

# Investigations 101

## Laboratory Services Fraud and Abuse

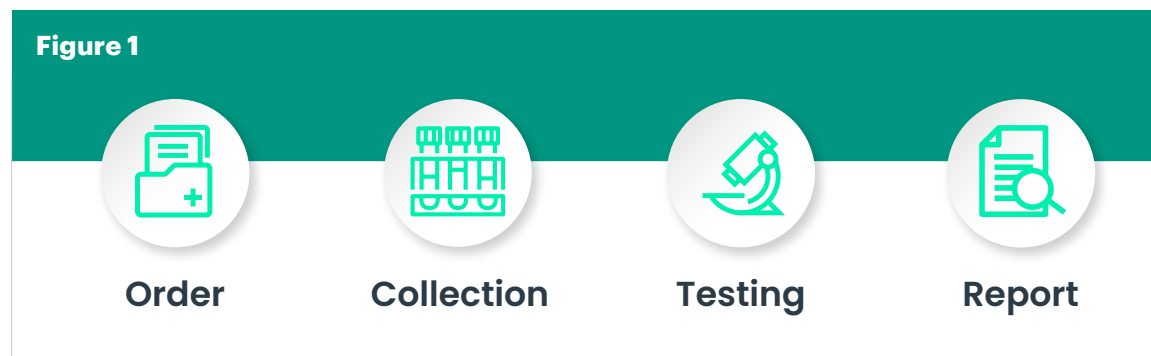


Laboratory testing is a service that every healthcare fraud investigator will come across in the course of their work. In fact, over a third of all patient encounters involve one or more laboratory tests.<sup>1</sup> While the average cost per test tends to be quite low, the volume of services billed results in a total cost that is significant.

In 2015, in one of the largest laboratory services billing fraud cases to date, Millennium Health agreed to pay \$256 million to settle allegations by the U.S. government of improper billing and violations of the False Claims Act.<sup>2</sup> Millennium Health was alleged to have caused physicians to order excessive and unnecessary urine drug testing in exchange for illegal kickbacks. Millennium was the largest case of this type, but many other laboratories have been charged or convicted for similar schemes.

### Defining Clinical Laboratory Services

Laboratory testing (also referred to as clinical pathology) is considered a diagnostic service. Medical practitioners use laboratory tests to diagnose, prevent and monitor diseases. They also use laboratory testing to detect the presence of substances such as illicit drugs. These tests can be performed on different kinds of human specimens, including blood, urine, tissues and other fluids. Laboratory testing involves four main components as shown in Figure 1.



## Order (and Requisition)

The order is a communication from the treating practitioner requesting that a certain test be performed. This can be communicated in writing, via a phone call or email and is recorded in the patient's medical record. The Centers for Medicare & Medicaid Services (CMS) requires that the practitioner clearly document in the medical record his or her intent that the test be performed.<sup>3</sup>

The requisition form is the actual paperwork provided to the laboratory specifying the testing to be performed. In many cases, practitioners sign the requisition to indicate their intent for the testing and to simplify recordkeeping.

**Tip:** When requesting records for laboratory service claims, be sure to ask for the order and the requisition. If there are questions about the validity of the requisition, it may be necessary to review claims from the ordering practitioner to confirm their treatment and associated diagnoses for the member. In some cases it may be necessary to request the ordering practitioner's progress note to confirm their intent and the medical necessity for the testing.



## Collection and Handling

A specimen must be collected to undergo testing. Sterile procedures must be followed and the collection should be noted in the patient chart. Depending on the type of specimen (tissue, for example), the location on the person's body may be noted as well as the type of collection process used.

Specimen handling may be billed separately under Current Procedural Terminology (CPT) 99000, which is defined as "Handling and/or conveyance of specimen for transfer from the physician's office to a laboratory."<sup>4</sup> It is also important to note that for test results to be valid and useful to the ordering practitioner, specimen requirements for volume, storage temperature and any other special handling requirements must be followed.



