NEW YORK STATE BAR ASSOCIATION HEALTH LAW SECTION COVID-19 REPORT May 2, 2020

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This report is dedicated to New York's health care workers and workers in service jobs on the front lines of the pandemic.

Introduction

The COVID-19 crisis and New York on PAUSE¹ have presented a unique set of circumstances for New York healthcare providers, professionals and workers, and the persons, families and communities they serve. Over 19,000 New Yorkers have lost their lives based upon New York State Department of Health data reported through the period ending May 2nd, 2020.² While the apex of the pandemic appears to be flattening in New York, deaths are still hovering at an unacceptably high number. The health system as a whole has been struggling to deal with executive orders and overwhelmed capacities and capabilities, across the continuum of care, as well as the surge in capacity that occurred over a very short time period. Through drastic social control measures (i.e., closing businesses and enforcing social distancing), supported by innovation and resourcefulness (for example, in adaptation of equipment such as shared ventilators), explicit rationing of resources may have been averted in some parts of the system, or mitigated in others, at least for now, particularly as such rationing concerns allocation of ventilators in the hospital system. It has come to light that the long-term care system has not fared nearly as well, and there have been continuing shortages of personal protective equipment and staff in both the hospital and long-term care systems. Notwithstanding the unparalleled bravery we have witnessed at all levels of the system, issues concerning rationing scarce resources, including implicit forms of rationing, remain relevant while the pandemic continues to devastate populations and health care workers. This is particularly apparent in the long-term care sector. To the extent that crisis standards of care remain in place during the period the pandemic continues to flatten, as well as in future waves of COVID-19, there will continue to be concern about rationing.

In addressing the legal and ethical issues confronted by the health system, we must not forget the human face of COVID-19, the persons, families and communities affected by the pandemic, and the unspeakable assaults on the fabric of human life – loved ones dying alone in sterile hospital rooms, unemployment and food insecurity, the loss of sociality, and depths of bereavement and despair unknown in generations, at least in the western world. Communities of color and those historically disadvantaged and marginalized, including Black/African Americans with illness burden, isolated and vulnerable older adults, nursing home residents, persons with disabilities, persons who are homeless, workers in low-income jobs and on the frontlines, and inmates and immigrants, have been the hardest hit by the pandemic, reflecting the intersectionality of age, race and ethnicity, class, gender, and disability and immigration status. In these contexts, there has been a lack of systematic attention to the psychosocial needs of those affected by the pandemic, or the role of the helping professions including psychology and social work, perhaps with the exception of palliative care which is playing a central role in the pandemic. Palliative care physicians, nurses, nurse practitioners, social workers, psychologists, and chaplains are trained in working with families, goals of care discussions, pain assessment and mitigation of suffering, and providing bereavement support. Efforts to locate palliative care practitioners and teams in emergency rooms during the pandemic, as reported by hospital systems here in New York, is helping to relieve the stress of front-line workers, and provide critical support to patients and their family members as they confront the assaults of the virus and imminent risk of death.

¹ NEW YORK STATE, Gov. Cuomo Exec. Order, *New York State on Pause: 10 Point Plan*, Mar. 22, 2020, https://coronavirus.health.ny.gov/new-york-state-pause.

² New York State Department of Health COVID-19 Tracker, May 2, 2020, https://covid19tracker.health.ny.gov/views/NYS-COVID19-Tracker/NYSDOHCOVID-19Tracker-Fatalities?%3Aembed=yes&%3Atoolbar=no&%3Atabs=n.

As the crisis began to unfold, New York State Bar Association (NYSBA) President Hank Greenberg asked that the Health Law Section prepare a report on the legal issues presented by the COVID-19 epidemic. To meet the request, Section Chair Hermes Fernandez appointed a Task Force to address the unique legal and ethical questions raised by COVID-19.³ The Health Law Section Task Force began work in early March.⁴

The Task Force was charged with examining legal issues presented by the pandemic. As the Task Force pursued its work, it identified gaps in the law and legal and regulatory barriers to care delivery that have emerged during the pandemic. The Task Force also chose to make recommendations to address such gaps and barriers in the rapidly changing legal environment, based upon present knowledge.

Cluster groups were organized to examine public health, ethics, provider systems, telehealth, reimbursement, business and liability, workforce and vulnerable population issues.

The members of the Task Force and its various cluster groups convened approximately twice a week, starting on March 13th through April 24th, to identify goals and priorities, and also consulted with experts in medicine and bioethics on issues of concern. The members of the Task Force and cluster groups followed consensus processes of decision making throughout its work. During this time, governmental leadership has managed many of the issues the Task Force addresses through a series of declarations and emergency orders.⁵ The Task Force acknowledges the value and impact of such steps.

This report reflects the consensus of the Task Force on a wide range of legal and ethical issues and recommendations to further ease the challenges presented now and anticipated in the future. The following limitations of the report are noted: although we touch upon the interaction of federal and state law, the principal focus of the report is New York law; the key issues identified and examined by the Task Force members are by no means exhaustive; and as of this date, sources of reliable data and evidence about the pandemic remain limited. A summary set of Task Force recommendations, based upon current knowledge, may be found at the end of the report. These recommendations will need to be re-assessed over the course of the pandemic, and as more knowledge is gained about the science of COVID-19, health system vulnerabilities, and population outcomes.

I. Public Health Law Framework

Introduction

Public health law focuses on the legal powers and duties of the state to protect the public health, as well as limitations on state power to preserve the legally protected interests of individuals. Public health law provides critical tools to support the response of federal, state, and local governments to public health emergencies (PHEs).⁷

³ See a full list of appointed members of the Task Force, as well as consulting advisors, scholars and legal professionals, and attorney and law student volunteers who provided support to the Task Force, Appendix H.

⁴ The opinions expressed herein are those of the Health Law Section, and not those of the New York State Bar Association until approved by the House of Delegates or the Executive Committee, or the individual members of the Task Force. The New York State Bar Association is a statewide bar association with 74,000 members. We are proud to have a robust Health Law Section with active members in diverse areas of practice concentration and legal scholarship.

⁵ See New York State Bar Association Health Law Section Task Force Letter to Governor and Department of Health, March 26, 2020, footnotes 4, 5, 6 and 7, Appendix A.

⁶ See Task Force Recommendations, Appendix G.

⁷ JAMES G. HODGE, JR., PUBLIC HEALTH LAW IN A NUTSHELL, 227-247 (West Academic Publishing 2014).

Legal Reforms

Legal reforms have sought to improve planning and response for public health emergencies through development of legal response capabilities, comprehensive federal and state declarations, and improved classifications of PHEs utilizing modern approaches to react to current threats.⁸ Public health law experts and academics have promoted adoption of model emergency preparedness acts to equip government officials with the legal tools to respond to novel and emerging public health threats. For example, the Model State Emergency Health Powers Act (MSEHPA), developed by the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities in 2001, provides a set of model provisions for state and local government to respond to public health crises.⁹ The MSEHPA balances individual and communal interests when government is responding to a public health threat that may result in a large number of deaths and/or mass morbidity. It provides a framework for governments to respond efficiently and effectively to public health emergencies without unjustly infringing upon individual rights.^{10,11}

New York can benefit from examining the principles established in the model legislation for coordinating an effective public health response during the coronavirus pandemic. Knowledge of a uniform structure of laws in New York, enabling a public health emergency response, is especially important in protecting community health as more residents become infected, demanding more resources from the state's healthcare system. Once the pandemic is over, New York should review and consider adopting the MSEHPA provisions, as is or as otherwise amended, using the Columbia University Center for Health Policy Gap Analysis, ¹² developed at the impetus of, and in collaboration with, the NYSBA Public Health Law Committee.

New York State Executive Law Article 2-B,¹³ as significantly expanded in April 2020 (Ch. 23, Laws 2020),¹⁴ grants emergency powers to both local heads of government and to the Governor. Epidemics are included in its definition of what is an emergency.¹⁵ The chief executive of a town or city in which an epidemic is occurring may issue directives to safeguard the health of the public that include setting curfews and restricting people from gathering in public places.¹⁶ If an epidemic cannot be contained by local action, the Governor may declare a disaster and issue directives to protect the public. Applicable laws require implementation of the least restrictive measures to protect the public, as well as reliance on specialists to prevent adverse effects of any public health emergency measures during the pandemic. The Public Health Manual, recently updated by the New York State Bar Association and New York's Office of Court Administration, provides an overview of the laws that apply to public health issues. ¹⁷ As evidenced by the

⁸ James G. Hodge, Jr. et al., From Anthrax to Zika: Key Lessons in Public Health Legal Preparedness, 15 INDIANA L. REV., 23, 25-26 (2018).

⁹ See Lawrence O. Gostin et al., *Model State Emergency Health Powers Act*, CENTER FOR LAW AND THE PUBLIC'S HEALTH (Georgetown University 2001), http://publichealthlaw.net/MSEHPA/MSEHPA.pdf.

¹⁰ See Lawrence O. Gostin & James G. Hodge, State Public Health Law Assessment Report, TURNING POINT PUBLIC HEALTH STATUTE MODERNIZATION NATIONAL COLLABORATIVE (2002).

¹¹ See id.

¹² Benjamin Mason Meier & Jocelyn Getgen, *Gap Analysis: Comparing the Model State Emergency Health Powers Act with Corresponding New York State And New York City Statutory Authority*, CENTER FOR HEALTH POLICY (Columbia University 2008).

¹³ N.Y. EXEC. L. Art. 2-B – State and Local Natural and Man-Made Disaster Preparedness.

¹⁴ Ch. 23, Laws 2020.

¹⁵ N.Y. EXEC. L. §20(2)(B).

¹⁶ N.Y. EXEC. L. §24.

¹⁷ NYS PUBLIC HEALTH LEGAL MANUAL, A GUIDE FOR JUDGES, ATTORNEYS AND PUBLIC HEALTH PROFESSIONALS, 2d Edition, Currently available as free ebook at: https://nysba.org/products/new-york-state-public-health-legal-manual-second-edition-ebook/?numberOfItemsInCart=1&salesOrderId=a1J1U000002yZ5PUAU&status=SUCCESS.

numerous Executive Orders issued over the past several months, more review, analysis, and legislation potentially, are needed.

Developing a systematic framework to prioritize scarce resources in the face of the coronavirus pandemic is essential to protect both individual rights and the public's health. This requires a robust evaluation of constitutional rights, ethical triage of scarce resources, guidance regarding existing advance care directives, and adverse effects of decisions on vulnerable populations and communities of color – all components of legal and ethical decision-making to ensure fairness, transparency and equity. Issues of equity present the most challenging allocation decisions, and call upon us to grapple with questions of implicit bias and risks of discrimination in crisis standards and decision processes. For example, if people of color or with comorbidities and other burdens are less likely to survive hospitalization due to social and economic determinants of health that have compromised their health status over the life years and resulted in advance illness and compromise, is it ethical to consider long-term survival in making allocation decisions? Federal law bars discrimination on the basis of disability, and in the case of discriminatory triage guidelines, enforcement actions may result.¹⁸

Crisis Standards of Care

New York State, and other jurisdictions, have lacked sufficient resources (e.g., practitioners, personal protective equipment, ventilators, and dialysis machines) to provide critical care during the coronavirus pandemic and may face similar situations in possible future surges. Rationing resources may thus be unavoidable at such times. The development of a framework to guide decision making in a crisis -- a pervasive (e.g., pandemic) or catastrophic (e.g., earthquake) disaster¹⁹ -- is important to preserve the rule of law and maintain focus on ethical considerations. Crisis standards of care ensure that scarce resources during these times are allocated based on evidence and data, with the participation of a broad range of public and private stakeholders, and that decisions are communicated in a transparent manner to preserve the community's trust.²⁰

The Institute of Medicine, in a 2009 letter and 2012 report, set forth a comprehensive approach to the development and implementation of crisis standards of care The Crisis Standards of Care (CSC) proposed by the IOM provide one path for shifting from usual healthcare operation to crisis response required to address the need for a surge response.²¹ They acknowledge the interdependency of public and private emergency responders and suggest a process to adjust the state's response to address medical surge and scarce resources. The CSC ensure provider and community engagement to adjust the delivery of care based on fair and equitable principles. Furthermore, the CSC offer guidelines to enable providers to make difficult life and death decisions and reduce suffering.²²

The development of consensus standards of care can be particularly beneficial to New York State when navigating crises, such as the coronavirus pandemic, because it focuses on adherence to ethical and

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¹⁸ 42 U.S.C. §12132 (1990); 42 U.S.C. §12182 (1990); *See* HHS OFFICE OF CIVIL RIGHTS, *OCR Reaches Early Case Resolution With Alabama After It Removes Discriminatory Ventilator Triaging Guidelines*, Apr. 8, 2020, https://www.hhs.gov/about/news/2020/04/08/ocr-reaches-early-case-resolution-alabama-after-it-removes-discriminatory-ventilator-triaging.html?; *See* also discussion of these issues, *infra*, Sections II and VII.

¹⁹ Institute of Medicine, Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response: Volume 1, (Dan Hanfling, et al., eds., The National Academies Press 2012), https://doi.org/10.17226/13351, https://commed.vcu.edu/IntroPH/2012/crisisManagement_IOM.pdf.
²⁰ Id.

²¹ James G. Hodge et al., *Practical, Ethical, and Legal Challenges Underlying Crisis Standard of Care*, J. L. MED. & ETHICS, Spring 2013 at 2.

²² *Id*.

professional standards.²³ The IOM's standards are based on three substantive principles: fairness, duty of care, and duty to steward resources. Underlying the concept of fairness in allocating resources is the duty to base decisions on ethically sound principles. This presupposes the allocation of resources in a consistent and standardized way across all types of provider types and settings. Furthermore, it contemplates the rigorous assessment of decisions against professional ethics. A process for resource allocation should be developed based on specified goals.²⁴ For example, if healthcare practitioners will receive priority for being placed on a ventilator, public health officials must clearly identify the goals and rationale for establishing this priority. The process must be based on non-discriminatory and reasonable standards for protecting the public's health.²⁵

The CSC-planning approach seeks to facilitate community and provider trust through transparency, consistency, proportionality, and accountability. Adoption requires public health officials to strictly adhere to ethical principles, as well as the development of standardized processes, and transparent communication with providers and the community about the processes.²⁶ Standardization protects and supports healthcare providers in resource allocation by providing a clear framework. The CSC-planning approach promotes trust through transparency about the resource allocation process with the community.

Ideally, the CSC-planning approach should be implemented before a public health emergency, when difficult decision-making can occur without the threat of immediate harm and private-public relationships can be cultivated. However, crisis standards of care can and should be implemented even during the crisis to create clear guidelines for practitioner and public health decision-making. While this report recommends adoption of a CSC-planning approach, which requires long term planning outside of a public health emergency, it will also identify components of crisis standards of care that can be considered for potential implementation, on a temporary basis, during a crisis.

Provider and Community Engagement

Protecting the public health during the coronavirus pandemic requires a commitment from a multitude of stakeholders, from public health agencies, private organizations, emergency response personnel, and bordering state agencies. Cooperation and collaboration are critical for sharing of resources and equipment. As part of a CSC-planning process, New York State should consider establishing memoranda of understanding and other agreements to facilitate interjurisdictional cooperation and coordination among different entities. Agreements²⁷ can ensure consistency with existing New York laws, as well as address specific concerns about resource allocation.²⁸

²⁴ *Id.* at 3-4.

²³ *Id.* at 3.

²⁵ Of course, the IOM standards, based on ethical, legal, and medical principles, must comport with federal and New York law, including New York's Constitution, statutes, and case law. New York State has long recognized the individual right to self-determination in health care and has a robust law of informed consent, including the right to refuse medical treatment, and the right to information and access to palliative care. The sensitive question of ventilator allocation must also satisfy federal and New York law. For example, under the Americans with Disabilities Act, as interpreted in Supreme Court decisions, health care providers may not discriminate against any patient in the provision of care based on the patient's disability, as discussed *infra* in Section II. Similarly, all providers have an ethical and legal duty not to abandon their patients, as discussed *infra* in Section II.

²⁶ James G. Hodge et al., *Practical, Ethical, and Legal Challenges Underlying Crisis Standard of Care, J. L. MED. & ETHICS, Spring 2013 at 5.*

²⁷ U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, Public Health Law/Publications and Resources/Emergency Preparedness, https://www.cdc.gov/phlp/publications/topic/emergency.html (last reviewed: Apr.10, 2020).

²⁸ Institute of Medicine, Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response: Volume 1, 1-6 (Dan Hanfling, et al., eds., The National Academies Press 2012), https://doi.org/10.17226/13351, https://commed.vcu.edu/IntroPH/2012/crisisManagement IOM.pdf.

Provider and community engagement are essential for the delivery of healthcare services during the pandemic. Using the CSC-planning framework, public health officials can work with healthcare organizations and the community to develop mechanisms to ensure compliance with surveillance, reporting, testing, screening, quarantine, social isolation, or other public health mandates. Patient issues, such as accommodations for disabled patients, preserving informed consent, and protecting patient privacy, can be addressed through engagement.²⁹

Adoption and Communication of Consistent Methods of Resource Allocation

Achieving consistency in allocation of scarce resources can impact community and individual health outcomes. The CSC-planning approach would establish meaningful guidance on shifting standards of care during public health emergencies and establish legal authority for shifting standards of care. Recognition of changing standards of care in a declared emergency alleviates healthcare practitioner concerns regarding liability when allocating resources. By changing the scope of practice during a declared emergency, public health officials can also suspend certain licensure requirements to meet increased healthcare demands.³⁰ Licensure and other requirements can be temporarily revised to allow healthcare providers to practice at the top of their license (e.g., reducing supervision requirements or authorizing practitioners with overlapping skills to fulfill service gaps).³¹ (See Section III for a full discussion of licensure issues.)

Continuous Performance Improvement

The coronavirus pandemic has resulted in fluid decision-making as more information is released from the federal government and more patients recover from the virus. The CSC-planning approach would promote continuous performance improvement to refine processes to provide the best level of care possible, even during the crisis. It would allow for the use of data and evidence-based decision making to make mid-course corrections, even during the crisis.³²

Provider Education About the CSC

Healthcare providers are trained to focus on individual patient needs and improving clinical outcomes. Coordinating the allocation of scarce medical resources could well require a dramatic shift in their approach to healthcare and difficult choices regarding patient care. Practitioners would need education on the CSC framework, and the conditions under which the crisis standards would come into play.³³

The CSC is based on modern public health principles to provide a consistent and ethically sound approach to delivering the best level of healthcare services to the community during the coronavirus pandemic. New York State should consider educating healthcare practitioners about the CSC to ensure transparency and fairness in all healthcare decision-making processes. Consistent application of CSC would also be important specifically in broadly reducing geographic variability or inconsistency in applications to evolving standards of care. Even variability can occur across health systems in the same metropolitan region.

²⁹ *Id*.

³⁰ James G. Hodge, Jr., Public Health Law in a Nutshell, 227-247 (West Academic Publishing 2014).

³¹ Id at 1

³² Institute of Medicine, Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response: Volume 1, 1-3 (Dan Hanfling, et al., eds., The National Academies Press 2012), https://doi.org/10.17226/13351, https://commed.vcu.edu/IntroPH/2012/crisisManagement IOM.pdf.

³³ *Id.* at 1-33-1-34.

Constitutional Protections and Civil Liberties

New York's ability to respond to public health emergencies is derived from its police powers and parens patriae powers.³⁴ The New York Constitution under Article XVII, Section 3 states, "The protection and promotion of the health of the inhabitants of the state are matters of public concern and provision therefor shall be made by the state and by such of its subdivisions and in such manner, and by such means as the legislature shall from time to time determine." With this constitutional authority, the legislature on March 2, 2020, passed an amendment to Executive Law §29-a granting the Governor broad discretion to address the emergent COVID-19 Pandemic.

The steps that New York has taken to control this novel virus are largely unprecedented. Exercising its power to address the coronavirus pandemic, the State implemented social distancing measures to protect public health during the pandemic, stay-at-home orders, the shutdown of "non-essential businesses," a moratorium on elective health procedures, and other directives that significantly infringe upon the rights of New York citizens. Such actions should be sparingly used, and only when there is a compelling reason to believe that these extreme measures are necessary to save lives. Accordingly, when implementing them, government officials must continually balance individual civil liberties against the need to protect the public health. They must be transparent about why such steps are needed, and they must impose the restrictions fairly and for only as long as they are needed.

For example, restrictions of movement should only be employed when they are necessary and public health officials can cite clear and compelling evidence that the disease, because of its communicability and severity, poses a grave risk to public health.³⁵ The government should ensure fair and equitable treatment, avoiding stigma or discrimination against individuals or groups. Furthermore, public health measures should be no more restrictive than necessary to accomplish public health objectives.³⁶ The evidence about the coronavirus and recovery outcomes are changing daily; therefore, New York should continually review the public health restrictions against evolving scientific evidence. Public health officials should revise executive orders and adjust restrictions accordingly to ensure least restrictive and fair measures.

Additionally, New York public health officials should implement safeguards to protect patient privacy during the pandemic. Patients have a right to privacy pursuant to the Health Information Portability and Accountability Act (HIPAA), as well as a state constitutional right to privacy. However, the right to privacy is not an absolute right; public health reporting is a standard exemption for providers, and public health officials and healthcare covered entities may share protected health information to advance public health surveillance and reporting activities.³⁷ While such data sharing promotes transparency, covered entities and public health officials must carefully consider protecting patient information by disclosing the minimum necessary information to achieve public health objectives.

