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ALERT

Health Care Practice

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Key Health Care Legal and Business Issues in the Transitional/Post-COVID-19 World

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INTRODUCTION

The health care world – in fact, THE WORLD – has changed significantly since March with the onset of COVID-19. As we collectively work to return to a "new normal," the health care delivery system will be one of the key industries that will and must adapt to survive. Below, our health care lawyers and lawyers who are members of our COVID-19 Task Force share predictions about the future in the new COVID-19 environment and the legal and business issues that will need to be addressed.

Predictions for Post-COVID Telehealth Regulation

Samantha R. Gross

Prior to the COVID-19 pandemic, the implementation of health care services via telehealth in the United States was slow and incremental, with states taking a myriad of approaches to regulating these services. The pandemic has made it significantly more difficult to provide health care services in person, and many jurisdictions are requiring services be provided via telehealth (where appropriate) as part of efforts to reduce the spread of COVID-19. As a result, this previously underutilized resource in health care has been adopted in some capacity in nearly every state. While many changes are temporary, we may see long-lasting regulatory changes that encourage telehealth.

During the pandemic, the Office for Civil Rights at the U.S. Department of Health and Human Services announced it was exercising enforcement discretion for providers delivering services through telehealth without complying with all Health Insurance Portability and Accountability Act (HIPAA) requirements. This relaxation of enforcement is temporary – lasting only for the duration of the pandemic – and HIPAA enforcement will likely return to normal thereafter. While restrictions have been eased, many telehealth platforms have entered the market and health care providers have adopted new telehealth processes for their patients. After the pandemic, providers and telehealth vendors must ensure they are exchanging data in a secure manner that complies with HIPAA rules.

Many states have temporarily modified practitioner licensure rules to allow providers to practice across state lines during the pandemic and to allow out-of-state licensed practitioners to practice without in-state licensure. In addition, HHS waived the Medicare billing requirement that out-of-state licensed providers be licensed in the state where they are providing services. While these measures are temporary, they are intended to increase access to telehealth services. Post-pandemic we are likely to see increased practitioner demand for more flexible and portable licensure rules with regard to telehealth. Some states have opened up the possibility of greater flexibility, including Pennsylvania that passed a law allowing the Commonwealth to join the Psychology Interjurisdictional Company, which allows psychology services to be provided across state lines. Other states may take similar measures to allow for increased telehealth services in the future. Providers and entities providing telehealth should closely monitor licensure rules and regulations as to ensure they remain in compliance.

COVID-19 has dramatically affected how health care providers provide care to their patients and has led to increased use of telehealth services nationwide. As restrictions ease, providers must ensure they remain compliant with changing telehealth statutes and regulations.

Could COVID-19 Serve as the Impetus to Decrease Violence to Health Care Workers?

Harriet E. Cooperman

Every day, hospital employees are proving through their selfless, tireless and dedicated work that they are the true heroes in our war against the COVID-19 pandemic. Yet for decades, hospital workers have been the victims of another very serious ailment in our society—workplace violence. In fact, workplace violence is at epidemic levels in U.S. hospitals. According to the Occupational Safety and Health Administration (OSHA), violence-related injuries to health care workers account for almost as many similar injuries sustained by workers in all other industries combined. A 2018 study published by the Joint Commission found that 75 percent of nearly 25,000 workplace assaults occur annually in health care settings. OSHA reported that in 2019, 13 percent of nurses missed work days are due to workplace violence. While there are various perpetrators of violence in hospitals, violence committed by patients, their families, or their friends is the most prevalent cause of violence against health care workers. Phillips J. Workplace Violence Against Health Care Workers in the United States. New England Journal of Medicine, 2016.

During the COVID-19 pandemic, many hospitals eliminated virtually all patient visitors. Now, hospitals are seeing a drastic reduction in the number of violent incidents since the implementation of these restrictions. Nursing leaders are finding these lower numbers quite significant even after factoring in the hospitals' lower occupancy rates and relatively large percentage of COVID-19 patients. So what does this mean for the future? Once the pandemic subsides and hospital begin to return to "normal," they may not simply flick the switch and do everything as they did before. Hospitals may critically review their visitation policies and impose limits on the number of visitors per patient at any given time and reduce visiting hours, as well as institute other restrictions on hospital visitors and access into and within the facilities. If such measures correlate with a reduction in workplace violence incidents, they very well may become the new normal.

