G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

March 2019

INSIDE THIS ISSUE

Compliance Perspectives: CMS Reviews PAMA Reporting Basics for Hospital Outreach Labs

PAMA reporting is tricky business in which mistakes and omissions carry the risk of civil monetary penalties of up to $10,000 per day. So, whether you're with a freestanding lab that's been through the rigors or a hospital-based outreach lab that's new to the process, a quick review of PAMA reporting principles is a valuable investment of your time. To simplify, we've boiled down the basics covered by CMS during its recent "refresher call."

What's Going On

PAMA, The Protecting Access to Medicare Act of 2014, requires "applicable laboratories" to report private payor rates paid for clinical

Continued on page 2

Enforcement Trends: New DOJ Policy Targeting Whistleblowers with Weak Cases May Make Life Easier for Labs

It's not just new laws, regulations or even court cases. Trends in health care fraud enforcement are sometimes driven by changes in prosecution policies, including those that aren't made public. Such a potential game-changer came out of the Justice Department about a year ago in the form of an internal memo instructing prosecutors to not only decline to participate in but also actively seek dismissal of *qui tam* whistleblower lawsuits that lack merit. A year later, it appears that the new tough-love whistleblowers policy, aka the Granston Memo (after Michael Granston, the DOJ official who authored it) is having a real impact on federal health care enforcement activity.

The Granston Memo

Here's a quick recap of the Granston Memo. (If you want all the gory details, see *Lab Compliance Insider* (LCA), March 20, 2018) Whistleblower Law, 101. When and if the DOJ decides to take over a whistleblower's claim, the defendant's risks go way up as does the pressure to settle. If, on the other hand,

Continued on page 6

COMPLIANCE PERSPECTIVES, *from page 1*

diagnostic laboratory tests (CDLTs) to CMS for use in calculating Medicare payment rates. CMS' original definition of "applicable laboratories" excluded the majority of hospital outreach labs which skewed Medicare payments lower than they should have been.

- The good news: In issuing the 2019 Clinical Laboratory Fee Schedule (CLFS), CMS the definition of "applicable laboratories" to include more hospital outreach labs.
- The bad news: The newly included labs didn't get a breathing period and have to participate in the next round of data collection, which began in 2019.

With this in mind, CMS hosted a Jan. 22, 2019 "refresher call" to go over the requirements for reporting private payor rates and volume data for clinical diagnostic lab tests paid under the CLFS in three crucial areas:

1. Which Hospital Outreach Labs Count as an "Applicable Laboratory"

PAMA defines applicable laboratory as one that has the majority of its Medicare revenues paid under the CLFS or Physician Fee Schedule. For reporting purposes, CMS originally defined "applicable laboratory" as an entity which, using its National Provider Identifier (NPI), receives the majority or more than 50% of total Medicare revenues from payments under the CLFS and the Physician's Fee Schedule. The CMS definition of applicable labs excluded NPI level entities that receive less than $12.500 dollars from CLFS during the data collection period. The $12,500 threshold didn't apply to some labs furnishing Advanced Diagnostic Laboratory Tests (ADLTs) for the ADLTs they furnish.

As of Jan. 1, 2019, CMS amended the definition of "applicable laboratory" to include certain hospital outreach labs provided that they meet the applicable criteria. The 2019 CLFS defines a "hospital outreach laboratory" as a hospital-based lab that furnished lab tests to patients other than admitted inpatients or registered outpatients of the hospital. CMS also clarifies the rules for hospital outreach labs to calculate Medicare lab revenues for purposes of determining whether they fall into the new "applicable laboratories" definition by:

- Excluding Medicare Advantage plan payments from total Medicare revenues;
- Requiring hospital outreach labs that bill for their non-patient lab services using the hospital's NPI to use Medicare revenues from the Form CMS-1450 14x Type of Bill to determine whether they meet the majority of Medicare revenue threshold and low expenditure threshold;
- Requiring hospital outreach labs that bill Medicare Part B for non-patient lab services using the hospital NPI instead of their own NPI to determine applicable laboratory status from their Medicare revenue attributed to the form CMS 1450 14X TOB.