## Testing

A variety of tests may be performed under the umbrella of laboratory testing, including chemistry tests, microscopic examination (microscopy) genetic tests and infectious disease tests. Certain simple tests with low risk for erroneous results may be performed by facilities holding a Clinical Laboratory Improvement Amendments (CLIA) waiver certificate. More complex testing requires a higher level of certification and oversight, as described later in this paper.

For the test results to be valid, the proper testing protocol must be followed, and the lab must possess the proper licensure and certification for that specific test. Some tests are considered point-of-care testing (POCT) while others may be more complex and need to be sent to an outside laboratory. An investigator may have to validate in the medical records exactly where the testing was performed if there is a question of duplicate billing or lack of proper licensure and certification.



## Report

While laboratory reports can vary greatly in appearance and the information included, CLIA requires certain standard components for all reports.<sup>5</sup> For an investigator reviewing records, it's important to locate and review some basic items on any report of laboratory test results. These include:

- Patient name/identification
- Type of testing performed
- Date of collection
- Test results
- Date of the test

## Foundational Requirements — Valid and Appropriate

This paper primarily focuses on problems with the lab order, the credentialing and oversight of the labs or, more generally, improper billing. However, it is critical to recognize that problems with the specimen collection and handling or testing procedures themselves can cause a test to be invalid and potentially a non-payable service. For example, a specimen may be mislabeled with the wrong patient information, the specimen may not be temperature controlled (when required), the equipment may be faulty or the staff performing the test may not be properly trained.

These issues and others can invalidate the results. Remember the trouble caused by ill-fated Theranos for issuing unreliable test results to patients?<sup>6</sup> While the cumulative dollars involved in laboratory fraud and abuse are significant, patient harm also can be a dangerous byproduct of these schemes.

For a lab test to be appropriate, the following also must be true:

- It must be ordered properly
- It must be medically necessary
- The specimen must be properly collected, labeled, handled and transported
- The test performed must be the one that was ordered
- It must be conducted on properly working equipment
- The results must be documented clearly and accurately in a report
- The results must be sent back to the ordering practitioner, who reviews and interprets them and ultimately makes a clinical decision based on the findings

## How Laboratories Are Regulated, Certified and Licensed

CLIA regulate laboratory testing and require clinical laboratories to be certified by their state as well as CMS before they can accept human samples for diagnostic testing. Laboratories can obtain multiple CLIA certificates based on the types of diagnostic tests they conduct.



Three federal agencies are responsible for CLIA — the U.S. Food and Drug Administration (FDA), CMS and the Centers for Disease Control and Prevention (CDC). Each agency has a unique role in assuring quality laboratory testing.<sup>7,8</sup>

### FDA

- Categorizes tests based on complexity
- Reviews requests for Waiver by Application
- Develops rules and guidance for CLIA complexity categorization

### CMS

- Issues laboratory certificates
- Collects user fees
- Conducts inspections and enforces regulatory compliance

- Approves private accreditation organizations for performing inspections and approves state exemptions
- Monitors laboratory performance on Proficiency Testing (PT) and approves PT programs
- Publishes CLIA rules and regulations

## CDC

- Provides analysis, research and technical assistance
- Develops technical standards and laboratory practice guidelines, including standards and guidelines for cytology
- Conducts laboratory quality improvement studies
- Monitors proficiency testing practices
- Develops and distributes professional information and educational resources
- Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)

Investigators can verify a laboratory's CLIA certification on the CLIA Demographics Lookup page.<sup>9</sup> This is an important step to verify whether the laboratory is properly certified for the level of testing being billed and performed. It also can be a great starting point to gather information about the laboratory.



## CLIA Certification Levels

CLIA generally requires all facilities that perform even one applicable test on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet requirements and obtain a certificate (unless exempted). This requirement includes waived tests.

