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The Top Coronavirus Questions Health Attys Are Hearing

By **Jeff Overley**

Law360 (March 17, 2020, 10:43 PM EDT) -- The coronavirus pandemic is forcing health care lawyers to field a barrage of client queries and deliver creative advice on deeply serious subjects, including an approaching tidal wave of infected Americans and legal liability related to drug dangers, patient privacy and free treatments.

Law360 asked lawyers with a wide range of health care and life sciences clients to discuss the most significant questions that are coming across their desks as the novel coronavirus wreaks havoc across the globe. The virus causes a severe respiratory disease called COVID-19 that has reportedly infected more than 5,000 Americans and killed more than 100 — numbers that could be understated, given that testing is only beginning to ramp up.

Here, attorneys tell Law360 about the big questions they're getting — and the answers.

What options exist for satisfying a potentially unprecedented demand for hospital beds?

In the early days of the coronavirus outbreak, China received widespread attention when it erected a massive new hospital in just 10 days, and it's possible that U.S. hospitals and policymakers may soon find themselves compelled to pursue similar solutions.

David Deaton, health practice chair at O'Melveny & Myers LLP and a member of the firm's coronavirus task force, told Law360 that he's brainstorming how to handle a tsunami of patients that could quickly overwhelm U.S. hospitals.

"We are assisting clients in evaluating numerous out-of-the-box solutions, including reopening mothballed hospitals and clinics and converting large non-health-care facilities — like hotels, stadiums, schools and other public and private facilities within our local communities — into temporary surge treatment centers," Deaton said.

Health care workers in outpatient settings may also need to be swiftly switched to inpatient and emergency settings, the Newport Beach, California-based lawyer said.

In typical times, law firms would just tap their expertise to shepherd clients through a thicket of health regulations and building codes. But during this extraordinary moment in history, attorneys are also

imagining how state and federal emergency declarations might clear the way for truly audacious endeavors.

"The rules of the game are very much in flux," Deaton said. "Many regulators will be looking for opportunities to scrap red tape in favor of readiness. ... And since freedom breeds creativity, I am hopeful that the hidden opportunity here is potential innovation as regulatory barriers are knocked down to make way for fast action."

Does the Health Insurance Portability and Accountability Act prevent me from disclosing information about a U.S. employee who tested positive for the coronavirus or is showing symptoms?

Usually the answer is no, said WilmerHale partner Kirk Nahra, who is based in Washington, D.C., and co-chairs the firm's privacy practice.

"Unless you are a hospital or other health care provider providing health care services to your own employees, HIPAA will almost never be relevant to the average employer in this situation," Nahra said.

If an employer first learned of a coronavirus diagnosis through a health insurance claim filed by an employee, that would likely trigger HIPAA, but that scenario is unlikely, Nahra added.

Dawnmarie Matlock, an Atlanta-based partner at Alston & Bird LLP, told Law360 that companies should promptly inform workers if one of their colleagues tests positive. But she said it may be possible to do so effectively without divulging details about the infected worker's identity.

"Tell employees who may have had exposure that they may have been exposed to COVID-19, but do not disclose the identity of the employee who is ill," Matlock said.

On a related front, employers that learn about COVID-19 diagnoses in their workforces usually shouldn't bother reporting the information to public health authorities, Nahra told Law360.

"Several health departments have in fact said they do not want you to report the results to them because they already have them and they already are overwhelmed," he said.

What is the impact of the U.S. Department of Health and Human Services declaration addressing medical countermeasures against COVID-19?

Sidley Austin LLP partner Meena Datta said clients have been asking about a recent HHS declaration that largely immunized drug and device makers from legal liability for harm related to COVID-19 treatments delivered under federal contracts or pursuant to a public health emergency.

"The declaration is a helpful starting point but could go further to ensure patients maintain adequate access to their therapies," Datta, who is based in Chicago and co-chairs the firm's health practice, told Law360.

She suggested that a broader declaration could shield health care providers and suppliers from liability under the Anti-Kickback Statute, at least in limited ways, for providing therapeutic goods or services free of charge.

"These types of activities that support patient access are commendable, support the public health in a time of a national crisis and could be covered by an expanded declaration," Datta said.

How will clinical trials and related agreements be impacted?

Sponsors of clinical trials have been adapting to new social distancing norms by mailing drugs to patients, measuring results remotely and figuring out workarounds for various paperwork issues.

"For clinical trials that are currently ongoing, sponsors are considering innovative approaches to ensuring trial subjects can access investigational [products] to limit participant disruption," Veleka Peeples-Dyer, a D.C.-based partner at Baker McKenzie, told Law360.