LCA

Glenn S. Demby, Executive Editor
Elayne Demby, Contributing Editor
Paula Santonocito, Contributing Editor
Lori Solomon, Contributing Editor
Catherine Jones, Contributing Editor and Social Media Manager
Barbara Manning Grimm, Managing Editor
Jim Pearmain, Layout & Design
Myra Langsam, Business Development
Michael Sherman, Director of Marketing
Pete Stowe, Managing Partner
Mark T. Ziebarth, Publisher

Lab Compliance Advisor
(ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

2. Which "Applicable Information" Must Be Reported

If the hospital outreach lab finds that it does meet the definition of "applicable laboratory," it must report "application information" to CMS during data reporting periods. CMS clarified that the Taxpayer Identification Number (TIN) level entity, not the applicable laboratory, is responsible for reporting applicable information for each CDLT furnished by its component applicable laboratories. During the refresher call, CMS also explained that "applicable information" includes:

- The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test;
- Each private payor rate for which final payment was made during a data collection period (by date of final payment); and
- The associated volume of tests performed for each private payor rate.
- CMS then listed examples of applicable information, including:
- Multiple payment rates for the same test—if a lab has more than one payment rate for the same private payor for the same test or more than one payment rate for different private payors for the same test, the reporting entity must report each such payment rate and the volume for the tests at each such rate;
- Resolved appeals;
- Non-contracted amounts for out-of-network labs or services; and
- Final payments from secondary insurance payors.

CMS then added that applicable information does not include:

- Unresolved appeals;
- Payments that don't reflect specific HCPCS code level amounts;
- Remittances where the payor has grouped test-level payments into a claim level payment; and
- Denied payments.

3. Private Payor Data Collection and Reporting Policies

CMS then went on to explain private payor data collection and reporting policies, starting with the PAMA definition of private payor, i.e.:

- A health insurance issuer and a group health plan (as defined in section 2791 of the Public Health Service Act);
- A Medicare Advantage plan under Part C; and
- A Medicaid managed care organization (as defined in section 1903(m)).

Next, CMS outlined what should be reported to CMS as far as the private payor rate goes, including:

- All payment rates for a test;

Continued on page 4

COMPLIANCE PERSPECTIVES, *from page 3*

- The final amount paid by a private payor for a CDLT after all private payor price concessions are applied; and
- Private payor payment rates for CDLTs paid for under the CLFS and any patient cost sharing amounts.

Private payor rates do not include:

- Private concessions applied by labs; and
- Information about denied payments.

Case of the Month: Facing 3 against 1, Texas Lab Settles EHR Consulting Kickback Charges

Question: What happens when multiple whistleblowers bring separate *qui tam* lawsuits against a lab for the same offense?

Answer: Under the False Claims Act (FCA), only the first whistleblower to file gets to bring the case.

However, this general principle, known as the first-to-file rule, is subject to exceptions. A Texas pathology lab recently learned this lesson the hard way.

The EHR Services Safe Harbor

Providing referring physicians free or discounted consulting services is a form of remuneration banned by the Anti-Kickback Statute (AKS) and Stark Law. But back in 2006, as part of an HHS effort to make it easier for physicians to switch from paper records to electronic health record (EHR) systems, a temporary AKS safe harbor and Stark exception was created letting non-physician providers pay up to 85% of physicians' costs to help them transition through 2014.

The Inform Diagnostics Case

A number of lawsuits have been filed charging labs and other providers with taking advantage of those rules. The latest case targets Inform Diagnostics (which was then known as Miraca Life Sciences Inc.) for allegedly stretching things beyond the breaking point by offering physicians discounts on EHR consulting services in exchange for lab referrals. Three different whistleblowers, including the Miraca's former Life Science Sr. Vice President of Commercial Operations and dermapathologists, as well as a company called LPF LLC, claimed that Inform/Miraca limited the discount

deal to physicians it identified as potentially high-volume referral sources and basing individual discount amounts on the anticipated return on investment the particular physician's referrals would generate.

Were the allegations true?

We may never know. That's because Inform/Miraca has decided not to risk a trial and instead agreed to settle the claims for $63.5 million, which will be paid by its former parent, Japanese company Miraca Holdings Inc.

Why the First-to-File Rule Didn't Apply

The case might have had a different outcome had Informa/Miraca been able to take advantage of the first-to-file rule to get two of the three cases dismissed. And it looked like that would be the case considering that all three lawsuits involved the same scheme. But the federal court in Tennessee allowed all three claims to proceed.