Fair due process procedures are required when the government deprives an individual of property or liberty. The level of due process afforded must be commensurate with the extent of deprivation of life or liberty. Determining whether an informal process or a formal judicial process will preserve civil liberties rests on the level of coercive measures imposed, the risk of an erroneous decision, and the burden of additional

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³⁴ Jacobson v. Massachusetts, 197 U.S. 11 (1905); Lawrence O. Gostin, Public Health Law: Power, Duty, and Restraint, 92-98 (Univ. of California Press 2008).

³⁵ Wendy Parmet & Michael Sinha, COVID-19: The Law and Limits of Quarantine, 15 New Eng. J. Med. 28 (2020).

³⁷ 45 C.F.R. 160 (2012).

judicial procedures.³⁸ In New York, access to the courts has been curtailed temporarily due to the pandemic; however, virtual proceedings are increasingly available.

II. Ethical Issues in the Management of COVID-19

Introduction

There are two central ethical issues presented by the COVID-19 pandemic in the United State: i) the fair allocation of scarce resources; and ii) the balancing of autonomy, that is, individual rights and liberty interests, versus protection of the public's health. These are separate issues and merit consideration as such.

Allocation of Life-Saving Equipment

Allocating limited resources during the pandemic is among the greatest challenges in balancing our obligation to save the most lives against concerns of equity and the right to liberty. Such resources include tests to determine who is infected, personal protective equipment (PPE) to prevent spread, life-saving medical equipment – notably ventilators – and trained health care workers. Even items as mundane as hospital beds are scarce and must be allocated fairly.

Virus Testing

As other countries have demonstrated,³⁹ the value of having adequate testing early enough to tailor social distancing measures can significantly reduce the apex of infection and prevent strain on life-saving resources. Test-availability and test access triage are variable across domestic regions, which both reflects and reinforces inequities across socioeconomic lines. This has created unjustifiable disparity in access to better protection measures and treatment stratified by financial and social means.

There is evolving discussion about two specific types of testing now - diagnostic testing and post-exposure (antibody) testing. Both need to be in place and scaled. In light of the Governor's expressed intent to strategically execute a phased plan for reopening, a coordinated state-wide plan for diagnostic testing may be needed to ensure that special consideration be consistently and uniformly given to the most vulnerable New Yorkers from both a health and business operations standpoint.⁴⁰ Frontline and essential employees who are forced to engage in significant close contact with other essential employees to perform their duties, and cannot easily be replaced, are critical to ensure that essential businesses are able to continue to operate effectively in support of our community members, while also proactively protecting our community members who rely on services and products from these essential business entities.

PPE

The United States is also severely short on PPE for health care workers, such as gowns, face masks, eye protection, and surgical masks,⁴¹ which leads to difficult questions about who among them should have access to the existing limited supply. Production and distribution should have ramped up sooner, preventing such shortages. Members of the general public are understandably inclined to use PPE to protect themselves, but such use could be limited according to actual effectiveness and curtailed according to the far greater need of health care workers. Whereas socially distanced members of the public can effectively protect

³⁸ LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, AND RESTRAINT, 130-132 (Univ. of California Press 2008); *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

³⁹ Heather Stewart, *UK Must Learn from German Response to COVID-19, says Whitty*, THE GUARDIAN, Apr. 7, 2020, https://www.theguardian.com/world/2020/apr/07/uk-must-learn-from-german-response-to-COVID-19-says-whitty.

⁴⁰ NEW YORK STATE, Amid Ongoing Covid-19 Pandemic, Governor Cuomo Outlines Phased Plan to Re-open New York Starting with Construction and Manufacturing, Apr. 26, 2020, available at: https://www.governor.ny.gov/news/amid-ongoing-covid-19-pandemic-governor-cuomo-outlines-phased-plan-re-open-new-york-starting.

⁴¹ Andrew Jacobs et al., 'At War With No Ammo': Doctors Say Shortage of Protective Gear is Dire, N.Y. TIMES, Mar. 19, 2020, https://www.nytimes.com/2020/03/19/health/coronavirus-masks-shortage.html.

themselves and others with carefully placed cloth coverings,⁴² health care workers require more advanced N95 respirators because they are intimately and unavoidably exposed to infected people. Those hoarding PPE⁴³ represent the extreme violation of our collective ethical duty to steward precious resources.

Ventilators and Other Scarce Equipment

Allocation of life-saving equipment such as ventilators, which enable breathing for patients whose lung function is compromised by coronavirus infection, is the starkest exercise of justice during the pandemic. Access to a ventilator may make the difference between life and death for many individuals. Based upon all reports, there has been no explicit rationing of ventilators by providers upstate, and upstate systems actually sent available ventilators downstate. However, providers downstate were forced to adapt equipment to meet need, such as through ventilator sharing. It is not clear whether any patient was expressly denied access to a ventilator or other scarce equipment, although the state was on the brink of such decisions, and may very well not have enough scare equipment for everyone in future waves of the pandemic,, as experienced in Italy.⁴⁴ Accordingly, we may be faced in the future with difficult decisions about who will have access and for how long, and hence, must be adequately prepared.

Several organizations foresaw the possibility of pandemic-related ventilator shortage and developed guidelines for how to allocate fairly. These guidelines, including those produced by the New York State Task Force on Life and the Law (NYSTFLL) in 2015,⁴⁵ first issued in 2008, as well as the University of Pittsburgh, ⁴⁶ the North Carolina Protocol for Allocating Scarce Inpatient Critical Care Resources in a Pandemica, ⁴⁷ Maryland ⁴⁸ and other states, and the Catholic Health Association of the United States, ⁴⁹ follow certain similar patterns. It is of note, however, that the updated 2015 New York Task Force on Life and the Law (NYSTFLL) Guidelines do not grant priority to health care workers. Some existing guidelines do give priority to health care workers, based upon the implicit assumption that such professionals can receive limited ventilation and then return to the workforce while the need still exists, which remains uncertain from both an individual and systems perspective. ⁵⁰ Furthermore, the definition of a health care worker is unclear. Is it just physicians and nurses, or just those who serve during a pandemic, or just those with expertise to treat pandemic patients? For example, should a Florida dermatologist who let his license lapse be prioritized in a New York hospital? The issue of the treatment of health care workers in the event

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⁴² Prevent Getting Sick, CTRS FOR DISEASE CONTROL & PREVENTION, Apr. 13, 2020, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html.

⁴³ Marty Stempniak, *Feds seize 900,000-plus pieces of PPE from hoarding price gouger, distribute to providers*, RADIOLOGY BUSINESS, Apr. 2, 2020, https://www.radiologybusiness.com/topics/policy/ppe-COVID-19-pandemic-coronavirus-william-barr-doj.

⁴⁴ Marco Pavesi, *I'm a Doctor in Italy. We Have Never Seen Anything Like This*, N.Y. TIMES, Mar. 18, 2020, https://www.nytimes.com/2020/03/18/opinion/coronavirus-italy.html.

⁴⁵ New York State Task Force on Life and the Law, Ventilator Allocation Guidelines, Nov. 2015, https://www.health.ny.gov/regulations/task_force/reports_publications/docs/ventilator_guidelines.pdf. *See* University of Rochester Medical Center grid attached, Appendix B.

⁴⁶ Allocation of Scarce Critical Care Resources During a Public Health Emergency, U. PITTSBURGH, DEPT. OF CRITICAL CARE MED. Apr.15, 2020, https://ccm.pitt.edu/sites/default/files/UnivPittsburgh_ModelHospitalResourcePolicy_2020_04_15.pdf.

⁴⁷ North Carolina Protocol for Allocating Scarce Inpatient Critical Care Resources in a Pandemica, Douglas White, A Model Hospital Policy for Allocating Scarce Critical Care Resources, U. PITTSBURGH SCHOOL OF MED. Mar. 23, 2020, https://ccm.pitt.edu/?q=content/model-hospital-policy-allocating-scarce-critical-care-resources-available-online-now.

⁴⁸ Maryland Framework for the Allocation of Scarce Life-sustaining Medical Resources in a Catastrophic Public Health

⁴⁸ Maryland Framework for the Allocation of Scarce Life-sustaining Medical Resources in a Catastrophic Public Health Emergency, U. MARYLAND SCHOOL OF LAW Aug. 24, 2017, https://www.law.umaryland.edu/media/SOL/pdfs/Programs/Health-Law/MHECN/ASR%20Framework Final.pdf.

⁴⁹ Ethical Guidelines for Scarce Resources in a Pandemic, CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES 2020, https://www.chausa.org/docs/default-source/ethics/ethical-guidelines-for-scarce-resources-in-a-pandemic.pdf?sfvrsn=2.

⁵⁰ Mark A. Rothstein, *Should Health Care Providers Get Treatment in an Influenza Pandemic?*, 38 J. L. MED. & ETHICS, 412-419 (2010).

of scarce ventilator resources calls for re-examination in light of our experience and knowledge gained during the COVID-19 pandemic.

Most frameworks prioritize survival benefit, which means prioritizing patients for whom ventilator use will lead to hospital discharge and return to normal life. Such evaluations can be quite sophisticated in separating cases that seem similar. For example, the NYSTFLL guidelines recommend using the Sequential Organ Failure Assessment (SOFA) score⁵¹ that quantifies the possibility of mortality based on the degree of dysfunction of six organ systems. Most frameworks then allow for the possibility that such a comparison will not be able to differentiate all patients, leading to the need for "tie-breakers." A recent article in the New England Journal of Medicine⁵² describes such tie-breakers as involving assessment of co-morbid conditions that would indicate which patients would likely have better post-treatment life-length and life-quality, or age, for which younger patients would get priority because they have yet to experience the full life-cycle. Advocates for those with disabilities have raised serious questions about the ethics of any guidelines that would discriminate against persons with disabilities,⁵³ and the HHS Office of Civil Rights has cautioned that such discrimination on the basis of disability or age is barred by federal law.⁵⁴

Many allocation frameworks describe the importance of avoiding decisions that in practice discriminate on non-medical grounds and suggest the use of a lottery only if all other factors are equal. While objective and utilitarian, decisions that differentiate patients on grounds such as assessment of co-morbidities and age cannot be free from unintentional discrimination. Many with co-morbid conditions are so affected because of prior social injustices, leading to their inability to access adequate care or maintain healthy lifestyles. Accordingly, this prioritization scheme will inevitably save the lives of many whose health was better before the pandemic, which demonstrates the tension between the goal of saving the most lives and achieving distributive justice. Early data already suggest this pandemic is disproportionately affecting Black/African Americans, something that should be studied carefully and potentially used to ensure that social and economic determinants of health are considered in the fair allocation of life-saving resources.

Age has also been suggested as an allocation criterion. Older persons have historically been marginalized, but the value of remaining life is not necessarily diminished by age, which draws age into question as an allocation criterion. Yet some take the position that we may have a duty to help children and younger adults

⁵¹ Sequential Organ Failure Assessment (SOFA) Score, MD+CALC, (last accessed Apr. 24, 2020), https://www.mdcalc.com/sequential-organ-failure-assessment-sofa-score.

⁵² Ezekiel Emanuel et al., *Fair Allocation of Scarce Medical Resources in the Time of COVID-19*, New Eng. J. Med., Mar. 23, 2020, https://www.nejm.org/doi/full/10.1056/NEJMsb2005114.

⁵³ Ari Ne'eman, When It Comes To Rationing Disability Rights Law Prohibits More than Prejudice, Bioethics Forum Essay, HASTINGS CTR., Apr. 10, 2020, https://www.thehastingscenter.org/when-it-comes-to-rationing-disability-rights-law-prohibits-more-than-prejudice/; Joseph J. Fins, Disabusing the Disability Critique of the New York State Task Force Report on Ventilator Allocation, HASTINGS CTR., Apr. 1, 2020, https://www.thehastingscenter.org/disabusing-the-disability-critique-of-the-new-york-state-task-force-report-on-ventilator-allocation/; Joseph J. Fins, New York State Task Force on Life and the Law Ventilator Allocation Guidelines: How Our Views on Disability Evolved, HASTINGS CTR., Apr. 7, 2020, https://www.thehastingscenter.org/new-york-state-task-force-on-life-and-the-law-ventilator-allocation-guidelines-how-our-views-on-disability-evolved/.

⁵⁴ HHS OFFICE OF CIVIL RIGHTS, Bulletin: *Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19)*, Mar. 28, 2020, https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf; Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010).

⁵⁵ SHORTER LIVES, POORER HEALTH (Steven H. Wolf and Landon Aaron, eds., National Academies Press 2013); FROM NEURONS TO NEIGHBORHOODS: THE SCIENCE OF EARLY CHILDHOOD DEVELOPMENT (Jack P. Shonkoff and Deborah A. Phillips, eds., National Academies Press, 2000).

⁵⁶ Kenya Evelyn, 'It's a Racial Justice Issue': Black Americans are Dying in Greater Numbers from COVID-19, THE GUARDIAN, Apr. 8, 2020, https://www.theguardian.com/world/2020/apr/08/its-a-racial-justice-issue-black-americans-are-dying-in-greater -numbers-from-COVID-19.

experience more life when possible, meaning that the value of experiencing more life-phases might necessitate age comparison in some cases. Clearly, an age difference of just one year or two will rarely be ethical grounds on which to allocate, but our intuitions might sometimes support a decision to ventilate a 9-year old over a 79-year old when ventilator access would give them an equal chance of hospital discharge. This intuition reflects a basic human impulse to afford special protection to small children, as reflected for example in child abuse laws.

Many allocation frameworks provide thoughtful yet general guidelines. The challenge in their development is to be prescriptive enough so that overburdened health care workers can make confident decisions without fear of liability, yet general enough to allow flexibility when similar scenarios should be handled differently. For example, if one ventilator must be allocated between two patients equally likely to survive the acute respiratory infection yet one has a heart condition that would indicate fewer remaining life-years, a comorbidities assessment would favor the unaffected patient. However, if the heart condition is congenital due to Down Syndrome, guidance might suggest avoiding allocation decisions that hinge on the presence of disability, even if indirectly. If the heart condition is the product of a poor diet from living in poverty, guidance might suggest avoiding allocation decisions based on factors that grow out of oppressive socioeconomic structures. Relevant facts should thus inform ethical decisions to maximize lives saved while also avoiding unjust discrimination. At the same time, the allocation criteria should be sufficiently clear and concise that they can be understood and implemented by all front-line health care workers.

The development of a ventilator triage framework based on ethical principles should consider the social and cultural norms of the implementing system. It is also important to ensure healthcare staff are trained on the policy and processes and that they are universally applied. All clinicians should know how they are expected to assess survival benefit in accordance with a standardized, consistent process. Adherence to the accepted framework should serve to protect clinicians' allocation decisions, such as withdrawing care from someone who will not survive with maximum care to make resources available to another patient who is likely to benefit. There are mechanisms to relieve the attending health care staff of making the most difficult decisions that risk unjust discrimination on nonmedical grounds should not be made by the attending health care staff. To alleviate some of their burden and further insulate them from liability during this morally challenging time, a triage committee, or ethics committee, can be established and available to carefully apply the allocation policy and reach consensus about justified decisions in these cases. It is an unfortunate reality that many institutions do not have the capacity to train their staff on policy implementation or provide triage or ethics committee support for hard cases.

Withdrawal, DNR, and Futility

Usually, ventilator supply exceeds need. Under normal circumstances, when a ventilated patient will not likely survive after ventilator withdrawal, decisions regarding the course of care will involve a discussion of patient and family wishes, and appropriate implementation of palliative care to mitigate suffering, with limitations in public health emergency contexts such as the present one. Similarly, decisions to resuscitate a patient who is at risk of cardiac arrest will be informed by the patient's previously expressed wishes, or the family's wishes.⁵⁷ Such respect for patient autonomy represents the ideal of shared-decision making in modern western medicine. One way to better respect patient autonomy during the pandemic is to lower the

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⁵⁷ N.Y. PHL Art. 29-B, formerly the "DNR Law," now only applies in psych units and hospitals. It provides that, "It shall be lawful" for practitioners to write a DNR based on patient or agent/surrogate consent, or in the case of an isolated patient (i.e., a patient who lacks capacity and has no agent or surrogate) for two physicians to write a DNR based on medical futility. N.Y. PHL Art. 29-CC, the Family Health Care Decisions Act, authorizes decisions – including DNR – by surrogates for incapable patients who meet clinical criteria, and by two physicians for isolated patients when treatment would be in effect futile. N.Y. CLS SCPA § 1750-b relates to patients who have an intellectual disability. It authorizes decisions – including DNR – by surrogates for incapable patients who meet clinical criteria, and by a surrogate decision-making committee for isolated patients when treatment would be in effect futile.

existing bar for individuals to designate health care proxies, such as the recent Executive Order enabling remote witnessing of such legal designations. ⁵⁸ In light of severely restricted access to serving as a witness for patients, more could be done including dropping the required two witnesses to one, or if none is available only requiring a remote notary. ⁵⁹

There will be many cases for which the existence of a health care proxy will not morally bear on the need to justly allocate or reallocate resources. Honoring the ideal of patient autonomy in all cases where advance directives and surrogate decision makers ask for continued care that meets the definition of futility during the pandemic would prevent distribution of resources to those who would survive hospital discharge and would lead to significantly more deaths. This said, some guidelines include a variation of "first come first served," which means that once patients are on ventilators, if the family or the patient objects to withdrawal, this resource cannot be re-allocated to another patient who might benefit even if continued care meets the definition of futility. One potential foundation for this principle is that reallocation necessitates a direct and unjust comparison of the worth of two lives. This might be refuted by the fact that reallocation would only be considered if the presently-ventilated patient has negligible existing quality of life that can never be improved, whereas the new patient could have full quality of life with access to care.

Crisis standards of care⁶⁰ protect withdrawing and withholding care from patients when such care would be medically futile. The challenge arises when the patient's advance directive conflicts, or the surrogate decision-maker disagrees, with the decision to withdraw or withhold care. Although laws exist in states like California and Texas⁶¹ that protect a clinical determination of futility leading to a do not resuscitate (DNR) order or the withdrawal of a ventilator against a surrogate's wishes if the patient is still alive (with adequate time given to say goodbye), New York does not have such laws. This can lead to unhelpful resuscitation attempts in futile cases when families demand it. First, it exposes the resuscitation team to a high risk of infection – a risk not usually present in resuscitation attempts in non-pandemic circumstances. However, the issuance of a DNR without consent or over objection is not explicitly prohibited, leading to ambiguous territory especially during the pandemic. While we unavoidably need to ask health care professionals to risk their lives to save patients, we cannot ethically ask them to do so when there is no realistic prospect of saving the patient's life. Moreover, even apart from that consideration, directing resuscitation attempts when there is no prospect of benefit to the patient is morally injurious to staff, and reallocation of resources can save far more lives.

Although an Executive Order has been issued⁶² protecting health care workers from liability for making decisions in accordance with existing law or other executive orders,⁶³ there are no laws in New York that would protect physicians making decisions based on futility over family objection. This could lead to significant litigation and liability for all health systems for making ethical decisions to protect the greatest number of human lives, unless such an order is issued. A statute or Executive Order could override several existing laws including PHL 308, PHL § 2504, PHL Art. 30-D, PHL Articles 29-B, 29-C, 29-CC and 29-CCC, MHL Art. 33, MHL Art. 47, and Surrogate's Court Procedure Act section 1750-b, Penal Law Title H, SSL Art. 11, the Justice Center Act, and other laws to the extent that such laws, and any regulations promulgated pursuant to them, constrain the ability of an attending practitioner, as defined by PHL 2994-a,

⁵⁸ N.Y. EXEC. ORDER No. 202.10 (Mar. 23, 2020).

⁵⁹ See Health Care Proxy proposal, Appendix C.

⁶⁰ Institute of Medicine, Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response: Volume 1, 1-3 (Dan Hanfling, et al., eds., The National Academies Press 2012), https://doi.org/10.17226/13351, https://commed.vcu.edu/IntroPH/2012/crisisManagement_IOM.pdf.

⁶¹ Michael D. Cantor et al., Do-Not-Resuscitate Orders and Medical Facility, 163 (22) ARCH. INTERN. MED. 2689 (2003).

⁶² N.Y. EXEC. ORDER No. 202.10 (Mar. 23, 2020), https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency.

⁶³ N.Y. PHL Art. 30.

to issue a do-not-resuscitate order based on a determination that resuscitation would be "medically futile," as defined in PHL 2961.12, provided there is a concurring determination by a second practitioner. It is also recommended that such determinations be documented in the medical record.

Balancing of Autonomy Versus Protection of Public Health

The second issue concerns the extent to which individual rights and liberty interests⁶⁴ may be superseded by measures to protect public health. This determination hinges on the magnitude of the affected population, the severity of symptoms, and the degree of resource limitation. As of this writing, in the United States the coronavirus has infected more than 1.1 million people and killed over 67,000. New York has suffered over 19,000 deaths, primarily in the New York Metropolitan area. Of course, these numbers are changing rapidly. As there is presently no vaccine or antiviral or other interventions available for COVID-19, the primary resources are the ability to test for its presence, and the use of personal protective equipment (PPE) to reduce transmission and clinical support equipment, such as ventilators to enable those with compromised lung capacity to breathe. Many regions have only enough tests for those who must be hospitalized,⁶⁵ hospital systems are creating makeshift PPE out of trash bags,⁶⁶ and in New York (the U.S. COVID-19 epicenter), while it appears that catastrophic shortages of ventilators in the March-April surge were avoided, New York must be prepared to deal with shortages in future surges.⁶⁷ The issue is whether, and the extent to which, the speed, breadth, and lethality of COVID-19, and our inadequate preparation, create a ground for restricting liberty in order to save lives.

