G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 39th Year of Publication

Vol. 18, Iss. 4, April 2018

INSIDE THIS ISSUE

www.G2Intelligence.com

G2 Intelligence Upcoming Events

Lab Institute 2018

Surviving Disruption: Rethinking Business Models, Technologies, and Competitive Strategies in a Changing Lab Market

Oct. 24-26, Washington, DC

www.labinstitute.com

Enforcement Trends: Labs Getting Swept into the Opioid Crackdown Vortex

Best known for its employment applications, urine drug testing is also medical protocol for patients prescribed opioid drugs. Urine tests are used to ensure patients are not developing addictions and confirm they are actually taking the meds rather than selling them on the black market. Accordingly, such testing figures prominently in what is rapidly becoming Public Enemy Number 1 for federal health care enforcers: prescription opioid abuse.

Continued on page 2

Medicare Reimbursement: CMS Launches New LVA Process for Settling Payment Appeals

While Part B lab reimbursements may be going down, the good news is that it just became easier to challenge Medicare payment denials. Here is an overview of the new CMS Low Volume Appeals settlement process and how to take advantage of it with regard to both Part A and Part B claims. Here is an overview of the LVA process and how to take advantage of it.

Potential Recovery

The LVA settlement process, which officially began on Feb. 5, 2018, offers timely partial payment of 62% of the net Medicare approved amount.

Eligible Providers

LVA settlement is open to Medicare Part A and Part B providers, including labs, as well as physicians and suppliers (referred to collectively as "appellants") with fewer than 500 combined pending appeals with the Office of Medicare and Appeals and Medicare Appeals Council (Council) at the Departmental Appeals Board as of Nov. 3, 2017. Your lab is **not** eligible to file LVA settlement appeals if it is currently involved in *False Claims Act* (FCA) litigation or is subject of a pending criminal, civil or administrative investigation for FCA or other program integrity concerns. Other ineligible appellants include:

Continued on page 11

Enforcement Trends: Labs Getting Swept into the Opioid Crackdown Vortex, *from page 1*

Old Problem, New Urgency

Urine drug testing has been on the government's radar for years. Increases in opioid prescriptions have coincided with increases in utilization. But the real red flag has been the rising prices of such tests. Once a simple and inexpensive procedure involving a test cup and strip, many labs have upped the ante by installing high tech testing machines. In addition to being pricier, machine tests have offered another financial advantage: Under Medicare rules, each individual drug tested for could be billed individually.

All of this has caused urine testing reimbursements to skyrocket. Thus from 2011 to 2014, Medicare and private insurer spending on urine screens and related genetic tests quadrupled to roughly $8.5 billion per year, according to Kaiser Health News and Mayo Clinic analysis. In 2014, the federal government paid more in urine drug tests than for the four most recommended cancer screenings *combined*.

This additional spending has proven a windfall for some physicians, especially those that operate their own testing labs, typically as part of a pain management, drug screening or other clinic. Bloomberg reports that in 2014-2015, Medicare paid over 50 different pain management practices at least $1 million for drug-related urine tests. According to Bloomberg, 31 pain practitioners derived at least 80% of their Medicare income from urine testing.

Suspicion Grows

Of course, none of this has been lost on the feds. Back in 2010, CMS tightened up on billing for simple urine screens. But the new rules did not cover machine testing. Prosecutors, too, began taking note of the spike in reimbursements and the incongruously high rates for what were thought to be simple tests. The remark of a Jacksonville, Florida assistant U.S. attorney reportedly quoted in Bloomberg sums up the attitude: "We're focused on the fact that many physicians are making more money on testing than treating patients. It is troubling to see providers test everyone for every class of drugs every time they come in."

The Millennium Case

The enforcement breakthrough came in 2011 when one of the country's leading billers of urine drug tests, Millennium Health LLC, faced an onslaught of whistleblower suits for allegedly billing Medicare and Medicaid for millions in unnecessary urine drug and genetic tests and providing freebies to physicians in exchange for referrals. The Justice Department picked up the case and in October 2015, Millennium agreed to fork over $256 million to settle the claims. Faced with such a liability, Millennium soon filed for bankruptcy.

