



# There's A Rule For That

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**Health care is “under innovation.”** No matter how health care is reformed, new and old arrangements will remain highly regulated, with new technology and collaborations moving faster than the law can adapt. Outdated regulations, some not amended in over two decades, may seem no longer relevant, but regulators won't hesitate to use them. Innovators in health care must navigate regulatory minefields, as illustrated below.

**Telemedicine** is becoming part of the standard of care. But rules of professional conduct remain focused on in-person medicine. While many states have adopted telemedicine statutes, there is no uniformity across state lines and, like New Jersey, few implementing regulations. Because the law where the patient receives the virtual services is the law that applies, a telemedicine practice that extends beyond a state's borders must extend its regulatory compliance accordingly. And CMS' new telehealth and communication technology-based services initiatives will bring new rules.

HIPAA/HITECH regulations governing **Privacy, Security and Data Breach** are well known in health care, but are set to be amended. Layered on HITECH are data breach laws in all fifty states. The patient's state of residence defines which state's data breach rules apply. The General Data Protection Regulation recently became effective and now a wave of new state laws providing strong consumer privacy rights has begun in California. Meanwhile, the FTC will prosecute those whose practices don't live up to their

website policies. Those who deal in health care data are under new scrutiny, as well. Vermont leads the way with its data broker law, while the FDA issued “best practices” on the use of EHR data in clinical investigations. Incorporating wearable devices, artificial intelligence, and blockchain technology into health care presents similar “layered” regulatory requirements for innovators.

Through **Collaboration**, licensed health care professionals increasingly are joined by lay entrepreneurs in delivering health care. This requires attention to the prohibition on the corporate practice of medicine, affecting choice of legal entity and limiting layperson influence over medical decision-making. In addition, every category of health care professional in a venture has differing professional practice rules. As for self-referral restrictions affecting ownership, compensation, lease payments, etc., federal Stark rules are on the chopping block but state laws lag behind or contain exceptions that are inconsistent with federal exceptions. The grey area created by differing sets of rules becomes a danger zone.

Innovators, by their nature, may be less risk averse than others. But when signing off on a representation promising “compliance with all applicable laws,” lack of follow up can have severe consequences. Compliance with these myriad regulations is a daunting task, a challenge best met with a comprehensive risk assessment, effective compliance program, and vigilance. In other words, a traditional approach.