As the right to liberty is fundamental, ⁶⁸ burdening or restricting the right must be limited to just those means that will prevent avoidable loss of life or property. Additional facts about this pandemic inform prevention efforts, specifically those aimed at reducing spread in the general community. While the virus is highly contagious, based on information presently available, it appears that many infected are asymptomatic for many days, many will remain asymptomatic, and a significant portion will only experience mild symptoms. Although it would seem at this point without rigorous research evidence that the risk of significant health consequences is lower for young healthy people, the evidence is not all in, and the risk is not negligible.⁶⁹ Moreover, this population can infect more vulnerable populations at great risk of dying. We have increasing evidence that suggests how the virus is transmitted and how long it lasts, but such data are not yet supported by robust scientific evidence and no curative treatment exists. Presently, it may serve society to be overprotective rather than under protective. Individuals do not have adequate information to engage in their own risk calculus regarding where to go and with whom to interact. Such decisions have enormous impact on others and the state's exercise of its police power in these circumstances to protect the population as a whole may justify a curtailment on the exercise of individual liberty. 70 As we have seen, those limitations, among other things, have been extensive, including prohibitions on gatherings, social distancing, the wearing of face coverings, and restrictions on the operations of businesses. Accordingly, it can be argued

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⁶⁴ Jacobson v. Massachusetts, 197 U.S. 11 (1905); LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, AND RESTRAINT, 92-98 (Univ. of California Press 2008).

⁶⁵ New Coronavirus Testing Guidelines, NYC Health and Hospitals, https://www.nychealthandhospitals.org/coronavirus-testing-guidelines/.

⁶⁶ Chris Brooks, *Using Trash Bags for Gowns: Interview with a New York Nurse*, LABORNOTES, (Mar. 30 2020), https://www.labornotes.org/2020/03/using-trash-bags-gowns-interview-new-york-nurse.

⁶⁷ COVID-19 Projections, INS. FOR HEALTH METRICS & EVALUATION, https://Covid19.healthdata.org/united-states-of-america, (last visited Apr. 17, 2020).

⁶⁸ Jacobson v. Massachusetts, 197 U.S. 11 (1905); LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, AND RESTRAINT, at 92-98 (Univ. of California Press 2008).

⁶⁹ Sanjay Gupta, *The Mystery of Why Coronavirus Kills Some Young People*, CNN, Apr. 6, 2020, https://www.cnn.com/2020/04/05/health/young-people-dying-coronavirus-sanjay-gupta/index.html.

⁷⁰ See Jacobson v Massachusetts, 197 U.S. 11 (1905).

that the executive orders putting New York on PAUSE⁷¹ and urgent campaigns to get us staying home are ethically warranted. However, more draconian measures, such as quarantine with penalties as issued in China, ⁷² run so deeply counter to the core values of liberty and self-determination in the U.S. that they would only be considered if several measures more drastic than PAUSE prove insufficient, and even then might prove impossible to implement.

The harms of being overprotective run far beyond the boredom of being stuck indoors. Shutting down the economy is leading to extraordinary unemployment and financial suffering, which over the long term adversely affects health outcomes, for example, such as risks of drug use and suicide in some cases. Deferring the availability of essential services, elective medical procedures, and medicine production for vulnerable populations may lead to harm and death.⁷³ However, studies suggest that social distancing and mitigation strategies reduce the community spread of COVID-19 and concomitant mortality.⁷⁴ Enacted protection measures must constantly balance these harms by being responsive to new discoveries about the disease and the best scientific predictions about the consequences of revisions to social distancing policies, such as allowing limited return to work.

Essential Services

Despite the fact that we must all consider ourselves at risk and despite the effectiveness of social distancing, "essential services" are excluded from government orders prohibiting in-person operations. However, the exemption imposes greater risk on those who provide essential services. It is unclear which employees providing such services have an ethical duty to continue working. What constitutes an essential service is debatable, even with New York's executive order laying out categorical descriptions. ⁷⁵ Arguably, some essential services must remain open to prevent complete societal collapse, but few professionals are ethically bound to serve others at the expense of their own wellbeing.

Medical Research

Research to study both the nature of this coronavirus and how to treat it must proceed during this time.

Ethical Considerations

The pandemic heightens research ethics concerns regarding equal respect for those participating in research and fairness in terms of who is included in trials, ⁷⁶ as well as not allowing either profit motive or fear to

⁷¹ NEW YORK STATE, New York State on Pause: 10 Point Plan, Mar. 22, 2020, https://coronavirus.health.ny.gov/new-york-

⁷² Hilary Brueck et al., China Took at Least 12 Strict Measures to Control the Coronavirus, They Could Work fo the U.S. but Would Likely Be Impossible to Implement, BUSINESS INSIDER, Mar. 24, 2020, https://www.businessinsider.com/chinascoronavirus-quarantines-other-countries-arent-ready-2020-3#the-country-postponed-non-urgent-medical-care-and-movedmany-doctors-visits-online-not-all-patients-were-given-the-critical-care-they-needed-during-the-outbreak-though-3; Lawrence O. Gostin & James. G. Hodge, US emergency Legal Responses to Novel Coronavirus Balancing Public Health and Civil Liberties, JAMA, Feb. 13, 2020, doi:10.1001/jama.2020.2025.

⁷³ Robert Arnott & Stephen Moore, Shutdown is Killing the Economy - and is Also No Good For Our Health, THE HILL, Mar. 25, 2020, https://thehill.com/opinion/finance/489566-shutdown-is-killing-the-economy-and-is-also-no-good-for-our-health.

⁷⁴ Brian Resnik, 12 Things Everyone Needs to Know About the Coronavirus Pandemic, Vox, Apr. 2, 2020, https://www.vox.com/science-and-health/2020/4/2/21197617/coronavirus-pandemic-COVID-19-death-rate-transmission-riskfactors-lockdowns-social-distancing; Rochelle P. Walensky & Carlos del Rio, From Mitigation to Containment of the COVID-19 Pandemic Putting the SARS-CoV-2 Genie Back in the Bottle, JAMA, Apr. 17, 2020, doi:10.1001/jama.2020.6572.

⁷⁵ Press Release, Governor Cuomo Issues Guidance on Essential Services Under The 'New York State on PAUSE' Executive Order, Mar. 20, 2020, https://www.governor.ny.gov/news/governor-cuomo-issues-guidance-essential-services-under-newyork-state-pause-executive-order.

⁷⁶ Beatriz Da Costa Thome, Research in the Time of Coronavirus: Keep it Ethical, STAT REP., Mar. 2, 2020, https://www.statnews.com/2020/03/02/research-public-health-emergencies-ethics/.

drive unjust or reckless trial development. ⁷⁷ It also places enormous pressure on the procedures and safeguards that have been put in place over years to protect research subjects. We must commit to ensuring sufficient resources for studying the disease and treatment, and not move too fast with unproven treatments, whether to treat the general infected population or to treat infected frontline health care workers. We must also protect the vulnerable from incurring greater risk in dangerous trials, but also include traditionally marginalized populations in appropriate research without exploiting them. Moreover, we must not divert resources from proven methods of risk mitigation, and find the most careful ways to preserve non-pandemic essential health services.

Incapacitated subjects

Many patients who are on ventilators, such as advanced COVID-19 patients, are incapacitated and unable to agree to participate in a clinical trial. It is important that the rights and dignity of such patients, as well as all other individuals who lack capacity to consent, be respected should they be considered for enrollment as study subjects. We recommend that researchers follow the guidelines set forth in, "Report and Recommendations For Research with Human Subjects Who Lack Consent Capacity," of the New York State Task Force on Life and the Law.⁷⁸

Sharing of Data and Specimen

We encourage the sharing of data and specimen among interested researchers to expand the breadth of potential research in COVID-19 related matters with adequate informed consent from research subjects. In all cases, the results of all studies should be made available to the public so that other researchers may better understand study results and limitations. These steps will also help support a research environment that encourages rapid funding of well-designed studies, advancing understanding of the disease, effective preventive measures and the development of novel treatments and a vaccine.

Health Care Workers as Study Subjects

We should be particularly sensitive to studies involving our frontline health care workers. We should not place additional stress on them or their families by engaging them in research that may have marginal or no direct benefit to them, or result in increased risk of infection. For example, if sufficient PPE is available at an institution, the health care workers should not be enrolled into a study testing an experimental new mask or face shield as such mask or shield will not have been shown to be as effective as the PPE already available.

However, we recommend consideration of qualitative inquiry and employment of diverse qualitative methods, including oral histories, to document the experience of health care workers both during the pandemic and the post-pandemic recovery period. Such research can be conducted during the pandemic with sensitivity to health care workers who consent to be research participants, and interviews arranged and conducted based upon their availability and comfort, including accommodating their needs as to place and time and limiting length of interview. Qualitative approaches may actually give health care workers an opportunity to share their experience of moral distress during the pandemic.

⁷⁷ Olivia Goldhill, *The Race to Develop Coronavirus Treatments Pushes the Ethics of Clinical Trials*, QUARTZ, Mar. 28, 2020, https://qz.com/1826431/the-ethics-of-clinical-trials-for-coronavirus-treatments/.

⁷⁸ See New York State Task Force on Life and the Law, Report And Recommendations For Research With Human Subjects Who Lack Consent Capacity, Jan. 2014,

https://www.health.ny.gov/regulations/task force/docs/report human subjects research.pdf.

III. Provider Systems and Issues

Introduction

Hospitals, long-term care facilities, home health care, and physicians, nurses, and other health care workers, are in the front lines of our battle with COVID-19. We as members of the New York State Bar Association need to do all that we can to advocate for the removal of legal and regulatory obstacles that hinder health care providers' ability to fully respond to the challenges posed by the pandemic. This section covers many potential legal and regulatory barriers confronted by health care providers that can impede the thorough response to the pandemic. They include impediments relating to the following topics: supplies, bed capacity, resident work hours, facility licensure, anti-kickback and Stark laws, telehealth, and testing, as well as recommendations for overcoming such hurdles.

Purchasing Necessary Supplies for Hospitals and Other Health Care Providers during a State of Emergency

Health care facilities, as well as other health care providers, should be protected from price gouging and excessive pricing due to extraordinary market conditions for necessary supplies during the disruption of the marketplace due to a state of emergency.

The extent of such abusive business behavior nationwide is evident from the enormous and continually increasing number of complaints filed with the Federal Trade Commission.⁷⁹ Over 23,000 complaints were filed as of April 21, 2020.⁸⁰ One of the responsive federal actions includes the United States joint federal, state, and local COVID-19 Fraud Task Force to combat coronavirus-related fraud.⁸¹

In New York, the Department of Consumer and Worker Protection ("DCWP") promulgated an emergency Rule under the City's Consumer Protection Law⁸² that makes price gouging illegal for any personal or household good or any service that is needed to prevent or limit the spread of or treat COVID-19. The Rule makes it illegal to increase prices by 10 percent or more, follows DCWP's previous declaration that face masks, hand sanitizer, and disinfectant wipes are in short supply, and expands the Agency's ability to protect New Yorkers from price gouging.⁸³ This emergency rule "is in effect ([since]March 16, 2020) and, under the city's emergency rulemaking process, will be valid for 60 days. The Rule can be extended once for an additional 60 days." ⁸⁴

In the absence of any violation of the antitrust laws, 85 there does not appear to be any prior New York Law governing exorbitant pricing due to profiteering from an emergency situation that is directly applicable to supplies used by health care facilities and health care providers, such as ventilators, surgical gowns, and

⁸² N.Y.C. ADMIN. CODE § 20-701(b).

⁷⁹ See FEDERAL TRADE COMMISSION, Coronavirus (COVID-19) Consumer Complaint Data, https://www.ftc.gov/coronavirus/complaint-data.

⁸⁰ See FEDERAL TRADE COMMISSION, FTC COVID-19 Complaints, January 1, 2020-April 21, 2020, https://www.ftc.gov/system/files/attachments/coronavirus-COVID-19-consumer-complaint-data/COVID-19-daily-public-complaints-042120.pdf.

⁸¹See United States Attorney 's Office, District of Arizona, *United States Attorney Michael Bailey and Arizona Attorney General Mark Brnovich Launch COVID-19 Fraud Task Force*, U.S. Dept. of Justice, Apr. 8, 2020, https://www.justice.gov/usao-az/pr/us-attorney-bailey-and-ag-brnovich-launch-COVID-19-fraud-task-force.

⁸³ NEW YORK CITY DEPT. OF CONSUMER AFFAIRS, Notice of Adoption of Emergency Rule Prohibiting Price Gouging of Certain Personal and Household Goods and Services, Mar. 15, 2020,

https://www1.nyc.gov/assets/dca/downloads/pdf/about/Emergency-Rule-Adoption-Price-Gouging.pdf. 84 *Id.*

⁸⁵ FEDERAL TRADE COMMISSION & US DEPARTMENT OF JUSTICE, *Joint Antitrust Statement Regarding COVID-19*, (regarding expedited antitrust procedure and guidance), Mar. 2020,

https://www.ftc.gov/system/files/documents/public statements/1569593/statement on coronavirus ftc-doj-3-24-20.pdf.

face masks. New York General Business Law Sec. 396-r⁸⁶ is intended to protect consumers against excessive pricing of necessary consumer goods (goods used, bought or rendered primarily for personal, family or household purposes) and services during an abnormal disruption of the market at the time of extraordinarily adverse circumstances, such as the stress of weather, climate events or disasters, failure or shortage of electric power or other source of energy, strike, civil disorder, war, military action, national or local emergency. It empowers the New York State Attorney General to bring an action on behalf of the state to enjoin the activity, obtain civil penalties, and get restitution for the aggrieved individuals. There must be a nexus between the emergency situation and the specific goods at issue.

During periods of abnormal disruption of the market caused by strikes, power failures, severe shortages or other extraordinary adverse circumstances, market forces competing for necessary products will cause crucial supplies to inordinately rocket upwards in price. Moreover, there also may be instances of suppliers engaging in price gouging taking advantage of the circumstances. Where those supplies are critical to hospitals and other health care providers for the care and treatment of patients, it becomes a matter of public safety for the state to ensure access to those supplies. Regardless of whether it is market forces or price gouging, the law must provide a means to protect the distribution of such products at reasonable prices. While national leadership is needed during these times to organize national purchasing and distribution of needed supplies, in the absence of such national initiative, the state should enact laws that encourage and facilitate the creation of buying cooperatively under these circumstances. In the short term, the Emergency Rule discussed above should be extended through the end of the pandemic. Subsequently, consumer protections extant under the General Business Law ought to be extended to cover hospitals and health care providers.

Ability to Exceed Certified Bed Capacity for Acute Care Hospitals

In a state of emergency that requires an immediate increase in acute care bed capacity to handle the surge of acutely ill persons within the state, we examine whether the regulatory restrictions limiting the number of inpatients at acute care hospitals to the respective total number of certified beds should be waived, thereby permitting each facility to go beyond the number of certified beds during the pendency of the emergency.

The total number of beds for which the facility has approval from the Commissioner of Health to operate is the number of beds that appears on the operating certificate.⁸⁷

In the 1974, the National Health Planning and Resources Development Act⁸⁸ was enacted to, among other things, control the costs and regulate the expansion of health care facilities and redundancy in medical services nationwide. As part of that federal legislation, states received grants for their Health Services Agencies to coordinate health care planning and to establish a "certificate of need" ("CON") process acceptable to the U.S. Department of Health Education and Welfare, now known as, Health and Human Services. The CON process governs the establishment, construction, renovation and major medical equipment acquisitions of health care facilities, such as hospitals, nursing homes, home care agencies, and diagnostic and treatment centers. It seeks to determine where there is sufficient demand for new hospital or expanded hospital services within a given service area of the state. In addition to the need component of the process, there is financial feasibility, and character and competency aspects to the CON review process. This process then culminates in a review and approval by the Department of Health that can establish a new facility, or an expansion of an existing facility, with a set number of certified beds approved by the New York State Department of Health ("DOH"). The facilities are legally charged with operating at or below the number of certified beds approved DOH.

87 10 NYCRR §441.60.

⁸⁶ N.Y. GBL §396-r.

⁸⁸ Pub. L. No. 93-641, 42 U.S.C. §§300k et seq.

In the circumstances of a statewide emergency, where the need for increased hospital beds is urgently required, the limitation on the number of approved certified beds can present an obstacle to delivering necessary services to the people of New York State. Moreover, the time element for seeking an increase in bed capacity is contra-indicated, and the CON process does not contemplate situations involving temporary need. Presently, Governor Cuomo's Executive Order 202.1⁸⁹ accomplishes that goal by providing waivers of section 401.3 and section 710.1 of Title 10 of the NYCRR,⁹⁰ to the extent necessary, to allow hospitals to make temporary changes to physical plant, bed capacities, and services provided, upon approval of the Commissioner of Health, in response to a surge in patient census. The Executive Order was reissued in 202.10.⁹¹

The waiver of the New York State Department of Health regulations governing certified bed restrictions resulting from the Governor's Executive Orders 202.1 and 202.10 should be continued during the pendency of the state of emergency in New York.

Limitation on Resident Hours Working in Acute Care Hospitals

New York State was a pioneer in the adoption of limits on resident working hours, and they remain among the strictest in the country. Among other limitations, residents are not allowed to be scheduled to work more than 80 hours in a week, or 24 hours straight, or more than 12 consecutive hours in the emergency department.⁹²

In ordinary circumstances, limiting the number of hours that post-graduate trainees (residents) are permitted to work best serves the interests of patient care and the residents' training experiences. However, where there is an extraordinary need for health care professions to care for numerous patients in a pandemic, and the state is requesting help from retired physicians and physicians from other jurisdictions, it is not helpful to limit the number of hours that graduate medical doctors can attend to patients at hospitals. It is anticipated that relaxation of these requirements will be implemented in a judicious manner that will not expose patients to unnecessary risk, but will provide needed care to patient. By dint of Governor Cuomo's original Executive Order 202,⁹³ a broadly worded waiver of section 405 that includes regulation of resident work hours was issued, providing that, Section 405 of Title 10 of the NYCRR⁹⁴ was waived to the extent necessary to maintain the public health with respect to treatment or containment of individuals with or suspected to have COVID-19. That Executive Order has been reissued in Executive Order 202.10.⁹⁵

It is recommended that the waiver of the resident hour requirements during the pendency of an emergency state in response to the pandemic be continued.

 $^{^{89}}$ N.Y. EXEC. ORDER No. 202.1, Mar. 12, 2020, https://www.governor.ny.gov/news/no-2021-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency.

⁹⁰ 10 NYCRR §§401.3, 710.1.

⁹¹ N.Y. EXEC. ORDER No. 202.10, Mar. 23, 2020, https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency.

^{92 10} NYCRR §405.4(b)(6).

⁹³ N.Y. EXEC. ORDER No. 202, Mar. 7, 2020, https://www.governor.ny.gov/news/no-202-declaring-disaster-emergency-state-new-york.

^{94 10} NYCRR §405.

⁹⁵ N.Y. EXEC. ORDER No. 202.10, Mar. 23, 2020, https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency.

Temporary Changes to Existing Hospital Facility Licensed Services, and the Construction and Operation of Temporary Hospital Locations and Extensions

Finally, we look at whether Article 28 of the New York State Public Health Law and DOH regulations governing the approval for changing hospital licensed services, and the construction and operation of temporary hospital locations and extensions, should be waived during the pendency of a state of emergency to permit hospitals to modify their services, and create temporary extension and other locations to better address the health care needs of the people of New York State.

New York State envisions that hospitals plan to achieve efficiency and economy of operation while producing care of high quality. To that end, the State has a comprehensive review and approval process for considering proposed changes to licensed hospital services, as well as the construction and operation of temporary hospital and location sites.

Public Health Law section 2803,⁹⁶ and DOH regulations at 10 NYCRR sections 400, 401, 405, 409, 710, 711 and 712,⁹⁷ govern the process for approval. They provide a comprehensive and elaborate scheme to regulate the building, alteration, reconstruction, improvement, extension or modification of a hospital facility, including its equipment and services. Among other things, the following types of proposals, regardless of cost, generally are subject to CON application and review requirements:

- (i) the addition, modification or decertification of a licensed service, or the addition or deletion of approval to operate part-time clinics;
- (ii) a change in the method of delivery of a licensed service, regardless of cost;
- (iii) the initial acquisition or addition of any equipment,;
- (iv) a conversion of beds.

Moreover, there are certain limited proposals that are eligible for administrative review. They mainly must be within specific cost limitations, or involve supporting certain policy objectives of the New York State Department of Health.

In response to the PHE, Governor Cuomo has issued a number of Executive Orders to expand the availability of health care resources and staff. On March 7, in Executive Order 202,98 the Governor waived all regulatory provisions that might limit the use of hospital beds. Thereafter, as the crises exceeded capacity, on March 23, the Governor issued Executive Order 202.10,99 which suspended the application of the law and regulations cited above, "to the extent necessary to permit and require general hospitals to take all measures necessary to increase the number of beds available to patients."

New York State utilizes complex regulatory processes to govern changes in hospital service, as well as construction and operation of temporary hospital locations and extension sites. Some procedures are solely administrative and can be expedited, while others generally require a more in-depth review by bodies within the New York State Department of Health. These reviews are intended to validate the need, the costs, and the ability to competently operate the approved services and patient care sites. In a state of emergency, responding to the public health needs of the people of the state of New York is of paramount concern. The

⁹⁶ N.Y. PHL §2803.

