Seyfarth

The Future of Health Care in the US

What A Post-Pandemic Health Care System Could Look Like

Seyfarth Shaw LLP

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INTRODUCTION

In a very short period of time, we have witnessed the unprecedented impact of the COVID-19 pandemic on the physical and economic health of the US population. As we write this paper, the numbers of cases and deaths have climbed significantly despite federal, state, and local government orders to contain the spread of the virus. As a result of this public health crisis and myriad emergency orders, our health care system, its providers, suppliers, and payers have entered a new state of existence. We are no longer asking when things will go back to normal, but asking instead, "What is the new normal?" Many are predicting this "new normal" will be focused on leveraging our technology, innovation, and capabilities to better respond to the next pandemic or other public health emergency.

This piece, authored by attorneys in Seyfarth's Health Care group, provides insights into what this "new normal" may entail. It identifies the potential consequences of the crisis, suggest potential outcomes, and lessons learned from the emergency measures put in place to make a fragmented system more secure while expediting reliable testing and the development of a vaccine.

While every industry has been affected by COVID-19, few will be as fundamentally changed as the health care industry, which is at the epicenter of most of the recent regulatory changes. Our goal is to discuss how these changes will affect the future of health care in the US and what the health care system "post-pandemic" will look like. Our hope is that what we write today may help inform those in a position to plan or deliver care prepare for what is coming next. The COVID-19 pandemic has revealed the many problems inherent in our fragmented health care system; but also provides important information on how the system can improve into the future.

The authors of this piece explore how those changes will impact key participants in the health care industry with a focus on how the future of the industry will be informed and shaped. Our focus is on key players in the US health care system that have been affected by and will likely be affected in the next public health emergency. These include licensed health care professionals (the providers), licensed health care facilities (the institutional providers), the third party payers (including government payers), the workforce, and the research community that will eventually find a reliable diagnostic test and a vaccine for future protection against the virus.

Contributors to this treatise have attempted to address a range of substantive issues within their areas of expertise. We intend that this treatise will be a "living" document that will be regularly updated as we move from the COVID-19 crisis to our post-COVID state. We encourage you to regularly visit our website to follow our ongoing updates as we make this transition.

In our analysis, we have relied on currently available resources and information as well as communications with medical and health policy experts. The following chapters are written by attorneys in Seyfarth's Health Care group. These attorneys have the knowledge and experience to address the issues posed in each chapter, applying their expertise and reasoned analysis to present what they believe will be our "new normal."

CHAPTER 1

THE EVOLUTION OF PHYSICIAN AND HEALTH PROFESSIONAL REGULATION

— By Dr. Sheryl Dacso and Chris DeMeo

In response to the COVID-19 crisis, the US government issued an unprecedented array of temporary regulation waivers and new rules. These were aimed at bolstering the health care system and providing maximum flexibility for health care facilities and providers to respond to the pandemic.

These temporary actions were intended to meet several important goals to address the providers seeking to care for those at risk or affected by the virus and included: removing barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states; increasing access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; expanding in-place testing to minimize transmission; and putting "patients over paperwork" by giving providers, health care facilities, Medicare Advantage and Part D plans, and states temporary relief from many reporting and audit requirements so they can focus on patient care.[1]

These waivers and new rules have rapidly and radically changed how care is delivered. We can expect that this "new normal" will continue post-COVID-19 to impact how practitioners deliver services, from engaging in clinical practice and getting paid for services, to staffing clinics and interacting with patients. In this chapter, we address the areas of clinical practice that will be most affected by the public health emergency and speculate on the future state of practice. A complete listing of actions taken by Centers for Medicare & Medicaid Services (CMS) to address the pandemic can be found on the CMS COVID-19 website. In this article, we address the areas that are specifically relevant to the delivery, payment, and overall regulation of the health care sector. This is a work in progress. At the time of writing, federal, state, and local governments are developing new guidelines for reopening the economy during a public health emergency. The inherent conflict between the economy and the future of the public's safety is at the heart of these reopening plans.

This chapter raises five important areas for how practitioners may deliver care post-COVID-19:

1. How will the rapid expansion of digital health technology be used and regulated?
2. Will the current relaxation of professional licensing requirements during the crisis continue? What will be the effect on quality and standards of care?
3. How will COVID-19 affect the way practitioners schedule staff and see patients in their offices/facilities?
4. Will the location of the patient and the physician continue to be an issue in determining the point of service and delivery of care?
5. How will this affect provider reimbursement?

The Use and Regulation of Digital Health Technology, Post-COVID-19

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. Some examples of how the US health care system was implementing telehealth include:

- Medicare was in the process of expanding coverage of telehealth services for its Medicare Advantage beneficiaries by adding new CPT and HCPCS codes reimbursable as of 2020. Commercial carriers and self-funded plans were rapidly deploying the availability and use of telemedicine consultation for covered persons.
- Supervision and "same building" requirements previously required for billing remote patient monitoring (RPM) services were being relaxed, meaning that a physician could "generally" supervise a non-physician practitioner in a different location using telehealth technology.
- State laws began to evolve despite the variation among the different states on regulating telemedicine, which presented challenges when the physician had to be licensed in the same state as the patient being seen.
- Getting paid for telehealth services remained inconsistent, depending on the state laws, the particular payor and the availability of coverage.
- In states that retain a prohibition against the corporate practice of medicine, financial arrangements by companies with physicians and use of certain telehealth platforms could violate state corporate practice regulations. (e.g. Texas, California, New York).

With the COVID-19 outbreak, the use of remote technology to enable clinical interactions became a necessity to keep both providers and patients safe.

Examples include:

- 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 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 wherever they are located.
- Co-pay waivers could be given to established patients.
- New services were added as covered telehealth services.

In a post-COVID-19 health care delivery system, telehealth will 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 family members, work colleagues, and others during the pandemic. Although it cannot replace a face-to-face assessment/examination, once that relationship is established and baseline information is established, 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 payer as well. Disadvantages continue to exist with inconsistent coverage and reimbursement for telehealth services by non-government fully-insured or self-funded payers. There are also challenges to managing the quality of patient care and measuring outcomes because of questions about the meaningfulness of the a meaningful patient encounter. Telehealth will never fully replace an in-person encounter.

What is unclear is how the federal regulation expansions described above will be addressed when there is no longer an a public health emergency. 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 can 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 inevitably co-exist side-by-side with traditional in-person delivery. However, regulators, professionals, and practice administrators need to prepare to be more adaptable. Should pandemics like COVID-19 become a recurring phenomenon, practices and professionals will need to be able to quickly "flip the switch" to transition to telehealth as a primary delivery method with little disruption. This requires lowering barriers of entry (primarily price, but also factors like interoperability with EMR software and other local providers) onto telemedicine platforms, and making sure that IT and security infrastructure are in place and ready to go at the first notice of an approaching pandemic.

The COVID-19 pandemic has tested the US health system's response and resilience in the face of a tragic public health crisis. We also know that seasonal flu follows an annual cycle and the flu vaccines are developed in anticipation of the particular strain. We are unsure if COVID-19 will follow a similar seasonal cycle and, as of yet, there is no vaccine. However, prior planning for post-COVID operations and patient care must begin now.

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

Traditional notions of licensing and standards of care are based on consumer protection—persons calling themselves professionals must meet a certain level of skill and ethics such that patients are not harmed physically or financially. This is accomplished through entry-level licensure requirements for education, testing, and ethics and ongoing enforcement that imposes consequences for falling below what the licensing board determines is an acceptable level. Add to this an element of protectionism that limits the scope of practice for some professionals such that other professionals have an exclusive or primary role in certain modalities and imposes barriers to practice across state lines. The cumulative effect of these measures has been to create a predictable level of quality which has protected patient safety.

The downside is that these traditional notions can be inefficient and 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.) They can also lead to a health care system that is more costly if the standard of care can only be accomplished through expensive modalities, which in turn can only be performed by certain providers or under their direction. These downsides were only underscored by the recent pandemic. 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.

With respect to scope of practice, the winds of change have been blowing for quite some time and the recent pandemic may likely be the tipping point for a noticeable restructuring of the delivery of health

care by professionals. This change will most likely be driven by economic pressures and new priorities for provider/patient interaction, which are discussed later in this Chapter.

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 some employers' ability to fund health care plans—either on their own or with insurance premiums—at traditional levels.

From the providers' perspective, they are facing the same economic pressures as other businesses with the result of the likely closure of many independent practices. Factor in the providers workforce, which could contract or transmit the virus in the performance of their duties. When supplies of testing and personal protective equipment (PPE) are insufficient, these practices may not have enough staff to treat their patients. For a detailed discussion of the impact on the health care workforce see Chapter 3 and Chapter 6.

COVID-19 has also affected the provider/patient experience. Traditional hallmarks of patients wanting to see their physician (where "see" involves a meaningful office visit) may give way to incentives of ease of interaction where and when it is available. Current local government orders and personal preferences to stay at home have created a dynamic where virtual interaction with a provider during non-traditional hours will likely become the norm. This emphasis on consumer-oriented ease of use can have the effect of de-emphasizing the necessity of any one individual or license type for the majority of patient interactions, which may in turn work with the impetus to reduce costs.

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 practices expand, standards of care requiring supervision and oversight will likely be relaxed.

With respect to surgeries and other procedures which can only be safely performed by certain providers, the necessity of those procedures will contract. As explained in the payment section, the limitations on so-called "elective" surgeries may lead to reductions in what types of procedure are covered by insurance and government health programs and at what level. Specifically, where medical necessity to treat or remedy an injury or condition was once the predicate for coverage, new conditions for payor approval may arise. For example, payment decisions may be driven by whether a procedure must be performed in order preserve the patient's health or life in the next 6-8 weeks. Reduction in the frequency of surgeries will be made up by less-intensive and less-specialized interventions that do not need to be performed by a physician.

We also believe that the COVID-19 experience will accelerate the trend of practice consolidations and the growth of large regional or national practices with infusion of cash by private equity and other investor funds. These groups are 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 providers will continue to close

down avenues whereby small, independent practices have kept themselves afloat.

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 Will Affect the Way Practitioners Schedule Staff and See Patients in Offices and Facilities

This section regarding the impact on workforce issues for independent practitioners will focus on changes wrought by the need for a safe workplace and patient care environment.

Health care practices face the challenge of a work environment that is uniquely susceptible to the spread of COVID-19 due to treatment of affected patients as well as undiagnosed individuals who may be contagious. Until there is a vaccine and/or effective treatment, the most reliable way to ensure the safety of patients and co-workers is to establish transparency of the health status of the workforce when it comes to the disease. This will involve testing for the disease (or its antibodies) and addressing positive results. While such responses should be made in a way to avoid identifying the affected individual, this may not always be possible or practical. As a result, individual privacy may need to give way to a safe health care work environment.

