Pharmaceutical and Medical Device Manufacturer and Telehealth Provider Partnerships: Compliance Issues for Consideration

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As health care entities continue to transition beyond the COVID-19 pandemic and prepare for a post-PHE environment, telemedicine providers continue to be at the forefront of healthcare innovation and creating collaborations across industry delivery systems. In particular, direct-to-consumer drug advertising and arrangements between telemedicine providers and pharmaceutical and medical device manufacturers have been recently developing in the marketplace as both telemedicine providers seek to expand the reach of their care offerings and manufacturers look to develop synergies in the direct-to-consumer marketplace.

However, arrangements between healthcare providers and pharmaceutical and medical device manufacturers have historically been and continue to garner considerable government scrutiny. Additionally, regulators are focused on the activities of telemedicine providers as recently evidenced by the July 20, 2022, OIG Special Fraud Alert on Suspect Telemedicine Arrangements.[1] Arrangements involving telemedicine providers and pharmaceutical and medical device manufacturers are likely to enjoy the same scrutiny.

Entities considering such arrangements should pay close attention to the following areas: (1) anti-kickback and beneficiary inducement risk, (2) corporate practice of medicine and maintaining independent medical decisionmaking, (3), improper data sharing, and (4) general operational compliance considerations. Below we highlight how arrangements between drug and device manufacturers and telemedicine providers implicate these risk areas and provide some thoughts regarding how entities can begin to think about structuring these types of arrangements to attempt to mitigate such risks.

The Federal Anti-Kickback Statute and the Beneficiary Inducements Civil Monetary Penalties Law

Payments from a pharmaceutical or medical device manufacturer provided by a telemedicine provider (even for bona fide services such as technology development services) to the manufacturer could be construed as remuneration intended to influence providers to prescribe the manufacturer's drugs or devices. Manufacturers have begun seeking out the technological expertise of telemedicine companies, paying for the development of websites and other direct-to-consumer marketing activities, which present to the public a collaboration between a manufacturer's product and the telehealth providers who can write patients a corresponding prescription when medically necessary. These payments could implicate anti-kickback laws if such payments were intended to increase prescription volumes using the telemedicine provider as the targeted channel.

The federal Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer or pay any remuneration to any person to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any item or service reimbursable under a Federal health care program.[2] In addition, the federal Anti-Kickback Statute prohibits any person from soliciting or receiving any remuneration in return for arranging for the purchasing of any item for which payment may be made in whole or in part under a federal health care program. For purposes of the federal Anti-Kickback Statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Further, the statute ascribes criminal liability to both sides of an impermissible "kickback" transaction, and has been interpreted to apply to any arrangement where even one purpose of the remuneration offered, paid, received, etc. is to obtain remuneration in exchange for referrals or to induce referrals.[3] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment for up to 10 years, or both.

The beneficiary inducements provision of the Civil Monetary Penalties Law provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Civil Monetary Penalties Law, as including "transfers of items or services for free or for other than fair market value."[4]

To potentially mitigate anti-kickback risk, any telemedicine providers or manufacturers should carefully consider an arrangement's structure. These arrangements should be structured to meet a Safe Harbor of the Anti-Kickback Statute, with the most likely applicable Safe Harbor being the Safe Harbor for Personal Services and Management Contracts under the federal Anti-Kickback Statute (42 CFR § 1001.952(d)). While there are six elements to 42 CFR § 1001.952(d)(1), all of which must be met in order for entities to meet the Safe Harbor, here we focus on how payments should be structured under these arrangements.