Reason: There's an exception to the first-to-file rule allowing for separate suits involving the same scheme when each of the whistleblowers offers unique information about how the defendant carried out the scheme. And that's what happened in this case, with each of the three whistleblowers shedding light on a different aspect of Informa/Miraca's alleged kickback arrangement with referring physicians.

Takeaway: Settlements Are Often More About Leverage than Truth

Leaving aside the bad apples who get caught red handed, labs generally don't settle claims because they're true. More often than not, settlement is based not on the truth of the allegations but the business dynamics involved. Stated simply, settling a claim is much safer and, frequently, cheaper than waging a legal defense. The situation in this case is a classic example. As if three-on-one wasn't tough enough, the fact that the DOJ had decided to intervene in each case decisively tipped the leverage equation in the whistleblowers' favor and made it all but imperative for Informa/Miraca to settle the cases.

For More Information:

- In case you want to look them up, the three cases are called: *United States ex rel. Dorsa v. Miraca Life Sciences, Inc.*, Case No. 13-cv-1025 (M.D. Tenn.); *United States ex rel. LPF, LLC v. Miraca Life Sciences, Inc., et al.*, 3:16-cv-1355 (M.D. Tenn.); and *United State ex rel. Heaphy, et al. v. Miraca Life Sciences, Inc.*, 3:18-cv-1027 (M.D. Tenn.).

Enforcement Trends: New DOJ Policy Targeting Whistleblowers, *from page 1*

the DOJ declines to intervene, the risk and pressure to settle shifts to the whistleblower. But there's also a rarely used part of the False Claims Act, (Section 3170(c)(2)(A)) that lets the government actually seek dismissal of the case if it thinks the suit doesn't serve the government's interests.

The Granston Memo, which we only know about because somebody leaked it to the press in January 2018, calls on federal prosecutors to use Sec. 3710(c)(2)(A) power aggressively and lists the kinds of cases that prosecutors should try to get dismissed.

The 7 Cases the Granston Memo Targets for Dismissal

1. Meritless claims asserting an "inherently defective" legal theory or "frivolous factual allegations;"
2. Parasitic or opportunistic claims that duplicate pre-existing government investigations and add no useful information to the investigation;
3. Cases that pose threats to government policies or programs;
4. Actions interfering with other FCA cases;
5. Cases threatening harm to national security, e.g., actions that may compromise classified information or involve intelligence agency operations;
6. Cases where costs will exceed gain, including "opportunity costs" of not utilizing resources for higher priority cases with a better chance of recovery; and
7. Claims that may frustrate an investigation.

The Granston Memo also instructs prosecutors to notify whistleblowers when they're thinking about pursuing a Sec. 3710(c)(2)(A) dismissal. Reasoning: Whistleblowers will be more likely to drop the case once they realize that the DOJ not only isn't going to intervene on their behalf but may actually try to get the case thrown out of court.

Impact of the Granston Memo

While the DOJ generates more than its fair share of internal memos, the early returns suggest that the Granston Memo is actually shaping policy. We do know that FCA whistleblower recoveries in the health care segment declined in 2018, from $2.151 billion to $1.945 billion. But year-to-year recoveries were also down from 2016-17, a year before the Granston Memo came into existence.

A much more reliable indicator of the Memo's influence is that prosecutors

are now actually bringing Sec. 3710(c)(2)(A) dismissal claims against whistleblowers, most notably on Dec. 17, 2018, when the DOJ moved to dismiss 11 *qui tam* actions in seven judicial districts. The cases were brought by the National Healthcare Analysis Group (NHCA), a company that specializes in generating FCA cases, and essentially asserted the same complaints with different defendants, at least in the DOJ's opinion. In its dismissal claims, the DOJ accuses the NHCA of dishonesty contending that transcripts from the "witness interviews reveals the false pretenses NHCA uses to obtain information."

Takeaway

Regardless of the ultimate outcome, the DOJ's move to get the NHCA cases tossed out of court is 100% consistent with the principles outlined in the Granston Memo. It remains to be seen whether the DOJ will pursue these actions more frequently. But if it does, health care will reap the greatest benefit considering that such a disproportionate number of whistleblower FCA claims target the industry.