Traditionally, employees have certain privacy rights that limit the disclosure of their health care information. In a public health emergency, where there are legal and ethical obligations to disclose evidence of the disease and transmission, these rights are impacted. The Department of Health and Human Services Office for Civil Rights (OCR) has issued waivers for disclosure of protected health information (PHI) related to exposure to COVID-19. In addition, certain employees are being asked to waive some of these rights as a condition of returning to work.

This will not end when the tide of the pandemic is stemmed. The need to investigate this virus generally and to prepare for the next outbreak will remain a national and professional priority. For the foreseeable future, therefore, the health care workforce will likely see a de-emphasis on individual privacy rights to the extent necessary to ensure continued testing for COVID-19, aggregation and studying of individual health data from the test results, and disclosure of information deemed necessary to protect individuals in the workplace and public.

Moreover, this pattern may be repeated for subsequent diseases as reflections on the US response to COVID-19 provoke more vigilance regarding the next virus. Experts have cited errors of not listening to valid warnings of unpreparedness, underestimating the impact of the disease, an unfocused public health response, and an obstacle course of regulatory barriers as reasons why the pandemic has been worse than it needed to be. One common thread weaving through the lens of hindsight is the need to identify who has the virus, isolate them, and provide them treatment. When the next pandemic surfaces, governmental authorities and employers may work more swiftly to implement testing and disclosure.

How Patient and Physician Location Will Determine the Point of Service and Delivery of Care

The CDC has published many recommendations for COVID-19 preparedness and response. We anticipate that these preparations will continue to be emphasized and should be integrated with provider's normal business operations and planning processes.

These steps include:

- Address need to stage patient demand affecting staffing and supplies.

- Determine scope of services based on patient and operational needs.
- Assure availability of supply chain for PPE and cleaning supplies.
- Maintain physical distancing, wear masks, and continuously clean surfaces.
- Educate patients about new practice protocols.
- Develop a triage process for handling high risk/seriously ill patients to minimize exposure to staff and other patients.

As states and localities move toward reopening, and providers begin clearing a backlog of delayed or deferred care and procedures, testing will be critical for care management. For this and other reasons, clinicians should begin to incorporate new ways of operation. Most state medical associations offer suggestions for re-opening a practice:[2]

- A mask must be worn by both the patient and physician or the physician's delegate when in proximity of the patient (meaning less than a six-foot distance between the patient and the physician or the physician's delegate).
- Follow policies the physician, medical and health care practice, or facility has in place regarding COVID-19 testing and/or screening patients.
- Before any encounter, patients must be screened for potential symptoms of COVID-19 or verified as previously screened within the last 20 days.
- Prior to care involving a medical procedure or surgery on the mucous membranes, including the respiratory tract, with a high risk of aerosol transmission, the minimum safety equipment used by a physician or physician's delegate should include N95 masks, or an equivalent protection from aerosolized particles, and face shields.

Although many states have been promised more PPE, it remains to be seen how the medical boards will enforce its use when getting it is outside the reasonable control of the physician.

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

For 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 as telehealth can reduce costs. If that is the only use of telehealth post-pandemic, however, then the health care system will missed an opportunity.

As noted above, the main payors for health care are government and employers. Both may have significantly less funding for health care in the foreseeable future. As a result, reimbursement rates will drop and more costs will be shifted to patients. These patients, many of whom are also suffering economically, will likely choose to avoid high deductibles and co-pays and forego even basic care, not to mention surgeries and procedures. We must also take into account the fact that many people are losing coverage entirely—whether as a result of layoffs or constriction of the Affordable Care Act and Medicaid programs in states that have chosen not to expand.

Telemedicine in its current form provides a partial solution by allowing patients to receive certain types of care at significantly 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 can 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 improved, and may in fact be worse off 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 which 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.

Telemedicine cannot substitute for surgeries and other procedures that require the physical presence of the physician. Instead, one of the standard responses to the pandemic has been to prohibit surgeries that are not emergent or necessary in the near term to protect the patient's life or health. These "elective surgery bans" delayed numerous surgeries and other procedures that were medically necessary to treat debilitating and degenerative conditions. These procedures are also costly, however, and the future economic model may further limit these procedures by changing the condition for coverage from medical necessity to that which must be done in the next 6-8 weeks to save the patient's life or prevent irreversible deterioration of condition.

Providers will be to leverage different modalities, including telehealth, to deliver more efficient care. Many surgeries are already subject to protocols that require the patient to try non-surgical interventions without relief before the surgery is authorized. These required non-surgical interventions will likely increase in number and duration with the intent of limiting the incidence and associated costs of certain surgeries. In some cases, this process will not be in the patient's best interest as they are referred to unaffiliated therapists and other professionals without adequate follow up or inter-disciplinary communication. An integrated delivery model and implementing telehealth provides an opportunity to optimize communication among providers and the patient. Such communication can identify more quickly those patients who would benefit from surgeries and those who would not and generate outcomes data that can lead to more reliable and efficient payor protocols.

For Payors: With an estimated 3.5 million (and this number continues to grow) workers losing their employer-sponsored and other health plans coverage, and filing for unemployment insurance, coupled with and the lack of government support for subsidizing the ACA, it is anticipated that there will be a significant number of uninsured individuals and families requiring health care. There is already pressure on group health plans to cover COVID-19 testing 100%. Covering telehealth services will allow potential savings as patients are treated outside an office or clinic setting.

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 last US pandemic and how COVID-19 differs.
- 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, 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.

CHAPTER 2

A TURNING POINT FOR HOSPITALS AND OTHER FACILITIES

— By Jesse Coleman and Janice Suchyta

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. Besides health care challenges, the current pandemic crisis has created a financial catastrophe not seen since the Great Depression.

The economic fallout from COVID-19 has resulted in millions of unemployed Americans who have lost their employer-covered health insurance. The number of uninsured Americans increases daily and will likely continue to increase if the pandemic returns in waves until a vaccine is created. Hospitals will be confronted with treating more uninsured patients while at the same time still dealing with declining population health. The uninsured will not be able to manage their chronic health conditions and the social determinants of health will only yield ever greater impacts.

These changes raise a number of questions that we will address in this chapter:

1. How will hospitals and other acute care settings be impacted in the aftermath of COVID-19?
2. What can long-term care facilities expect in a post-COVID-19 world?
3. What are state and federal agencies doing to expedite medical peer review and credentialing in the wake of COVID-19?
4. What impact might expedited medical peer review and credentialing have on patient care?
5. What impact might expedited medical peer review and credentialing have on peer review litigation?
6. What is the PREP Act and what is its anticipated impact on COVID-19-related litigation against health care facilities?
7. How long can we anticipate the PREP Act to impact COVID-19-related litigation?
8. What can health facilities do to avail themselves of the PREP Act immunities?
9. 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.[3] 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.[4] 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 facility's treating COVID-19 patient with limited facility resources and supplies. Supply chain security for procuring 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 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.[5] 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 the CARES Act 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.[6]

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.[7]

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 Look-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 staff.

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 can benefit hospitals by avoiding costly hospital visits by the uninsured in the emergency room. Evaluation and Management (E&M) visits instead would take place at an FQHC, however, testing and more intensive services may still be performed at the hospital which are covered by Medicaid or other payors.

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 Organizations to 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. Over the past few months, the values of publicly-traded nursing home firms have collapsed.

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.[8]

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. In SNFs, occupancy rates in Q2 2018 hit a record low of 81.7 percent.[9] 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 Fee for Service (FFS).[10]

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. This trend is likely to continue until a vaccine is available. 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.[11]

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.[12]

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 (PPD) 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.[13]

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.[14] 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.[15]

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.[16]

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. 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.[17]

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.[18]

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.[19] 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.[20]

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 (MCOs) have increased nearly 68 percent in many markets.[21] Many SNFs may find the use of centralized models will allow them to outsource risk and maintain focus on their core business—patient care.[22]

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 who 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, the Centers for Medicare and Medicaid Services (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 Waives Query Fees: To assist hospitals in credentialing physicians during the COVID-19 pandemic, the Health Resources and Services Administration (HRSA) has waived fees for mandatory queries of the National Practitioner Data Bank (NDPB)—the federal clearinghouse for adverse action reports against physicians. This waiver is retroactive to March 1 and goes through May 31, 2020.

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. 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 jurisdiction 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 Public Readiness and Emergency Preparedness Act (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.[23] On March 10, 2020, the Secretary for the Health and Human Services (Secretary) issued a declaration applying the immunities of the Act to the fight against COVID-19 (effective February 4, 2020).[24]

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.[25] 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.[26] 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.[27]

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" 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.[28] HHS has issued a list of non-exhaustive medical devices and therapeutics that have been authorized for emergency use in combating COVID-19.[29]

Covered Persons: "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.[30] Among these persons a "program planner" includes state and local government organizations that are supervising or administering programs to administer or distribute approved countermeasures.[31] This may include private sector employers or community groups when carrying out one of these state or local government programs.[32] In addition, a "qualified person" includes licensed health professionals authorized under state law to administer countermeasures;[33] 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.[34]

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 (OASH) 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.[35]

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.[36] 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.[37]

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.[38] 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.).

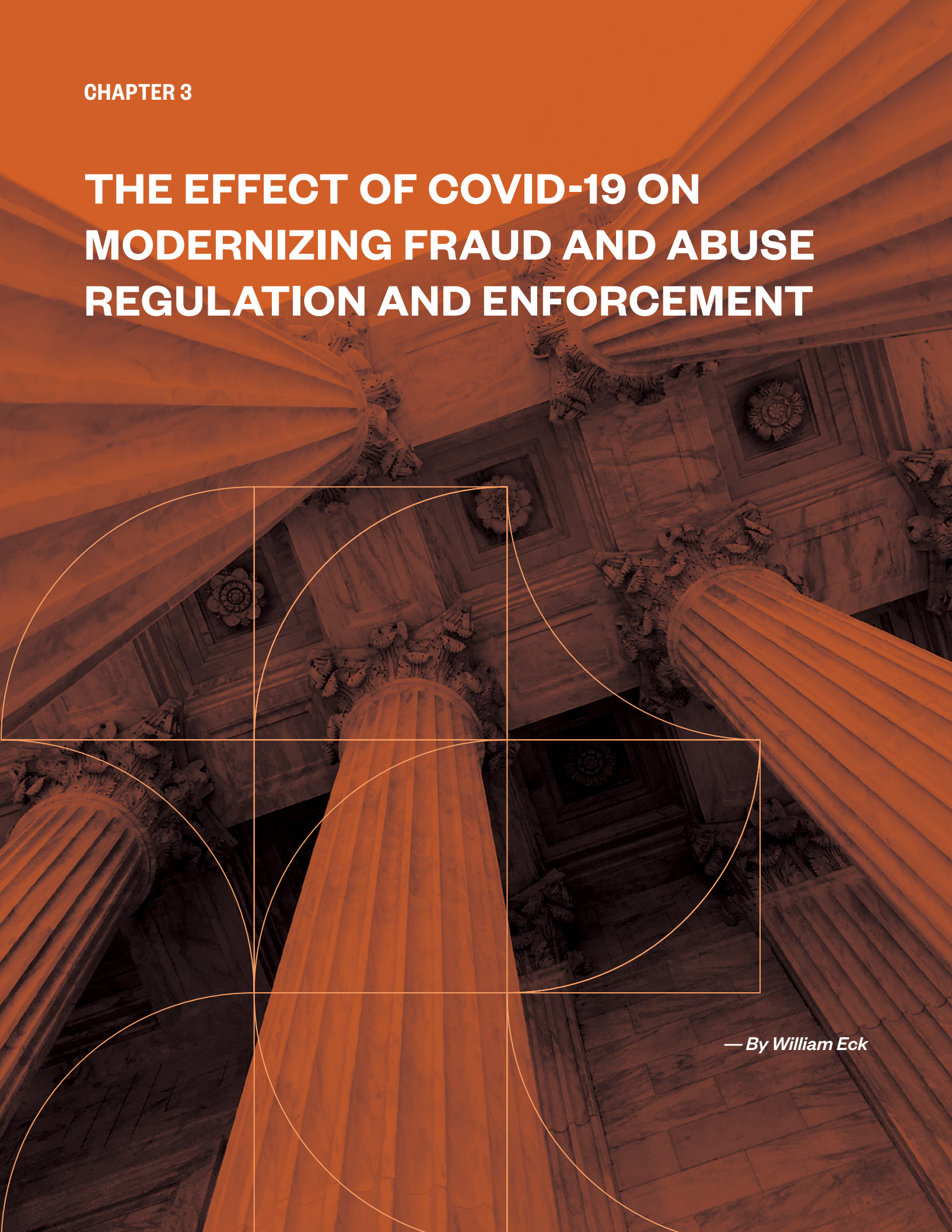
- Explore federal emergency use authorizations, guidance publications, and other announcements to determine if the facility's administration or use of a covered countermeasure falls within any federal agreements or arrangements.

