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Integrating Telehealth Services into Compliance Programs

Strategies and Features that Make a Compliance Program Successful Continue to Apply in Telemedicine and Telehealth Contexts

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When new programs launch, health care providers and facilities often have existing compliance programs in place. In the telehealth space, companies involved may be new to health care and may not realize the requirements and benefits of a compliance program or how to get the most out of working with one. In either situation, a compliance program can support business goals by demonstrating how a company meets or exceeds applicable legal requirements, which protects investors, owners, employees, patients, and everyone in between. The importance of making sure there are no compliance gaps in a new product or service, or at the very least becoming aware of what those gaps are and the associated risks, ensures that the decision-makers have the best information possible when navigating the health care regulatory landscape.

As telehealth models expand in both variety and industry presence, situations have emerged in which companies or providers find themselves facing significant enforcement actions or other risk due to some aspect of a telehealth service or model. Experienced compliance professionals and their legal counterparts help companies avoid enforcement actions and mitigate risk. The situations can be instructive examples for others on how to consider integrating telehealth programs into an existing compliance program or building a new compliance program that addresses the telehealth services.

THE VISIBLY EXAMPLE

In August 2019, the Food and Drug Administration (FDA) issued a recall notice to the mobile app Visibly.[1] Visibly offered a refractive vision test through an app, and patients would receive prescriptions for their glasses as a result of the test. Many states allow some optometric services to be provided via telehealth,

including use of apps like Visibly. The American Optometrists Association, however, filed several complaints with the FDA in opposition to Visibly, questioning the validity of the tests and other aspects of the app.[2]

As of this writing, due to the recall notice, the app is not available on the Apple or Android app stores and has been taken off the market. In the FDA's view, the app was an adulterated medical device for which a 510k clearance was required but not obtained. The FDA had previously sent a warning letter to Visibly as well.[3] (Visibly's specific responses and strategies are unknown.)

Perspectives may differ on whether an app meets the standard for being a mobile medical device that must go through the FDA approval process. In a situation where the company has a single product, and the alternative to obtaining approval is the risk of not being in the marketplace at all, the stakes are high. This is particularly true when a trade association is going after the technology provider. Including risk assessment as part of a product's compliance evaluation does not eliminate risk or prevent large, established groups with a vested interest in the status quo from their vocal opposition, but it can help companies prepare in advance for these risks, consider what kind of communication with regulators would be appropriate and beneficial, and identify additional strategies that could alleviate the high cost of pulling a product off the market amid a cloud of uncertainty.

Did Visibly have a compliance program? Would the compliance program have caught this mobile medical device issue in time to help the company think through the risks and options? I don't know. But I do know that this is an example of the challenges that innovators will continue to face as they develop new strategies for health care—industry veterans and experts, powerful regulators, and ambiguous regulatory standards sometimes combine into a level of certainty that might not be better than reading tea leaves.

Instead of hoping for the best amid a multitude of unknowns, plan. Partnering from the very beginning with legal and compliance departments to work toward better outcomes will blaze a more reliable path.

When launching a new product or program, consider questions such as:

- Which, if any, licensure and regulatory approval requirements apply?
- If licensure requirements are ambiguous and there's not a way to obtain certainty, what is the risk of harm to the company of not seeking the license or registration?
- What additional compliance challenges must be addressed for the business to succeed?
- Which agencies and regulators will have jurisdiction over this offering?
- If a product or program is market disrupting and there are forces known or likely to challenge it, what compliance strategies can the company use to mitigate that risk?
- Which vendors will be involved, and what type of due diligence should be performed for each?

In the example of Visibly, or any other company introducing an innovative product or service, it is conceivable that a company would consider strategies such as:

- Obtaining relevant licenses, accreditations, or registrations that may be viewed as a best practice or convey other benefits, even if there are legal arguments that they aren't technically required;
- Communicating with the relevant regulators in advance, if appropriate; and
- Anticipating regulatory concerns to incorporate mitigating features into the service or model.

