REVIEW ARTICLE

# Evaluating motives: Two simple tests to identify and avoid entanglement in legally dubious urine drug testing schemes

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ABSTRACT

***Objective:*** *This article educates healthcare practitioners on the legal framework prohibiting abusive practices in urine drug testing (UDT) in medical settings, discusses several profit-driven UDT schemes that have resulted in enforcement actions, and provides recommendations for best practices in UDT to comply with state and federal fraud and anti-kickback statutes.*

***Methods:*** *The authors carefully reviewed and analyzed statutes, regulations, adivsory opinions, case law, court documents, articles from legal journals, and news articles.*

***Results:*** *Certain facts-driven UDT arrangements tend to violate federal and state healthcare laws and regulations, including Stark law, the anti-kickback statute, the criminal health care fraud statute, and the False Claims Act.*

***Conclusions:*** *Healthcare practitioners who use UDT can help ensure that they are in compliance with applicable federal and state laws by evaluating whether their actions are motivated by providing proper care to their patients rather than by profits. They must avoid schemes that violate the spirit of the law while appearing to comply with the letter of the law. Such a simple self-evaluation of motive can reduce a practitioner's likelihood of civil fines and criminal liability.*

## INTRODUCTION

Prescription drug abuse is an epidemic that affects Americans regardless of age, education, income level, gender, and ethnic background. Approximately 2.8 million people aged 12 or above begin abusing prescription drugs for the first time each year in the United States,[1] and approximately 1.9 million people suffer from a substance use disorder (SUD) stemming from the misuse or abuse of opioid analgesics, which are controlled substances prescribed to relieve pain.[1]

Nevertheless, an estimated 100 million Americans experience chronic pain and have a legitimate need for treatment.[2] To preserve access to treatment while reducing the potential for diversion (ie, the illegal redirection of prescription medications away from the legal channels of distribution), misuse (ie, the use of a medication for a medical purpose other than as directed or indicated, whether willful or unintentional, and whether harm results or not), and abuse (ie, the intentional self-administration of a medication for nonmedical purposes, such as "getting high"),[3] healthcare practitioners who prescribe controlled substances must use tools, such as urine drug testing (UDT), to detect or monitor controlled substance use and spot warning signs.

UDT is a group of analytical techniques that involve testing urine samples to identify the presence, absence, or concentration of controlled substances, including illicit and prescription drugs, or their metabolites. UDT can improve health outcomes, decrease the stigma attached to SUDs, and reduce addiction-related costs.[4] As such, guidelines on the prescribing of controlled substances commonly recommend UDT,[5,6] and some states recommend or require UDT in the treatment of pain or addiction.[7,8]

Bad actors are increasingly facing legal consequences for improper use of UDT. Unfortunately, some practitioners lack training or experience in medically sound and legal uses of UDT, leading to negligent overutilization of UDT. UDT expenditures are significant in the United States: In 2012, Medicare paid medical providers $457 million for 16 million tests.[9] In 2013, sales at diagnostic testing laboratories that offer UDT reached an estimated $2 billion, a substantial increase from $800 million in 1990.[10] Unethical practitioners motivated primarily by profit have seized on the surge in spending on UDT by ordering tests for their patients and billing third-party payers when no valid medical necessity exists.[9]

Federal agencies have been taking aggressive actions to reduce healthcare waste, fraud, and abuse. In 2013, $4.3 billion was returned to the federal government as part of recovery efforts.[11] Practitioners who wish to use UDT in compliance with the law must, therefore, learn how to identify and avoid participating in legally dubious UDT schemes, follow guidelines or best practices in their field, and document medical necessity and the bases of their UDT selections.

Both federal and state laws and regulations prohibit fraud, waste, and abuse in UDT, but some of these laws only apply to federal healthcare programs, contain ambiguities or "loopholes" that are exploited, or are so complex so as to leave practitioners confused regarding how to comply. While not exhaustive, this article discusses some of the legal doctrines under which practitioners may face liability for improper utilization of UDT and recommends methods for compliance. Ultimately, it proposes two simple guiding principles. First, to comply with federal and state laws and regulations, healthcare practitioners must ensure they order UDT to meet their patients' medical needs and not to make a profit. Second, if an arrangement appears to violate the spirit of a healthcare fraud law, even if it appears to comply with the letter of the law, it should be avoided.