- 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.[39] Taking these steps will further increase the likelihood of immunity coverage.

CHAPTER 3

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



— By William Eck

The post-pandemic era promises substantial changes for the health care industry. This extends to how the federal government regulates health care fraud and abuse, from Stark Law exceptions and modernization, to changes to the Anti-Kickback Statute. This article includes a primer on these regulations, while also exploring the potential for regulatory flexibility as we move towards a post-COVID-19 world.

Overview of the Stark Law

The Stark Law was enacted in 1989 in an effort to curb physician referrals for specified designated health services (DHS) covered by Medicare, where the physician or an immediate family member of the physician had an ownership, compensation, or other financial relationship with the entity.[40] The law prohibited claims related to such arrangements to be submitted to Medicare or any other person for services furnished pursuant to such a prohibited referral. DHS include clinical lab services, certain therapy services, radiology and radiation therapy services, certain other services and, significantly, inpatient and outpatient hospital services.

Violations of the Stark Law are strict liability—intent is not required. Penalties include overpayments and substantial civil monetary penalties. In addition, violations of the Stark Law are a basis for liability under the False Claims Act (FCA).[41] The FCA can be enforced by private party whistleblowers, known as relators. Violations of the FCA carry a liability of treble damages, plus civil monetary penalties of currently $25,372 per claim. Because each service rendered can result in a separate claim, damages for violations of the Stark Law can run into the hundreds of millions of dollars.[42]

Current Stark Law Exceptions

The breadth of the Stark Law's prohibitions, and the complexity of the law, led CMS to promulgate nearly 30 exceptions. Some of the exceptions address rental of office space or equipment, bona fide employment relationships, certain in-group referrals, certain personal services arrangements, and electronic health records. Yet even these exceptions are highly complex and have led to substantial judgments.[43] Moreover, the exceptions were designed for a fee-for-service payment ecosystem and are not available for many value-based payment arrangements.

New Proposed Exceptions

In response to these problems, CMS proposed new Stark exceptions in late 2019, before the COVID-19 pandemic.[44] CMS proposed three new exceptions for value-based payment arrangements. CMS also proposed significant modernizations of the existing exceptions.

Value-Based Payment Arrangements: The first value-based payment exception applies to value-based arrangements involving value-based enterprises (usually networks) that are fully financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target population served (i.e., they

are at full financial risk). This includes arrangements that involve capitated payments based on predetermined rates. Chief among the requirements to satisfy the exception is a requirement that remuneration to a physician is for or results from value-based activities undertaken by the physician for patients in the target population to be served.

The second exception for value-based payment arrangements is for arrangements that involve meaningful downside financial risk to the physician. In these arrangements, the physician is at risk for not less than 25 percent of the value the physician receives under the arrangement, or is responsible on a prospective basis for all or a defined set of covered patient care items and services for each patient in the target population to be served, in the event the physician fails to meet the arrangement's specified benchmarks.

The third exception for value-based payment arrangements do not require physicians to be at financial risk. It requires, among other things, that the methodology used to determine the amount of the remuneration to physicians be set in advance of the undertaking of the value-based activities for which the remuneration is paid. Taken together, and if adopted as proposed, these three exceptions afford significant room for value-based payment arrangements that did not previously exist under the Stark Law. Value-based payment arrangements are likely to be an increasing part of the health care landscape post-COVID-19, and if adopted, these exceptions will be an important part of facilitating new provider arrangements that favor coordinated care, although not all of the kinds of arrangements desired by the industry are permitted by the proposed exceptions.

Modernizing the Existing Exceptions: In the new proposed Stark regulations, CMS also proposed modernizing the existing exceptions. To begin with, CMS addressed the meaning of the phrase "commercially reasonable," which appears in several existing exceptions as a requirement (i.e., that an arrangement be commercially reasonable). For the first time, CMS states that an arrangement may be commercially reasonable even if it does not result in a profit for one or more of the parties. This is significant because it at least implicitly overrules some of the prior judicial interpretation of the phrase, and permits parties to enter into arrangements that further legitimate purposes of the parties and are on similar terms and conditions as like arrangements, even if they may result in losses for one of the parties.

Many existing exceptions also require that the physician's compensation be unrelated to the volume or value of the physician's referrals to, or other business generated for, the entity paying the compensation. Just as significantly, CMS pronounced that compensation is only related to the volume or value of a physician's referrals or other business generated if the formula used to calculate the compensation includes the physician's referrals or other business generated as a variable, resulting in compensation that positively correlates with the number or value of the physician's referrals or generation of other business. This stands as a clear statement that, among other things, compensation solely for a physician's own services will not be deemed related to the volume or value of technical billing for surgeries performed by the physician.

Finally, in the new proposed Stark regulations, CMS clarified that the requirement of many exceptions, that physician's compensation be at fair market value, is an independent requirement, and that compensation could be fair market value even if it took into account the volume or value of referrals. By these three regulatory clarifications, CMS substantially increased the usefulness of the existing Stark exceptions for many arrangements, such as employment of physicians by hospital and health systems, that will continue if not increase in the post-COVID-19 environment.

Overview of the Anti-Kickback Statute

The federal health care program anti-kickback statute (AKS) prohibits the offer or payment, or solicitation or receipt, of any remuneration, in any form, in return for or to induce referrals for items or services for which federal health care program payment may be made.[45] Federal health care programs include Medicare, Medicaid and Tricare. The AKS is a criminal statute, and violations are subject to imprisonment, fines, and exclusion from federal health care programs. Violations of the AKS are also violations of the FCA, which may be enforced by whistleblowers, and includes treble damages and substantial civil monetary penalties. Courts have held that the AKS is violated if one purpose is to induce referrals, even if it is not the only or even the primary purpose.[46]

Safe Harbors: The breadth of the AKS, as interpreted by the Courts, led the HHS Office of Inspector General (OIG) to promulgate safe harbors, specifying conduct that would be deemed not to violate the AKS.[47] An arrangement that is not within a safe harbor does not necessarily violate the AKS, However, it must be evaluated on the facts and circumstances, and it presents some regulatory risk. To date, OIG has promulgated 30 safe harbors. However, as in the case of Stark, the exceptions were designed for a fee-for-service payment environment and are not available for many value-based payment arrangements that will increasingly be part of the post-COVID-19 health care landscape.

New Proposed Safe Harbors: Like CMS, the OIG published proposed regulations to modernize the safe harbors under the AKS. Similar to the proposed Stark regulations, the OIG noted that the AKS potentially inhibits value-based payment arrangements, and that the existing safe harbors are inadequate to address the problem. Therefore, the OIG proposed three new safe harbors to address value-based payment arrangements. Notably, none of them protects arrangements with pharmaceutical manufacturers, or manufacturers distributors, or suppliers of DMEPOS, or laboratories.[48]

Participants in full financial risk arrangements would be eligible for protection for both in kind and monetary remunerations. However, OIG would protect only remuneration from a value-based enterprise (usually a network) to a participant. OIG would not protect remuneration among participants, or between a participant and a downstream contractor.

Under a proposed safe harbor where the participants are at substantial financial risk, both in kind and monetary remuneration are protected. There must be exposure for 40 percent of shared losses on the part of the value-based enterprise (again, usually a network). The downstream participants must share at least 8 percent of the value-based enterprise's risk under the payer agreement.

Under a proposed safe harbor that does not require participants to take financial risk, only non-monetary compensation is protected. In addition, a contribution requirement would be imposed whereby a party receiving in-kind remuneration would be required to pay 15 percent of the offeror's cost of the in-kind remuneration. Certain additional requirements apply. Through these safe harbors, OIG has taken steps to provide protection for value-based payment arrangements.

Many in the industry believe that these safe harbors do not go far enough to protect appropriate value-based payment arrangements. Many commenters, for example, have criticized the level of financial risk required of participants for substantial financial risk arrangements as unrealistic, and have criticized the limitation of the non-financial risk safe harbor to in-kind remuneration. Some of the proposals may become less restrictive in the final regulations. In any event, the new proposed safe harbor represents a significant move toward protection of value-based payment arrangements.

Enabling a Rapid Response to the COVID-19 Public Health Emergency

COVID-19 Blanket Waivers: CMS and OIG have each issued waivers under the Stark Law and AKS, respectively, with regard to conduct that might otherwise be unlawful, during the public health emergency resulting from the outbreak of the COVID-19 virus.[49] Taken together, these blanket waivers provide that eleven types of conduct will not be deemed to violate Stark or the AKS during the COVID-19 emergency; provided that the conduct is related solely to COVID-19 purposes, as defined in the CMS blanket waiver, and absent a determination of fraud or abuse. COVID-19 purposes are enumerated in the waiver, and in general relate to addressing patient and community needs in relation to the COVID-19 outbreak.

In general, the 11 waivers involve remuneration between an entity and a physician that is not fair market value for personal services, rent, purchased items or services, or medical staff incidental benefits or nonmonetary compensation that exceeds regulatory limits. Importantly, these waivers last only for so long as the Emergency Declaration.

Although we do not suggest that fair market value will be dispensed with under Stark and AKS in a post-COVID-19 world, experience under these blanket waivers during the pandemic may well suggest that a less complex and hypertechnical applications of these statutes is in the public interest after the pandemic.

