Seyfarth

The Future of Health Care in the US

What a Post-Pandemic Health Care System Could Look Like

Second Edition

Seyfarth Shaw LLP

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INTRODUCTION

Last year, in June 2020, we published the first edition of this treatise asking: "When will things return to normal?" At the time, we expected the COVID-19 pandemic would have subsided before we published this, our second edition. More than a year later, it is clear the answer to the question is "Not yet." While we find ourselves still somewhere in the middle of the pandemic with continuing infections and deaths, much has happened that offers hope and reflects significant progress in the battle against this deadly virus. We have a new Administration and four different vaccines that are being deployed at an amazing rate, with the numbers of those vaccinated in the millions. The federal government has taken aggressive steps to address the problems of a year ago—increased PPE, credible CDC guidance and, most importantly, the American Rescue Act, which authorizes $1.9 trillion in spending across a variety of programs, some of which we analyze here. We have also observed a dramatic disparity in the impact of the virus on ethnic groups and persons of color, reflecting the effects of systemic racism on health.

Given these developments, and with the expectation of continued population health improvements with vaccination and treatment, we felt that it was appropriate to revisit last year's analysis, test our predictions, and revise them as best we can. Our analysis and predictions are predicated on information that is current as of Thursday, September 2, 2021; as new programs, rulemaking, and legislative actions evolve, we will continue to update our analyses. We can now say that our experiences, accrued knowledge, and insights over the past 12 months will provide an important window into the next phase of our "new normal." Furthermore, we believe that there is still room and time for effective action. Our orienting principle in the first edition was "the future is a function of our choices"—we believe this remains true. As the pandemic and its ravages have migrated from city to city and region to region, with new variants appearing, health care providers and systems have been tested and tried like never before. While additional waves (and troughs) may be anticipated before the pandemic is finally conquered, the providers and systems that have weathered the storm best have been those that were the most nimble and adaptable. In the face of economic disruptions such as the pandemic, an organization's response may be usefully subdivided into three periods: (1) pre-crisis (preparation or lack thereof for an upcoming crisis), (2) the crisis itself (applying lessons learned and implementing preparations), and (3) post-crisis (analyzing and learning lessons to apply to the next crisis). Failure to situate the organization properly within these three stages, take the proper steps in sequence, or promptly transition from one stage to the next can hinder or sink an organization.

As Obama White House Chief of Staff and former Chicago Mayor Rahm Emanuel once infamously said of the 2008 global financial crisis, "You never want a serious crisis to go to waste. And what I mean by that [is] it's an opportunity to do things that you think you could not before." Many would assert that a return to normal as we knew it would be just that—a crisis gone to waste. We are compelled to also assert that we believe that the term "normal" must now be defined by our current state of affairs and that it is no longer the "normal" that existed prior to the start of the pandemic. What we intend to do in this edition of our treatise

is to both point out a possible future and an improvement on the old “normal” resulting from the lessons learned by health care providers and others who have lived through this past year during the pandemic. We continue our focus on the health care industry, particularly the professionals, providers, and facilities that have been at the epicenter of the response to the coronavirus pandemic. This industry continues to be at the front lines of fighting the disease and can do so with new technology, treatments and, finally, vaccination.

Some chapters from the previous edition have been significantly revised and updated in the wake of new developments in business and the regulatory landscape. Other chapters introduce new information and deal with aspects of the industry which we did not include in the prior edition. We hope that readers will find our analyses and predictions of use to their organizations. Many of our previous predictions were on target and offer to you these for the upcoming year.

CHAPTER 1:
THE EVOLUTION OF PHYSICIAN AND HEALTH PROFESSIONAL REGULATION FOLLOWING COVID-19

By Sheryl Tatar Dacso

In 2020, in response to the COVID-19 crisis, federal and state governments in the United States issued an unprecedented array of temporary regulation waivers and new rules. These were aimed at bolstering the nation's health care system by providing maximum flexibility for health care facilities and providers to respond to the pandemic. These temporary actions were also intended to address several important public health goals while enabling providers to continue to care for their patients during a viral pandemic. Initial efforts focused on securing the health care workforce by removing barriers for licensed professionals coming from other states; increasing use of remote technology such as telehealth to ensure patients had access to physicians and other clinicians while keeping patients safe at home; and adding a number of other measures intended to reduce the "transaction friction" of a fee-for-service health system.[1]

Now, sitting in 2021, we have entered a new phase as new COVID-19 strains continue to spread around the globe. As a result of the rapid deployment of several effective vaccines, by the time we publish this chapter, more than 50% of the US population has been vaccinated, with the numbers slowly increasing. States are slowly reopening and the Centers for Disease Control and Prevention (CDC) has issued new public health guidelines that reflect the positive response of vaccinations. With a new Administration, much has changed, as well. For example the Administration successfully passed the American Rescue Plan Act (ARPA) [2]. In this chapter, we will address the effect several provisions in the ARPA have on the regulation of health care practitioners. ARPA extends unemployment insurance benefits and provides direct $1,400 stimulus payments to qualifying Americans, but it also makes several important health policy-related changes. These include, among others, providing funding for vaccine distribution and testing to combat the COVID-19 pandemic, making policy adjustments to the Medicaid program, facilitating health insurance coverage, and providing more money to health care providers.

We believe that the direct and indirect infusion of funds into the health care system will be a "shot in the arm" for providers. The return of the CDC's focus on science-based public health guidance normalizes an important aspect of health care delivery on which practitioners rely. We also believe many, but not all, of the waivers will remain in some form or other. These waivers and new rules during the early stages of the pandemic rapidly and radically changed how care was delivered during the pandemic. What was normal in 2019 changed dramatically in 2020. It must be viewed as fluid and will continue to change into and after 2021 as science develops new means of testing, treatment, and prevention of an ever-evolving virus. For the health care industry (and many others), there is no returning to the normal that was 2019. Rather, the industry must now focus on being able to stay ahead of disease, improving the public's health, and utilizing new tools for treatment and prevention. These tools will impact how practitioners deliver services, engage

in clinical practice and get paid for services, staff clinics, and interact with patients. In the previous version of this chapter, we addressed the areas of clinical practice that we believed would be most affected by the public health emergency. With the enactment of ARPA and a pending infrastructure bill being submitted to Congress as of the time of writing this chapter, we can only speculate on the future state of health care. Defining what is normal will be based on appropriate clinical standards and guidelines—a work in progress. As we have seen most recently with the Delta variant, we can expect the virus to mutate into new strains, some more virulent than others. We can also expect new types of viruses to appear, which is why there are so many resources being directed to vaccinating the population, reopening the schools, and returning to business.

Finally, the COVID-19 pandemic has revealed serious health disparities related to the US population's health, based on income and race. Some of the policies laid out in ARPA are intended to address these through funding and rulemaking, but more targeted legislation will be needed.

This chapter addresses several important areas for health care delivery during this time of intervention and transition:

- What will be the role of digital health technology on the future of health care delivery?
- How will the ARPA and future funding initiatives affect physicians? How will the proposed infrastructure bill help address physician needs in the event of the next pandemic?
- Will states continue to allow practitioners from one state to engage with patients in another?
- How has COVID-19 affected the relationship of the physician and the patient?
- How will the increase in remote health care delivery affect the manner in which physicians bill and get paid?
- How has the pandemic affected third party payors and what has been their role in responding to the public health emergency?

The Role of Digital Health Technology on the Future of Health Care Delivery

The use of technology to provide health care services remotely has never been more important than during the pandemic. Prior to the pandemic, telehealth (meaning any technology used to provide health care services between a practitioner and patient at different locations) was moving at a deliberate pace. The goal—to expand access to health care outside of the clinical or hospital setting using remote health technology—was progressing slower than many expected or wanted, given the state and availability of technology. This dramatically changed with the COVID-19 pandemic. (For a review of the pre-COVID use of digital health technology, please see our first edition of this publication.)

Before scientists and physicians had the new techniques, vaccines, and medications to prevent and treat patients with COVID-19, remote technology was used to assure continuity of care and to enable clinical interactions while keeping both providers and patients safe. The focus was to relax barriers to patient access to health care.

In 2020, a Summary:

- Medicare telehealth rules expanded to allow more services to beneficiaries so clinicians could take care of patients while mitigating the risk of exposure.
- Clinicians could provide professional services to both existing and *new* patients.
- During the emergency, all beneficiaries across the country could receive Medicare telehealth and other communications via technology-based services regardless of location.
- Patient co-pay could be waived for established patients.
- New services were added as covered telehealth services.

In 2021:

It is expected that the use of telehealth will continue, if not expand. The Centers for Medicare & Medicaid Services (CMS) has added a number of additional covered services to its list of previously approved telehealth services.[3] Many states have extended the emergency measures put in place during early COVID. For a current list of state actions taken during COVID-19, see the March 31, 2021 publication of the Federation of State Medical Boards: https://www.fsmb.org/advocacy/covid-19/.

In February 2021, the Medical Group Management Association (MGMA) polled health care leaders regarding their use of telemedicine with almost two-thirds of respondents expecting it to stay the same or increase compared with one-third of respondents who expected its use to decrease for their organizations.[4]

Under the ARPA, the Public Health Emergency (PHE) rules of 2020 will continue for the use of telehealth in Medicare with assurances from the Department of Health and Human Services (HHS) that providers will be given at least 60 days advance notice of any expiration or plans to terminate. In December of 2020, CMS finalized rules to the Medicare Physician Fee Schedule for calendar year 2021 to add 60 more services to the list of Medicare covered telehealth services.[5]

Trends in how patients utilized telehealth services during 2020 that should be watched over 2021 include the following:

- Behavioral health issues and chronic conditions showed the largest increases in telehealth utilization during the pandemic.

- Emergency room visits associated with mental health conditions (overdoses, violence, etc.) that could have been addressed using telemedicine increased during the pandemic.[6]

- Medical specialists and subspecialists have experienced significant utilization of telehealth over the past year.[7] Other specialists may see opportunities to utilize telehealth for stroke patients.

- Communities with higher poverty rates showed a much lower utilization rate for telemedicine.[8]

Telehealth has become more a necessity than an option. Many patients (including those covered by Medicare) have become accustomed to using laptops, smartphones, and tablets to communicate with their physicians and other practitioners during the pandemic. Although it should not replace a face-to-face assessment/examination, many clinician-patient interactions can take place remotely. The advantages of using telemedicine include convenience to the patient and reduced cost to the provider and, possibly, the payor as well. Disadvantages continue to exist with inconsistent coverage and reimbursement for telehealth services by non-government fully insured or self-funded payors. There are also challenges to managing the quality of patient care and measuring outcomes. Telehealth should never be a substitute for "hands-on" patient care.

Even as COVID-19 comes under some degree of control, it will be very difficult to go back to the previous patchwork quilt of state rules and regulations. We can envision a national telehealth credentialing process similar to that used in the VA system for physicians allowing them to work in any state at a VA facility. We could also see one that allows licensed practitioners to obtain a license or registration in multiple states similar to that available to licensed nurses through its National Council of State Boards of Nursing "credentialing compact." This allows a licensed nurse in good standing in one state the opportunity to be credentialed in another state without a protracted process.

While we believe that telehealth and the utilization of technology to deliver health care services remotely will increase as a share of overall health care delivery, it will likely co-exist side-by-side with traditional in-person delivery. It is not for all medical specialties, as surgeons will still need to perform surgeries and obstetricians deliver babies. However, increased use of robotic surgery may allow surgeons to perform procedures remotely. Regulators, professionals, and practice administrators need to prepare to become more adaptable. The CDC predicts that the COVID-19 pandemic will continue as a recurring disease similar to the flu. While it may no longer be an emergency, practices and professionals will need to be able to quickly adapt their practices for the next new virus using telehealth as a primary delivery method to avoid disruption in care. This requires lowering barriers to practitioners incorporating telehealth in their practices (primarily price and technology) and making sure that IT and security infrastructure are in place and ready to go at the first notice of an approaching emergency.

How does ARPA affect medical providers? What are the portions of the proposed infrastructure bill that will affect providers?

Within the ARPA is a Provider Relief Fund that, as of April 14, 2021, directs substantial resources to the HHS for testing, contact tracing, vaccines, treatment, and supplies, and for developing, expanding, and sustaining the public health system and associated workforce. Specific relief is directed as follows:

- **Operation Warp Speed**. $10 billion was allocated during the Trump administration to vaccine development and has fostered the availability of at least four new vaccines.

- **Rural providers.** $11.1 billion has been allocated to addressing rural health. $8.5 billion is directed as payments to eligible rural Medicare and Medicaid providers (hospitals, clinics, home health, hospice, and long-term care services and supports) for COVID-19-related expenses and lost revenue.

- **Community health centers**. ARPA authorizes $7.6 billion for grants, contracts, and cooperative agreements by HHS for expenses used to distribute/administer COVID-19 vaccines; diagnose, monitor, and mitigate COVID-19 infections; establish mobile testing for vaccinations; and enhance COVID-19 health care services, workforce supply, infrastructure development, community outreach, and education.

- **Graduate medical education**. ARPA appropriates $330 million (to remain available until Sept. 30, 2023) for teaching health centers that operate graduate medical education for the following activities:

    - Establishing new approved graduate medical residency training programs.

    - Increasing the per resident amount.

    - Maintaining filled positions at existing approved graduate medical residency training programs.

    - Expanding existing approved graduated medical residency training programs.

    - Establishing new accredited or expanded primary residency training programs.

- **COVID-19 vaccination and treatment**. Mandates COVID-19 vaccine coverage (including administration and treatment) without cost-sharing for Medicaid and CHIP beneficiaries at 100% of the federal medical assistance percentage (FMAP) rate for Medicaid through the end of the first calendar quarter that begins one year after the PHE ends, or for CHIP through the end of one year after the PHE ends. States may opt to provide this same coverage for the uninsured without cost-sharing and at the enhanced FMAP rate. Providers may not charge patients for vaccinations.

- **Proposed infrastructure plan (American Jobs Plan)**. On March 31, 2021, the Biden Administration unveiled an approximately $2 trillion jobs and infrastructure plan that includes expanding access to long-term care services and other health care-related measures. The proposal, called the American Jobs Plan, targets aging highways and bridges, as well as climate change, the nation's digital infrastructure, and home care. For health care providers, the following is relevant:
    - $18 billion for upgrading veterans' hospitals and clinics.
    - $400 billion to expand access to home- or community-based care for older Americans and disabled people under Medicaid.
    - Boost use of home and community-based services and reduce use of nursing homes and other institutionally based services.

Relaxation of Interstate Licensing Requirements and the Effect on Quality and Standards of Care

We previously identified a number of changes required of health care providers in order to assure continued access to care during a time of restriction in travel and in-person professional care. Among these were the relaxation of such restrictions such as scope of practice, cross-state licensing standards (allowing physicians from other states to practice in a different state without a formal license), and lowering requirements for telehealth consultations. All have traditionally served to protect consumers from those who may misrepresent themselves as licensed professionals or who have been under regulatory scrutiny for quality-based concerns. There are legitimate concerns for consumer protection; however, the basic requirements for any physician by a state licensing board include common factors such as graduation from medical school, passage of a licensure test in a state, and a check of the applicable databases such as the National Practitioner Data Bank.

This process creates a burden on qualified professionals being able to respond in an emergency since each entity (the state boards, the hospitals, health plans, and CMS) requests and requires confirmation of the same primary source information in order to process applications. These traditional requirements are not only inefficient but can lead to shortages of critical personnel, particularly during a public health crisis. Note also the lack, outside of the American College of Graduate Medical Education (ACGME), of any mechanism for coordination or planning for resource and personnel needs across specialties and states. Similar concerns have been raised for credentialing qualified non-physician providers who are perfectly qualified to provider services within the scope of their licenses but who must be supervised by a licensed physician. The recent pandemic has underscored the need to review these practices. The question now is whether the socioeconomic fallout from the public health emergency will lead to an expansion of scopes of practice and loosening of barriers to interstate practices. This extends to not only physician scope of practice, but also expanded scopes of practice for certain non-physician practitioners.

The likely effect moving forward will be a departure from the system of limiting the types of professionals who can provide most health care services to a system of expanding scopes of practice and reducing barriers to interstate telehealth practices. As scopes of practice expand, standards of care requiring supervision and oversight will likely be relaxed. The challenge will be to adjust standards of practice and care based on the changes to the provider/patient interaction. New methods of reimbursement (bundled payments, pay for performance, and similar quality-based reimbursement) will have to be modified to reflect these changes in measurement of performance. There is likely to be a "domino effect" with each modification affecting a component of reimbursement that will need adjustment.

In summary, we believe that the COVID-19 public health emergency has and will continue to impact professional licensing and standards of care by expanding scopes of practice and loosening restrictions against interstate health care practice using telehealth technology, so that there are more types of providers who can provide most patient care services at a lower cost with less physician personal supervision and oversight.

How COVID-19 has Affected Practitioners

The COVID-19 experience has already impacted practitioners financially. We can expect several changes in the wake of the pandemic and with the new Administration. These include (1) bolstering the Affordable Care Act (ACA), (2) accelerating efforts to transform payment policies from fee-for-service to something based on value with a goal of driving lower cost and higher value, and (3) addressing the impact that social conditions affect a person's health. The effects of COVID-19 have resulted in lasting changes to the way many physicians practice medicine.

- **Changes in office-based services.** Although in-person services have gradually increased with vaccinations and a reduction in new cases, it is unlikely that office-based visits will return to pre-pandemic levels. For those physicians who do not utilize telemedicine, there is a distinct disadvantage. Eighty-one percent of the physicians surveyed by the American Medical Association (AMA) in July and August of 2020 reported revenues lower than prior to the pandemic, with an average drop of 32%.[9]

- **Changes in practice policies.** The CDC has published many recommendations for physician office preparedness and response. These have been modified to reflect the vaccinations of most practice office staff and many of their patients. Updated recommendations distinguish between vaccinated and unvaccinated persons in different settings. These are published at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html.

- **Increased use of personal protective equipment**. New safety practices require the continued use of PPE. So long as supplies are difficult to get, smaller practices will have to pay more than larger practices and health systems.

