under Medicare rules, urine drug testing is deemed medically necessary to detect and quantify the presence of drugs in a patient's body. However, SVT, which analyzes the urine specimen to ensure that it hasn't been tampered with or adulterated, is not deemed medically necessary if its sole purpose is to validate the specimen because the test results aren't being used to manage the beneficiary's treatment.

Significance: Last year, the OIG audited $67+ million in Medicare Part B payments for SVTs billed in combination with urine drug tests, i.e., on the same dates of service, from 2014 through 2016. The findings: $66.3 million of the payments were improper. Those payments were received by 4,480 clinical labs and physician offices. (See, *NIR*, March 16, 2018, for more details.) The OIG called on CMS to recover those SVT payments from labs, which apparently included the Kentucky clinic involved in this settlement.

Aetna to Pay California $935K for HIV Envelope Privacy Fiasco

Case: The price tag for the privacy snafu that occurred in July 2017 when Aetna mailed 12,000 beneficiaries sensitive information about their HIV medication in envelopes with a transparent window keeps going up. In January 2018, the insurance giant settled a class action lawsuit for $17.2 million. (For the details of the case, see *LCA*, March 12, 2018). Now, Aetna is settling with the states of the beneficiaries. After agreeing to pay $365.2K to New Jersey, $175K to Washington, D.C. and $100K to Connecticut, Aetna has concluded its most expensive state settlement to date—$935K to California.

Significance: You don't need to be reminded of the seriousness of HIPAA breaches. The real takeaway for lab managers: The measures the settlements require Aetna to take to ensure the privacy of patient mailings containing PHI, including:

- Using envelopes that obscure the contents;
- Ensuring that the return address contains no identifying information other than a P.O. box, city, state and ZIP code; and
- Putting a statement on the envelope front stating: "Confidential Legal Information—To Be Opened Only By the Addressee."

Health Care Reform: HHS Proposes Eliminating Drug Rebates to Cut Medicare Prescription Costs

On Jan. 31, Department of Health and Human Services Secretary **Alex Azar** floated a proposed rule to lower the prices and out-of-pocket costs of prescription drugs by having manufacturers give discounts to patients instead of insurers. HHS essentially wants to eliminate the existing drug rebate process and encourage direct discounts to Medicare patients.

HHS also claims it wants to provide transparency in the prescription drug market and remove the veil of hidden rebates and other pricing methods currently conducted between companies and pharmacy benefits managers (PBMs). Typically, the rebates and other pricing initiates given by manufacturers to PBMs and insurers are not passed through to patients.

"Every day, Americans—particularly our seniors—pay more than they need to for their prescription drugs because of a hidden system of kickbacks to middlemen. President Trump is proposing to end this era of backdoor deals in the drug industry, bring real transparency to drug markets, and deliver savings directly to patients when they walk into the pharmacy," said Secretary Azar, a former Eli Lilly executive, in a statement.

"This historic action, combined with other administrative and legislative efforts on prescription drug pricing, is a major departure from a broken status quo that serves special interests and moves toward a new system that puts American patients first. Democrats and Republicans looking to lower prescription drug costs have criticized this opaque system for years, and they could pass our proposal into law immediately," the statement went on to say.

What's the Problem?

Currently, pharmaceutical companies pay rebates as a percentage of a drug's list price, a discount that payers then can spread around to lower costs for all members of an insurance plan. On average, the net price of a drug after rebates is between 26% to 30% less than the list price set by drug-makers, HHS said. One major problem, says HHS, is that this system doesn't necessarily reduce patient out-of-pocket costs for any given drug. Rather than lowering patient out-of-pocket costs, the chief purpose of the current system of rebates has become securing favorable drug coverage—an effect HHS called "pernicious" in a fact sheet released alongside the proposed rule.

So, what is HHS Doing?

If finalized, the HHS proposal would:

- Expressly exclude from safe harbor protection under the Anti-Kickback Statute rebates on prescription drugs paid by manufacturers to pharmacy benefit managers, Part D plans and Medicaid managed care organizations.
- Create a new safe harbor for prescription drug discounts offered directly

to patients, as well as fixed fee service arrangements between drug manufacturers and PBMs.

- Provide a new level of transparency to a system.
- Prescription drug rebates may be passed on directly to patients and reflected in what they pay at the pharmacy counter.
- Address the most significant incentive drug manufacturers cite in raising their list prices every year, the pressure to provide larger and larger rebates. This rule provides a clear pathway for drug companies instead to compete to have the lower price and out-of-pocket cost to the patient.