There are five levels of CLIA certification:

### 1. Certificate of Waiver

This certificate is issued to a laboratory to perform only waived tests.

### 2. Certificate for Provider-Performed Microscopy Procedures (PPMP)

This certificate is issued to a laboratory in which a physician, mid-level practitioner or dentist performs no tests other than microscopy procedures. The certificate also permits the laboratory to perform waived tests.

### 3. Certificate of Registration

This certificate is issued to a laboratory that enables the entity to conduct moderate or high-complexity laboratory testing, or both, until the entity is determined by survey to be compliant with CLIA regulations.

### 4. Certificate of Compliance

This certificate is issued to a laboratory after an inspection that finds the laboratory to be compliant with all applicable CLIA requirements.

### 5. Certificate of Accreditation

This certificate is issued to a laboratory based on the laboratory's authorization by a CMS-approved accreditation organization.





While it is important to understand each level of certification and what testing is allowed under each, the Certificate of Waiver is the most commonly issued. Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. CLIA requires that waived tests must be simple and have a low risk for erroneous results. A list of the tests allowed under a CLIA waiver can be found on the CDC website.<sup>10</sup>

### State-specific Licensure

While most states contract with CMS to administer the CLIA program for lab facilities (independent, hospital or physician-office lab), the states of New York and Washington have adopted laws that are equivalent to CLIA certification.<sup>11</sup> Therefore, labs licensed in these states are considered “CLIA exempt.”

In addition to CLIA certification, many states require a separate state license or permit for the lab facility, issued by the State Department of Health or similar agency. In some states, this is required only for lab facilities physically located within the state; in others it is required for out-of-state labs performing testing on specimens obtained within the state.

In some states, certain types of laboratories (e.g., hospital based) are exempt from the state requirement. Exemptions like this can be exploited by pass-through billing schemes described below; however, the bottom line is that each state is different, and it is important to research and understand the state-level regulations applicable to your investigation.

## How Lab Services Can Be Billed Improperly

In addition to overpayments resulting from providers who are not properly licensed or CLIA-certified for the testing to be reimbursed, you also may encounter problems with medical necessity or services not rendered. Following are a few more laboratory-specific schemes to be aware of as you investigate these claims.

### Unbundling and Multi-unit Billing

Improper billing can occur in laboratory billing that includes incorrect coding for multi-unit drug testing where a test panel exists. For example, if definitive testing is performed for 25 drug classes on a single specimen from the same order, the correct code is G0483 [drug test(s), definitive, 22 or more drug class(es)] — which covers 22+ drug classes. Instead, some providers will incorrectly bill using G0480 [drug test(s), definitive, 1-7 drug class(es)] and bill for four units of that code.

As shown in Figure 2, let's assume G0480 pays \$60 and G0483 pays \$150. A payment of four units of G0480 would be \$240 and would result in a \$90 overpayment compared to the proper code. When this type of testing and billing occurs in high volume, improper payments can add up quickly.

Figure 2				
Billing Behavior	Service Code	Units Billed	Unit Cost	Total Cost
Proper	G0483 (22+)	1	\$150	\$150
Improper	G0480 (1-7)	4	\$60	\$240

### Duplicate Claims

When a clinic or provider sends a specimen to an outside lab for testing, they can bill for specimen handling and conveyance but should not bill for the actual testing. If the clinic and the independent laboratory both bill for this test, a duplicate payment is issued.

These claims fall into a category of improper billing known as “cross-provider duplicates” in which two different providers billed the same code for the same patient on the same date of service with the same modifiers, if applicable. Often these claims are not detected through claims edits, so post-pay analytics is the best method of identification. Medical records rarely are needed to identify these overpayments and instead can be addressed via recovery letters or offsetting takebacks if state provisions or provider contracts allow.

When querying claims data, be sure to look for situations where the same lab code is billed on the same date of service for a single member, but with two different providers. Another approach might be to first query the lab claims of a large outside laboratory that bills a significant number of claims. Then from that larger set of data, identify matching procedure codes on the same date for the same member to isolate the potential duplicates.