A DOJ operating on Granston Memo principles would also strengthen the hand of attorneys defending your lab in a *qui tam* suit by offering a new strategic option: Making the case to the prosecutor that the case should be dismissed under one or more of the seven Granston Memo factors.

CLIA: After Nearly 3 Decades, CMS Proposes Updates to Proficiency Testing Rules

When the CLIA (the Clinical Laboratory Improvement Amendments of 1988) proficiency testing (PT) regulations were first implemented in 1992, George H.W. Bush was President, gas cost about $1.05 per gallon and the Washington Redskins won the Super Bowl. Lab technology has sure changed a lot since those days. But the PT regulations haven't been updated to deal with those changes. Until now, that is. On Feb. 4, 2019, CMS and the Centers for Disease Control and Prevention (CDC) finally got around to issuing a new proposed rule to modernize PT requirements.

Background

As of 2017, there were 246,143 CLIA-certified laboratories, 36,777 of which are required to enroll in a CMS-approved PT program and comply with the PT regulations. There are also currently 81 analytes on the list of regulated analytes requiring proficiency testing.

Not surprisingly, labs have been calling for PT updates for years, noting that testing has evolved significantly since 1992, current technology is far more precise and tests for analytes that weren't included in the original CLIA regulations are now in routine clinical use.

Continued on page 8

CLIA: After Nearly 3 Decades, CMS Proposes Updates to Proficiency Testing Rules, *from page 8*

CLIAC Recommendations

The Clinical Laboratory Improvement Advisory Committee (CLIAC), the federal advisory committee charged with providing regulatory and lab quality advice to the CLIA program, kicked things off by issuing recommendations for updating PT rules, including:

- Updating the list of required PT analytes;
- Revising scoring criteria for acceptable performance;
- Updating requirements for microbiology to include broad categories of organisms rather than a list of specific organisms; and,
- Clarifying requirements for PT referrals.

In response, CMS published a request for information in December 2017. The new proposed rule responds to the public input from the RFI.

The 3 Key Proposed Changes

CMS and CDC are proposing changes in three broad areas:

1. Addition of 29 Analytes

For non-microbiology specialties and subspecialties, the agencies are proposing to add 29 analytes to Subpart I of the CLIA regulations, based upon five criteria:

- Current availability of PT materials;
- The number of PT programs that can provide analytes;
- Volume of patient testing performed nationwide;
- Impact on patient health and/or public health; and
- Cost and feasibility of implementation.

2. Updating of PT Categories

For microbiology specialties and subspecialties, the proposed rule would require updates to specify broad categories of tests requiring PT to allow for flexibility of new technologies currently in use and those that may be developed in the future.

3. Revised Referral Rules for Waived Tests

The proposed rule would amend regulations on how PT referral rules apply to moderate and high complexity labs that also perform waived tests. Specifically, the change is designed to align CLIA regulations with the CLIA statute provisions allowing CMS to apply sanctions on labs performing waived testing found participating in PT referral.

Deadline to Comment

CMS will be accepting comments on the proposed rule until April 5, 2019.

Billing: How to Determine Date of Service for Part B Billing of Outpatient Lab Tests

Date of service rules affect whether outpatient lab tests are part of the Hospital Outpatient Prospective Payment System (HOPPS) bundled payment or can be billed separately under Part B. Last month, CMS issued guidance clarifying how providers should apply the new rules on their CMS-1500 and/or X12 837 Professional Claim forms. Here's what you need to know if you bill outpatient lab tests under Part B.

General Date of Service Rule

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, as the guidance notes, there are three exceptions:

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 ≤ 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

Continued on page 10

How to Determine Date of Service for Part B Billing of Outpatient Lab Tests, *From Page 9*

- 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:

- 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.

Medicare Reimbursement: CMS Limits NGS Early Cancer Test Coverage but Industry Fires Back

Getting Medicare to cover Next Generation Sequencing (NGS) tests has been a slow go. And the latest CMS National Coverage Determination (NCD) for early stage cancer NGS testing of patients with hereditary risks is the latest disappointment. Here's a look at the NCD and what the lab industry is doing to get it revised.

