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How Urine Drug Testing Fraud and Abuse Is Impacting the Treatment Community

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The utilization of Urine Drug Testing (UDT) by health-care providers has grown exponentially in recent years. The popularity of UDT surged over the past decade, initially in connection with testing patients with chronic pain who were being treated with narcotic opioids and, more recently, in the addiction treatment context.

In a pattern reminiscent of other new diagnostic testing or reimbursement opportunities in health care, the growth in UDT utilization attracted not only providers drawn to its potential for improving quality of care, but also those promoters in the profit opportunity. The year-over-year increases in testing volume over the past decade are staggering[1] and difficult to defend as not being at least partially due to profit-driven.

This has, in turn, led to a growing number of health-care fraud and abuse investigations, most prominently a false claims case settled by laboratory services provider Millennium for $256 million and a pending lawsuit filed by Cigna in Florida against Sky Toxicology and multiple affiliated labs. These are only the most prominent of a large number of current fraud investigations and enforcement actions in process focusing on UDT.

On Nov. 15, 2015, a federal grand jury in Kentucky indicted five former owners of Premier Tox for UDT fraud. The FBI has arrested doctors for receiving kickbacks for ordering drug testing.

These cases are the tip of the iceberg. Around the country, third-party payers and law enforcement agencies are taking aim squarely at UDT fraud and abuse.

In the addiction treatment community, scrutiny has extended to the relationships between and among physicians, marketers, laboratories and drug treatment facilities (both residential and outpatient).

This article examines the impact of these cases on the treatment community:

- Part I reviews the recent Millennium case for the anatomy of recent fraud and abuse cases.
- Part II considers the appropriate utilization of UDT in the treatment context.
- Part III considers the issues surrounding medical necessity and abusive UDT billing practices.
- Part IV considers anti-kickback and self-referrals.
- Part V offers some concluding observations, including recommendations for the avoidance of conduct that may trigger fraud and abuse investigations.

I. Anatomy of UDT Fraud Case: Millennium Health

The recent $256 million settlement of false claims allegations by Millennium Health, a national clinical laboratory (19 HFRA 787, 10/28/15), offers an ideal example of the issues around UDT fraud.

[1] http://www.nytimes.com/2013/08/02/business/increase-in-urine-testing-raises-ethical-questions.html?_r=0

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The case initiated as a dispute among competitors. Ameritox sued Millennium, alleging its provision of free point-of-care (POC) testing cups[2] to physicians was illegal and amounted to unfair competition and tortious interference.[3]

Millennium marketers had offered free POC cups to doctors on the condition that the doctors agreed not to bill any insurer (including federal health plans) for the test, and instead return each test cup to Millennium for laboratory testing of the urine specimen. Under its ''cup agreements,'' Millennium would charge physicians for the cost of the cups if they failed to send urine specimens to Millennium for further testing.

Following trial, a jury found in favor of Ameritox and awarded it nearly $5 million in damages, which Millennium appealed.[4]

In an unusual step, the Department of Justice intervened, filing an *amicus* brief challenging Millennium's interpretation of the regulatory guidance on the definition of, and exceptions to, remuneration under the federal anti-kickback statute and self-referral law.

Subsequently, DOJ initiated its own case against Millennium, which involved questions beyond Ameritox's allegations, such as billing for testing senior citizens for unlikely drugs (such as PCP) and billing for patients who had died. The case culminated in Millennium's agreement to pay $256 million to settle the case. In November 2015, Millennium filed for bankruptcy (19 HFRA 865, 11/25/15).[5]

The central issues in the case involved whether the doctors who referred tests had been induced by the free POC cups to refer tests and had a direct financial interest in the referrals.

Millennium had argued that providing POC cups to doctors fell within a well established statutory exception for laboratory supplies that allows labs to provide supplies for purposes of collecting, transporting, and storing specimens.

The argument failed because what Millennium was giving the doctors—not merely an ordinary specimen cup, but rather one embedded with an immunoassay test strip that provide a cognizable and quantifiable benefit as diagnostic tool—was far more valuable.

