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THE FOLLOWING DISCLAIMER APPLIES: All Healthcare Fraud Prevention Partnership (HFPP) communications and activities are purely voluntary. All HFPP activities, including all committees and the Executive Board, are to be used solely as venues for discussion whereby individual partners can voluntarily share facts, information, or individual input. No group consensus, advice, recommendations, policy-making, or decision-making will be sought or performed as a result of HFPP activities. The Secretary and the Attorney General or their designees will make final policies or other decisions.
Clinical laboratory services generated an estimated $87.3 billion in revenue in 2017, totaling 2.6% of annual healthcare spending in North America. This represents a large target for potential fraud and abuse. While the typical laboratory claim is relatively low in cost (less than $200), the sheer volume of laboratory services performed provides an opportunity for potential losses related to fraud and abuse in these services to reach the hundreds of millions of dollars. In addition, because claims for potentially fraudulent or abusive services can be made either by individuals or disseminated networks of providers and laboratories, fraud in this area can be particularly challenging for private and public payers, law enforcement, and other responsible entities to identify and investigate.

While accounts of specific fraud schemes and vulnerabilities related to clinical laboratory services exist, few resources are found that provide a comprehensive summary of the issues involved in this area. The Healthcare Fraud Prevention Partnership (HFPP), a public-private partnership of healthcare payers and allied organizations, seeks to use this paper to provide foundational information and to set the stage for additional discussions and interventions to address fraud and abuse in this area. Specifically, this paper identifies several systemic challenges that can lead to the potential for fraud and abuse in clinical laboratory services, including the:

- Number and variability of laboratories
- High-volume, low-dollar nature of ordering, providing, and billing for clinical laboratory services
- Technical complexity and continuing evolution of clinical laboratory services

This paper also provides high-level discussions of specific areas of concern identified by HFPP Partner organizations related to abuse of billing standards, improper laboratory relationships, and medically unnecessary testing.

The HFPP intends this paper to provide a starting point to a long-term project to combat fraud and abuse in laboratory services. Particular areas for future work may include:

- Review of and recommendations for payer oversight and analytics of laboratory services
- Efforts to foster collaboration and information sharing to enhance the proactive detection of potential fraud and abuse
- Development, refinement, and delivery of provider monitoring and education programs to reduce fraud and abuse
- Development of organized, cross-industry responses to urine drug testing schemes and other areas of high concern
BACKGROUND, INTRODUCTION, & OBJECTIVES

The HFPP is a voluntary, public-private partnership between the Federal Government, state and local government agencies, law enforcement, private health insurance plans, employer organizations, and healthcare anti-fraud associations that seeks to identify and reduce fraud, waste, and abuse across the healthcare sector.[1] To advance this effort, entities that participate in the HFPP, known as Partners, regularly collaborate, share information and data, and conduct studies using a unique cross-payer data set. Additionally, the HFPP’s broad membership provides a platform to address healthcare issues. This paper examines the challenges associated with the prevention and identification of fraud and abuse in the area of clinical laboratory services, a problem that can negatively impact the financial health of organizations and physical health of patients.

Clinical laboratory services, when appropriately applied, can assist to diagnose illness or disease, monitor risk factors for serious illness, detect the presence of foreign substances such as illicit drugs or toxic agents, or monitor disease progression. In contrast, fraudulent or abusive laboratory services and claims increase healthcare expenditures and can result in medical errors, false positive or false negative test results, incorrect diagnoses, and unnecessary and potentially invasive medical procedures.[2] In some instances, fraud schemes have resulted in the victimization and harm of patients, as well as financial bankruptcy of legitimate organizations.

The appropriate use of laboratory monitoring and diagnostic testing is an essential component of medical services. However, potentially fraudulent and abusive billing for laboratory services has become an area of growing concern, particularly for tests that are subject to minimal regulatory oversight.

