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# LAW 360: A CAUTIONARY WORD FOR PROVIDERS OF DRUG ADDICTION TREATMENT

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Individuals suffering opioid addiction face tremendous obstacles in finding effective treatment. Simply put, the national opioid crisis has outpaced the current ability of the fragmented addiction treatment industry — consisting mostly of small clinics and solo providers — to meet current need. It is estimated that some 20 million Americans meet the criteria for substance use disorders. Of that total, approximately 2 million have opioid use disorders.

However, opioid addiction treatment has never been the focus of traditional health care systems. It simply has not generated revenue comparable to the treatment of other chronic conditions such as heart disease, joint replacement and cancer treatment, to name a few.

In accordance with the age old axiom that nature abhors a vacuum, private equity firms and other smaller investors are stepping in to fill the treatment void. In 2018, 20 private equity deals, totaling $320 million dollars, involved addiction treatment providers.

The reasons? First, the sheer numbers demanding treatment. Second, the Mental Health Parity Act of 1996 requires health insurers to cover behavioral health and substance use disorder treatment on parity with physical health care. Third, the Affordable Care Act has expanded Medicaid coverage to millions of low-income adults and mandated that private insurers cover behavioral and addiction treatment as an essential benefit. Finally, several states, including Pennsylvania, have used the Medicaid waiver program to pay for inpatient substance use disorders in larger facilities.

### Fraud and Abuse

These market trends have resulted in an influx of providers who are unscrupulous, inexperienced or both. As this industry experiences beneficial economic growth enhanced through federal and private insurance reimbursement, these payers will amplify their enforcement and audit posture. Enforcement activity follows the dollars. Evidence of fraud or abuse may result in fines, penalties and clawbacks for both past and present billing activity.

Federal prosecution for opioid-based fraud activity is heating up. On May 2, 2019, a federal jury in Boston found the onetime billionaire and founder of Insys Therapeutics, John Kapoor, guilty of

racketeering charges in a criminal prosecution for contributing to the nation's opioid epidemic. The jury, after deliberating for 15 days, issued guilty verdicts against Kapoor and four other Insys executives finding they had conspired to fuel sales of its Subsys, a highly potent sublingual form of Fentanyl. The jury determined that the defendants not only bribed doctors to prescribe their product but also misled insurers about patients' need for the drug. This conviction likely is the harbinger of others to come.

In the absence of such outright fraud, many providers fail to realize the legal complexities in providing substance use disorder services and what constitutes illegal conduct. For example, patient brokering has long been an accepted industry practice. Common activity includes paying marketers for patient referrals, giving prospective patients gifts, free airfare, housing or insurance premiums to enroll as patients so that insurance can be billed.

Additionally, there may be financial perks exchanged between sober living houses and inpatient facilities where patients are housed in a sober living house while the inpatient facility bills insurance for an inpatient stay. Providers may also receive payments from outside laboratories for patient referrals for urinalysis or other tests.

Since these practices have long been entrenched, providers fail to recognize that these patient brokering activities are illegal kickbacks. Federal prosecutors use the potent federal Anti-kickback Statute to prosecute this abuse. The federal Anti-kickback Statute makes it a crime to knowingly and willfully solicit, receive or pay any remuneration (including any kickback, bribe or rebate) in exchange for referring a patient with federal health insurance. Punishment include felony criminal liability, imprisonment up to five years and fines up to $25,000.

Layered onto these criminal penalties are those imposed under the federal False Claims Act that creates civil liability for "false claims." False claims, as defined, include a range of misconduct related to the submission of false claims for payment or approval for payment to the federal government. Liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose his noncompliance with a statutory, regulatory or contractual requirement.

Civil monetary penalties for false claims range between $5,000 to $10,000 per claim, treble damages and the costs of bringing the civil action. Since the False Claims Act does not require proof of intent, and allows the imposition of these draconian penalties per claim, potential prosecution leads to frequent settlements that can bankrupt a provider.

Federal prosecutors have used the False Claims Act in nursing home cases where the care provided to residents is so substandard that claims submitted for government payment are deemed

patently false. It is reasonable to predict that phony treatment in sober living houses will be the next frontier.

Sober living or half-way houses have been investigated for lack of effective client supervision and support-leading to frequent overdoses and sometimes deaths. Several recent federal investigations in Florida have concluded that some unscrupulous sober home operators maintain such low standards that the homes amount to little more than flop houses.

There are no federal requirements governing the operation of sober living home. Many states have been slow to regulate them, in part, because states have not historically seen recovery support as a component of a larger population need. Now, the demand for these homes is outpacing the ability to regulate them. Some states, such a Pennsylvania, have moved forward with applicable draft regulations, but no date certain for finalization is near.

**Confidentiality, Licensure and Other Regulatory Compliance Issues**

The compliance obligations don't end with fraud or abuse. Providers must also navigate state licensure regulations, federal and state confidentiality laws, including the Health Insurance Portability and Accountability Act, that heavily restrict the sharing of confidential treatment information. Federal substance use disorder law essentially prohibits sharing of patient information — even between treating health care providers — without patient consent.

The federal substance abuse confidentiality law imposes significant fines for improper disclosure of any information about a patient (including the mere fact that an individual is a patient at a treatment facility) without a patient's written consent. Layered atop the federal confidentiality laws of substance use treatment, and HIPAA, are specific state confidentiality laws which may be more stringent. These confidentiality requirements must be read and applied in conjunction.

Inpatient and outpatient treatment programs generally must each be separately licensed and comply with state licensure and Medicaid program standards. Standards related to the physical plant and facilities, staffing, physician and other professional services, clinical oversight, medical records, peer review, federal Drug Enforcement Agency requirements, quality and continuity of care issues, and risk management activities all demand attention. Failure to obtain or maintain licensure means the provider cannot bill for the services rendered. Bad publicity and reputational harm can be significant collateral damage for a provider who loses its licensure.

**Assessing Risk and Counseling Clients**

As an initial compliance step, counsel should first look at the financial and "in-kind" relationships a

client has with referral partners and vendors. These relationships include medical directors and independent contractor physicians. Pay particular attention to known risk areas such as laboratory arrangements and overlapping ownership between and among entities. If related parties are identified, verify if needed contracts are in place-and if so, are the terms commercially reasonable and consistent with applicable regulatory requirements. At minimum, these requirements would include the federal Anti-Kickback provisions as well as applicable state law.

Determine if your client has a compliance plan in place. The existence of a compliance plan is often an indicator of a client's understanding of the complexity of its regulatory compliance obligations, or worse, if a client choses to ignore them. A compliance plan review will permit simultaneous assessment of multiple areas such as licensure, certifications and accreditations. Potential billing risks exist when a fundamental element like licensure is absent or the license is in jeopardy.

Of course, if no plan exists, work with clients to develop, adopt and implement a plan, ensuring the plan addresses the needs of substance use disorder providers generally and is tailored to focus on unique risk factors the compliance plan assessment uncovered. Following review of basic compliance issues, attention should be turned to quality assurance and risk management.

**Conclusion**

The explosion of substance use disorder treatment providers and the opioid crisis will continue to engender intensified scrutiny. To be sure, keeping well-informed of quickly evolving substance use disorder fraud and abuse enforcement and regulatory oversight is a challenge for providers and counsel. As this health care sector matures, regulatory compliance requirements should become crystallized and standardized. Until then, substantial time and effort to remain current is fundamental to avoiding painful legal consequences.

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