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Health Tech Boom In 2020s Will Test Fraud, Privacy Laws

By **Jeff Overley**

Law360 (January 14, 2020, 4:59 PM EST) -- The brave new world of high-tech health care — marked by drug-delivery drones and cancer-spotting artificial intelligence systems — will stretch the boundaries of anti-fraud statutes, patient privacy laws and health insurance reimbursement in the 2020s, attorneys predict.

Law360 recently asked lawyers at numerous firms how the practice of health law might change in the decade ahead, and the most frequent forecast by far was that new health care technology will spawn new theories of legal liability and perhaps force policymakers to reboot important laws and regulations.

Daniel F. Murphy, a partner at Bradley Arant Boult Cummings LLP, predicted that "technology will continue to transform health care delivery and payment systems" and that "across all aspects of health care law, the existing regulatory structure will prove ill-suited to rapidly shifting approaches to providing and paying for health care."

"Legislators, regulators and judges will be required to adapt outmoded health care law to emerging industry realities," Murphy said.

Fraud Scrutiny Looms for New Tech Tools

One of the biggest emerging realities is the spread of artificial intelligence tools. AI is often the secret sauce in so-called clinical decision support software that lends a helping hand to doctors, and the U.S. Food and Drug Administration has scheduled a public workshop for Feb. 25-26 to explore the risks and benefits of AI in medical imaging.

One of the better-known examples of artificial intelligence software is a stroke-detecting app, sold by California-based Viz.ai Inc., that the FDA greenlighted in 2018. More recently, Google Inc. on Jan. 1 reported that its AI technology did better than humans with medical degrees at sleuthing out breast cancer in X-ray images.

George Breen, an Epstein Becker Green member, told Law360 that artificial intelligence may soon be targeted under anti-fraud laws, with plaintiffs potentially arguing that products aren't delivering on lofty promises.

“There will be certification issues related to the use of AI, and there will be arguments by some that the certification wasn’t accurate,” Breen said.

Murphy also warned of AI pitfalls ahead, saying that some health technology systems or developers may end up having the unlawful purpose of inducing patient referrals or the unlawful intent of facilitating improper billing.

“Can artificial intelligence, or its creators, violate the ‘one purpose’ test under the Anti-Kickback Statute? Can an algorithm, or its programmers, have prohibited intent under the False Claims Act?” Murphy asked.

Lawyers are also increasingly fretting about fraud liability for cybersecurity failings. In an eye-catching development, Cisco Systems Inc. in mid-2019 paid almost $9 million to resolve False Claims Act litigation over its alleged sale of hackable video surveillance gear to government agencies.

The payout represented the first successful FCA suit involving cybersecurity fraud, according to Constantine Cannon LLP, which along with Phillips & Cohen LLP represented the case’s whistleblower. Attorneys say that similar FCA cases involving health care now look practically inevitable.

“We’ve only seen the tip of the iceberg,” Breen said.

Big Data Puts Strain on Health Privacy Protections

Privacy concerns with cybersecurity are even more palpable. In 2018, health insurance giant Anthem Inc. inked a record-smashing $16 million settlement after cyberattacks exposed the protected health information of 79 million people; the deal made clear that the Health Insurance Portability and Accountability Act, best known simply as HIPAA, has real teeth.

At the same time, some attorneys are asking whether HIPAA — which became law in 1996 — can keep pace with endless innovation in the digital age.

“With so much patient protected health information stored in electronic format … will existing HIPAA regulations be sufficient to protect patient privacy, or will a rewrite of the law become necessary?” Tucker Ellis LLP counsel Raymond Krncevic asked.

W. Reece Hirsch, a Morgan Lewis & Bockius LLP partner, made a similar observation in the context of wearable health apps that are cataloging practically every move their owners make.

“Digital health products will continue to collect enormous volumes of medical information, and those new technologies will test the limits of existing health care privacy laws and regulations,” Hirsch said.

Melinda Dutton, a Manatt Health partner, echoed that point in the context of “social determinants of health,” a concept that considers how economic and environmental factors affect patient well-being. Health care providers have been teaming up with nonmedical entities to address social factors, raising questions about whether adherence to HIPAA and state privacy laws is sufficient to safeguard sensitive health information.

“Current state and federal privacy and security requirements do not contemplate such cross-sector information exchange,” Dutton said. “Over the next decade, expect the dialogue about the exchange of

information necessary to facilitate patient health to broaden to contemplate new players, new types of information and new methods for ensuring consumer protections."

The new players include tech firms — such as Apple Inc., Samsung Electronics Co. Ltd. and Fitbit Inc. — that are handling huge amounts of personal health data and increasingly working with the FDA to win streamlined approvals of myriad health software products.

Speaking generally, Reed Smith LLP partner Brad Rostolsky told Law360 that "as digital health companies continue to disrupt the market," it appears "likely that there will be some serious thought given to whether there needs to be an amplification of the traditional health privacy rules."

Old Payment Approaches Poised for Disruption

The trend toward high-tech health care also has lawyers, executives and regulators moving to overhaul traditional payment policies. In one particularly significant endeavor, the Centers for Medicare & Medicaid Services is working on a proposed rule intended to "streamline coverage of breakthrough technologies."

As part of that effort, officials from CMS, the White House and medical device lobbying group AdvaMed met in late October to discuss automatic coverage and special add-on payments for "the most innovative and disruptive medical technologies," according to an Office of Management and Budget summary.

Lots of chatter in recent years has also focused on pay-for-performance pricing that makes reimbursement contingent on products working as advertised. The concept is not without controversy; one concern is that companies can predict rates of success and failure and then price their products accordingly, making any purported refunds illusory.

That being said, observers still expect that changes in health care technology will drive changes in health care payments during the 2020s.

"Outcomes-based and other risk-sharing payment models will continue to proliferate," Wendy C. Goldstein, health practice chair at Cooley LLP, told Law360. "As new technology and scientific advancements result in higher-cost drug therapies, payors and manufacturers will need to work together for more aligned payment models."

New payment approaches may also become necessary as new models of health care delivery take flight. United Parcel Service Inc. in March 2019 began making drone deliveries to the flagship campus of North Carolina hospital chain WakeMed, and as of October, it had made more than 1,500 airborne shipments. In November, UPS announced two successful drone deliveries of prescriptions from a CVS pharmacy to residential customers.

In addition, FedEx Express in September reported a collaboration with Walgreen Co. and Google parent company Alphabet Inc. on drone deliveries in Virginia.

Bradley Arant's Murphy told Law360 that the developments may spark discussion about how special billing codes, technically known as CPT codes, should be created to pay for medication deliveries via drones.

“Lawyers in the 2020s will grapple with these and many other novel issues brought to the fore by technological developments,” Murphy said.

--Editing by Rebecca Flanagan and Alyssa Miller.