Modernization and Expansion of Laws and Enforcement Post-COVID-19

Looking Ahead on Fraud and Abuse: In the pre-COVID-19 proposed regulations, CMS and OIG moved forward towards accommodating a health care environment of value-based payment. In our view, the trend toward value-based payment will only continue and accelerate in the wake of the COVID-19 pandemic. The proposed regulations will accommodate some, but not all, of the non-abusive arrangements providers and physicians will desire to implement in this new environment. Perhaps the experience of CMS and OIG under the blanket waivers will auger greater regulatory flexibility in the area of fraud and abuse as we move forward in a post-COVID-19 world.

Most of the COVID-19-based waivers were focused on relaxing enforcement of specific areas considered essential to responding to the public health emergency. We expect these waivers to eventually expire and that the flexibility granted the providers, drug manufacturers and others who engaged to meet the needs of local patient and facility needs will decrease. It is likely that for some period of time, the regulators will exercise discretionary enforcement so long as the conduct in question was not egregious.

Anticipated "Qui Tam" Lawsuits Under the FCA: COVID-19 Loan and Grant Programs

COVID-19 Relief Legislation: In response to the COVID-19 pandemic, Congress passed the Coronavirus Aid, Relief and Economic Security Act, the Paycheck Protection Program and Health Care Enhancement Act (collectively, the "CARES Act"), and other COVID-19 relief legislation.[50] This legislation is the largest emergency stimulus package in US history, devoting nearly in excess of $2.5 trillion of government funds to address the impact of COVID-19 on the US economy through the direct impact of the disease itself as well as the self-induced damage to the US economy caused by shutdowns and shelter in place restrictions.

The CARES Act establishes the Paycheck Protection Program, which provides forgivable loans to small businesses, including health care providers and medical practices that in general employ not more than 500 employees to cover payroll costs and certain other expenses for an eight week period.

More importantly, the CARES Act and the other legislation also establish and provide special appropriations for health care provider grants, including grants to hospitals and other providers, providers of COVID-19 testing, recipients providing COVID-19 services to the uninsured, providers in high impact areas and rural providers.

Required Certifications: Each recipient of a PPP loan or one of these grants is required, as a condition of receiving or retaining the loan or grant, to make various certifications. Under the Paycheck Protection Program, recipients of loans must certify, among other things, that: (i) the borrower is eligible to receive the loan; (ii) the necessity of the loan to support the ongoing operations of the borrower given current economic uncertainty; (iii) that the loan proceeds will be used for permitted purposes; and (iv) if forgiveness is sought, the amounts for which forgiveness is claimed are accurate and eligible for forgiveness.

Under the health care provider relief grant programs described above, providers (who may be providers, suppliers or individuals) are required to certify, in general, that: (i) the grant was used for its intended purposes; (ii) the provider is not terminated from participation in Medicare or precluded from receiving payment through Medicare Advantage or Part D, and is not excluded from Medicare, Medicaid or other federal health care programs; (iii) the grant payment will only be used to reimburse the provider for health care related expenses or lost revenues that are attributable to coronavirus; (iv) the accuracy and completeness, to the best of the provider's knowledge, of all information submitted to the government in connection with the grant; and (v) the provider will not charge presumptive or actual COVID-19 patients out of pocket expenses in excess of what the patient would otherwise have been required to pay had the care been provided by an in-network provider.

Suits Under the FCA: The veracity of the above certifications may be challenged by suits under the FCA. As noted, the FCA provides for treble damages, plus substantial civil monetary penalties, for false claims against the United States. A false claim includes a false certification in connection with Paycheck Protection Program loan, and in connection health care provider COVID-19 grant. A false certification gives rise to FCA liability so long as that certification is material to the government's decision to pay. Although the issue remains to be litigated, surely the government will take the position that the certifications above are material to the government's decision to lend under the Paycheck Protection Program or, alternatively, make grants under the health care provider relief programs summarized above.

Allegations could include, but would not necessarily be limited to, false certification of eligibility for a Paycheck Protection Program Loan or necessity for the loan, or of any of the statements made in connection with the application for forgiveness of the loan.

With respect to health care provider grants, allegations could include, but would not necessarily be limited to, false certifications of the use of the grant, the accuracy of information submitted to the government, or charges to presumptive or actual COVID-19 patients.

As also noted above, suits under the FCA may be filed by whistleblowers, known formally as "relators." A suit filed by a relator is known as a "qui tam" suit. The government may elect to intervene in and take over a qui tam suit. A relator may but need not necessarily be a present or former employee, or a competitor. There are several reasons that one might be a relator. These include: (i) financial reward (if the government intervenes in the suit, the relator is entitled to receive between 15 and 25 percent of the recovery; if the government declines to intervene, the relator's share is increased to up to 30 percent); (ii) to obtain whistleblower status and protect against termination or other adverse employment actions; (iii) to punish the defendant; or (iv) to take action against perceived wrongdoing for moral reasons.

We anticipate that the large number of Paycheck Protection Program loans and health care provider COVID-19 relief grants will engender a myriad of FCA qui tam lawsuits. The best way for providers to protect themselves against these suits is to handle Paycheck Protection Program loan forgiveness and

grant expenditures and conditions properly and to document them meticulously. Nevertheless, in our view FCA lawsuits involving the Paycheck Protection Program and health care provider relief grants will be a significant part of the post-COVID-19 health care landscape.

CHAPTER 4

SIX WAYS FDA REGULATIONS, OVERSIGHT, COLLABORATIONS, AND FUNDING WILL CHANGE

— By Dean Fanelli, Jamaica Szeliga, Vincent Smolczynski, and Robert Terzoli

FDA has taken unprecedented actions during the COVID-19 crisis to bolster medical supplies, rush testing-to-market, and help to develop potential treatments. The actions have had both positive and negative consequences, which are just beginning to emerge. At the least, FDA's response during COVID-19 will provide a guide for what to expect when the next public health emergency occurs in the United States.

More likely, however, the COVID-19 pandemic may lead to changes in how FDA regulates and polices products; how it develops treatments, both for broad distribution and for experimental use; how it interacts with the public, private companies, charities, and other entities; and how it conducts and drives research.

A few themes have emerged from the responses to COVID-19 that could become institutionalized. FDA is historically notorious for its caution, for the extended vetting, testing, and inspecting it performs on medical products to make sure they are both safe and effective before the products are allowed on the market. During the crisis, however, FDA stepped back from its gatekeeping role allowing some products to be commercialized without FDA review or with much less evidence than traditionally required. We foresee that trend continuing, reflecting a shift away from prevention toward enforcement, with FDA encouraging new testing, products, and treatments to reach the public as soon as possible.

COVID-19 has also changed how FDA handles the monitoring of products and devices once they are on the market. For several FDA authorized COVID-19 medical devices the unique identifier requirements of the agency are not enforced. When issues arise relating to such COVID-19 devices, FDA can only take broad action rather than pinpoint and solely remove the noncompliant product. In addition, some products no longer require the manufacturer or distributor to monitor for adverse effects at all. FDA instead has relied on the public, watchdog groups, and competitors to flag products as harmful or, more often, not effective.

The collaborative efforts seen during COVID-19 are another element likely to remain after the crisis is over. FDA has entered into partnerships with established companies to speed up testing, treatments, and product supply. FDA is also collaborating with other government agencies; as an example, it is working with the National Cancer Institute to test and validate products released on the market without screening. FDA also is working closely with non-profits, universities, and other sources, particularly with respect to the development of new treatments.

We also foresee that FDA will continue to develop standards for products, innovation, testing, and treatment. While FDA does not require compliance with these standards, they have been streamlining the development process. For example, FDA has made simplified guides to help new companies produce authorized medical devices like hand sanitizer and face masks. FDA has employed these protocols as part of its efforts to accelerate the development process.

FDA also has set the criteria for diagnostic tests on COVID-19 and has worked with testing developers to adapt and respond to their development issues. FDA has also taken "the lead on a national effort to facilitate the development of, and access to, two investigational therapies derived from human blood. These are called convalescent plasma and hyperimmune globulin."[51]

While it is likely FDA will continue to reduce certain requirements for products to enter the market, bad actors and current adverse events will shape how FDA continues or implements such changes in a post-pandemic world. For example, FDA has greatly reduced the requirements for entities to produce alcohol for alcohol-based hand sanitizer as well as the production of the hand sanitizer itself. Following these changes in regulation, FDA is aware of a steep increase in calls to the National Poison Data System related to hand sanitizer.[52] These adverse events are due, at least in part, to failure of producers to properly follow the reduced guidelines issued by FDA in response to COVID-19. These adverse events highlight the importance of FDA's oversight and will also shape how FDA exercises its authority in the future.

The remainder of this article outlines six specific changes that FDA may carry forward to the post-COVID-19 word, including changes to diagnostic test regulation, medical device regulation, treatments and clinical trial procedures, cooperation, funding, and research.

CHANGE ONE: Diagnostic Test Regulation

One of the most publicized issues arising from FDA's actions during COVID-19 is the proliferation of misleading and/or inaccurate antibody tests. FDA permitted commercial marketing of antibody tests without receiving proof of validation and a request for emergency use authorization (EUA), which would provide them with label information. Compared to face masks, where the public can at least spot a defect or recognize the use of shoddy materials from the label, antibody tests are a black box—it is difficult for FDA, the public, patients, and health care providers to judge quality without specialized skill and effort. FDA's updated policy that requires antibody testing manufacturers to apply for EUAs quickly after marketing suggests that FDA is unlikely in the future to take companies at their word in supplying complex products to the market. A submission of, at least, basic information will be necessary.

What may continue in the future, however, is FDA's use of guidance and public presentations to more broadly encourage the development of testing where needed. For COVID-19, FDA provided extensive advice on the parameters for successful tests, validation methods (which now include an option for a government-led validation process), and the approval process. FDA even offered virtual "town hall" meetings on COVID-19 diagnostic testing development, open to the public without registration, to help efficiently guide developers.[53] FDA may in the future continue to disseminate information and support the development of diagnostic testing more broadly than individualized input on tests only after their development and submission for approval, particularly to help develop testing in hard-to-diagnose areas.

CHANGE TWO: Medical Device Regulation

FDA has already cautioned manufacturers and distributors that they will need to pursue traditional FDA approval of products covered by EUAs once the COVID-19 emergency is resolved. At the end of April, 2020 FDA provided answers to Frequently Asked Questions about EUAs on medical devices highlighting that EUAs were temporary in nature:[54]

Q: What happens to authorized devices after the public health emergency is over?

A: As with all declared emergencies, all COVID-19 EUAs will no longer be in effect once the declared public health emergency is terminated. Additionally, FDA may revise or revoke EUAs during a declared emergency for certain reasons, including if revising or revoking the EUA is appropriate to protect the public health or safety. … Sponsors of EUA

products are encouraged to follow up the EUA with a pre-market submission so that it can remain on the market once the emergency is over.