The "letter of the law" is defined as the literal meaning of a statute, rule, regulation, or principle; it is the law as it is written.[12] The "spirit of the law" is the "general meaning or purpose, as opposed to its literal content," that is, the intention of the law.[12] The spirit of the law may be determined based on the circumstances surrounding a law's enactment. An individual can violate the spirit of the law and incur culpability, even without violating the letter of the law.[12] This may be done by exploiting a technicality or loophole in the law.

As applied to UDT, healthcare law is unsettled and evolving to account for new technologies and practice trends, thereby leaving room for interpretation regarding the application of existing laws and regulations. For instance, recent fraud alerts from the Office of the Inspector General (OIG), a division of the Department of Health and Human Services (HHS), shed light on laboratory payments to referring physicians under the anti-kickback statute (AKS), but the application of other federal laws remains unclear. For example, the OIG has made ambiguous statements about the possibility of liability under Stark law if certain self-referrals are made, claims are submitted to private third-party payers, and such claims have a spillover effect on federal healthcare plans, as discussed below in detail.[13] Federal authorities have become more aggressive in their investigations and prosecutions of UDT-related healthcare fraud. From a legal risk management perspective, a UDT arrangement that enables a practitioner to meet patients' medical needs, earn a living, and avoid the possibility of serving as a test case in court is preferable. Furthermore, the principle of statutory construction—examining the intent of a particular statute so that it may be applied accurately—supports a decision in favor of the spirit of the law. This article is not intended as legal advice and should not be relied on as such. State-specific legal advice should be sought as it pertains to each practitioner's circumstances. As with all healthcare practice areas, documentation of patient-specific facts and the rationale behind treatment choices in UDT is a professional duty.

## LEGAL FRAMEWORK GOVERNING UDT

An extensive legal structure currently exists to deter profit-driven UDT. This section provides a brief overview of some of the applicable legal doctrines.

### Stark law

Stark law and its regulations prohibit a physician from referring a Medicare or Medicaid patient to an entity for designated health services (DHS) if the physician or his immediate family member has a financial relationship with the entity, unless an exception applies.[14] (Stark provides numerous exceptions; however, they are detailed, fact specific,

and mostly outside the scope of this article.) This prohibition applies to DHS received by patients enrolled in Medicare and Medicaid even if the services are billed to an individual or other third-party payer.[13,15]

DHS includes clinical laboratory services, such as UDT,[13] and an entity includes any person or business that performed the DHS or has presented a claim to Medicare or Medicaid for DHS.[16] A referral is defined as a physician's request for items or services payable by Medicare or Medicaid, or the establishment of a plan of care that includes the provision of DHS.[13] A "financial relationship" is a direct or indirect 1) ownership or investment interest or 2) compensation arrangement between the physician and the entity to which a physician referred a patient for DHS.[13] A person who knowingly violates Stark law is subject to a civil penalty of up to $15,000 plus three times the amount claimed for the DHS.[13]

The "spirit" of Stark law is to address the assumption that "financial incentives skew a physician's judgment, increasing utilization, undermining competition, and potentially compromising quality."[17] The complex law is guided by a simple principle: the medical needs of the patient, rather than the prospect of financial gain, must control physician referrals.[16] To prevent physicians from evading this principle by violating the spirit of the law while complying with the letter of the law, Stark law contains a "circumvention schemes" clause, which prohibits physicians and entities from entering into an arrangement for referrals that the parties know or should know would violate Stark law if the referrals had been made directly to the entity (eg, a cross referral arrangement) and may result in up to $100,000 civil fines for each arrangement.[13]

### Anti-kickback statute

The federal AKS prohibits the exchange of, or offer to exchange, "remunerations" (ie, anything of value) in efforts to induce or reward the referral of federal healthcare program business.[18] To violate the AKS, the parties must possess the requisite intent (ie, "knowingly and willfully" engaging in prohibited referrals).[17] Whenever an entity offers or gives an item or service to a potential or actual referral source for free or below market value, an inference may be drawn that the item or service was offered to induce referral business.[19] For instance, in *United States v Lipkis*, when a laboratory paid more than fair market value for services provided by a medical group, the court inferred that the laboratory was also paying for lab work referrals.[20]

