NELSON HARDIMAN
HEALTHCARE LAWYERS

Client Alert: The Top Ten: 2022's New Healthcare Laws

1. **Telehealth:** For decades, long waits for the doctor have been an accepted albeit frustrating feature of U.S. patient experience. Pandemic-driven fears of the dangers of unnecessary in-person visits accelerated a shift away from unnecessary face-to-face doctor-patient contact through telehealth. Though Covid-10 safety concerns drove a surge in virtual visits, this change has driven better time management in healthcare, a needed improvement, and telehealth is continuing at levels roughly 40x pre-pandemic utilization. Initially, the Centers for Medicare and Medicaid Services (CMS) waived numerous requirements for physical appointments, but only for the duration of the Public Health Emergency. They also raised telehealth compensation to levels comparable to actual office visits. Regulators and legislators are now considering making these temporary changes permanent. Republicans, such as Rep. Liz Cheney (R-WY) and Senator Cassidy (R-LA) have introduced telehealth bills. (H.R.4040 & S. 2061) Democrats have made telehealth part of their "Build Back Better" omnibus bill that they remain determined to pass. Other states are expected to follow Texas' example and attempt to implement telehealth solutions within prison systems. The big obstacle for telehealth is serving those who cannot afford internet and older patients who struggle with unfamiliar technology. But telehealth utilization is at unprecedented levels, which means more telehealth regulation and compliance are on the way.

1. **Vaccination Mandates for Adults & Children:** On January 7th, the Supreme Court will hear challenges to two federal vaccination mandates: the healthcare worker mandate and the 100-employee mandate. (We previously provided guidance for California employers and a guide to the national mandates.) Legally, the question is: to what extent can government compel people to vaccinate? While the political challenge is what can the public tolerate? California was the first state to announce that it would prevent unvaccinated pupils from physically attending public schools. But once officials realized that in LA County alone, some 34,000 students would be learning remotely, they backed off. Remote learning has been a disaster for children and young adults. Learning suffers, children get less exercise, and isolation is no boon to mental health. Additionally, impoverished children cannot rely on school lunch programs, and without school, there is often no reprieve if there is instability or abuse at home. Meanwhile, California wants as many medical professionals as it can find administering vaccines. Currently, doctors, nurses, pharmacists and optometrists can give vaccines. A new California law (AB 526) allows dentists and podiatrists to offer vaccinations as well.

1. **Psychedelics as a Mental Health Therapeutic:** In 2020, Oregon voters made their state the first in the country to decriminalize psilocybin for therapeutic use. 2022 is likely to see California and several other states follow this trend of psilocybin decriminalization. The continued growth of interest in and demand for ketamine as a therapeutic for treatment-resistant depression, post-traumatic stress disorder reflects a parallel trend, reflecting pressure for innovation to address America's burgeoning mental health crisis.

1. **Abortion:** In December, the Supreme Court heard arguments in *Dobbs v. Jackson Women's Health*, dealing with a Mississippi law banning abortion after 15 weeks. Lower courts ruled that the law violated *Casey v. Planned Parenthood*, which allows abortions up to 24 weeks. With the current Supreme Court conservative majority, many observers are expecting the *Dobbs* decision to overturn *Roe v. Wade.* This expectation has already led to state legislative actions challenging *Roe,* such as Texas' September 2021 'fetal heartbeat law' (TX SB8) allowing private citizens to sue any party that furnishes an abortion, absent a medical emergency. 2022 is likely to see more states enacting new laws and legal challenges in this ongoing conflict.

1. **Next Generation Diagnostics:** Yesterday, the jury found former Theranos CEO, Elizabeth Holmes, to be guilty of defrauding investors with respect to sham blood-test technology. Notwithstanding Holmes' deceit, 2022 is likely to see progress on multiple, genuine next-generation diagnostics, in multiple areas, including genomics-based analytics and in-home diagnostic devices and software. In addition to technology advances, the FDA has also eased rules on remote patient monitoring devices due to the pressure for in-home diagnostics during the pandemic. Devices that were certified for hospital-use only were temporarily approved for home use. Telehealth utilization is likely to expand by integrating reliable, easy-to-use, diagnostic devices that can send information directly to the "attending" physician, as well as expanding use of genomic-based information to drive healthcare decisions.