Enter the Opioid Epidemic

The seeds for a crackdown on urine drug testing sowed earlier have been brought into full bloom by the opioid epidemic.

The issue has morphed from financial rip-off to full blown national health crisis. What is being questioned now is not simply the billing or even order-

NIR

Glenn S. Demby, Editor

Lori Solomon, Contributing Editor

Catherine Jones, Contributing Editor and Social Media Manager

Barbara Manning Grimm, Managing Editor

David van der Gulik, Designer

Randy Cochran, Corporate Licensing Manager

Myra Langsam, Business Development

Michael Sherman, Director of Marketing

Jim Pearmain, General Manager

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher

National Intelligence Report (ISSN 2332-1466) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 1-888-729-2315
Fax: 1-855-649-1623
Web site: www.G2Intelligence.com.

ing of the tests but the underlying decision to prescribe opioids in the first place. Accordingly, during the recent explosion of opioid abuse cases, physicians and not labs have been the primary target.

Takeaway: First the Doctors, Then the Labs

While testing labs are not the prime concern, they are still an integral part of the case. In the early cases labs have come into play only to the extent they were part of the ordering physician's "pill mill" operation. Accordingly, labs owned or operated by physicians currently have the most to fear. But that is bound to change. The opioid crackdown is just starting and it is only a matter of time before hospital and independent labs come under scrutiny.

In fact, the OIG may have just fired the first warning shot across the bow. On Feb. 20, the agency published a new report stating that between 2014 and 2016, Medicare made $66.3 million worth of improper specimen validity tests billed in combination with urine drug tests to 4,480 clinical labs and physician offices. (See the story below for more details.)

Bottom Line: Any and every lab that is involved in urine drug testing of opioid patients, whether physician-owned or independent, has to be on high alert.

Part B Reimbursement: OIG Flags $66.3 Million in Improper Urine Specimen Validity Test Payments

These are tense times for providers of urine drug tests for Medicare and Medicaid patients. And on Feb. 20, the hot seat got even hotter with the issuance of a new OIG report saying CMS made $66.3 million worth of improper payments for specimen validity tests billed in combination with urine drug tests. Here's an overview of the report and what it portends for labs and physician offices.

Urine Drug & Specimen Validity Testing

Under Medicare rules, urine drug testing is deemed medically necessary to detect and quantify the presence of drugs in a patient's body. Specimen validity testing, which analyzes the urine specimen to ensure that it has not been tampered with or adulterated, is not deemed medically necessary if its sole purpose is to is to validate the specimen because the test results are not being used to manage the beneficiary's treatment.

Exception: Specimen validity testing is medically necessary in limited cases when it is used in combination with a urine drug test done on the same day for purposes of diagnosing certain conditions such as kidney stones or urinary tract infection. However, the latter cases should be relatively rare, according to CMS officials cited in the report.

OIG Findings

With that in mind, the OIG audited $67+ million in Medicare Part B payments for specimen validity tests billed in combination with urine drug tests, i.e., on the same dates of service, from 2014 through 2016. The find-

ings: $66.3 million of the payments were improper. Those payments were received by 4,480 clinical labs and physician offices. The report cites two reasons for the improper payments:

- The providers' failure to follow existing Medicare guidance; and
- The inadequacy of CMS system edits designed to prevent payment for specimen validity tests billed in combination with urine drug tests.

In fact, CMS did implement revised edits on April 1, 2016. But while the revised edits helped, $1.8 million worth of improper payments still got past the goalie during the first nine months they were in place. That projects to an unacceptable rate of $12.1 million over five years.

OIG Recommendations

The report lists two recommendations, both of which CMS has accepted:

- Medicare contractors should recover the $66.3 million it improperly paid out for specimen validity testing; and
- CMS and its software contractors should go back to the drawing board and come up with a better system edit solution for flagging improper billing of specimen validity tests in combination with urine drug tests edits to repair the leakage in the current edits.

Impact on You

If yours is among the 4,480 labs and physician offices to receive improper payments for specimen validity tests during the audit period, you can expect a repayment request from your Medicare contractor. But the recovery process may not be so simple and straightforward. True, your contractor knows who you are since the OIG audit identifies the improper payment recipients. The problem, at least for the contractors, is that the audit looks only at specific claim lines. As a result, contractors will have to conduct medical review of the entire claim to determine whether it includes a relevant diagnosis code.

