Alert | Health Care & FDA Practice/ White Collar Defense & Special Investigations

November 2020

2020 DOJ Health Care Fraud Takedown

On Sept. 30, 2020, the United States Department of Justice (DOJ) released updates on its ongoing efforts to combat health care fraud and abuse by publishing the results of its 2020 takedown effort targeting, among others, fraud and abuse in the telemedicine and prescription drug industries (2020 Takedown). The DOJ announced it was bringing charges against 345 defendants, spread across 51 federal districts, involved in the telemedicine, clinical laboratory, substance abuse disorder (SUD) treatment, and durable medical equipment (DME) industries. In parallel to these criminal cases, the Centers for Medicare and Medicaid Services (CMS) also revoked Medicare billing privileges from 256 additional health care professionals for their alleged involvement in the fraudulent schemes. According to Gary Cantrell, Deputy Inspector General for Investigations for the Office of Inspector General, this is the "largest administrative action in history to avoid suspicious claims and revoke the billing privileges of providers[.]"

The largest share (by dollar amount) of the new charges relates to items or services prescribed via a telemedicine consult. Almost all of these cases involve telemedicine companies – through their owners, executives, managers, or physician employees – allegedly working with other ancillary providers and suppliers (e.g., clinical laboratories, DME suppliers, pharmacies, etc.) to bill federal and commercial payors for the provision of medically unnecessary or fictitious items or services for patients with whom the prescribing provider had little or no interaction, in exchange for kickbacks. According to the DOJ, 86 defendants in 19 districts have been charged for submitting an approximate total of $4.5 billion in false and fraudulent claims in connection with these schemes.

© 2020 Greenberg Traurig, LLP

Continuation, Expansion of DOJ's 'Operation Brace Yourself'

In April 2019, a few months after William Barr took over as Attorney General (AG), the DOJ made clear its renewed focus on rooting out fraud in the nation's health care system with the announcement of "Operation Brace Yourself" and the criminal charges that stemmed from it. This initiative centered on fraudulent practices in the telemedicine and DME industries, which generally involved telemedicine companies conspiring with DME providers to write prescriptions for DME supplies and then dispense the supplies to beneficiaries for whom the prescriptions were medically unnecessary or with whom the providers did not have sufficient prior contact to write a lawful prescription. The most recently announced charges demonstrate not only the government's continuing focus on these types of cases but also the government's expanding scope of inquiry into cases involving fraud and abuse by providers offering treatment related to Coronavirus Disease 2019 (COVID-19) via telemedicine (as AG Barr promised to target in March 2020) and in the SUD treatment industry.

All told, the DOJ says, the defendants charged in the latest round of prosecutions submitted roughly $6 billion in false and fraudulent claims to federal health care programs (e.g., Medicare, Medicaid, TRICARE) and private insurers. Combined with the $1.2 billion in illicit billings charged under Operation Brace Yourself – which, the DOJ reports, saved the Medicare program $209 for every $1 the DOJ spent investigating – this level of criminal activity and associated depletion of federal coffers suggest that the DOJ has ample reasons to continue to target fraud in the health care arena.

Summary of Recent Charges

Among the charges are those for paying and receiving various types of illegal kickbacks; billing for fictitious or medically unnecessary services; and writing illegitimate prescriptions for drugs and items such as orthotic braces.

A few noteworthy themes in the DOJ announcement:

1. Viewed together with the DOJ's 2019 Operation Brace Yourself, the 2020 Takedown shows that the DOJ's focus on bad actors in the health care field is not going away any time soon and is trained on individuals and entities involved with pharmaceuticals, clinical laboratories, SUDs, and DME.

2. While telemedicine has been an invaluable resource for the nation's health care system during the COVID-19 pandemic, the recently announced prosecutions show that telemedicine, like other forms of health care delivery, is also susceptible to misuse and abuse.

3. Though only a few in number, the DOJ's charges under the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) further indicate that the DOJ does not intend to wait for regulatory guidance before it enforces the controversial law.

Implications for Telemedicine

To be clear, the DOJ's 2020 Takedown did not concern billing or coding for "telehealth services," as defined by Medicare regulations, but rather the use of telemedicine, as a platform, to order medically unnecessary items and services billed to federal health care programs. That is, the telemedicine companies and physician employees that were allegedly involved in these fraudulent schemes did not submit claims for telehealth services to Medicare and other payors, but rather received payment directly

© 2020 Greenberg Traurig, LLP

from the ancillary providers and suppliers (e.g., clinical laboratories, DME suppliers, pharmacies, etc.) with the monies they collected for the items and services prescribed by the telemedicine companies.