There is broad consensus among the HFPP Partners on the need to do more to combat potential fraud and abuse in laboratory service billing. This paper seeks to accomplish the following:

- Describe laboratory services in a way that highlights the service vulnerabilities susceptible to fraud and abuse
- Define systemic challenges that can enable fraud and abuse
- Describe specific types of potential fraud or abuse that have been identified by HFPP Partner organizations

The section that follows will provide an overview of the clinical laboratory service industry with a specific focus on aspects of the industry that create opportunities for potential fraud and abuse (see The Laboratory Testing Industry In The Context Of Fraud, on page 4). Next, the paper outlines some of the systemic challenges that may contribute to or enable clinical laboratory services fraud and abuse (see Systemic Challenges, on page 6), followed by a description of specific, potentially fraudulent or abusive problems or practices reported by the HFPP Partners (see Major Fraud and Abuse Schemes, on page 7).
Clinical pathology, or laboratory medicine, involves the analysis of blood, urine, and other bodily fluids and tissues, as well as microscopic examination of individual cells, to provide information that supports the diagnosis, prevention, or treatment of human health disorders, diseases, and infections. The field of clinical pathology is characterized by common processes, procedures, specimen collection, and transport practices across all healthcare service providers.

Although some laboratory tests can be quite expensive, the majority of tests performed are paid at a low dollar amount, usually well below $200. For example, a 2017 Department of Health and Human Services (HHS) Office of Inspector General (OIG) review of laboratory services found that in 2010 over 60% of Medicare laboratory payments, or $4.29 billion, were paid to cover 25 routine tests. For 19 of the 25 tests, Medicare payment rates ranged from $5.36 to $79.24, with half being less than $25. The top six tests ordered accounted for 35% of all Medicare payments, and all six were associated with Medicare payments below $41 per test.

**The Laboratory Industry**

Medicare payment data offers a general picture of where clinical laboratory services are performed. Predominantly, laboratory services are conducted as patient point-of-care tests in hospital outpatient or physician offices (44.2% of Medicare Part B payments). Point-of-care testing allows simple tests to be performed during the patient encounter, enabling the results to inform clinical decision-making in real-time. Another 38.1% of Medicare Part B payments are for clinical laboratory services performed in non-patient settings by independent laboratories that may specialize in specific types of testing or clientele. The two largest U.S. commercial laboratory companies make up almost half of independent laboratory payments. The remaining laboratory services covered by Medicare Part B include tests performed by critical access hospitals, skilled nursing, and other facilities.

**Regulation and Oversight**

Laboratories are primarily regulated based on the complexity of the tests they conduct to assure the accuracy and reliability of test results and protect patient safety. Laboratory tests are classified as waived, moderate, or high complexity, as defined under the implementing regulations for the Clinical Laboratory Improvement Amendments (CLIA) legislation of 1988, as amended.

Tests with waived status are those listed in the implementing regulations or determined by the U.S. Food & Drug Administration (FDA) to be simple laboratory examinations or procedures having a low risk of an erroneous result. Laboratories performing only tests with waived status have less regulatory scrutiny than laboratories conducting moderate to high complexity tests.

Approximately 100 tests have been granted waived status, including all of the most commonly paid laboratory tests. The waived status allows the performance of point-of-care testing to support clinical...
decision-making in a variety of settings, including physician offices, drug rehabilitation centers, and sober living facilities.

Manufacturers have competed to develop easily performed, waived point-of-care tests in order to tap the large market of providers who perform waived laboratory tests. The large volume of waived tests creates specific challenges for fraud and abuse prevention, which will be discussed later in this paper.

Laboratory ownership, billing, and referral practices are subject to criminal and civil law at the federal [e.g. Federal False Claims Act (42 U.S.C. § 1320a-7b), Anti-Kickback Statute (42 U.S.C. § 1320a-7b), Physician Self-Referral (Stark) Law (42 U.S.C § 1359 and 42 CFR Part 411 Subpart J)] and state levels, many of which broadly apply to fraud, waste, and abuse and not solely to laboratory services. Many payers also rely on coverage policies to limit the potential for fraud and abuse. For example, Medicare generally only covers items and services that are within the scope of a Medicare benefit category and are reasonable and necessary for the diagnosis or treatment of an illness or injury. More specific coverage criteria under the Medicare program is detailed in statutes, regulations, and sub-regulatory guidance such as Local Coverage Determination (LCDs), and National Coverage Determinations (NCDs).