Courts and regulators are largely unforgiving in their scrutiny of suspect referral arrangements. In *United States v Greber*, the Third Circuit Court of Appeals found that the defendant, an owner of a medical laboratory, had violated the AKS when he paid physicians for "interpretation fees" of laboratory results.[21] According to the court, "if one purpose of the payment was to induce future referrals, the [AKS] has been violated," and here, the defendant intended for the payments to induce the physician to use his laboratory's services, even though the payments were also intended to compensate for professional services.[20] The Fifth, Ninth, and Tenth Circuits have also adopted this "one purpose" standard.[22-24]

The AKS defines "federal healthcare program" as any plan or program that is funded by the federal or state government.[17] The AKS may also extend to nonfederal healthcare programs (eg, those of private third-party payers) if a referral arrangement involving a nonfederal healthcare program results in a "spillover" effect on billing or coding for federal healthcare program services and one or both parties intended for such an effect to occur.[13] For example, a spillover effect may exist if a practitioner receives remuneration for referrals of patients with private plans, yet no remuneration for referrals of patients who are federal healthcare program beneficiaries. Such arrangements can have a negative impact on the federal healthcare programs by establishing a lucrative quid pro quo relationship in which a remunerated practitioner provides a corresponding benefit to the laboratory in the form of high-volume referrals of federal program beneficiaries, including cases in which no medical need for services exists. Compensated referrals should not be made regardless of whether the patient is enrolled in a federal healthcare program or any other type of plan.

Those who violate the AKS may face fines of up to $25,000 and imprisonment for up to 5 years.[17] Violations may also result in mandatory exclusion from federal healthcare programs and additional civil penalties of $50,000 per violation.[25]

### Criminal healthcare fraud statute

Under the federal criminal healthcare fraud statute, it is illegal to knowingly execute a scheme to

defraud any "health benefit program," including private plans, or to obtain by means of false or fraudulent pretenses, representations, or promises any money or property owned by, or under the custody or control of, any healthcare benefit program.[26,27] Proof of actual knowledge or specific intent to violate this law is not required.[27] Penalties for violations include fines, imprisonment, or both.[27] The submission of claims for UDT to a third-party payer that are medically unnecessary violates this statute. The breadth of this statute underscores the need for thorough documentation of treatment decisions and their rationales in patients' medical records.

### The False Claims Act

The False Claims Act (FCA) imposes civil or criminal liability on any person who submits a claim for payment or approval to the government that the person knows or should know to be false.[28] The FCA is a powerful deterrent against fraud on the government; in addition to civil penalties, the FCA allows for private "whistleblowers" to bring suit for violations of the FCA and retain a portion of any monies recovered in the suit.[29] Under the civil FCA provisions, no specific intent to defraud is required, and "knowing" includes instances in which the person acted in deliberate ignorance or reckless disregard of the truth.[30] Often, a violation of Stark law, the AKS, or the criminal healthcare fraud statute is also a violation of the FCA.

### Miscellaneous federal and state violations

Other federal statutes under which healthcare practitioners may be held liable for profiteering schemes involving UDT include bank, mail, and wire fraud and conspiracy to defraud the United States.[31-34] Moreover, states also have their own statutes and regulations governing kickbacks, self-referrals, markups, and other types of healthcare fraud involving UDT schemes—some of which are even more stringent than federal laws.

## QUESTIONABLE UDT SCHEMES

To avoid liability, healthcare practitioners must make UDT decisions based on the patient's needs rather than a consideration of profit. They should avoid participating in questionable UDT schemes, such as those described below, which often violate at least one, if not several, federal and state laws and regulations. Arrangements that may not technically violate the letter of the law but that conflict with the spirit of the law should also raise red flags in the minds of practitioners.

### Physician-owned or family-owned labs

Some laboratories share profits with practitioners by bringing them on as investors. In other cases, practitioners refer their patients to a laboratory owned by an immediate family member. Often times, such arrangements violate Stark law and possibly others.