The case drew significant attention nationwide because, over the past decade, UDT has expanded dramatically thanks to marketing efforts of labs and intermediary entities that have attempted to use incidental benefits to make it easier to order UDT.

In addition to POC cups, marketers have offered other benefits to facilitate claims, such as personnel to assist with collection and referral, among other benefits.

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The case sends a strong message about the danger of over-aggressive marketing as the rate of UDT testing continues to climb.

II. When Is UDT Appropriate?

It may be useful to begin with some background as to how UDT can be utilized in a compliant manner.

UDT enables providers to monitor compliance, detect drug abuse, and motivate patients to avoid the temptation to use illicit or unprescribed drugs.

UDT can occur quickly and less expensively through POC testing, which can detect many drugs, including marijuana, cocaine, amphetamine, morphine, codeine, and heroin.

Often positive results or concerns about other opioids that do not register on point-of-care testing are confirmed through gas chromatography/mass spectrometry or high-performance liquid chromatography testing.

Positive tests typically reflect use of the drug within the previous one to three days.

In the addiction treatment context, UDT is a valuable tool to screen patients for substance abuse and recovery.

The signs of drug abuse and addiction can be difficult to discern behaviorally in contrast to the black-and-white objectivity of UDT results. It corroborates the patient's compliance or betrays noncompliance.

One question is how frequently UDT testing should occur. The Substance Abuse and Mental Health Services Administration (SAMHSA), the federal agency charged with responsibility for articulating clinical standards, recommends in the addiction context that UDT be used on a step-down basis, beginning with more regular testing (every several days, to avoid false positives as drugs metabolize and remain detectable in urine) and increasingly tapering to less frequent, at risk points (*e.g.* after a holiday weekend), based on erratic behavior, and on a random basis.

Insurers have generally acknowledged the need for more frequent UDT during treatment for chemical dependency in order to monitor compliance.

One of the hotly disputed issues in UDT has arisen over the billing codes used to submit claims and the number of drugs tested for.[6]

[2] POC cups are specimen collection cups with embedded immunoassay testing strips, which enable physicians at the point-of-care to screen the urine samples of patients who may be taking illegal drugs or who are prescribed drugs that are subject to abuse or diversion.

[3] *Ameritox, Ltd. v. Millennium Labs., Inc.*, 11th Cir., No. 14-14281, *appeal filed*, 9/19/14.

[4] Jury Verdict at 9.

[5] http://www.bloomberg.com/news/articles/2015-11-10/millennium-lab-holdings-files-bankruptcy-after-u-s-settlement

[6] Applicable CPT/procedure codes:
Most Commonly Used UDT Codes and Descriptions—
G0431 Drug screen, qualitative, multiple drug classes by high complexity test method (e.g. immunoassay, enzyme assay), per patient encounter

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The choice of codes and number of codes billed dramatically affects the potential amount of the claim. The most commonly used and uncontroversial HCPCS billing codes for UDT are G0431 or G0434. The choice of alternative reimbursement codes may be appropriate in other cases, but can significantly affect the reimbursement.

In general, providers are expected to test only for likely suspected substances, and payers have refused to cover excessive testing in favor.

Many payers have rejected certain UDT billing practices, such as the more expensive practice of qualitative screening for distinct drug classes or per procedure (utilizing CPT 80101 and 80104) and confirmation testing (CPT 80102) following a negative qualitative test.

Many payers have declined to cover urine spectrophotometry and column chromatography/mass spectrometry as experimental/investigational.

In addition to a reduced scope of permitted codes, many payers have reduced and are continuing to reduce the reimbursement for permitted UDT codes, responding to a growing number of labs offering the test and indirectly seeking to reduce the incentive for profit-seeking through overutilization.

With this background, we turn to the question of when UDT claims are at risk of crossing the line into fraud based on lack of medical necessity.