- **Continued consolidation and transformation of medical practice.** We are already seeing an acceleration of practice consolidations, acquisitions, and private-equity participation in physician practice ownership. These practices will be better able to weather and address risk from pandemic-related disruptions, as well as finance the investments needed for the efficient adoption of technology to enable remote patient interactions, such as telehealth. This trend of consolidation has been firmly in place for several years, primarily due to steadily falling reimbursement rates from all payors. We expect that falling reimbursements will continue, and very possibly accelerate, and that payors and institutional providers will continue to limit options for smaller, independent practices to operate "on the grid." For that reason, we can expect some of the primary care practitioners to move towards a "Direct Primary Care" (DPC) model of patient care.[10] Others may adopt a concierge model and focus on more wealthy patients.

It is clear that the pandemic negatively impacted physicians practices in terms of decreased revenue and increased costs. While federal relief programs were helpful to practice survival, few smaller groups have been able to return to pre-pandemic financial health.

COVID-19 and Health Disparities

The COVID-19 pandemic has exposed serious problems in this country related to social and racial injustice at the forefront of its public health emergency. The virus has unequally affected many racial and ethnic minorities as reflected in the disproportionate numbers of cases and deaths. CDC has recognized that conditions in the places we live, learn, work, play, and worship are social determinants that affect a wide range of health risks and outcomes.[11] Factors identified as contributing to the risk include poverty, health care access, living conditions, and food insecurity to name a few. The inequities identified as social determinants of health include:

- **Discrimination.** Discrimination exists in many systems, such as health care, housing, education, criminal justice and finance. Racism can lead to chronic and toxic stress, placing such persons at increased risk of acquiring and experiencing increased morbidity and mortality.

- **Health care access and use.** Some racial and ethnic minority groups experience more barriers to accessing health care—lack of insurance, transportation, child care, or ability to take time off work can make it difficult to see a doctor. Cultural differences and language barriers affect patient-provider interactions and quality. Some historical events (e.g. Tuskegee syphilis study) have resulted in distrust of the system.

- **Occupation.** Many essential workers include minorities and people of color. This places them at higher risk when coupled with the other social determinants.

- **Education, income, and wealth gaps.** Inability of many racial and ethnic minorities to obtain a high-quality education contributes to challenges in getting good jobs, earning a reasonable wage, and often contributes to a cycle of poverty. People in low-paying jobs cannot take off work as easily.

- **Housing.** Many minority groups live in crowded conditions that limit social distancing during an illness, thus increasing the risk of exposure to COVID-19.

Addressing Health Disparities Through Medical-Legal Partnerships[12]

Medical-legal partnerships (MLPs) have been operating in the US for almost 10 years. The MLP can help address the impact of health disparities by incorporating attorneys into the clinical team to address health harming legal issues that interfere with a patient's health. Working collaboratively, the health care provider and the attorney address these issues together and then work as a team to identify and resolve the problem. The provider can screen the patient for health-harming legal factors as part of the medical examination from which an attorney can be consulted. If there is a legal solution to the problem, the attorney can address this as part of the overall solution. COVID has highlighted the impact of social determinants on health resulting from disparities. Where an attorney becomes a part of the health care team, the contributing legal factor can be identified and addressed to enhance the clinician's ability to address and manage a clinical condition. MLPs can operate in hospitals, clinics, and other health care facilities.

Changes to Provider Reimbursement Post-COVID-19, for Providers and Payors

Economic pressures come both from the payors and from the providers. Payors of health care include the government, employers, and insurance companies. With respect to government payors, the inability of the federal government to fund the Medicare program and the underfunding of state Medicaid programs were reaching (or in the opinion of some had already reached) crises levels before the pandemic. The trillions of dollars laid out by the federal government in response to the pandemic and the economic shock to state governments will further reduce the government's ability to fund these health care programs moving forward. These programs will likely respond by reducing coverage and capitalizing on efficiencies in any way they can.

Employers sponsor health care payments through employee benefit plans. These plans are either self-funded or rely on a health insurance policy. The economic downturn that is already impacting many businesses will almost certainly limit employers' ability to fund health care plans—either on their own or with insurance premiums—at traditional levels.

Increase in denied claims. Although the ARPA infused billions of dollars into health care, the effects of distributing funds through traditional reimbursement systems remain unclear. Changes to health care delivery resulting from the increased use of telehealth has created problems for payors whose systems were not yet ready to receive, analyze and pay claims for virtual services. Payor contracts lacked specifics on payment rates and associated billing codes with appropriate modifiers. It is expected that the rate of

denials of claims will escalate despite the federal waivers. As they say, “the devil is in the details.” Some denials are based on missing information, including documentation of a positive COVID test. Others are based on payor system limitations. Many of these denied claims were never appealed in the absence of resources. Staff working at home were unable to manage the processing efficiently.

Economic impact to providers. Changes to the economic model for payment and cost control from the provider perspective will largely be driven by two factors: the significant economic downturn caused by the pandemic and the widespread adoption of telehealth. In many ways these two factors work together although implementing telehealth has a cost.

As noted above, the main payors for health care are government and employers. Despite the recent stimulus payments, it is likely that reimbursement rates will drop and more costs will be shifted to patients as the current system of funding and delivering health care is not sustainable. We must also take into account the fact that many people are losing coverage entirely and will have to look to coverage through the Affordable Care Act and expanded Medicaid programs in states that have chosen to expand.

Telemedicine in its current form provides a partial solution by allowing patients to receive certain types of care at lower rates. Reimbursement for telehealth services vary depending on many factors, such as the type of payor, the location of the patient, and type of facility. For example, a telemedicine visit may be reimbursed at half the rate of an in-person office visit. If utilization of telemedicine stops there, and is simply a means to cut “overhead costs”—less office space, cheaper labor, more patients treated by fewer professionals—then the health care system will not be better, and may in fact be worse than before the pandemic. In this scenario, the benefits of having a personal relationship with a highly skilled professional are sacrificed in order to control costs.

The challenge for providers will be to take the lead in leveraging telehealth as a way to increase access to health care and coordination of care and efficiencies across provider types, both of which can lead to a healthier society that is better equipped to address future pandemics. This type of coordination does not have to mean acquisition or merger. Independent practice associations (IPAs) and other integrated delivery models can appropriately utilize telehealth to achieve these goals.

Effect on payors. According to the Association of Health Insurance Plans (AHIP), payors responded to federal government requests to cooperate with the emergency measure required by the COVID-19 pandemic to assure all Americans had access to prevention, testing and treatment. This include free access to COVID-19 vaccines. Steps taken by payors included:

- Testing and treatment at no cost to patients.
- Waiver of prior authorizations.
- Expanding and covering telehealth services.

- Strengthening provider capacity by waiving patient cost-sharing for telehealth services (including expanded coverage for behavioral health), advance payments for services and other financial assistance.

- Payors began to recognize and address issues affecting vulnerable populations through various forms of support.

With an estimated 3.5 million (and this number continues to grow) workers losing their employer-sponsored and other health plans and filing for unemployment insurance, coupled with and the previous lack of government support for subsidizing the ACA, a number of Americans find themselves without insurance. As a result of the economic impact of COVID, many employers could not continue insurance coverage or keep their employees. Some went out of business.

With the passage of the $1.9 trillion COVID relief package, it is expected that the ACA will be bolstered by premium subsidies that are available on the federal and state exchanges for 2021 and 2022. Expanding eligibility for financial help and forgiving taxpayers who received too much in subsidies will greatly improve access to insurance and coverage for many. Those already enrolled will receive premium tax credits.

Most of the payor concerns will be market-specific based on how employer groups, providers, and local governments deal with COVID-19. Most payor concerns will be associated with the unpredictability of the pandemic and the difficulty in obtaining reliable data from which to quantitatively and qualitatively analyze the costs.

Plans will need access to data including:

- Medical expense trends from the pandemic.

- Future cost models and projections as needed to serve clients (employers, etc.).

- Change in demographic factors such as birth rates.

- Requirements imposed by CMS on provider networks serving Medicare Advantage and other high-risk populations.

According to a study conducted by Deloitte, they predict that the long-term effect on insurance companies will be dependent on classes and mix of business they underwrite, their pricing and reserving, policy wordings, and reinsurance coverages. They predict that there will be a time lag for insurers to be notified of insurance claims, evaluated, and paid. The report states that insurers have begun the process of evaluating their claims reserves in light of COVID-19 and it is expected that this will be ongoing. We look forward to their next report.

Conclusion

The COVID-19 pandemic hit the health care industry like a tsunami. The sudden presence and virulence of the virus left hundreds of thousands of people infected, resulting in many deaths in the beginning. The rapid response of the scientific community enabled testing and eventually vaccinations. However, basic infection control processes like masking, distancing, and avoiding closed or crowded spaces went a long way toward changing the curve. Health care providers and their patients were impacted by hospitals filling up with COVID patients, to the exclusion of others whose conditions were not considered as dire. In the first edition of this article, we discussed the initial effects and attempted to predict certain trends based on the many rules and regulations enacted by federal and state governments (many of which were inconsistent). We now see more consistency, better guidance, and clarity in how care is provided, with some returning to in-person services (some delayed over the past year) as many become vaccinated, leaving a segment of the population declining such protection. What remains to be seen is how legislators and regulators will (or won't) react to these trends to protect physicians or expose them to the full force of the market. Physicians can (and should) be proactive to future viral epidemics by adopting a careful and expansive telemedicine strategy where permitted by law, encouraging and mentoring young physicians in new modalities of virtual care, and promoting responsible practices among physicians and payors.

CHAPTER 2:
A TURNING POINT FOR HOSPITALS AND OTHER FACILITIES

— By Jesse Coleman and William Eck

This chapter includes content published in the first edition of our treatise. We provide it here as a reminder, and include an update at the end of the chapter.

The COVID-19 crisis is a turning point for US health care, and has left many leaders and practitioners with important, unanswered questions about how services are delivered, and how they will adapt and thrive post-COVID-19. These changes raise a number of questions that we will address in this chapter:

- How will hospitals and other acute care settings be impacted in the aftermath of COVID-19?
- What can long-term care facilities expect in a post-COVID-19 world?
- What are state and federal agencies doing to expedite medical peer review and credentialing in the wake of COVID-19?
- What impact might expedited medical peer review and credentialing have on patient care?
- What impact might expedited medical peer review and credentialing have on peer review litigation?
- What is the Public Readiness and Emergency Preparedness Act (PREP Act) and what is its anticipated impact on COVID-19- related litigation against health care facilities?
- How long can we anticipate the PREP Act to impact COVID-19-related litigation?
- What can health facilities do to avail themselves of the PREP Act immunities?
- What will the American health care facilities look like the after the current pandemic crisis?

The Impact on Hospitals and Other Acute Care Settings

Even before COVID-19, the trend for health care providers was to manage their patients and the public's health by identifying and managing the social determinants of health. These include factors such as lack of literacy, transportation, housing, and food security. These factors will only worsen as the economic fallout from the pandemic continues.[13] Millions of Americans are without health insurance and as result, the need for a broader health care safety net increases. The last decade has seen a trend to reduce the total number of hospital beds in the US, especially in community hospitals.[14] Prior to the pandemic the perceived need in health care was a trend from acute care to chronic care provided outside of a hospital setting. Our population's health is made up of a sicker population as a result of behavioral impacts and an aging cohort of Baby Boomers. The current pandemic crisis highlights the challenge of facilities' treating COVID-19

patients with limited facility resources and supplies. Supply chain security for procuring personal protective equipment (PPE) has never been so important.

While hospitals and their ventilator capacity have been rightly prized during the pandemic, and their care personnel rightly lauded in many countries, will intensive acute-care settings face a backlash in a post-COVID-19 world? We believe that the response to COVID-19 may accelerate existing trends to decenter hospitals as organizers of care, pushing patients into lower acuity and lower density settings (which are presumably more difficult settings for viruses to spread). This goes hand-in-hand with potential limitations, originating both in government and with third-party payors, on elective procedures. These limitations may expand as the range of interventions that are truly medically necessary contracts.

One of the key components of the federal government's response to the pandemic crisis was the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which provides funding for hospitals and other health care facilities treating uninsured COVID-19 patients. The Kaiser Family Foundation estimates that the total number of payments for uninsured patients ranges from $13.9 billion to $41.8 billion, approximately 40% of the CARES Act Budget.[15] The CARES Act was supplemented by the Paycheck Protection Program and Health Care Enhancement Act, which increased funding for the Paycheck Protection Program and created a $75 billion Provider Relief Fund.[16] Finally, vaccine funding is substantially increased in the $1.9 trillion American Rescue Plan Act stimulus package passed in March 2021.[17]

It is estimated that pandemic infections will likely occur in several waves over the next year. Therefore, current funding for the uninsured will lead to a higher share of federal funding going to hospitals in states with higher uninsured rates because those states did not expand Medicaid under the Affordable Care Act (ACA). Relatedly, it is likely there will be less funding for hospitals in states that expanded Medicaid since they have lower uninsured rates.[18] This effect may be mitigated by the American Rescue Plan Act's inclusion of incentives for states to expand Medicaid funding.

As a result, it is more than likely the current pandemic will influence states to expand their Medicaid programs to deal with the rising number of uninsured patients. States with expanded Medicaid programs create a wider safety net for the uninsured population. The current federal policy, which reimburses only hospitals for uninsured COVID-19 patients, could encourage uninsured patients to seek care in a hospital instead of in lower-cost settings for outpatient care related to COVID-19, including follow-up care.[19]

Reimbursement trends under the CARES Act reflect increased funding for the uninsured. As a result, a national health care safety net will expand via state Medicaid program expansion. The traditional safety net provider for the medically uninsured has always been Federally Qualified Health Centers (FQHCs). As hospitals adapt to treating more uninsured patients with a greater number of untreated chronic conditions, there will likely be an increase in collaborations between hospitals and safety net providers. FQHCs are

non-profit community clinics serving low income and medically underserved populations. Examples of FQHCs include migrant health centers, community health centers, and FQHC aook-alike clinics. FQHCs enjoy the benefits of enhanced reimbursement under the Medicaid Prospective Payment System (PPS); participation in the federal 340B Drug Price Program; and Federal Tort Claims Act (FTCA) protection for their medical staffs.

Collaboration examples between hospitals and FQHCs include:

- Transferring a hospital clinic to an existing FQHC.
- Creating a new FQHC by the hospital by working with an external community group.
- Establishing a hospital emergency room diversion program with a local FQHC.

Additionally, hospitals can enter into other arrangements with an FQHC, such as:

- Specialist arrangements.
- Resident rotation arrangements.
- Leasing arrangements.
- Referral arrangements.

Specialist arrangements. Hospitals can benefit from specialist arrangements with an FQHC by avoiding costly emergency room visits by the uninsured. Evaluation and management (E&M) visits instead would take place at an FQHC; however, testing and more intensive services which are covered by Medicaid or other payors may still be performed at the hospital.

Resident rotation arrangements. Resident rotation arrangements with an FQHC by having its residents receive hands-on experience in primary care and continue to receive Graduate Medical Education (GME) funding for the time their residents spend at the FQHC.

Value-based arrangements. Population health management will only increase in importance due to COVID-19 and the increase in at-risk patients. Hospitals and FQHCs can work together through value-based arrangements, clinically integrated networks, and accountable care oto manage population health in a post-COVID-19 health care system. The ongoing pandemic health crisis will only expand the health policy trend of value-based reimbursement arrangements. The increased number of medically uninsured patients will heighten the need to shift care from expensive settings in hospitals to less expensive settings, such as FQHCs.

By using creative collaborations and strategies with safety net providers, hospitals will be able to navigate the challenges of COVID-19 while serving more uninsured patients and improving the health of their patients.

What Long-Term Care Facilities Can Expect

Even before the catastrophic events of the COVID-19 pandemic, post-acute care facilities faced myriad issues and challenges. Skilled nursing facilities (SNFs) and senior living facilities, such as assisted living centers, have been overwhelmed by higher costs and shrinking revenues for years. The current public health crisis has only made that financial reality worse.

SNFs have a unique business model because, unlike most health care facilities, they generate nearly all their patient revenue from government reimbursement. Therefore, they are highly sensitive to changes in Medicare and Medicaid payment rates. Medicare pays mostly for short-stay skilled nursing care. Medicaid pays for a large portion of long-term care residents. In contrast, assisted living facilities are almost entirely private pay.