Stark law allows a physician to refer Medicare and Medicaid patients to laboratories with which they have a financial relationship or to laboratories owned by immediate family members[35] only if they are structured to strictly comply with complex Stark law exceptions. For example, the in-office ancillary services (IOAS) exception allows a group practice to refer and bill for DHS ancillary to professional services as long as the following requirements are met (*note:* various, complex tests exist to meet each of these three requirements):

- Ancillary services are provided by the referring physician, a member of the referring physician's group practice, or an individual supervised by the referring physician.
- The DHS is furnished in the same or a centralized building as the professional services.
- DHS is billed by the performing or supervising physician, the group practice, an entity wholly owned by the group or the performing or supervising physician, or by an independent third-party pursuant to reassignment requirements.[36]

According to former Representative Pete Stark, after whom the law is named, the statutory exceptions, as commonly applied, no longer conform to the original intent of the law,[37] that is, to ensure that financial motives do not skew a physician's judgment. In fact, several attempts to pass legislation to revoke the IOAS exception have been made over the past 2 years,[38] and practitioners are advised that changes to the law's exceptions may be forthcoming.

The OIG has criticized laboratory investment arrangements for "lock[ing] up a stream of referrals

from the physician investors" by compensating them indirectly for these referrals.[39] Moreover, some states, including New York and West Virginia, prohibit such arrangements more broadly.[40,41]

To illustrate this point, in a 2008 settlement, Bernhardt Laboratories, Inc. (BLI) and Dr. Michael J. Bernhardt agreed to pay $100,000 for submitting claims to federal healthcare programs in violation of Stark law.[42] Dr. Bernhardt referred patients for clinical laboratory services to BLI, which was owned by his brother, and therefore, claims arising from such referrals violated the law.[42]

Practitioners should also spurn indirect ownership or investment interests. Under Stark law, an indirect ownership or investment interest is created if 1) there exists between the referring physician (or immediate family member) and a laboratory an unbroken chain of persons or entities having ownership or investment interests and 2) the laboratory has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest in the laboratory.[43] For example, if physician A invests in laboratory 1 and physician B invests in laboratory 2, and laboratories 1 and 2 have coinvestors in common, then physicians A and B may not refer patients to laboratories 1 or 2. If physician A invests in laboratory 1 and physician B invests in laboratory 2, and laboratories 1 and 2 have a laboratory management firm in common, then physicians A and B should not refer patients to laboratories 1 or 2; otherwise, physicians A and B could be deemed to have entered into an impermissible direct or indirect compensation arrangement or a circumvention scheme.

Similarly, if a physician owns or invests in a management firm, and the management firm owns part of a laboratory, the physician may not refer patients to the laboratory. By the same token, if a management firm that owns part of a laboratory aids the physician in opening an office-based laboratory or provides the office-based laboratory various services, and the physician refers patients to the laboratory for more complex testing services than the physician provides, then such scheme may also violate the AKS, even if the physician only refers beneficiaries of nonfederal healthcare programs.[44] According to the OIG, financial incentives offered in exchange for referrals of private-pay clinical laboratory services are likely to affect the physician's decision making as to all of his patients, including federal healthcare program beneficiaries, potentially having a spillover effect resulting in the overutilization of laboratory services and increased costs to the federal healthcare programs.[44]

Another suspect arrangement is one in which the ownership of a practice or facility may invest directly or indirectly in a laboratory, and then require the physicians employed by that practice or facility to refer specimens to that laboratory. The ownership may be liable under FCA for requiring employees to refer specimens without regard for medical necessity. The referring physicians may also be liable under Stark law because the financial relationship is unbroken between the referrals of the patients, revenue provided to the practice in exchange for the referrals, and the salaries and benefits of the physician employees.

To reduce the possibility of Stark law liability, physicians should avoid investing in laboratories and laboratory management firms. They should also decline to refer to laboratories owned by family members or to any laboratories with which they may have a direct or indirect financial relationship, whether through ownership, management, or otherwise.