DOJ to Prosecutors: Show Tough Love to Whistleblowers with Weak Cases

A newly leaked internal Justice Department memo signals a new prosecution policy that may make it harder for whistleblowers to bring *qui tam* whistleblower lawsuits under the *False Claims Act* (FCA). Here is a look at the policy and why it may be good news for your lab and its attorneys

Qui Tam, 101

The so called *qui tam* provisions of the FCA allow individual whistleblowers, known as "relators," to act as private attorneys general and sue companies for ripping off the government. In addition to being moral, whistleblowing can also be highly profitable. If the suit is ultimately successful, the government can collect triple damages and the relator can walk away with up to 35% of the recovery.

But there are also big risks. FCA cases must be filed under seal to give the DOJ time to investigate and decide whether it wants to intervene:

- If the government joins, pressure mounts on the defendant to settle the case; but
- If the government declines, the relator can still go forward with the case but with far less leverage and legal firepower.

There is also one more possibility: The FCA (Section 3170(c)(2)(A)) actually gives the government the right to seek dismissal over the relator's objection if it thinks its interests are not served by the suit. But while it is on the books, the DOJ almost never uses its Section 3170(c)(2)(A) dismissal powers.

The Granston Memo

An internal memo issued by DOJ Civil Fraud Section Director Michael Granston on Jan. 10 aims to change that. The so called Granston Memo instructs U.S. Attorneys to use Section 3170(c)(2)(A) more aggressively. The right to seek dismissal is an important "tool" enabling the DOJ to exercise its "gatekeeper role" in preserving enforcement resources, protecting government interests and preventing weak cases from resulting in adverse judgments that weaken the government's enforcement powers.

The Seven Factors for Seeking Dismissal

The Memo sets out seven factors that U.S. Attorneys should consider in deciding whether to seek dismissal of a whistleblower suit under Section 3170(c)(2)(A):

1. Meritless Claims, i.e., where a *qui tam* complaint appears to be lacking in merit because the relator's legal theory is "inherently defective," or because his/her "factual allegations are frivolous."

2. Parasitic or Opportunistic Claims, i.e., *qui tam* actions that duplicate pre-existing government investigations and add no useful information to the investigation and bestow the relator with an unwarranted windfall in taxpayer dollars for providing merely duplicative information.

3. Threats to Policies or Programs, i.e., *qui tam* actions that threaten to interfere with a government agency's policies or programs.

4. Actions Interfering with Other FCA Cases, e.g., a separate *qui tam* case in which the government has already chosen to intervene.

5. Cases Threatening Harm to National Security Harm, e.g., *qui tam* actions that may compromise classified information, involve intelligence agency operations or military contracts.

6. Cases Where Costs Will Exceed Gain, the calculation of which should include the "opportunity cost" of utilizing resources on other matters of higher priority with a surer probability of recovery.

7. Claims that May Frustrate an Investigation, i.e., whether there are issues, such as procedural errors, with the relator's action that frustrate the government's effort to conduct a proper investigation.

Impact on Labs & Health Care

Caveat: It remains to be seen whether prosecutors actually follow the Granston Memo guidance. If they do, it might lead to a reduction of *qui tam* suits by discourage whistleblowers and their attorneys from asserting questionable claims. While such an impact would benefit all industries covered by the FCA, health care would reap the greatest benefit considering the disproportionate number of *qui tam* claims targeting that sector.

If it takes, the new Granston Memo policy may also strengthen the hand of attorneys defending your lab in a *qui tam* suit under seal by offering a new strategic option: Making the case to the prosecutor that the case should be dismissed under the Granston Memo factors.