### Presumptive vs. Definitive Urine Drug Screens

Urine drug testing (UDT) is used to detect the presence or quantity of a substance. In many cases, the test seeks to confirm the presence of an illicit substance such as drugs or alcohol. However, these tests also can be used to verify that a patient is adhering to their medical regimen by taking the medications prescribed.

The presumptive test (formerly referred to as qualitative) detects the presence of a specific drug or drug class. The results of the presumptive test are either positive or negative. These are often rapid POCT (point-of-care testing), which means they are not sent to a clinical laboratory and instead are administered when the patient is in the medical facility or testing center.

It is not uncommon for a POCT urine drug cup to include 12 test strips that react with the urine collected in the cup and can show immediate results. These are inexpensive and relatively easy to administer. However, these tests are not as sensitive as definitive testing and cannot differentiate specific drugs within a parent grouping of drugs. False negatives can be an issue, particularly if the specimen contains a level lower than the cutoff value for the test to detect.<sup>12</sup>

Definitive tests (formerly referred to as quantitative) focus on detecting specific drugs and quantify the amount of drug present in a patient's system. The tests often are sent to a higher-level credentialed lab to be tested since the specialized equipment required is usually unavailable in a typical clinic. Definitive tests can detect lower trace levels of a drug and are highly sensitive, resulting in fewer false test results. These tests can also monitor how much of a prescribed drug is in a patient's system to see if it is at a therapeutic level.

Figure 3 compares the two types of testing, presumptive and definitive, their level of detail and accuracy.

Figure 3	
Presumptive	Definitive
✓ Results = positive/negative	✓ Results = amount of drug present
✓ Often a class of drugs and not specific drugs	✓ Specific drugs
✓ Can be POCT (rapid) test	✓ More sensitive (less false results)
✓ If negative for illicit drugs, then a definitive is typically not necessary	✓ Useful in therapeutic level testing (prescribed drugs)

The codes used to bill presumptive and definitive lab tests can be correlated to their relative reimbursement levels as the complexity increases. The Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding Systems (HCPCS) codes used to bill for these lab tests are listed in numeric order. The higher the code number, the more advanced and expensive the equipment will be to complete the tests (see Figure 4). Similarly, the higher the code value, the higher the reimbursement rate.

Figure 4	
Presumptive (difference in how)	Definitive (difference in how many)
✓ <b>80305</b> Optical observation (i.e., dipstick/cartridge) \$	✓ <b>G0480</b> 1 to 7 drug classes \$\$\$\$\$\$
✓ <b>80306</b> Instrument-assisted direct optical observation \$\$\$	✓ <b>G0481</b> 8 to 14 drug classes \$\$\$\$\$\$\$
✓ <b>80307</b> Numerous devices, instrument chemistry and analyzers \$\$\$\$\$	✓ <b>G0482</b> 15 to 21 drug classes \$\$\$\$\$\$\$\$\$
\$ = approximately \$10	✓ <b>G0483</b> 22 or more drug classes \$\$\$\$\$\$\$\$\$\$\$\$\$