Boost for Interstate Licensing Legislation for Health Care Professionals

Joe R. Ourth

Moving from one state to another often means that physicians, nurses, dentists and other health care professionals must obtain new state licenses to practice their profession. In Illinois, for example, nurses could expect to wait weeks if not a month to obtain their Illinois license. For physicians, it was not uncommon for the process to take several months. Yet, with the onset of COVID-19 and the concern about a medical surge, Illinois and many other states implemented through emergency powers an expedited licensure process. Out-of-state nurses could get approval in as little as 48 hours, with physicians only slightly longer.

There has long been criticism of the cumbersome state-by-state process for professional licensing. In response to this problem, many states have adopted the Enhanced Nurse Licensure Compact (eNLC). Under this compact, states that had adopted an agreement whereby nurses that meet the agreed upon criteria of the compact can practice in other compact states. A large majority of states have adopted the compact, with notable exceptions being the Northeast, Upper Midwest and East Coast regions of the nation. See the map here.

Ironically, Governors in states without eNLC were among the first to issue Executive Orders waiving licensure requirements not only for nurses, but for many other health care professionals. Legislation to adopt the Nursing Compact has stalled in recent years in these states. Once a state has opened its borders to out-of-state licensing, with few reported problems, there will be momentum for states to adopt the Enhanced Nursing Licensure Compact and move towards opening its licensing process for other professions.

Deal or No Deal: The Implication of COVID-19 on Deal Terms

Jourdan S. Garvey and Matthew S. Draper

As COVID-19 continues to change our world and financial markets in unprecedented ways, it is important to remain mindful of the implications COVID-19 may have on M&A transactions. While the status of many M&A transactions – both those already signed, and those being negotiated – is a bit unclear, discussion surrounding certain trending deal terms can lead us to better understand developments in the deal world.

Purchase Price

Uncertainty surrounding COVID-19 may lead buyers to ask for renegotiation/lowering of the agreed upon purchase price of a target company. As purchase price is typically tied to a target business' valuation, and market uncertainty can lead to negative future performance projections, a buyer may take this as an opportunity to argue that the target company's valuation will be negatively impacted by the pandemic, resulting in a lower purchase price. Consequently, buyers may seek to negotiate to hold back a certain

portion of the purchase price, lower the purchase price, or negotiate a favorable purchase price adjustment clause. Standard methods to bridge gaps in valuation – such as earnouts or other means of contingent consideration – may become more typical, especially in sectors (such as health care-related industries) in which valuations have been hit hard by the pandemic. This trend is projected to outlast COVID-19's presence, as business and market normalization occurs.

Operating Covenants

Buyers may request that a seller incorporate additional interim operating covenants into an acquisition agreement to address implications of COVID-19. These operating covenants may require continuation of "ordinary course" operations, or obligate a seller to provide frequent compliance reporting against changing governmental or agency laws and orders. Sellers are cautioned against agreeing to blanket "ordinary course" covenants, as many actions being taken by health care providers in the current environment are necessitated by the pandemic, and may be, in fact, anything but "ordinary course."

Closing Conditions

Buyers weary of the future of COVID-19 may condition the closing of an M&A transaction on certain conditions that may be triggered by the worsening, or resurgence, of COVID-19. Buyers and sellers will undoubtedly negotiate "pandemic" and "COVID-19" exceptions/inclusions into "Material Adverse Change" conditions in an acquisition agreement. Parties should strive for clarity regarding a buyer's "walk rights" from a transaction due to a worsening of the COVID-19 pandemic – negotiating clear and concise closing conditions/termination rights provide the parties with certainty regarding transactional risk, and the likelihood of a closing occurring. Additional COVID-19-specific closing conditions are likely to be inserted into agreements, relating to business operations, revenue concerns and, specifically in the health care industry, a large population of employees or patients contracting COVID-19.