FDA Watch: Agency Approves DTC Genetic Breast Cancer Test—But Attaches Strings

On March 6, the FDA announced its first ever approval of a direct-to-consumer breast cancer gene test—23andMe's genetic health risk report for detecting BRCA1 and BRCA2 genetic mutations most commonly found in people of Ashkenazi Jewish descent. But in announcing the approval, the FDA also took pains to point out its "caveats." According to Donald St. Pierre, FDA acting director of the Office of In Vitro Diagnostics and Radiological Health:

- The test should not be used as a substitute for seeing your doctor for cancer screenings or counseling on genetic and lifestyle factors that can affect cancer risk;
- The test does not provide information on a person's overall risk of developing any type of cancer;
- Use of the test carries significant risks if individuals use the test results without consulting a physician or genetic counselor;
- Test results should not be used to make treatment decisions such as prophylactic removal of breasts or ovaries.

Still, the approval continues the FDA's new liberal policies on DTC testing.

On Valentine's Day, the FDA announced another new milestone: the first agency approval of a blood test for use in diagnosing concussions.

Last April, the agency gave 23andMe the greenlight to engage in DTC marketing of its Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions. (See *NIR*, April 26, 2017 for the details.) And in December, the FDA proposed new rules allowing for DTC marketing of genetic tests without premarket approval in limited situations. (See *NIR*, Dec. 11, 2017 for the details.)

2017 Record Year for Personalized Medicine Approvals

Another manifestation of the FDA's liberalization is the16 new personalized medicine products the agency approved in 2017, 34% of all new of all new drugs, agents, or therapeutic biologics approved during the year. Key approvals included:

- Expanded approval of Keytruda to all tumor types, the first approval of an oncology drug based on a biomarker rather than location in the body;
- DTC marketing of 23andMe's Personal Genome Service Genetic Health Risk tests noted above;
- Approval of personalized medicine biosimilar for Herceptin (trastuzumab); and
- Joint FDA approval and CMS coverage decision for Foundation Medicine's NGS-based FoundationOne CDx test.

A Blood Test Breakthrough

On Valentine's Day, the FDA announced another new milestone: the first agency approval of a blood test for use in diagnosing concussions. The Brain Trauma Indicator, marketed by Banyan Biomarkers Inc., measures two proteins associated with concussion when detected in high levels via CT scan. The new assay is blood-based and has been approved for use by physicians in ruling out concussion. Abbott is among the other firms reported to be developing their own blood test for detecting the proteins without CT scan.

Flu Tests

Meanwhile, as the U.S. struggled with its nastiest flu season in years, the FDA approved five different products for the qualitative detection of influenza in January and February, including:

- QuickVue Influenza A+B, an assay from Quidel that detects and differentiates between influenza types A and B in 10 minutes, which the agency reclassified as a class II rapid influenza diagnostic test;
- Two different rapid, instrument influenza detection and A vs. B differentiation tests from Alere, now part of Abbot;
- Xpert Xpress Flu, Cepheid's new test system and molecular test for detecting A and B influenza from either nasopharyngeal or nasal swabs; and
- Mesa Biotech's Accula Flu A/Flu B test which runs on the firm's Accula system.

Labs IN COURT

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

ACLA Seeks Decisive Blow in PAMA Challenge Case

Case: Attorneys for the American Clinical Laboratory Association asked the federal court for summary judgment in its lawsuit challenging the legality of the new PAMA-based Medicare Part B fee schedule for lab tests. Specifically, ACLA contends that the HHS exceeded its authority and ignored the PAMA legislation by omitting hospital and reference labs from pricing data used to set fee rates for lab services under the law. For more about the lawsuit, see *GCA*, Dec. 11, 2017.

Significance: If the court does grant summary judgment it would essentially be saying that it has enough basis to rule that ACLA's claims are legally valid without holding a trial. If it denies the motion, a trial will be necessary—unless, that is, HHS brings and wins its own summary judgment motion.

Vermont Hospital Settles Outpatient Tests False Billing Claims for $1.65 Million

Case: The DOJ contended that between 2012 and 2014 Brattleboro Memorial Hospital (BMH) knowingly submitted claims for outpatient lab tests without the required medical necessity documentation. "In some instances, the clinicians' orders for laboratory tests did not appear to adequately document the diagnosis code included on the billing claim form as required," according to the U.S. Attorney. Rather than risk a trial, BMH coughed up $1,655,000 to settle the case.