Recently, Medicare fee-for-service (FFS) payment reform was the biggest financial issue for post-acute care facilities. Centers for Medicare & Medicaid Services (CMS) finalized new payment systems for both SNFs and home health agencies (HHAs). In both sectors, payment reform focused on replacing therapy-driven payment with payment based in large part on patient characteristics. For SNFs, length of stay is the main consideration for some patients requiring therapy, while HHAs require 30-day episodes instead of the previous 60-day episodes.[20]

In addition to adapting to government reimbursement changes, SNFs are dealing with the COVID-19 trend of residents moving out faster than they are moving in. Even before the pandemic, occupancy rates were trending downward in post-acute care facilities. However, the pandemic exacerbated this trend. In SNFs, occupancy rates in Q4 2020 hit a record low of 71.7%.[21] Even though Medicare Advantage plans are growing in popularity, an increased number of Medicare Advantage enrollees does not equate to an increase in Medicare Advantage residents in the SNF population. Also, Medicare Advantage residents have a shorter average length of stay and a lower average daily rate than FFS.[22]

The current downward occupancy trend can be attributed in part to the high risk of COVID-19 infection in post-acute care facilities; the inability of family members to visit their loved ones during a lockdown; and the high costs of care during a time of economic chaos. The availability of vaccines may limit or to some extent reverse this trend. Nevertheless, SNFs will need to adapt their business model to survive the continuing challenges of COVID-19. Even though CMS has issued regulatory waivers for SNFs to help facilitate patient care, these waivers are only temporary during the public health emergency.[23]

Workforce challenges have also grown substantially for post-acute care providers. Due to COVID-19, SNFs will face staffing model challenges, workforce shortages, wage and benefit increased costs, employment law enforcement, and increased state and federal regulatory oversight.[24]

To adapt to these workplace challenges, SNFs are likely to engage workforce technology to manage personnel. For example, they can use real-time labor management systems which allow staffing to be quickly and accurately adjusted on a per-patient-day basis. This technology is an example of what may become essential for managing labor costs and productivity even after the current public health crisis subsides.[25]

In a post-COVID-19 environment, all health care organizations, but especially SNFs, will need to develop workforce acquisition strategies and engaged personnel to increase employee retention. The new business model focus should be on improving the level of quality care, customer satisfaction, and financial performance.[26] Another possible strategy for adaptation among senior care health service providers and even competitors is staff sharing (when safe) and centralized back-office functions. These strategies will allow SNFs to focus on high-quality patient care and service.[27]

Prior to COVID-19, post-acute care health facilities saw an increase in investment capital as investors anticipated the increased need for senior living care due to the aging baby boomer population. In a post-COVID-19 business environment, investors now have operating experience in the senior care sector and seek partnerships with health care operators that can navigate the operating challenges brought on by COVID-19. Investors should utilize safeguards that will provide accurate and timely reporting of operating trends so that mitigation of any new pandemic surge can be adapted quickly.[28]

COVID-19 will only increase the development of new managed care models for senior care. In addition to the increase in Medicare Advantage plans, as previously discussed, the Program of All-Inclusive Care for the Elderly (PACE) is also gaining popularity. PACE is an at-risk program designed to care for frail individuals by combining Medicaid and Medicare funding. Significantly, beneficiaries cared for through the PACE program remain in their homes and do not reside in long term care facilities. The National PACE Association (NPA) has created PACE 2.0, which has a goal of increasing participant enrollment from nearly 50,000 nationally in 2018 to 200,000 by 2028 through increased penetration of potential populations and continued increase in the number of programs.[29]

Another trend that will likely continue in the post-COVID-19 era is the redesign of SNFs. The current pandemic and its aftermath will only accelerate the declines in post-acute care utilization and the onslaught of increased regulatory oversight on both the federal and state level. There will likely be a trend in adapting new senior housing alternatives, such as low-income and market rental apartments; specialized units in SNFs, such as recovering COVID-19 patients; and assisted living facilities for only memory care patients.[30]

Rural providers face even bigger challenges with COVID-19 due to the geographic challenges of declining populations and staffing shortages. Rural SNFs will need to innovate quickly in a post-COVID-19 environment by developing new revenue streams, innovate new service line development, and create new staffing models.[31] Successful rural SNFs will aggressively develop new partnerships to support a new business model adaptation. Also, the increased use of telehealth will only expand for rural SNFs. By embracing innovations and new technology, rural SNFs will continue to provide post-acute care in rural areas that have decreasing labor market and aging demographics.[32]

With the myriad of changes brought on by COVID-19, long-term care facilities face ongoing cash management challenges. Medicare reform, with complicated managed care contracts, and a limited labor market will make revenue cycle management even more important. Managed care organizations have increased nearly 68% in many markets.[33] Many SNFs may find the use of centralized models will allow them to outsource risk and maintain focus on their core business—patient care[34]

During the current COVID-19 crisis, post-acute care facilities have been impacted the most. High infection rates and constant publicity make the business environment challenging to say the least. However, the possibility of developing or enhancing new service lines and increased use of technology, such as telemedicine, creates exciting opportunities to expand the scope of services and increase efficiency for SNFs and assisted living facilities. The successful facilities will be the ones that quickly adapt to a new business environment and diversify their services. This will enable them to succeed if another public health emergency develops.

The role of leadership will also be more important than ever. The business demands to thrive after a public health emergency will require a culture of continuous learning and ensuring an adaptable organization to meet the changing demands of senior living care.

The pressures of new value-based payment arrangements, with both private and government payors, will require innovative partnerships and cross-continuum service development. Providers and investors will be looking beyond traditional models of senior care to create partnerships with others, like Medicare Advantage payors, pharmacies and retail giants, home health, technology, and other provider groups. These innovative partnerships can create a new model for the care continuum to work together to manage the quality and cost of senior care—not only for housing and health care, but for products and services as well. In a post-COVID-19 business environment, the capital and technology likely to be available will allow for collaboration and partnerships that previously were not possible.

Tricky Trade-Off: Expedited Medical Peer Review and Credentialing In the Age of COVID-19

COVID-19 has placed a tremendous strain on this country's health care resources, including the availability of qualified physicians. In an attempt to increase that number to combat COVID-19, federal and state

agencies have relaxed physician licensing requirements, waived certain conditions of participation in federally funded health care programs, and waived fees for mandatory background checks on physicians.

These legal changes have assisted in expediting medical peer review and credentialing, and hospitals are using these changes, along with various forms of temporary privileges, to augment their medical staffs. But with relaxed restrictions and expedited credentialing comes greater risk for incompetent medical care and adverse outcomes. The ultimate impact on patient care and appropriate peer review therefore remains to be seen.

This section looks at the major efforts to facilitate medical peer review credentialing of physicians during the COVID-19 pandemic and their immediately likely impact.

All states have modified or waived certain licensure requirements for physicians: All 50 states and the District of Columbia have waived or modified licensure requirements for physicians in response to COVID-19. Waivers and modifications include temporary licensing of out-of-state physicians and other health care workers (obtained via hospital-to-hospital credentialing or via state medical board), and automatically extending license and permit expiration dates. Continuing medical education requirements have also been waived.

CMS waives certain privileging requirements: To address workforce concerns related to COVID-19, CMS has waived certain requirements under its conditions of participation in the Medicare and Medicaid programs regarding the eligibility and process for appointment of physicians to a hospital medical staff. Specifically, CMS now allows physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff or governing body review and approval. CMS has also temporarily waived requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state and they meet certain additional requirements.

NPDB requirements remain in effect: To assist hospitals in credentialing physicians during the COVID-19 pandemic, the Health Resources and Services Administration (HRSA) waived fees for mandatory queries of the National Practitioner Data Bank (NPDB)—the federal clearinghouse for adverse action reports against physicians. This waiver is retroactive to March l and goes through September 30, 2020. However, the query fee waiver has ended, and query fees are back in effect.

Under federal law, hospitals must query the NPDB when an individual applies for staff appointment or clinical privileges and again every 2 years when medical staff members seek to renew those privileges. Importantly, the requirement of querying every 2 years continues even if credentialing is extended by a hospital due to the pandemic. Hospitals must also report any time a physician undergoes a restriction in clinical privileges lasting more than 30 days, or when a physician resigns while under, or to avoid, an investigation by the health care entity where that physician has privileges. Failure to report may result in fines and loss of federal immunities for professional review actions.

The impact of emergency efforts on medical peer review and credentialing: Hospitals and health systems are taking advantage of these waivers and modifications in federal and state law to credential and grant privileges to an increasing number of physicians, using modified privileging categories in their medical staff bylaws such as "emergency privileges," "temporary privileges," and "disaster privileges."

These actions may have an immediate benefit to address the waves of COVID-19 cases appearing in certain jurisdictions throughout the country, even as the nation hits peak mortality. And it is very likely most of these waivers and modifications to standard practices will temporarily expire once this crisis passes. Nevertheless, as of the time of this article, there is no set date for many of these waivers to expire, meaning that expedited privileging and relaxed licensure in some form may be a reality for a long time to come.

Expedited privileging and relaxed licensure necessarily means that many physicians who were previously ineligible to practice are now at hospitals providing care. Expedited privileging, relaxed licensure, and the demands of this pandemic also likely will result in a decreased amount of medical peer review overall as providers focus primarily on patient care. This may naturally lead to an increased risk of substandard care and avoidable adverse outcomes. In addition to the potential harm this may cause to patients, hospitals and their medical staffs may be exposing themselves to higher rates of health care liability claims and, in some jurisdictions, claims for negligent credentialing.

This is a tricky trade-off, and one that hospitals and their medical staffs should carefully monitor as this pandemic runs its course. Congress declared more than 30 years ago that effective professional peer review was the appropriate remedy to the nationwide problem of incompetent physicians moving from state to state without disclosure or discovery of the physician's previous damaging or incompetent performance. Medical peer review remains the frontline defense against this problem and other related problems today, even in the face of a worldwide pandemic.

PREP Act Immunities for Health Care Facilities Fighting COVID-19

Federal, state, and local governments are working to find appropriate countermeasures and authorize combatants who are best situated to fight COVID-19. One way to empower these combatants is to provide them legal protection from liability for their efforts. The PREP Act affords broad federal immunity to a covered person with respect to claims relating to the authorized administration or use of a covered countermeasure.[35] On March 10, 2020, the Secretary for the Health and Human Services issued a declaration applying the immunities of the Act to the fight against COVID-19 (effective February 4, 2020).[36]

Federal immunity under the PREP Act is broad. As a general matter, if all the elements of immunity are met, it covers all claims for loss except for willful misconduct that proximately caused death or serious injury.[37] Because it is a federal immunity, it covers claims sounding in tort or contract, as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements.[38] HHS has recently issued an advisory opinion further setting forth the view that a person using or administering a

countermeasure retains immunity even if the person or countermeasure is not actually covered by the PREP Act, as long as the person reasonably could have believed that the person and countermeasure were covered.[39]

It is therefore important to understand the elements that give rise to immunity for health care providers. Below is an analysis regarding key provisions of the PREP Act.

Covered countermeasures: "Covered countermeasures" includes, among other things, a "qualified pandemic product," and includes any FDA-approved devices, as well as drugs, devices, and products authorized for emergency use or that are being researched under certain investigational provisions.[40] HHS has issued a non-exhaustive list of medical devices and therapeutics that have been authorized for emergency use in combating COVID-19.[41]

Covered persons: "Covered persons" includes, among others, manufacturers and distributors of covered countermeasures, along with "program planners, "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act.[42] Among these persons a "program planner" includes state and local government organizations that are supervising or administering programs to administer or distribute approved countermeasures.[43] This may include private sector employers or community groups when carrying out one of these state or local government programs.[44] In addition, a "qualified person" includes licensed health professionals authorized under state law to administer countermeasures;[45] and any person authorized by an appropriate federal, state, or local governmental agency (e.g., an "Authority with Jurisdiction") to administer, deliver, distribute or dispense covered countermeasures.[46]

The list of qualified persons is continually expanding. For example, on April 8, 2020, in an effort to further increase access to COVID-19 testing, the Office of the Assistant Secretary for Health issued guidance authorizing licensed pharmacists to order and administer COVID-19 tests, including FDA-approved serology tests.

Immunity: Immunity applies only to covered persons engaged in certain activities that involve covered countermeasures. These include:

- Activities related to present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements.
- Activities authorized in accordance with the public health and medical response of the appropriate governmental agency to prescribe, administer, deliver, distribute or dispense the covered countermeasures.[47]

In other words, immunity applies only when a covered person engages in activities related to an agreement or arrangement with the federal government, or when a covered person acts according to an "authority having jurisdiction" to respond to a declared emergency.[48] HHS has interpreted this broadly to include any arrangement with the federal government, or any activity that is part of an authorized emergency response at the federal, regional, state, or local level. Such activities can be authorized through, among other things, guidance, requests for assistance, agreements, or other arrangements.[49]

Long-Term Impact and Recommendations for the PREP Act

The secretary has declared the immunities of the PREP Act are in place to fight COVID-19 until October 1, 2024.[50] Accordingly, the PREP Act immunities will have a long-term impact on hospital and health care facilities and the risk for liability in the years to come.

To take advantage of the robust immunities afforded under the PREP Act, it is critical for health care facilities to ensure their efforts to fight COVID-19 fall within the stated elements of the Act. Accordingly, we recommend health care facilities take the following measures to ensure the highest likelihood of obtaining PREP Act immunity:

- Ensure that devices, products, drugs, therapeutics used to fight COVID-19 are "covered countermeasures" (e.g., FDA approved, CDC authorized, NIOSH approved, etc.).
- Ensure those using or administering covered countermeasures are "covered persons" (qualified medical personnel and/or "program planners" partnering with local jurisdictions to fight the disease, etc.).
- Explore federal emergency use authorizations, guidance publications, and other announcements to determine if the facility's administration or use of a covered countermeasure falls within any federal agreements or arrangements.
- Reach out to state and local agencies charged with responding to the pandemic to identify the facility as part of its local efforts, thereby falling within the recognized arrangements that are protected by PREP Act immunities.

Finally, HHS has encouraged covered persons to take all reasonable precautions in the administration or use of the covered countermeasure and to document those efforts.[51] Taking these steps will further increase the likelihood of immunity coverage.

Looking Forward

The post-COVID-19 environment augers increased federal funding for institutional and other health care providers through Medicaid program expansion, ACA expansion, and other means. As discussed above,

the pandemic has exposed significant population needs and gaps in our health care system. In our view, the measures taken to address these needs and gaps, which have become acute during the pandemic, will persist or be largely replaced by longer-term measures as the COVID-19 pandemic recedes.

In addition, we believe the pandemic is accelerating change in the ways in which health care is delivered, and that these changes in large part will continue and be lasting. A clear example of this is telemedicine, particularly important to rural facilities. Telemedicine also affords opportunities for business line expansion to subacute providers. Other examples are increased decentralization of care, and increased coordination of care between acute care facilities and providers such as FQHCs.

In view of the importance of quality of care, it is not clear that relaxations of credentialing requirements related to the COVID-19 pandemic will survive long-term. We anticipate that as the pandemic-created need for these relaxations recedes, so too will the relaxations. Nevertheless, as noted, the important PREP Act immunities will last until 2024, and it will continue to be important for providers to take advantage of these immunities.

In sum, in our view the changes wrought by the COVID-19 pandemic will largely be lasting, albeit not completely in the case of credentialing. The trend toward decentralized outpatient care will continue and accelerate. And the adoption of new technology that fosters and supports this trend will similarly accelerate. Finally, government funding of health care will increase.

CHAPTER 3:
PREP ACT AND ANTICIPATED IMPACT ON COVID-RELATED TORT AND CONTRACTS LITIGATION

— By Jesse Coleman and Drew del Junco

Executive Summary

The Public Readiness and Emergency Preparedness Act (PREP Act) is a dramatic and wide-ranging grant of liability and suit immunity to private entities that the government wishes to enlist in the battle against COVID-19. Its goal is clear: to shift the costs away from those wishing to engage in the fight and grant them certainty and protection against lawsuits for negligence. However, as of this writing, very few organizations have been successful in invoking its protections in the waves of litigation surrounding harm arising from the disease.

Meanwhile, the federal government's guidance regarding the PREP Act has evolved dramatically since the pandemic began rapidly spreading across the United States in March 2020. On March 10, 2020, the Secretary for the US Department of Health and Human Services (HHS) issued a declaration applying the liability immunities of the Act to medical countermeasures against COVID-19.

Since then, HHS has issued seven amendments and six advisory opinions clarifying the declaration's scope and enlarging its application. Although the PREP Act became law in 2005, its invocation has been rare and never on a scale so potentially far-reaching. More recently the courts have split on whether the PREP Act is a complete preemption statute conferring federal jurisdiction, with the majority concluding it is not, contrary to guidance from HHS and the US Department of Justice (DOJ).

This article endeavors to summarize these recent developments and raise important questions as to who is, and is not, taking advantage of this powerful statute.

Background of PREP Act and Overview of Key Provisions

Background

The PREP Act is invoked when the Secretary of HHS issues a declaration determining that a disease or other health condition constitutes a public health emergency.[52] If that determination is made, the s"may make a declaration, through publication in the Federal Register, recommending . . . the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that [certain liability immunities are] in effect with respect to the activities so recommended."[53] Once the secretary has issued a declaration, the PREP Act provides sweeping immunity for certain claims against certain covered individuals. On March 10, 2020, the secretary invoked his authority under the PREP Act to

provide immunity for medical countermeasures against COVID-19 to certain health care professionals tasked with responding to the crisis.[54]

Scope of Immunity

The PREP Act affords broad federal immunity to a "covered person" with respect to claims relating to the authorized administration or use of a "covered countermeasure."[55] As a general matter, if all the elements of immunity are met, it makes a covered person immune from suit and liability under federal and state law with respect to "all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure."[56]

The PREP Act further defines the scope of its coverage to apply to "***any claim for loss*** that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure."[57] Covered losses include claims for death, physical, mental, or emotional injury, illness, disability, or condition, fear of such harm or need for medical monitoring, and loss of or damage to property, including business interruption loss.[58]

Because it is a ***federal*** immunity, the PREP Act covers claims sounding in tort or contract, as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements.[59] The PREP Act also preempts "any provision of law or legal requirement that . . . is different from, or is in conflict with, any requirement applicable under this section" and that is "relate[d] to" those countermeasures.[60]

In place of tort remedies, Congress created the Covered Countermeasure Process Fund to compensate eligible individuals for serious physical injuries or deaths from countermeasures identified in declarations issued by the secretary.[61] The PREP Act also creates, as "the sole exception to the immunity from suit and liability," an "exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct" of that person.[62] It further establishes an exclusive venue for such excepted claims: "only" before a three-judge panel of the United States District Court for the District of Columbia.[63] Even such excepted claimants, though, must first apply for benefits through the federal Covered Countermeasure Process Fund, which permits individuals to make no-fault benefits claims for certain injuries.[64]

Overview of PREP Act's Provisions

It is important to understand the elements that give rise to immunity for health care providers and others. Below is an analysis regarding key provisions of the PREP Act.

What constitutes a "covered person"?

"Covered persons" include, among others, manufacturers and distributors of covered countermeasures, along with "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act.[65] Among these persons, a "program planner" includes state and local government organizations that are supervising or administering programs to administer or distribute approved countermeasures.[66] This may include private sector employers or community groups when carrying out one of these state or local government programs.[67] In addition, a "qualified person" includes licensed health professionals authorized under state law to administer countermeasures,[68] and any person authorized by an appropriate federal, state, or local governmental agency (e.g., an "authority with jurisdiction") to administer, deliver, distribute, or dispense covered countermeasures.[69]

What constitutes a "covered countermeasure"?

"Covered countermeasures" include, among other things, a "qualified pandemic product," and includes any FDA-approved devices, as well as drugs, devices, and products authorized for emergency use or that are being researched under certain investigational provisions, and which to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or to limit the harm such pandemic or epidemic might otherwise cause.[70] HHS has issued a list of non-exhaustive medical devices and therapeutics that have been authorized for emergency use in combatting COVID-19.[71]

What constitutes authorized "administration" or "use" of a covered countermeasure?

With respect to what constitutes authorized "**administration**" or "**use**" of a covered countermeasure, liability immunity is afforded to covered persons ***only*** for "recommended activities" (which include the "distribution, administration, and use of the Covered Countermeasures") involving covered countermeasures that are related to:

- Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements;
- Activities authorized in accordance with the public health and medical response of the authority having jurisdiction to prescribe, administer, deliver, distribute or dispense the covered countermeasures following a declaration of an emergency;
- Any covered countermeasure that is FDA-approved to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19 and administered pursuant to an FDA emergency use authorization.

