

UPDATES

Life Sciences Partnerships With Telemedicine Platforms Invite New Congressional Scrutiny

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In recent weeks, several U.S. senators have sent letters directly to certain pharmaceutical manufacturers raising renewed questions regarding telemedicine platforms affiliated with pharmaceutical manufacturers that link patients directly with healthcare providers (the Congressional Letters). In particular, senators have expressed concerns that such telemedicine platforms may

- encourage telehealth prescribers to favor certain medications, regardless of medical necessity or clinical appropriateness, which could lead to inappropriate prescribing practices and increased federal healthcare program spending in violation of the federal Anti-Kickback Statute
- increase the demand for specific medications through direct-to-consumer (DTC) advertising, even if such medications may not be medically necessary, thereby inflating costs for federal healthcare programs
- fail to provide comprehensive healthcare services to patients that ensure thorough patient evaluations and follow-ups

The Congressional Letters pose a series of detailed questions to the manufacturers about their telemedicine platform arrangements, including the following:

- the amount of money the manufacturers have spent on DTC advertisements for specific medications in the most recent six-month period for which data is available
- the percentage of consumers who, after consulting with a healthcare provider on a manufacturer-affiliated telemedicine platform, receive a prescription for one of the manufacturer's medications
- the revenue generated by the manufacturers from telehealth platforms in the most recent 30-day period for which information is available

OIG's Special Fraud Alert on Telemedicine Platforms

These questions align with considerations raised by the Department of Health and Human Services, Office of Inspector General (OIG), in a July 2022 [Special Fraud Alert](#), which was explicitly referenced in the Congressional Letters, warning practitioners about potential fraud schemes involving telemedicine platforms in violation of the federal Anti-Kickback Statute. As we wrote in our prior [Sidley Update](#), OIG's

Special Fraud Alert identified several suspect characteristics that could suggest an arrangement presents a heightened risk of fraud and abuse, such as:

- **Limited Patient Interaction:** Telemedicine platforms may instruct practitioners that they do not need to contact the patient or need only speak to them by telephone, without reviewing the patient's medical records.
- **Preselected Items or Services:** Practitioners may be directed to prescribe preselected items or services regardless of medical necessity or clinical appropriateness.
- **Volume-Based Compensation:** Telemedicine platforms may compensate practitioners based on the volume of items or services ordered, which can incentivize unnecessary prescribing.
- **Insurance Status:** Telemedicine platforms may furnish items and services only to federal healthcare program beneficiaries or attempt to "carve out" such beneficiaries.
- **No Expectation of Follow-up:** Telemedicine platforms do not expect practitioners to follow up with patients, nor do they provide practitioners with the information required to follow up with patients.

OIG warned that practitioners who enter arrangements with telemedicine platforms in which one or more of these suspect characteristics are present may potentially face criminal, civil, or administrative liability depending on the facts and circumstances, including under the Anti-Kickback Statute.

Key Considerations

Given this renewed scrutiny, pharmaceutical manufacturers as well as other companies that utilize or partner with telemedicine platforms (e.g., medtech, clinical laboratories) should consider several key questions highlighted in the Congressional Letters before proceeding with such arrangements. These considerations include:

- Is the telemedicine platform using telemarketing, sales agents, or advertising to reach patients?
- Do the telemedicine practitioners have sufficient contact with patients to meaningfully assess the medical necessity of the prescribed items or services?
- Are telemedicine practitioners or the telemedicine platform compensated based on the volume of items or services ordered?
- Are the telemedicine practitioners made aware of the underlying arrangement with the pharmaceutical manufacturer, clinical laboratory, or other contracting entity?
- As a practical matter, do the telemedicine practitioners prescribe or order competitor items or services?
- Does the telemedicine platform furnish items and services only to federal health care program beneficiaries?
- Does the telemedicine company expect practitioners to follow up with patients, and are they provided with the necessary information to do so? If there is no follow-on care by the telemedicine practitioner, are there other avenues where the patient will receive reasonable follow-on care (e.g., a treating provider)?

Depending on the nature of the arrangement, additional diligence beyond those questions identified specifically in the Congressional Letters or OIG Special Fraud Alert may also be warranted to evaluate whether an arrangement presents a heightened risk of fraud and abuse or violation of other laws (e.g., state prescribing laws).

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The increasing use of telemedicine platforms by healthcare entities to enhance access to care presents opportunities and challenges. While these platforms can significantly benefit patients, especially those in underserved or hard-to-reach areas, they also raise potential legal and ethical concerns. The Congressional Letters and the OIG Special Fraud Alert underscore the potential risks associated with these models and the need for pharmaceutical manufacturers or other life sciences entities partnering with telemedicine platforms to exercise caution and due diligence when partnering with or directing patients to these platforms.

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