By encouraging negotiated discounts that are reflected in cost-sharing methods like co-insurance, used for many expensive drugs in Medicare Part D, the proposal is projected to provide the greatest benefits to seniors with high drug costs. Additionally, because savings would be passed on directly to patients, the agency is anticipating reduced out-of-pocket costs on medications.

Industry Reaction

The Pharmaceutical Research and Manufacturers of America, the industry's top lobbying group, immediately praised the rule for focusing on patients. "We need to ensure that the $150 billion in negotiated rebates and discounts are used to lower costs for patients at the pharmacy," said **Stephen Ubl**, president and CEO of PhRMA. Drug-makers have argued for years that the rebates they pay are not actually benefiting patients.

However, as could be expected, the Pharmaceutical Care Management Association, the main PBM lobbying group, blasted eliminating the safe harbor protection for rebates. The move would "increase drug costs and force Medicare beneficiaries to pay higher premiums and out-of-pocket expenses, unless there is a viable alternative for PBMs to negotiate on behalf of beneficiaries," the group said in a statement.

"We need to ensure that the $150 billion in negotiated rebates and discounts are used to lower costs for patients at the pharmacy."

- Stephen Ubl
president and CEO of PhRMA

America's Health Insurance Plans, a trade group representing insurers, also criticized the proposal claiming that HHS' plan would undermine its ability to extract savings.

The critics may have a point. In a call with reporters HHS admitted that actuarial analyses found Part D premiums could go up on average $3 to $5 per member per month. The proposed rule does acknowledge that the rule's benefits would accrue to beneficiaries who use drugs most often, particularly expensive ones. For most, decreases in out-of-pocket costs may not offset the expected rise in premiums.

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And, on the Horizon

While HHS has the regulatory authority to make changes to Medicare rules, it has to rely on Congress to implement a similar plan for the commercial market. Lawmakers in Congress and the Senate are on it, and are exploring options to lower drug costs as well. The U.S. Senate Finance Committee and the House Oversight Committee started hearings on Tuesday, Jan. 29, focused on dealing with high drug prices. The House Oversight and Reform Committee announced sweeping investigations of drug pricing and indicated he had sent detailed information requests to 12 major drug manufacturers.

HHS is currently accepting comments on the proposal. Under the current proposal, the changes to the Anti-Kickback Statute would take effect Jan. 1, 2020, while the new safe harbors envisioned would become effective 60 days after the final rule is published in the Federal Register.

"This proposal has the potential to be the most significant change in how Americans' drugs are priced at the pharmacy counter, ever, and finally ease the burden of the sticker shock that millions of Americans experience every month for the drugs they need," said Azar in a statement.

Medicare Reimbursement: New Guidance on Date of Service Rules for Part B Billing of Hospital Outpatient Lab Tests, *from page 1*

Exception 1: Date of Service for Tests on Stored Specimen

The date of service depends on how long the specimen was stored:

If specimen is stored less than 30 calendar days from date it was collected: The date of service of the test/service is the date the test/service was performed, provided that:

- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test/service don't guide treatment provided during the hospital stay; and
- The test/service was reasonable and necessary for the treatment of an illness.

If specimen is stored more than 30 calendar days before testing: The specimen is considered to have been archived and the date of service of the test/service is the date the specimen was obtained from storage.

Exception 2: Date of Service for Chemotherapy Sensitivity Tests on Live Tissue

The date of service of the test/service is the date the test/service was performed, provided that:

- The decision as to the specific chemotherapy agent to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test/service don't guide treatment provided during the hospital stay; and
- The test/service was reasonable and medically necessary for treatment of an illness.

Exception 3: Date of Service for Advanced Diagnostic Laboratory Tests (ADLTs) and Molecular Pathology Tests

The date of testing for a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in 42 CFR 414.502, is the date the test was performed, provided that:

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- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter;
- It was medically appropriate to collect the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test don't guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and necessary for the treatment of an illness.

For More Information

A list of ADLTs and molecular pathology tests subject to the third exception is available on the Medicare Clinical Laboratory Fee Schedule web page under the Laboratory Date of Service Policy tab. Additional information is also available in the Medicare Claims Processing Manual, Chapter 16, Section 40.8.