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"It was quickly recognized that we were not going to be able to continue nursing and the model of care that we had. Something had to change."

Debra Marinari, associate vice president of hospital operations at Stafford Hospital in Virginia, part of Mary Washington Healthcare, Page 12

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Lawyers weigh in on their healthcare clients' biggest concerns

BY LAUREN BERRYMAN

he healthcare industry has been thrown numerous curveballs over the past year, from an unprecedented Supreme Court decision regarding access to abortion care nearly a year ago to the end of the COVID-19 public health emergency last month—along with a rocky economy and workforce challenges.

In response to the uncertainty, lawyers working with health systems, nursing homes, digital health startups and provider groups have seen the demand for certain services spike.

Here are four of the biggest reasons healthcare lawyers say their clients are seeking counsel.

Scrutiny of deals

President Joe Biden's Federal Trade Commission and Justice Department have put an emphasis on preventing anti-competitive business practices across industries, leading healthcare leaders in many sectors to think strategically before inking deals.

The FTC filed a lawsuit in June 2022 to block Nashville, Tennesseebased HCA Healthcare's proposed acquisition of five Steward Health Care hospitals in Utah. The health system scrapped the deal two weeks later.

In September, the agency launched an investigation into Amazon's acquisition of primary care provider One Medical. Though the FTC did not block the companies from finalizing the deal in February, it said the probe would continue.

Companies with stronger financials and a greater ability to take on risk are going to be the ones pursuing mergers and acquisitions.

Cross-market deals may also fare better than those that could consolidate healthcare services and drive up costs.

"For most providers, especially nonprofit health systems that are already squeezed coming out of the pandemic and are facing staffing shortages ... the threat of an FTC action is something that's going to have a chilling effect on a deal," said Robert Miller, co-chair of the business department at law firm Hooper, Lundy & Bookman.

Companies should conduct an analysis early on in the dealmaking process to determine if there's

potential for an FTC concern, said Sarah Ernst, co-chair of Alston & Bird's corporate practice area and past chair of its healthcare group. She recommends sellers reach out to multiple potential buyers during the auction process to drive interest in an acquisition and assess the antitrust risk of a deal with each entity before selecting the strongest partner.

A federal antitrust investigation could amount to millions of dollars, involve outside counsel expenses and distract from productivity—even if the government finds no wrongdoing.

"Even if [the agencies stand] down at the end of it, that is a very large expense that can eat into the additive value of the transaction or even make your customers worry during that investigation, and so you lost some business just for going through the fight," said Adam Biegel, co-chair of Alston & Bird's antitrust team.

Reproductive care hurdles

Since the Supreme Court overturned Roe v. Wade in June 2022, abortion access has been left to the discretion of the states. A federal judge in Texas also suspended the Food and Drug Administration's 2000 approval of the abortion medication mifepristone in April, causing further uncertainty as the case winds its way through the courts.

Law firms have modified their operations to address the increased demand in questions from clients that provide reproductive care, such as health systems that employ OB-GYNs or operators of telehealth abortion companies.

"[Providers] are getting tripped up or nervous about compliance with laws that may have been on the books for a while," said Alicia Macklin, cochair of the behavioral health practice group and the health equity task force at Hooper, Lundy & Bookman. For example, they are asking more questions about patient consent requirements, she said.

"It's a tough position to be in for a provider when you have conflicting or even uncertain laws," Macklin said.

Many firms are tracking state legislation and ballot initiatives in order to help clients understand which services they can provide or if they can refer patients to another provider across state lines.

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Hooper, Lundy & Bookman formed a practice group in July to help provider clients understand various policies' practical implications. Manatt, Phelps & Phillips established a community of practice where stakeholders can share their expertise navigating reproductive health issues. The law firm and two venture funds are also conducting workshops this month with more than a dozen companies, including regional health systems, digital health companies and payers, to discuss barriers to care and develop solutions and partnerships to address reproductive health access.

Law firm leaders say ongoing challenges are likely on the way. In July, Biden used his authority to sign an executive order directing the Health and Human Services
Department to expand access to
emergency contraception and protect
patient privacy, said Stephanie
Gross, co-chair of the reproductive
health practice at Hooper, Lundy &
Bookman. A new president could walk
back such initiatives.

Remote prescribing regulations

The Drug Enforcement Administration and the Substance Abuse and Mental Health Services Administration said in May that they would extend pandemic-era telehealth flexibilities regarding controlled substances for six months, allowing providers to prescribe medications such as Adderall, Xanax and the opioid addiction medication buprenorphine remotely without an in-person visit. Lawyers say their digital health clients have come to them with questions about how to stay compliant with federal regulations after November.

"We've advised that companies and providers impacted by these changes need to come up with contingency plans. ... At this point, it's clear that we'll be landing somewhere in between that pre-pandemic landscape and the expansive waivers currently in place," said Jeremy Sherer, co-chair of the digital health practice at Hooper, Lundy & Bookman.

Sean Sullivan, a partner with the healthcare group at Alston & Bird, recommends having documented compliance programs in place, which could include modifying operations by opening new brick-and-mortar clinics, referring patients to other providers with physical locations, or using other counseling to treat certain conditions.

Even as virtual-first companies modify operations or pivot to inperson visits, Sherer expects the DEA to continue probing some providers. The agency launched investigations into mental health startups Cerebral and Done last year regarding their prescribing practices for Adderall and other controlled substances.

Workforce challenges

Ongoing workforce shortages have triggered worries among healthcare organizations about staffing.

Skilled nursing facility operators are particularly anxious, given President Biden's signal in February 2022 that his administration plans to propose a minimum staffing rule for such organizations. Clients are concerned about the costs of meeting the potential requirement and finding workers, said Sean Fahey, an attorney at Hall, Render, Killian, Heath & Lyman representing skilled nursing facilities.

He is talking with his clients about the rulemaking process and urging them to comment on a proposal once it's released, which the Centers for Medicare and Medicaid Services said could happen this spring. In the meantime, operators have been assessing how to improve recruitment and retention.

"We hear our clients taking many different avenues to try to address and build their workforce. From exploring immigration to culture to working with staffing agencies, they're trying everything," Fahey said.

Leaders at health systems, which also face difficulties filling clinical roles, are seeking ways to strengthen employment agreements.

"At the end of the day, you want to be able to incentivize folks to not leave you so that no patient care is going to be hurt," said Jaime Tuite, shareholder and head of Buchanan Ingersoll & Rooney's Pittsburgh office.

Health systems need to play the long game, whether that's incorporating long-term work contracts in employment agreements or offering bonuses and tuition reimbursement after a certain amount of time with the company, Tuite said.

"The goal is we're going to invest in you, and we're going to spend money that we otherwise wouldn't, because we want you to grow here," Tuite said.