#### Leasing office space or equipment

Arrangements under which laboratories lease office space from or lease equipment to a physician may implicate Stark law, as well as certain state laws. Under Stark law, the leasing of office space or equipment is considered a compensation arrangement.[45] A physician is permitted to make referrals to an entity with which he or she or an immediate family member has a leasing arrangement (provided that the physician does not also have an ownership interest in the entity) if the physician or family member and the entity have entered into a lease agreement that meets certain conditions.[45] The lease must be in writing, signed by both parties, and for a term of 1 year or longer; the terms must be commercially reasonable; and the rental charges must be consistent with fair market value.[45] Moreover, the lease agreement may not take into consideration the volume or value of referrals.[13] If the laboratory pays more than fair market value or compensation is tied to referrals, the arrangement violates Stark law.[46]

Certain state laws may be even more stringent. A recent amendment to the Pennsylvania Clinical Laboratory Act prohibits clinical labs from leasing or renting space, shelves, equipment, or services within healthcare provider's offices altogether.[47]

Leasing arrangements may also violate the FCA. For instance, between 2006 and 2009, Bristol Gastroenterology Associates, P.C. (BGA) occupied a suite within Bristol Hospital without paying rent or entering into a written lease agreement, in violation of Stark law.[48] During the time when BGA used the hospital's space rent free, and therefore had a compensation arrangement with the hospital, BGA regularly referred Medicare patients to the hospital, and the hospital submitted claims to Medicare for those patients.[48] The Stark law violation tainted claims for reimbursement submitted under Medicare, and such claims also gave rise to FCA violations. As part of the settlement agreement, the hospital agreed to pay the US government $157,830, with the violating physicians paying a percentage of the settlement.[48]

To avoid similar outcomes, physicians using UDT should be careful to structure any lease agreements with laboratories providing UDT or with companies leasing UDT equipment to strictly meet the relevant Stark law provisions and should avoid leasing arrangements altogether in states that ban such arrangements outright.

#### Providing free supplies or services

UDT laboratories and healthcare practitioners violate the AKS by giving and receiving anything of value for free or at less than fair market value, including supplies, to induce practitioners to provide referrals.[49] The OIG has clarified that the good or service provided to a referral source raises anti-kickback concerns if:

- the good or service provides a tangible or financial benefit;
- the gift has an independent value to the referral source;
- the service is something that the referral source would otherwise be obligated to provide;
- the service or good is something for which the referral source would be otherwise obligated to incur costs; or
- services would be substituted for those currently provided by the referral sources at their own expense.[50]

The OIG has also stated that clinical laboratories that provide free services, such as "reviewing doctors' orders and establishing, changing, or discontinuing 'standing orders' for certain tests based on that review; determining whether doctors' orders for laboratory tests have been carried out and recorded, along with the results, in patients' charts; reviewing patients' drug regimens and determining whether there is a need for laboratory monitoring or tests, etc." violate the AKS.[49] Such schemes can also violate the FCA. For instance, in November 2010, Ameritox, a UDT laboratory, entered into a settlement agreement for $16.3 million for allegedly violating the FCA through kickbacks to healthcare practitioners, including providing free collector personnel to its physician clientele, to induce referrals.[51]

Although this law applies mainly to federal healthcare programs, some states have similar laws that include claims to all third-party payers. Free goods or services can affect medical judgment and influence prescribing practices.[52] Therefore, practitioners should not accept for free or for less than fair market value any item or service of value. All arrangements should represent a fair, appropriate, and commercially reasonable exchange for goods and services.[52]

#### Improper markups, coding, and billing.

Common UDT markups, coding, and billing include 1) billing above cost for either a technical or professional component (eg, test interpretation) of diagnostic tests that an outside supplier performs but for which the practitioner bills, 2) work-around coding (ie, using codes to circumnavigate plan prohibitions against using more expensive tests), and 3) up-billing (ie, coding and billing for more expensive tests than those actually conducted).[53]

***Markups.*** Under a standard markup scheme, practitioners may pay a flat fee to a UDT laboratory, and then bill a third-party payer above cost as if they had conducted the test personally, keeping any profit from the third-party payer. Alternatively, the laboratory will bill the third-party payer, keep only a portion of the fee that the laboratory receives from the payer, and provide the practitioner with the remainder of the fee. These markup schemes can violate Medicare's Anti-Markup Rule, as well as the AKS and the FCA.

Pursuant to the Anti-Markup Rule, if a practitioner bills for diagnostic testing conducted by a supplier

who is not a member of the billing practitioner's practice, the payment to the billing practitioner may not exceed the lowest of the following amounts:

- the performing supplier's net charge to the billing practitioner;
- the billing practitioner's actual charge; or
- the fee schedule amount for the test that would be allowed if the performing supplier billed directly.[54]

Moreover, the billing practitioner must identify the performing supplier and indicate the performing supplier's net charge for the test.[54] If the billing practitioner fails to provide this information, the Centers for Medicare and Medicaid Services (CMS) will not pay the billing practitioner, and the billing practitioner may not bill the beneficiary.[54] Some states, including but not limited to California, Florida, Michigan, Oregon, and Virginia, also have laws prohibiting markup arrangements for their state-funded programs and commercial payers.