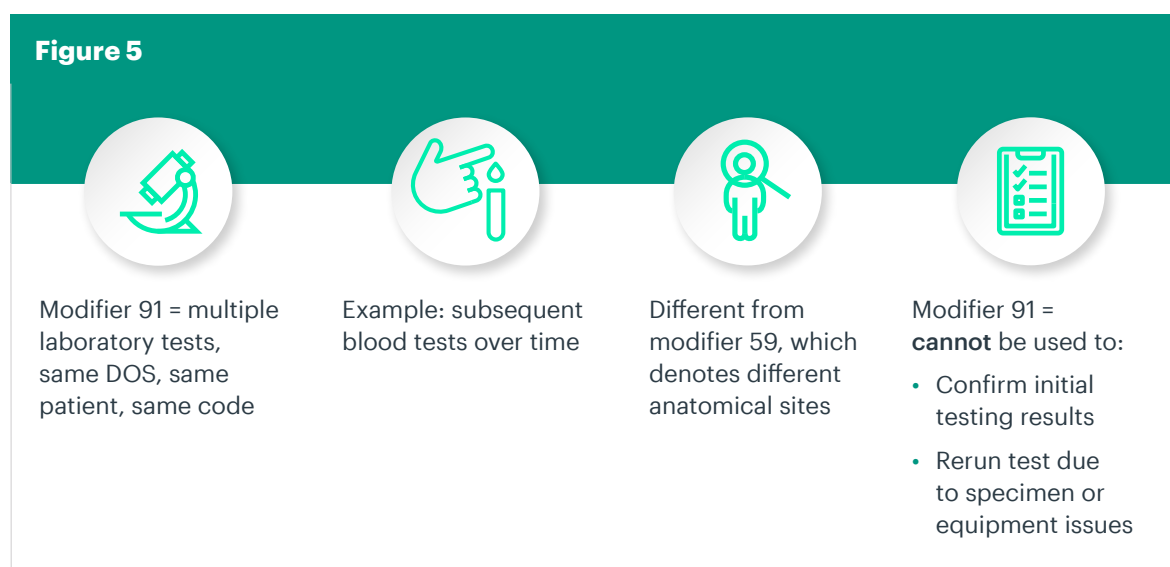


When a provider improperly bills for a definitive test when a presumptive test was actually performed, this results in significant overpayments. Further, there may be situations where a definitive test is not medically necessary or warranted without first conducting a presumptive test. In those situations, the added cost for ordering and performing the more sophisticated test is not medically necessary, and some payers have established clinical policies to curb such behavior.

### Modifier 91 (Repeat Clinical Diagnostic Laboratory Test)

Modifier 91 is specific to lab testing codes. If you find this modifier on non-lab codes, the provider may be inexperienced with claims billing or may be attempting to circumvent system edits. In either circumstance, the use of Modifier 91 is improper.

When appended to lab testing codes, this modifier is only appropriate in certain limited circumstances and only when preceded by the same code, for the same patient, on the same date of service — but without the modifier. When you understand the appropriate use of this modifier, it becomes clear why you would be unlikely to see it on a high percentage of lab claims from a particular provider (see Figure 5).



### Pass-through Billing

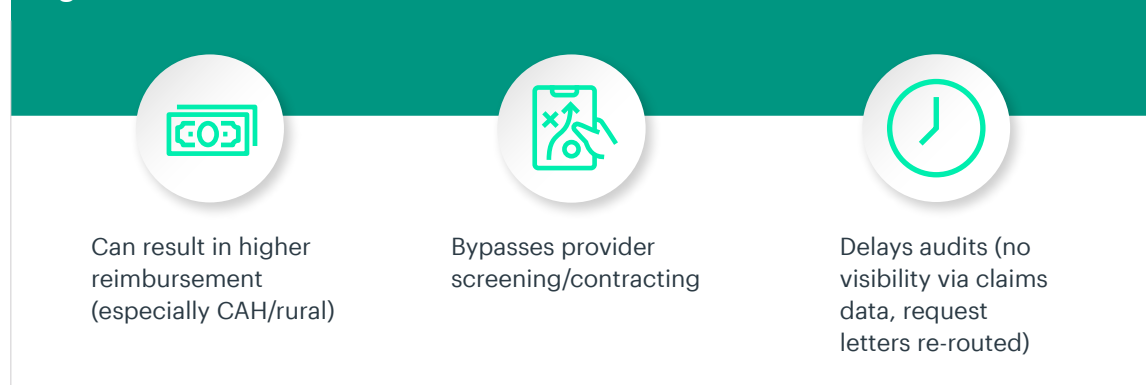
Pass-through billing occurs when the provider who billed for the lab service did not actually perform it; the test was sent out and performed by another laboratory facility. Often the outside lab that performed the testing may be unable to directly bill the payer or may be colluding with the ordering provider to obtain a higher rate of payment.

