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A First-of-its-Kind Telemedicine Criminal Prosecution: Key Takeaways

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The indictment, arrest, and arraignment of Ruthia He, the founder, CEO, and clinical president of Done Global (Done), and David Brody, clinical president of Done and the sole shareholder of Done Health, P.C. (PC) in connection with their alleged criminal conspiracy to distribute controlled substances, commit health care fraud, and obstruct justice may bring heightened scrutiny to behavioral health telemedicine companies and other virtual health platforms. The seven-count **indictment** represents the Department of Justice's (DOJ's) first criminal drug distribution prosecutions related to telemedicine prescribing. The prosecution of the defendants is proceeding in federal court in the Northern District of California and several additional Done personnel including an executive, physician, and nurse practitioners are similarly being prosecuted.

Pandemic Era Prescribing Flexibilities and Growth of the Virtual Behavioral Health Industry

Done and several other telemedicine companies focused upon providing behavioral health services to patients were launched in 2019, immediately prior to the COVID-19 pandemic. Like other virtual behavioral health companies, Done leveraged several telehealth flexibilities and policy changes promulgated by the Department of Health and Human Services and Drug Enforcement Administration (DEA) during the COVID-19 public health emergency and subsequently extended through December 31, 2024 (see our previous post here). Critically, the federal agencies suspended the requirement that physicians and other practitioners could prescribe controlled substances virtually only after an initial inperson patient consultation.

The DOJ's Allegations

In the indictment, the DOJ alleges that during the period on or about February 2020 through January 2023, the PC's practitioners prescribed to Done's subscription members over 40 million prescriptions of Adderall and other stimulants for the treatment of attention deficit hyperactivity disorder, a chronic neurodevelopmental disorder. The indictment further alleges that Done engaged in a deceptive social media campaign and received over \$100 million in prescription revenue during the period.

As part of an alleged criminal conspiracy to distribute controlled substances, the DOJ alleges that the defendants violated California's long-standing prohibition against the corporate practice of medicine. Specifically, He and Brody allegedly created the false appearance that the PC was an independent company. Instead, Done allegedly inappropriately interfered with the clinical decision-making of the PC's prescribing practitioners ultimately resulting in millions of prescriptions unsupported by a legitimate medical purpose. Specifically, Done purportedly:

- mandated initial patient encounters not exceed 30 minutes;
- utilized short, non-comprehensive clinical intake forms with limited or no patient audio/video communication;
- instructed PC practitioners to prescribe Adderall and other stimulants even if not clinically supported;
- implemented an "auto-refill" policy and discouraged follow-up patient encounters; and

• compensated prescribers solely based upon the number of patients receiving prescriptions, with no payments for initial or follow-up consultations.

With respect to the prescriber compensation model, He allegedly utilized the structure to "dis-encourage follow-up." Further, He and Brody, allegedly caused PC practitioners to prescribe for patients in states where the practitioners both lacked appropriate licensure and authority to prescribe and in violation of state physician supervision and collaboration laws applicable to nurse practitioners. Moreover, Done allegedly submitted claims and received payment from federal, state, and commercial insurers based upon false prior authorizations, representations, and documents (including patient medical records) resulting in improper reimbursement exceeding \$14 million.

In an alleged conspiracy to obstruct justice in response to both media assertions of improprieties at Done and a grand jury subpoena, He and Brody also engaged in the concealment and destruction of documents. Further, following receipt of the subpoena, He and Brody allegedly refrained from utilizing the Done e-mail platform and instead conducted communications through encrypted messaging platforms and personal email accounts.

Based upon the indictment, He and Brody are subject to the potential forfeiture of assets and incarceration up to a maximum of 20 years. Done has publicly stated that the company disagrees with the allegations in the indictment and intends to continue operations – including the prescribing of controlled substances.

Takeaways and What to Expect Next

This first-of-its-kind telemedicine criminal prosecution confirms the importance of companies providing management, administrative, and related services to professional corporations refraining from interfering in the clinical decision-making of affiliated practitioners – whether the clinicians are prescribing controlled substances or not. To support independent decision-making, professional corporations should ensure that they have robust intake policies, utilize virtual patient encounters consistent with applicable standards of care, and compensate practitioners pursuant to models that are unrelated to the ultimate issuance of a prescription.

Additionally, the DEA may consider this indictment when updating the rules related to the use of telemedicine in prescribing controlled substances. As we stated in our previous **post**, physicians and other clinicians are concerned that limiting the pandemic era flexibilities for virtually prescribing controlled substances could limit access to lifesaving or life-altering medications and disproportionally impact patients in rural areas and marginalized communities.

We will continue to monitor the prosecutions, any further enforcement actions implicating state corporate practice laws, and administrative activity regarding virtual controlled substance proscribing.

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