A particularly bold and daring attorney might argue or conclude that such markup schemes are legal as long as they are not applied to patients enrolled in federal healthcare programs. For instance, Veritas Laboratories, LLC, a multistate laboratory, had entered into standard markup arrangements under which it contracted with physicians to provide laboratory testing for patients, bill the patients' commercial insurance payers, and remit the insurance collection to the ordering physician, minus a $100 clinical laboratory fee.[55] The physicians who took part in the scheme purported earned profits of $400 per test. Veritas's legal counsel argued that the scheme was legal because the contract excluded Medicaid, Medicare, and Tricare patients.[55] Yet as discussed above, billing private third-party payers under schemes that would violate Stark law, AKS, or FCA if federal healthcare programs were billed instead may violate other laws, including the federal criminal healthcare fraud statute. Furthermore, even if federal healthcare program beneficiaries are excluded from such arrangements, these schemes can result in a spillover effect on federal healthcare programs, thereby still violating Stark law, the AKS, and the FCA.

The OIG, in a special fraud alert dated June 25, 2014, specifically discussed these concerns as follows: "Arrangements that 'carve out' Federal healthcare program beneficiaries or business from otherwise questionable arrangements implicate the anti-kickback statute and may violate it by disguising remuneration for Federal healthcare program business through the payment of amounts purportedly related to non-Federal healthcare program business."[56]

Veritas's legal counsel also construed the facts in such a way that the physicians were deemed to be "merely outsourcing the high-tech part of the lab work" rather than referring their patients to another healthcare provider.[55] Therefore, the arrangement fell under the AKS's safe harbor, counsel concluded, because "it's arms-length . . . [and] the payment is set at fair market value."[55] Yet the AKS's personal services and management contracts safe harbor, which requires that "the aggregate compensation paid to the agent over the term of the agreement [be] … consistent with fair market value in arm's length transactions," is just one component of a multifactor test, and the rest of the components were not met under the Veritas model. For example, the safe harbor requires that the arrangement not take into account the volume of referrals generated between the parties, a standard that was not met in this case. Physicians were incentivized to refer patients to Veritas to receive as much as $400 from their patients' insurance reimbursements. The more patients a physician referred to Veritas, the more money the physician made, thereby creating an incentive for the physician to increase the number of referrals to Veritas.

***Work-around coding.*** Having employed a work-around coding scheme, Massachusetts-based Calloway Laboratories Inc. entered into a settlement agreement in May 2014 for routinely using the wrong UDT billing codes in violation of the FCA.[57] It billed for pathology services in addition to UDT services, even though treating healthcare providers did not deem the pathology services necessary and did not knowingly order such services.[57] The lab performed a type of medical review with every UDT; however, the review was not covered by Medicare or Medicaid.[57] Nevertheless, the healthcare programs paid for the services because Calloway submitted them under the codes for covered pathology services.[57]

***Up-billing and double billing.*** In September 2014, Clinical Lab Partners (CLP), a Connecticut laboratory that performed UDT, entered into a $145,789 settlement agreement with the OIG for allegedly

submitting false or fraudulent claims to Medicare involving up-billing.[58] CLP submitted claims for UDT in excess of the permitted amount, circumventing limitations using a code for a different UDT technology, which allowed the lab's claims to bypass computer programming that would have otherwise blocked coverage for the excessive testing.[58]

Pain Specialists of Greater Chicago (PSGC), an Illinois physician practice that performs in-office UDT, entered into a $590,763 settlement, and Nabil Attalla Barsoum, a Florida physician who performed in-office UDT, entered into a $334,538 settlement with the OIG both for submitting claims for high complexity drug tests even though they had performed less-expensive low to moderate complexity tests instead.[58]

In the same month, Carolina Liquid Chemistries Corp was raided for alleged wire fraud, healthcare fraud, and conspiracy to commit wire and healthcare fraud for misrepresenting their products' capabilities, leading their clients to overbill public and private third-party payers.[59] The company purportedly marketed a benchtop chemistry analyzer, a type of UDT technology that is designed to inform healthcare practitioners as to whether a patient has a substance present in his or her system.[59] According to a news story, the FBI accused the company of misinforming practitioners that the UDT system could accurately measure the concentration of the drug without sending the sample to laboratories.[59] The article further alleged that the company then told clients that they could seek higher reimbursements from Medicare and other third-party payers using billing codes set aside for high complexity UDT technology.[59] The outcome of this case has not been reported.