Cannabis in the Age of COVID-19: Lessons Learned and What Lies Ahead

Lauren A. Farruggia, Adam Fayne, and Jonathan A. Havens

The COVID-19 pandemic has impacted and will continue to impact the cannabis industry, including those operating in the hemp, cannabidiol (CBD) and marijuana (both medical and adult-use) spaces.

The U.S. Food and Drug Administration (FDA or the Agency) has already taken action against at least two CBD firms (here and here) for marketing products purporting to treat COVID-19 symptoms. FDA's latest enforcement actions are consistent with its historical approach to CBD enforcement, confirming yet again that the Agency will not permit the marketing of products that bear aggressive disease claims. CBD firms (and others) making COVID-19 claims can expect a Warning Letter from FDA, as the Agency has stated that it is taking "urgent measures" to "protect consumers" by ridding the market of "certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people."

The CBD industry hoped to have more clarity from FDA this year regarding the Agency's intended regulatory treatment of CBD going forward. However, other than a recent March report to Congress—in which the Agency said more research was needed and it would focus on enforcement against bad actors for the time being—little progress has been made in terms of clarifying when or how the FDA will change its regulatory approach. The current pandemic is unlikely to change this, as FDA has internally adjusted its priorities (and, in some instances, staffing) to focus on COVID-19-related efforts. For the time being, it seems that the status quo will continue (i.e., enforcement only if marketers are making very aggressive claims).

As state legislatures scramble to address the urgent health care and economic needs related to the pandemic (while also practicing social distancing), regulations around hemp, CBD and adult-use marijuana could be delayed or put on hold. New York, for instance, initially had plans to fully legalize adult-use cannabis in 2020, but Governor Andrew Cuomo stated recently that legalization this year is unlikely due to COVID-19. Similarly, states such as Illinois have put on hold the issuance of additional adult-use dispensary licenses due to the state's inability to properly review and score applications. We expect the pandemic could have a chilling effect on other states' adult-use cannabis program rollouts, as well, although we note that many state stay-at-home orders have designated medical marijuana businesses as "essential," meaning that they can remain open. In fact, demand for medical cannabis has spiked in recent weeks, and some operators have announced strong earnings. Despite challenges facing essential businesses, sales of medical cannabis have certainly increased during the pandemic, a trend that will likely continue.

Finally, while raising capital in the marijuana space could naturally be chilled by COVID-19 priorities, we anticipate that tough economic times could actually spur cannabis merger and acquisition (M&A) activity. As multistate operators focus on core assets and operational efficiency, they could either decide to dispose of underperforming assets, or conversely, use the opportunity to pursue expansion opportunities at attractive price points.

We encourage those interested in staying abreast of the developments in the cannabis law space to subscribe to our Regulatory Roundup blog, sign up for our Cannabis Law e-mail list and connect with our practice leadership on LinkedIn and Twitter.

Reorganization, Restructuring or Bankruptcy? Will One Be Right for You?

Mark Minuti and Jeffrey C. Hampton

The onset of COVID-19 has disrupted, and will continue to disrupt, health care providers and health care-related businesses; exacerbating existing challenges and creating new ones. Even as states ease shut down restrictions and businesses start to reopen, it will be some time before the business of health care returns to "normal." Inevitably, many health care companies may be forced to file for bankruptcy and either attempt to reorganize or use the bankruptcy process to sell assets or lines of business. Health care companies must be proactive now in planning for the "new normal" by correctly assessing their existing lending arrangements, updating and revising projections and taking steps to ensure the continued availability of necessary supplies and services. Right now, health care companies should identify existing or anticipated defaults in their credit facilities and, with the help of their restructuring advisors, begin a dialog with lenders to resolve any issues and align expectations and credit availability with expected performance. Health care companies should take steps to anticipate payor and vendor challenges by, inter alia, reviewing existing contractual arrangements and evaluating vendor viability. While COVID-19 has caused disruption, it has and will also create opportunities to increase services, acquire assets and increase market share, as not all companies will survive the pandemic. Finally, managers and directors of health care companies must recognize that board activities and duties may change if the company is insolvent or in the zone of insolvency.