**Estimates of the Costs of Fraud and Abuse**

The clinical laboratory services industry in North America generated an estimated $87.3 billion in revenue in 2017, which presents a large potential for fraud and abuse. Although the total volume of laboratory fraud and abuse is unknown, investigations have demonstrated that the losses can be in excess of tens or even hundreds of millions of dollars. For example, according to the Department of Justice (DOJ), Millennium Health agreed to pay a settlement of $256 million in 2015, of which $237 Million was paid to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid, and other federal health care programs for medically unnecessary urine drug and genetic testing and for providing free items to physicians who agreed to refer expensive laboratory testing business to Millennium. The United States alleged that Millennium caused physicians to order excessive numbers of urine drug tests, in part through the promotion of “custom profiles,” which, instead of being tailored to individual patients, were in effect standing orders that caused physicians to order large numbers of tests without an individualized assessment of each patient’s needs. Although the financial impact of these allegations to the Federal Government was not fully assessed, the size of the settlement indicates the potential magnitude of the cost of the scheme.
SYSTEMIC CHALLENGES

The clinical laboratory services industry presents several systematic challenges for detecting fraud and abuse. These include:

- **The number and variability of laboratories.** There are a variety of possible settings and provider types that provide laboratory services which can make abnormal behavior more difficult to detect. Provider relationships with, and ownership of, laboratories can also create opportunities for waste or fraud that are difficult to spot from analysis of claims payments alone. For example, while referrals to physician-owned point-of-care laboratories are permissible in some circumstances, bad actors may attempt to take advantage of the relationship to maximize financial returns. In such cases, providers may divert their clinical testing to a new laboratory or dismantle and re-establish the laboratory to avoid detection.

- **The high-volume, low-dollar nature of ordering, providing, and billing for clinical laboratory services.** Payers are naturally inclined to focus their limited fraud prevention resources on claims with higher individual costs and that are easier to analyze. The generally low dollar value of individual laboratory tests means that laboratories typically run a low risk of being audited for any one claim. Payer organizations also have varying capabilities to detect wasteful or abusive practices and the number of possible billing combinations makes identification of aberrancies difficult using automated or routine monitoring. Common laboratory practices that aim to streamline medical practice, such as the use of laboratory/physician customized panels and auto-confirmatory testing, can exasperate these detection challenges for payers as well.

- **The technical complexity and continuing evolution of clinical laboratory services.** Clinical pathology is a large, complex, and ever-evolving field that requires specialized knowledge to evaluate the quality and necessity of specific tests performed. Fraudulent or abusive practices can be developed around newly covered tests before payers are able to fully understand the pathology and billing risks.

In short, these challenges often combine to create opportunities for bad actors to exploit. The next section discusses specific fraud and abuse schemes that have been identified by HFPP Partner organizations as particularly concerning in recent years.
This section describes major potential fraud and abuse schemes that have been identified by HFPP Partners. The intent was to consolidate a list of potential problems that can guide future discussions and interventions. This list is divided into three sections for clarity: (1) abuse of billing standards, (2) improper laboratory relationships, and (3) medically unnecessary testing. Dividing problems into sections is not intended to make distinctions between them or imply that any one form of problem is necessarily worse than any other. The HFPP also notes that many of the activities listed below may occur in combination.

Abuse of Billing Standards

HFPP Partners identified many tests, services, or other categories of care that are particularly susceptible to fraudulent or abusive billing practices. This includes misusing established billing conventions and seeking additional or unearned reimbursement for tests that were performed for medically necessary reasons. Practices identified as particular areas of concern by the HFPP partners are described below.

• Improper use of Modifier 91: The Current Procedural Terminology (CPT) code Modifier 91 is used to indicate when a test needs to be repeated on the same day to monitor the health of a patient. Improper and potentially abusive uses of the 91-modifier occur when it is used to indicate something other than a follow-up test or to bill for an additional test that was never performed. The modifier is sometimes incorrectly used to code additional tests performed on another day in another location or to code a test that has no same day prior test. For a 91-modifier to be valid, it must be preceded by a claim for the same billing code, without the 91-modifier, for the same patient, on the same day and at the same laboratory.

