Guidance for Market Entrants in Telemedicine

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IMAGINE YOURSELF AS AN ENTREPRENEUR back during the Federally-declared Public Health Emergency of January 2020–May 2023 (the "PHE"). With millions of new people suddenly using the internet to work from home, many are expecting to do more and more under this same setup—ordering groceries, streaming new movie releases, attending live cycling classes, and now healthcare. Every other podcast commercial you listen to is advertising some type of telehealth service. You have been involved in e-commerce and e-marketing for years, you have several physician and pharmacist friends, and you sense a unique opportunity to do a lot of business and a lot of good at the same time. Diving in, you quickly develop a telehealth network, doing the best you can to meet the very real and unprecedented need.

Your customers (now patients as some would call them) love the user-friendly experience—the ability to see doctors via their computer and get prescription drugs through the mail—all at the click of a button. You expand from one state to ten to thirty-five (and counting). Towards the end of the PHE, as some semblance of normalcy starts to kick back in, you start to get letters from various state medical boards alleging all sorts of things that simply couldn't apply to you—"unlicensed practice of medicine, corporate practice of medicine, impermissible professional fee splitting, patient brokering, violation of the Controlled Substances Act, etc." As you never claimed you were a doctor or a pharmacist, you disregard these letters as they must be some sort of mistake.

Then a letter comes from the attorney general's office in your home state that sounds a little more serious. Finally you read that insurance may not pay for tele-health at the end of 2024.

Was this all a mistake? What should you do?

1 https://www.grsm.com/practices/health-care/health-care-regulatory-and-transactional

Don't Panic, But Remember That Medicine (And Its Rules) Existed Before the Computer

During the PHE, by necessity, as many commentators have pointed out, almost every provider became a telemedicine provider overnight. An attitude of "make it work" permeated the atmosphere and many held the image of building a plane midflight in their heads. Regulators and payors also suspended many eligibility and reimbursement rules regarding telemedicine to help facilitate the sudden shift in need. While everything may have been different in a sense, it was also the same. The same basics that had always existed (and been expected) still apply—that is, make sure a physician patient relationship is established, informed consent is obtained, the standard of care is adhered to, and that the doctor is speaking to the actual patient! The new modality was just that—simply a new means to help facilitate a process that had always been there and still was, not a wholesale replacement of the process.

Telemedicine Before the PHE

Prior to the PHE, telemedicine was primarily the realm of rural health care and the slow emerging trend of large retail stores establishing urgent care clinics. Notably, a patient's home did not count as a qualifying originating site for a telehealth visit to be reimbursed under Medicare. In rural counties, telemedicine typically consisted of patients driving to a public health clinic and then attending a virtual visit with a specialist in a distant urban location; arguably some of the rules around telehealth were antiquated even before the PHE. The PHE itself presented such a titanic demand for the service that the regulators really had no choice but to temporarily suspend the prior restrictions and triage the situation. In a sense, the dam on telemedicine proliferation burst but it did not mean that the rules applicable to the practice of medicine and pharmacy went away, they have been with us the whole time.

Telemedicine After the PHE

Post PHE, the "telehealth cliff" has so far yet to materialize – the fear that suddenly after years of getting used to convenient remote services, the payors and regulators will return to the world before the PHE. This is unlikely to happen and Medicare has already extended coverage for telehealth under the relaxed coverage rules through the end of 2024. It is likely that a new compromise will emerge and over time clarity will improve on the parameters of appropriate use of telemedicine. The key, regardless of what happens to reimbursement and licensure particulars is to never lose sight of the fundamentals that existed before the PHE, existed throughout, and still exist; for example the fundamentals of establishing the physician patient relationship, obtaining informed consent, authenticating patient identity, establishing the patient's medical history, identifying contradictions to any particular drug or treatment, etc. In other words, the overall lesson is that just because telemedicine rules have and continue to be relaxed to some extent, it is not a free for all. The perception among many regulators is that many telehealth networks are essentially

tech companies that function with a disruptive model and desire the higher returns that the health care industry may promise. In their opinion, this can lead to issues when the tech mindset of "move fast and break things" is laid over a preexisting and highly regulated environment such as health care (think Theranos). Often a surprise to market entrants, in health care the act of incentivizing generation of health care business is often illegal under the government's theory of it increasing health care expenses for the overall population. Importing sales methods from other industries into health care can be extremely risky for those not familiar with health care's unique regulatory scheme.

Typical Issues That Come Up with Telemedicine Joint Ventures

A number of legal issues often pop up when lay entity market entrants establish provider networks and join forces with licensed providers. To list a few:

1. **Corporate practice of medicine** — where a doctor is disciplined for essentially giving up professional autonomy or medical practice ownership or control to a non-professional entity or business interest (resulting in potential liability for the non-professional entity as well);
2. **Fee Splitting / Patient Brokering Fees** — where a marketing or web company or some other type of lay entity receives a percentage of professional fees that it may generate for the network or a "success fee" for each patient it drums up and sends to the network;
3. **Licensure** — where a network grows so fast that it does not have an available provider licensed for each state where it is seeing patients (in telemedicine the location of the practice is typically where the patient is located);
4. **Certain prescription drugs** being converted into essentially over the counter on demand medication given lack of controls and necessary formality or order;
5. **DEA rules** with respect to controlled substances and cross border prescription of the same;
6. Inappropriate use of **asynchronous** telemedicine and reliance on patient **questionnaires** where it could jeopardize reimbursement, patient safety, and medical credibility;
7. **Improper corporate structure** where lay entities are hiring physicians instead of the patients or other professional entities hiring the physicians;
8. **Kickbacks** and other alleged schemes where patients and/or referring providers are given inducements to generate health care charges, even in the context of cash pay / self-pay by patient in certain states;
9. **HIPAA** penalties after operating under a misunderstanding that since the market entrant is not a provider and they are not "really" involved in the provision of health care, they do not "really" need to be concerned about patient privacy; and
10. **FTC** rules on consumer privacy and advertising.

Enforcement Areas of Focus

In addition to all of the above enforcement, health law counsel and industry observers have seen recent Federal criminal enforcement in the area of alleged Medicare fraud schemes where marketing companies aggressively sold durable medical equipment **("DME")** and genetic testing services by collecting insurance information, relaying the same to DME and laboratory companies that utilized a very loose network of physicians willing to sign prescriptions and orders for patients they had not established a sufficient doctor-patient relationship with. Regardless of the market entrant's knowledge of the overall arrangement, they have still been swept up under the government's criminal "conspiracy" theory.

Next Steps

Back to the not-so-hypothetical situation from the introduction:

Was it a mistake to become involved in telemedicine? Absolutely not. It has promise to help a lot of people but we must remember that it is not something that replaces the practice of medicine and pharmacy – it is simply another modality to facilitate the care that these professions provide. Don't fall into the trap of thinking that because it's online it's not "really" practicing a profession.

What should you do now? Now is the time to be disciplined, be methodical, and make any necessary changes so that your business can be sustainable. Take a hard look at how the company and its potential joint ventures are currently formed and whether much or any care was given to the issues listed above. The "fire drill" excuse of the PHE will only work for so long, to the extent it ever really did. To reiterate, don't panic but do remember that medicine (and its rules) existed long before telemedicine. **Ask yourself the big "obvious questions"—namely is my company doing anything that it needs a license to do and is my company getting paid for what it actually performs itself or a percentage of what someone else with a license is doing?** Most importantly, don't give up on your goal to do some good in the world.

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