The Effects of COVID-19 on Real Estate

Igor Pleskov

COVID-19 will dramatically affect health care related real estate. Owners and occupants will need to carefully consider social distancing and guidance from the Centers for Disease Control and Prevention and the local, state and federal government regarding appropriate measures in addressing COVID-19, as they pertain to medical office space. Many spaces will need to be redesigned and waiting rooms may need to be reconfigured entirely. While these trends would suggest a need for more office space, we also expect a counter trend towards more telemedicine and a need for less exam rooms.

Cleaning specifications and other operational standards will need to be revisited to ensure all appropriate measures are taken to protect occupants. Further, building design and base building systems (HVAC, in particular) will need to be considered. We expect the cost of operating expenses to increase as a result. Demand for buildings that can provide a safe and "clean" environment will also see an increase.

The economic ramifications of COVID-19 will continue to have its own effect on commercial real estate. The trends here will likely be similar to trends that apply to the market more generally. Health care institutions have been hit hard financially from the crisis which will, at least in the short-term, slow down existing projects and potential new projects. Similarly, we expect lease modifications and accommodations to continue in an effort to avoid evictions in the short-term. That said, we are hopeful that the health care real estate market will recover more quickly as elective procedures resume and the country reopens.

Health Care Acquisitions: What to Expect

Marshall B. Paul

Health care deals are on hold for the most part. But, as the lyrics of "Goodbye Girl" go, goodbye doesn't (necessarily) mean forever.

Practice acquisitions, mergers, joint ventures and other health care combinations have slowed to a trickle. After all, if you are a buyer, why would you close a deal now if you face the likely prospect of months of future losses? Does that mean, however, that the market for health care acquisitions is gone forever? Probably not. If the economics make sense, the appetite for acquisitions still should be strong when the pandemic finally subsides. This should particularly be true in the case of large practices that have the capacity to deliver (or interest in delivering) telemedicine services and that are looking for a presence in every state in the country, particularly if the present relaxation of telemedicine requirements becomes permanent.

Still, there remain questions. First, the risk of a second surge (or even a third) could permanently devalue practices, given that the risk of loss of future revenues would clearly factor into buyers' discounted cash flow analyses of prospective targets. Secondly, private equity firms that are behind many acquisitions may not have the same level of available cash to fund deals if they are presently

deploying their resources to prop up existing practices in their portfolios that are losing money because of the reduction of elective appointments and procedures due to the pandemic.

The Tale of Tax Relief

Richard T. Frazier

In the aftermath of the COVIC-19 pandemic, many health care providers will be assessing and planning the best ways to use the tax laws to lessen the impact on their businesses of the devastation that has befallen them in the months when they could not run normal operations. Whether they took money from the Payroll Protection Program ("PPP") or took advantage of the Employee Retention Credits, they will need to make their certifications in order to have their loans forgiven or they will be filing claims for the refundable tax credit. In either case, those two items will provide some help in their recovery. As of this writing, if they did take PPP but want to switch to the Retention Credit, they may do so by repaying the PPP loan by May 18, 2020. We still do not know if Congress will treat the expense items that they paid with the PPP loans as deductible for income tax purposes, but, in any case, there is a net benefit of utilizing the PPP loan or the Retention Credit. Not to be overlooked, there are also the following tax provisions providing additional help: FFRCA Refundable Tax Credits for Emergency Sick Leave and Expanded Medical Sick Leave; Payroll Tax Deferral; Net Operating Loss carryback and carryforward changes, suspending Excess Business Loss limitation of noncorporate taxpayers, Expanded Deductibility of Business Interest Expense, and Acceleration of AMT credit carryforwards. All of these provisions will help businesses keep or recoup some of the funds that they lost during the pandemic, and Congress may provide even more relief in the weeks or months ahead.