In pertinent part, 42 CFR § 1001.952(d)(1)(iv) requires that the methodology for determining the compensation paid over the term of the agreement is set in advance, is consistent with a fair market value in arm-length transactions, and is

not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

The opportunity to link payments with the measurable effectiveness of arrangements between providers and manufacturers can present a potential kickback risk. Basing payments on metrics such as the number of website impressions or landing page clicks, the number of patients examined by a telehealth provider, or the number of prescriptions written can be attractive to pharmaceutical and medical device manufacturers as tangible measures of marketing success. Such payments, however, can be interpreted by regulators as a proxy for prescription throughput and steering patients to receive a manufacturer's product. Entities contemplating these types of arrangements should carefully examine payments that can be linked to the volume or value of any sort of business or clinical metric such as prescriptions written, patients examined or on-boarded to a telehealth provider's platform, or an increase in a manufacturer's market share. The methodology for determining the compensation over the term of the agreement should ideally be set in advance, consistent with a fair market value in arm-length transactions and should not take into account volume or value of any referrals or business otherwise generated between the parties. Given the increased possibility of scrutiny regarding arrangements between telehealth providers and pharmaceutical and medical device manufacturers, entities considering these arrangements should give additional consideration to taking a more conservative approach when considering payments for services rendered (even if those services are non-clinical in nature, such as digital services provided by a technologically savvy telemedicine provider). For instance, utilizing a fixed fee structure, which was a requirement under the prior version of the Safe Harbor requiring compensation be fixed in the aggregate for at least yearlong terms (e.g., $50,000 per year) can further mitigate risk by helping to attenuate any connection between remuneration from a manufacturer and any volume or value of clinical services conducted by a telemedicine provider.[5] Parties may consider obtaining a written, third-party opinion from a healthcare valuation firm to assess that payments under the arrangement are fair market value and commercially reasonable.

In connection with beneficiary inducement risk, these arrangements should be structured to not create a situation where patients may be choosing to seek care from a telehealth provider because they are incentivized to do so. Patients who would potentially receive a manufacturer's product should not be afforded any type of reduced price to avoid: (1) the implication that the manufacturer is subsidizing the patient's cost of treatment and (2) enticing a patient to seek care that they might otherwise forgo but for the sudden affordability of treatment. OIG has expressed concerns about manufacturers subsidizing beneficiaries' cost sharing for a manufacturer's own products, with OIG most recently taking issue with these types of activities related to patient assistance programs in OIG Advisory Opinion 22-19 (October 5, 2022).

In addition, the cost of professional medical services charged by a telehealth provider to a patient is also an important consideration when manufacturers are making payments to telemedicine providers. Telehealth providers should charge patients an amount that would create positive revenue for the medical consult irrespective of any relationship with a pharmaceutical or medical device manufacturer. If a telehealth provider operates at a loss in connection with services associated with a manufacturer's product, an

implication exists that payments from such a manufacturer are intended to subsidize a provider's compensation. Such a subsidy could suggest that telehealth providers are being influenced to prescribe a manufacturer's product, thereby implicating the Anti-Kickback Statute.

Corporate Practice of Medicine and Maintaining Independent Medical Decision-making

It is not uncommon for telehealth offerings to be structured as PC-MSOs, where the management services organization (MSO) provides management services to affiliated medical groups (PCs). The MSO may seek to establish arrangements with the pharmaceutical and medical device manufacturers in an attempt to grow new lines of business. Neither the MSO nor the pharmaceutical and medical device manufacturers should undertake any actions that would exert control over or infringe upon the medical decisionmaking judgement or independence of individual telehealth providers. Individual telehealth providers should never feel influenced to prescribe certain drugs or devices as a result of any arrangement that may exist between an MSO and a pharmaceutical or medical device manufacturer. Compliance with applicable corporate practice of medicine prohibitions must be assiduously followed as arrangements between telehealth providers and manufacturers is a likely area for regulatory scrutiny. At issue is likely the extent to which such MSOs and these arrangements with manufacturers unduly influence prescribing patterns.

To delineate the clinical independence of telehealth providers involved in arrangements and pharmaceutical and medical device manufacturers, telemedicine providers should consider implementing and adhering to compliance programs and policies that track various metrics to determine if clinical activities drift outside the normal spectrum of expected practice procedures and outcomes (e.g., informed consent, assessment of utilization rates and medical necessity, patient clinical outcomes, patient experience). All clinical oversight functionality should be performed by medical directors and the physician owner(s) of the telehealth practices, with the medical directors and practice owners being directly employed by the medical practices.

