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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

What Health Attys Are Bracing For As Virus Rages Nationwide

By **Jeff Overley**

Law360 (December 4, 2020, 8:45 PM EST) -- The cold-weather wave of COVID-19 cases crashing over America will be a defining moment for health care attorneys, who are scrambling to shore up hospital workforces and navigate two presidential administrations' pandemic plans.

With COVID-19 infections, deaths and hospitalizations at record highs and pivotal decisions looming for vaccine approvals and allocations, Law360 asked attorneys for hospitals, drugmakers and other health care companies to discuss the top issues they're watching as the pandemic appears poised to enter one of its most harrowing chapters.

"This is a critical time in the evolution of the coronavirus pandemic," Veleka Peeples-Dyer, chair of the U.S. Food and Drug Administration group at Baker McKenzie, told Law360.

Some of the issues are unwelcome throwbacks to March, when Law360 interviewed attorneys about their clients' biggest questions at the pandemic's outset. For instance, hospitals are once again rushing to add beds, and while they have a firmer grasp of their options, they're increasingly beleaguered by staff shortages and burnout.

Other issues are entirely new. Perhaps most prominently, the incoming Biden administration is vowing to adopt a more assertive posture on diagnostic testing, vaccine deployment and "price gouging" for COVID-19 drugs.

There are also fresh compliance concerns surrounding lawful uses of federal relief dollars and billing for COVID-19 tests. Although many compliance risks have been recognized since the spring, lawyers say that legal pitfalls are mounting along with the explosive growth of spending and testing.

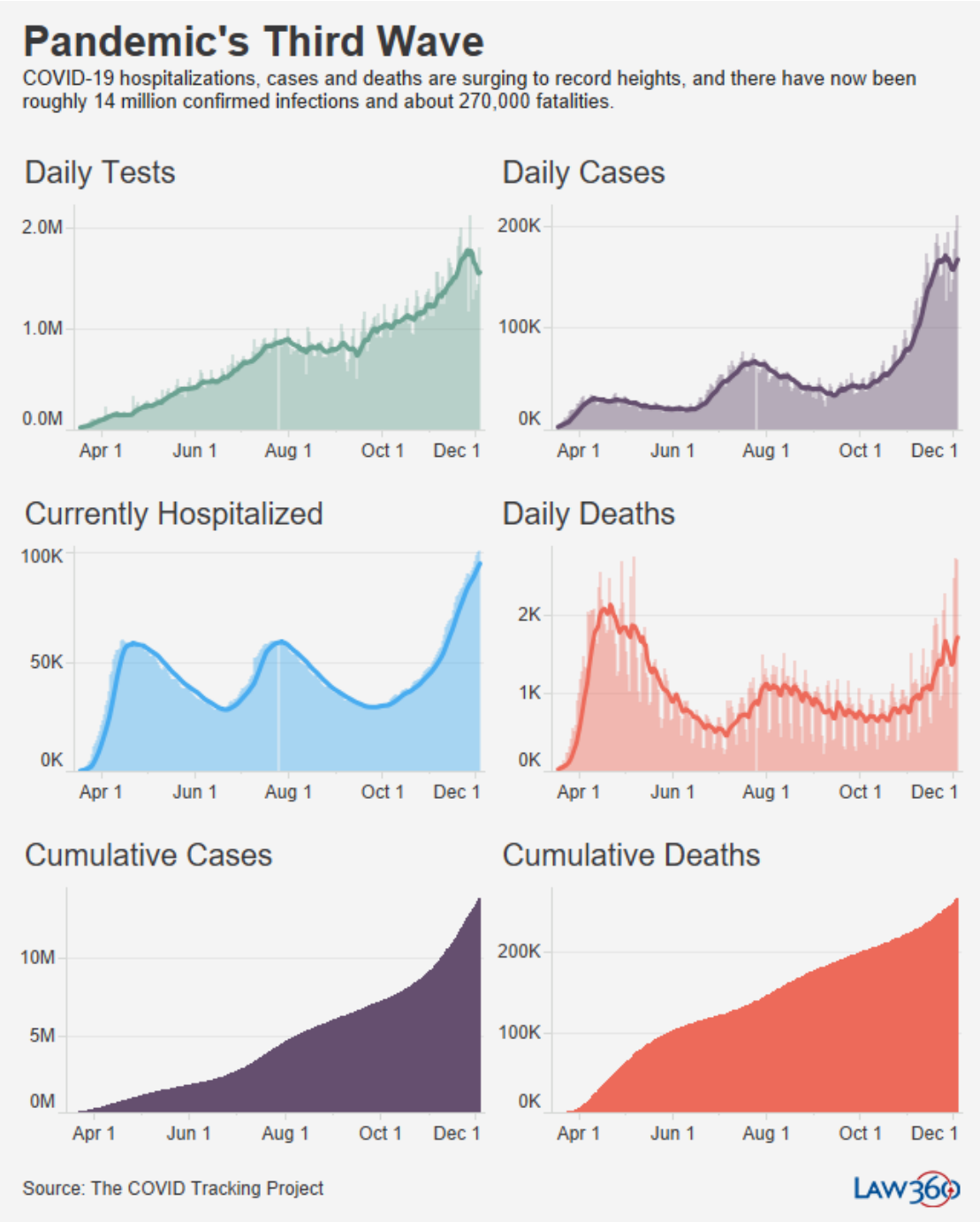
Here, Law360 explores several key issues that health care lawyers are steeling themselves for in the coming weeks and months.