⁹⁷ 10 NYCRR §§400, 401, 405, 409, 710, 711 and 712.

⁹⁸ N.Y. EXEC. ORDER No. 202, Mar. 7, 2020, https://www.governor.ny.gov/news/no-202-declaring-disaster-emergency-state-new-york.

⁹⁹ N.Y. EXEC. ORDER No. 202.10, Mar. 23, 2020, https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency.

health facilities that regularly serve their communities are in the best position in the first instance to assess the needs of their respective service areas. Moreover, those facilities also are trusted, indeed required, to deliver the necessary service within their respective existing sites, as well as any additional locations that they deem essential to providing important health care interventions. Finally, the rapid response to the emergency conditions is critical for the health and safety of all New Yorkers. Therefore, the Governor appropriately removed all legal or regulatory barriers to the timely delivery of expanded, crucial health care services, and did not require the consent of DOH (though notice was anticipated) nor the recommendation of the Public Health and Health Planning Council or other body.

We recommend continuation of the waiver provided under Executive Orders 202.1¹⁰⁰ and 202.10¹⁰¹ of state requirements that would restrict the ability of hospitals to reconfigure and expand operations as necessary to deal with the PHE.

Issues in Long-Term Care, Residential and Home Health Care, and Correctional and Detention Facilities: Human Rights Crisis

Long-term care providers, and other institutional, residential, and home health care settings, are facing numerous challenges during this pandemic. These settings include, for example, group homes for persons with disabilities; religious communities maintaining nursing home residences on their campuses; correctional facilities housing older inmates, inmates with dementia and inmates who experience accelerated aging and accompanying disease burden at younger ages; and detention facilities housing immigrants and refugees and their family members. This is not just a matter of a public health emergency, but it is also a human rights crisis.

Policies implemented largely by executive orders have not adequately addressed the problems that nursing homes, adult care facilities, home care providers and group homes continue to face. In non-health care settings housing persons with healthcare needs, there has been a near total failure in developing and implementing policy or guidance to protect inmates and immigrants, who are often living in sub-human conditions with very limited access to health or mental health services under optimal circumstances, and remain at very high risk of COVID-19 as conditions have exacerbated. The plight of vulnerable older adults and other vulnerable persons in diverse facility and residential settings demands immediate attention as the COVID-19 pandemic continues to ravage these communities. This is not only a legal obligation, but a moral imperative. The 2012 Crisis Standards of Care make clear there is a duty of care and a duty of non-abandonment to all persons under disaster and emergency conditions. ¹⁰²

More specifically, with respect to nursing homes, the New York State Department of Health issued an advisory on March 25th, 2020, prohibiting nursing homes from denying admission or re-admission to a nursing home solely based on a confirmed or suspected diagnosis of COVID-19.¹⁰³ It also prohibits nursing homes from requiring a hospitalized resident who is determined medically stable to be tested for COVID-19 prior to admission or readmission.¹⁰⁴ The Department of Health issued a nearly identical advisory for

¹⁰⁰ N.Y. EXEC. ORDER No. 202.1, Mar. 12, 2020, https://www.governor.ny.gov/news/no-2021-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency.

¹⁰¹ N.Y. EXEC. ORDER No. 202.10, Mar. 23, 2020, https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency.

¹⁰² Institute of Medicine, Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response: Volume 1, 1-3, (Dan Hanfling, et al., eds., The National Academies Press 2012), https://doi.org/10.17226/13351, https://commed.vcu.edu/IntroPH/2012/crisisManagement IOM.pdf.

¹⁰³ NYS DOH Advisory: Hospital Discharges and Admissions to Nursing Homes, Mar. 25, 2020, available at: https://coronavirus.health.ny.gov/system/files/documents/2020/03/doh_Covid19-_nhadmissionsreadmissions_-032520.pdf.
¹⁰⁴ Id.

adult care facilities.¹⁰⁵ The introduction of a COVID-19 positive resident to a nursing home presents risk of the spread of infection even under the strongest preventative measures, yet nursing homes were not able to access county emergency stockpiles across the state until recently. Comments by the Governor suggested that the rationale for this decision was that many of these facilities were privately owned, and therefore it was the owner/operator's responsibility to purchase and provide PPE. However, to our knowledge hospitals were assisted in obtaining PPE.

In addition, long-term care institutions have faced obstacles due to other state requirements, which have generally imposed new burdens on under-staffed facilities and administrators during the pandemic, taking precious time away from disease prevention efforts and reporting activities under applicable requirements. For example, the Governor signed S.8091/A.10153 to enact the COVID-19 Paid Sick Leave Law. This was followed by a liberal interpretation of the law by the Department of Labor in its related guidance. Further, as mentioned above, supply chain challenges and PPE shortages have exacerbated staffing challenges.

Conditions in the nursing home sector have also been inaccurately represented in the media reports. For example, media sources have described nursing home failures, including not adequately communicating to the state and to families of residents the status of coronavirus in facilities. ¹⁰⁷ CMS has issued new guidance tightening nursing home COVID-19 reporting requirements. ¹⁰⁸ However, media reports of nursing home failures need to be balanced by available evidence that communications with families and next of kin have become increasingly challenging due to a number of factors, including limitations on visitation by families imposed by New York State, and the very nature of operations in long-term care facilities, especially during the pandemic, including the growing numbers of both COVID-19 positive cases and deaths, staffing and PPE equipment shortages, and historically low reimbursement rates that threaten the stability of the long-term care sector. Many frail residents need assistance with activities of daily living and require staff to be in close contact with the residents they serve. There is ample evidence that health care workers in nursing homes count among the bravest in the battle against COVID-19 and have a high potential risk of infection themselves without the appropriate PPE. Allocation of sufficient resources to nursing homes during the pandemic must be a New York State priority. In sum, under-resourced nursing homes amounts to a form of implicit rationing, detrimentally affecting New York's most vulnerable older adult populations.

In light of the heightened vulnerability of nursing home residents and nursing home staff to COVID-19 infection, as well as increased risk to all vulnerable persons in institutional, residential or home health care settings, including correctional¹⁰⁹ and detention facilities, and the legal and ethical obligations to older adults and such other vulnerable persons, health care workers and workers in service jobs, we recommend

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https://www.cms.gov/files/document/qso-20-26-nh.pdf.

NYS DOH Advisory: Hospital Discharges and Admissions to Adult Care Facilities, April 7, 2020, available at:
 https://coronavirus.health.ny.gov/system/files/documents/2020/04/doh_Covid19_acfreturnofpositiveresidents_040720.pdf.
 New York Paid Family Leave COVID-19, Mar. 18, 2020, Frequently Asked Questions, https://paidfamilyleave.ny.gov/new-york-paid-family-leave-COVID-19-faqs; Guidance For Obtaining An Order For Mandatory Or Precautionary Quarantine, https://paidfamilyleave.ny.gov/system/files/documents/2020/03/obtaining-order-of-quarantine.pdf.

¹⁰⁷ Jan Ransom, Coronavirus Entered My Father's Nursing Home and Nobody Warned Me. I Did Not Get the Chance to Save Him, PROPUBLICA, Apr. 21, 2020, https://www.propublica.org/article/coronavirus-entered-my-fathers-nursing-home-and-nobody-warned-me-i-did-not-get-the-chance-to-save-him; John Leland, At Least 14 N.Y. Nursing Homes Have Had More Than 25 Virus Deaths, N.Y. TIMES, Apr. 17, 2020, https://www.nytimes.com/2020/04/17/nyregion/new-york-nursing-homes-coronavirus-deaths.html; Michael Goodwin, Andrew Cuomo's Coronavirus Nursing Home Policy Proves Tragic: Goodwin, The Post, Apr. 21, 2020, https://nypost.com/2020/04/21/cuomo-coronavirus-nursing-home-policy-proves-tragic-goodwin/?utm_campaign=iphone_nyp&utm_source=mail_app; Bernadette Hogan, Carl Campanile, Priscilla DeGregory & Tamar Lapin, Woman Kept In Dark About Dad's Condition By Coronavirus-Stricken NYC Nursing Home, THE Post, Apr. 21, 2020, https://nypost.com/2020/04/21/coronavirus-in-ny-nursing-home-kept-woman-in-dark-about-dads-condition/.

108 CMS, Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, Ref: QSO-20-26-NH, Apr. 19, 2020,

¹⁰⁹ See Josiah Bates, 'We Feel Like All of Us Are Gonna Get Corona.' Anticipating COVID-19 Outbreaks, Rikers Island Offers Warning For U.S. Jails, Prisons, TIME (Magazine), Mar. 24, 2020, https://time.com/5808020/rikers-island-coronavirus/.

that the following actions be duly considered and implemented by the Governor, Department of Health and other government agencies, as applicable:

Older Adults, Nursing Home Providers and Nursing Home Residents: Governor, Department of Health (DOH), DOH Bureau of Long Term Care and State Office for Aging to assure:

- Equitable allocation of scarce resources from the Public Health and Social Services Emergency Fund—established by the CARES Act—to older adults and their health care providers, prioritizing under-resourced long-term care providers;¹¹⁰
- Adequate provision of personal protective equipment (PPE);
- Adequate levels of staffing;
- Consistent and timely tracking and reporting of case and death data;
- Adoption of non-discriminatory crisis standards and ethics guidelines; and
- Recognition and honoring of Older New Yorkers' right to health and human rights, as protected under international conventions; and
- Adequate resources for the Office of the State Long Term Care Ombudsman, which provides advocacy for nursing home residents and families and helps residents understand and exercise their rights to quality care and quality of life.

Persons with Disabilities in Residential Facilities or Group Homes: Governor, Department of Health and OPWDD to assure:

- Access of persons with disabilities to adequate COVID-19 testing and appropriate medical care, mental health and other supportive services, including appropriate day services to substitute for community-based day programs that need to be discontinued during a pandemic;
- Adequate and appropriate staffing, of residential facilities and group homes, for both day and evening shifts, and provision of appropriate funding for such staff and for appropriate COVID-19 staff training;
- Access of residential facility and group home staff to adequate testing and appropriate medical care and mental health and other supportive services;
- Oversight of residential facilities and group homes and programs to assure nondiscriminatory management of persons with disabilities during the COVID-19 crisis conditions; and
- Recognition and honoring of persons with disabilities' right to health and human rights, as protected under international conventions.

Inmates and Correctional Facilities: Governor, NYS Department of Corrections and NYC Department of Corrections, to assure:

- 1. Adequate access of inmates to COVID-19 testing, medical care and mental health and supportive services;
- 2. COVID-19 testing of correctional staff and adequate provision of gloves, masks and other protective equipment;
- 3. Release to the community of older inmates and inmates with advanced illness who do not pose a danger to the community; and

¹¹⁰ U.S. SENATE COMMITTEE ON FINANCE, Senator Charles E. Grassley, Chairman, Letter to HHS Secretary Alex Azar and CMS Administrator Verma, Apr. 17, 2020, (asking about the federal response to COVID-19 in nursing homes, group homes, and assisted living facilities, and expressing concerns about testing capacity, data tracking inconsistencies, lack of personal protective equipment (PPE) for nursing home staff, and federal spending transparency) https://www.finance.senate.gov/imo/media/doc/HHSCOVIDLetter17Apr2020Final.pdf.

- 4. Adequate funding of prison-to-community transitions including access to housing, meals, and supportive services, and non-discriminatory access to employment opportunities.
- 5. Recognition and honoring of inmates' right to health and human rights, as protected under international conventions.

Immigrants in Detention Facilities:

1. In its exercise of its police powers in the COVID-19 public health emergency, New York State must take steps, similar to those outlined above, in cooperation with federal agencies to reduce the spread of COVID-19 among immigrants being held in detention centers.¹¹¹

Anti-Kickback and Stark Law Compliance During the COVID-19 Emergency

During the public health emergency ("PHE"), routine anti-kickback and compliance activities at hospitals and in other provider settings are largely suspended, contractual arrangements are being re-structured or ignored, and routine requirements of arms-length transactions, such as commercial reasonableness and fair market value ("FMV"), are often simply not considered, or if considered, not subject to standard verification. Under the circumstances, compliance with the federal and state Anti-kickback statute ("AKS") and Physician Self-referral ("Stark") laws is particularly challenging. While the Centers for Medicare and Medicaid Services ("CMS") has provided a broad (but not unlimited) waiver of the Stark law as necessary to respond to the epidemic, and the Office of the Inspector General of the United States Department of Health and Human Services ("OIG") has issued a "comfort letter" regarding AKS enforcement, uncertainty remains.

Federal and state AKS and Stark laws, and their associated regulations, set standards governing certain behaviors of and arrangements between medical professionals, institutions, and associated contractors, affiliates, and other interested parties.

The federal AKS is a criminal statute that prohibits the knowing or willing offering, paying, soliciting, or receiving any remuneration, rebate, kickback, bribe, or thing of value, directly or indirectly, in cash or in kind to induce or in exchange for the recommending of or actual purchasing, leasing, ordering of any good, facility, or item under federal health care programs. The federal AKS covers those who both pay for and receive kickbacks or remuneration (i.e. anything of value), "including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind." However, a payment of remuneration or similar scheme may violate AKS if "one purpose" is to wrongfully induce referrals, even if there are alternative valid motivations. The statute is interpreted broadly, there are various narrow regulatory exceptions, called "safe harbors," for practices recognized as beneficial.

The federal Stark law is a strict liability statute that prohibits physicians from referring patients to receive certain "designated health services" under federal health care programs from entities with which the physician or an immediate family member has a financial relationship. 117 The Stark law prohibits the submission, or causing the submission of claims that violate the prohibitions. 118 The Stark law also has

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¹¹¹ See Cole J.P Cole, Federal and State Quarantine Isolation Authority, CONGRESSIONAL RESEARCH SERVICE, Oct. 19, 2014, https://www.ncsl.org/documents/statefed/health/FedandStateQIAuth.pdf.

¹¹² 42 U.S.C. § 1320a-7b(b).

¹¹³ 42 C.F.R. § 1001.951.

¹¹⁴ United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985).

¹¹⁵ United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985).

¹¹⁶ See 42 U.S.C. 6 1320a-7b(b)(3); 42 C.F.R. § 1001.952.

¹¹⁷ 42 U.S.C. § 1395nn(a); 42 C.F.R 411.351.

¹¹⁸ *Id*.

certain regulatory exceptions for practices and arrangements that are sufficiently and strictly tailored as to avoid impropriety of referrals.¹¹⁹

However, if violations are found, they can form the basis of direct liability under the applicable statute, which can include substantial legal penalties, such as civil monetary penalties per violation or per claim, plus up to three times the remuneration involved, exclusion from participation in federal health care programs, including Medicare and Medicaid, and in the case of AKS violations, potential criminal penalties. ¹²⁰

In addition, these providers also face federal False Claims Act ("FCA") liability, ¹²¹ which imposes civil (and potentially criminal ¹²²) liability on persons who knowingly submit false or fraudulent claims for reimbursement to government health care programs. ¹²³ The FCA is a particularly useful tool for fraud and abuse enforcement because it enables civil actions to be brought the Attorney General, or as a *qui tam* action initiated by whistleblowing "relators" who have independent knowledge of wrongdoing and who can recover between 15 and 30 percent of monetary proceeds, plus attorney fees, from successful judgments. ¹²⁴ Note that with available treble damages, plus more than \$22,000 per false claim, ¹²⁵ these judgments can quickly become catastrophic.

Notably, in October of 2019, the Department of Health & Human Services ("HHS") proposed changes to the AKS and Stark law regulations aimed at reducing regulatory burdens on the expansion of value-based care, which have yet to be finalized.¹²⁶

New York State ("NYS") has state law versions of both AKS and Stark law. The NYS AKS largely tracks the federal statute, is tied to Medicaid, but includes separate provisions detailing that violations are also considered professional misconduct, which could lead to administrative professional licensure penalties in addition to civil and criminal penalties.¹²⁷ The NYS Stark law is broader in scope of persons covered than is the federal Stark law as it applies to referrals from a broader range of "practitioners," not only from "physicians," but it is more limited in the services covered.¹²⁸ The NYS Stark law also covers claims submitted to all payors, not only to government payors, and does not have as many exceptions as does its federal counterpart, but the exceptions broadly apply to hospital/practitioner relationships. Although penalties under the NYS Stark law are limited and there is no private right of action, New York has a parallel False Claims Act, with substantial treble damages, per claim penalties and attorney fee provisions, which can be used for violations of the NYS Stark law and AKS.¹²⁹

¹¹⁹ 42 U.S.C. § 1395nn(b); 42 C.F.R. § § 411.355-57.

¹²⁰ See generally, Office of Att'y General, Dep't of Heath and Human Services, A Roadmap for New Physicians, Fraud & Abuse Laws, https://www.oig.hhs.gov/compliance/physician-education/01laws.asp.

¹²¹ 42 U.S.C. § 1320a-7b(g); 42 U.S.C. § 1395nn(g).

¹²² 18 U.S.C. § 287.

¹²³ 31 U.S.C. §3729-33.

¹²⁴ 18 U.S.C. § 3730(b), (c) & (d).

¹²⁵ 31 U.S.C. § 3729; 28 C.F.R. § 85.3(a)(9). For updated figures, see https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=28:2.0.1.1.37.

¹²⁶ For Department of Health and Human Services Office of Inspector General proposed regulations concerning AKS, *see* 84 FED. REG. 55694-765 (Oct. 17, 2019). For Centers for Medicare and Medicaid Services proposed regulations concerning Stark law, *see* 84 FED. REG. 55766-847 (Oct. 17, 2019).

¹²⁷ N.Y. Ed. Law §§ 6530(18) & (19); N.Y. Social Services Law § 366-d.

¹²⁸ N.Y. PHL §§ 238-a - 238-e.

¹²⁹ N.Y. STATE FINANCE LAW §§ 187-194.

There is no general pandemic exception to the application of the federal AKS and Stark laws. However, on March 30, 2020, each of the OIG and CMS issued guidance designed to assist providers in responding to the epidemic.

CMS limited the application of the federal Stark law until the end of the public health emergency caused by COVID-19 through a waiver and attendant guidance. CMS announced that it will waive penalties for violations of the Stark law in regard to compensation relationships between physicians and entities, such as hospitals, to which they refer if "solely related to" the COVID-19 pandemic. In particular, the waiver applies, among other things, to:

- violations of FMV requirements in the services, space and equipment lease exceptions,
- medical staff incidental benefits in excess of the regulatory cap,
- non-monetary or in-kind compensation to physicians that exceeds the regulatory cap,
- interest-free or low-interest loans,
- use of space by group practices that does not meet the "same building" requirements, and
- violations of the signature and documentation requirements.

The following are examples of actions that would be deemed "related to the COVID-19 pandemic":

- diagnosis and treatment of COVID-19 patients,
- securing the services of physicians to provide services even if unrelated to COVID-19,
- ensuring the ability and expanding the capacity of providers to meet patient needs,
- shifting patient care locations to alternative sites, and
- addressing medical practice or business interruptions.

CMS cites a number of specific examples of permissible or expected activity, including:

- paying a premium or below market compensation,
- providing free office space,
- offering non-monetary services and incidental benefit increases (e.g., food, childcare, housing, clothing) beyond regulatory limits,
- providing hospital staff to assist private physicians' offices in staff training related to COVID-19, patient intake and treatment, and care coordination tied to the crisis,
- paying physicians' 15% electronic health records subsidy obligation,
- a group practice performing Stark-covered services at an expansion site that would otherwise be impermissible,
- ambulatory surgical center ("ASC") owners continuing to refer to the ASC even though the ASC is licensed as a hospital during the PHE,
- providing services to patients in rural areas, and
- failing to obtain a signature or writing as required for a compensation relationship that is otherwise compliant.

¹³⁰ CMS, *Blanket Waivers of Section 1877(g) of the Social Security Act*, https://www.cms.gov/files/document/COVID-19-blanket-waivers-section-1877g.pdf.

The waiver only applies, "absent the government's determination of fraud and abuse." In this regard, the premise of the waiver is that the party is acting in good faith, and is unable to meet the otherwise generally applicable exceptions, which may limit the benefit if interpreted literally; how does "unable" apply when technical compliance is feasible but at unnecessary delay and expense? Another concern is the use of the word "solely" before "related," because very few things are "solely" the product of another. Nevertheless, the examples of the types of arrangements that CMS would appear to bless provide some comfort as to how "unable" and "solely related" will be defined.

The waiver is effective March 1, 2020, and will last for the duration of the emergency.

The OIG simultaneously issued a "message from leadership on minimizing burdens on providers." It notes that the "OIG places a high priority on providing the health care community with the flexibility to provide needed care during the emergency." [R]especting the great challenges currently facing the health care industry," the OIG, "to the extent possible" will try to "minimize burdens on providers and be flexible where [it] can. ¹³³ Providers are encouraged to reach out to the OIG if they need extensions of deadlines. Finally, and perhaps most significantly, "For any conduct during the emergency that may be subject to OIG administrative enforcement, OIG will carefully consider the context and intent of the parties when assessing whether to proceed with any enforcement action." The latter comment may well be a feature of defenses of direct and certainly FCA *qui tam* claims concerning conduct during the PHE.