Immunity applies ***only*** when a covered person engages in activities authorized by an "authority having jurisdiction" to respond to a declared emergency.[72] HHS has interpreted this broadly to include (1) any

arrangement with the federal government, or (2) any activity that is part of an authorized emergency response at the federal, regional, state, or local level.[73]

Evolution of the PREP Act Over the Past Year

Through further interpretation of the act, and by providing key examples, the declaration, its seven amendments, and six advisory opinions demonstrate the wide potential application of PREP Act immunity and preemption across various industries. Whether federal courts will follow HHS's recent guidance interpreting the act remains a key question in how broadly the act will apply to cases moving forward.

PREP Act Declaration and Its Seven Amendments

The PREP Act declaration and its seven amendments have significantly expanded the scope of the PREP Act's application to the COVID-19 pandemic.

PREP Act Declaration

As mentioned above, on March 10, 2020, former Secretary of HHS Alex Azar issued a declaration, effective February 4, 2020, under the PREP Act declaring that certain "covered countermeasures" are necessary to beat back a public health emergency such as COVID-19.[74]

The secretary's COVID-19 declaration specifically affords immunity for "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures." The declaration also defines "covered countermeasures" as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19 . . . or any device used in the administration of any such product, and all components and constituent materials of any such product," limited to activities concerning federal agreements or to "activities authorized in accordance with the public health and medical response" of state or local public agencies."[75] The secretary has declared the immunities of the PREP Act are in place to fight COVID-19 until October 1, 2024.[76]

First Amendment to Declaration

On April 10, 2020, the HHS secretary issued the first amendment[77] to the COVID-19 declaration to extend liability immunity to covered countermeasures authorized under the newly passed CARES Act.[78] Enacted on March 27, 2020, the CARES Act created a new category of covered countermeasures eligible for liability immunity under the PREP Act, namely respiratory protective devices approved by the National Institute for Occupational Safety and Health (NIOSH) or any successor regulations that the secretary determines to be a priority for use during a public health emergency.

Second Amendment to Declaration

On June 4, 2020, the secretary issued a second amendment[79] to his March 10, 2020 declaration applying the federal immunities of the PREP Act to the fight against COVID-19. This amendment was brought about because the secretary's March 10 declaration had inadvertently omitted a key phrase in the statutory definition of covered countermeasure, which states that qualified pandemic and epidemic products may also include products that "limit the harm such a pandemic or epidemic might otherwise cause." To correct this omission, therefore, the second amendment clarified that HHS intended to include all qualified pandemic and epidemic products defined under the PREP Act as covered countermeasures.

Third Amendment to Declaration

On August 24, 2020, the secretary for HHS issued a third amendment[80] to his COVID-19 declaration, broadening the liability immunity protections afforded by the PREP Act. Specifically, the third amendment to the declaration identifies an additional category of persons as "qualified persons" covered under the PREP Act: certain licensed pharmacists who order and administer, and pharmacy interns (who are acting under the supervision of a licensed pharmacist) who administer, any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages 3 through 18.

Fourth Amendment to Declaration

On December 3, 2020, HHS issued the fourth amendment to the declaration under the PREP Act. Among other things, the fourth amendment[81] expressly adopts and incorporates the HHS general counsel's prior advisory opinions, lays the foundation for litigants to assert federal-question jurisdiction, and unequivocally states that the PREP Act also applies in certain cases of ***non-use***, failure to use, and even refusal to use covered countermeasures.

Perhaps most important among its provisions, the fourth amendment makes explicit that "there are substantial federal legal and policy issues, and substantial federal legal and policy interests, in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities." This statement paves the way for defendants seeking federal jurisdiction to remove state-court cases that implicate PREP Act immunities.[82] It also attempts to resolve a longstanding dispute in the state and federal courts over whether the PREP Act can serve as the basis of federal-question jurisdiction, to the extent those courts now defer to this administrative agency's interpretation of the PREP Act.

The fourth amendment, moreover, clarifies the scope of PREP Act immunity by, for example, making explicit that even the failure to administer a covered countermeasure to a particular individual can nevertheless fit within the wide reach of the PREP Act's liability protections. This runs counter to a host of recent court cases interpreting the PREP Act's liability protections to only apply to circumstances involving affirmative misuse of covered countermeasures.

Fifth Amendment to Declaration

On January 28, 2021, HHS issued the fifth amendment to the PREP Act declaration.[83] This Amendment expands the categories of qualified individuals authorized to administer FDA-approved COVID-19 vaccines such that doctors and nurses whose licenses expired within the past five years can now administer COVID-19 vaccines, subject to certain training and observation requirements.

Although this amendment represents the fifth time the PREP Act declaration has been amended, it's the first such amendment issued by the Biden Administration. Given the further expansion of the PREP Act that the fifth amendment entails, it suggests the new administration is not inclined to scale back PREP Act coverage—at least not initially.

Sixth Amendment to Declaration

On February 10, 2021, HHS issued the sixth amendment to the PREP Act declaration.[84] This amendment immunizes federal employees, contractors, and volunteers authorized by their department or agency to prescribe, administer, deliver, distribute, or dispense the covered countermeasure as any part of their duties or responsibilities. The purpose of this amendment is to address what HHS identified as "an urgent need to expand the pool of available COVID-19 vaccinators in order to respond effectively to the pandemic."[85] The amendment further emphasizes that any state law that would otherwise prohibit a member of any of the classes of "qualified persons" specified in the declaration from administering a covered countermeasure is likewise preempted.

Seventh Amendment to Declaration

On March 12, 2021, HHS issued the seventh amendment to the PREP Act declaration.[86] This amendment further expands the category of individuals authorized to administer COVID-19 vaccines to properly trained individuals even if prescribing, dispensing, and administering vaccines is not within the scope of their license or usual responsibilities. Specifically, the amendment authorizes dentists, EMTs, midwives, optometrists, paramedics, physician assistants, podiatrists, respiratory therapists, and veterinarians, as well as medical students, nursing students, and other health care students in the professions listed under the PREP Act with proper training and professional supervision, to serve as vaccinators. As "covered persons" under the act, the amendment also affords these individuals sweeping PREP Act immunities from state and federal personal injury claims arising from the authorized administration of the vaccine.

Six Advisory Opinions Interpreting PREP Act and Declaration

As of the date of publication, the HHS Office of the General Counsel (OGC) has released six advisory opinions in response to various requests from stakeholders about whether certain activities in connection with COVID-19 qualify for PREP Act immunity.

Although the later advisory opinions which have not been incorporated by the declaration do not have the force of law and therefore do not bind HHS or the federal courts, they set forth the current views of the OGC and endeavor to provide needed clarity to the scope of PREP Act immunity during the COVID-19 pandemic. And like the various amendments to the declaration, the advisory opinions emphasize the breadth of PREP Act immunity and provide guidance which demonstrates its expansive application to a broad range of entities that take reasonable steps to follow public health guidelines and directives in using covered medical products.

Advisory Opinion 20-01

On April 14, 2020, the OGC issued Advisory Opinion 20-01[87] specifying that PREP Act immunity may extend beyond actual "qualified persons" and approved "countermeasures"—even though they are technically not covered by the PREP Act—if one could have reasonably believed the persons or countermeasures were covered. The advisory opinion concludes by encouraging all covered persons using or administering covered countermeasures to document the reasonable precautions they have taken to safely use the covered countermeasures.

Advisory Opinion 20-02

On May 19, 2020, the HHS OGC published Advisory Opinion 20-02[88] concluding that the PREP Act preempts any state or local law which prohibits a pharmacist from ordering and administering authorized COVID-19 tests.

Advisory Opinion 20-03

On October 23, 2020, the OGC issued Advisory Opinion 20-03.[89] AO 20-03 reiterates that states or their sub-units may not impose any requirement that effectively prohibits a pharmacist from ordering and administering vaccines as authorized by the HHS secretary.

Advisory Opinion 20-04

On the same day it issued AO 20-03, OGC also released Advisory Opinion 20-04.[90] In AO 20-04, the OGC addresses the scope and meaning of the terms "program planner" and "authority having jurisdiction" under the PREP Act and its implementing declaration, and re-emphasizes the wide-ranging nature of PREP Act immunity. It also breaks with recent current court interpretations of the PREP Act and argues they are too narrow.

Under the PREP Act, the term "covered person" includes the United States or "manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees."[91] The PREP Act broadly defines a "program planner,"[92] and the secretary's original declaration explains that a program planner can be a "private sector employer or community group."[93] In short, ***any individual or organization***

can potentially be a program planner and receive PREP Act coverage. According to AO 20-04, private businesses, public and private transportation providers, public and private schools, and religious organizations are all eligible for immunity under the PREP Act when they act in accordance with its requirements.

In addition, AO 20-04 expressly disagrees with the *Casabianca v. Mount Sinai Medical Center*[94] case in which a New York state court evaluated the PREP Act in the context of the H1N1 influenza pandemic and concluded that the PREP Act does not apply to inaction. The court observed that immunity under the PREP Act is limited to claims "resulting from the administration . . . or use" of a covered countermeasure, and that non-administration is not addressed, noting that "[n]othing is spoken of regarding a decision not to use the vaccine or of a failure to use it."[95] According to the OGC, the *Casabianca* "court was wrong" because it failed to interpret the PREP Act consistent with its plain meaning by concluding that the PREP Act did not apply to the hospital's inaction.

Advisory Opinion 21-01

On January 8, 2021, HHS issued Advisory Opinion 21-01,[96] reinforcing the extent to which the PREP Act (1) provides complete preemptive federal jurisdiction and (2) applies to cases where the alleged harm results from failure to use (and even ***refusal to use***) a covered countermeasure when that failure arises out of the conscious allocation and prioritization of the countermeasures.

AO 21-01 also appears to evince HHS's frustration with private businesses' apparent failure to make full use of the PREP Act and the federal courts' apparent failure to properly interpret the PREP Act. Like AO 20-04, AO 21-01 criticizes recent courts' application of the Act as contrary to the plain language of the statute, while noting that courts appear "perplexed" by what circumstances may trigger federal PREP Act jurisdiction and immunity.

Advisory Opinion 21-02

On January 12, 2021, HHS issued Advisory Opinion 21-02[97] on the PREP Act and the secretary's declaration. This advisory opinion clarifies the meaning of the requirement, in the third amendment to the declaration, that a COVID-19 vaccination "must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s)." Any person who orders or administers the COVID-19 vaccine to individuals within the ACIP-recommended age group satisfies the third amendment's requirement that the vaccination be "ordered and administered according to ACIP's COVID-19 vaccine recommendation(s)." This is true regardless of whether the vaccine was ordered or administered to a person in a prioritized group.

The Courts, US Attorneys' Office, and Office of Legal Counsel Tackle PREP Act Issues Involving Non-Use, Preemption, and Federal Jurisdiction

As we discuss below, many thorny questions regarding PREP Act immunity are making their way through the courts, such as (1) whether the PREP Act provides immunity in cases where a claim for loss arises from a defendant's failure to use, or even refusal to use, a covered countermeasure; (2) the extent to which the PREP Act and declaration preempt conflicting state and local laws; and (3) whether the PREP Act provides complete federal preemption and, as a result, serves as a basis for federal jurisdiction.

Are claims arising from non-use of covered countermeasures subject to PREP Act immunity?

A growing number of suits are addressing whether PREP Act immunity arises in the use or non-use of covered countermeasures against COVID-19, including personal protective equipment (PPE). Many of these recent lawsuits involve nursing homes and other health care facilities, where patients or their estates allege that patients contracted COVID-19 because the facility, among other things, failed to provide its staff with PPE, failed to teach the staff how to properly use that equipment, or failed to ensure that its staff properly used the PPE that it had been given.

As mentioned above, the fourth amendment explicitly provides that the PREP Act's liability protections may apply to certain cases of ***non-use***, failure to use, and even refusal to administer a covered countermeasures to a particular individual. However, many courts have thus far reached the opposite conclusion, finding that the non-use of a covered countermeasure does ***not*** trigger the PREP Act.

For example, in *Lutz v. Big Blue Healthcare*, the district court concluded that "[t]here is simply no room to read [the PREP Act] as equally applicable to the non-administration or non-use of covered countermeasures." [98] Similarly, in *Casabianca v. Mount Sinai Medical Center*,[99] the district court held that PREP Act immunity is restricted to claims "resulting from the administration . . . or use" of a covered countermeasure, and that "[n]othing is spoken of regarding a decision not to use the vaccine or of a failure to use it."[100] As discussed above, AO 21-01 called out the court's holding in *Casabianca*, saying "the court was wrong." And in *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*,[101] which is currently on appeal, the court held that the PREP Act only provides immunity to facilities "when a claim is brought against them for the countermeasures the facility actually utilized," rather than failed to use.

HHS has been sharply critical of these courts, emphasizing that program planning inherently involves the allocation of resources and is expressly covered by the PREP Act. According to HHS, because the PREP Act extends immunity to anything "relating to" the administration of a covered countermeasure, decision-making that leads to the non-use of covered countermeasures by certain individuals is the core of program planning, and is expressly covered by PREP Act. However, a provider may not be covered, according to HHS, if the provider (1) purposefully fails to follow priorities contained in a Declaration and is therefore not a "covered person"[102]; or (2) fails to act purposefully or without making any decision at all.[103]

Do the PREP Act and declaration preempt conflicting state and local laws?

The PREP Act's express preemption provision is 42 U.S.C. § 247d-6d(b)(8), which states in full:

> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
>
> (A) is different from, or is in conflict with, any requirement applicable under this section; and
>
> (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.[104]

As such, the PREP Act clearly preempts conflicting state and local laws. Indeed, on January 19, 2021, the Office of Legal Counsel (OLC) for the DOJ issued a memorandum opinion regarding the preemption of state and local requirements under the declaration.[105] In this memo, the OLC affirmed that both the PREP Act and declaration preempt state or local requirements, such as state licensing laws, that would prohibit or effectively prohibit qualifying state-licensed pharmacists from ordering and administering both FDA-approved COVID-19 tests and vaccines. The memo formalizes the same conclusion reached in AO 20-02 discussed above regarding COVID-19 tests, and answers the related question of whether the same conclusion applies not just to COVID-19 tests but also to the administration of COVID-19 vaccines.

Does the PREP Act afford "complete preemption" such that its invocation results in federal jurisdiction?

Nursing home cases involving COVID-19 tend to be filed in state courts and assert a variety of state law-based torts. Thereafter, defendants often file removal petitions and plaintiffs respond with remand motions. To resolve the remand motions, courts first assess whether the doctrine of complete preemption applies.

At the time this article was submitted for publication, almost all of the cases applying the PREP Act in the context of COVID-19 have concluded the PREP Act does not offer complete preemption or give rise to federal jurisdiction. However, two out of the dozens of federal district courts to have reached the issue have found that the PREP Act provides complete preemption.[106]

Background on Federal Preemptive Jurisdiction

Ordinary preemption is a defense and does not support Article III subject matter jurisdiction,[107] which is a prerequisite for removal.[108] In contrast, complete preemption is "really a jurisdictional rather than a preemption doctrine, [as it] confers exclusive federal jurisdiction in certain instances where Congress intended the scope of a federal law to be so broad as to entirely replace any state-law claim."[109] Thus, complete preemption is fundamentally unlike the express preemption provided by 42 U.S.C. § 247d-6d(b)(8) as well as other, substantive preemption doctrines (e.g., implied, field, conflict, impossibility, or obstacle preemption), which do not in and of themselves give rise to removability. And complete preemption sidesteps the general rule that a federal defense (like other, substantive types of preemption) does not provide grounds for removal to federal court.[110]

HHS Argues the PREP Act Is a Complete Preemption Statute

In AO 21-01, HHS has taken the position that the PREP Act is a complete preemption statute, opining that: "The *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both."

Fourth Amendment to the Declaration Invokes the *Grable* Doctrine

In addition to complete preemption as the basis for Article III jurisdiction and removal, the Supreme Court in *Grable & Sons Metal Products, Inc. v. Darue Eng'g & Mf'g*.,[111] recognized a separate but related doctrine. Under *Grable*, even in the absence of a claim arising under federal law, "a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues."[112]

The secretary, in the fourth amendment to his PREP declaration, effectively concluded that a case implicating the PREP Act during the COVID-19 pandemic belongs in federal court, stating that

> [t]here are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g*., 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.[113]

As such, the fourth amendment provides the underlying basis for invoking the *Grable* doctrine with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.

In addition, 42 U.S.C. § 247d-6d(b)(7) provides that "[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection." Relying on that provision, the secretary's fourth amendment states that "[t]hrough the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations." This statement therefore suggests that the secretary's statement invoking *Grable* in the fourth amendment may be an unreviewable action pursuant to 42 U.S.C. § 247d-6d(b)(7).

Recent Developments on Federal Preemptive Jurisdiction

Federal district courts recently examining whether the PREP Act is a complete preemption statute have arrived at inconsistent conclusions. Although appellate courts have not yet opined on this exact issue, the overwhelming majority of the district courts that have considered it have held that the PREP Act dos not completely preempt state-law claims against nursing homes. However, two cases have reached the opposite conclusion.

Two Courts Have Recognized That the PREP Act Does Provide for Complete Preemption

To date, neither the Supreme Court nor any of the Court of Appeals has found complete preemption over claims implicating the PREP Act. A recent ruling from the Middle District of California in *Garcia v. Welltower OpCo Group, LLC*,[114] however, appears to be the first district court to have found that the plaintiffs' claims were completely preempted under the PREP Act.

In *Garcia*, the plaintiffs asserted various causes of action under California law including wrongful death. The defendants operate and manage a senior living facility. The decedent was a resident of the facility during the COVID-19 pandemic. Certain family members of the decedent filed suit in California state court alleging that the decedent died from COVID-19 while he was a resident of the facility, and the defendants removed the action to federal court in part based on federal question jurisdiction.

The plaintiffs filed a motion to remand, claiming that the PREP Act is inapplicable because it does not provide immunity to medical providers for negligence claims unrelated to vaccine administration and use. The defendants responded that federal question jurisdiction exists because the suit is completely preempted in light of the OGC's recent guidance in AO 21-01, which confirms Congress's intent that the PREP Act completely preempt state laws.