III. When Does UDT Cross the Line Into Fraud and Abuse? (Unnecessary Testing)

Payers use medical necessity standards to root out fraud, waste and abuse. The basic guideline for medical necessity is simple: for drug testing to be reimbursable as medically necessary, it has to fit the same parameters as other diagnostic laboratory specimen testing, *i.e.* ordered by a physician using his or her independent judgment in order to gather some valuable diagnostic data.

The first question to ask when reviewing compliance is therefore whether a physician has clinically documented a patient diagnosis involving risk of drug abuse, along with a signed order for UDT.

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In the treatment community, this most basic question of physician documentation has arisen frequently. Most residential and outpatient drug treatment programs are non-medical ''social model'' programs, not including physician care. In many cases, drug treatment programs are imposing standing UDT protocols without physician involvement.

While chemical dependency treatment programs are free to order UDT without active physician engagement and assessment of patients leading to physician orders, submitting insurance claims for those tests should be a red flag for a potential fraud and abuse issue in the making.

To compound the issue, in many cases, testing continues at a high frequency that does not get adjusted based on outcomes (*e.g.* where SAMHSA recommends gradual extension of the intervals between testing based on demonstrated compliance).

One challenge is that, in the drug treatment context, UDT serves multiple distinct purposes: not only to enable the physician to assess a patient's progress in overcoming a substance use disorder, but also as a behavioral deterrent to drug use and a verification of continued sobriety.

These purposes may be aligned with reimbursement standards when a physician assesses a patient and orders UDT, but come apart when non-physicians do so.

Using medical need and physician review as determinants of insurance reimbursement, the work does not end with the ordering of the tests.

To be appropriately reimbursable, the doctor also needs to actually review the results to determine if there is something actionable or, at a minimum, to observe the patient's successful maintenance of sobriety and comment on the patient's treatment, if appropriate.

In general, physician documentation should adhere to SOAP note standard (***s***ubjective reporting of the patient's stated condition, ***o***bjective reporting of the data (including UDT results), ***a***ssessment of the patient, and ***p***lan for the patient's future treatment).

Many of the medical necessity problems arise in the addiction treatment context precisely because physician review does not reach the depth that would occur in a traditional physician-patient encounter. If physicians applied the same standards of documentation to

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G0434 Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter

80102 Drug confirmation, each procedure

Other UDT Codes for Qualitative and Quantitative Testing (Not Covered in Many Plans)—

80100 Drug screen, qualitative; multiple drug classes chromatographic method, each procedure

80101 Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class

80104 Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

80154 Benzodiazepines (quantitative)

80160 Desipramine (quantitative)

80174 Imipramine (quantitative)

80182 Nortriptyline (quantitative)

82145 Amphetamines or methamphetamines (quantitative)

82205/80184 Barbiturates not otherwise specified (quantitative)

82520 Cocaine and metabolites (quantitative)

83805 Meprobamate (quantitative)

83840 Methadone (quantitative)

82491/80299 Methaqualone (quantitative)

83925 Opiate(s), drug and metabolites, each procedure (quantitative)

83992 Phencyclidine (PCP) (quantitative)

82491/80299 Propoxyphene (quantitative)

82491/80299 Tetrahydrocannabinoids (quantitative)

82646 Dihydrocodeinone

82649 Dihydromorphinone

83789 Mass spectrometry and tandem mass spectrometry, analyte not elsewhere specified; quantitative each specimen

82541-82544 Column chromatography/mass spectrometry (e.g., GC/MS, or HPLC/MS), analyte not elsewhere specified; quantitative, single stationary and mobile phase

84311 Spectrophotometry, analyte not elsewhere specified

patients in the addiction treatment context, it is likely that many of the medical necessity issues that lead to fraud and abuse claims would disappear.

IV. When Does UDT Marketing Become Fraudulent? (Kickbacks/Self-Referral)

As reflected in the Millennium case, the relationship between labs and drug treatment centers is perhaps the most loaded with potential fraud and abuse issues. Part of the reason for many of the recent cases that have made the news are not only the questions about subtle inducements, such as POC cups, but flagrant kickbacks, in which a drug treatment center or physician is offered compensation on a per-test or volume-based measure for each test they refer to the lab. Inducements from labs to drug rehabs are a big fraud problem.