MODIFIER 91:
Claims payment systems may be programmed to override any payment claim edit in the system when a 91-modifier is detected. This enables the 91-modifier to be used to trick the automated payment system into paying a claim it would not otherwise pay.

The complexity of scanning patient claims history, matching claims, and developing different algorithmic rules for every test eligible for a 91-modifier complicates the ability of payment systems to identify potential fraud and abuse of this modifier in an automated fashion.

• Unbundling of Laboratory Panels:
Multiple related tests can often be combined into testing panels that are requested with a single testing order, completed with a single biological specimen, and billed using a single code. Testing panels are typically less costly to complete and are reimbursed at a lower rate than if each test were ordered and performed individually. Unbundling occurs when a laboratory bills
LAB TEST UNBUNDLING:
A Comprehensive Metabolic Panel (CMP) consists of 14 tests that can provide information about a patient’s kidneys, liver, electrolytes, acid/base balance, blood sugar, and blood proteins. In unbundling, a laboratory would perform some or all of the 14 tests and bill for them individually in order to recoup higher payments than would be paid for the panel.

Improper Laboratory Relationships

Improper laboratory relationships refers to illicit referral, billing, or ownership arrangements between multiple laboratories or between laboratories and physicians. These arrangements can either be established with the intent to defraud or represent the corruption of a formerly legitimate laboratory or organization. Specific potential schemes of concern to HFPP Partners are listed below.

- **Pass-through Billing:** Pass-through billing schemes occur when a provider, such as a physician or hospital, pays a laboratory to perform their tests and then files the claims as though they had performed the tests themselves. This activity occurs outside the appropriate practices for reference-laboratory billing between laboratories, and is often done to work around the lack of contractual relationships between a laboratory and payer organizations, to avoid scrutiny of the laboratory in question, or to allow the provider to recoup some of the financial benefits of in-office testing without requiring them to operate a laboratory themselves. This may result in double billing to payer organizations if both the laboratory and the provider submit claims for payment. Pass-through billing can undermine the intent and purpose in point-of-care testing. Of note, this scheme can also occur when such referral and billing arrangements are made between laboratories.

- **Rural Health Pass-through Billing:** Rural health pass-through billing, a variation of the pass-through billing scenario described above, represents another serious scheme of high concern to HFPP Partners. Some rural providers and suppliers are reimbursed at a higher rate to create incentives for the provision of services in traditionally underserved areas. Rural health pass-through billing schemes specifically target rural facilities to take advantage of these higher reimbursements.

Schemes include sending or billing lab work from non-rural settings through rural providers for higher reimbursement.
In some schemes, an individual claiming to represent a private consulting company will approach a rural facility and offer to set up a laboratory or use the facility’s existing laboratory to provide the testing services. The plan is often described as a legitimate method to process laboratory tests, and the rural facility - often financially strapped - is offered inducements to participate either in the form of partial ownership of the laboratory or by collecting direct kickbacks from the consulting company. The company then send samples collected in non-rural communities to the laboratory for processing at the higher reimbursement rate. In other instances, the samples are processed in non-rural laboratories but billed to payers as though they were conducted in the rural facility laboratory. In still other instances, laboratory samples are never tested at all and are only billed as though they were conducted in the rural facility.

One HFPP Partner described an episode in which hundreds of laboratory orders from urban Philadelphia were billed as having been processed in a laboratory in rural Kansas. Situations like this may result in lower quality healthcare if essential and time sensitive laboratory results are delayed or samples are contaminated because they are being transported for processing in rural areas.

In addition to having a financial impact on the payer, hospitals that participate in the scheme can go bankrupt or incur severe financial penalties. In either case, patients may suffer harm as rural providers either close or limit their available services to save costs.

• Physician Partial Ownership of Laboratories and Co-referral Networks: Another mechanism of suspected laboratory fraud is physician partial ownership of laboratories combined with possible conspiracies to refer testing to select laboratories in exchange for reciprocal referrals. In this scheme, physicians are approached by outside parties, often presenting themselves as representatives of a healthcare consulting company, and asked to set up their own laboratories in partnership with a larger laboratory. Physicians are offered a stake in the laboratory and are encouraged to refer testing to laboratories owned by other physicians involved in the scheme to conceal the fact that they are directly profiting from self-referrals.