Health Systems Face 'Most Difficult Time'

About 100,000 Americans are currently hospitalized with COVID-19, up from earlier peaks of roughly 60,000 in April and July, according to the COVID Tracking Project.

"We are continuing to see a concerning increase in the pressure on the health care delivery system

across hospital systems and other providers," Elizabeth Bock, Los Angeles-based counsel at O'Melveny & Myers LLP, told Law360.



The nation's health system as a whole still has some free space — about 70% of hospital inpatient beds and 60% of intensive care beds are occupied, according to the U.S. Department of Health and Human Services.

But some regions, including parts of the Midwest and the South, are more strained than others. And public health officials are warning that mounting pressure on the health care system will soon have hospitals bursting at the seams.

"The reality is, December and January and February are going to be rough times," Robert Redfield, director of the Centers for Disease Control and Prevention, said Wednesday at a U.S. Chamber of Commerce Foundation event. "I actually believe they're going to be the most difficult time in the public health history of this nation, largely because of the stress that it's going to put on our health care system."

It's a situation that Redfield and other health officials have publicly dreaded for many months. One concern has been **a** one-two punch of COVID-19 and the seasonal flu. But the 2020 flu season was remarkably mild during the Southern Hemisphere's fall and winter, and it's possible that the Northern Hemisphere could experience the same.

"Flu activity is unusually low at this time but may increase in the coming months," the CDC's latest Influenza Surveillance Report said in late November.

Regardless, it's expected that COVID-19 hospitalizations will rise as the mercury drops and Americans seek warmth indoors, where the virus spreads more easily.

That may already be one factor in the recent spike of infections — per capita cases have been climbing faster in chillier states than on the nation's relatively temperate coasts, according to data from Johns Hopkins University. Similarly, the Sun Belt saw a summer surge of infections as residents gathered in air-conditioned settings.

To boost hospital capacity, HHS in late November expanded its Hospitals Without Walls program to allow at-home inpatient care and wider use of outpatient surgery centers as temporary hospitals. In addition, hospitals are once again looking to squeeze extra beds onto their campuses, build surge-treatment centers and send patients to other nontraditional venues, which under special HHS leeway can include hotels, homes and college dorms.

"Hospitals and health systems that had shuttered alternate care sites or mothballed plans to construct them are pivoting back to those plans," Sandra DiVarco, a McDermott Will & Emery LLP partner in Chicago, told Law360.

Hospitals Fear 'Widespread Staffing Shortages'

COVID-19 patients don't just need places to get treatment — they also need health care practitioners who can deliver it. For much of the pandemic, hospitals in hot spot cities have recruited physicians and travel nurses from other locales to help address coronavirus surges.

But with infections now growing astronomically across much of the country, observers increasingly fear that there simply won't be enough caregivers to go around. That fear is especially acute in less-wealthy areas, given that health care staffing agencies began hiking their rates months ago in response to soaring demand.

"Because the number of medical personnel is finite, individuals who can travel are more likely to take opportunities with hospitals and in cities that can absorb the higher rates," O'Melveny's Bock said. "This will lead to staffing shortages throughout the country and particularly in rural areas."

Any shortages could be exacerbated by a depletion of the regular health care workforce. The U.S. is averaging about 170,000 new infections each day, making it likelier that doctors and nurses will

themselves test positive or be forced to isolate because of close contact with someone who's infected.

Attorneys say there's also growing burnout among workers who've been on the pandemic's front lines for nearly nine months while also dealing with stresses such as loneliness and the need to manage remote education for children.

"Even if hospitals are able to find innovative ways to use and maximize space to care for patients during a surge, they may not be able to provide sufficient staff to care for patients in those spaces," DiVarco said.

In a Wednesday letter, American Hospital Association CEO Rick Pollack urged HHS to expand a waiver of physician supervision requirements so that nurse practitioners can "help mitigate widespread staffing shortages across the country."

Pollack also requested deployment of U.S. Department of Defense doctors and nurses to hard-hit hospitals, as well as government support for training to help "underutilized health care workers" and administrative staff take on more duties in the pandemic response.

Yet another tool for maximizing COVID-19 capacity is for elective, or nonemergency, procedures to be canceled, which happened earlier in the pandemic at a massive scale. Pollack's letter mentioned that cancellations are again occurring, but hospitals are reluctant to do so because the procedures are crucial revenue sources and often vital to patient well-being.