Q: Will devices authorized under an EUA during this public health emergency need to go off the market? Will they need a 510(k)?

A: For medical products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the FD&C Act, manufacturers may submit the appropriate premarket submission to legally market their product after the EUA declaration is terminated or the EUA is otherwise revised or revoked. Manufacturers are encouraged to pursue premarket submissions through the appropriate regulatory pathway (e.g., 510(k), De Novo request, PMA) during the emergency so that devices can remain on the market after the emergency.

While it is expected that EUAs and enforcement policies will change, FDA's experience during COVID-19 could lead to certain regulatory reforms or relaxations. Almost all of the guidance and EUAs relating to basic medical devices permitted companies to avoid pre-notification requirements, particularly for goods that do not require pre-authorization.[55] Registration and listing requirements were also waived, as were the unique identifier requirements. FDA instead relied heavily on labeling guidelines and cautionary statements to alert the public to the limitations of the products.

Based on its COVID-19 policies, FDA could eliminate entry hurdles to manufacturing and distribution such as pre-market notifications, registrations, and listing requirements for a broader array of "simple" medical devices. FDA also could take a hard look at the products it oversees. The rapid onset of shortages of basic personnel protective equipment like gloves, patient gowns, and face masks suggests there is a need to have more sources, and readily available emergency suppliers, for these products in the future. If such products are not considered "medical devices," a ramp up in product would go faster in the future.

Another potential area for medical device reform relates to minor hardware and software updates. In granting EUAs and providing guidance on more substantial and complex mechanical and electronic medical devices, FDA has permitted companies during the COVID-19 emergency to make minor changes to help expand the use of the devices, particularly in terms of allowing remote capabilities and making the products more portable. It is possible that FDA may consider permitting more routine alterations to products without evaluation or vetting, especially to keep up with the demand for remote and wireless devices and portability.

FDA has had setbacks, however, in bringing medical devices to market during COVID-19. Notably, on May 7, 2020, in response to sub-standard respirators imported from China, FDA revised its EUA on respirators manufactured in China. The original EUA permitted importers and manufacturers to request authorization based on, *inter alia*, testing results from independent laboratories. The revised EUA eliminated that pathway, insisting that respirators from China be made from a manufacturer who already makes NIOSH[56] -approved gear or that the respirator be a medically approved device. We predict that FDA may be more cautious in accepting free market testing of devices, but it may be willing to defer to foreign regulatory processes or to manufacturers with established reputations for quality.

CHANGE THREE: Treatments and Clinical Trial Procedures

FDA has overhauled its structure and enforcement priorities to expedite assistance to researchers and developers of treatments to COVID-19. For example, FDA has authorized extensive expanded access to investigational new drugs for the treatment of COVID-19. In addition, FDA has reduced requirements for donation of blood and plasma, which has potential to be a treatment to COVID-19. It is possible that at least some of FDA's changes will be kept or otherwise adopted after the crisis.

Compassionate Use: It is common knowledge that it can take years and in some instances billions of dollars to get a potential drug approved by FDA. The clinical trial process to receive FDA approval generally consists of three phases of testing, requiring in total thousands of patients to participate. It is only after this lengthy testing period providing positive results and additional back and forth with FDA that a drug might be approved. This process, of course, is not suitable to treat novel immediately life-threatening diseases or viruses such as COVID-19.

FDA has "expanded access protocol" and single patient emergency investigational new drug (IND) (sometimes referred to as "compassionate use") procedures that permit the use of an unapproved investigational drug when a patient has an immediate or life-threatening condition or serious disease or condition, there are no satisfactory therapies, and the patient cannot participate in an ongoing clinical trial.

As part of its response and the CTAP program, FDA has authorized broad expanded access use of drugs and treatments to patients suffering from COVID-19 on an expedited basis. These treatments include drugs such as remdesivir, hydroxychloroquine, and chloroquine as well as treatments using convalescent blood plasma and hyperimmune globulin collected from the blood of patients that have recovered from COVID-19.[57] Indeed, FDA has taken the lead on a national effort to facilitate the development of, and access to, two investigational therapies—convalescent blood plasma and hyperimmune globulin—both derived from human blood.[58]

During the COVID-19 health emergency, FDA has created an infrastructure that allows for near immediate interactive communication between FDA and health care professionals, and in certain instances, authorization for compassionate use in cases of COVID-19. While requests for compassionate use are likely to decrease after COVID-19, at least eventually,[59] it is possible that FDA may continue a an expedited program to address compassionate use in other contexts and settings. FDA, health care professionals, and even the public have become more accustomed to the regulations and requirements for compassionate use. Streamlined forms and FDA hotlines have resulted in a sharp increase in requests for compassionate use of unapproved drugs. With the increased knowledge of the procedure to request compassionate use and FDA's ability to quickly respond to such requests, FDA is likely to see increased requests for compassionate use to extend beyond COVID-19. If the results associated with the current compassionate uses of unapproved drugs shows beneficial results, FDA may decide to keep the current infrastructure expediting such uses. If adverse effects result from compassionate use authorizations, however, continuation or expansion of the program may be unlikely.

Clinical Trials: Like nearly everything else in the world, clinical trials have been affected by the COVID-19 health emergency.

FDA recognizes that various challenges, such as quarantines, site closures, travel limitations, interruption to the supply chain for the investigational product, and similar obstacles may impact the conduct of clinical trials. Indeed, FDA issued guidance directed to industry, investigators, and institutional review boards providing affirmative steps that each could take to prepare for the inevitable challenges that may arise during clinical trials.[60]

Certain changes to clinical trials are likely to remain after the COVID-19 health emergency is over. For instance, many clinical trials are now implementing or utilizing telehealth to monitor patients and collect data. While this use may not be appropriate for all clinical trials or for all visits, the practicality and likely reduced costs of telehealth capabilities, if shown to be appropriate, are likely to remain.

A large concern that will limit current and future changes to clinical trials is the protection of PHI. For instance, PHI may be compromised if a virtual visit with a patient is hacked.[61]

FDA is prioritizing review for COVID-19 related clinical trials, drastically reducing the time it takes to get trials up and running. Following the current COVID-19 emergency, it is likely that FDA will strive to speed up

their initial review of clinical trial plans. Indeed, they have shown the capability to do so by getting COVID-19 related clinical trials up and running in a matter of days rather than a matter of months. Industry will undoubtedly hope and push for such speedy reviews and authorization in the future.

CHANGE FOUR: Continued Cooperation

FDA is very likely to continue to look for meaningful, collaborative approaches to investigating and treating diseases, as well as developing medical devices, after the COVID-19 crisis has resolved.

FDA recognized that many stakeholders are interested in designing and producing 3D printed devices during the COVID-19 public health emergency, but that many stakeholders often do not know what device designs to choose or how much to print. Accordingly, FDA initiated a process for information-sharing regarding the use of 3D printing and other advanced manufacturing technologies in the context of personal protective equipment (PPE) and other medical device parts.[62] To this end, FDA entered a Memorandum of Understanding (MoU) with the Department of Veterans Affairs (VA) Innovation Ecosystem and the National Institutes of Health (NIH) 3D Print Exchange, to share data, and coordinate on open-source medical products for the COVID-19 response. These governmental agencies, including FDA, are also working closely with America Makes to provide resources that will connect health care providers and 3D printing organizations. America Makes is a large public-private partnership with members, including FDA, that span all sectors of the 3D printing industries.[63]

Even before the COVID-19 outbreak, FDA announced the global launch of CURE ID, an internet-based repository permitting the clinical community to report experiences treating infectious diseases with novel uses of existing FDA-approved drugs.[64] Amy Abernethy, FDA Principal Deputy Commissioner, stated "[our] hope is that this app will serve as a connector among major treatment centers, academics, private practitioners, government facilities and other health care professionals from around the world and ultimately get treatments to patients faster."[65]

It is expected that FDA's collaborations and crowdsourcing, which began prior to COVID-19, will continue even after the immediate threat from COVID-19 subsides.

CHANGE FIVE: Funding for Infectious Diseases

Spending by public and philanthropic research organizations on infectious diseases has generally been reactive. Based on an analysis by researchers at the University of Southampton, from 2000 to the start of 2020, about $550 million was spent on coronavirus-related research. Spending has risen to $985 million since the current outbreak began. The figures cover spending by more than 1,000 funders worldwide.[66]

Included within the March 27, 2020 CARES Act legislation that provided roughly $2 trillion in economic relief measures were a number of provisions supporting research for federal agencies, including NIH and other science agencies. The Act specifically included:

- $945 million for NIH.
- $415 million for the Department of Defense's health research and development activities, including development of vaccines, anti-viral drugs, and diagnostic tests.
- $75 million for the National Science Foundation's research programs and $1 million for other coronavirus related expenses, such as grant administration. NSF has activated its RAPID grant mechanism to support coronavirus research.
- $66 million for the National Institute of Standards and Technology, of which $10 million is for the National Institute for Innovation in Manufacturing Biopharmaceuticals and $6 million is for "measurement science to support viral testing and biomanufacturing."

- $2.25 million for Environmental Protection Agency's Science and Technology program, of which $1.5 million is for research on "methods to reduce the risks from environmental transmission of coronavirus via contaminated surfaces or materials."[67]

Similar increases in spending accompanied the SARS and MERS outbreaks in 2004 and 2015, respectively, then regressed to the mean in the years that followed.[68] While spending on coronavirus research is likely to remain high in the near future, similar decreases toward average yearly spend levels is expected.

CHANGE SIX: Research

FDA's Center for Biologics Evaluation and Research (CBER) protects and promotes the public health, in part by ensuring the safety and efficacy of the products it regulates including biological products such as prophylactic and therapeutic vaccines, whole blood and blood products, cellular products and exosomal preparations, gene therapies, tissue products and live biotherapeutic agents. CBER also regulates selected drugs and devices used in the testing and/or manufacture of biological products. Currently CBER is working on multiple fronts to address the COVID-19 pandemic such as:

- Expediting clinical trials for preventive vaccines and other therapeutic biological products that hold promise to prevent or treat COVID-19 by providing timely advice and interactions.
- Supporting product development and scaling up of manufacturing capacity for high priority products for COVID-19.
- Helping to ensure an adequate blood supply in light of reduced blood donations due to social distancing and the cancellation of blood drives.
- Facilitating access to convalescent plasma and other investigational products for patients with COVID-19, including through collaborations with the private and public sectors to establish the National Expanded Access Treatment Protocol that can be widely used.
- Providing information to health care providers and researchers to help them submit emergency IND requests to use investigational products for patients with COVID-19.

In addition to CBER taking aggressive steps to address the pandemic, NIH, and the Foundation for the NIH (FNIH) announced a public-private partnership with FDA and others to hasten the development of COVID-19 vaccine and treatment options. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership brings together a dozen leading biopharmaceutical companies,[69] the Health and Human Services Office of the Assistant Secretary for Preparedness and Response, CDC, FDA and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID-19 pandemic. The partnership will develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics. This is part of the whole-of-government, whole-of-America response the Administration has led to beat COVID-19.