As we all know, there's no panacea or guarantee that experiences like Visibly's can be avoided entirely, but examples are popping up all the time where telehealth

innovations suffer setbacks that may have been avoided or mitigated through compliance planning.

Individual Responsibility Example

In the past several years, compliance officers throughout the country have noticed an increase in regulators seeking penalties against individuals for the activities of a business. In the telehealth space, the focus on individuals, particularly prescribers, is a natural outgrowth of this enforcement strategy. In 2018, for example, the Department of Justice (DOJ) charged Dr. Bernard Ogon with one count of conspiracy to commit health care fraud as a result of his role in various telemedicine services. According to DOJ, the services would pre-populate prescriptions for compounded medications and transmit the prepared prescriptions to Dr. Ogon for review and signature. Dr. Ogon was paid per prescription, and the allegations state that the prescriptions were filled at pharmacies that had financial relationships with the parties.

The DOJ arrested Dr. Ogon, accusing him of signing prescriptions resulting from the telehealth service without having established appropriate patient-prescriber relationships and for prescribing in states where he was not licensed at the time.[4] Dr. Ogon pled guilty in September 2019.[5] This example is not unique. Telehealth programs may be particularly susceptible to risks in this area due to the number of entities and providers involved in a single arrangement, or due to confusion over who in the arrangement is responsible for which aspects of the compliance efforts.

Takeaways to consider when a telehealth program is going to result in prescriptions include:

- Ensure the model itself is an activity that is not prohibited or otherwise unacceptably high risk;
- Update policies, procedures, and training so prescribers and others involved in the service understand their roles and responsibilities;
- Confirm applicable licensure requirements for prescribers and include individual prescriber licenses in the company's existing licensure tracking, if that exists;
- Confirm whether states involved have separate telehealth or telemedicine provider registrations in addition to or separate from licenses required to practice medicine or prescribe;
- If health plans of any kind are being billed for services, support regular training for the billing team to ensure they are able to stay up-to-date on telehealth-related claim submission requirements, which change regularly;
- Assess all referral and payment relationships to make sure there isn't an undetected kickback, self-referral, or inducement issue;
- Assess all data transmissions to ensure uses and disclosures of data comply with applicable data privacy and security laws, and institute business associate agreements, patient authorizations or consents, and notices where required;
- Understand and document how a valid patient-prescriber relationship is created through the service (including as required for controlled substance prescribing); and
- Update internal recordkeeping requirements and practices to ensure that complete patient records are created and maintained.

Overall, strategies and features that make a compliance program successful continue to apply in telemedicine and telehealth contexts. Health Insurance Portability and Accountability Act (HIPAA), kickback issues, licensure requirements, scope of practice standards, reimbursement accuracy, audit appeals, and other issues that compliance programs routinely address are key foundations that support the growth of these innovative models.

Endnotes

1. U.S. Food and Drug Administration, "Class 2 Device Recall refractive vision test," *available at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=174633* (August 8, 2019).
2. E.g., American Optometrists Association, "AOA Files Expansive Complaint Against Opternative" (Visibly's former name), *available at www.aoa.org/news/advocacy/aoa-files-expansive-fda-complaint-against-opternative* (April 4, 2016).
3. U.S. Food and Drug Administration, "Warning Letter, Opternative, Inc." *available at www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/opternative-inc-532477-10302017* (October 30, 2017).
4. U.S. Department of Justice, press release, *available at www.justice.gov/usao-nj/pr/burlington-new-jersey-doctor-arrested-role-20-million-telemedicine-compounded-medication*.
5. Courier-Post, "Burlington Township doctor admits role in compounding-medication scam" *available at www.courierpostonline.com/story/news/2019/09/27/bernard-ogon-phony-prescriptions-compounded-medications-scam/3784084002/* (Sept. 27, 2019).

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