The NCD & Shift on NGS Testing

The NCD was requested for an NGS test for Medicare beneficiaries with advanced cancer. Even though the request was limited to a somatic-based test, CMS instructed Medicare Administrative Contractors (MACs) to apply the NCD to both somatic and germline NGS testing. This is significant because it suggests that patients with early-stage cancer who have a genetic predisposition based on family history or other acceptable criteria should not be eligible for Medicare coverage for testing using NGS-based methods.

Explanation: MACs have adopted local coverage determinations (LCDs) providing coverage of NGS-based genetic testing for mutations associated with inherited cancer syndromes, like BRCA mutations and Lynch syndrome. But because an NCD supersedes an LCD, the new NCD would cancel out those favorable LCDs allowing patients with early-stage cancers to access hereditary testing.

Industry Reaction

The American Clinical Laboratory Association (ACLA) and other organizations are pushing back against the Medicare coverage policy shift. On Jan. 31, the ACLA and 60 other health care organizations and companies sent a letter to CMS administrator Seema Verma asking the agency to revise the NCD. The letter makes two principle arguments:

Poorer Outcomes: The letter contends that denying NGS testing for early stage cancers to patients with hereditary risks will lead to poorer outcomes. "It is essential that CMS unequivocally maintain coverage for medically necessary NGS-based tests," argues ACLA President Julie Khani. "Imposing broad restrictions on standard of care testing will have serious consequences for Medicare beneficiaries and negatively impact their care."

Lack of Policy Review: The letter also points out that CMS adopted the NCD with no notice or comment period on its impact and the fact that under the new coverage policy only tests utilizing older, less advanced and more expensive non-NGS methods will be eligible for Medicare coverage. The organizations urge CMS to revise its current interpretation of the NCD by limiting it to somatic tumor testing and to communicate this change to the MACs.

What Next?

As of the date we went to press, CMS has yet to issue its response to the letter or clarify its position on the NCD. Stay tuned for further developments.

OIG Monthly Work Plan Review: So far in 2019

In February, there were two new Work Plan items. One of these may have implications for some labs and is detailed below.

Characteristics of Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose

Issue: In 2017, there were an estimated 49,000 opioid-related overdose deaths in the United States. In a recent data brief, Opioid Use in Medicare Part D Remains Concerning, OIG found that about 71,000 Part D beneficiaries were at serious risk of misuse or overdose in 2017. Gaining a deeper understanding of the beneficiaries OIG identified as at serious risk of misuse or overdose is an important next step in addressing the crisis.

OIG Action: An OIG study will provide needed information about: (1) the characteristics of these beneficiaries, including their demographics and diagnoses; (2) the opioid utilization of these beneficiaries; and (3) the extent to which these beneficiaries have had adverse health effects related to opioids and any overdose incidents.

In January there were six new Work Plan items. The two pertaining to labs are detailed below. The first one has widespread implications for labs; the

Continued on page 12

OIG Monthly Work Plan Review: So far in 2019, *From Page 11*

second may have implications for some labs.

1. Medicare Payments for Clinical Diagnostic Laboratory Tests in 2018: New Payment Rates

Issue: Medicare is the largest payer of clinical laboratory services in the nation. Medicare Part B covers most lab tests and pays 100% of allowable charges, with no beneficiary copayment. In 2017, Medicare paid $7.1 billion for lab tests, a total that has changed very little in the four-year period from 2014 through 2017. The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to set payment rates for lab tests using current charges in the private healthcare market, under Title XVIII of the Social Security Act. On Jan. 1, 2018, CMS began paying for lab tests under the new system mandated by PAMA.

OIG Action: PAMA requires OIG to publicly release an annual analysis of the top 25 laboratory tests by expenditures. In accordance with PAMA, OIG will publicly release this analysis for 2018, the first year of payments made under the new system for setting payment rates.

2. States' Compliance with New Requirements to Prevent Medicaid Payments to Terminated Providers

Issue: To prevent terminated providers from treating Medicaid enrollees or receiving Medicaid payments, the 21st Century Cures Act requires CMS to provide information to all states on Medicaid providers that have been terminated for cause.

OIG Action: A study, mandated by the Cures Act, will examine the extent to which terminated providers included in CMS's terminations database have been terminated from all state Medicaid programs and the amount of Medicaid payments for items/services associated with terminated providers. Additionally, this study will examine the extent to which state contracts with managed care entities include a provision that terminated providers are excluded from all managed care networks.