The ACTIV government and industry partners will provide infrastructure, subject matter expertise and/or funding (both new and in-kind) to identify, prioritize and facilitate the entry of some of the most promising candidates into clinical trials. Industry partners also will make available certain prioritized compounds, some of which have already cleared various phases of development, and associated data to support research related to COVID-19. The partnership is being developed with input from a steering committee managed by FNIH which includes leaders from NIH, FDA and the research and development organizations of biopharmaceutical companies.

The research community is currently striving to sift through more than 100 potential preventives and therapeutics for COVID-19. ACTIV will aim to provide guidance which can be used to prioritize the plethora of vaccine and therapeutic candidates in development

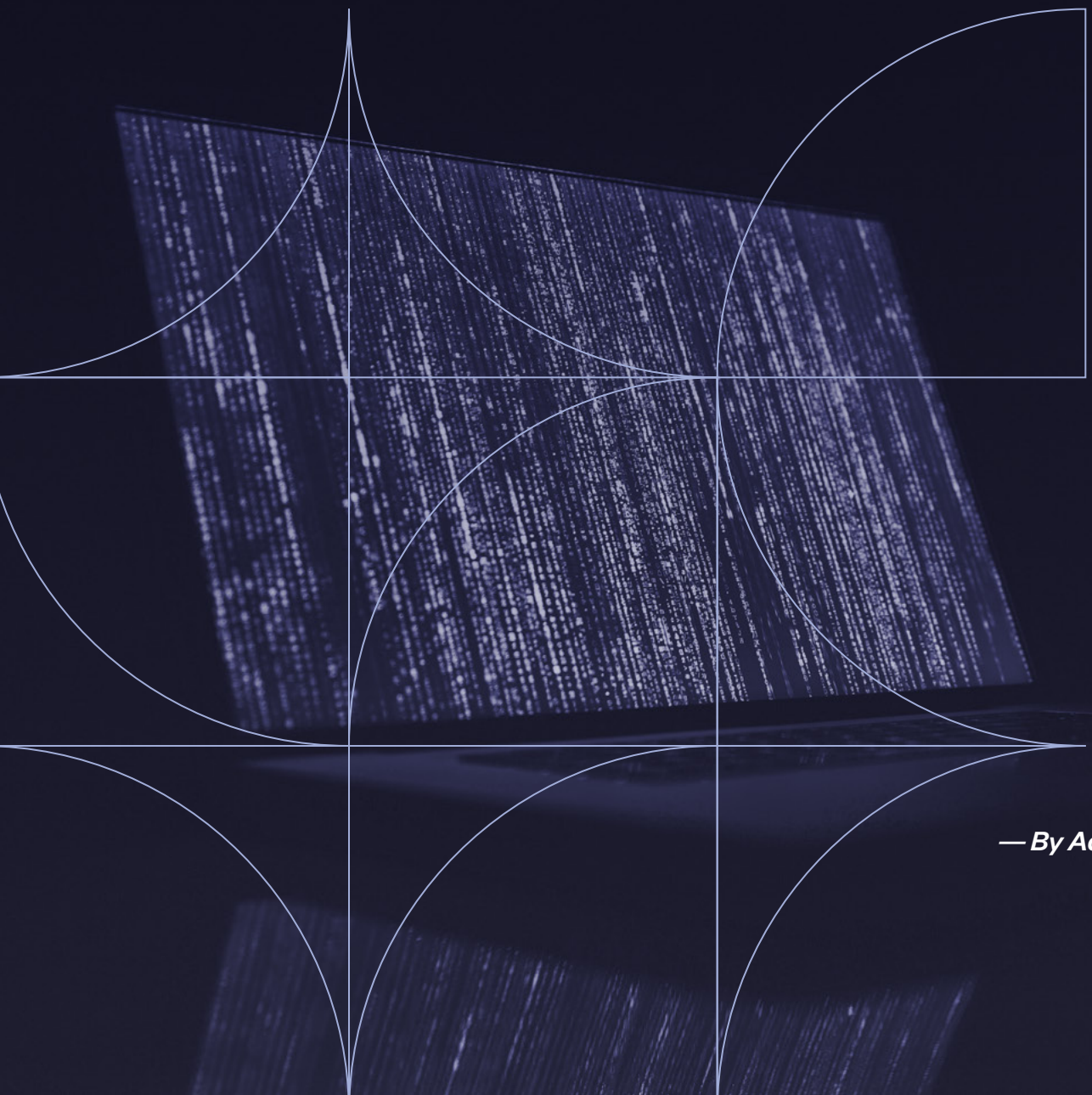
and connect clinical trial networks to test new and repurposed candidates quickly and efficiently. "Using the most advanced clinical trial methods to rapidly test multiple interventions will help get the answers we need as soon as possible to expedite potential prevention and treatment approaches to fight COVID-19," said FDA Commissioner Stephen M. Hahn, M.D. "Collaboration is a critical ingredient for success and FDA will continue to use every tool possible under our Coronavirus Treatment Acceleration Program to speed the development of safe and effective medical countermeasures."[70]

ACTIV will have four fast-track focus areas, each of which will be led by a highly motivated working group of senior scientists representing government, industry and academia. Each area will be supported by a number of tactics that can be viewed at the NIH website.

While FDA has made many changes during the COVID-19 emergency, it is unclear how many of these changes are emergency measures and how many will persist beyond the current emergency. What is clear is that the actions taken by FDA and other research organizations have resulted in a shift in the way research and development may look in a post-COVID-19 world.

CHAPTER 5

HIPAA AND PRIVACY REGULATION, POST-PANDEMIC



— By Adam Laughton

COVID-19 promises to have broad, long-term effects on the HIPAA obligations and compliance of health care organizations. We have already seen a broad loosening of HIPAA restrictions, as well as more targeted changes, some of which are aimed deliberately at facilitating a more effective response to COVID-19. Others are meant simply to lessen burdens on providers so they can be more responsive and adaptive to challenges occasioned by COVID-19 and the various business disruptions that resulted from it.

Emergency Actions

For example, on April 2, the Department of Health and Human Services Office of Civil Rights (OCR), the main federal agency responsible for matters of HIPAA compliance, issued a Notification of Enforcement Discretion allowing business associates to disclose personal health information (PHI) for public health and health oversight activities (both are governmental activities). This is an example of a narrow and targeted regulatory response. On the other side are the various announcements made by HHS and OCR in March 2020 allowing providers to adopt telemedicine platforms that would have historically not met the criteria for HIPAA compliance, as well as waiving certain patient-centered HIPAA protections (including patient's right to receive a notice of privacy practices, or limits on a covered entity's ability to disclose PHI to a patient's family and friends). These changes, less related to a direct response to COVID-19, freed up organizational bandwidth that would ordinarily be devoted to HIPAA compliance to deal with more serious concerns of adapting operations to a pandemic scenario and allowed additional flexibility so changes to patient interactions could be adopted quickly and without extensive due diligence delays.

Future Possibilities for HIPAA and Privacy Issues

Before the pandemic, weakening or outright repeal of HIPAA regulations was a goal of political activists since long before there was a compelling public health rationale for doing so. And because pandemics and other serious public health crises may recur in coming years, some of the "temporary" relaxations announced over the past several months may be here to stay. Additionally, there will be more sustained efforts to reform (primarily in the direction of loosening) HIPAA regulations to give additional flexibility to providers and business associates, some of which may become useful in the next pandemic. In a post-COVID-19 world, this creates the perfect recipe for relaxed HIPAA and privacy regulation in four areas outlined here: public health activities; expanded research exceptions; telemedicine and privacy; and enforcement of pandemic-era violations.

Increased Flexibility in an Emergency for Public Health Activities

One area of regulatory flexibility we expect to see is an expanded exception for disclosures to public health authorities. The existing HIPAA exception covers the following disclosures:

1. Disclosures to public health authorities (i.e. government agencies) related to public health surveillance, investigations and interventions.

2. Reports of child abuse or neglect.

3. Reports to an FDA-regulated entity regarding a product or activity for purposes of determining the safety, efficacy, or quality of such product or activity.

4. Disclosures to a person or persons who may have been exposed to a communicable disease or may be at risk of being exposed if such disclosure is authorized or required by other law.

5. Certain employer disclosures.

6. Certain disclosures by an educational institution regarding the immunization status of a student. For these disclosures, no patient authorization is required.

Some of these excepted disclosures are not relevant to the present context (e.g. number two); others are relatively non-controversial and undisputed (number one). For these, we expect that they will continue unaltered. However, for others, the pandemic has raised new issues and questions. For example, if protected health information may be disclosed to people who may have been exposed or are "at risk" of being exposed to a communicable disease, how is this exception to be applied when the universe of persons to whom disclosure is permitted is so broad that only disclosure through major press outlets, or through means of the Internet or other messaging technologies (Amber Alert?) would be sufficient to notify? In a scenario when millions are returning to schools and workplaces in the aftermath of a pandemic, what are the rights of students, workers and their families to know who has been infected, who has been tested, who has been vaccinated and who has developed antibodies (through exposure)?[71] This also brings in questions about diagnostic measures introduced among employers or in other venues, such as mandatory mass testing of employees/visitors or thermal scans to detect elevated temperature. When and how can such test results be shared more widely among the workplace or other visitors in a particular location, and how much information can be shared to effectively warn people who may have been exposed to infected individuals?

We anticipate further guidance will need to be developed and released for how public health disclosures will occur in a pandemic context, particularly the scope and breadth of disclosures that would be permitted under this exception. While OCR can clarify the scope of the disclosure, its existing terms already depend on the scope of disclosures permitted under state public health laws. Thus, we also expect these issues to be taken up by governors, state legislatures and regulatory agencies. The following questions should be considered: When (if ever) can disclosures including PHI of individuals be made through the press or on publicly available Internet sites? How do we balance the need for individuals who may have been exposed to know about that exposure (so they can be tested, self-isolate or seek treatment) versus the potential for a mobbing effect if the names of infected people become widely known? Do we need to allow for wider disclosure regarding tests and trials of potential treatments, therapies or diagnostic methods, particularly to combat misinformation circulating in other public venues? Realistically, we believe there will be a sustained demand by the public for more and more detailed disclosure regarding infected persons, locations with infections or potential infections, and potential therapies and treatments (as well as their benefits and side effects).

As an example of how this might be implemented, during the COVID-19 pandemic in April 2020, METRO, the public transit authority of Harris County (Houston), Texas, which is not a public

health authority, issued press releases, which were subsequently transmitted via SMS to those who had signed up for METRO alerts, regarding bus drivers and other transit employees who had tested positive for COVID-19. The names of the individuals were not disclosed; however, their route(s) and the dates on which they last worked were disclosed in the press release. While to the general public, these disclosures would not be sufficient to identify the infected individuals, for those who were riders of those routes, it was probably sufficient make these persons identifiable, while giving them adequate warning about their need for testing and self-isolation. This disclosure could fit within an expansive interpretation of the fourth exception described above, which is similar to the interpretation we expect to prevail in the aftermath of COVID-19.