Related to up-billing is the issue of double billing. On February 20, 2014, the Dallas-based Medicus Laboratories entered into a settlement for $5 million and a 5-year corporate integrity agreement with the OIG for false or fraudulent activities involving submitting multiple claims for UDT. Medicus allegedly "knowingly presented multiple, prohibited claims to Medicare for a single patient encounter and submitted claims for other laboratory tests not covered by Medicare."[60]

Practitioners must ensure that they bill properly and use the code that accurately describes the UDT technology used and services provided when submitting claims for reimbursement. They should keep accurate and complete medical records and documentation of UDT services to support any claims submitted.[52] Practitioners should never submit a claim that they suspect is false or inaccurate in any way, and they must take measures to correct any erroneous claim.[52] Pursuant to the Patient Protection and Affordable Care Act, those who have submitted claims for overpayment by filing improper codes must disclose and refund such overpayments within 60 days of discovering the error.[61,62]

#### Ordering medically unnecessary tests

Some laboratories encourage practitioners to overuse UDT by ordering medically unnecessary tests. Such practices are often part of other schemes discussed herein and are prohibited by the criminal healthcare fraud statute, as well as Medicare Part B.[63] According to HHS, no UDT is "reasonable [or] necessary" unless it was ordered by a qualified healthcare professional who "furnishes a consultation or treats a beneficiary for a special medical problem and who uses the results in the management of the beneficiary's specific medical problem."[62] A test will be considered medically unnecessary if the practitioner orders the test but fails to review or use the results to guide the treatment of his patients.[64]

A recent Massachusetts Medicaid (MassHealth) audit report revealed $21 million in excessive, unnecessary, or potentially fraudulent billing.[65] For instance, the report uncovered 15,606 instances in which patients were tested more than once a day, contrary to testing recommendations issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) and substance use treatment professionals, and totaling approximately $286,000.[65] One actor involved in Massachusetts was Dr. Punyamurtula Kishore, the owner of Preventive Medicine Associates, Inc. (PMA). Dr. Kishore induced sober house owners to require all residents to submit to UDT by PMA's physician office laboratories at a minimum of three times per week, regardless of the individual residents' unique needs.[65] Yet the sober homes often ignored positive test results rather than using the results for medical purposes.[66] Dr. Kishore manipulated these business relationships to bill MassHealth for tens of thousands of medically unnecessary tests. Dr. Kishore was charged under the state's Medicaid Kickbacks and Medicaid False Claims statutes.[67]

The facts are similar in *United States v Palin*, which involved multiple types of dubious practices.[64] In September 2014, Beth Palin and Joseph

Webb, addiction treatment physicians and owners of Bristol Laboratories, allegedly engaged in a scheme in which they tested patients but then did not use the results to direct the care of their patients. They also purportedly coded for more expensive tests than those actually performed, marked up the costs of tests, and referred patients to their self-owned laboratories.[64] They were charged with several federal violations, including conspiracy to commit healthcare fraud, violation the Federal Health Care Fraud Act, and making false statements.[64]

Likewise, SelfRefind, a chain of addiction treatment clinics; PremierTox LLC, a clinical laboratory that performs UDT; and Drs. Bryan Wood and Robin Peavler, owners of SelfRefind and PremierTox, agreed to pay $15.75 million for allegedly violating the FCA by submitting claims to Medicare and Medicaid for tests that were medically unnecessary, more expensive than those performed, and in violation of the Stark law.[68] The federal government alleged that, after Wood and Peavler became owners of PremierTox, SelfRefind began referring patients to PremierTox for comprehensive UDTs that were unnecessary and many times more expensive than suitable alternative tests.[68]

Practitioners must be sure to order only medically necessary UDT in accordance with guidelines or best practices in their field. They should document the rationale for ordering such tests,[52] and they should be sure to review test results and incorporate the results into the patient's treatment plan, modifying the course of care when indicated.