Subsequently, on April 3, the OIG responded explicitly to the CMS Stark waiver of March 30.¹³⁵ It agreed to not to seek administrative sanctions against most of the behavior specifically permitted by CMS during the PHE. There are, however, differences. The OIG was not willing to accept, on a blanket basis, the CMS exceptions for referring to (i) an owned hospital that has expanded (or former ASC now operating as a hospital), (ii) an owned home care company, or (iii) a group practice for covered services at otherwise impermissible expansion sites or at a patient's residence.¹³⁶ In addition, the blanket CMS waivers for patients in rural areas, and for arrangements that are compliant but for documentation requirements, are not accepted by the OIG.¹³⁷

The OIG has also established a process for obtaining prompt informal and non-binding advice during the PHE, including in regard to the Civil Monetary Penalty Law provisions on beneficiary inducements.¹³⁸

As of now, there are no waivers of the NYS Stark law or AKS for the PHE.

Provider/Referring practitioner relationships always need to be structured with care to assure compliance with the technical requirements of the Stark law and AKS exceptions and safe harbors, and to assure that

¹³¹ HHS OIG, Message From Leadership On Minimizing Burdens On Providers, Mar. 30, 2020, https://oig.hhs.gov/coronavirus/letter-grimm-03302020.asp.

 $[\]overline{132}$ Id.

¹³³ *Id*.

¹³⁴ *Id*.

¹³⁵ OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency, DEP'T OF HEALTH & HUMAN SVCS, OFFICE OF INSPECTOR GENERAL, Apr. 3, 2020, https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf; HHS OIG, FAQs – Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Apr. 24, 2020, https://oig.hhs.gov/coronavirus/authorities-faq.asp.

¹³⁶ *Id*.

¹³⁷ *Id*.

¹³⁸ *Id*.

the agreements are commercially reasonable and the compensation thereunder is FMV. In the usual course, agreements are often subject to independent valuation consultant review to assure compliance. However, in the current crisis environment, these relationships are being created, modified and terminated "on the fly," and without the normal regulatory review. Under the circumstances, providers should not have to be concerned about technical compliance, "absent any determination of fraud or abuse" (the words of the federal Stark law waiver). This would have the effect of focusing on the reality of the relationship and not the technicalities of the exceptions and safe harbors that cannot be met.

Given the statements from CMS and the OIG that are helpful in this regard, an order for the NYS Stark law and AKS from either the Governor of New York or the New York State Department of Health that is substantially similar to the CMS Stark law waiver and OIG letters would be prudent. Some might say that no waiver is needed since well-intentioned providers would not be charged with a violation in the absence of fraud and abuse. However, often the AKS safe harbors are treated as requirements by providers, and the failure to provide explicit grace in this context will both delay necessary implementation of restructurings between providers and practitioners, and place those providers and practitioners at risk for potentially catastrophic damages. Moreover, the Stark Law does not require intent; it is a strict liability statute, so its suspension is very important.

The waivers provided by CMS and the letters provided by the OIG are helpful in providing some security to providers that enforcement discretion will be exercised in regard to reasonable responses to the PHE (the inconsistencies between the CMS and OIG guidance are unfortunate, but likely not curable and providers will need to navigate the inconsistencies). The waivers and guidance should be adopted in substantially similar form by NYS for the State versions of the Stark law and AKS, each as tailored for the particular statute at issue.

Expanded Use of Telehealth During the COVID-19 Emergency

Telehealth is a valuable tool to deliver healthcare, but longstanding statutory and regulatory barriers, including in the area reimbursement, have stunted the growth of telehealth and delayed its implementation.

The federal telehealth statute¹³⁹ imposes five requirements for Medicare fee-for-service coverage. Of these, one of the most significant hurdles to the expansion of telehealth has been the Medicare "originating site" requirement. Prior to COVID-19, Medicare fee-for-service reimbursement was available only when the patient receiving the telehealth service was in a designated rural area, and in a physician's office or in a specified healthcare facility. The definition of a rural location is narrow, limited in general to an area either outside a Metropolitan Statistical Area or in a Health Professional Shortage Area within a rural census tract. ¹⁴⁰ Additionally, only eligible practitioners ¹⁴¹ could provide Medicare telehealth services. In New York, ¹⁴² state law allows a wide range of professionals ¹⁴³ to deliver services through telehealth in New

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¹³⁹ 42 U.S.C. § 1395m(m).

¹⁴⁰ HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Medicare Telehealth Payment Eligibility Analyzer*, https://data.hrsa.gov/tools/medicare/telehealth, (providing guidance on whether a particular site is eligible for Medicare telehealth payment).

¹⁴¹ Under 42 U.S.C. § 1395m(m)(3)(A) and 42 C.F.R. § 410.78(b), Medicare-eligible telehealth practitioners are: physicians, physician assistants, nurse practitioners, clinical nurse specialists, nurse-midwives, clinical psychologists, clinical social workers, registered dieticians and nutritional professionals, and certified registered nurse anesthetists.

142 N.Y. PHL § 2999-dd(1); N.Y. Soc. Servs. Law § 367-u(2).

¹⁴³ Under N.Y. PHL § 2999-cc(2), New York Medicaid-eligible telehealth practitioners are: physicians, physician assistants, dentists, nurse practitioners, registered professional nurses, podiatrists, optometrists, psychologists, social workers, speech language pathologists and audiologists, midwives, physical therapists, occupational therapists, certified diabetes educators, certified asthma educators, certified genetic counselors, hospitals, residential healthcare facilities serving special needs populations, home care services agencies, hospices, credentialed alcoholism and substance abuse counselors, early intervention

York, to patients located in a wide range of originating sites, including in the patient's own home. ¹⁴⁴ In February 2019, however, in a Special Medicaid Telehealth, ¹⁴⁵ New York instituted limitations, including the rule that for dual individuals (those eligible for both Medicare and Medicaid), "[i]f a service is within Medicare's scope of benefits (e.g., physician), but Medicare does not cover the service when provided via telehealth, Medicaid will defer to Medicare's decision and will not cover the telehealth encounter at this time." The effect is to deny Medicaid for telehealth services outside of rural originating sites, and from non-Medicare-eligible practitioners for dually eligible beneficiaries,

The pre-COVID-19 federal and state reimbursement rules limited the expansion of telehealth. As a result, when the coronavirus spread in New York, the healthcare system was woefully underprepared to deploy this important tool quickly and effectively to minimize the spread of infection. The delay, in turn, allowed the disease to gain a foothold in the community and impeded efforts to limit exposure to and slow the viral spread.

The coronavirus pandemic ushered in a new age for telehealth reimbursement. In a major public policy shift, on March 6, 2020, Congress enacted the "Telehealth Services during Certain Emergency Periods Act of 2020," ¹⁴⁶ which lifted the "originating site" requirement for Medicare telehealth payment during certain public health emergencies. This statute authorized the waiver of Medicare requirements in a public health emergency to allow qualified providers – those with a pre-existing relationship with the patient – to deliver telehealth to beneficiaries: (i) outside of rural areas, (ii) in their homes, and (iii) by means of a telephone with audio and video capabilities. On March 27, 2020, Congress enacted the "Coronavirus Aid, Relief, and Economic Security Act" (CARES Act). ¹⁴⁷ In addition to injecting trillions into the economy, the CARES Act authorized the waiver of the pre-existing relationship requirement and other telehealth expansions. On March 23, 2020, the U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR), which enforces the Health Insurance Portability and Accountability Act (HIPAA), announced the exercise of enforcement discretion for HIPAA restrictions that might otherwise have limited the use of telehealth services during the public health emergency. ¹⁴⁸ These changes allowed for Medicare reimbursement for the delivery or health care services using smartphones.

Likewise in New York, the New York State Department of Health ("DOH") took action to promote the use of telehealth and telephonic evaluation. An Executive Order issued March 12, 2020, 149 suspended the New York telehealth statute and regulations, to the extent necessary to allow additional telehealth provider categories and modalities, to permit other types of practitioners to deliver services within their scopes of practice and to authorize the use of certain technologies for the delivery of health care services to established patients. Beginning on March 10, 2020, DOH issued a series of guidance documents regarding the use of telehealth, including telephonic services, for dates of service on or after March 1, 2020 and through the

program providers, clinics licensed or certified by the Office of Mental Health or funded or operated by the Office for People with Developmental Disabilities, and others subject to agency determination.

144 *Id.*, § 2999-cc (3).

¹⁴⁵ New York Medicaid Update, Special Edition, Expansion of Telehealth Vol. 35, No. 2, N.Y.S. DEP'T OF HEALTH, Feb. 2019, https://www.health.ny.gov/health_care/medicaid/program/update/2019/feb19 mu_speced.pdf.

¹⁴⁶ Coronavirus Preparedness and Response Supplemental Appropriations Act, Pub. L. § 116-123, Mar. 6, 2020, https://www.congress.gov/116/plaws/publ123/PLAW-116publ123.pdf.

¹⁴⁷Coronavirus Aid, Relief, and Economic Security Act, Pub. L. § 116-136, Mar. 27, 2020, https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf.

¹⁴⁸ Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, HHS OFFICE OF CIVIL RIGHTS, last reviewed Mar. 30, 2020, https://www.hhs.gov/hipaa/forprofessionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.

¹⁴⁹ N.Y. EXEC. ORDER No. 202.1, (Mar. 12, 2020), https://www.governor.ny.gov/news/no-2021-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency.

duration of the New York State COVID-19 emergency.¹⁵⁰ These guidance documents alleviate some of the barriers to telehealth by allowing clinicians and health care organizations to bill for telephonic services if they cannot provide the audiovisual technology traditionally referred to as "telemedicine."

Pre-COVID-19, the federal and state patchwork of federal and state law limited the expansion of telehealth. As a result, the healthcare system was woefully underprepared to deploy this important tool quickly and effectively to respond to the pandemic. The delay, in turn, allowed the disease to gain a foothold in the community and impeded efforts to limit exposure to and slow the viral spread. We can and should do better.

In the midst of the coronavirus, the temporary rollback of regulatory restrictions enabled providers to marshal telehealth to expand the delivery of services while reducing the spread of infection. This reduced the strain on the healthcare system and prevent further spread of disease. But why only temporary? Though telehealth, providers can deliver medical care much more quickly and serve more patients, without the need for them to travel long distances to the provider's office to receive care. Telehealth proved itself under fire, and its benefits extend well beyond the emergency context. Moving forward, the coronavirus experience argues for the need for updated reimbursement policies to encourage the use of telehealth to provide proper, effective and efficient care for patients.

Testing During Pandemic

We examine the issue as to whether private research laboratories should be authorized to do serology testing for epidemiological studies during an emergency pandemic.

NYS PHL § 580 states, "[n]othing in this title shall be construed as affecting facilities which perform laboratory tests solely for research purposes, nor as affecting laboratory testing by a public health officer as part of an epidemiological investigation in which no patient identified result is reported for diagnostic purposes to a health care provider or the subject of the test." ¹⁵¹

Essentially, section 580 of the Public Health Law exempts and authorizes research laboratories to pursue tests so long as clinical diagnoses of patients for treatment are not being conducted. At present, 10 NYCRR Part 58-1¹⁵² prevents research laboratories from reporting their results to individual patients.¹⁵³

Serological tests measure the number of antibodies or proteins present in the blood when the body is responding to a specific infection, like COVID-19. In other words, the test detects the body's immune response to the infection caused by the virus rather than detecting the virus itself. This may potentially be used to help determine, together with other clinical data, that such individuals are no longer susceptible to infection and can return to work. In addition, these test results can aid in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19.

 $^{^{150}}$ 2020 DOH Medicaid Updates, Volume 36, N.Y.S. DEP'T of HEALTH, rev'd Apr. 2020, $https://www.health.ny.gov/health_care/medicaid/program/update/2020/index.htm.$

¹⁵¹ N.Y. PHL § 580.

¹⁵² 10 NYCRR § 58-1.

¹⁵³ The Health Law Section of the New York State Bar Association has proposed a rulemaking for the DOH that would permit research laboratories to report results to the health care provider designated by a study subject under specific limited conditions. Such health care provider may then determine if confirmatory tests should be pursued utilizing CLEP approved diagnostic testing in a CLEP approved laboratory. The Committee recommended the following be added as 10 NYCRR § 58-1.8b: "Results of tests conducted in the context of IRB approved research protocols by non-permitted research laboratories may be reported to the research subject's designated health care provider solely for the purpose of referral of the subject for confirmatory testing by a permitted laboratory using approved test methodology." *See* Letter from Ronald Kennedy, Director of Government Relations, NYSBA, to Stephanie Schulman, Ph.D, Director CLEP, Regarding Proposed Rule by NYSBA Health Law Section, April 3, 2018, Appendix D.

Research laboratories present an untapped resource to scale mass testing to respond to COVID-19. The only portion of the Public Health Law that prevents a general research laboratory from engaging in epidemiological serology testing is the requirement that the testing be conducted by a public health officer.

To the extent private research laboratories have capacity and are capable of assisting with epidemiological testing, the Governor should exercise his authority under NYS Executive Law § 29-a¹⁵⁴ to suspend that portion of NYS PHL § 580¹⁵⁵ that requires the testing to be provided by a public health officer to enable private research labs to assist with scaling serology testing.

Nevertheless, as of this writing, certain significant ambiguities regarding hospital clinic payment rates remain.

IV. Business/Contracts/Risk Management

Introduction

There is no doubt that the Covid-19 pandemic has had tremendous economic impact upon businesses. The Wall Street Journal reports that, "U.S. economy in the first quarter shrank at its fastest pace since the last recession as the coronavirus pandemic shut down much of the country." As non-essential businesses are put on "pause" and many essential businesses' operations are limited, both individuals and businesses will be hard pressed to meet contractual obligations and must look to risk mitigation strategies to manage the financial impact. Although many businesses have insurance policies that are meant to kick in when disaster strikes, such business interruption coverage typically requires physical damage to the workplace making it impossible for workers to do their job. Quarantines and travel bans imposed by federal and state authorities in an effort to control contagion can make it just as impossible for workers to do their jobs as destruction from a fire, flood or earthquake, but do not cause the physical damage to workplaces that is necessary to trigger successful business interruption claims. From an insurance perspective, such policies are not designed to cover the widespread business interruption caused by the shuttering of businesses across the country. Losses due to bacteria and virus such as the COVID-19 pandemic impacts the entire risk pool, leaving insurers at significant risk because such policies are designed to cover losses resulting from individual insured's chance events and not catastrophic events that impact the entire risk pool. 158

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law as a \$2.2 trillion stimulus package designed to mitigate the cataclysmic economic impact resulting from the Covid-19 pandemic. The CARES Act provided substantial economic relief, but also includes several temporary modifications to chapter 7 and chapter 13 of the U.S. Bankruptcy Code that modify the definition of "current monthly income" to exclude payments made under federal law relating to a declared national emergency and permit chapter 13 debtors with prior-confirmed plans to seek modifications due to Covid-19 related hardships. ¹⁵⁹ These provisions provide some relief for consumers, but do not address the

¹⁵⁴ N.Y. EXEC. L. § 29-a.

¹⁵⁵ N.Y. PHL § 580.

¹⁵⁶ Harriet Torry, *Virus Shrinks Economy by 4.8%*, WALL STREET JOURNAL, Apr. 30, 2020 (Last accessed 04/30/2020), https://www.wsj.com/articles/first-quarter-gdp-us-growth-coronavirus-11588123665.

¹⁵⁷ Mary Williams Walsh, *Coronavirus Will Cost Businesses Billions. Insurance May Not Help*, N.Y. TIMES, Mar. 5, 2020, https://www.nytimes.com/2020/03/05/business/coronavirus-business-insurance.html (Last accessed Apr. 10, 2020).

¹⁵⁸ Jim Sams, *Some Insurance Regulators Skeptical About Business Interruption Claims*, CLAIMS JOURNAL, Apr. 27, 2020, (Last accessed May 3, 2020).

¹⁵⁹ K&L Gates, LLP. COVID-19: How the CARES Act Will Impact Chapter 7 and Chapter 13 Consumer Bankruptcies. JDSUPRA.COM, Mar. 31, 2020, https://www.jdsupra.com/legalnews/covid-19-how-the-cares-act-will-impact-48826/ (Last accessed Apr. 30, 2020).

risk of city and state bankruptcies as tax revenues fall due to plummeting gas prices, lack of tourism, and shuttering of the hospitality industry, and emergency spending on unemployment claims soars. ¹⁶⁰ On April 22, 2020, U.S. Senate Majority Leader Mitch McConnell "opened the door to allowing U.S. states to file for bankruptcy to deal with economic losses stemming from the coronavirus outbreak that are punching big holes in their budgets." ¹⁶¹ However, whether such relief is available to U.S. states remains a looming legal issue. Federal, state and local public health authorities must consider innovation solutions to (i) allow essential businesses to collaborate under CSC and channel resources to address the public health emergency; (ii) permit essential licensed health care workers in good standing to cross state lines and health care systems to help manage patient surges wherever they occur; and (iii) protect good faith efforts to maintain workplace and public safety and control the spread of contagion where is scarce. Likewise, business leaders should identify the weaknesses in their respective business operations and consider immediate, mid-term and long-term risk management strategies to assure recovery, resiliency, and financial stability. ¹⁶²

Potential liability for breach of contract during coronavirus pandemic

We examine whether nonperformance of contractual obligations during the coronavirus pandemic may result in liability for breach of contract.

Ordinarily, a failure to perform under a contract results in potential liability for the party who is in breach of his or her obligations. A supplier of goods, for example, may be held liable if he or she fails to deliver the goods as promised. Or a purchaser of goods may be held liable if he or she fails to pay for goods purchased from a supplier. Similarly, a lease contract may result in liability if either the tenant or the landlord breaches his or her obligations. Or a service provider may be held liable for failure to perform services, or the recipient may be held liable for failure to pay for the services. The law is clear: If you breach a contractual obligation, you may be held liable for the breach.

But what happens if a party does not – or cannot – perform his or her obligations under a contract in the middle of a pandemic? This question has taken on increased urgency in recent days, as companies across a wide range of industries have begun to alter their business practices and contractual arrangements in response to the outbreak of COVID-19. Will the COVID-19 outbreak excuse the nonperformance of a contract?

Under New York law, there are a limited set of circumstances under which the COVID-19 outbreak might excuse contractual non-performance. Those circumstances include: (1) when the relevant contract contains a provision that excuses performance—such as a *force majeure* clause; (2) when certain common law doctrines—such as the doctrines of frustration of purpose or impossibility – excuse non-performance.

Finally, New York's Uniform Code Section 2-615(a) excuses delay or non-delivery under a contract for sale under certain circumstances, including where performance has been made impracticable by an event that goes to the heart of the contract or where the delay or non-delivery was caused by good faith compliance with governmental regulation.

¹⁶¹ McConnell says he favors state bankruptcy over more federal aid, Apr. 22, 2020, REUTERS, reuters.com/article/us-health-coronavirus-usa-states/mcconnell-says-he-favors-state-bankruptcy-over-more-federal-aid-idUSKCN2242U7, (Last accessed 04/30/2020)

¹⁶⁰ Richard McGahey, *COVID-19 Could Bankrupt Your State*, FORBES, Apr. 6, 2020, www.forbes.com/sites/richardmcgahey/2020/04/06/covid-19-could-bankrupt-your-state/#72fd)d565489 (Last accessed 04/30/2020).

¹⁶² See, The world remade by COVID-19, DELOITTE, COVID-19/Collection Perspectives, www2.deloitte.com/global/en/about-deloitte/articles/covid-19-scenarios-and-impacts-for-business-and-society-world-remade.html.

Force Majeure

Some contracts contain provisions that excuse nonperformance due to circumstances beyond the control of the parties. These provisions are known as *force majeure* clauses. ¹⁶³ A *force majeure* clause generally allows a party relief if a specified event materially impacts, or renders impossible, the performance of the contract. Typically, if a force majeure clause applies, the parties' obligations under the contract are suspended during the pendency of the event, and, if the event continues for a certain period of time, the parties may have a right to terminate the contract.

Under New York law, force majeure clauses are narrowly construed and applied. As one New York court recently explained, force majeure clauses are designed to limit damages "where the reasonable expectation of the parties and the performance of the contract have been frustrated by circumstances beyond the control of the parties." ¹⁶⁴ Moreover, the courts will generally strictly construe the types of events that give rise to relief under a force majeure event. "[O]nly if the force majeure clause specifically includes the event that actually prevents a party's performance will that party be excused." When the parties have themselves defined the contours of *force majeure* in their agreement, "those contours dictate the application, effect, and scope of force majeure."166

Some contracts may include "epidemic" as a specific example of a *force majeure* event. 167 Other contracts may not specifically list epidemic as a *force majeure* event, but may include a catch-all provision. If the coronavirus pandemic is sufficiently similar to the events listed in the force majeure clause, then—under the rule of contract construction known as *ejusdem generis* – the coronavirus pandemic may be considered a force majeure event. 168

Common law doctrines: Frustration of purpose and impossibility

In the absence of a *force majeure* clause, two common law doctrines are potentially applicable: the doctrine of impossibility and the doctrine of frustration of purpose. Under New York law, the doctrine of impossibility provides only a limited path to relief and has been narrowly applied by the courts "due in part to judicial recognition that the purpose of contract law is to allocate the risks that might affect performance and that performance should be excused only in extreme circumstances." 169 Under the doctrine of impossibility, a party's performance will be excused "only when the destruction of the subject matter of the contract or the means of performance makes performance objectively impossible." 170 "Moreover, the impossibility of performance must be produced by an unanticipated event that could not have been foreseen or guarded against in the contract."¹⁷¹ "Thus, where impossibility or difficulty of performance is occasioned only by financial difficulty or economic hardship, even to the extent of insolvency or bankruptcy, performance of a contract is not excused."172

The frustration of purpose doctrine excuses non-performance when a change in circumstances is such that one party's performance would no longer give the other party what induced him to make the bargain in the

¹⁶³ Kel Kim v. Central Mkts., 70 N.Y.2d 900, 902 (1987).