The court first considered whether the PREP Act provides for complete preemption. The court noted that other courts in the Central District of California have found that it did not.[115] Importantly, however, each of those cases preceded the issuance of AO 21-01. Without stating whether it was applying *Chevron* or *Skidmore* deference,[116] the court cited both Supreme Court decisions in agreeing with and ultimately adopting AO 21-01's interpretation that the act is a complete preemption statute. The court also pointed out that AO 21-01 disagreed with the other courts in the Central District of California and elsewhere that had

come to the opposite conclusion, because they took too limited of a view concerning use or non-use of a covered countermeasure.

The court next considered whether the plaintiffs' allegations fall within the scope of the PREP Act. To fall within the ambit of the PREP Act, the plaintiffs' loss must have been caused by "a covered person" and "aris[e] out of, relat[e] to, or result[] from the administration to or the use by an individual of a covered countermeasure."[117] Here, the plaintiffs did not allege that the facility failed to provide any of its staff or patients with PPE but rather that the timing, quantity, and training with respect to the PPE provided by the facility was inadequate. The court relied on AO 20-02 and AO 20-04 in support of its conclusion that the defendants' actions in response to the pandemic easily fell within the scope of the act. Therefore, the court held that an adequate basis for federal question jurisdiction exists.

Similarly, in its decision in *Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC*,[118] issued two months after *Garcia*, the district court in Louisiana cited *Garcia* approvingly and held that the PREP Act is a complete preemption statute.

The Overwhelming Majority of District Courts Conclude That the PREP Act Does Not Provide Complete Preemption

Garcia and *Rachal*, however, are in the minority, and subsequent courts that have addressed the issue have declined to follow them. Indeed, with the exception of these two cases, the unanimous consensus among the district courts across the country is that the PREP Act is not a complete preemption statute.[119]

The DOJ Weighs in

On January 19, 2021, the DOJ submitted a statement of interest in a civil matter before the US District Court for the Middle District of Tennessee to address the preemptive effect of the PREP Act and assist the court in resolving a pending motion to remand.[120] In its statement of interest, the DOJ took the position that the PREP Act completely preempts claims relating to the administration or use of covered countermeasures with respect to a public health emergency, as declared by the secretary. Thus, according to the DOJ, cases that include such claims necessarily include federal questions and are therefore removable. However, as a nonparty, the United States took no position as to whether the act applies to any particular claim alleged in the plaintiff's complaint in the case.[121]

The statement of interest further argues that a recent and oft-cited case to the contrary, *Maglioli v. Andover Subacute Rehabilitation Center*,[122] appears to have interpreted the complete preemption doctrine and the PREP Act "imprecisely." The court's holding, "that the PREP Act does not so occupy the field as to squeeze out state court jurisdiction over what are state-law claims of negligence and require an exclusive federal forum,"[123] frames the inquiry incorrectly. Field preemption is a different doctrine than complete preemption

and the PREP Act ***does*** include a completely preemptive provision, as evidenced by its creation of immunity for a certain class of claims and an exclusive federal forum for exceptions to that immunity.[124]

In its decision, the court, while "mindful of the United States' policy arguments that reasonably emphasize the urgent need for the federal judiciary to provide a consistent national interpretation of the PREP Act during a pandemic that has taken the lives of more than 500,000 citizens," ultimately rejected the DOJ's argument and remanded the matter to Tennessee state court.[125] The court also noted that *Garcia* is nonbinding, and joined the other district courts that have unanimously concluded that the HHS's advisory opinions should not receive unlimited deference.[126] The court disagreed that the advisory opinion is entitled *Chevron* deference because the advisory opinion itself expressly states that "[i]t is not a final agency action or a final order" and "does not have the force or effect of law."[127] Moreover, "[e]ven if the [Advisory Opinion] did not include the clear disclaimer language, the authority Congress delegated to HHS to make rules carrying the force of law did not include authority to interpret the jurisdiction of the federal courts."[128] Finally, and most important to the court, the advisory opinion's interpretation lacks the "power to persuade," because it "cites no cases for its proposition that an exclusive federal administrative remedy is sufficient for complete preemption."[129]

Where is the PREP Act headed? Anticipated future impact on vaccine distribution systems and changes in light of the new Biden Administration.

Vaccine Distribution Systems

With respect to the world of vaccine distribution systems, many employers are hesitant to mandate their employees get the COVID-19 vaccine out of fear being sued by their employees and/or the general public. The PREP Act clearly applies in this situation. In fact, the CDC COVID-19 vaccination program provider agreement[130] even expressly references the PREP Act, stating that "[c]overage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services."

Anticipated Changes From the Nascent Biden Administration

All but two of the amendments to the PREP Act declaration and all of the advisory opinions were issued by HHS under the Trump Administration, which raises the question of whether the new Biden Administration might have different priorities in this regard and whether the new Secretary of HHS might amend the declaration to expand or contract its application.

However, we can likely expect more of the same from the Biden Administration. The fifth, sixth, and seventh amendments to the declaration was issued in the first few days of the Biden Administration. Given the further expansion of the PREP Act that these amendments afford, they suggest the new administration is not inclined to scale back PREP Act coverage.

Conclusion

As stated above, the PREP Act affords extraordinarily broad federal immunity from suit and liability to a covered person with respect to claims relating to the authorized administration or use of a covered countermeasure. Except for willful misconduct that proximately causes death or serious injury, it covers all claims for loss, including contract and tort claims as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements.

Immediately after COVID-19 reached the United States, HHS issued a series of declaration amendments and advisory opinions interpreting the contours of the PREP Act in an even more expansive way, e.g., opining that it provides complete preemptive federal jurisdiction and even may apply to cases where the alleged harm results from non-use of a covered countermeasure so long as the non-use was the result of conscious decision-making.

However, federal courts haven't all interpreted it in the broad manner suggested in guidance from HHS. Whatever the case may be, there is ample time to invoke its protections. Again, the secretary has declared the immunities of the PREP Act are in place to fight COVID-19 until October 1, 2024, so the PREP Act immunities will have a long term impact on health care facilities as well as many other industries and settings and the risk for liability in the years to come.

CHAPTER 4:
THE EFFECT OF COVID-19 ON MODERNIZING FRAUD AND ABUSE REGULATION AND ENFORCEMENT

— By William Eck

As part of the first edition of the treatise, this chapter provided readers with an overview of how the federal government continues to regulate health care fraud and abuse through the modernization of, and ongoing changes to, the Stark Law and Anti-Kickback Statute. Included below are noteworthy updates to the original chapter, as well as future expectations and forecasts for a post-COVID environment in this space.

Objective Falsity Under the False Claims Act (FCA)

Until recently, it had been the case that a statement had to be objectively false under the FCA in order to give rise to liability. However, in 2020, this changed in two of the federal circuits, the Third and the Ninth. The decisions of the Third and Ninth Circuits have given rise to a split among the circuits, and a petition for certiorari review by the US Supreme Court has been filed in the Third Circuit case to resolve the split. This petition may be accepted by the Supreme Court, and a decision could have significant consequences for FCA enforcement post-COVID.

Initially, the FCA does not define "false or fraudulent," leaving courts and the common law to interpret what constitutes a false claim. Four circuits have held that a statement must be "objectively false" to support an FCA claim—the Fourth, Seventh, Tenth and Eleventh. This means that a claim cannot be false when there is a genuine dispute and the claim is based on a subjective assessment.

Until recently, the Third Circuit had also adopted this view, holding that under the FCA, "a statement is 'false' when it is objectively untrue."[131] In addition, "expressions of opinion, scientific judgments or statements as conclusion which reasonable minds may differ cannot be false."[132] Thus, a statement that is not objectively false cannot be a basis of liability under the FCA.

However, the Third Circuit reversed itself in *United States v. Care Alternatives.*[133] This case involved physician certifications of diagnoses that would make patients eligible for the Medicare hospice benefit. The court found that claims could be "legally false" if they did not meet statutory or regulatory requirements—in other words, that a false claim could arise if expert testimony reached a conclusion that contradicted a doctor's basis for the hospice diagnosis that would make the patient eligible for the Medicare hospice benefit.[134]

Similarly, in March, 2020, the Ninth Circuit went perhaps even further, holding that, "the FCA does not require a plaintiff to plead an 'objective falsehood.'"[135] This case involved physician certifications that

inpatient admissions were reasonable and necessary. The court determined that these certifications could be false for FCA purposes.

As noted, a petition for certiorari review of the *Care Alternatives* case has been filed with the US Supreme Court, requesting the court to rule that objective falsehood is necessary under the FCA, thus resolving the split in the circuit courts.[136] If the Supreme Court takes this case, its decision could have important ramifications for the scope of FCA liability in the post-COVID environment. A decision that claims need only be legally false, for example, would significantly expand the scope of FCA liability in many Circuits.

Looking Toward a Post-COVID-19 Environment

The enforcement of fraud and abuse laws will continue to be important post-COVID-19. The toll taken by fraud and abuse on the health care system, and on the public, is simply too substantial to predict a relaxation of enforcement of fraud and abuse laws and regulations in the post-COVID-19 world. In federal fiscal year 2019, for example, the government recovered $2.6 billion in judgments and settlements of fraud and abuse claims.[137] By most estimates, this is just the tip of the iceberg, and health care fraud costs in excess of $100 billion per year. Moreover, some of the most significant health care fraud cases have been in areas fostered by COVID-19, such as telemedicine.

Instead, we anticipate that there will be the adoption of regulations and enforcement policies that take into account how health care is delivered in a post-COVID-19 environment. Financial inducements aimed at encouraging cost controls or improving outcomes should be supported. The new regulations, and modernization of prior regulations, under the Stark Law and AKS create some flexibility for certain value-based and other arrangements among providers. In addition to the blanket waivers that apply during the COVID emergency, there is also a potential for a less hypertechnical application of these laws, reflected in the new regulations and possibly in lessons learned about the industry during the pandemic. On the other hand, certifications under the various grant programs, as well as potential new developments in the interpretation of the FCA, may provide fertile ground for FCA relators to pursue health care providers.

Nevertheless, although fraud and abuse enforcement will continue to be robust, we anticipate that the contours of what constitutes fraud will evolve in the post-COVID-19 environment to recognize the realities of the ways in which health care is delivered, and to enable and permit models to achieve cost savings and improvement of outcomes.

CHAPTER 5:
BACK TO THE FUTURE: WHAT'S NEXT FOR THE HEALTH CARE WORKPLACE 2.0

— By Kristin McGurn, Ashley Cano, Elizabeth MacGregor, and Andrew Paley

After over a year of battling surge after surge, health care employers were asked to pivot once again in late 2020. Facing intense pressure to convert treatment to testing to vaccination roll-out, clinical settings struggled to staff up and implement large and small vaccination sites across the country. Supply chain deficiencies and worker shortages, highlighted at the outset of the pandemic, resurfaced, and challenged vaccine roll out strategies nationwide.

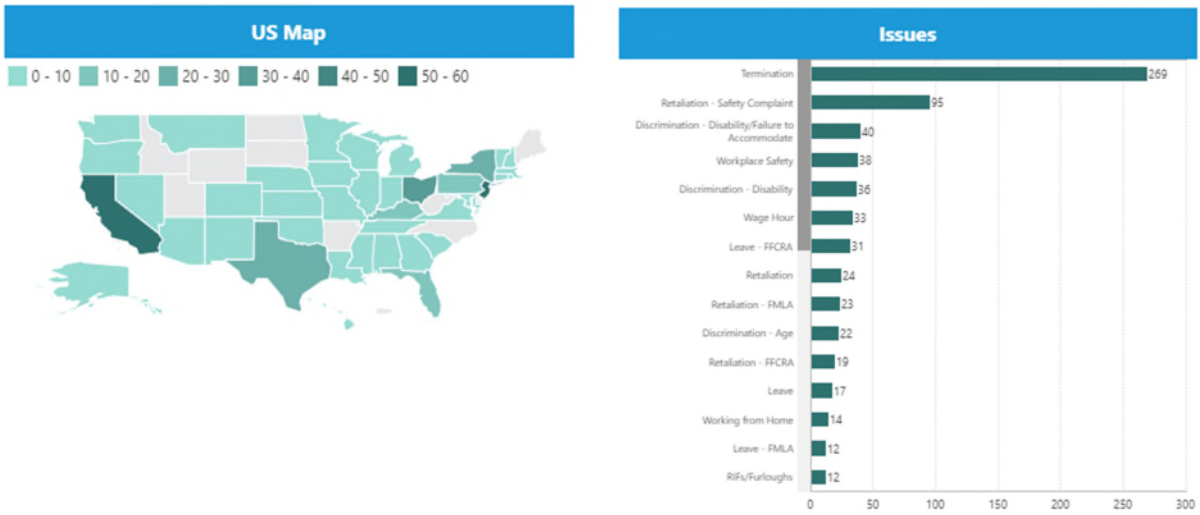
As massive vaccination sites now wind down and vaccine adoption rates slip, and person-by-person encouragement continues in many communities committed to increasing the number of vaccinated individuals among reluctant populations, the industry is at a turning point—reimagining the health care workforce of tomorrow. As providing care returns to a semblance of normal in medical centers, acute care and long-term facilities, behavioral and mental health settings, and home care, questions resonate: What have we learned and how will we change?

Health care employers are planning for the time when the majority of willing Americans are vaccinated, ushering in a new era of health care service delivery. Tomorrow's health care workplace will be forever modified by pandemic lessons. A continued focus on employee wellness, labor relations, workforce development and deployment, and risk mitigation strategies should remain at the forefront as employers plan for what's to come.

Litigation Trends

A year and a half into the pandemic, the health care industry still leads all others in employment-related claims. Staffing reductions necessitated by canceled procedures, revenue shortfalls and other unavoidable, painful decisions that had to be made at the start of the pandemic resulted in hundreds of termination-related claims. The uptick in workplace safety and retaliation claims is a close second, given widespread and ongoing personal protective equipment and pandemic-inspired safety concerns. Leave, disability, and accommodation-related claims will continue to rise, including allegations relating to remote work accommodations that were unimaginable in the pre-pandemic health care environment. Vaccine-related disputes will also climb as some health care employers gradually move from strongly encouraging to mandating the vaccine for patient-facing employees while the Food and Drug Administration considers converting from emergency use authorization to familiar regulatory approval of certain vaccines. Those employees who are unwilling or unable to receive the vaccine, as well as employees who express unwillingness to work alongside colleagues who refuse, will present competing challenges for employers.

As always, health and safety, wage and hour, and related labor relations concerns, combined with staffing challenges fueled by pandemic fatigue, will remain a threat industry-wide.



Savvy health care employers are taking the necessary steps to ensure that, amidst the strain of the ongoing pandemic and optimism born from recovery efforts, their policies remain compliant with changing regulations, their processes are followed consistently, and managers are well-trained to spot issues and seek competent assistance when risk presents itself. The growing number of employee complaints and accommodation requests must be tackled proactively to head off litigation threats. Risk mitigation strategies discussed below will prepare health care employers to plan for the "What's Next" workplace.

Focus on Wellness

The emotional toll of the pandemic hit no industry harder than health care. Throughout the caregiver ecosystem, patient-facing staff witnessed more trauma than perhaps ever before. Health care workers—worldwide—watched mental and behavior health concerns escalate and health care inequity exacerbate. Simultaneously, these employees were treating sicker and frailer patients, as consumers predictably refused or avoided treatment during pandemic surges. As the critical work continues, the ramifications of burnout, worsened by continuing child-care challenges that threaten to drain mid-career professionals from the talent pipeline, insistently cry out for concerted and innovative wellness strategies.

Chief wellness officers should expect their enhanced roles to grow in prominence. Wellness champions who unabashedly identified areas for improvement in 2020 will remain critical to the caregiver wellness movement. Food, drink, and gratitude bestowed on care providers at the height of the crisis offered small lessons in employee morale. Pre-paid and nearby/on-site child care, scrub service and other hygiene offerings, and caregiver relief funds may be worth retaining, albeit conceived as a temporary benefit.

Attendant to morale, many employers learned the importance of providing adequate support for professional competency and timely education during crisis reassignments. Now these employers can leverage transferable skills to flexibly deploy caregivers while generating less angst. But eliminating or delegating non-essential tasks, role by role, along with enhanced efficiencies through policy change and continuous procedure improvement, should be fostered as a necessary component of worker wellness. As crisis-level operations normalize, allowing employee input and flexibility in reassignments, well supported by retraining and mentorship, will alleviate familiar stressors.

Likewise, the enhanced technological tools implemented for burnout support and to identify and redress mental and behavioral health concerns, including 24/7 hotlines, virtual visits, and virtual-enabled social support systems, will remain a critical part of wellness initiatives of the future. Health care employers have learned that leadership that is visible, offering outspoken support for behavioral health resiliency, sets the right tone for seeking and receiving help without stigma. By implementing intensive in-person rounding, chief wellness officers—alongside CEOs and others in leadership—can help normalize the use of recovery aids and diminish barriers to acceptance among clinical and other health care workers. Deployment of on-site therapists in the cafes, lounges, emergency, and other challenged departments and via confidential, HIPAA-compliant telehealth platforms, should remain the norm. Huddles and debriefs to openly, cordially discuss lessons learned—both what went well during crises and what needs improvement—and to share positive stories should remain a normal part of the workflow to nurture employee morale and head off patient safety and team-related concerns.

Smart investments in employee wellness benefit programming will be critical to attracting and retaining talent. Regularized stress assessments and benefit enhancements—including paid time off to rest, covered out-of-pocket expenses, ample time away, easy-to-access counseling, and facilitated self-reflection to find meaning in work—will be instrumental to entice and hang on to the increasingly contested pool of talent.

Workforce Development and Deployment

At the height of the COVID-19 crisis, American health care providers collaborated like never before, even across and among competitive health systems, to provide timely and effective care for needy patients. Information, supplies, and staffing were shared in innovative ways. While this level of interdependency predictably will wane as normal operations resume, the lessons learned from industry peers may enhance operations across the board and should lead to the exploration of creative ventures and unique affiliations.

Against this backdrop, attracting, retaining, and nurturing the health care worker population will continue to be a top challenge for the foreseeable future. Effectively competing for talent in the face of fierce competition remains vexing. Reliance on health care staffing companies that proliferated in 2020 and continue to scramble to help employers fully staff units hampered by COVID- and child care-related absences will likely give way to more affordable, innovative recruiting strategies. Remote work options for administrative and non-patient facing roles, perhaps unthinkable before early 2020, may now seem an obvious creative

solution to expand effectively the pool of industry-trained talent an employer can pursue, wherever they may sit.

