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The DOJ Continues to Scrutinize Telemedicine

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Telemedicine saw a dramatic increase during the COVID-19 pandemic. A recent study from the U.S. Department of Health and Human Services (HHS), released in December 2021, showed an increase in Medicare telemedicine visits during the pandemic from approximately 840,000 in 2019 to 52.7 million in 2020. The rapid improvement of information technology has led to the increase in the use of telemedicine as a legitimate delivery platform with the COVID-19 pandemic placing telemedicine in the mainstream of health care delivery.

Notwithstanding telemedicine's legitimate use as a health care delivery model, the questionable use of telemedicine in certain business models has led the Department of Justice (DOJ) to take an aggressive review of arrangements using telemedicine. On July 20, 2022, the DOJ issued a press release announcing a concerted effort to combat specific areas of health care fraud, including telemedicine. The release highlighted criminal charges brought against 36 defendants in 13 federal districts totaling over $1.2 billion in criminal proceeds (over $1 billion of which stem from unlawful telemedicine practices).

This latest crack down continues a trend of enforcement actions against business models involving telemedicine companies. For example, previous DOJ initiatives include 2019's Operation Brace Yourself, 2019's Operation Double Helix, 2020's Operation Rubber Stamp, and the telemedicine component of the 2021 National Health Care Fraud Enforcement Action. The Operation Brace Yourself Telemedicine and Durable Medical Equipment Takedown,

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according to the DOJ, alone resulted in an estimated cost avoidance of more than $1.9 billion in the amount paid by Medicare for orthotic braces in the 20 months following that enforcement action.

On the same day as the July 20, 2022, DOJ announcement, the HHS Office of Inspector General issued a Special Fraud Alert aimed at telemedicine practitioners. The Special Fraud Alert enumerated many "suspect characteristics" that present a heightened risk of fraud and abuse. The OIG carefully pointed out that not all telemedicine companies are suspicious and the Special Fraud Alert was not intended to discourage legitimate telemedicine arrangements. Indeed, for most the expansion of telemedicine is viewed as a positive advancement in promoting access to care. However, the Special Fraud Alert emphasizes that the OIG will exercise heightened enforcement scrutiny of such arrangements.

The most common characteristics that appear to catch the DOJ's attention when examining the use of telemedicine in various business models is the reason for the telemedicine visit and the quality of the telemedicine visit. The suspect business models typically involve a health care business that requires a prescription from a practitioner to sell its product proactively reaching out to potential patients via a call center or telemarketer. While these suspect business models have been in existence long before the advent of telemedicine, coordinating a practitioner-patient visit on a large scale using telemedicine is now relatively easy.

The quality of the telemedicine visit is critically important for all telemedicine business models, even for the most legitimate use of telemedicine. The quality of the telemedicine visit is many times the undoing of the entire business model. The stronger the quality of the telemedicine visits, the stronger the defense against allegations of fraud. A quality telemedicine visit creates the support for the medical decision-making and the medical necessity for any recommendation or prescription.

The quality of the telemedicine visit involves such things as the level of interaction between the practitioner and patient, the modalities used during the visit and the tools available for the practitioner to make a definitive diagnosis and recommendation. Quite simply, does the practitioner have sufficient contact with the patient and/or information about the patient to meaningfully assess the medical necessity of the items or services ordered or prescribed. Many times the answer to this question reverts back to the reason for the telemedicine visit, e.g. was it because the patient was truly seeking out health care advice and treatment options or was it because a telemarketer, call center or sales representative called the potential patient and connected them with the practitioner?

Another obvious suspect characteristic is the payment methodology used to pay the practitioners. Very few arrangements are brazen enough to compensate the practitioner per prescription. Most arrangements pay the practitioner per visit or based upon a time element such as per hour. These methods can become closely linked to a "per click" arrangement, particularly if there is an incentive such as a bonus payment for the practitioner.

Other important factors include the quality of and access to the patient's medical records by the practitioner. Practitioners must be able to defend their medical decision-making if ever challenged. As a result, the medical record maintained by the telemedicine company must be readily retrievable and/or

accessible by the practitioner. It should be formatted as a standard medical record and sufficiently document the encounter to justify the medical decision-making. The axiom in health care of "if it is not documented it did not happen" is zealously adhered to by prosecutors.

Telemedicine companies and practitioners should evaluate their arrangements with care to ensure that they structure them appropriately and in compliance with the Anti-Kickback Statute and other state and federal laws. Enforcement scrutiny will continue and will likely take the form of grand jury or administrative subpoenas, search warrants, civil investigative demands, HHS-OIG inquiries and state investigations or audits.

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