Most payers, including Medicare, specifically prohibit this practice. For other payers, contractual or regulatory language may preclude this behavior even if the practice is not specifically called out by name in provider manuals or payment policies.

Recently, improper relationships between rural hospitals and providers have brought the impact of this practice to light. Rural providers typically are reimbursed at higher rates. In some cases, they have colluded with outside laboratories that perform testing. The rural provider submits the claim and obtains a higher payment than the outside lab would be paid typically. Sometimes the rural provider ordered the lab while in other instances, the rural provider had no established relationship with the patient.

## Problems

**Figure 6**



### A Note on Reference Labs vs. Pass-through Billing

Sometimes pass-through billing can be confused with the legitimate practice of using reference labs. What's the difference? Reference labs receive a specimen from another lab and perform one or more tests on that specimen. In some cases, a lab may send certain specialty tests out to a reference lab. Some payers, including some Medicare carriers, allow reference lab billing.

Typically, when reference lab billing is an approved arrangement, the reference lab is enrolled or contracted with the payer and agrees to the fee schedule or method of payment. In those instances, the reference lab directly bills the payer.

This is different from pass-through billing because the payer is aware of the arrangement and has agreed to the process. Additionally, the reference lab is directly billing the payer and accepting the established payment rate. There is no misrepresentation or additional payment construct involved.

## Preventing Laboratory Services Fraud and Abuse

### Screen Providers

One way to prevent fraud and abuse is to screen lab providers prior to payment (including non-participating labs). Below is a list of items to review when screening a lab provider before issuing a contract or payment:

- Verify licensure
- Search for federal and state exclusions
- Review inspection history
- Perform a thorough background review for ownership links, past criminal and civil allegations, etc.
- Review CLIA records, including review of lab registration reports (looking for enforcement action)
- View the CMS 116 application form within CLIA records for any disclosure that the lab director is associated with other labs (and if so, review records for the other labs to identify enforcement action, past fraud and abuse, etc.)
- Query state and federal exclusion records for the lab director and all disclosed personnel

It's a good idea to determine whether your organization has properly screened lab providers that are currently billing. A best practice is to undertake a focused audit and screening review to confirm these details so either remedial network action can be taken or claims can be denied going forward.

Research whether you can implement a non-par lab pre-pay screening, whereby the first non-par claim submitted requires proof of CLIA certification or state licensure prior to payment. For Medicaid and Medicare claims, there is likely a step similar to this whereby a non-par provider is screened for federal and state exclusion before the first claim payment. Consider stacking these additional verifications onto existing processes for greater control.



### **Implement Controls: Payment Policies and Edits**

Review your payment policies for lab services and work internally to see what additional policies you may be able to implement to curb fraud and abuse with this provider type. For example, some payers no longer cover definitive testing codes G0482 (definitive testing of 15-21 drug classes) and G0483 (definitive testing of 22+ drug classes) without prior approval. Some payers have determined that these two codes have no clinical use in an ambulatory setting.

Also consider adding terms in your provider manual or provider contracts that specifically prohibit pass-through billing. This could strengthen your ability to take action when such behavior occurs and send a strong message to the provider community.

Another best practice is performing network outreach and education regarding the requirements for definitive drug testing and other problem areas you have encountered. Pain management and substance abuse providers can be a particular focus area for newsletters and targeted outreach.

## Detecting Laboratory Services Fraud and Abuse

### Capture the Ordering Provider ID and National Provider Identifier (NPI)

The ordering provider is a field on the lab claims. Do you capture this field for reporting purposes? If not, collecting this data should become priority number one. Otherwise, you will be unable to determine which ordering providers or clinics are driving certain lab services billing and behavior. In some cases, payers have discovered that the ordering provider is not qualified to order labs (i.e., Licensed Professional Clinical Counselors or other non-ordering provider types).