Continued attention to employee engagement, robust pipelines for development, and thoughtful succession planning are critical. Each strategy must account for the social justice and equity movements that have touched every American workforce throughout 2020. A focus on equity—in health care and pay—enhanced diversity in leadership, and an emphasis on inclusion and belonging throughout worker populations are table stakes for healthy workforce cultures of tomorrow.

Labor Relations

The pandemic's impact on health care labor relations will reverberate for years. Whether unionized or non-unionized, health care facilities must be attentive to workplace optimization and predictable labor relations themes.

Unionized Workforces: Substance and Procedure

For unionized institutions, the tone and tenor of the relationship established between the employer and the union during pandemic surges will persist for years. To the extent the employer and the union viewed their relationship as a partnership, with both sides working toward common goals (e.g., continuing to provide excellent patient care while at the same time keeping employees safe, and balancing the institution's need to maintain financial health against the need of employees to continue earning a decent living), this collaborative spirit offers the promise of ongoing fruitful labor relations. On the other hand, if the employer and union took a largely adversarial posture during surges, that antipathy will not soon be forgotten and could give rise to predictable flashpoints. Lengthy strikes by nursing staff in certain corners of the country provide a stark example.

Substance: Unionized employers also can expect a number of COVID-related bargaining proposals from unions when their collective bargaining agreements are up for renegotiation. These may include proposals for hazard or incentive pay (including related to vaccination program compliance), and additional sick or child care-related leave—even as many states issue legislation of their own. Bargaining employers also should expect non-economic proposals, such as commitments to keep certain safety measures in place, maintaining social distancing protocols, and providing employees with sufficient PPE. Bargaining proposals from unions related to employees' COVID-19 vaccinations may aim to address how often those vaccinations will be administered, the extent to which employees who take issue with the vaccine can "opt out" or be accommodated, and providing time off or financial incentives to vaccinated employees. By the same token, unionized employers may introduce proposals that aim to maintain maximum employer flexibility in these areas.

These expectations are bolstered by an OSHA standard, issued in early June, as a long-awaited emergency temporary standard (ETS). The ETS unexpectedly focused only on health care employers, and will impact

labor relations for as long as the provisional standard exists. It *requires* hospitals, nursing homes, and assisted living facilities; emergency responders; home health care workers; and employees in ambulatory care settings where suspected or confirmed coronavirus patients are treated to develop a plan to mitigate the virus's spread.[138] The ETS also *requires* covered employers to provide workers with paid time off to get vaccinated and to recover from any side effects, as well as remote work or separation from co-workers when employees contract COVID or may be contagious. Employees and unions unquestionably will hold employers accountable to the letter and spirit of this ETS.

Procedure*:* For those unionized employers who have been using videoconferencing platforms to conduct union negotiations during the pandemic, expect this to continue for bargaining, grievances, and arbitrations alike. While adoption depends on both sides' willingness to continue using such platforms, many have found that the benefits associated with the use of these platforms, including the ability to meet more frequently, efficiently, and cost-effectively, outweigh the negatives.

Unionized employers should expect labor arbitration hearings to continue to be conducted by videoconference, accounting for the preferences of the parties and the arbitrator. Videoconference hearings cut down on travel expenses for all. As technological challenges gradually were overcome, arbitrators learned to effectively assess witness credibility during virtual hearings, reading facial expressions, body language, and tone—largely without issue. When shenanigans arose among witnesses or counsel, arbitrators became better prepared to prevent, deal with, and mete out consequences for misbehavior.

Non-unionized Workforces

For non-unionized health care employers, the measures taken in response to COVID-19 will produce ripple effects on any applicable union avoidance strategy in both the short and long term. To the extent employees were displeased with those measures, or felt as though the employer did not adequately communicate about those measures and why they were deemed necessary, such failed communication strategies may germinate union organizing efforts. When employees feel as though their employer is not listening to their concerns or adequately communicating about them, they are more likely to turn to labor unions for help.

Non-unionized health care institutions may therefore want to examine the degree to which measures taken during the pandemic may have been unpopular with employees or not persuasively communicated. If unpopular measures can be rolled back without negative consequence, employers may choose to proactively do so.

Gaps in mid-pandemic communications between health care executives and employees would certainly be understandable given the speed with which decisions had to be made and implemented during the unprecedented global health emergency. As the dust settles, however, health care employers might consider putting extra effort into restoring, reopening, and re-establishing lines of communication with employees. Effective communication is a two-way street. Positive employee relations training for managers

and supervisors helps clear that pathway. Such training includes education on potential signs of union organizing and strategies for lawfully trying to prevent it.

Statutory Protections

Both unionized and non-unionized health care employers must continue to be mindful of Section 7 of the National Labor Relations Act, which protects employees' rights to join together to advance their interests as employees. Section 7 makes it unlawful for an employer to interfere with or restrain employees in the exercise of those rights. During the course of the pandemic, protected concerted activity by health care employees became fairly ubiquitous, especially concerning worker health and safety. Expect such activity to continue for years, and remain attuned to the fact that taking adverse action against employees who engage in such activity could lead to unfair labor practice charges being filed with the National Labor Relations Board (NLRB).

Under the Biden Administration, the NLRB is certain to become more employee- and union-friendly. Defending unfair labor practices charges before the NLRB will be increasingly difficult in coming years. The NLRB will scrutinize employer work rules and employee handbook provisions much more closely for potential interference with employees' Section 7 rights. Health care employers should consider proactively reviewing and revising such rules and policies, to avoid appearing before the Biden NLRB.

Health care employers will undoubtedly feel the aftereffects of the pandemic in the area of employee relations for years to come. The pandemic understandably heightened concerns about employee safety, and those concerns are unlikely to disappear any time soon. Health care employers can therefore expect to see continued discussion and debate with and among employees and their representatives on these issues. An uptick in union activism and organizing within the industry is palpable and on the rise. Combined with a more pro-employee and pro-union stance by the Biden Administration, health care employers will face an uphill battle in fending off such efforts.

Liability Considerations

Given the significant uptick in claims against health care employers during the pandemic, discussed above, risk mitigation strategies are paramount for litigation avoidance. In addition to proliferated termination, discipline, vaccine, leave, and accommodation-related claims, wage and hour compliance must remain in sharp focus for 24/7 health care employers. Accumulating and aggregated hourly workers' compensable time across health care sites, on-call and reporting pay issues, proper regular rate calculations, per visit and live-in (home care) compensation structures, travel time and expenses, rounding, and training time claims will inevitably persist. Remote worker off the clock and expense reimbursement claims are on the rise. Joint employer liability theories may take a more prominent role wherever entities sought to collaborate on staffing to meet pandemic demands. Meal and rest break compliance must be emphasized, even where staffing is lean and emergent care is ongoing. Health care staff working as independent contractors will increasingly be scrutinized by the Biden Administration's agency personnel.

As discussed in Chapter 3, the PREP Act provides broad immunity for covered persons performing covered countermeasures. That immunity includes liability under federal and state law for "all claims for loss" related to the administration or use of a covered countermeasure.[139] As employers begin to see litigation related to practices adopted during the COVID-19 pandemic, one question to consider is whether the PREP Act may provide immunity for losses caused by alleged state wage and hour violations.

The PREP Act defines "loss" to include: "(i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotion injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss."[140] Although the definition focuses on losses related to personal injury, the inclusion of "loss of or damage to property" significantly expands the types of claims that may be covered by the act. Under a broad reading of the language, such loss could potentially include claims for lost wages related to time spent on precautionary measures adopted during the pandemic, such as temperature screenings.

Apart from immunity, the PREP Act also provides for preemption of any state law that is "different from, or is in conflict with, any requirement applicable under this section" and which relates to "dispensing, or administration by qualified persons" of covered countermeasures.[141] A Department of Health and Human Services advisory opinion describes the PREP Act as a "complete preemption" statute: "The *sine qua non* of a statute that completely preempts is that it establishes either federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both."[142] As with the potential scope of immunity, the implications for PREP Act preemption are broad.

There is little case law interpreting the scope of the PREP Act and many questions remain unanswered. For example, would a court find that potential damages from alleged wage and hour violations constitute a loss to property within the meaning of the act? If so, would a court find that those losses are related to dispensing or administering covered countermeasures? And in considering preemption, would a court find that state wage and hour laws are in conflict with the requirements of the act? Depending on how the law develops, the PREP Act may provide a potential defense for employers facing COVID-related state wage and hour claims.

The Beyond

In 2022 and beyond, non-patient-facing employees supporting health care delivery will work in more far flung locations, supported by technology investments that ensure increased worksite flexibility while offering more robust data privacy and security. Medical center real estate investments will pivot as a result. However, weaving together and maintaining a strong workplace culture that is capable of both achieving regulatory compliance despite dispersed work locations and also delivers inclusion and belonging to all team members, regardless of role or location, will pose a deep challenge for some employers, Those employees who continue to show up on site to provide direct patient care will continue to expect, and benefit

from, increased dedication to morale, workplace optimization strategies and creative wellness initiatives. Safety considerations will persist at the forefront of labor relations concerns. Managing staffing shortages, worker redeployment, and proactively developing talent pipelines, while continuing to accommodate increasing leave time and vaccine-related challenges, will require unwavering attention to nurture the health care ecosystem of tomorrow.

CHAPTER 6:
NURSING HOMES AND LONG-TERM CARE FACILITIES

— By Cynthia Mitchell and Chris DeMeo

Perhaps no single provider group has been more closely linked to the COVID-19 pandemic than nursing homes and long-term care facilities (collectively "senior living and long-term care facilities").[143] The congregate setting and vulnerable patient population combined to make these providers a focal point, if not a leading indicator, of the impact of the virus as well as the clinical and legal response. These same factors suggest that senior living and long-term care facilities will be the sector over which COVID-19 will cast its longest shadow. In the near term and beyond, this sector will focus on the legal implications of responding to the virus and accounting for government relief, but will also be looking ahead to new business and service delivery models through consolidation, expanding the offerings of facilities and services and introducing more clinical services into traditionally residence-based settings.

New Policy Initiatives and Legislation

The federal government has proposed policy initiatives and legislation targeted to senior living and long-term care facilities based on lessons learned from the pandemic. Before taking office, the Biden Administration announced its "Plan to Make Nursing Homes and Long-Term Care Facilities Safe."[144] The plan noted what it characterized as failures by the prior Administration, including lack of accountability with respect to CARES Act relief funds and liability protections for senior living and long-term care facilities. The plan outlined four broad initiatives directed toward (1) facility safety for residents and staff; (2) regulatory oversight of facility services; (3) oversight on use of taxpayer funds; and (4) increasing access to home and community based cares. Specific initiatives include increased survey activity and penalties by the Centers for Medicare and Medicaid Services (CMS), rejection of liability protections, and scrutiny of facility finances through Office of Inspector General (OIG) cost report audits. The plan also included increasing access to personal protective equipment (PPE**)**, increased staffing and training requirements, emergency OSHA safety standards, and promotion of alternatives to institutional care settings.

Since the Biden plan was first announced just before the election, President Biden signed the American Rescue Plan Act of 2021 (ARPA)[145] on March 11, which among other things, allocates $10 billion through the Defense Production Act for testing, PPE, vaccines, and other materials; extends Medicaid waivers for home and community-based care; and provides $250 million to States to "establish and implement strike team[s] that will be deployed to a skilled nursing facility in the State with diagnosed or suspected cases of COVID-19 among residents or staff for the purposes of assisting with clinical care, infection control, or staffing." The Administration has also doubled-down on expanding home and community based settings by dedicating $400 billion to Medicaid funding of such services in the current proposed infrastructure bill.

The Senate has also been active with proposed legislation lead by Senators Elizabeth Warren and Robert Casey, Jr. Senator Warren's proposed bill would require states to report COVID-19 data from assisted living facilities (ALFs**)**, including infection and death rates, as a condition to receiving further COVID-19 relief funds. These reporting obligations were not included in the ARPA. Senator Casey's proposed legislation included funding for quality improvement contracts to support infection control efforts in skilled nursing facilities (SNFs) and for infection-response strike teams, both of which were included (with less funding) in the ARPA.

As these policy initiatives and legislative show, the future for senior living and long-term care facilities will include specific, targeted legislation impacting—and in some cases ceding to the government—facilities' ongoing response to COVID-19. In this regard, the strike team and infection control provisions of the ARPA extend for a year beyond the expiration of the current public health emergency. Facilities should expect these actions to generate further enforcement actions impacting payment and certification.

Enforcement Priorities

Enforcement priorities in the foreseeable future will revolve around monitoring the use of money from the Provider Relief Fund (PRF) and whether care has improved at facilities that accepted those funds. The final reporting deadline for providers who did not fully expend PRF funds prior to December 31, 2020, was July 31, 2021. Providers got a sense early in 2021 of the level of scrutiny they will face in reporting PRF fund use when Senator Warren issued a letter to Genesis Healthcare, Inc. complaining that that the company, which received $300 million in state and federal aid under the CARES Act, paid a $5.2 million retention bonus to its CEO despite 2,800 in reported resident deaths from COVID-19. The letter included a request for detailed information from Genesis regarding government aid received and payments to the CEO and other executives.

For the remainder of 2021, senior living and long-term care facilities that have accepted money from the PRF can expect to hear similar concerns over any funds not traceable to PPE, direct patient care, and frontline workers. When reporting payment from the PRF funds that compensated administrative and executive personnel, senior living and long-term care facilities should completely and accurately tie such payments to services provided by those individuals that directly responded to the pandemic.

Likewise, increased survey activity focusing on infection control measures and outcomes will have the effect of determining whether senior living and long-term care facilities properly used the funds to address the pandemic. Even before the Biden Administration announced its initiative to increase survey activity, CMS issued guidance on June 1, 2020, for ensuring that SNFs and NFs better control COVID-19 infection rates.[146] Among other things, this guidance tied a state's future CARES Act funding to the state's completion rate of nursing home infection control and COVID-19 investigation surveys and increased corrective actions and fines for deficiency citations.

In January of 2021, CMS updated the criteria for triggering an on-site infection control survey under this policy and clarified that, for fiscal year 2021, states must complete stand-alone infection control surveys in 20% of their covered facilities. As suggested by Senator Warren's letter, deficiencies in infection control for facilities that received PRF funds could very well trigger investigation into the use of that money. In this regard, senior living and long-term care facilities should be prepared to show a "return on investment" for PRF funds in terms of improved patient care and outcomes.

Beyond direct liability to the PRF, federal authorities have made clear that applications to the PRF are "claims" for purposes of the False Claims Act, 31 USC § 3729, *et seq*. As a condition of receiving PRF money, facilities must certify that they money will be used to prevent, prepare for, and respond to coronavirus. One theory through which liability under the False Claims Act often occurs (among other scenarios) when a claim for payment is made for a service that is not provided. Federal courts have, however, recognized the potential for liability even when services were provided but were "so deficient that for all practical purposes [they were] the equivalent of no performance at all."[147] Facilities with increased COVID-19 infection rates and deaths may be subject to False Claims Act liability under such worthless services theory. The risk in this context is clear: a facility spending PRF money on approved uses could still be liable if it knowingly, or in deliberate ignorance, spent money in a manner that did not reduce the risk of COVID-19 as evidenced by an infection control deficiency.

The future for senior living and long-term care facilities in this regard includes an enforcement regime under which they will not only need to account for eligibility and use of PRF funds but also need to show that the funds were used prudently to improve patient care and respond to the pandemic successfully.

Liability, the PREP Act, and State Immunity Laws

One thing COVID-19 did not change is that senior living and long-term care facilities are still targets of professional liability lawsuits by residents and their families. What is different is how facilities may defend these cases. As noted in Chapter 3, the PREP Act provides potential immunity for a broad range of activities related to responding to the COVID-19 public health emergency. In addition, several states are backing up their executive and administrative orders from 2020 with legislation in 2021 providing immunity to health care providers, including senior living and long-term care facilities. On the opposite end of this trend, New York has reversed its earlier immunity legislation, following revelations of higher numbers of COVID-19 infections and deaths than were originally reported. In the near term, and through 2021, litigation in this area will be marked by increased motion practice to test the boundaries of federal and state immunity.

As noted in Chapter 3, early indications on the PREP Act are that courts are taking a much different view of the act's provisions than that taken by HHS. At a minimum, a claim must do more that implicate COVID-19 to trigger the PREP Act. Instead, there must be complaints of the actual use of a covered countermeasure in order for immunity to be available.[148] As more rulings come out, lawsuits will be drafted to take advantage of such gaps in immunity.

Litigation at the state level will likely follow a similar trajectory. For example, in Texas, bills have been presented in both the House and Senate that provide liability protection for health care providers, including senior living and long-term care facilities, against claims arising from "care or treatment relating to or impacted by a pandemic disease or a disaster declaration related to a pandemic disease" except in instances of reckless conduct or intentional, willful, or wanton misconduct.[149] To the extent of any discrepancy between state law and the PREP Act, there will likely be additional legal battles over the scope of the PREP Act's preemption provisions.

The future for senior living and long-term care facilities in this regard will involve lawsuits focusing on direct liability of the facility for administrative acts and omissions related to countermeasures and other COVID-19 response, rather than vicarious liability related to the acts or omissions of individual caregivers. These cases will bring a higher level of scrutiny to administrative decisions regarding countermeasures and the individuals who make them, including facility administrators and CEOs.

Vaccine Mandates and Passports

Senior living and long-term care facilities are on the front line of another legal battle regarding the ability of private industry to make proof of vaccination a condition of employment or access by the public to facilities and services. At the heart of this battle is the fact that all currently available vaccines have been approved for use by the Food and Drug Administration (FDA) under emergency use authorizations (EUAs), rather than full licensure. The Food, Drug and Cosmetic Act (FDCA) places certain limits on making such vaccines mandatory.[150] The Federal Equal Employment Opportunity Commission (EEOC) has taken the position that these limitations do not apply to employers, but that other federal laws requiring accommodations to be offered must still be followed.[151] Nevertheless, controversy remains as employees who do not wish to receive any of the currently available vaccines seek opportunities for redress in the face of losing their jobs.

