Digital health forecast 2024: legal implications of technological, policy, and business developments

By Jeremy D. Sherer, Esq., and Amy M. Joseph, Esq., Hooper Lundy

FEBRUARY 26, 2024

Digital health has been squarely in the spotlight since the onset of the COVID-19 public health emergency, during which increased adoption of virtual care technology emerged as one of the most important public health ramifications of the pandemic. Heading into 2024, a gradual transition is underway, as the use of digital health tools becomes propelled less by need associated with a global pandemic, but rather by its capacity to increase access to high-quality care while limiting cost and increasing access to care and convenience for patients.

It is clear that digital health will remain an important part of the American health care ecosystem moving forward. But, like any worthwhile innovation in health care delivery, digital health's emergence and continued growth are causing ripples across health care in both expected and surprising ways. This article outlines some of the legal and business trends involving digital health that expect to be most impactful to industry stakeholders in 2024.

Artificial intelligence solutions will prompt new thinking

The use of tools driven by artificial intelligence (AI) is not a new development in health care. Clinical decision support tools like chatbots (remember IBM's Watson?) and AI-powered applications in medical imaging are powerful tools that clinicians have leveraged in patient care for years. What *is* different in today's AI frenzy fueled by the likes of Chat GPT and others is the perception in some corners that AI can actually perform autonomous decision making.

Medicine and other clinical professions are highly regulated in the United States. State-level medical and other health care professional boards are (and will continue) doubling down on the notion that AI tools can be leveraged for *support*, so long as there is actual intervention by a treating practitioner with ultimate responsibility for the treatment furnished. However, as industry continues to innovate and deploy new AI solutions into health care delivery, regulators will (and industry stakeholders, therefore, must) be wary of the line separating decision support from active decision making.

Understanding the immense potential for expanded AI utilization in health care, the federal government began laying the groundwork for meaningful regulation of AI tools in care delivery in 2023, which trend will very much continue in 2024. To date, both the Biden Administration and the Office of the National Coordinator of Health Information Technology within the Department of Health and Human Services have emphasized the urgency of implementing more oversight of AI solutions, including addressing key concerns such as the risk of unlawful discrimination and risks to individual data privacy rights.

Like any worthwhile innovation in health care delivery, digital health's emergence and continued growth are causing ripples across health care in both expected and surprising ways.

The importance of transparency in AI solutions has also been strongly emphasized, as additional transparency permits further vetting of solutions, which is in turn expected to generate confidence among practitioners and patients in the tools at issue. States are similarly taking action to regulate use of AI. While some regulatory oversight is already in place, it is anticipated that within the next year there will be a lot of activity in this space as lawmakers seek to strike a balance between promoting innovation and protecting against the potential risks.

New clarity on Medicare telehealth services and virtual prescribing of controlled substances?

One of the early pandemic-era changes that was most necessary to catalyze the growth of virtual care was the temporary abandonment of several longstanding federal limitations on the coverage and reimbursement of telehealth services.

Some of the most significant restrictions waived during the pandemic require Medicare beneficiaries to be located in a brick and mortar health care facility located in a rural area (with limited exceptions) for telehealth services to be covered, and rules prohibiting clinicians to prescribe controlled substances without first examining the patient in-person, unless limited exceptions that have failed to keep pace with modern care delivery models are satisfied.

The result of these waivers was an explosion in telehealth utilization. Among Medicare beneficiaries, telehealth utilization increased tenfold from 2019 to 2020 according to the U.S. Government Accountability Office (GAO). *See* GAO, Telehealth in the Pandemic — How Has it Changed Healthcare Delivery in Medicare and Medicaid? (Sept. 29, 2022). On the virtual prescribing side, innovative virtual delivery models that were previously impossible because of in-person examination requirements emerged in areas including behavioral health, gender-affirming care, and obesity medicine.

After Congress declined to make permanent decisions regarding the future of these waivers during the pandemic, the end of calendar year 2024 was identified as the deadline by which Congress must determine whether these waivers will be codified into law, or discontinued. How Congress navigates this critical issue will be one of the most important developments for health care industry stakeholders in 2024.

Joint ventures and other strategic affiliations with telehealth companies

Virtual care practices are significantly less restricted by geographic limitations than brick and mortar providers. As a result, virtual practices often succeed in focusing on highly specialized care and narrow use-cases in ways that traditional practices cannot; they can draw on resources from a larger geographic pool (such as by utilizing specialists with multi-state licensure that can offer the services to a broader patient population), and often their business model is reacting to identified gaps in in-person care delivery across the healthcare marketplace.