Significance: The good news is that BMH avoided a much higher fine by fully cooperating with the investigation and implementing billing system and personnel changes to address the problem that led to the improper billing. The bad news is that BMH might have been able to prevent the case from being brought in the first place had it heeded the warnings of the veteran administrator in the finance department who allegedly observed the billing improprieties. But after her "vigorous protests" went ignored and she began experience what felt like recriminations, she went the legal route by filing a qui tam whistleblower lawsuit against BMH. The government joined the suit, all but forcing the settlement and the whistleblower will share 15% to 20% of the recovery.

Court Nixes Whistleblower Suit Blaming Software Firm for Medicare Double-Billing

Case: A physician coding supervisor for a North Carolina health system that used billing software from Epic filed a qui tam lawsuit against the firm claiming that the product caused it to double-bill the government for "hundreds of millions of dollars" worth of anesthesia services. The government declined to join the case and the district court judge in Florida tossed it out without a trial [*US ex rel. Petrowski v. Epic Systems Corp.*].

Significance: The whistleblower's legal problems stemmed less from the claim's substantive merits—or lack thereof—but the amateurish and ineffective way in which it was asserted. The judge chastised the whistleblower for merely parroting language from the *False Claims Act* and failing to provide specific, credible allegations of how Epic had violated it. To make matters worse, she didn't try to amend and clarify the complaint even after Epic moved to have it dismissed due to vagueness and lack of specificity. But the whistleblower is considering her appeal options and the case may not yet be over.

Doctor Busted for Drug Test Abuses as Part of "Pill Mill" Scam

Case: Dr. Rodney Moret, a 67-year-old Michigan M.D, pleaded guilty to using his pain management and HIV infusion clinic as a "pill mill." In addition to illegally dispensing $15 million worth of prescription drugs, including controlled substances Hydrocodone, Alprazolam, and promethazine with codeine cough syrup, the doctor billed Medicare for $6 million worth of tests that were either not medically necessary or not performed at all. Sexually molesting and harassing female patients made an ugly situation that much more hideous and surely weighed in the judge's decision to sentence the doctor to 75 months' imprisonment.

Significance: Dr. Moret is the most recent doctor taken down in what has become a crucial part of the federal government's opioid drug crusade: urine tests ordered by prescribing physicians to be performed at the labs they own. See the related story on page 3 for more details.

Drug Testing Lab & Referring Psychiatrist Indicted for Kickbacks

Case: After a lengthy investigation, the feds indicted the owner of a now-defunct Kentucky clinical drug testing and screening lab for allegedly paying $843,242 to a psychiatrist in illegal kickbacks for Medicaid patient referrals. The psychiatrist was also indicted.

Significance: Each defendant faces a maximum sentence of $250,000 in fines and/or five years in jail. The lab owner denies the charges citing his 50+ years of sanction-less service; the psychiatrist has yet to respond.

Test Ordering & Utilization: Labs Stand to Benefit from Industry Efforts to Minimize Prior Authorization Red Tape

Although not specifically directed at labs, a new collaboration between the American Medical Association and insurance giant Anthem may offer solutions to a perennial thorn in the side of labs: payor prior authorization requirements of physician ordered treatments.

The Consensus Statement

The seeds for the initiative were planted on Jan. 17, 2018 when a group of leading health care organizations, including the AMA, American Hospital Association, America's Health Insurance Plans and the Medical Group Management Association published a Consensus Statement outlining five areas where the stakeholders could work together to streamline and minimize the burdens imposed by the prior authorization process, including:

- Selective application of prior authorization based on provider performance on quality measures and adherence to evidence-based medicine or contractual agreements such as risk-sharing arrangements;
- Regular review of medical services and prescription drugs requiring prior authorization to identify therapies that no longer warrant prior authorization;

- Transparency and effective two-way communication channels among plans, providers and patients to ensure timely resolution of prior authorization requests and minimize care delays;
- Ensuring that prior authorization does not compromise continuity of care for patients undergoing treatment subject to changes in formulary, coverage or health plan; and
- Industry-wide adoption of electronic prior authorization transactions based on existing national standards.