Similarly, a battle is brewing over private businesses' ability to limit access to facilities based on proof of vaccination status. Many states implicitly allow private businesses to implement such access limitations. Even states such as Florida and Texas, which generally prohibit businesses from doing so, allow exceptions for senior living and long-term care facilities. In Florida, the governor signed legislation on May 3, 2021, that prohibits any business operating in the state from requiring "patrons or customers to provide any documentation certifying COVID-19 vaccination or post-infection recovery to gain access to, entry upon, or service from the business operations."[152] This prohibition does not apply to health care providers such as senior living and long-term care facilities, however.[153]

In Texas, the governor issued an executive order that prohibits state government entities and private entities that receive public funds from requiring proof of vaccination status to access facilities and services.[154] Notably, this executive order expressly carves out senior living and long-term care facilities such that they are able to require documentation of a resident's COVID-19 vaccination status.[155]

This issue is particularly acute in the senior living and long-term care industry. The congregate setting housing a vulnerable population makes it particularly important to take all available measures to prohibit the transmission of the virus. The special circumstances of senior living and long-term care facilities are recognized in the new Florida statute and Texas executive order. In this regard, senior living and long-term care facilities may open themselves up to liability, without the prospect for PREP Act immunity, by not requiring vaccines of staff and visitors.[156]

The fact remains, however, that while this is projected to change in the coming months, right now many people still do not have access to the currently available vaccines. In addition, others have deeply held religious beliefs or health conditions that may justify not receiving the vaccine. As such, any course selected by senior living and long-term care facilities with respect to vaccination mandate will come with some risk of litigation so facilities must chose an option that is in residents' best interest.

Privacy concerns must also be considered. While maintaining vaccination history on residents and on staff (through a facility's health plan) will come within ordinary course of health information privacy operations, maintaining such information on family, vendors and other visitors may pose information privacy obligations to which the facility is not accustomed, especially if that information is maintained electronically. Senior living and long-term care facilities will need to understand state law requirements for consents, cybersecurity, and breach reporting applicable to visitor vaccine histories.

The future for senior living and long-term care facilities in this regard will require thoughtful planning and implementation of vaccine requirement protocols, including: adoption of measures through the health plan to make staff vaccine programs accessible, convenient, and flexible; community awareness campaigns that notify family and other visitors of any vaccine mandates; and development of information privacy and security measures directed to vaccine information that is not covered by HIPAA.

New Business and Service-Delivery Models

COVID-19 also brought to the forefront the age-old question senior living and long-term care facilities have struggled with: Should they be prioritizing hospitality/socialization or quality clinical care? In fact, the pandemic may have finally answered that question; senior living and long-term care facilities are first and foremost providers of health care services. This is how the government and the public view them, and they should be expected to be treated in a similar fashion to other providers.

What does this mean for the business model? Going forward, future consumers will first want to know what health care protocols are in place, but this will be in addition to, not in place of, what amenities will be offered. They will expect infection control measures beyond requiring masks, social distancing and temperature checks. They will bring with them deeper anxieties but the same high (if not higher) expectations.

The industry is already responding to these new consumer priorities. While it differs from provider to provider, some of these measures being implemented include new, cutting-edge technology (like touchscreen visitor logs), "outdoor" socialization pods, updated/more sophisticated air filtering systems, and in-house or third-party infection control teams to oversee it all.[157] New communities now have an even bigger advantage as they are opening with increasingly sophisticated infection control measures already built in.[158] Going forward, senior living providers will use these lessons learned to get more and more creative with their marketing and communication strategies, as well as with design, configuration, and use of their physical space. This will be not only evident in new constructions, but also in the capex projects of the existing facilities. There will be a focus on "more outdoor access, ways to isolate residents more comfortably, more touchless technology, more intensive air purification systems, dedicated telehealth spaces and on-site clinics, and other health-focused adaptations."[159] To meet the rising demand, we are going to see an even bigger investment in technology and infrastructure within the community[160], and larger health care offerings (by increasing staff, implanting telehealth capabilities and partnering with larger health systems).[161]

While the vaccine roll-out has given providers a bit of breathing room and measures like the above are being successfully implemented, as we state above, the pandemic will continue to have long-lasting effects and challenges on the senior living and long-term care facilities industry. Staying on top of the ever-changing needs and having the funds to make these changes will prove to be quite burdensome, and some providers will simply not be able meet the demands and survive. We will see a bit of consolidation in the industry as those providers merge with others or fold altogether. In addition, there are rumblings that tensions between owners and operators are on the rise, as owners are beginning to expect financial improvements and providers are still facing a weakened demand and high levels of competition. REITs and other owners are likely to get frustrated and replace existing operators with new management companies, which tend to be focused on the bottom line and not necessarily sustainable long-term models of quality care.[162] There is also talk that special purpose acquisition companies (SPACs) are targeting senior living to acquire and take companies that they feel have a high growth potential public.[163] Inevitably, the players in the industry are going to mix, merge, and change. Likewise, their physical presence. The "hot spot" locations have moved away from the big cities, such as New York City and San Francisco, to smaller, rural markets in response to the mass exodus from the big cities and the overall change in the population's lifestyle and priorities.[164]

The one thing that is certain amidst all this uncertainty is that the senior living and long-term care industry is changing and, while we are starting to see the results of some of those changes, it will be some time before the dust settles and the industry stabilizes again.

CHAPTER 7:
HIPAA AND PRIVACY REGULATION

— By Adam Laughton

Summary of HIPAA Changes in COVID-19 Responses

In the previous edition of this treatise, we examined some of the changes instituted by the Department of Health and Human Services (HHS) that relaxed Health Insurance Portability and Accountability Act (HIPAA) enforcement in response to COVID-19. Both new and returning readers can revisit that analysis here. The main questions to which we turn our attention in this chapter are (i) the impact that new and developing virtual and remote technologies will have on the shape and scope of HIPAA and associated privacy issues, and (ii) whether the COVID-19 contingency waivers will be repealed entirely, remain in place, or substantially survive in some modified form. Finally, we look at two recent developments not directly related to the COVID-19 pandemic, but which still have significant potential to alter HIPAA regulations and enforcement in the future.

New and Emerging Technologies; New Legal Regimes

One new development to be expected in the coming years would be a major revamping of HIPAA regulations around new and emerging technologies. The current Privacy Rule and Security Rule regulations were developed in a world that was moving from paper charts to electronic records and communications. These regulations mostly adhere to traditional notions of record custody and ownership, as well as the in-person and more traditional professional-patient relationships.

We believe that the potential use of blockchain in health care documentation and communications will be used more extensively to address data integrity and chain of custody for data transmissions. Space does not permit a full explanation of the blockchain system (it is the technology on which cryptocurrencies such as Bitcoin are based), but the application would be to give individuals more control over their own personal and health care information, which is stored in multiple locations from which access can be granted to those requiring such information from these different locations. Transition of health data to a blockchain format would give greater power and freedom to individuals to use their health data as they wish, while ensuring reliability because identical copies are stored at multiple points along the chain. However, it decenters providers and others who have traditionally served as repositories or custodians of medical information.

Moving into a blockchain health data system would necessitate major changes to HIPAA regulations, if not an entire rewrite, as it radically changes the balance of power and responsibilities among providers and patients. While many non-governmental and industry organizations have been looking into blockchain technology for health care purposes, the Office of Civil Rights (OCR) has yet to take it up. This has not stopped blockchain-derived startups in health care from attracting major investor dollars.

Another potential change with a disruptive effect would be the passage of a national European- (GDPR) or California- (CCPA) style privacy law. Privacy law in the United States has long been tied to particular types of transactions (credit cards & banking, health care), while Europe has adopted a more holistic model that treats privacy and data protection as fundamental and individual human rights. In 2018, California adopted the California Consumer Privacy Act adopting similar provisions as GDPR.

Although not yet proposed or in serious discussion, such a law could (though would not necessarily have to) supplant and replace HIPAA as the chief regulator of health data privacy.[165] The expansion of health privacy to a broader "personal" privacy through new laws that track GDPR and CCPA will present a challenge as it would upend more than a decades' worth of policies, procedures and regulations that are now standards for the industry. The passage of these expansive privacy laws on a state-wide level is a development worth watching, as they could impose (as California's does) requirements beyond or in addition to HIPAA.

Waivers and Enforcement Discretion

In our prior edition, we described in some detail the discretionary measures and waivers that OCR put into place to deal with the COVID-19 pandemic. Technology providers in and platforms used for telemedicine were allowed to expand using technology that was not entirely HIPAA-compliant in order to ensure patients access to providers during the pandemic. The need to rapidly pivot to a telemedicine-first, if not telemedicine-only approach to patient care necessitated immediate action to enable providers to transition to virtual care without a lengthy period of evaluation and implementation of expensive software and support platforms. As a result, widely available commercial platforms such as Skype and Zoom were approved for telemedicine use.

The questions we ask are: (1) whether these waivers and other modifications will be eliminated or repealed in their entirety, (2) will they remain in place, or (3) will they survive in some modified form, but remain substantially intact. As discussed in Chapter 1, we believe that option No. 1 is unlikely since it would hinder telemedicine adoption and the development of further technologies and methodologies. Telemedicine has become a ubiquitous part of health care delivery as it gains acceptance by providers, payors, and patients. Returning to an exclusively "in-person" delivery system is no longer possible given the ease of patient access and service delivery—no parking, reduced waiting, and less exposure to other ill patients.

Likewise, we do not believe that all waivers and relaxed standards will continue as described in option No. 2 (keeping all waivers in place). It is more likely that during the period of time in which there were few restrictions, incidents, deficiencies, and violations will be reviewed. Recent investigations into security breaches or other serious incidents which occurred during the COVID-19 public health emergency will likely reveal areas of regulatory adjustment. If it is revealed that the waivers and other modifications to standard OCR policies resulted in increased or more significant breaches, or other abuses under HIPAA, then some form of restriction or full repeal is more likely. If, however, this period passes largely without incident, many

outside OCR (including stakeholders and legislators) may wish to retain this more flexible system. In such a scenario, OCR's remit would be substantially limited and could create disruptions to HIPAA enforcement in the future. While such a development would be attractive to many stakeholders, OCR and other government agencies (the ones who actually control these rulemaking and enforcement actions) would be less enthused.

By process of elimination, option No. 3 appears to be the most likely outcome. The more important question is, "What exactly does that mean?" As discussed above, neither fully repealing nor retaining the more flexible COVID-19 system seems to be in the interest of all stakeholders. We believe that OCR will seek to balance these interests, pulling the "waiver system" within a modified umbrella of HIPAA protection. As discussed in the previous edition, some of these pandemic modifications will likely be made permanent exceptions for public health and research disclosures. In particular, expanding public health disclosures to deal with infectious disease in workplaces, living areas, and other facilities seems likely. The current public health exception primarily covers disclosures to the government, but also includes provisions for disclosures to employers (for workplace medical surveillance) and to persons at risk of contracting or spreading a disease. The additional experience of living through COVID-19 and the drastic alterations it has made to workplace employment standards and operations (both within and outside of health care) favor adopting broader and more permissive standards for disclosures in the workplace setting as well as in assisted living facilities, residences (such as apartment buildings), and other congregate spaces, given that employers, property managers, and business owners may not be willing to call attention to themselves in this manner.

Likewise, the rapid development of more effective COVID-19 testing, treatments, and historic release of vaccines in less than a year supports the need to maintain expanded authorization for research to be conducted for the purpose of diagnosis and prevention—particularly research looking retroactively at medical records for patients where research authorization was not contemplated or obtained at the time the records were created. To the extent that pandemics and other similar emergencies and crises are likely to become a recurring phenomenon, researchers, scientists, and industry will want to quickly be able to do analytics on large patient databases to aid in identifying strategies, therapies, and methods that can be used to combat the crisis. Opening up special research disclosure permissions tied to priority public health projects should be on the checklist of regulators, legislators, industry, and academics alike.

If we return to the factual scenario discussed above, regarding greater leniency from OCR in the use of widely available (and, in many cases, free) commercial communications platforms for the delivery of telemedicine services, adopting the middle road option would likely require creating additional exceptions as well as "retrofitting" those platforms with additional HIPAA protections from the standard model. Once the public health emergency is declared over, OCR should convene a review panel to evaluate and develop proposed standards, following which it would publish the proposed changes for comment. Implementation of the changes will require appropriate public notice and a sufficient time for stakeholders to make the necessary changes to their platforms, implementing certain front-end and back-end HIPAA protections

which can be adopted by all providers using those platforms. This would avoid the adverse effect of any telemedicine platforms that arose during the pandemic, while also offering additional protections to consumers and patients.

OCR Audits and December 2020 Notice of Proposed Rulemaking

Finally, we want to make note here of two developments occurring after the date of the previous edition of this treatise, but which may point us toward the future development of HIPAA rulemaking and enforcement. First, in December 2020, OCR released for the first time the results of its privacy and security audits conducted in 2016 and 2017 (the "audits").[166] The audits examined the policies and practices of both covered entities (of various types and sizes) as well as business associates. While not comprehensive in their scope, the audits did produce some striking findings regarding the failings of the audited organizations, chiefly that very high percentages of both covered entities and business associates:

- Failed to include all required content in their notice of privacy practices.
- Failed to include all required content in breach notifications to individuals.
- Failed to implement right of access requirements, including timeliness and access fees.
- Failed to properly and regularly conduct risk assessments, analyses and management.

While the results of the audits directly impact only those covered entities and associated businesses who were the subject of the audits, we think that the audits will point the way for OCR in future rulemaking and enforcement activities. Whether OCR conducts a similar series of intensive audits in the future (and this seems unlikely, since they took about four years to fully unfold), more focused review activities with an emphasis on the major deficiency items identified in the audits, supplemented by other foci as identified in recent breaches and settlements, could be on the table. Additional guidance, whether in rulemaking or through less formal means, would seem to be inevitable.

In fact, during the same month that the results of the audits were released, OCR also issued a notice of proposed rulemaking (NPRM), a preliminary step toward finalizing new regulations under the Privacy Rule and Security Rule.[167] Remarkably, though perhaps not surprisingly, several of the key areas identified in the December 2020 NPRM directly relate to the findings of the audits. Specifically:

- Broadening individual right of access by adopting standards for disclosing personal health information (PHI) to personal health applications.
- Strengthening in-person PHI inspection rights and shortening deadlines for individuals' right to access their own records.

- Modifying rules around fees for medical records requests and the circumstances under which patients can direct records to be released to third parties (e.g. attorneys representing patients in lawsuits).

In addition to these items, the December 2020 NPRM proposed other changes, including: (i) adding permitted uses and disclosures for care coordination and care management activities; (ii) defining "electronic health record;" and (iii) allowing expanded uses or disclosures by covered entities when "in the best interest of the patient" or when a threat to health or safety is "seriously and reasonably foreseeable" (rather than the former "serious and imminent" standard).

While many of the changes in the December 2020 NPRM call back to concerns raised in the findings of the audits, others are fulfilling long-expressed needs and wishes of providers and patients alike. Care coordination and care management have received renewed attention since the passage of the Affordable Care Act and in the subsequent area of greater experimentation around cost savings. However, existing HIPAA rules often posed obstacles to sharing patient information that would unlock some of the savings promised by certain innovative models. This NPRM seeks to solve that problem, while strengthening individuals' ability to access their own records at times and formats (as well as costs) convenient to them.

We can expect continued changes to the virtual interaction between providers and patients, which exposes both to increased exposure to violations of privacy and security. Although these will continue to expand in both scope of services and service providers, it is likely that the manner in which these services are provided and the qualifications those who provide those services will come under increased regulations to protect their patients. The purpose of the laws will continue to evolve to increase patient protections; but the manner in which these laws are applied and enforced will have to change.

CONCLUSION

While we acknowledge the fact that the future, both of health care and our economy, looks more hopeful than it did last year at the publication of our previous edition, it still remains to be seen whether and how stakeholders, regulators, and the public at large will use this crisis to address the disparities in how health care is accessed, funded, and delivered. Much depends on the public's acceptance and support of popular health initiatives such as telemedicine, reinvigoration of the Affordable Care Act, and adding a public option. Paralysis among regulators and gridlock in federal and state governments, not to mention risk aversion among business leaders, could trap the system in a perpetual pseudo-crisis, neither moving forward nor returning to a pre-COVID state. We suggest there is a third option based on the information we have assembled in this document. Rather than highlighting the failures of the recent past, we suggest taking a direction that is not only better for shareholders, corporations, and professionals, but also for patients and their families.

We are proud of our work in both the first edition and this second one. We hope our clients and others working in and around the health care industry use and build from this publication in charting a path toward normalizing and realigning their operations in a "new normal." While our first edition was certainly not 100% accurate, the uncertainty of the coronavirus coupled with major policy changes in a new presidential administration changed the course of events. By focusing on defeating the virus through enhanced public health measures and vaccinations, following the prior Administration's rapid-fire guidance and emergency policies, makes predicting the future a challenge. We intend to make future editions of this treatise a regular feature of our practice, and hope it will be something that you and your colleagues will look forward to in the years to come.

We welcome your feedback and suggestions for future content.

ENDNOTES

[1] See Centers for Medicare & Medicaid Services, Press Release "Trump Administration Issues Second Round of Sweeping Changes to Support U.S. Healthcare System During COVID-19 Pandemic" (April 30, 2020), *available at* https://www.cms.gov/newsroom/press-releases/trump-administration-issues-second-round-sweeping-changes-support-us-healthcare-system-during-covid.

[2] See: H.R.1319 - American Rescue Plan Act of 2021 that budgeted $1.9 Trillion to address a number of health care and economic needs brought about by the emergency pandemic.

[3] https://www.cms.gov/files/zip/list-telehealth-services-calendar-year-2021.zip

[4] MGMA Stat Poll February 9. 2021; 752 responses; MGMA.com/Stat

[5] See https://www.cms.gov/newsroom/ract-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-1.

[6] See study published in *JAMA Psychiatry.* Published online February 3, 2021. doi:10.1001/jamapsychiatry.2020.4402

[7] See https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.01786

[8] Ibid.

[9] https://www.ama-assn.org/practice-management/sustainability/covid-19-financial-impact-physician-practices

[10] This model gives primary care providers an alternative to fee-for-service insurance billing using a retainer model through direct contracting where patients pay fees for all services on a monthly, quarterly or annual basis. It is not the same as concierge medicine which uses a "membership" model.

[11] See: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.

[12] For more information, go to the website of the National Center for Medical Legal Partnership, https://medical-legalpartnership.org/about-us/

[13] Robert S. Huckman, "What Will U.S. Health Care Look Like After The Pandemic?" *Harvard Business Review,* April 7, 2020.

[14] David Shaywitz, "How Will Coronavirus Change The Healthcare Industry?" *National Review,* April 1, 2020.