But when adapting isn't feasible and trials must be halted, it's likely that so-called force majeure provisions in drug development agreements will be triggered. That should prevent any unavoidable delays from giving rise to breach-of-agreement claims, said Baker McKenzie partner Oren Livne, who is based in New York City.

"This means we can expect that, in many cases, the carefully negotiated timelines, development milestones and commercially-reasonable-efforts standards in these agreements will be put on hold until we have recovered," Livne said.

Could a company be liable for negligence if it hasn't instituted enhanced cleaning routines in publicly accessible areas?

Alston & Bird counsel Angela Burnette, who is based in Atlanta, told Law360 that she's advising clients to follow recommendations for cleaning and disinfecting from the Centers for Disease Control and Prevention.

It's also a smart idea to keep a log that describes the dates and details of cleaning that's performed, Burnette said.

"Although not mandatory, CDC recommendations could likely be seen as the standard of care, and following those recommendations could provide a defense in the case of a lawsuit in the future," she said.

After President Donald Trump declared a national emergency, the Centers for Medicare & Medicaid Services issued Section 1135 waivers — what are they?

Some Section 1135 waivers have "blanket" provisions that defer certain legal requirements — such as limits on lengths of patient stays in rural hospitals — for a broad range of providers, said Sarah Swank, D.C.-based counsel at Nixon Peabody LLP and a member of the firm's coronavirus response team.

But it's also possible for individual providers to seek waivers, and it's expected that CMS "will remain timely and responsive to waiver requests" during the coronavirus crisis, Swank said.

For hospitals eyeing possible waivers, the best approach "is to understand how COVID-19 will change health care delivery in our country," Swank said.

As examples, she observed that dramatic growth in patient volume might drive hospitals to seek increases in maximum capacity and exemptions from requirements that physicians sign certain contracts.

How might the U.S. Food and Drug Administration's postponement of foreign inspections affect my company?

Bethany Hills, a Morrison & Foerster LLP partner based in New York, told Law360 that clients are wondering what the FDA's stoppage of overseas inspections, which was announced March 10, means for open warning letters, pending product approvals or scheduled inspections.

"Unfortunately, the answer is that all of these are impacted to varying degrees," Hills said.

The expectation, she said, is that agency officials will tackle certain medium- and high-risk issues with desk audits, which involve examining written documents instead of actually visiting manufacturing sites.

"But there will inevitably be a backlog of inspections that will have a lasting impact," Hills said.

Does COVID-19 alter requirements under the Emergency Medical Treatment and Labor Act?

The short answer is no, Foley & Lardner LLP of counsel Alan Einhorn said, while adding that there are "complicated and far-reaching" EMTALA issues depending on the specific situation.

According to Einhorn, if patients show up with COVID-19 symptoms, hospitals and other emergency care providers — including entities without intensive care units — still must fulfill their duties under EMTALA. The law, which also entered the spotlight during the Ebola outbreak of 2014, creates certain obligations for screening and stabilizing patients with urgent medical needs.

Those duties could change if coronavirus infections skyrocket and leave providers operating beyond capacity and unable to secure sufficient staff. In such a scenario, hospitals can shutter their emergency departments "without violating EMTALA if they do not have the capacity and capability to properly screen and treat patients," Einhorn, who is based in Boston, told Law360.

He added that hospitals still must carry out EMTALA obligations for any existing patients, and that if a patient arrives at a closed emergency department, the hospital still must provide screening and stabilizing care if possible.

In yet another scenario, hospitals can create alternate screening sites — either on-campus or off-campus — for COVID-19. But they must ensure that any employees who direct patients to alternate sites are qualified "to recognize individuals who are in obvious need of immediate treatment" in the emergency department, Einhorn said.

How can I get physicians and other practitioners working at a hospital ASAP?

This question is "very relevant for hospitals in ramping up their services" to expand critical care capabilities, Foley & Lardner partner Emily Weber said.

"A pandemic such as COVID-19 does not relieve referral sources from complying with the relevant portions of the Stark and Anti-Kickback statutes," Weber said, explaining that many hospitals are

"creating simple and easy contracts" to ensure compliance with the laws, which police financial conflicts of interest in patient referrals.

The rapid expansion of staffing also implicates privileges that hospitals grant to physicians. Although some states are allowing out-of-state doctors to obtain temporary medical licenses, hospitals "still need to comply with the applicable medical staff requirements for emergency or temporary privileges," said Weber, who is based in Denver.

In the short term, many hospital staffs "will likely have to revise their bylaws now to allow for privileges," Weber said. And in the longer term, many staffs will probably revamp their privilege requirements to "make it easier to get such emergency providers for the next pandemic," she said.

--Editing by Aaron Pelc and Emily Kokoll.