¹⁶⁴ Constellation Energy Servs. of N.Y. v. New Water St., 146 A.D.3d 557, 558 (1st Dept. 2017).

¹⁶⁶ *Id*.

¹⁶⁷ See, e.g., Touche Ross & Co. Manufacturers Hanover Trust Co., 107 Misc. 2d 438, 441 (Sup. Ct. N.Y. County 1980) (quoting contract that defines force majeure as including "flood, epidemics, earthquake, [and] war"). ¹⁶⁸ See Kel Kim, 70 N.Y.2d 900 at 903.

¹⁶⁹ *Id.* at 902. ¹⁷⁰ *Id*.

¹⁷¹ *Id*.

¹⁷² 407 East 61st Garage, Inc. v. Savoy Fifth Ave. Corp., 23 N.Y.2d 275, 281-282 (1968).

first place.¹⁷³ Like the doctrine of impossibility, the doctrine of frustration of purpose is a narrow one. Its application is "limited to instances where a virtually cataclysmic, wholly unforeseeable event renders the contract valueless to one party."¹⁷⁴ In order to successfully invoke the doctrine of frustration of purpose, a party must show that the purpose that is frustrated is the principal purpose of that party in making the contract. "The object must be so completely the basis of the contract that, as both parties understand, without it the transaction would make little sense."¹⁷⁵ Restatement (Second) of Contracts § 265 (comment). The doctrine does not apply where performing under a contract would merely cause some degree of financial hardship.

New York's Uniform Commercial Code Section 2-615

Finally, even in the absence of a force majeure provision, New York's Uniform Commercial Code may excuse non-performance. Section 2-615(a) of the N.Y. U.C.C. provides that "[d]elay in delivery or non-delivery... is not a breach under a contract for sale if performance as agreed has been made impracticable by the occurrence of a contingency the non-occurrence of which was a basic assumption on which the contract was made or by compliance in good faith with any applicable foreign or domestic governmental regulation or order whether or not it later proves to be invalid." Under this provision, a seller is excused where its performance is "commercially impracticable because of unforeseen supervening circumstances not within the contemplation of the parties at the time of contracting." There is an important caveat to Section 2-615(a): Where a seller's ability to supply is only partially impacted, the seller must allocate production/supply among its customers in a fair and reasonable manner.

With respect to impracticability caused by government regulation or order, such "governmental interference cannot excuse unless it truly 'supervenes' in such a manner as to be beyond the seller's assumption of risk." Moreover, a party cannot rely on supervening government action if he or she brought about the action that renders performance impracticable. "[A]ny action by the party claiming excuse which causes or colludes in inducing the governmental action preventing his performance would be in breach of good faith and would destroy his exemption." ¹⁷⁹

If the contract does not contain a *force majeure* clause, then courts will look to the language of the provision to determine if the clause excuses non-performance under the circumstances. *Force majeure* clauses vary widely, and the precise language will be critical. Some *force majeure* clauses specifically reference "epidemic" as a *force majeure* event; others do not. Even in the absence of a specific reference to epidemic, a *force majeure* clause may apply if it contains a catch-all provision and an epidemic event is sufficiently similar to the listed triggering events.

In the absence of a *force majeure* clause, nonperformance may be excused under the limited circumstances permitted by the doctrines of impossibility or frustration of purpose. These common law doctrines are applied narrowly by the courts of New York. The impossibility doctrine applies when an unanticipated and unforeseeable event occurs and, as a result of the event, the destruction of the subject matter of the contract or the means of performance makes performance objectively impossible. The frustration of purpose doctrine applies when a wholly unforeseeable event renders the contract valueless to one party and the principal purpose of the contract is no longer achievable.

¹⁷³ Bierer v. Glaze, Inc., 2006 U.S. Dist. LEXIS 73042, *21-22 (E.D.N.Y. Oct. 6, 2006); U.S. v. General Douglas MacArthur Senior Village, Inc., 508 F.2d 377, 381 (2d Cir. 1974).

¹⁷⁴ Id.

¹⁷⁵ RESTATEMENT (SECOND) OF CONTRACTS § 265 (comment).

¹⁷⁶ UCC § 2-615, Official Comment 1.

¹⁷⁷ UCC § 2-615(b).

¹⁷⁸ UCC § 2-615, Official Comment 11.

¹⁷⁹ *Id*.

Finally, New York's Uniform Code Section 2-615(a) may excuse breach of certain sales contracts where performance has been made impracticable by an unforeseen supervening occurrence or where the breach was caused by good faith compliance with governmental regulation.

Paycheck Protection Program

It is important to note that the U.S. Small Business Administration established the Paycheck Protection Program (PPP) specifically designed to support small businesses experiencing economic harm from the pandemic and to encourage employers to maintain or rehire their employees, by offering forgiveness for those entities who use the loan proceeds to cover payroll costs and related costs at a specified level for a specified period of time and employee and compensation levels are maintained. As such funding has been depleted quickly due to overwhelming response, additional funds have been granted through an amendment to the CARES Act. Economic initiatives such as this which provide direct funding are critical to ensuring that New Yorkers remain employed and businesses across professional sectors are able to continue operating. However, it is evident that greater care must be given to ensuring that the business entities with greatest need are not dominated by those with greatest resources and influence.

Immunity

Federal Immunity Declarations in Response to COVID-19

CMS Blanket Waivers for Health Care Providers

Pursuant to section 319 of the Public Health Service Act, ¹⁸² if the President declares a major disaster or emergency, the Department of Health and Human Services ("HHS") may declare a Public Health Emergency ("PHE") which triggers the authority of the Secretary of HHS under section 1135 of the Social Security Act ¹⁸³ to temporarily waive or permit flexibility of certain Medicare, Medicaid and HIPAA requirements. These 1135 waivers are adopted to allow hospitals, laboratories, nursing homes, hospice, psychiatric hospitals and critical access hospitals and other regulated organizations and facilities ¹⁸⁴ to provide timely care to as many people as possible and may impact the following requirements:

- Conditions of participation and other certification requirements;
- Program participation and similar requirements;
- Preapproval requirements;
- Requirements that physicians and other health care professionals be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State, subject to any applicable State laws governing licensure;
- Emergency Medical Treatment and Labor Act (EMTALA);
- Stark self-referral sanctions; and
- Limitations on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers.¹⁸⁵

¹⁸⁰ See U.S. SMALL BUS. ADMIN., Coronavirus (COVID-19): Small Business Guidance & Loan Resources, https://www.sba.gov/page/coronavirus-COVID-19-small-business-guidance-loan-resources.

Paycheck Protection Program and Health Care Enhancement Act, H.R. 266, 116th Cong. (2020), https://www.congress.gov/amendment/116th-congress/senate-amendment/1580/all-info?s=4&r=1.

¹⁸² 42 U.S.C. § 201 et seq.

¹⁸³ 42 U.S.C. § 301 et seq.

¹⁸⁴ EMERGENCY MEDICAL TREATMENT & ACTIVE LABOR ACT, 42 U.C.S § 1395dd.

¹⁸⁵ CMC, CMS Declaration of Waivers under 1135, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers (last visited Apr. 22, 2020).

These waivers allow for unconventional adjustments to operations governed by federal law to control contagion, assure sufficient staffing levels, efficiently treat patients, and allocate scarce resources to preserve and save as many lives as possible during the pandemic under CSC principles while using best efforts to assure the safety of its clinical staff and patient milieu, sometimes at the expense of individual patient's rights. Such curtailment of individual patient rights however, may lead to regulatory complaints and investigation, penalties, and/or civil and criminal litigation when outcomes are not optimal. Likewise, notwithstanding these waivers, health care organizations and facilities must take caution to avoid fraud and abuse and other overt violations of the laws and regulations governing the health care delivery system. In addition, health care organizations and facilities remain subject to applicable state laws and regulations not under federal jurisdiction. Hence, the immunity afforded by both federal and state authorities to health care organizations and facilities as they navigate the health care delivery system during the coronavirus pandemic is critical to the implementation of CSC. Without such immunity, health care organizations and facilities could be exposed to liability ranging from medical malpractice, violation of federal and state non-discrimination laws, violations of regulatory requirements which may lead to investigation, prosecution under the False Claims Act, and possibly exclusion of federal and commercial payment programs.

CARES Act

As noted above, the Federal Coronavirus Appropriations Package or CARES Act, was enacted largely to stimulate the U.S. economy, but there are several provisions included in the legislation that also aim to relax typical restrictions on the healthcare industry workforce that is on the "frontlines" in providing patient care amid the pandemic, including a liability protection for health care providers who volunteer to provide health care services relating to the diagnosis, prevention or treatment of COVID-19 or the assessment or care of a person who has or is suspected to have COVID-19 (CARES Act § 3215). To qualify for the protection, a healthcare provider must be licensed, registered, and/or certified to provide health care services under State or Federal law and providing services within the scope of their license, registration or certification in good faith (*see id.*). Additionally, an individual must not be compensated for providing the services at issue (*see id.*). The protection is limited in time to the duration of the period of the public health emergency declared by the U.S. Health and Human Services.

PREP Act

The Public Readiness and Emergency Preparedness Act or PREP Act (42 USC §§ 247d-6d-6e), permits U.S. HHS to issue a declaration to provide liability protections to individuals and entities (referred to as "covered persons") who manufacture, distribute or administer "medical countermeasures" in response to a public health crisis. After determining COVID-19 constituted a public health emergency, on January 31, 2020, the U.S. HHS Secretary issued a declaration under PREP. Thereafter, consistent with the PREP Act, on March 10, 2020, the U.S. HHS Secretary issued a declaration under PREP that set forth specific covered persons and medical countermeasures that receive liability protection during the COVID-19 pandemic. The covered persons include manufacturers, distributors, and program planners of medical countermeasures and their agents and employees and persons who prescribe, administer, deliver, distribute or dispense medical countermeasures. The medical countermeasures include the following: any antiviral, other drug, biologic, diagnostic, other device or vaccine used to treat, diagnose, cure, prevent or mitigate

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¹⁸⁶ See id.

¹⁸⁷ DEP'T OF HEALTH AND HUMAN SERVICES, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, Mar. 17, 2020, FEDERAL REGISTER,

https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures#footnote-1-p15198 (last visited Apr. 17, 2020).

¹⁸⁸ See 85 FR 15198.

¹⁸⁹ Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, Mar. 17, 2020, https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures#footnote-1-p15198 (last visited Apr. 17, 2020).

COVID-19 or any virus mutating therefrom; or any device used in the administration of such product and the components and materials of same.¹⁹⁰

Since the these official pronouncements by the US HHS Secretary, on April 14, 2020, HHS's Office of General Counsel has issued an Advisory Opinion discussing the declarations and the purpose and limitations of same ("the Advisory Opinion"). The stated goal of the Advisory Opinion was to respond to the scores of questions HHS has apparently received as to what is and what is no covered by the liability protections offered under the PREP Act. Notably, the Advisory Opinion indicates the scope of liability protections afforded under the PREP Act is intended to be broad, and, as such, it is the opinion of the General Counsel's Office that if a person or entity that qualifies as a "covered person," that person or entity will likely not "lose" the immunity intended by the law if it turns out later a product believed in good faith to be a "medical countermeasure" was not actually a "medical countermeasure" outlined in the PREP declaration. ¹⁹²

Finally, because covered persons are immune from suit, absent gross negligence, under the PREP Act, there is a Countermeasures Injury Compensation Program ("CICP") that provides compensation to individuals who are seriously injured or killed from medical countermeasures. ¹⁹³ Notably, however, CICP is a "payor of last resort," and will only pay for medical costs not otherwise covered by third-party payors, including personal medical insurers, lost income, and survival benefits in some cases. ¹⁹⁴ To file for compensation under CICP, claimants must submit their requests for same within one (1) year of receipt of the countermeasure. ¹⁹⁵ It is too soon to tell whether CICP claims will increase beyond what is typical, but it seems very likely they will with what we know at this time.

New York State-Specific Immunity Declarations in Response to COVID-19

Organizational Immunity: Negligent Credentialing

Health care organizations and health care facilities are mandated by New York State laws and regulations to duly credential health care practitioners providing health care services at their facilities. ¹⁹⁶ Organizations have a duty to select and retain competent practitioners. Failure to meet established standards of credentialing and privileging may lead to regulatory exposure and/or organizational liability for negligent credentialing in the event of patient harm caused by a credentialed practitioner. Typical strategies employed by health care facilities and their governing boards to minimize risk in the credentialing process are time consuming and may prove impractical in the face of the coronavirus pandemic situation. Typical strategies include:

- Identifying red flags in a practitioner's history (e.g., NPDB reports)
- Thoroughly documenting the practitioner's professional competence through references
- Using a consistent, evidence-based evaluation process
- Collecting performance data on an on-going basis

¹⁹¹ Advisory Opinion on The Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under The Act (Dep't of Health & Human Services, Office of the Sec'y Apr. 14, 2020), https://www.hhs.gov/sites/default/files/prepact-advisory-opinion-april-14-2020.pdf.

¹⁹⁰ See id.

¹⁹² See id. at 4.

¹⁹³ Countermeasures Injury Compensation Program, 76 FED. REG. 62, 306 (Oct. 7, 2011), https://www.hrsa.gov/sites/default/files/cicp/about/forms/adminfinalrule.pdf (last visited Apr. 23, 2020).

 ¹⁹⁴ Frequently Asked Questions For Individual Requesters/Recipients, Health Resources & Services Administration, https://www.hrsa.gov/cicp/faq/requesters.html (last visited Apr. 23, 2020).
 ¹⁹⁵ See id.

¹⁹⁶ N.Y. PHL § 2805-k.

- Establishing and enforcing standard evaluation parameters
- Assuring adequate facility resources to perform health care services in a safe, effective and efficient manner
- Leadership oversight of the credentialing process (Board review and approval of candidates after careful review of a complete application)

The Governor's EOs appropriately extend to health care entities and facilities immunity from liability resulting from reliance on credentialing processes of other health care organizations and health care facilities in New York and any other state.¹⁹⁷

Individual Immunity

Likewise, individual practitioners who cross state lines to offer professional medical services to manage patient surges risk professional liability exposure. It is deemed professional misconduct for any licensed practitioner to practice in the State of New York without a valid license. As healthcare practitioners cross state lines to address patient surges, they risk being charged with professional misconduct on the grounds that they are practicing in New York without a license. 198 Similarly, as practitioners and other healthcare workforce members are re-deployed or otherwise take on additional administrative and clinical duties and responsibilities outside the scope of their employment contracts, will health care organizations and health care facilities offer coverage and/or indemnification for potential liability exposure that may arise in the course of treating patients with COVID-19 given the relaxation of other regulatory requirements governing the delivery of health care and patients' rights? The Governor's EO 202.5 provides individual civil and criminal immunity to those duly licensed practitioners crossing state lines without a license to practice in New York state to assist their New York state colleagues in managing the surge of patients needing acute clinical care beyond that which health systems in New York can handle. More recently, EO 202.18 expanded civil and criminal immunity to those individual practitioners ranging from physicians to licensed clinical social workers to laboratory staff and pharmacy staff who are licensed and in current good standing in any province or territory of Canada. Such immunity however is limited to those acts of omission or commission in the management of COVID-19 consistent with the CSC.

Finally, from a risk management perspective, health care organizations and facilities should assure that termination of interjurisdictional credentialing arrangements and expansion of delineation of privileges should terminate contemporaneously with termination of the current public health emergency crisis as determined by governmental entities or when the health organization has sufficient capacity to handle census. Health care organizations and facilities should clarify for individual practitioners that termination does not amount to a termination or other denial of clinical privileges that would otherwise be deemed an adverse event triggering a report to the state Office of Professional Medical Conduct, Office of Professions or National Practitioner Data Bank.¹⁹⁹

More significant, however, is the individual immunity necessary for health care workers who must make the life and death decisions about allocation of scarce resources such as ventilators, PPE and clinical staff when emergency departments and intensive care units are overwhelmed beyond their capacity. In this regard, EO 202.10 provides health care professionals with immunity from civil liability. Unfortunately, the immunity provision does not extend to individual criminal liability, nor does it extend to the health care

¹⁹⁷ See EXECUTIVE ORDER 202.10, "Continuing Suspension and Modification of Laws Relating to the Disaster Emergency," Mar. 23 2020, https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency (Last accessed Apr. 17, 2020).

¹⁹⁸ N.Y. Ed. L., Art. VIII.

¹⁹⁹ 42 USC § 1320a, 42 CFR § 1003.810, Failure to report to NPDB may result in significant Civil Monetary Penalties.

facility at which the services are provided. Article 30-D of the Public Health Law,²⁰⁰ signed by Governor Cuomo on April 3, 2020, as part of the New York State budget extends "immunity for any liability, civil and criminal, for any health care professional or facility alleged to have been sustained as a result of any act or omission" in the provision of care pursuant to a COVID-19 emergency rule or is otherwise lawful.²⁰¹

HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act ("HIPAA") is likely best known for its privacy protections. Indeed, HIPAA sets forth national standards to protect against the wrongful disclosure of information contained in patients' medical records, as well as the disclosure of other personal health information. Importantly, the restrictions set forth in HIPAA apply to "covered entities," which is defined to include health plans (i.e., individual or group plans that provide or pay the cost of medical care), heath care clearinghouses (i.e., public or private entities that process or facilitate the processing of health information received from another entity, including, but not limited to billing companies), and health care providers who typically transmit health information in electronic form (and their "business associates"); and ordinarily restrict those entities from disclosing "health information," defined as "any information . . . that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual" without certain required consent from patients or their representatives or in certain limited defined exceptions.

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Several of those defined exceptions are applicable now amid the COVID-19 crisis. There is an exception that permits covered entities to disclose otherwise protected health information to public health authorities "for the purpose of preventing or controlling disease . . . including, but not limited to, the reporting of disease" and where a patient "may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition." There is also an exception that allows covered entities to disclose information to a patient's family members or other persons identified by the patient as being involved with his/her/their care if the information is directly relevant to the patient's care – e.g., that certain precautions need to be taken if the patient has or is suspected to have COVID-19. 205

Related to this, there is also an additional exception that allows covered entities to disclose health information to when it is "necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public," and that disclosure can be made to any "person or persons reasonably able to prevent or lessen the threat." Notably, however, in a bulletin issued on February 3, 2020 ("the February Bulletin"), HHS cautions that this exception should only be used when the "professional judgment of health professionals" indicate it is necessary because of the nature and severity of the threat. The February Bulletin also warns against reporting health information to the media or the public at large, absent a patient's consent to do so, and reminds covered entities and their business associates that they must make reasonable efforts to limit the disclosed information to the "minimum necessary." Meaning, it would be permissible for a hospital to provide a public health authority requesting information on COVID-19 status, but the

²⁰¹ N.Y. Pub. H. L. § 3082.

²⁰² See 45 CFR § 160 et seq.

²⁰³ See 45 CFR § 160.103; see also 45 CFR 164.500 et seq.

²⁰⁴ See 45 CFR 164.512(b)(i) and (b)(iv).

²⁰⁵ See 45 CFR 164.510(b).

²⁰⁶ See 45 CFR 164.512(i).

²⁰⁷ U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HIPAA Privacy and Novel Coronavirus, Feb. 2020, https://www.hhs.gov/sites/default/files/february-2020-hipaa-and-novel-coronavirus.pdf (last visited Apr. 23, 2020).

hospital should refrain from also provide information about that patient's surgical history and other unrelated medical conditions, absent a reason for doing so.²⁰⁸

In March 2020, HHS issued another HIPAA-related bulletin for the stated purpose of addressing the question of whether covered entities could share names of patients and other identifying information about patients who have been infected with or exposed to COVID-19 with law enforcement, paramedics, other first responders, and public health authorities ("the March Bulletin").²⁰⁹ The March Bulletin references the exceptions discussed above, and provides examples of how those exceptions apply.²¹⁰

In sum, while HHS has not "waived" the privacy restrictions that are set forth in the HIPAA Privacy Rule, the available exceptions that already exist in the law appear sufficient to provide public health authorities with the information they need to stop the spread of the pandemic. Importantly, in both the February Bulletin and the March Bulletin, HHS made clear patient confidentiality is extremely important and reasonable efforts should be made to ensure it is maintained to the greatest extent possible.

Workplace Liability Exposure

Employment Practices

As non-essential businesses press "pause" in response to the COVID-19 Pandemic, and as essential businesses reallocate their workforce, many employers have conducted layoffs, furloughs and implemented workshare programs to reduce salary and other overhead expenses during a time of limited cash flow. As more fully discussed in the Workforce Section of this Report, Federal and State laws governing paid sick leave, unemployment benefits, and FMLA have been expanded to account for some of the workforce reductions and lessen the devastating impact on individuals and the economy. However, as employers implement the difficult decisions pertaining to their employees, they must be cognizant of civil rights laws that prohibit discrimination in the workplace.²¹¹ Decisions pertaining to sick leave, layoffs, furloughs, workshare and reassignment of duties must be made in a non-discriminatory manner to avoid allegations of adverse employment actions, failure to provide reasonable accommodations, and wrongful termination. In addition, when implementing workshare or other reductions in work hours, employers must strictly comply with wage and hour provisions to protect employees' right to unemployment benefits and avoid unnecessary liability for overtime hours worked. Finally, prior to implementing such reductions in force, employers subject to the Worker Adjustment and Retraining Notification Act must be sure to provide adequate notice as may be required by law.²¹²

Workplace Safety

Inevitably, essential workers risk exposure to COVID-19 and may suffer illness as a result. Such illness, when it is demonstrated that it was contracted during work-related activity in the course of employment, will be covered by workers' compensation coverage. However, demonstrating a direct causal effect may prove difficult where employees may be exposed to the virus in their normal course of daily activities, likely leaving employers to work through workers' compensation claims long after the crisis abates.