[15] Larry Levitt, Karyn Schwartz, Karyn Schwartz, and Eric Lopez, Kaiser Family Foundation Issue Brief, "Estimated Cost of Treating the Uninsured Hospitalized with COVID-19," *available at* https://www.kfflorg/coronavirus-covid-19/issue-brieffestimated-cost-of-treating-the-uninsured-hospitalized-with-covid-19/view/footnotes/ (last updated June 9, 2020).

[16] Paycheck Protection Program and Healthcare Enhancement Act, P.L 116-139 (2020).

[17] American Rescue Plan Act, P.L. 117-2 (2021).

[18] Levitt, Schwartz, Schwartz, and Lopez, *supra.*

[19] *Id.*

[20] *Id.*

[21] Patrick Connole, *Skilled Nursing Facility Rates Hit New Low Before Vaccines Took Hold*, Provider Magazine (March 5, 2021).

[22] Levitt, Schwartz, Schwartz, and Lopez, *supra.*

[23] Centers for Medicare & Medicaid Services, "Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19," *available at* https://www.cms.gov/files/document/covid-long-term-care-facilities.pdf (last updated May 15, 2020).

[24] Maurie Backman, "Will COVID-19 Drive Up the Cost of Long-Term Care?," *The Motley Fool (May 1,* 2020), *available at* https://www.fool.com/retirement/2020/05/01/will-covid-19-drive-up-the-cost-of-long-term-care.aspx (last updated May 15, 2020).

[25] Health Dimensions Group, "Top Trends in Aging Services in 2019" (December 3, 2018), available at https://healthdimensionsgroup.com/top-trends-aging-services-2019/ (last updated May 15, 2020).

[26] *Id.,* Gleckman.

[27] *Id.,* Health Dimensions Group.

[28] *Id.*

[29] *Id.*

[30] Ken Abrams, Olive O'Rourke, and Wendy Gerhardt, "Viewing post-acute care in a new light: Strategies to drive value," *available at* https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-post-acute-care-innovation-report.pdf (last updated May15, 2020).

[31] *Id.*

[32] *Id.*

[33] *Id.,* Health Dimensions Group.

[34] *Id.,* Abrams et al.

[35] 42 U.S.C. § 247d-6(d)(a)(1).

[36] *See* 85 Fed. Reg. 15,198,15,202 (March 17, 2020) ("Declaration"); *see* also Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.

[37] 42 U.S.C. § 247d-6d(c)(3).

[38] *See* 42 U.S.C. § 247d-6d(b)(8); In addition, exclusive federal jurisdiction exists over any claims for willful misconduct that must be brought in the United State District Court for the District of Columbia. 42 U.S.C. § 247d-6d(e).

[39] HHS Adv. Op. "Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act April 17, 2020, as Modified on May 19, 2020" ("Advisory Opinion") *available at* https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf (last updated June 9, 2020).

[40] 42 U.S.C.A. § 247d-6d(i)(7); 21 C.F.R. pts 312 and 812.

[41] FDA, "FDA Combating COVID-19 with Medical Devices," *available* at https://www.fda.gov/media/136702/download (last updated November 24, 2020); FDA, "FDA Combating COVID-19 with Therapeutics," *available at* https://www.fda.gov/media/136832/download (last updated December 2, 2020).

[42] 42 U.S.C. 247d-6d(i)(2), (3), (4), (6), (8)(A) and (B).

[43] 42 U.S.C. § 247d-6d(i)(6).

[44] *See* Declaration, *supra* at 15202.

[45] 42 U.S.C. § 247d-6d(i)(8).

[46] Decl. 85 Fed. Reg. 15,198, 15,202.

[47] *See* Declaration, *supra* at 15202.

[48] *See id.;* Advisory Opinion, *supra* at 2; *see also* 42 U.S.C. 247d-6d(a)(5) and (b)(2).

[49] Advisory Opinion, *supra* at 2.

[50] *See* Declaration, *supra* at 15202.

[51] Advisory Opinion, *supra* at 2.

[52] 42 U.S.C. § 247d-6d(b).

[53] *Id.*

[54] *Id.* §§ 247d-6d, 247d-6e.

[55] *Id*. § 247d-6(d)(a)(1).

[56] *Id*. § 247d-6d(c)(3).

[57] *Id*. § 247d-6d(a)(2)(B).

[58] *Id*. § 247d-6d(a)(2)(A)(iv).

[59] *See id.* § 247d-6d(b)(8).

[60] *Id*. § 247d-6d(b)(8).

[61] *See id*. § 247d-6e.

[62] *Id*. § 247d-6d(d)(1); *see also id*. § 247d-6d(c), (e)(1).

[63] *Id*. § 247d-6d(e)(1), (e)(5).

[64] *See id*. § 247d-6e(d)(1).

[65] *Id.* § 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B).

[66] *Id.* § 247d-6d(i)(6).

[67] *See* 85 Fed. Reg. 15,198, 15,202.

[68] 42 U.S.C. § 247d-6d(i)(8).

[69] 85 Fed. Reg. 15,198, 15,202.

[70] 42 U.S.C. § 247d-6d(i)(7); 21 C.F.R. pts 312 and 812.

[71] *See* https://www.fda.gov/media/136702/download; https://www.fda.gov/media/136832/download.

[72] *See* 42 U.S.C. 247d–6d(a)(5) and (b)(2)(E).

[73] HHS Advisory Opinion 20-01, Apr. 14, 2020.

[74] *See* 85 Fed. Reg. 15,198 (Mar. 10, 2020).

[75] *Id*. at 15,202.

[76] *Id.*

[77] *See* 85 Fed. Reg. 21,012 (Apr. 15, 2020).

[78] Public Law 116–136.

[79] *See* 85 Fed. Reg. 35,100 (June 8, 2020).

[80] *See* 85 Fed. Reg. 52,136 (Aug. 24, 2020).

[81] *See* 85 Fed. Reg. 79,190 (Dec. 9, 2020).

[82] *See Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g*., 545 U.S. 308 (2005) (holding that state-law claims which implicate significant federal issues allow for federal-court jurisdiction).

[83] *See* 86 Fed. Reg. 7,872 (Feb. 2, 2021).

[84] *See* 86 Fed. Reg. 10,588 (Feb. 22, 2021).

[85] https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID-Amendment-6.aspx.

[86] *See* 86 Fed. Reg. 14,462 (Mar. 16, 2021).

[87] https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf.

[88] https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf.

[89] https://www.hhs.gov/sites/default/files/advisory-opinion-20-03-hhs-ogc-public-readiness-emergency-preparedness-act.pdf.

[90] https://www.hhs.gov/sites/default/files/advisory-opinion-20-04-hhs-ogc-public-readiness-emergency-preparedness-act.pdf.

[91] 42 U.S.C. § 247d-6d(a)(4)(B).

[92] *Id*. § 247d-6d(i).

[93] *See* 85 Fed. Reg. at 15,199.

[94] 2014 WL 10413521 (N.Y. Sup. 2014).

[95] *Id.* *3-4.

[96] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf.

[97] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO-21-02-PREP-Act_1-12-2021_FINAL_SIGNED.pdf.

[98] 480 F. Supp. 3d 1207, 1218 (D. Kan. 2020).

[99] 2014 WL 10413521 (N.Y. Sup. 2014).

[100] *Id.* *3-4.

[101] No. 20-cv-1198, 2020 WL 6140474 at *7 (W.D. Pa. Oct. 16, 2020).

[102] AO 20-04 at 3.

[103] AO 21-01 at 3.

[104] 42 U.S.C. § 247d-6d(b)(8).

[105] https://www.justice.gov/olc/file/1356956/download.

[106] *See Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC*, No. 1:21-cv-00334, *3 n.3 (W.D. La. Apr. 30, 2021); *Garcia v. Welltower OPCO Group LLC,* 2021 WL 492581, at *7 (C.D. Cal. Feb. 10, 2021).

[107] *See* 28 U.S.C. § 1331.

[108] *See Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804 (1986).

[109] *Marin General Hosp. v. Modesto & Empire Traction Co.*, 581 F.3d 941, 945 (9th Cir. 2009).

[110] *See Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63, 66 (1987).

[111] 545 U.S. 308 (2005).

[112] *Id.* at 312.

[113] 85 Fed. Reg. at 79,197.

[114] SACV2002250JVSKESX, 2021 WL 492581 (C.D. Cal. Feb. 10, 2021).

[115] *See, e.g.*, *Jackie Saldana v. Glenhaven Healthcare LLC*, No. CV205631FMOMAAX, 2020 WL 6713995, at *2 (C.D. Cal. Oct. 14, 2020) (finding that the PREP Act did not preempt plaintiffs' state law claims); *Martin v. Serrano Post Acute LLC*, 2020 WL 5422949, *1-2 (C.D. Cal. 2020) (same).

[116] *Chevron* deference requires a federal court to defer to an agency's interpretation of an ambiguous statute if the interpretation is deemed to be reasonable. *Chevron, Inc. v. NDRC, Inc*., 467 U.S. 837, 843 (1984). Unlike *Chevron* deference, *Skidmore* deference allows a federal court to determine the appropriate level of deference for each case based on the agency's ability to support its position. *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). While *Chevron* deference is binding for agency rules developed through administrative rulemaking (including notice and comment), *Skidmore* deference is applied to agency interpretations, such as advisory opinion letters, that are not required to be developed through the rulemaking process.

[117] *See* 42 U.S.C. § 247d-6d(a)(1).

[118] No. 1:21-cv-00334, *3 n.3 (W.D. La. Apr. 30, 2021).

[119] *See, e.g.*, *Robin Roebuck v. Mayo Clinic*, No. CV-21-00510-PHX-DLR, 2021 WL 1851414, at *5 (D. Ariz. May 10, 2021) ("[T]he Court joins the growing consensus finding that the PREP Act is not a complete preemption statute. The PREP Act does not satisfy the Ninth Circuit's complete preemption test because it does not completely replace state law claims related to COVID-19 and does not provide a substitute cause of action for [plaintiff's] medical negligence claim."); *Golbad v. GHC of Canoga Park*, No. 221CV01967ODWPDX, 2021 WL 1753624, at *2 (C.D. Cal. May 4, 2021) ("Simply put, the PREP Act does not satisfy the Ninth Circuit's two-part complete preemption test."); *Padilla v. Brookfield Healthcare Ctr.*, No. CV 21-2062-DMG (ASX), 2021 WL 1549689, at *4 (C.D. Cal. Apr. 19, 2021) ("Nearly every other federal court addressing the issue of complete preemption has found that the PREP Act is not a statute with complete preemptive effect."); *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, No. 3:20-CV-00683, 2021 WL 1561306, at *7 (M.D. Tenn. Apr. 21, 2021) ("[N]early every district court to consider whether the PREP Act completely preempts similar state-law claims against nursing homes has concluded the PREP Act is not a complete preemption statute, or at least does not have such an effect on claims like those presented here."); *Riggs v. Country Manor La Mesa Healthcare Center*, 21-CV-331-CAB-DEB, 2021 WL 2103017, at *2 (S.D. Cal. May 25, 2021) (holding that the plaintiffs' state-law claims against a nursing home were not completely preempted by the PREP Act);

Evans v. Melbourne Terrace Rcc, LLC, No. 6:21-CV-381-JA-GJK, 2021 WL 1687173, at *2 (M.D. Fla. Apr. 29, 2021) ("[T]he PREP Act is not a complete preemption statute. . . . And even if it were, [plaintiff's] allegations accusing [defendant] of inaction—versus prioritization or purposeful allocation of countermeasures—are not within the scope of the PREP Act. Federal district courts across the country have nearly unanimously so held since the start of the pandemic."); *see also Shapnik v. Hebrew Home for the Aged At Riverdale*, No. 20-CV-6774 (LJL), 2021 WL 1614818, at *16 (S.D.N.Y. Apr. 26, 2021) (collecting cases); *Dupervil*, 2021 WL 355137, at *12 (E.D.N.Y. Feb. 2, 2021) (collecting cases).

[120] *Bolton v. Gallatin Center for Rehabilitation & Healing, LLC*, Case No. 3:20-cv-00683.

[121] *See* Dkt 35-1, at 1, Case No. 3:20-cv-00683.

[122] No. 20-6605, 2020 WL 4671091 (D.N.J. 2020).

[123] *Id*. at *11.

[124] 42 U.S.C. § 247d-6d(a), (d)(1).

[125] *Bolton v. Gallatin Ctr. for Rehab. & Healing, LL*C, 3:20-CV-00683, 2021 WL 1561306, at *9 (M.D. Tenn. Apr. 21, 2021).

[126] *E.g.*, *Dupervil*, 2021 WL 355137; *Winfred Cowan*, 2021 WL 1225965; *Robertson v. Big Blue Healthcare, Inc*., No. 2:20-cv-02561-HLT-TJJ, 2021 WL 764566 (D. Kan. Feb. 26, 2021); *Estate of McCalabb v. AG Lynwood, LLC*, No. 2:20-cv-09746-SB-PVC, 2021 WL 911951 (C.D. Cal. Mar. 1, 2021); *Lopez v. Life Care Ctr. of Am., Inc*., No. CV 20-0958 JCH/LF, 2021 WL 1121034 (D.N.M. Mar. 24, 2021); *Schuster v. Percheron Healthcare, Inc*., No. 4:21-cv-00156-P, 2021 WL 1222149 (N.D. Tex. Apr. 1, 2021); *see also Ivey v. Serrano Post Acute, LLC*, No. CV 20-11773 DSF, 2021 WL 1139741 (C.D. Cal. Mar. 25, 2021) (concluding that "HHS has not been delegated authority over the interpretation of judge-created federal jurisdiction doctrines such as complete preemption and is due no deference for its musings on such matters"); *Golbad*, 2021 WL 1753624, at *3 (noting that "[t]he court in *Garcia* deferred to the HHS Secretary's opinion of PREP Act complete preemption, but did not consider the Ninth Circuit's two-part complete preemption test).

[127] *Bolton*, 2021 WL 1561306, at *9 (citing *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 642 (6th Cir. 2004) ("[O]nly those administrative interpretations that Congress and the agency intend to have the 'force of law,' as opposed to those merely characterized as 'authoritative,' qualify for *Chevron* deference.").

[128] *Id.* (quoting *Estate of Jones v. St. Jude Operating Co., LLC*, No. 3:20-cv-01088-SB, 2021 WL 900672, *6 (D. Or. Feb. 16, 2021)).

[129] *Id.* (citing *Dupervil*, 2021 WL 355137, at *10).

[130] https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html.

[131] *United States ex rel. Thomas v. Seimans AG,* 593 F. App'x. 139, 143 (3d Cir. 2014).

[132] *United States ex rel. Hill v. University of Medicine and Dentistry of N.J.,* 448 F. Appx. 314, 316 (3d Cir. 2011).

[133] *United States v. Care Alternatives,* 952 F.3d 89 (3d Cir. 2020).

[134] *Id.* at 96.

[135] *United States ex rel. Winter v. Gardens Regional Hospital & Medical Center, Inc.,* 953 F.3d 1108, 1119 (9th Cir. 2020).

[136] *Petition for Certiorari Docketed,* 952 F.3d 89.

[137] U.S. Dept. of Health and Human Services and U.S. Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for FY 2019* (June 2020), at 1.

[138] Subpart U, § 1910.502 (Healthcare). The ETS also requires health care employers to limit entry points, screen non-employees, adhere to CDC precautions, provide PPE, comply with certain procedures during aerosol-generating patient care, enforce physical distancing, clean, disinfect and ventilate, train, maintain records, and report COVID fatalities and hospitalizations.

[139] 42 U.S.C. § 247d-6d(a)(1).

[140] 42 U.S.C. § 247d-6d(a)(2)(A).

[141] 42 U.S.C. § 247d-6d(b)(8).

[142] Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision, January 8, 2021 ("Fifth Advisory Opinion"), p. 2.

[143] Senior living and long-term care facilities include skilled nursing facilities (SNFs) under Medicare Part A; nursing facilities (NFs) under Medicaid; and private pay assisted living facilities (ALFs) and similar residential-oriented communities.

[144] https://joebiden.com/wp-content/uploads/2020/10/Nursing-Home-Policy.pdf.

[145] H.R.1319 - American Rescue Plan Act of 2021, https://www.congress.gov/117/bills/hr1319/BILLS-117hr1319enr.xml#toc-H990C5793DC6540A9A4BB2359F93F48BC.

[146] https://www.cms.gov/files/document/qso-20-31-all.pdf.

[147] *Mikes v. Straus*, 274 F.3d 687, 703 (2nd Cir. 2001) (citing *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048 (9th Cir. 2001)).

[148] *See, e.g., Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, 2020 WL 6140474 at *7 (W.D. Pa. Oct. 16, 2020) (on appeal).

[149] Texas S.B. 6, § 2 (Introduced Version).

[150] 21 U.S.C. § 360bbb-3.

[151] *See* "What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws," https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

[152] Florida SB 2600, § 18.

[153] *Id.*

[154] EO-GA-35 (April 5, 2021).

[155] EO-GA-35 § 4.

[156] *See Casabianca v. Mt. Sinai Med. Ctr.*, 2014 WL 10413521 at *4 (N.Y. Sup. Dec. 2, 2014) (decision not to administer H1N1 vaccine "is in no way covered by PREP, and the immunity from suit claimed by the defendants here simply does not exist").

[157] *See* "Covid-19 Propels Shift Toward More Health Care-Focused Model of Senior Living" https://seniorhousingnews.com/2020/07/23/covid-19-propels-shift-toward-more-health-care-focused-model-of-senior-living/.

[158] *Id.*

[159] *See* "Top Senior Housing Trends for 2021" https://seniorhousingnews.com/2021/01/02/top-senior-housing-trends-for-2021/.

[160] *See* "How Senior Living Providers Are Investing in Tech in the Age of Covid-19," https://seniorhousingnews.com/2021/03/22/how-senior-living-providers-are-investing-in-tech-in-the-age-of-covid-19/.

[161] *See* "Top Senior Housing Trends for 2021," https://seniorhousingnews.com/2021/01/02/top-senior-housing-trends-for-2021/.

[162] *Id.*

[163] *Id.*

[164] *Id.*

[165] We note here that the CCPA contains a specific exception for HIPAA and health data transactions, but such an exception could be omitted from future state or federal legislation.

[166] https://www.hhs.gov/sites/default/files/hipaa-audits-industry-report.pdf.

[167] https://www.hhs.gov/sites/default/files/hhs-ocr-hipaa-nprm.pdf.

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