In addition to payment and receipt of illegal kickbacks, many of the charges announced in the 2020 Takedown concern orders for items and services, such as DME and diagnostic clinical laboratory tests, issued by providers associated with telemedicine companies. Medicare regulations and many state laws generally require such prescriptions or orders to be made in the context of a valid provider-patient relationship in order to be considered medically necessary and reimbursable. The specific requirements for a valid provider-patient relationship may vary depending on the item or service at issue but, in general, include a requirement that, before issuing any prescription or order, the provider examine the patient, document the patient's need for the applicable item or service and how it will be used in their treatment – and, following delivery of the item or service ordered, how the patient's response or test results, as applicable, factor into the provider's management of the patient – so that there is documented evidence of a provider-patient relationship. The DOJ alleges that the telemedicine companies and their physician employees named in the 2020 Takedown did not establish such a relationship with beneficiaries; thus, the items and services prescribed could not be considered medically necessary.

The risk of fraud and abuse by individuals and entities that use telemedicine is no less acute than the risk posed by the use of other delivery models (i.e., face-to-face), but admittedly does present new opportunities. The DOJ's 2020 Takedown stems from activities that occurred prior to the COVID-19 public health emergency, but the use of telehealth services expanded greatly in response to the crisis. As we have written before, the COVID-19 pandemic required the temporary relaxation or waiver of numerous federal and state laws and regulations concerning the delivery of, and payment for, health care to ensure patients could observe legally mandated social distancing measures without forgoing needed care. While some of the waivers will expire when the COVID-19 public health emergency subsides, CMS Administrator Verma has indicated that others are likely to remain, and her agency has already released its proposed 2021 Physician Fee Schedule rule, which includes coverage for many new telehealth services under the Medicare program. In other words, now that telehealth appears to be a primary fixture in the United States health care system, it is anticipated that the DOJ will only become more interested in detecting and snuffing out fraud and abuse by individuals and entities utilizing telehealth services.

Conclusion

The DOJ's announcement of the 2020 Takedown offers potentially valuable insight into the federal government's health care fraud and abuse enforcement priorities. Some of them, such as illegal practices in the DME industry, are simply extensions of longstanding DOJ priorities, while others, such as the emerging fraud and abuse issues associated with increased telemedicine usage or the enforcement of EKRA, represent new potential obstacles that health care industry stakeholders will have to navigate. Providers and other individuals and entities who work in these arenas are encouraged to consult with their legal counsel to determine whether and how the 2020 Takedown will affect their operations going forward.

© 2020 Greenberg Traurig, LLP

Authors

This GT Alert was prepared by:

- Charles C. Dunham, IV | +1 713.374.3555 | dunhamc@gtlaw.com
- Todd A. Pickles | +1 916.868.0628 | picklest@gtlaw.com
- Ben Nipper | +1 713.374.3574 | nipperb@gtlaw.com

Albany. Amsterdam. Atlanta. Austin. Boston. Chicago. Dallas. Delaware. Denver. Fort Lauderdale. Germany.¬ Houston. Las Vegas. London.* Los Angeles. Mexico City.+ Miami. Milan.» Minneapolis. New Jersey. New York. Northern Virginia. Orange County. Orlando. Philadelphia. Phoenix. Sacramento. Salt Lake City. San Francisco. Seoul.∞ Shanghai. Silicon Valley. Tallahassee. Tampa. Tel Aviv.^ Tokyo.¤ Warsaw.~ Washington, D.C.. West Palm Beach. Westchester County.

*This Greenberg Traurig Alert is issued for informational purposes only and is not intended to be construed or used as general legal advice nor as a solicitation of any type. Please contact the author(s) or your Greenberg Traurig contact if you have questions regarding the currency of this information. The hiring of a lawyer is an important decision. Before you decide, ask for written information about the lawyer's legal qualifications and experience. Greenberg Traurig is a service mark and trade name of Greenberg Traurig, LLP and Greenberg Traurig, P.A. ¬Greenberg Traurig's Berlin office is operated by Greenberg Traurig Germany, an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. *Operates as a separate UK registered legal entity. +Greenberg Traurig's Mexico City office is operated by Greenberg Traurig, S.C., an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. »Greenberg Traurig's Milan office is operated by Greenberg Traurig Santa Maria, an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. ∞Operates as Greenberg Traurig LLP Foreign Legal Consultant Office. ^Greenberg Traurig's Tel Aviv office is a branch of Greenberg Traurig, P.A., Florida, USA. ¤Greenberg Traurig's Tokyo Office is operated by GT Tokyo Horitsu Jimusho and Greenberg Traurig Gaikokuhojimubengoshi Jimusho, affiliates of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. ~Greenberg Traurig's Warsaw office is operated by Greenberg Traurig Grzesiak sp.k., an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. Certain partners in Greenberg Traurig Grzesiak sp.k. are also shareholders in Greenberg Traurig, P.A. Images in this advertisement do not depict Greenberg Traurig attorneys, clients, staff or facilities. No aspect of this advertisement has been approved by the Supreme Court of New Jersey. ©2020 Greenberg Traurig, LLP. All rights reserved.*