²⁰⁸ See id.

²⁰⁹ U.S. DEP'T OF HEALTH AND HUMAN SERVICES, COVID-19 and HIPAA: Disclosures to law enforcement, paramedics, other first responders and public health authorities, https://www.hhs.gov/sites/default/files/COVID-19-hipaa-and-first-responders-508.pdf (last accessed Apr. 23, 2020).

²¹⁰ See id.

²¹¹ See Age Discrimination in Employment Act of 1967, 29 U.S.C. §§ 621-634; Title VII of the Civil Rights Act of 1964, (Pub. L. 88-352) 42 U.S.C. § 2000e et seg; Americans with Disabilities Act of 1990, 42 U.S.C. ch. 126 § 12101 et seg; Consolidated Omnibus Reconciliation Act of 1985, IRC §4980B and 29 U.S.C. §§ 1161-1168; Family Medical Leave Act, 29 U.S.C. ch. 28 $\S\S$ 2601-2654. 212 Worker Adjustment and Retraining Notification Act of 1988, 29 U.S.C. $\S\S$ 2101-2109.

On the other hand, where employers do not or are not able to comply with OSHA and other workplace safety requirements, they may be exposed to organizational liability including, but not limited to significant civil monetary penalties imposed by the Department of Labor under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended.²¹³ Failure to assure that adequate risk management strategies are adopted to minimize the risk of infection for employees, customers and others who interact directly with the public may expose employers to not only significant regulatory penalties, but claims arising from customers who may be exposed. Essential businesses including, but not limited to, grocery stores and other food markets, child-care centers, and utility providers must adopt infection prevention protocols such as standard and universal precautions that they, unlike health care delivery providers, may not otherwise be familiar with. Employers must assure that PPE and hand sanitizer is readily available and properly used, and that environmental surfaces and equipment are cleansed and disinfected effectively and often, and that social distancing policies are strictly enforced.

Given the health care services workers' shortage and patient surges during the COVID-19 Pandemic, the CDC has adopted guidance for occupational health programs and public health officials making decisions about return to work for healthcare personnel with confirmed COVID-19 or who have suspected COVID-19 but have not been tested.²¹⁴ Healthcare services employers must balance the risk of early return to work with their local need for healthcare services personnel on the front lines to manage patient care needs and adopt standard policies that are consistently enforced to avoid unnecessary exposure for deviations from accepted CSC.

V. Workforce Issues Associated with COVID-19

Introduction to Workforce

Implementation of crisis standards of care in response to a public health emergency mandates that the interests of the public's health be deemed paramount and that all efforts and resources be devoted toward saving as many lives as possible. Governmental entities must determine how businesses and entities and their respective employees, independent contractors and volunteers are legally distinguished for the purpose of coordinating essential services while maintaining public and worker safety. The Centers for Disease Control ("CDC") and other public health authorities have acknowledged community spread of COVID-19 in the United States and have issued precautions to slow the spread, such as significant restrictions on public gatherings. In addition, numerous state and local authorities have issued directives to minimize the risk of contagion by requiring quarantine, suspending non-essential commercial business operations, closing schools and taking other measures to prevent public gatherings in close quarters.

Governor Andrew Cuomo's Executive Orders ("EOs") coordinating restrictions on in-person business operations, school closures, and stay-at-home mandates across New York State in response to the ongoing COVID-19 pandemic have had a catalytic impact on New York State's economy, workforce, and education system, while also incidentally hindering access to essential resources and health care services for many individuals.²¹⁵ Despite desperate efforts by federal, state and local government officials to minimize the inevitable harms associated with a deadly pandemic such as this, the debilitating effect of the existing mandates has exposed societal weaknesses specific to public health and safety which cannot be easily

²¹³ 28 U.S.C. § 2461.

²¹⁴ CTRS FOR DISEASE CONTROL & PREVENTION, *Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19*, Apr. 13, 2020, https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html (last accessed Apr. 23, 2020). ²¹⁵ *See* EXECUTIVE ORDER 202.14 (Extends restrictions on public and private businesses; postponement or cancellation of all non-essential gathering of individuals of any size for any reason, and closure of schools stateside until 11:59 on April 29, 2020).

rectified in the present. Nonetheless, such efforts and the results thereof provide insight regarding potential opportunities to remedy recognized weaknesses and build upon discovered strengths.

Through a series of EOs, the Governor necessarily categorized businesses into non-essential and essential whereby workers in non-essential businesses, or non-essential positions in essential businesses, must "shelter-in-place." Timely and definitive guidance on what constitutes an essential business, or an essential worker, is critical to balance societal access to vital resources with control over contagion to avoid overwhelming our health care systems. This requires thoughtful allocation of human resources where the public need is greatest. As a result, tensions between public health interests including those of vulnerable populations, with those of individual workers inevitably rise to the surface.

As the Governor's office, the New York City Mayor's office and other related stakeholders try to determine the appropriate timing and manner in which the economy should reopen in collaboration with surrounding states, Governor Cuomo has continued to emphasize the inseverable symbiotic relationship between businesses, schools, workforce, and transportation, while clearly stating that one cannot reopen independent of the others. ²¹⁷ This section highlights the tight interconnections between business, workforce and education and the associated issues that quasi "shelter-in-place" mandates have surfaced to date.

Allocation of Human Resources

Beginning in mid-March 2020, Governor Cuomo began issuing executive orders requiring government entities and businesses to have non-essential personnel work from home or take leave without charging accruals. Effective March 20, 2020, Executive Order 202.6 required all businesses and not-for-profit entities to utilize telecommuting or work from home procedures to the maximum extent possible. Within days, a new executive order was issued, reducing the in-person workforce at any work locations by 100% no later than March 22, 2020 with a limited exemption for essential businesses. This mandate, though undeniably one of the most successfully impactful State initiatives to "flatten the curve," triggered a whirlwind of anxiety and uncertainty amongst employers and employees alike as they diligently attempted to comply with often vague and ever-changing "essential business/employee" definitions; fiscally and logistically manage business operations; balance employer/employee rights and responsibilities; and fully engage in public health efforts to mitigate spread of the virus in the workplace, homes, communities, throughout the State and worldwide.

Essential and Non-Essential Business Categorization

As Governor Cuomo's workplace mandates evolved over time, the following business and employee categories emerged and shifted from a workforce population percentage standpoint as restrictions became more stringent.

Essential Businesses

- First Responders (Medical)
- First Responders (Non-medical)
- Essential significant contact with public and co-workers (grocery, manufacturing, shipping, transportation, etc.)

²¹⁶ See Executive Order 202.6; Executive Order 202.13; Appendix F.

²¹⁷ Governor Cuomo Press Conference, Apr. 18, 2020, https://www.rev.com/blog/transcripts/andrew-cuomo-new-york-COVID-19-briefing-transcript-april-18 (last accessed 04/20/2020).

²¹⁸ EXEC. ORDER No. 202.4, (Mar. 17, 2020).

²¹⁹ See Empire State Dev., Guidance for Determining Whether a Business Enterprise is Subject to a Workforce Reduction Under Recent Executive Orders (April 19, 2020), https://esd.ny.gov/guidance-executive-order-2026 (last visited Apr. 23, 2020).

- Essential – limited or no contact with public

Non-Essential Businesses

- On-site
- Telecommuting

Each category of professionals referenced above faces its own unique set of challenges, beyond those shared amongst all, as a consequence of the diverse roles and expected contributions required by society present day. Governor Cuomo reported that according to the Center for Economic and Policy Research, "41 percent of frontline workers are people of color, and of those frontline workers." In addition, "45 percent of transit workers, 57 percent of building cleaning service workers and 40 percent of health care workers are people of color. People of color are also disproportionately represented in delivery and childcare services."²²⁰ Furthermore, each category consists of numerous sub-categories of families and individuals who may be "sheltering" with family or loved ones; forced to "shelter" independently in isolation; working remotely with high productivity expectations which exceed the norm; or working with a reduced workload due to the economic impact of the pandemic. Each of these familial and individual categories are also differently situated socioeconomically, and thus must be closely scrutinized to ensure that unintended consequences do not result from overgeneralizing the perceived benefits and harms of existing and future initiatives, especially as we continue to navigate unchartered waters toward our "new normal."

As previously suggested, the greatest challenges for business leaders beyond revenue related considerations have been associated with employee rights as related to employment, benefits, and protection from work-related exposure to COVID-19. In-person workforce reduction and quasi "shelter in-place" mandates significantly impacted demand for existing and new business almost instantaneously. Furthermore, many companies have not been able to collect payment for past services rendered, thus forcing them to determine how to effectively prioritize and allocate their employees and related business projects and tasks. Concerted efforts to prevent spread of the virus within the workplace have been futile to date as employees have continued to test positive since the pandemic was declared. Consequently, numerous human rights related concerns such as the "right to stay home" and "freedom of speech" have arisen and escalated in response to the highly contagious and deadly nature of the virus, which are addressed in a later section.

Employer Workplace Considerations

In light of the unprecedented impact of the COVID-19 pandemic economically, socially, and emotionally, employers must make every effort to maintain a supportive and legally sound work environment, recognizing the significant bearing workplace culture has on employee morale, trust and performance. Considering this, all operating businesses (non-essential and essential) should make a concerted effort to design and diligently implement a plan that is both employer and employee focused to ensure compliance with the legal and ethical practices, while fostering a supportive work environment. Employees should be provided with reputable state and federal resources to effectively follow best practices in mitigating the spread of the virus. Employers should closely follow public health guidelines and offer any equipment and materials necessary, including personal protective equipment (PPE), to not only support a healthy work environment, but convey a clear message to employees that the health and safety of themselves and their loved ones are of utmost importance. The New York State Nurses Association has challenged the adequacy

²²⁰ Press Conference, *Amid Ongoing COVID-19 Pandemic, Governor Cuomo Calls on Federal Government to Provide Hazard Pay to Essential Public Workers*, Apr. 20, 2020, https://www.governor.ny.gov/news/amid-ongoing-COVID-19-pandemic-governor-cuomo-calls-federal-government-provide-hazard-pay.

of the PPE provided by certain hospitals during the PHE. The hospitals' perspective is that the PPE was compliant with guidance during the pandemic.²²¹

In light of the recent release of federal guidelines for reopening businesses²²², it is important that public health considerations remain at the foundation of any decision-making associated with business operations to mitigate spread.²²³ Business practices established during the early phase of the pandemic response which err on the side of caution, such as encouraging remote work when reasonably feasible, limiting non-essential travel and using reasonable discretion when employees display flu-like symptoms, will undeniably help expedite long-term health and economic success locally, nationally, and globally in the hours, days, and months to come.

Employee Benefits

The following economically focused benefits and initiatives are designed to support employees impacted by exposure to or diagnosis of the COVID-19 virus, furloughs and layoffs.

Sick Leave, Paid Time-Off (PTO), Unemployment

The Family First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief and Economic Security Act (CARES Act)

The Family First Coronavirus Response Act (FFCRA) is a Congressional Act designed to respond to the economic impact of the ongoing pandemic. The Act contains numerous provisions including, paid leave for workers affected by the pandemic. The Coronavirus Aid, Relief and Economic Security Act (CARES Act) builds upon such efforts by providing additional support for individuals and businesses, including pandemic emergency unemployment compensation, pandemic unemployment assistance, extended benefits, short-term compensation, trade readjustment allowances, disaster unemployment assistance, and payments under the self-employment assistance program.

Under both the FFCRA and the CARES Act, laws and policies that affect employee wages, scheduling, and overtime remain unchanged from the current statutory regime under title 29 of the United States Code. Federal wage standards governed under 29 U.S.C. §209 hold that employers must pay employees a minimum wage. Furthermore, 29 U.S.C. §207(a)(1) requires employers to pay employees who work an excess of forty hours a week overtime pay "at a rate not less than one and one-half times the regular rate at which he is employed." Exempt employees, such as contractual employees or employees subject to existing collective bargaining agreements, may be exempted from overtime pay under §209(a)(1) if such contract or agreement specifies an expectation that the workweek would exceed forty hours in accordance with 29 U.S.C. §209(b). These laws are designed to work in concert with State law. Under circumstances in which State benefits are more generous than federal benefits, such as that for family leave, the eligible individual will be able to obtain the difference of the amount owed from the State.²²⁴

²²¹ Proskauer Rose LLP represents Westchester Medical Center and Montefiore in the NYSNA cases noted above. Edward S. Kornreich, a Proskauer Partner, is a member of the Task Force. Mr. Kornreich did not participate in the creation of this section of the Report, or any other sections of the Report related to workforce issues, or to the Force Majeure and Impossibility discussions, and did not approve their contents. This Report does not represent the views of Proskauer, which disclaims any responsibility for, or association with, its contents.

²²² THE WHITE HOUSE, Guidelines: Openning Up America Again (2020), https://www.whitehouse.gov/wp-content/uploads/2020/04/Guidelines-for-Opening-Up-America-Again.pdf?mod=article_inline&mod=article_inline.

²²³ Jennifer Maloney, Mike Colias, Paul Ziobro, *Businesses Strive to Reopen From Coronavirus Shutdown*, WALL ST. J. (Apr. 20, 2020), https://www.wsj.com/articles/the-corporate-coronavirus-plan-to-reopen-make-it-up-as-you-go-11587404618.

²²⁴ N.Y. Legis 25 (2020), 2020 Sess. Law News of N.Y. Ch. 25 (S. 8091) (McKINNEY'S).

WARN - Worker Adjustment and Retraining Notifications

The FFRCA and the CARES Act do not alter the provisions of the Worker Adjustment and Retraining Notification statutes. ²²⁵ Under the federal WARN statutes, if a covered employer seeks a permanent or temporary shutdown – of a single site of employment, or one or more facilities or operating-units within a single site of employment – results in a reduction of fifty or more employees for a minimum of thirty days, then the covered employer must provide sixty day notice to those employees and relevant federal, state, and local government agencies of the pending closure. ²²⁶ When a natural disaster causes a shutdown – such as the COVID-19 pandemic – an employer is not required to adhere to the sixty day notice requirement. ²²⁷ The employer is still obligated to provide notice "as is practicable" and shall provide a brief statement of the basis of reducing the notification period. ²²⁸

Sick Leave and Paid Time-Off (PTO), Paid Family Leave Benefits

In New York State, a detailed paid family leave framework was enacted to provide sick leave, paid family leave and other benefits to employees subject to an order for mandatory or precautionary quarantine due to COVID-19.²²⁹ The provisions outline categories of eligible businesses, employee salary ranges, paid family leave or disability benefit eligibility standards and guaranteed job protections granted to individuals under the law.²³⁰ For the purposes of these provisions, "disability" is defined as "any inability of any employee to perform the regular duties of his or her employment or the duties of any other employment which his or her employer may offer him or her as a result of a mandatory or precautionary order of quarantine or isolation" issued by specified entities.²³¹ Furthermore, "family leave" includes any leave "taken by an employee from work when an employee is subject to a mandatory or precautionary order of quarantine or isolation" issued by specified entities due to COVID-19 or any leave taken "to provide care for a minor dependent child of the employee who is subject to a mandatory or precautionary order of quarantine or isolation" issued by the same specified entities due to COVID-19.²³² Under the FFCRA, employees who work for businesses which employ over 50 but under 500 employees can also qualify for paid sick leave if the leave is related to the COVID-19 health emergency.²³³ There are six conditions that trigger these provisions, which are more expansive than New York State law. These conditions include:

- (1) The employee is subject to federal, state or local order to quarantine or self-isolate;
- (2) A health care provider advises the employee to quarantine or self-isolate related to COVID-19;
- (3) The employee is experiencing symptoms of COVID-19;
- (4) The employee is caring for an individual who is subject to quarantine/isolations;
- (5) The employee is caring for a son or daughter under the age 18 because school closures and child care is unavailable;
- (6) The employee is experiencing any other substantially similar condition specified by the Secretary of Health and Human Services, in consultation with the Secretaries of Labor and Treasury.²³⁴

²²⁵ 29 U.S.C. §2101(a).

²²⁶ 20 C.F.R. § 639.4.

²²⁷ 29 U.S.C. § 2102(b)(2)(B).

²²⁸ 29 U.S.C. § 2107(b)(3).

²²⁹ N.Y. Legis 25 (2020), 2020 Sess. Law News of N.Y. Ch. 25 (S. 8091) (McKINNEY'S); New York State Paid Family Leave, Fact Sheets, COVID-19 Paid Sick Leave Employees,

https://paidfamilyleave.ny.gov/system/files/documents/2020/03/COVID-19-sick-leave-employees.pdf, (last visited Apr. 23, 2020).

 $^{^{230}}$ Id.

²³¹ *Id*.

²³² Id

²³³ See U.S. DEP'T OF LABOR, Families First Coronavirus Response Act: Employee Paid Leave Rights (2020), https://www.dol.gov/agencies/whd/pandemic/ffcra-employee-paid-leave (Last accessed Apr. 12, 2020). ²³⁴ *Id.*

The U.S. Department of the Treasury, the IRS, and the U.S. Department of Labor have collaborated to provide small and midsized business tax credits to help such entities recover the cost of such benefits.

It is important to note that if an employer has reduced an employee's normal work hours, the employee is not eligible to use sick leave or the expanded family and medical leave to replace the lost hours, unless a qualifying condition stated above renders the employee unable to work.²³⁵ Even so, the extraordinary impact of these benefits is notable. As of April 22, 2020, there were over 130,000 confirmed cases of novel coronavirus, 25,000 hospitalizations, and approximately 10,000 deaths associated with the virus in New York City alone. ²³⁶ Considering this, expanded paid leave and health insurance benefits have been critical to facilitating public health and safety for New Yorkers, in concert with the unemployment benefit initiatives referenced below.

Unemployment Benefits

An unprecedented number of employees have been laid-off, furloughed, or in some way severed from employment due to lack of work as a result of the pandemic.²³⁷ For the week of April 25, 2020, the total number of individuals filing initial claims for unemployment benefits was close to four million, bringing the total number of initial claims to over thirty million nationally. ²³⁸ In New York, unemployment applications spiked 16,000 percent. 239 Individuals may qualify for unemployment insurance benefits offered through the state and federal government, including pandemic specific assistance provided under the Cares Act referenced above, depending on their employee category and status. ²⁴⁰ In New York, individuals seeking unemployment insurance must (a) have adequate past earnings; (b) be unemployed for each day claimed; (c) be unemployed "through no fault of their own"; and be actively and viably seeking reemployment, in accordance with Section 500 of the New York State Labor Law.²⁴¹ On March 12, 2020, Governor Cuomo signed an executive order waiving the 7-day waiting period for individuals claiming unemployment insurance through New York State as a result of the COVID-19 pandemic.²⁴² Typically. unemployment benefits would exclude certain employee categories and be deemed considerably inadequate to financially support individuals, let alone families, under crisis circumstances such as this. However, New York State and the federal government have each made a concerted effort offer benefits at a livable wage and broaden the scope of employees eligible to receive them.

Under Title II of the CARES Act, unemployment insurance eligibility has been extended to self-employed workers, independent contractors, gig economy workers, clergy and others who are typically ineligible under a new temporary federal program called Pandemic Unemployment Assistance (PUA). 243

²³⁶ New York City Health, Covid, COVID-19: Data, https://www1.nyc.gov/site/doh/Covid/COVID-19-data.page (last visited Apr. 23, 2020).

²³⁷ New York Dept. of Labor, Number of Unemployment Insurance Beneficiaries and Benefit Amounts Paid Regular Unemployment Insurance New York State, Region and County February 2020 and Cumulative Since January 1, 2020, https://labor.ny.gov/stats/UI/Beneficiaries-and-Amounts-by-Region-and-County-February-2020.pdf, (total including out of state residents is 194,400 in Feb. 2020).

²³⁸ U.S. DEP'T OF LABOR, Unemployment Insurance Weekly Claims (Apr. 30, 2020), https://www.dol.gov/ui/data.pdf; https://oui.doleta.gov/unemploy/archive.asp (Last accessed May 3, 2020).

²³⁹ NEW YORK DEP'T OF LABOR, Facing Unprecedented Spike in COVID-19 Related Unemployment Insurance Applications, NYS Department of Labor Announces Partnerships to Boost Tech Capacity and Make It Easier for New Yorkers to File, Apr. 9, 2020, https://labor.ny.gov/pressreleases/2020/april-09-2020.shtm, (increase of application by 16,000%).

²⁴⁰ See U.S. DEP'T OF LABOR, Families First Coronavirus Response Act: Questions and Answers (2020), https://www.dol.gov/agencies/whd/pandemic/ffcra-questions (Last accessed 04/21/2020); CARES Act: sec. 6428 (S. Res. 3548, 116th Cong. §6428 (2020) https://www.congress.gov/116/bills/s3548/BILLS-116s3548is.pdf. ²⁴¹ 18 N.Y. LAB. LAW § 500 et. seg.