If this data isn't captured, you cannot systematically deny such claims up front. Additionally, without this critical information a number of items noted below will not be available to you for detecting fraud and abuse.

### 42 CFR (Code of Federal Regulations) 455.410 Ordering/Referring Providers

If the claims are covered by the Medicaid program, whether through managed care or fee for service, you'll also want to confirm that the ordering provider is enrolled in the program. 42 CFR 455.410 requires referring physicians or other professionals to be enrolled as participating providers in the Medicaid program.

**Note:** This applies more broadly than only those ordering lab services. Do you verify this for prescriptions, diagnostic testing, etc.?

### Run Analytics: Frequency of Test Administration

Tracking the frequency of test administration is an excellent starting point for investigating potential improper payments. This can be especially fruitful when researching definitive and presumptive urine drug screening codes.

Do you have a provider who routinely orders definitive testing on patients? Is their frequency abnormal compared to peers? Do they

bill definitive only without any presumptive tests? While there can be clinical indications for ordering a definitive test without the presumptive, it's a good idea to look more closely into providers with this billing pattern. The goal is to understand whether they are an outlier for legitimate reasons or whether something more nefarious is going on.

### Run Analytics: Rural Providers' Patient Geography

To identify potential pass-through billing schemes, query your claims for lab services paid to rural providers. From that set of data, do any providers stand out as having a significantly higher frequency or volume of lab testing than their peers? If so, drill deeper to identify the patients for whom those claims were billed and determine whether they live within the geographic area served by that rural provider. A high number of patients with lab claims from outside that area may be a red flag that pass-through billing is occurring.





### Run Analytics: Frequency of Modifier 91 and Modifier 59

As noted earlier, Modifier 91 is used to indicate a lab test that is repeated on the same day and on the same patient. This code should only be used when additional test results are needed after the first administration of the test. Modifier 91 cannot be used to confirm the original test results or redo a test due to an equipment or specimen-related issue. It is only appropriate on lab services.

It's a good idea to perform analytics to identify non-lab providers billing with Modifier 91. Also look for providers with a high frequency of Modifier 91 on their claims or when no prior claim for the same code on the same date for the same patient is found.

Although both of these modifiers can explain duplicate codes, Modifier 59 (distinct procedural service) is used to indicate when more than one lab test is repeated on different areas of the body on the same visit. If a particular provider stands out among peers as an outlier for use of Modifier 59, it could signal inappropriate billing and excessive payments.

### Run Analytics: Verify Ordering Provider Relationship

After you have identified suspect claims for lab services, drill deeper into the data to determine whether the ordering provider billed a medical claim for the patient. In some fraud and abuse schemes, physicians were found to be signing off on lab orders or requisitions in exchange for kickbacks. No claim activity or medical records supported that the ordering provider had any relationship with the patient or any medically necessary reason to order the test.

Additional schemes have been identified in which the lab falsely identified the ordering provider on the claim, which is a form of identity theft.



### Run Analytics: Specialty Review and Peer Comparison

Reviewing the specialty of ordering providers can shed light on previously undetected schemes. For example, if a pediatrician is ordering large numbers of urine drug tests, this would be a red flag. Peer comparisons can be useful for confirming that a provider is an outlier within their practice area and point you in the direction of questionable lab claims.

In some cases, you may even find that the ordering provider is not qualified to order labs. This may indicate the provider is either the victim of identity theft or may be colluding with the lab provider to submit improper claims. In some of the "sober-home schemes," behavioral health providers such as licensed counselors, marriage and family therapists and other non-qualified providers were improperly listed as ordering providers for labs. Without a valid order from a qualified healthcare professional, the claim is not payable.