One application we believe merits further discussion is the privacy implication of the United States developing and adopting contact tracing capacity, particularly via commonly available technologies. South Korea's response to COVID-19 focused heavily on this method of controlling and isolating infections. In April 2020, major technology companies announced changes to their proprietary cell phone technologies that would allow contact tracing via Bluetooth, which would allow a person's phone to be scanned if it belonged to an infected person, and the scan would reveal a list of other person's (via the Bluetooth connection on their phones) who had come into close proximity with the infected individual. While this method, or other similar contact tracing technologies, has the potential to be highly effective, it immediately raised questions about how user's privacy would be protected. In the future we imagine above, if a broader exception for public health disclosures becomes reality, disclosure by such systems could be permitted. Google and Apple themselves are not covered entities under HIPAA, and at least in the context of the passively generated data in the example above, would not necessarily be acting as the business associate of any covered entity; therefore, they would not directly have any HIPAA obligations. However, once the data reached a covered entity (e.g. a health care provider like a hospital), any further use or disclosure would need to fit within a defined HIPAA exception.

Any contact tracing method or technology would be subject to similar scrutiny. If carried out by public health authorities, their employees or agent, the data likely already fits within the exception for public health use. However, for the sake of getting a program up and running quickly, local governments may deputize local institutional providers or non-profit organizations to conduct testing and tracing. If so, how would data gathered fit within existing provider's medical record systems? Would they be allowed to share it if the affected individual was seen by another provider? What obligations would the local government be allowed to place on this group via contract which might be more stringent than HIPAA or applicable state law?

Expanded Research Exception

As soon as the immediate problems of dealing with the COVID-19 pandemic were addressed, efforts began to ramp up on tests, cures and therapies for the virus. As has been noted frequently, vaccine development is a long and laborious process. We believe that one of the lessons coming out of this pandemic is that the American economy cannot afford regular and recurring disruptions on the level (and for the duration) that has been experienced in 2020. Therefore, greater emphasis will be placed on facilitating and accelerating research to develop better and faster tests and therapies that will be able to go to market more quickly. We have addressed issues involving research and FDA process earlier. It also stands to reason that HIPAA and privacy protections for research participants will also be subject to change.

In general, the HIPAA rules regarding use or disclosure of PHI for research can be summarized as follows: No use or disclosure of PHI is permitted except (i) with the patient's authorization, (ii) with a documented waiver from an Institutional Review Board (IRB) or privacy board, (iii) if the PHI will stay within the covered entity and only be used in preparation for research, or (iv) if the data used is exclusively that of decedents. De-identified data, which is not PHI, can also be used for research purposes. Obviously, one way to effectively expand the use of PHI for research would be to either

obtain broad authorizations from patients (either now when they seek care or in the future), or to liberally grant waivers through the IRB or privacy board process. A significant source of research progress could be a retrospective review of the hundreds of thousands of COVID-19 cases (both survivors and the deceased) from across the country. This would preclude use of the third or fourth exception, and would make implementing the second exception extraordinarily onerous.

What we believe is likely to develop is an uneasy grafting of the public health exception (see previous section) onto the research exception. In short, research on historical patient data (not current clinical trial participants—which will continue to be handled via informed consent) will be permitted even in the absence of the patient's authorization if the purpose of the research is substantially to develop (or lead to the development of) tests, treatments or therapies for communicable diseases for which a public health emergency is or may be declared in the future. Because of the requirements of the Common Rule and the prevailing structure and processes of American medical research, this may continue to be implemented via the IRB process. However, we believe that research institutions and health care providers (many of whom have borne the brunt of the COVID-19 pandemic) will clamor for a broader exception written into the HIPAA regulations, which will require less oversight and less documentation from the IRB (and thus may further accelerate the approval and performance of research).

Telemedicine and Privacy

A detailed treatment of the future of telemedicine has been provided previously (see Chapter 1); however, here we wish to deal with some of the privacy implications of a world with an increasing use of telemedicine. The privacy and security of telemedicine technologies and platforms, both as a pipeline of data and as an intermediary between patient and physician, has historically been an obstacle to the quick adoption of telemedicine technologies by health care providers.

A variety of certification programs has arisen to help providers and professions in this industry navigate the range of platform options available to them, and consultants enjoy a brisk market in aiding providers through the adoption and implementation of a telemedicine platform. However, recent emergency regulations by HHS and OCR opened the door for more rapid implementation of a transition to telemedicine, out of concern for the risks of patients contracting COVID-19 in clinics and waiting rooms.

One of the principal outcomes of these emergency rules is to widen the range of technologies which can be utilized to provide telehealth to include popular commercially available videoconferencing platforms such as Skype and Zoom.[72] These platforms arguably do not carry the same protections and certifications as other devoted telemedicine technologies. The question becomes whether providers, once adopting an easy-to-use and low-cost platform, can be persuaded to hit "pause" on their telemedicine offerings, and spend monthly identifying and adopting a more complex and expensive platform. Once let out, can this horse be successfully put back in the barn?

Our conclusion is that the COVID-19 pandemic moment will push the development of telemedicine toward a middle ground. Once the public health emergency has passed, the flexibility which allowed use of these widely available platforms will be phased out, possibly with a transition period for providers to move patients and operations to a new set of technologies. However, the specter of future pandemics or other disruptions will make policymakers and providers aware that the industry may need to snap back into a telemedicine-first stance on short notice. Instead of pushing providers, many of whom have suffered financially due to COVID-19 disruptions, into expensive telemedicine contracts, we believe that the chief impetus will be on the large corporations who operate these commercially available platforms to add some bells and whistles and roll them out as HIPAA-compliant. Some of these offerings may cannibalize more specialized and more expensive platforms developed

by the same companies. Providers may have additional options, with a wider range of affordability, thus accelerating adoption by community providers with fewer resources. However, highly specialized platforms which depend on their security posture and HIPAA certifications, may be squeezed out over time. Patients will be offered more security and privacy protections than are currently offered by those platforms, but will be expected to agree and waive the full protections previously offered in exchange for the convenience of using platforms with which they are likely already familiar.

Enforcement of Pandemic-Era Violations

Finally, how will regulators and enforcement agencies treat HIPAA violations that occurred in the midst of the public health emergency related to COVID-19. OCR has already announced "enforcement discretion" related to business associates who disclose or use PHI pursuant to health oversight or public health activities, and for providers who make good faith use of telehealth technologies. As we have already explained, we believe these announcements will be extended and expanded in a post-pandemic world.

However, because in an emergency things move fast, and things get missed, mishaps, inadvertent disclosures and breaches are inevitable. Will authorities take any action against covered entities or business associates who suffer breaches or otherwise violate HIPAA during the public health emergency? Our conclusion is that OCR and other enforcement bodies with responsibility for HIPAA and other privacy regulations will be extraordinarily forgiving with such individuals or entities. We do not believe that regulators will use this as a moment to make an example out of a provider or any entity which was acting in good faith to provide treatment responsibly in a crisis. The sole exceptions we envision would be disclosures or uses of PHI in violation of HIPAA and its regulations which seem to suggest profiteering on the suffering of patients (perhaps counting on the attention of government agencies being directed elsewhere) or otherwise seeking to take advantage of a situation for undue private gain. While we do not recommend that any covered entity or business associate should treat this as a free pass, or a chance to get lax about HIPAA enforcement, we do believe that regulators will be understanding that organizational bandwidth was limited in a crisis, and mistakes would be inevitable (and may be harmless).

One last item for consideration concerns the recent discussions on tracking individual cases and movement as a means of rapid identification of "hot-spots" of viral exposure. This controversial public health measure was successfully deployed in China and is now used by 19 countries to monitor the disease by tracking of people using cell phones. These modalities raise interesting issues of individual privacy and public health safety to be addressed in the next edition of this treatise. (see: https://www.gpsworld.com/19-countries-track-mobile-locations-to-fight-covid-19/)

CHAPTER 6

ENVISIONING TOMORROW'S HEALTH CARE WORKPLACE

— By Kristin McGurn

Responding to the fast-moving coronavirus pandemic, teams across the health care ecosystem flexed their agility and collaboration muscles like never before. Specialty and shuttered facilities were repurposed in a matter of days. Supply chains were expanded, reinvented and likely forever altered. Operational work flows changed seemingly on the fly. Facilities were redesigned from entrance to exit, to prevent contamination. Front line colleagues gave voice to a new way of doing business borne out of necessity. The guidance from legal departments, coupled with clinical strategy, was instrumental.

It's time to do it all again. Health care providers are now treating an increasing number of patients whose care was delayed due to pandemic surges and infection concerns. We stand to learn from the command centers established for pandemic care, which adeptly responded to evolving regulatory schemes, as we redeploy workers once again. Postponed high-priority urgent procedures, well-visits and vaccines, elective surgeries, dental, ophthalmological, and expanded prophylactic care is now resuming outside COVID-19 units, while the work continues within them.

Considerations that guided initial pandemic decision-making remain critical now—an emphasis on ensuring the appropriate workforce is in place to respond to newly prioritized patient needs, physical space modifications, sourcing sufficient supplies to protect patients, their companions, and workers, and consistently applying policies to enforce changed expectations of workers, health care consumers, and facility visitors alike. Workers may return to traditional worksites, coming back from the pop-up testing sites in tents and facility garages, and hastily outfitted clinics in trailers and sports arenas, and from dorms and hotels to which they retreated when the pandemic began. What roles will they now play?

Many will not return to their pre-pandemic duties, forced to change along with the new health care landscape. Detailed planning remains essential, even though changes to those plans are inevitable during a phased restoration of services. The leaders who exhibit flexibility and adapt quickly to local, state, and federal directives will be best equipped to govern the health care of the future where coronavirus will be a part of the puzzle but not the predominant piece.

Teamwork 2.0

A strong plan begins with a clear and communicative leader at the helm. A coordinated reopening/renewal team will include human resources, labor relations, information technology, data analytics, cyber security and breach mitigation, facilities, health and safety, frontline managers, and public relations. Standout innovators, who stepped up in creative ways during the public health emergency, may exhibit critical traits that teach pivotal lessons or should effectively be modeled during this period of continuous change. Collaboration throughout and among health care systems, which proved critical during surges, may continue to lead to shared approaches and analytics.

Redefined Talent—Learning From Today

Many health care institutions were forced to make tough decisions while caring for scores of COVID-19 patients—cutting pay, reducing hours, and placing on leave workers in closed units and softened sub-specialty markets. At the outset of the public health emergency, providers took seismic steps to enhance capacity for patient care—implementing labor pools; recalling retired licensed practitioners; pulling clinical researchers from labs into patient-facing roles; deploying orthopedists and others whose procedures were banned to patient-facing roles and newly constructed testing sites; reassigning PACU and OR nurses to cohorted and newly dedicated COVID-19 units; and sending vast numbers of administrative personnel home to work, or into unfamiliar roles. Doors were closed to volunteers, many of whom redirected their efforts away from on-site visits toward mask-making, food service, and other expressions of gratitude. Talent was sourced from out of state when permitted by relaxed licensing requirements and expedited certification protocols. Today's question: how to unravel that complex web of redeployment, and assess what (if anything) those team members will do now?