1. **Medicine Delivery:** Jeff Bezos' plans to deliver your prescriptions are moving forward, competing with Uber and other delivery services entering the pharmacy market. For Amazon employees, Amazon Care already provides both in-person and telemedicine services. The retail behemoth employs nearly 1 million people in the US. If Amazon can provide healthcare for its own workforce, it is poised to grow and serve millions more. CVS, Walgreens, Walmart and other pharmacy chains are racing to build and expand their own onsite urgent-care clinics; leveraging the need for in-person services, like flu and Covid vaccines. The surge in competition for consumers' pharmacy and medical needs is likely to continue in 2022, keeping federal antitrust scrutiny front and center.

1. **Timely Mental Health Appointments** (SB 221) Waiting too long to see a psychiatrist or a substance abuse counselor can turn an impending problem into a crisis. Effective July 1, 2022, California will no longer abide tardiness from mental health professionals and primary care physicians. Now, Urgent Care appointments must be found within 48 hours of a patient's request (when no prior authorization is needed). Non-Urgent Care with a primary physician or non-physician mental health appointment must occur within 10 business days, while specialists have up to 15 days. Healthcare providers have six months to prepare for the new law. If it works in California, other states are expected to follow suit.

1. **Genetic Privacy and Genetic *Piracy*** On January 1, 2022, a new privacy statute, GIPA (the Genetic Information Privacy Act), went into law, introducing significant protections for California residents who undergo non-medical genetic testing. Over 30 million people have spat in a tube and shared their unique genetic data with prominent genealogy companies, like Ancestry.com and 23andMe. Customers expect their DNA will be used for tracking down distant relatives and discovering new branches on the family tree. But they will skip lengthy disclosures indicating how their personal genetic information might be sold or shared with third parties. A broader concern is that, once genetic data is uploaded to a digital database, it can potentially be exposed to accidental data breach or cyber-theft, like any other information stored in "the cloud." We are long accustomed to protecting our personal information, like social security numbers, credit card information, and bank records. As the genomics industry continues to evolve, attention to DNA as a form of personal information in need of safeguarding is likely to grow.

1. **The 'No Suprises' Act (NSA)** There are few things worse than unexpected medical bills for patients already dealing with a medical crisis. Peterson-KFF estimates that about 1 in 5 emergency room visits results in a surprise bill, most often occurring when an individual is brought to an out-of-network hospital. The same issue arises even during in-network hospitalizations. As of January 1st, private health plans must cover out-of-network emergency bills at *in-network* rates. There are also transparency provisions requiring non-emergency providers to give a good-faith estimate in writing to the patient at least 72 hours before the medical event, and obtain the patient's written acknowledgement.

1. **Artificial Intelligence/Machine Learning (AI/ML):** With the proliferation of artificial intelligence in healthcare technology, the FDA has proposed a regulatory framework for AI and Machine Learning medical devices. They also began tracking and providing to the public information about AI/ML medical devices that are on the market. One the biggest challenges surrounding AI pertains to flawed datasets used to train machine learning. A few years ago, Google's DeepMind came up with a promising predictive model for kidney failure. Relying on data from Veterans Affairs medical centers, it turned out that the dataset was overwhelmingly based on men, with only 6% of the dataset taken from women. Unsurprisingly, the AI wasn't nearly as successful when diagnosing women. Problems with datasets can skew results depending on age, incomes, race, and other differences. AI/ML represents a new health equity challenge for the FDA, putting pressure on regulators and industry not only to establish whether the technology works, but whether it works appropriately for everyone.

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