# Investigating Laboratory Services Fraud and Abuse

## Conduct Desk Audits

After you have identified suspicious claims to review, collecting records for a desk audit is often an appropriate next step. When requesting records for lab services, be sure to include the following:

- Order from the treating physician or other qualified healthcare professional
- Requisition forms, including custom panels
- Laboratory test reports and results
- Documentation showing results were communicated to the treating physician or other qualified healthcare professional
- Any additional documentation or correspondence with the treating physician or other qualified healthcare professional
- Copy of CLIA certificate (front and back) applicable for all dates of service in the request
- Copy of CMS 116 form
- Copy of CMS 209 form (including staffing changes not reflected)
- Copy of recent onsite inspection performed by cost-of-living adjustment (COLA), CLIA or similar
- List of technical employees (including the Lab Director) and their titles, education
- Type of equipment used for the testing, including equipment serial numbers and copy of proficiency testing reports applicable to the dates of service in the request
- List of types of samples accepted (i.e., blood, urine, swab, etc.)
- Names of any reference lab(s) used
- Specimen shipment documentation to reference labs (if applicable)
- List of tests that are sent out to reference lab(s)

As part of any investigation, perform a thorough background investigation into ordering providers and the lab providers. This should include a review of licensure, exclusion status, ownership links, past regulatory sanctions, criminal and civil litigation, social media and other relevant due diligence.

It's also advisable to perform background research on patient addresses and other link analysis to identify sober homes or other commonalities that may suggest improper practices or recruiting.

## Verify Ordering Providers

Consider sending a verification request letter to the ordering providers. For example, if Dr. Smith is the number one ordering provider for a lab with suspect claims you are reviewing, send Dr. Smith a verification request letter and include a copy of the signed requisition if you were able to obtain it. Consider requesting that he/she confirm their signature, confirm the patient relationship and provide copies of the progress notes containing details on why the test was ordered.

The progress notes should also contain documentation that results were communicated back to the provider and that the results were considered when determining the patient's course of treatment.

**Tip:** Verification by ordering provider also can be a good step for pre-payment review of suspect lab services.

## Review Lab Records

When reviewing the records obtained from the laboratory, be sure to:

- Match the name of the lab on the requisition to the lab that billed the claim. If different, ask more questions; this may be a pass-through billing situation.
- Confirm that the requisition/order is properly signed and dated by the ordering provider.
- Review the requisition for indication of “custom profiles” or standing orders that are not individualized to the patient’s needs or condition.\*
- Confirm that the test ordered matches the test performed and billed.
- Verify that the results were documented in a lab report.

### **\*Custom Profiles/Panels or Standing Orders**

Custom profiles or custom panels occur when a physician and laboratory establish a panel of tests to be run on all of the patients when ordered by the physician in question. The physician makes note of this on the requisition form rather than requesting individualized testing for each patient.

Custom panels are the equivalent of standing orders and, in many cases, circumvent federal healthcare payment rules, which require an individualized assessment of each patient’s needs. To establish medical necessity, the tests ordered must be unique to the patient and their condition.

While Medicare allows standing orders for recurring tests in certain situations,<sup>13</sup> this is a limited exception and other payers may have their own policies regarding this practice. It should be noted that in the federal government’s case against Millennium Health, this was one of the issues identified.<sup>14</sup> Unless it is covered by a clinical exception, this practice may result in claims cited as overpaid and improper.

## Conduct On-site Audits and Inspections

In a small number of situations, and depending on your established internal protocol, it may be necessary to make an on-site visit to a laboratory or even to perform an inspection. Be sure to develop an on-site inspection checklist and protocol and ensure that staff participating in the inspection have appropriate expertise in laboratory regulations.

## In Closing

With laboratory services occurring at regular frequency and making up a significant portion of healthcare expenditures, healthcare fraud personnel must arm themselves with the necessary expertise in this service area. From prevention to detection and ultimately investigation, this paper is designed to provide the basic framework to enable and support those efforts.

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