#### Clinical trials or registry arrangements

Some laboratories seek referrals of specimens for UDT by encouraging practitioners to enroll their patients in clinical trials. They frequently claim that the trials are legitimate "federally funded" programs because they are listed on the government-run Web site, *clinicaltrials.gov*. Practitioners should be cautioned that payment for enrollment of patients in a clinical trial may violate the AKS and FCA if, according to the OIG Special Fraud Alert of June 25, 2014, "even one purpose of the payments is to induce or reward referrals" covered by federal healthcare programs.[56]

Additional signs that a clinical trial may be suspect include:

- collection of patient insurance information, which indicates that the laboratory is seeking reimbursement for tests that are purportedly for research purposes,
- collection of specimens only from patients covered by selected payers based on whether or not the payer has demonstrated reimbursement for the tests, and
- narrow exclusion criteria.

In 2014, American International Biotechnology (AIB), a laboratory offering pharmacogenetic testing, paid the federal government $343,739 to settle alleged FCA violations.[69] AIB improperly billed genetic tests to Medicare related to a "clinical research study for which patients and insurers would not be billed."[69]

Another scheme that may violate the AKS involves laboratories paying practitioners to participate in or contribute to databases that purportedly collect information about the demographics, presentation, diagnosis, treatment, or outcomes of patients who undergo expensive tests performed by such laboratories and reimbursed by federal healthcare programs (Registry Arrangements).[56] Although such laboratories often assert that registry arrangements are intended to advance research and provide valuable clinical data, they typically pay practitioners for such things as submitting patient data, answering patient questions about the databases, or reviewing registry reports.[56] The OIG has stated that such arrangements may induce physicians to order unnecessary and duplicative tests or to choose the laboratory that made registry payments over a superior laboratory.[56] Unlawful intent, which would support a finding of an AKS violation, would include, for example, a laboratory requirement that practitioners who entered into registry arrangements perform UDT with a specified frequency to be eligible to receive, or to evade a reduction in, compensation.[56]

Practitioners should beware that, although the AKS does not prohibit laboratories from paying compensation for legitimate research activities, the OIG has stated that claims that registries are intended to promote and support clinical research and treatment are not sufficient to disprove unlawful intent.[56] Moreover, the ASK ascribes criminal liability to all parties involved in a false claims transaction, so practitioners may be found liable alongside the laboratories in such schemes.[56]

## RECOMMENDATIONS

Practitioners should conduct self-evaluations to determine whether a particular UDT arrangement likely violates healthcare fraud laws, using two guiding principles. First, the practitioner should ask himself or herself whether the arrangement facilitates UDT to guide the treatment of patients whose health depends on it, or whether the arrangement or testing decisions thereunder will be influenced by the potential for profit. If even one purpose of entering into an arrangement is to make a profit, the arrangement may violate a healthcare fraud law.[20] Second, even if the arrangement appears to comply with the letter of the law, the practitioner should consider whether the arrangement attempts or appears to avoid the spirit of a healthcare fraud law. If the arrangement attempts to circumvent the law in such a manner, it also likely violates a healthcare fraud law. Practitioners should be wary of such arrangements.

Additionally, practitioners in practice areas that use UDT, such as pain medicine, addiction medicine, primary care, emergency medicine, psychiatry, obstetrics, and surgery, should obtain proper training on UDT utilization. Practitioners should be trained on the benefits and detriments specific to each UDT methodology (eg, turnaround time, accuracy, and cost). Practitioners must also accurately and thoroughly document the medical necessity of their actions, including decisions regarding analytes, methodology, timing, and frequency of testing, and how the UDT result influences the specific patient's treatment plan. By taking such precautions, they can reduce their likelihood of liability.

## CONCLUSION

Healthcare practitioners who use UDT can help ensure that they are in compliance with applicable federal and state laws by evaluating whether their actions are motivated by providing proper care to their patients rather than by profits. They must avoid schemes that violate the spirit law while appearing to comply with the letter of the law. Such a simple self-evaluation of motive can reduce a practitioner's likelihood of civil fines and criminal liability.


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