In a variation on this scheme, physicians are paid sample processing fees in exchange for referrals to laboratories that the consulting company suggests. By 2016, laboratory fraud schemes involving physician partial laboratory ownership, illegal parent company kickbacks, and co-referral networks had proliferated to many parts of the U.S.[11]

Medically Unnecessary Testing

Medically unnecessary testing refers to the excessive or improper use of clinical laboratory services for reasons not related to the medical needs of a patient. These schemes can be costly and may result in actual danger to the patients, such as when they lead to additional invasive interventions that run the risk of patient harm.
Specific potential schemes of high concern and importance to HFPP Partners are described below.

- **Use of Excessively Large Panels:** A commonly reported problem is the use of more expensive, excessively broad panels in place of smaller panels. For example, a 5-panel urine drug screening test for cannabinoids, cocaine, amphetamines, opioids, and phencyclidine is typically sufficient to detect the use of commonly abused substances, such as marijuana, cocaine/crack, heroin, and methamphetamine. In contrast, larger and more expensive definitive panels (i.e., 12- or 14-panel) can be used to detect particular subsets of the substances identified in the smaller panels, as well as the presence of some other less-commonly abused substances. While this may be clinically warranted in some cases, the use of overly broad panels can also be used for the purpose of maximizing reimbursement in the absence of medical necessity. A related problem that can be difficult to control is the use of definitive drug testing for a wide range of substances for which the patient has no history of abuse.

- **Standing Orders for Laboratory Tests:** Standing orders refers to either a policy of prescribing a certain test or other medical service for all individuals that meet a specific set of inclusion criteria or a policy of setting up a recurring order for the course of an individual patient’s treatment. In the past, standing orders have been used to order testing for any patient that has a given condition or is a member of a specific population group. Current Medicare rules, which serve as the basis for rules of many private payers, allow for standing orders only in certain defined circumstances.[12] Broad, population-based orders are not reimbursable. Despite existing controls and requirements, the development of practices to avoid the labeling of population-based testing as standing orders have been implicated as a driver of laboratory fraud. For example, in settlement agreements with Millennium Health, the DOJ alleged that the company promoted a practice they called custom profiles to create a system of standing orders that violated federal healthcare payment rules.[8]

- **Excessive or Improper Urine Drug Testing:** Urine drug testing to detect drug or alcohol use is widely used and frequently billed to payer organizations even when used outside of traditional clinical settings. Virtually all HFPP Partners reported concerns about the widespread fraud and abuse associated with excessive urine drug testing being performed primarily to increase provider reimbursement. Partners note that urine drug testing has become a major source of revenue for many providers, thereby encouraging potential fraud and abuse.

EXCESSIVE URINE TESTING:

In Maryland, four men were convicted or pled guilty to conspiring to defraud the government through billing for excessive urine testing.[14] The men provided opioid prescriptions to patients in exchange for patients agreeing to excessive urine testing, and then sent the urine samples to an external lab in exchange for illegal kickbacks.[15] In addition to those convicted, an additional defendant fled the country, and another defendant committed suicide before standing trial.

In addition to monitoring that patients are appropriately using prescribed opioids, some providers may be required to test more regularly to comply with state laws or may be testing defensively as a way to minimize malpractice risks. The increased testing may also be as a result of concern regarding inappropriate prescribing given the increasing intensity of the opioid epidemic and the attention paid to the role of provider prescribing practices. The CDC currently recommends that patients who are prescribed opioids be tested to identify prescribed substances and undisclosed use at least annually.[13]
The routine use of definitive (quantitative) urine drug testing, in place of lower-cost presumptive (qualitative) testing, was another major concern described by Partners. Presumptive drug screening detects the presence of a suspected substance or demonstrates adherence to pharmacotherapy treatment by providing a “yes or no” answer regarding whether the substance has been consumed. Definitive drug screenings are used to assess the levels or quantity of a specific substance that was detected during screening. Some HFPP Partners suggested that definitive testing in the absence of a presumptive test result should trigger a clinical record exam or be unallowable.