Antitrust Issues Magnified by COVID-19

Michael A. Finio

Antitrust concerns in the COVID-19 world will rise to the surface from one fairly obvious set of circumstances: the opportunity — in fact, more likely — the need, for health care providers, among and between themselves, and with their supply chain vendors, to cooperate and collaborate. Providers and their suppliers are communicating with each other in unprecedented and urgent circumstances, for example, concerning the acquisition and availability of PPE and the investigation of treatment therapies. They also face the need to make difficult employee decisions. These are exactly the kinds of circumstances that create an opportunity to collude or otherwise produce anticompetitive missteps in several ways, including:

- Exchanging competitively sensitive information without proper confidentiality and other safeguards;
- Entering illegal agreements concerning price and the allocation of resources;
- Engaging in collaborative research without using statutory protections which can limit antitrust risk exposure;
- Enforcing non-compete and non-solicitation agreements against furloughed employees, either unilaterally or by agreement with other providers; and
- Being too opportunistic with respect to merger and affiliation possibilities that are bound to arise as providers stumble in the face of financial challenges.

The COVID-19 world does not singularly create these issues — it simply magnifies their presence beyond "normal." Regulators are paying closer attention because of the COVID-19 business environment. Each of these areas is always something that presents antitrust risk. Each is an area where antitrust counsel is important, to make sure that regulatory inquiry does not uncover anticompetitive conduct that could have been avoided, or antitrust risk that could have been minimized.

Managing Compensation and Benefit Costs During and After the COVID-19 Crisis

Dasha G. Brockmeyer & Sally Church

Health care organization are facing many challenges during the COVID-19 crisis. Financial pressures have accumulated as these organizations cancelled many non-emergency and elective procedures and patients who were unable to participate in telehealth visits, were either hesitant or unable to visit doctors in light of stay-at-home orders. The challenges presented by COVID-19 have compounded the existing financial pressures from slim margins and rising operational costs. As compensation and benefit expense is often the largest cost to any employer, many health care organizations have considered and/or have already implemented furloughs and layoffs. Even those employees and professionals crucial to the organization's business, have sometimes experienced pay and benefit reductions. Unfortunately, initial cost-cutting or austerity measures may not be enough.

In response, we anticipate more organizations will seek to make cost reductions by taking some of the following actions:

- Employer contributions to qualified and non-qualified plans may be reduced or suspended. Fiduciary governance is of most importance during this time, as the volatility in the market has significantly impacted performance of retirement plan investments.
- Employers contemplating a reduction in force will reduce severance pay and subsidized benefits previously provided upon termination of employment.
- Subject to the benefit mandates and limitations of the Affordable Care Act, organizations may seek to revise health care and prescription drug benefits to shift more costs to employees; although, in light of the increased need for health care due to COVID-19, it might not be a good time to reduce these benefits.
- Given the restrictions on non-qualified compensation arrangements, including employment contracts, under Internal Revenue Code Sections 409A and 457(f), revising these programs could be difficult and terminating these programs may not provide a good solution since such action may prohibit the adoption of new arrangements for a period of time into the future. To the extent these programs have been designed to be exempt from the non-qualified rules under the Code, as noted above, then we anticipate benefit reductions or plan terminations.

Employers considering changes to any of these programs will need to ensure that the reductions, suspensions or any revisions comply with the Internal Revenue Code, the Employee Retirement Income Security Act, as well as the terms of the applicable plan, employment agreement and any collective bargaining agreements. Employers need to consider how employee communications of any cost-saving measures should be crafted and delivered.

Post-COVID-19 Litigation Warfare

David S. Waxman

COVID-19 will expose the extremes of how health care providers conducted themselves in the pandemic, from the heroic, overwhelming majority who risked their lives, day after day, shift after shift, in dedication to their profession and to their patients, to those few who failed to rise to the challenge of the times. As the nation comes to grips with the devastating toll COVID-19 has and will continue to exact, how the American public views its health care providers and their response to COVID-19 will greatly shape the outcomes of the surge in litigation which will inevitably follow the steadily rising death totals.

HHS, Congress, governors and state legislatures have each attempted to shape the coming liability battles by creating a patchwork of immunity provisions which delineate the two fronts on which COVID-19 malpractice litigation will primarily be waged. With the exception of the absolute immunity provided in Good Samaritan provisions covering medical volunteers, these provisions generally do not eliminate potential liability. Instead, they raise the bar for plaintiffs to establish the commission of gross negligence, a standard historically associated with reckless or intentional conduct and usually seen in matters involving professional discipline or punitive damages. Thus, the first battle will focus on the ability of the plaintiffs' bar to expand the definition of gross negligence to encompass care that, pre-COVID, may have simply been considered by a jury to be a deviation from the standard of care but not be assessed as willful or wanton. Jurors across the country will be called upon to draw that line of demarcation in evaluating the care provided in a pandemic.