Urgent, High-Impact Procedures

First, ops teams must tackle the fraught analysis of which postponed non-COVID-19 procedures take precedence. The surgical, orthopedic, scan, and outpatient departments that stalled during surges may be the first to respond to pent-up demand. Community and direct-to-patient messaging plays a crucial part in assuaging public concerns about receiving necessary, non-emergency treatment despite the circulating virus. Teams from development, marketing, patient-outreach, and social media will be instrumental in spreading careful messaging at the right time—it is, and in most cases always has been, safe to go back to the hospital. In many cases, it will be the only care option when telehealth is unavailable, as ambulatory care sites experience a delayed resumption of services.

To support the redirected workflow, consider the implications for labor pool and furloughed colleagues. Which non-essential team members must be redirected or brought back on-site, when and for what purpose? Business needs, urgency of care, and reimbursement budgets will drive the analysis. Compliance with local restrictions on health care activities, and meeting thresholds for phased restoration of services, are critical and evolving considerations.

Back to the Future

Deciding how to return colleagues to the worksite should invoke a process similar to that which likely guided furlough decisions and remote work planning. Level-loading across health care systems, which was crucial during surges, may continue to play a post-pandemic role. The criteria that govern which employees will staff the facilities and patient care departments that re-open must depend on objective business needs, driven by consistently applied selection criteria based on legitimate and non-discriminatory factors. These should be fastidiously documented to defend against subsequent claims of caprice or mistreatment. Inadvertent negative impacts on various workforce populations must be studied, and avoided.

Employees called back from furlough should receive adequate advance notice of their return date to enable them to capably plan, and a clear description of what to expect upon return to the renewed worksite. Post-pandemic duties may well look different from pre-pandemic roles. Before implementing marked changes to duties for those who are classified as overtime exempt, consider the implications on equity and overtime eligibility. Memorialize duties changes in revised job descriptions that accurately reflect necessary role changes. Mid-level licensed professionals on whom the health care system relied far more heavily during pandemic surges can expect their roles to further elevate and evolve. Indeed, redefined roles have proliferated across the spectrum of care, emphasizing the need to source talent differently—an increased emphasis on infection control to ensure hour-by-hour hygiene and sanitation;

adapting to patients' experiences in isolation and navigating family member interactions virtually; using 3D print making spaces and talent in new and expanding ways; emphasizing voice and AI assisted scribe and diagnostic services.

The workforce must now flex to support the heightened use of these tools. The panoply of virtual care provided via telehealth, to protect patients by helping them stay safer at home, will remain a prominent delivery model across the continuum of care, and a critical tool in rural outreach and behavioral/mental health. Home health services and patient observation with home monitoring will also expand in rehabilitative and senior care. Roles dedicated to helping patients and families with health-related finances will be critical. Experts in personal and proprietary data protection throughout the health care ecosystem will proliferate.

Mind the Children

Unusual challenges may hinder efforts to return colleagues to the worksite. For workers with recovering relatives, eldercare responsibilities, or young children, the work/home struggles are real. Schools and non-emergency day care remain closed and summer camps are canceled in many jurisdictions. Non-essential workers who lack access to the emergency child care that was provided across the country to essential front line workers during the pandemic may not have day care alternatives that enable a return to an office or clinic. States continue to promote teleworking and advise a phased return as outlined in Opening Up America Again and state corollaries. Employers should anticipate that requests to continue working from home, when feasible, will proliferate given home-schooling responsibilities and wide-spread trepidation following shelter in place orders. A decision to permit remote work does not mean an employer must continue it indefinitely, but proactive employers will establish an efficient, mapped process for all such requests to be vetted with consistency and renewed flexibility. Lessons recently learned about the ability of many team members to productively work from home will inevitably inform the analysis.

Safety is Foremost

Health care of the future maintains patient care quality and worker safety as its highest priority. Appropriate safety protocols will guide the return of non-essential or furloughed workers to the workplace. This starts with the daily commute, which itself could increase risk of exposure in real and imagined ways especially where public transportation is involved. Consider modified work schedules: advance notice of new or staggered shift schedules, designed to avoid peak commuting hours, may be warranted. Metropolitan health care providers have enhanced shuttle services and ride-share opportunities, and are working actively with local government to proactively address public transportation concerns.

Health care organizations' essential workers inevitably have become accustomed to temperature-taking and testing protocols, and self-certification of symptoms, for patients and front-line workers alike. Subject to test availability, these procedures will affect everyone entering the worksite. Apps developed for temperature logging and health care screening upon entry are now common following the EEOC's recent guidance, which clarified that during the pandemic employers may track employee temperatures as a data point in the effort to safeguard workplaces. Testing for the disease, and antibodies, is being widely explored. Because the CDC and state/local health authorities have acknowledged COVID-19's community spread and issued attendant precautions, employers now are permitted (and expected) to conduct these medical examinations in health care settings. All resulting information, including data about employee illness, must be maintained as a confidential medical record in compliance with the ADA and HIPAA, and protected from privacy breach.

For many, fear is here to stay. Employers should plan for it as workers are re-trained for their return. The continued protection of vulnerable employee populations remains a driver. Increased latitude should be granted to those with conditions identified by the CDC as compromised or who otherwise

present as uniquely susceptible. Employees and their advocates are intensely focused on worker health and safety in all industries, but especially in health care where legislation in certain jurisdictions states that a contracted coronavirus is presumptively work-related. Individual and collective law suits are underway challenging OSHA compliance and expanding whistleblower theories. Fear of exposure will lead employees who are now working remotely or were furloughed to refuse outright to return the worksite. Supervisors must be trained to escalate, and involve well-trained HR professionals to assess whether a particular refusal merely reflects subjective preference or instead triggers a health-related or otherwise justified legally required accommodation discussion.

Given all the ways in which the nature of pre-pandemic health care work necessarily will change, labor relations will take a prominent role in planning for employees' re-entry, whether an institution is unionized or not. Across the country, returning workers are actively engaging in protected concerted activity under Section 7 of the National Labor Relations Act, whether or not represented by a union. These conversations will continue to highlight worker health and safety. Employers now subject to collective bargaining agreements must be prepared to negotiate with applicable unions any changes in wages (e.g. reductions and sun-setting incentive pay), benefits (e.g. additional sick or childcare-related leave), and other terms and conditions. The economic exigencies that may have excused a failure to bargain when the public health emergency first was declared are unlikely to justify unilateral employer decision-making during a gradual reentry to the workplace. Providing advance notice of proposed workforce changes will help maintain productive labor management relations. Union requests for information are now prolific, should be anticipated, and documents memorializing contingency plans, safety protocols and treatment of COVID-19-related absences should be readily available.

Envisioning Tomorrow

Succinct, frequent internal communications, including interactive top-down huddles where safety and loss mitigation strategies are shared, as well as curated external public relations messaging, are critical components of successful planning. Enhanced training conducted remotely (or in small groups) should accompany the new and modified policies that now will govern the workplace. Reorientation of returning employees, therefore, is also critical. Large in-person meetings (conferences, grand rounds, shift huddles) must be minimized, highlighting the importance of alternate modes of communication. Modified schedules must be clearly communicated in advance. Leave management processes must address new challenges created by the Families First Coronavirus Response Act, local leave entitlements and bereavement needs. Teleworking will continue wherever appropriate, necessitating equipment and reimbursement policy changes where required, and mandating enhanced oversight of confidential information and cybersecurity concerns.

Physical workspace modification is inevitable and may significantly drive who returns and when. Floor plans will be modified to enable patients with confirmed or suspected COVID-19 to access treatment areas without elevating the risk of further community spread. Parking structures and campus flow, entrances and exits, donning and doffing areas, elevator traffic, and common areas will be reimagined for optimal throughput with minimal exposure. As surges subside, COVID-19 ICUs will return to OR and PACU status, at the ready to flex once again to handle ICU needs should the disease cycle through again. Work stations will be redesigned to enhance social distance. No touch access, improved ventilation and filters, enhanced negative pressure zones, and comfortable respite areas will be prioritized. Employee communal break practices and locations will give way to separation. Use of shared tools will be minimized and high touch surfaces repeatedly sanitized. Waiting rooms will be repurposed, perhaps combining COVID-19 positive patients or yielding entirely to a notification system that grants entry to the facility only at the precise appointment time. Tech-enabled virtual visits will continue, thereby reducing fear, avoiding contagions, and facilitating adherence to clinical appointment scheduling.

Caregiver Well-Being

Caring for weary and distressed caregivers who saw us through the surges remains a critical priority. Social workers, chaplains, leveraged EAPs, enhanced mental health and wellness benefits, and persistent education will help manage burnout and post-treatment stress. Tax advantaged relief funds and an intense focus on philanthropy may help pave the path forward for the nation's beleaguered health care workers. Critically, leadership's commitment to set a healthy example will be instrumental as providers prepare for and continue, despite exhaustion, to navigate the impending surge of pent up demand for urgent, routine and elective care.

Lessons abound from our experiences since the public health emergency declaration. Those lessons will inform how providers may best adapt to tomorrow's health care and the individuals that make up this essential workforce. Resiliency will epitomize the new normal.

CONCLUSION

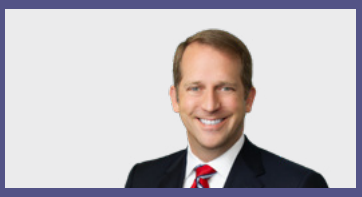
As set out at the beginning, this piece explored the future of health care in the US. It provided insights into what the health care industry's "new normal" may look like—one focused on leveraging regulatory changes, technology, innovation, and new capabilities to better respond to the next pandemic or other public health emergencies.

We identified the potential consequences of the crisis, suggest potential outcomes and lessons learned from the emergency measures put in place to weave together a fragmented health system.

Crises like these, while tragic, can also present opportunities and bring about change. Responding to the fast-moving coronavirus pandemic, teams across the health care system flexed their agility and collaboration muscles like never before. Working with payors, heavily relying on newly established internal incident command teams, and advocating vigorously alongside legislators, leaders at health care institutions played career-defining roles. They laid the foundation for tomorrow's health care while simultaneously helping their institutions meet unprecedented patient needs, steadfastly guiding the frontlines through a worldwide pandemic. Given the extraordinary complexity of the global coronavirus public health emergency, health care providers' expectations of and reliance on internal legal teams changed for good.

Whether or not the future of health care looks radically different, it is clear that this industry has been forced to adapt for a future state—one focused on improving the quality of care and outcome for patients.

For guidance on the issues outlined here, please contact the authors.



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ENDNOTES

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72 Other technologies, which are primarily used to broadcast content to a wide audience (YouTube, Twitch) remain prohibited.

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