• Sober Living Facilities (Sober Homes) That Profit From Urine Drug Testing. HFPP Partners are concerned about evidence of widespread abuse by sober homes engaging in excessive urine drug testing. Sober homes are group homes for individuals recovering from drug and alcohol problems. When appropriately run, sober homes offer those in recovery a stable, relatively low-cost housing environment with limited recovery services, a structured set of rules to ensure a safe and healthy environment, and random drug and alcohol urine testing to assure adherence to the facilities’ alcohol and substance use policy. Although sober home living services are not reimbursable by insurance, the urine drug testing conducted at the facility can be submitted for reimbursement to insurance.

Sober home schemes may involve the intentional creation and ongoing management of a sober home facility in order to profit from urine drug testing. In most cases, the scheme involves either the establishment of a laboratory capable of conducting and billing for urine drug testing within the facility or collusion with a capable co-owned or conspiring facility. In some instances, an existing sober home facility or low-income residence, such as an extended stay hotel, may be purchased by a fraudulent entity and converted into a sober home scheme. The scheme may be facilitated by bribes, free rent, or even the payment of insurance premiums for individuals who agree to reside in the facility, ultimately violating multiple laws.

On a larger level, while some sober homes provide needed services for the persons residing within, Partners report that in several documented instances, facilities provided only the lowest level of supportive services possible to be considered a sober home – such as resident self-organized 12-step meetings – and demonstrated a pattern of indifference to the use of alcohol or substances by their residents. Improperly or fraudulently operated sober home facilities can create patient health hazards that include substance abuse relapse, opioid overdose, interpersonal violence within a facility, and resident death.

• Pain Clinics That Profit From Urine Testing: Several instances of fraud have been reported in which providers at pain management clinics have provided cash or opioid prescriptions for no medical purpose in exchange for patient agreement to regularly attend the clinic and agree to medical tests.[17] These arrangements put patients at risk for substance use disorders and overdose death solely in order to enrich the pain clinic’s owners.
• **Excessive or Improper Genetic Testing:** When used correctly, genetic testing may offer opportunities to reshape the way healthcare is delivered and can potentially lead to substantial improvements in population health and individual health outcomes. Currently, most genetic tests are only applicable in specific circumstances and all genetic tests are generally only needed one time, as the results would typically not be expected to change in the absence of a new disease process.

HFPP Partners described existing problems with the use of genetic testing that are not related to actual or potential medical diagnoses, overuse of genetic testing where the tests have no clinical value (possibly related to an actual or potential medical diagnosis, but not germane to treatment decisions), and repeated genetic testing of the same person for the same genetic pattern, by the same provider facility. Genetic testing results generally do not change over time, but Partners have described situations where individual patients received the same genetic test multiple times. Multiple Partners noted that direct-to-consumer marketing increased patient demand for potentially unnecessary genetic testing. In some instances, physicians obliged by ordering the unnecessary test. One HFPP Partner reported high volumes of claims for new highly reimbursed genetic tests immediately after the tests are released. In other cases, test orders were provided despite an absence of a clinical relationship between the patient and the ordering physician.

**IMPROPER GENETIC TESTING:**

One Partner described a situation in which a provider was systematically screening men for the BRCA1 and BRCA2 genetic mutation that places an individual at higher risk for breast cancer. Male breast cancer is rare and usually occurs in older men. [18]
CONCLUSION

This paper represents a first attempt to organize and present the vast wealth of informal information on potential fraud and abuse known by HFPP Partners but that has not been commonly shared across all individuals or organizations. This paper aims to explore the susceptibility of clinical laboratory services to fraud and abuse by describing the systemic challenges involved in identifying and addressing current and emerging issues impacting HFPP Partners. It also provides a starting point to a long-term project to combat fraud and abuse in laboratory services. Particular areas of focus for future work may include review of and recommendations for payer oversight and analytics of laboratory services; efforts to foster collaboration and information sharing to enhance the proactive detection of potential fraud and abuse; development, refinement, and delivery of provider monitoring and education programs to reduce fraud and abuse; and the development of organized, cross-industry responses to urine drug testing schemes and other areas of high concern. With determination and collaboration, future work can lead to specific, coordinated actions by the HFPP and its Partners to combat fraud and abuse in clinical laboratory services.
REFERENCES