The second front of litigation warfare will focus on the requirement contained in some, but not all, of the immunity provisions that the alleged malpractice occurred in the course of providing COVID-19-related care. Does this require that the patient at issue carried, or should have carried, the diagnosis of COVID-19? If a patient with signs and symptoms of an acute stroke enters an ER swamped with COVID-19 patients and is not tended to until the window for tPA administration has effectively shut, is the restriction on treatment modalities offered in that instance COVID-19-related? It is conceivable that both judges and juries will have a say in delineating the scope of care considered COVID-19-related and therefore afforded greater protection.

Currently, it is nearly impossible to read or watch a news outlet without being offered another example of the personal heroism of those providing care in hospitals. In fact, many companies selling their wares have redirected their advertising to share in the goodwill enjoyed by Emergency Department and ICU providers. The same cannot be said, however, for nursing homes and their employees. While hospitals are widely associated with fighting the pandemic, nursing homes, routinely described as potential "hotspots," are sometimes associated with contributing to the pandemic. It should be anticipated that nursing homes will face continued scrutiny of their staffing practices, of their provision of protective gear for their employees, and of the care provided to their vulnerable residents. While this may result in government investigations and administrative actions, it will also play out in courtrooms across the country. Nursing homes will be called upon to defend the care given to their residents during a time when congregate living carried highly elevated levels of risk. These malpractice cases, unlike those directed against hospitals, may not begin with the defendants enjoying the benefit of the public's goodwill.

Too Big to Fail or Too Small to Succeed – or Is It the Other Way Around?

Bruce D. Armon

The COVID-19 crisis has dramatically altered the fundamentals of the health care delivery system for providers. Even with billions of dollars being given to help subsidize providers, the absence of elective surgeries and a steep decline in office visits – even with the use of expanded telehealth which is likely here to stay – has laid bare the perilous financial situation of many hospitals and medical practices. As the country and individual regions adjust to the realities of a new "normal", hospitals and medical practices will likely need to reevaluate their standing in their respective communities and ask themselves: is bigger better? Can I maintain viability by keeping the status quo? Do I need to expand or contract geographically? Or expand or contract service lines? Should my "core focus" be changed? What can our institution afford to do? Do we bring back all or some of the individuals who were terminated and or furloughed? Can I expect to receive any additional federal and or state assistance? Can I refinance existing debt? Will I be able to borrow new money given my current fiscal situation?

The good news for providers is that there is no "right" or "wrong" answer. And that is also the bad news. As is often the case, it is likely that providers who have more cash on hand and less debt will be more able to adjust to this economic upheaval. There will be opportunity for experimentation and failure. Stand-alone community hospitals – to the extent they remain – will likely need to find a larger partner, look for strategic alliances and/or streamline the services they offer. For profit hospitals with less than ideal balance sheets or investors looking for return on investment may have to shed underperforming hospitals. Hospitals may look to acquire strategic independent medical practices and terminate relationships with underperforming employed providers. Small medical practices may try and hunker down and survive in the new normal. Or they may look to join with other similar or complementary specialties and create their own version of mini super-groups, or look to strengthen a relationship with a local hospital. It would not be a surprise if more providers looked to partner with payors in creative arrangements to measure and reward quality outcomes. And payors who look to create preferred provider relationships with providers – hospitals and medical practices – to ensure adequate provider choices for their beneficiaries. Similarly, hospitals may look to create a payor affiliate and payors may look to create a provider affiliate, each so they can better control expenses and manage utilization.

Only one thing is certain: the next 18 to 24 months will likely result in substantive and significant changes – good and bad – for hospitals and physicians as a result of the COVID-19 pandemic.

CONCLUSION

As your organization considers next steps for reopening or expanding current operations, please reach out to the Saul Ewing Arnstein & Lehr attorney with whom you regularly work or one of the authors of this alert to better understand how we can be of assistance and help you and your organization proactively adjust to our society's new COVID-19 environment.