Digital health practices in this mold are increasingly exploring opportunities for strategic affiliations. These affiliations sometimes include collaborations with other virtual care companies, to facilitate closer care coordination and care management of certain patient populations, when the companies offer complementary services from which the same patient population could benefit.

For example, imagine that virtual care company A specializes in pediatric behavioral health services, and virtual care company B specializes in pediatric speech language pathology (SLP) services. Such companies might explore entering into a care coordination agreement (such as by establishing a value-based enterprise and availing themselves of a value-based safe harbor under the federal Anti-Kickback Statute). They may also enter a services agreement where one company contracts downstream with the other to expand its offerings to enterprise customers or individual patients by providing a more comprehensive solution. Or companies may otherwise consider a joint offering to customers.

Similarly, as it becomes increasingly clear that telehealth is now part of any clinician's toolkit of health care delivery tools moving forward, brick-and-mortar stakeholders like hospitals and skilled nursing facilities are embracing telehealth. While some health systems in particular are developing their own telehealth practices and programs (which may utilize a third-party telehealth platform through which their clinicians deliver services), many are leveraging the tremendous learnings and technology developed by telehealth companies, as well as the affiliated clinician workforce, rather than reinventing the wheel. Some are going so far as to develop new joint venture telehealth service lines, as well, to further promote patient choice and increase access to care.

Continued enforcement activity

For years, telehealth advocates have warned the provider community that increased utilization of telehealth services will yield greater scrutiny from regulators focused on weeding out bad actors. Throughout the pandemic this prediction rang true, with the Department of Justice, State Medicaid Fraud Control Units, and private payors each appearing to increase efforts to identify clinicians and practices submitting claims for services not rendered, upcoding to impermissibly increase reimbursement, and repurposing other illegal strategies commonplace in health care fraud schemes.

While the nature of virtual care allows for seamless care delivery across state lines, practitioners delivering that care have to navigate frameworks that simply were not designed with virtual care in mind.

Similarly, with the rise of various digital health solutions there has been an increased focus on patient privacy and security considerations virtual care models implicate at both the federal and state levels. For example, after taking issue with allegedly improper data tracking practices involving several sizable digital health companies (as well as other provider organizations), the Federal Trade Commission (FTC) and the Department of Health and Human Services Office for Civil Rights (HHS OCR) issued a joint letter to approximately 130 telehealth companies and hospital systems in July 2023 warning them about risks associated with tracking technologies, including Meta pixel and Google Analytics under applicable privacy laws.

In addition, following the adoption of the California Consumer Privacy Act, more states have since adopted comprehensive data protection laws, and this trend is expected to continue in 2024. While not specific to digital health, these developments are important for industry stakeholders to track, particularly given that many digital health solutions are facilitating the delivery of services to residents of multiple states.

Non-physician practitioner trend continues

A consistent trend in health care delivery in recent years has been leveraging practitioners to practice at the "top" of one's license. In practical terms, this means building clinical workflows around non-physician practitioners with prescriptive authority — generally advanced practice nurses, also known as nurse practitioners in many states, and physician assistants — who can, in many cases, occupy roles traditionally occupied by physicians whose labor is more expensive.

Perhaps the thorniest set of legal issues this trend involves is state-level requirements for collaborative practice and/or supervision. While the nature of virtual care allows for seamless care delivery across state lines, practitioners delivering that care have to navigate frameworks that simply were not designed with virtual care in mind.

Some of the more common challenges we see involve states which require in-person meetings between a non-physician practitioner and their collaborating physician, as well as the need to receive supervision from a physician appropriately licensed in the state where the non-physician practitioner is practicing. Particularly in national delivery models in which heavily licensed practitioners treat patients across a range of states, the process of identifying each state's specific requirements and ensuring appropriate supervision is in place is no small task. This trend is likely to continue to grow as provider organizations struggle with clinician workforce shortages and reimbursement levels compared to the cost of delivering care.

About the authors

Jeremy D. Sherer (L) is partner and co-chair of **Hooper Lundy**'s digital health practice. He advises digital health startups, telehealth platforms, investors and health systems on regulatory compliance and transactional issues. He has substantial experience navigating scope of practice considerations in novel care delivery models, structuring and scaling 50-state virtual care practices, and leading regulatory diligence for investors evaluating digital health investments. He can be reached at jsherer@hooperlundy.com. **Amy M. Joseph** (R) is a partner with the firm and counsels clients in the healthcare and technology sectors on a broad spectrum of regulatory and business matters, including digital health companies, health systems, and other public and private companies. She has a particular focus on developing and implementing innovative business models while navigating regulatory compliance considerations. She can be reached at ajoseph@hooperlundy.com.

This article was first published on Reuters Legal News and Westlaw Today on February 26, 2024.