"As we go into what is likely a third surge, many anticipate some return to the measures that we saw in the spring," Meena Datta, a Sidley Austin LLP partner in Chicago, told Law360. "But some of us also anticipate modifications to those measures, maybe seeing things that are a bit not as strict as what we saw in March and April."

Biden Poised to Shake Up Pandemic Response

The race to develop coronavirus vaccines — a lightning-fast campaign with few parallels in scientific history — will reach climactic points on Dec. 10 and 17 when an FDA advisory panel reviews inoculations created by Pfizer Inc. and Moderna Inc., respectively.

If, as expected, the panel recommends emergency use authorization and the FDA quickly accepts the advice, Pfizer and Moderna say they'll start shipments right away. As doses reach large portions of the population in ensuing months, the vaccines will probably chip away at sales of tests and therapeutics.

"Once a vaccine is launched, the demand for diagnostics and treatments will start to wane," Oren Livne, a Baker McKenzie partner in New York, told Law360.

In another near-term shift, the incoming administration is expected to overhaul the federal COVID-19 response. President-elect Joe Biden's seven-point pandemic plan pledges to seek $25 billion for vaccine production and distribution, invest more in at-home and instant tests, and ensure that "consumers are not price-gouged [for] new drugs and therapies." Newly proposed pandemic relief legislation, if enacted, could also address some of those goals.

The White House has tremendous power to decide how personal protective equipment, medications and vaccines are purchased and deployed. President Donald Trump has overseen billions of dollars in

COVID-19 contracts with drug companies, and he has leaned on the Defense Production Act to ramp up manufacturing of ventilators and N95 respirators.

Biden is promising even more spending and more aggressive use of the DPA to intervene in product allocation. An executive branch with a new approach and new leadership will force lawyers for medical device and drug companies to quickly adapt.

"The shift to a new administration means there will be new policy directions and new faces across the virtual table with whom to negotiate," Livne said. "The manner in which the federal government will intervene therefore becomes all the more unclear."

How the incoming administration chooses to utilize limited FDA resources will also shape the fortunes of drug and device corporations — something that can be seen already as the agency struggles to manage a gigantic pile of coronavirus-related approval applications.

Bethany J. Hills, a New York-based partner at Morrison & Foerster LLP, told Law360 that the agency is prioritizing emergency use authorizations for certain products — such as rapid coronavirus tests, vaccines and therapeutics — and "giving less attention to others," including mask decontamination units. FDA staffers also aren't even reviewing preliminary packages of information about EUA requests until they're virtually complete, she said.

"FDA is imposing necessary procedural limitations," Hills said. "They are totally overwhelmed with a huge volume of EUA-related submissions and [are] under-resourced, so in my view it is necessary, as they are trying to get control of the situation."

Compliance Duties Becoming 'Far Less Clear'

A number of health care lawyers also told Law360 that there's mounting confusion about appropriate uses of $175 billion in Provider Relief Fund money, which Congress approved early in the pandemic for COVID-19 expenses and lost revenue from canceled elective procedures.

That confusion could prove highly consequential. For one thing, attorneys have been predicting anti-fraud enforcement ever since the Provider Relief Fund started sending out greenbacks. In addition, HHS on Friday announced a False Claims Act Working Group to scrutinize pandemic spending, and it singled out the Provider Relief Fund in vowing to "focus resources on those bad actors who seek to defraud HHS' programs."

Ramana Rameswaran, a Katten Muchin Rosenman LLP associate in Washington, D.C., told Law360 that the Provider Relief Fund's compliance guidance "is far less clear today than it was in spring 2020 when HHS announced the details of the program."

According to Rameswaran, an FAQ guidance document "has morphed into an unwieldy 50-plus pages" — five times its original size — and "in the past two months, there have been significant changes that have sowed confusion" about whether a provider's COVID-19 expenses and lost revenue allow funds to be retained.

Sidley Austin's Datta offered a similar take, saying that while FAQs can be helpful, "the fact that there are these FAQs with all these questions is a reflection of just how complicated it is to know when you're doing the right thing."

Datta suggested that the government could create a compliance road map akin to the compliance guides that HHS' Office of Inspector General periodically develops. The U.S. Department of Justice in recent years has emphasized that robust compliance programs can help companies show that instances of improper billing were innocent mistakes, and Datta said that a Provider Relief Fund compliance guide could give companies a similar opportunity.

"The fact that you've got that type of [compliance] program in place is absolutely strong evidence that there was not a scheme to misuse the funds," she said.

On a separate front, Hills told Law360 that she increasingly foresees serious scrutiny of the vast and varied marketplace of COVID-19 tests. That marketplace emerged quickly and continues to grow, and many tests that grabbed headlines with bold claims about speed and accuracy were eventually found to be overhyped.

"This is the area that I worry about the most for the future," Hills said. "We expect that in a few years we will start seeing significant enforcement actions looking into how the COVID tests were advertised, how results were delivered, how much was charged and paid, and how accurate the tests actually were."

--Editing by Alanna Weissman and Breda Lund.