There appears to be confusion on the issue because, in many states, the laws envision laboratory referrals as going from the physician to the lab, and do not provide for the scenario of referrals going from chemical dependency programs to a lab. (This is also consistent with the principle applied by payers that lab tests are only medically necessary and reimbursable when ordered by a physician in the course of treatment of a medical condition.)

It is safe to anticipate that, to the extent current law does not prohibit financial inducements to chemical dependency programs, new legislation will be forthcoming in the near future to close gaps in laws.

The Millennium case should stand as a warning about the consequences of aggressive marketing practices. Payers and law enforcement will regard any form of inducement for referrals, whether cash or in kind (such as POC cups or free services), to be fraudulent.

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Many marketers or marketing departments of laboratories are experimenting with ways to increase convenience and visibility and need to be careful of anti-kickback and self-referral prohibitions.

In recent years, some drug treatment program owners have established their own labs to capture the economic benefit associated with a needed service and avoid the problem of illegal payment-for-referral relationships. While these affiliated laboratories are legally permissible in many states, it is essential to ensure that they are organized in a compliant manner, with attention to whether the particular state requires disclosure of the relationship or physician independent choice as to the lab. Some states have self-referral laws that also make these affiliated relationships problematic.

The bottom line is that laboratories need to review carefully the marketing being done in their name and what the marketing team—both in-house and outside contractors—is up to.

Laboratories should expect to see pervasive UDT fraud investigations for years to come. Labs that are incentivizing referrals are going to face overpayment actions and potentially even criminal liability risks in the worst cases.

Since anti-kickback laws generally prohibit not only the giving of but also the getting of inducements, the same caution should be exercised by anyone referring for laboratories ab services.

V. Recommendations for Compliance

For drug treatment providers, laboratories, and companies that work with them, the rampant profit-driven overutilization of UDT should be concerning. Cigna's attribution, for example, of out-of-control UDT costs as a driving factor in its decision to pull out of the Florida insurance exchange marketplace is an indicator of the seriousness with which all payers and, ultimately, law enforcement, are likely to take the issue.

To maximize compliance and reduce the risk of legal and regulatory problems, labs and the providers should ensure certain practices are in place, including:

- documentation of a new patient record that includes a detailed history, appropriate physical examination, and treatment order—as a doctor would make with any new patient—that includes a signed order;
- documentation of periodic follow-up visits;
- documentation of physician review of UDT results—including specific analysis of the implication of relevant results, not just circling or underlying relevant data (i.e. the doctor should be commenting on information in the test results and any changes in treatment—to demonstrate that they are being used in an ongoing course of care, not just a one-time visit followed by ad infinitum testing); and
- signed order and documentation of testing tapering off over time from more frequent to less frequent and ultimately random.

While the foregoing documentation is generally maintained by physicians or chemical dependency programs, laboratories would be well advised to be more proactive in verifying the physician justification for testing, to distinguish between reimbursable and non-reimbursable tests, because payers are ultimately going to be looking for money back from labs even if the problem of physician under-involvement occurred outside of the labs' control.

For chemical dependency programs that wish to test more frequently than may be medically valuable from a physician perspective, it may be advisable to bifurcate between UDT that is physician-ordered and treatment-focused (and therefore reimbursable), as opposed to testing that is strictly for the chemical dependency program's purposes to confirm abstinence irrespective of physician review (and therefore not reimbursable).

If drug treatment centers and labs distinguished between these categories and limited insurance billing to genuinely doctor-ordered tests—charging patients directly for the deterrence and continued sobriety testing, it is likely that fraud and abuse around UDT would not be perceived as a problem.

If labs and providers do not act to implement greater compliance, overtesting is likely to continue to be perceived as a compliance problem, leading to fraud and

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abuse allegations against a broader and broader range of providers and laboratories.

Those who want to avoid being low-hanging fruit should think about how to uphold the integrity of the legitimate medically valuable role of UDT in addiction treatment.