The AMA-Anthem Collaboration

On March 7, AMA and Anthem took the first concrete steps by announcing a collaboration designed to put the Consensus Statement principles into action. "Collaboration between payers and health care professionals is critical evolve and advance our health care system to one that is simpler, more accessible and more affordable for consumers," noted Anthem, Inc. chief clinical officer Craig Samitt, M.D. "Today we are reaffirming our commitment to work together to create a best-in-class health care system that delivers on this promise for patients across the country." said Craig Samitt, M.D., chief clinical officer at Anthem, Inc. "The AMA looks forward to finding common ground on ways to improve the delivery of affordable, high-quality, patient-centered care," added AMA Board Chair Gerald E. Harmon, M.D.

In addition to streamlining prior authorization, the AMA/Anthem collaboration aims to achieve other broad goals to enhance the speed, efficiency and effectiveness of the health care system via improved payor-physician relations, including:

- Enhancing consumer and patient health care literacy; and
- Development and implementation of value-based payment models for primary and specialty care physicians.

CMS Launches New LVA Process for Settling Payment Appeals, *from page 1*

- Beneficiaries, enrollees, their family members or estates;
- State Medicaid Agencies;
- Medicare Advantage Organizations (Medicare Part C); and
- Those that have filed for or expect to file for bankruptcy.

Eligible Appeals

Appeals must meet all seven of the following criteria to be eligible for LVA settlement:

- ☐ The appeal was pending before the Office of Medicare Hearing and Appeals (OMHA) and/or Council level as of Nov. 3, 2017;
- ☐ It was properly and timely at the OMHA or Council levels as of Nov. 3, 2017;
- ☐ The appeal is still pending as of the date the LMV agreement is signed (as explained in the Settlement Process section below);
- ☐ The appeal's total billed amount is $9,000 or less;
- ☐ The claims in the appeal were denied by a Medicare contractor and remain in a fully denied status within the Medicare system;
- ☐ The claims were submitted under either Medicare Part A or B; and
- ☐ The claims are not part of an extrapolation.

The All-or-Nothing Condition

If an your NPI is approved for participation in the LVA process, the resulting settlement covers all eligible appeals from you. In other words, the appellant is not allowed to choose to settle some eligible appeals but not others.

The Settlement Process

There are detailed procedural rules you must follow to use the LVA process.

Step 1: EOI Submission

It is up to you, the appellant, to initiate the process by filing a form called a Low Volume Appeals Settlement Expression of Interest (EOI) to CMS at MedicareAppealsSettlement@cms.hhs.gov during the appropriate window, based on your NPI.

EOI Submissions Windows

Appellants Designation	EOI Window
Appellants with NPIs ending in even numbers (including 0)	Feb. 5, 2018 to March 9, 2018
Appellants with NPIs ending in odd numbers	March 12, 2018 to April 11, 2018

Labs with multiple NPIs must submit one EOI per NPI with eligible appeals during the appropriate window depending on whether the NPI ends in an odd or even number.

Step 2: Determination of Participation Eligibility

CMS must review the EOI to determine if you are eligible to participate in the LVA process. If so, it will send you:

- A Spreadsheet of potentially eligible appeals and associated claims; and
- An Administrative Agreement.

Step 3: Validation & Signing

You must next review the Spreadsheet and either validate it or notify CMS of any discrepancies you identify by submitting an Eligibility Determination Request (EDR) form to MedicareAppealsSettlement@cms.hhs.gov within 15 days of receiving the Spreadsheet. If there are no discrepancies, you must also sign the Agreement and send it to CMS for counter signing; if there are discrepancies, Step 4 comes into play.

Step 4: Reconciliation

You have 30 days to resolve any identified Spreadsheet discrepancies with CMS. When and if that happens, you must sign the Agreement and send it to CMS for counter signature. Once CMS counter signs, whether via Step 3 or 4, it will send you a copy of the fully executed Agreement.

The Withdrawal Right

If you get cold feet about using the LVA to settle your pending appeals, you may withdraw from the process and retain full appeal rights, as long as you have not yet returned the signed Agreement to CMS. But once CMS gets the signed Agreement from you, it will "stay," i.e., freeze proceedings on all of your pending appeals and there will be no turning back.