In addition, pharmaceutical and medical device manufacturers should avoid creating or offering to create any clinical protocols, medical questionnaires, or intake process for a telehealth practice. Medical practice functions should, similar to the oversight function mentioned above, be performed by the medical advisors or medical directors of the telehealth practices and ultimately approved by the practice owners. A manufacturer can safely supply educational materials/information about a product, which a telehealth provider may use in developing its clinical protocols. However, this should be the extent of the manufacturer's involvement.

Finally, individual clinicians of a telehealth provider must be free to decline to prescribe any product that the clinician thinks, in their professional judgement, is not medically necessary or appropriate for a patient. Clinicians should be free to recommend alternative therapies if it is determined that an alternative is better suited to treat the specific patient's condition. This decisionmaking should be memorialized in a patient's medical record consistent with appropriate medical record retention procedures. Compensation to clinicians should not be contingent in any way to whether a prescription is issued or what type of treatment is prescribed. It becomes increasingly suspect if a telehealth provider's clinical care protocols recommend treatment only using the product made by manufacturers with whom a telehealth company has an arrangement. Restrictions on the clinicians' independence could be

considered improper steering based on remuneration.

Sharing of Patient Data and Platform Usage Data

The data generated by telehealth provider operations can be extremely valuable to a pharmaceutical or medical device manufacturer. However, telehealth providers who may be considered covered entities under HIPAA (and their business associates) must be careful to not improperly share patient data and ensure that all data is fully and properly de-identified. In addition, telehealth providers must also be cognizant of not sharing data that would allow a pharmaceutical or medical device manufacturer, which has entered into an arrangement for services with the telemedicine company, to receive information that the manufacturer could use to calculate specific "patient acquisition costs," conversion metrics, re-identify any patient information, or could be utilized to calculate future payments based on the volume or value of patient onboarding flows, medical consults or prescription history/patterns, or any activity of individual clinicians—increasing the kickback risk of any such arrangement. To reduce risk, telehealth companies could consider not sharing any data or sharing very limited data.

General Operational Compliance Considerations

Beyond assessing the more technical health regulatory aspects of these arrangements, such as anti-kickback liability and HIPAA compliance, day-to-day operational considerations also play an important role when thinking about compliance risks associated with arrangements between telehealth providers and pharmaceutical and medical device manufacturers.

As the window to both the general public and regulators, any websites such as landing pages or other marketing outlets, associated with these types of arrangements, should be carefully vetted. Parties are well advised to consider: Is a website suggesting steerage of patients to a particular provider or use of a certain product?; Are improper incentives utilized to induce patients to click-through a website and initiate a provider onboarding process?; Are patients told they will be guaranteed eligibility for treatment before any type of clinical assessment is conducted? Websites that are condition-forward versus product-forward, placing medical necessity at the forefront of any marketing activities, are the most compliant. In addition, disclosure of financial relationships between a telehealth provider and a pharmaceutical or medical device manufacturer should also be reviewed for transparency.

As noted previously, implementing a robust compliance program is important to help maintain the clinical independence of individual telehealth providers, but compliance goes beyond clinical considerations. Because of the inherent complexity and attendant risk with arrangements between providers and pharmaceutical and medical device manufacturers, having a dedicated compliance function is recommended to help safeguard against any relaxing of internal oversight, in particular when these arrangements are first developed and executed.

Finally, any telehealth company contemplating these types of arrangements should consider engaging with their outside advisors early in the process, fully scoping the proposed structure to understand the full extent of each party's activities.

Conclusion

As telehealth companies continue to showcase the robust, high-quality care their platforms can provide, the emergence of new business lines and growth of services will continue to expand along with the desire to create new strategic partnerships across industries. New arrangements with pharmaceutical and medical device manufacturers should be considered carefully as

these arrangements can involve a broad range of issue areas to consider, spanning from fraud and abuse to individual provider conduct, with serious potential consequences for noncompliance.

Endnotes

1. Available at *https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf*.
2. *See* Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b).
3. *See United States v. Nagelvoort*, 856 F.3d 1117 (7th Cir. 2017); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).
4. Section 1128A(i), 42 U.S.C. § 1320a-7a(i).
5. 85 Fed. Reg. 77684; 77839 (December 2, 2020).