²⁴² NEW YORK STATE, Know Your Rights, https://coronavirus.health.nv.gov/know-vour-rights#insurance; NEW YORK STATE, EXEC. ORDER No. 202.1 (Mar. 7, 2020), https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/EO 202 1.pdf. ²⁴³ *Id*.

Additionally, eligible parties are entitled to additional payment per week, on top of regular state benefits for an additional 13 weeks beyond the 26 weeks regularly provided, for a total of 39 weeks of coverage.²⁴⁴

Individuals are eligible under the CARES Act under the following circumstances:

- i. The individual has been diagnosed with COVID-19 or is experiencing symptoms of COVID-19 and is seeking a medical diagnosis;
- ii. A member of the individual's household has been diagnosed with COVID-19;
- iii. The individual is providing care for a family member or a member of the individual's household who has been diagnosed with COVID-19;
- iv. A child or other person in the household for which the individual has primary caregiving responsibility is unable to attend school or another facility that is closed as a direct result of the COVID-19 public health emergency and such school or facility care is required for the individual to work;
- v. The individual is unable to reach the place of employment because of a quarantine imposed as a direct result of the COVID-19 public health emergency;
- vi. The individual is unable to reach the place of employment because the individual has been advised by a health care provider to self-quarantine due to concerns related to COVID-19;
- vii. The individual was scheduled to commence employment and does not have a job or is unable to reach the job as a direct result of the COVID-19 public health emergency;
- viii. The individual has become the breadwinner or major support for a household because the head of the household has died as a direct result of COVID-19;
- ix. The individual has to quit his or her job as a direct result of COVID-19; or
- x. The individual's place of employment is closed as a direct result of the COVID-19 public health emergency.

These pandemic specific economic initiatives strive to keep both essential and non-essential businesses viable and individuals employed. It is important to note there are technical differences between furloughed and laid-off workers which should be taken into consideration when making employment decisions, such as the anticipated length of time the impacted individual is intended to be out of work and benefit eligibility. In order to most effectively take advantage of the various benefits highlighted above, in addition to others included in the CARES Act, employers and employees should seek guidance from the Department of Labor and professional and/or non-profit entities specializing in such matters.

Schools and Child Care

On April 11, 2020, the New York Times published an article highlighting diverging perspectives between the Mayor of New York City, Mayor Bill de Blasio, and the Governor of New York State, Governor Andrew Cuomo, regarding when schools and businesses should open, and which government leader has the authority to make such decision.²⁴⁵ The Mayor publicly announced that New York City schools, which at the time were shuttered since March 16th and required to adjust to distance learning, would remain closed for the remainder of the 2019-2020 academic year, while also proposing that businesses could potentially open in May 2020.²⁴⁶ However, Governor Cuomo soon thereafter stated that no decision had been made

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²⁴⁴ Id.

²⁴⁵ Eliza Shapiro, *N.Y.C. Closes Schools for Academic Year, but Cuomo Says it's His Decision*, N.Y. Times, Apr. 11, 2020, https://www.nytimes.com/2020/04/11/nyregion/nyc-schools-closed.html.

²⁴⁶ *Id.*; Governor Cuomo Press Conference, Apr. 18, 2020, https://www.rev.com/blog/transcripts/andrew-cuomo-new-york-COVID-19-briefing-transcript-april-18 (last accessed 04/20/2020).

regarding closing schools or opening businesses in New York City or the State.²⁴⁷ As previously noted, the Governor believes in the deep interconnection between business and school operations, and thus determines that they must open in concert.²⁴⁸ This symbiotic relationship contributes to various public health and social services related issues which must be closely analyzed and ultimately rectified going forward in the interest of future economic and social stability and most important, social justice.

New York State has the largest comprehensive public university system in the United States, the State University of New York (SUNY) system, with a total enrollment of over 400,000 students across 64 campuses and over 2 million continuing education enrollments.²⁴⁹ Additionally, the City School District of the City of New York (the New York City public schools) is the largest school district in the United States with over 1.1 million students.²⁵⁰ Almost 1.5 million children receive free or reduced lunch through the public school system.²⁵¹ In regards to child care, there are approximately 17,000 day care centers throughout New York State.²⁵² Despite having a total capacity of over 630,000 children across centers, child care shortages are an ongoing issue throughout the state.²⁵³ Bearing in mind that these statistics fail to include all public and private institutions and entities throughout the State, it is evident that New York State manages one of the most robust, coordinated educational and social services systems nationally. New York families heavily rely on these systems, in addition to supplemental after school programs, extra-curricular opportunities, day and residential camps, and other child and youth-directed programming, to supervise and provide care for their minor children while at work. Deprived of these resources, in-person business operations throughout the state effectively deteriorate with a markedly disparate impact on women, minorities, and economically vulnerable populations.

Child Care

Child care is undeniably one of the most fundamental, critical and coveted social services in New York State under the oversight of Office for Children and Family Services (OCFS) and the New York City Department of Health (NYC DOH). Such services are offered in varied forms, including day care centers, small day care centers, family day care homes, group family day care homes, and school-aged child care programs. Over the years and in recent past, associations and advocacy groups throughout New York State, such as the Empire State Campaign for Child Care, Winning Beginning NY, and Business Council of New York State, have highlighted the fact that child care services offerings throughout the State are woefully inadequate and prohibitively costly due to inadequate funding, limited staff²⁵⁶ and a stringent

²⁴⁷ Jesse McKinley, Eliza Shapiro and Jeffery C. Mays, *De Blasio Used Last-Minute Text to Tell Cuomo Schools Would Stay Shut*, N.Y. TIMES, Apr. 12, 2020, https://www.nytimes.com/2020/04/12/nyregion/schools-cuomo-de-blasio-nyc-coronavirus.html (last accessed Apr. 20, 2020).

²⁴⁸ Governor Cuomo Press Conference, Apr. 18, 2020, https://www.rev.com/blog/transcripts/andrew-cuomo-new-york-COVID-19-briefing-transcript-april-18 (last accessed 04/20/2020).

²⁴⁹ State Univ. of New York, Fast Facts (Jan. 2019), https://www.suny.edu/about/fast-facts/ (last visited Apr. 19, 2020).

²⁵⁰ New York City Dep't of Educ., DOE Data at a Glance, https://www.schools.nyc.gov/about-us/reports/doe-data-at-a-glance (last accessed Apr. 19, 2020).

²⁵¹ Council On Children & Families: Kids' Well-Being Indicators Clearinghouse, KWIC Indicator: Children Receiving Free of Reduced-Price School Lunch – Public Schools (Apr. 19, 2020),

https://www.nyskwic.org/get_data/indicator_profile.cfm?subIndicatorID=52.

²⁵² Office of Children and Family Serv., New York State 2017 Child Care Demographics (2017).

²⁵³ *Id.*; Childcare Careers, Addressing the Childcare Shortage: An Analysis of the Potential Benefits Offered by the Temporary Childcare Worker Industry 2 (Nov. 2018) (citing an estimated 60 percent of New York residents live in "childcare deserts," described as a location with inadequate child care facilities).

²⁵⁴ Find Child Care Providers New York State, Guidelines, https://www.ny.gov/services/find-child-care-providers-new-york-state, (last accessed Apr. 19, 2020).

²⁵⁵ See 18 N.Y.C.R.R. § 413.2.

²⁵⁶ Saima Akhta et al., Empire Justice Center, Joint Legislative Public Hearings on 2020-2021 Executive Budget Proposal 10-20, Jan. 30 2020; The Business Council, Support of S.5811-A, Jun. 4 2019; Winning Beginning NY, Testimony of Winning Beginning NY 2-3, Jan. 30, 2020; Timothy Denton, *Nassau County is Child Care Desert, Comptroller finds COVID-19*

regulatory framework related to adult-child ratios, training and experience, inspections, and employee eligibility requirements.²⁵⁷

Though childcare policies may vary, a significant number of childcare centers operate on a schedule that aligns with the school districts. In February 2020, OCFS began releasing COVID-19 pandemic updates to child care providers with public health and operations related updates.²⁵⁸ To date, OCFS has been collecting information from licensed and registered providers via surveys to determine "whether they have openings in their child care program, and if they have the capacity and desire to serve more children than their established capacity.²⁵⁹ Furthermore, surveys were distributed to determine parent or caregiver need.²⁶⁰ OCFS advises that child care *may* be available based on the responding party's "job, employer, number of children, and financial need."²⁶¹ Simultaneously, school leaders, special education directors, and charter school leaders were directed by Governor Cuomo to "establish and submit plans for the care of children of essential health care workers and first responders and to address other identified student needs" in preparation for school closures across the state.²⁶² Since then various stakeholders have started initiatives to ensure that health care workers, first responders and font-line workers have access to child care.²⁶³ In recognition of the shortage of child care workers and the significant impact potential infection could have on maintaining sufficient manpower, Governor Cuomo also altered background check requirements for child care workers.²⁶⁴

Now that in-person operations for all non-essential business are closed, many parents at home are forced to work remotely, if able to do so, and care for their children while many work productivity and performance expectations not only remain unchanged, but potentially increase in light of such dire economic circumstances. Additionally, it is uncertain whether all front-line workers in need of child care have sufficient and convenient access to it. The New York City Administration for Children's Services (ACS) has also issued guidelines to facilitate the identification of a child or children whose parent or primary caregiver is impacted by COVID-19 resulting in hospitalization. The issue is whether there is a sufficient number of healthy, trained, and experienced child care workers available to support the workforce as the

Lockdown Highlights High Cost to Families, Li Herald.com, Apr. 19, 2020, https://www.liherald.com/stories/nassau-county-is-childcare-desert-comptroller-finds,124247.

²⁵⁷ *Id*.

²⁵⁸ Letter from Office of Children and Family Serv., to Child Care Providers (Feb. 6, 2020) (online at https://ocfs.ny.gov/main/childcare/letterstoproviders/2020/Dear-Provider-2020Feb-Corona-Virus.pdf).

²⁵⁹ Office of Children and Family Serv., Coronavirus Information (COVID-19) News and Updates, Survey on Child Care Program Openings (March 25, 2020), https://ocfs.ny.gov/main/news/COVID-19/#t1-Letters-to-Child-Care-Providers (last accessed Apr. 20, 2020).

 $^{^{260}}$ *Id*.

²⁶¹ *Id*.

²⁶² Letter from New York State Ed. Dep't (March 17, 2020); N.Y. Exec. Order No. 202.4, Mar. 17, 2020.

²⁶³ See New York City Dep't of Ed., Regional Enrichment Centers, https://www.schools.nyc.gov/enrollment/enrollment-help/regional-enrichment-centers (last accessed Apr. 21, 2020); *NBC New York: New York Giants Fund Childcare for First Responders During COVID-19* (NBC Television Broadcast Mar. 23, 2020),

https://www.nbcnewyork.com/news/coronavirus/new-york-giants-fund-childcare-for-first-responders-during-COVID-19-crisis/2340883/ (last accessed Apr. 21, 2020); Press Release, Westchester Cty., Westchester County to Offer Child Care Opportunities for the Children of Healthcare Workers and First Responders, Mar. 25, 2020,

https://www.westchestergov.com/home/all-press-releases/8343-westchester-county-to-offer-child-care-opportunities-for-the-children-of-healthcare-workers-and-first-responders (last accessed Apr. 21,2020); Public Notice, Ichabod Crane Central Sch. Dist., Childcare for Essential Emergency Workforce Personal, March, 20, 2020,

https://www.ichabodcrane.org/2020/03/20/emergency-responder-health-worker-child-care/ (last accessed Apr. 21, 2020). ²⁶⁴ N.Y. Exec. Order No. 202.13, Mar. 29, 2020.

²⁶⁵ Adam Golick, *The Productivity Pitfalls of Working From Home in the Age of COVID-19*, Stanford News, Mar. 30, 2020, https://news.stanford.edu/2020/03/30/productivity-pitfalls-working-home-age-COVID-19/ (last accessed Apr. 21, 2020). ²⁶⁶ Identifying Caregivers for Children Unaccompanied and/or Unsupervised Due to the Hospitalization of their Primary Care Giver, NYC Childen Emergency Guidelines (April 9, 2020).

State's battle against the pandemic continues, and we begin phasing in the workforce.²⁶⁷ Such weaknesses in our social and workforce structure must be resolved.

The CARES Act contains increased appropriations for childcare services to help mitigate the impact of the COVID-19 health emergency. Monies were appropriated for the Child Care and Development Block Grant Act (CCDBG) and to remain available through September 20, 2021 to "prevent, prepare for, and respond" to the COVID-19 health emergency. The CARES Act also includes appropriations for Head Start, while reducing State cost-sharing contributions. Although these appropriations do not direct funding towards increasing access to childcare services to frontline workers, they provide States with increased flexibility to develop child care programs for these workers if warranted. Access to CCDBG grants typically require states to implement work plans that include background checks into State/local criminal databases, and the National Crime Information Center's National Sex Offender Registry. Currently, States that do not have access to the federal National Sex Offender Registry for various reasons, but the Office of Child Care has extended waivers for this provision which allow those States to continue to receive CCDBG grant funding.

On April 23, 2020, Governor Cuomo announced \$30 million in childcare scholarships for essential workers and supplies for health care providers through federal funding under the CARES Act.²⁷¹ Such essential workers include, "first responders such as health care providers, pharmaceutical staff, law enforcement, firefighters, food delivery workers, grocery store employees and others who are needed to respond to the COVID-19 pandemic."²⁷² The income level for eligibility is less than 300 percent of the federal poverty level, which is \$78,600 for a family of four.²⁷³ The funding may be used to cover existing care arrangements or to establish a new one.²⁷⁴ Funding will also provide child care providers critical resources, such as masks, gloves, diapers, baby wipes, baby formula and food, with child care resource and federal agencies receiving grants of approximately \$600 per provider.²⁷⁵ As child care resource and referral agencies, child care providers, and families persevere through this pandemic season and strategically prepare for the "new normal" that awaits, stakeholders must consider the resources, facility space, and manpower necessary to ensure the public health and safety of our children, their associated families and our child care workers, while still maintaining a welcoming and nurturing environment.

In regard to workforce, New York should consider granting staffing firms dedicated to childcare the provider status in the Statewide Central Register necessary to enable them to operate in the State and supplement our childcare workforce. In addition to the volunteers sought over the course of this pandemic, child care specific staffing firms could provide fully qualified and pre-screened teachers, assistant teachers and site directors for child care centers, preschools, and before & after school programs on an on-demand,

²⁶⁷ Lillian Mongeau, USA Today, *Coronavirus is Closing Day Cares; Child Care Providers Worry They Way Never Reopen* (Apr. 5, 2020) https://www.usatoday.com/story/news/education/2020/04/05/coronavirus-daycare-child-care-center-essential-cares-act-unemployment/2946710001/ (last accessed Apr. 21, 2020).

²⁶⁸ Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat 281 (2020).

²⁶⁹ Id.

²⁷⁰ See 45 C.F.R. 98.16(aa) (incorporating use of block grant funding to be used to assist with childcare and safety during a state-emergency); See also Office of Child Care, CCDF Frequently Asked Questions in Response to COVID-19, Mar. 13, 2020, https://www.acf.hhs.gov/occ/resource/ccdf-faqs-in-response-to-COVID-19 (last accessed 04/12/2020).

²⁷¹ Press Release, Governor Cuomo, Video, Audio, Photos & Rush Transcript: Amid Ongoing COVID-19 Pandemic, Governor Cuomo Announces State Health Department Will Partner with Attorney General James to Investigate Nursing Home Violations, Apr. 23, 2020, https://www.governor.ny.gov/news/video-audio-photos-rush-transcript-amid-ongoing-COVID-19-pandemic-governor-cuomo-announces-12 (announcing \$30 million in childcare scholarships for essential workers and supplies for childcare workers).

²⁷² *Id*.

²⁷³ *Id*.

²⁷⁴ *Id*.

²⁷⁵ *Id*.

same day, short-term, long-term, or permanent basis.²⁷⁶ Organizations such as this often employ a high percentage of graduate students and young adults seeking experience in pursuit of professional growth, parents seeking part-time work, and retired professionals to facilitate child care workforce stability within local communities on a routine and emergency basis, while also ensuring ensure the safety of one of our most treasured populations, our children. Furthermore, they have a significant impact on the school system, by alleviating the burdens that inevitably arise from sharing a limited pool of trained and fully vetted workforce members. Going forward, increased funding for existing centers supplemented by increased manpower must be prioritized to stabilize the existing childcare system and ultimately strengthen such system in anticipation of future emergencies such as this. Furthermore, we must ensure that the entire workforce is effectively supported by removing existing hurdles rooted in socioeconomic stratification.

Public and Private Schools, Colleges, and Universities

Once medical experts and government leaders realized that public and private academic institutions are high risk environments for the spread of the COVID-19 virus in light of the asymptomatic nature of the virus amongst children and young adults, such entities have faced numerous and diverse challenges which are not only ongoing, but also far-reaching beyond present day. Such challenges included the lack of regional uniformity and clarity regarding appropriate closure strategies and next steps upon recognition that the virus was a serious threat;²⁷⁷ the significant reliance on schools for food security for a large population of students;²⁷⁸ structural and economic disparities across academic institutions and students associated with home schooling and online learning;²⁷⁹ disparities associated with alternative grading systems within institutions and the modification,²⁸⁰ postponement and/or cancellation of institutional, state and/ or professional examinations;²⁸¹ the short-term and long-term impacts associated with the postponement and/or cancellation of graduation and other related ceremonies;²⁸² uncertainty regarding the timeline for reopening schools²⁸³ and the overarching financial, psychological and emotional impact of all of the above on the communities, institutional leaders, workforce members, parents, and children implicated.

Operational Uniformity across Academic Institutions

In light of the proven significance of "social distancing" in New York State's effort to mitigate the spread of COVID-19, it is essential that key stakeholders, including local health, education, school, college and university leaders, whether public or private, be provided clear and timely guidance regarding operational expectations and best practices to ensure that such individuals and entities are empowered with the information necessary to make sound decisions in the best interest of their individual communities and public health within the State as a whole. Local leaders and leaders were disoriented and frustrated in the

²⁷⁶ Child Care Careers, About Us, http://www.childcarecareers.net/about us (last visited Apr. 23, 2020).

²⁷⁷ Robyn Dixon, Karla Adam, Odysseus Patrick, *On Schools, No Global Consensus*, WASH. POST, Apr. 19, 2020, at A21 (discussing lack of consensus surrounding school closing/reopening policies).

²⁷⁸ Council On Children & Families: Kids' Well-Being Indicators Clearinghouse, *Supra* at note. 7.

²⁷⁹ Anna North, *The Shift to Online Learning Could Worsen Educational Inequality*, Vox (Apr. 9, 2020), https://www.vox.com/2020/4/9/21200159/coronavirus-school-digital-low-income-students-Covid-new-york.

Shannon Doyne, Michael Gonchar, *Should Schools Change How They Grade Students During the Pandemic?*, N.Y. TIMES, Apr. 6, 2020, https://www.nytimes.com/2020/04/06/learning/coronavirus-schools-grading.html; Teresa Watanabe, *A's for all? Pass/fail? Colleges grapple with grading fairness during coronavirus*, L.A. TIMES, Mar. 27, 2020,

https://www.latimes.com/california/story/2020-03-27/grades-vs-pass-fail-colleges-grapple-with-student-demands-to-change-grading-during-coronavirus.

²⁸¹ Court of Appeals (N.Y.), New York Bar Exam Rescheduled for Fall 2020, Mar. 27, 2020,

https://www.nybarexam.org/Press/PressRelease_NY_BarExam.pdf (rescheduling of July Bar Exam to September); NEW YORK DEP'T OF CIVIL SERV., News and Notifications, https://www.cs.ny.gov/home/news.cfm (last visited Apr. 22, 2020) (indicating postponed state civil service exams).

²⁸² Elissa Nadworny, *No Caps, No Gowns: For Many In The Class Of 2020, Commencement Is Called Off*, NPR, Apr. 1, 2020, https://www.npr.org/2020/04/01/823866801/no-caps-no-gowns-for-many-in-the-class-of-2020-commencement-is-called-off. ²⁸³ Dixon, et al, *supra*.

absence of strong direction from the State regarding school closures in the early phase of the pandemic.²⁸⁴ Despite local leaders' appreciation for autonomy in many instances, emergency circumstances such as this where regional differences and conflicting priorities, such as public safety, food safety, and childcare, are at issue, strategic efforts to act in a staggered or unified fashion directed by the State helps mitigate anxiety and fear amongst interested parties, while strengthening public trust that local decision-makers are acting in their best interest.

The Entanglement of the School System and Food Security

One of the most devastating issues from a logistical, public health and social equity standpoint beyond family reliance on schools for child care is the fact that so many children rely on the school system for food security, thus compromising New York State leaders' ability and willingness to close schools as early as they otherwise would have to mitigate the spread of the virus within schools and associated households. Although the availability of such benefits for families and children in need is paramount, the State should closely assess the government entities, organizations, personnel, and strategies utilized over the course of the past several weeks during the school closure period to determine which programs can be maintained long term in an effort to purposefully transition the sole responsibility of food security for children in economically challenged households from schools third-party entities. This proposal is not intended to suggest that schools systems be excluded from providing such benefit entirely, but more so emphasizing the need for a more robust support system for children and families outside of the school system.

Different than the inherent nature of school as an indirect form of "child care" based on our society's operational structure, schools are otherwise designed and intended to be sources of academic and social development and support, while providing additional opportunities and resources as ancillary benefits. The mission and vision of the New York State Education Department is "to raise the knowledge, skill, and opportunity of all the people in New York" and "to provide leadership for a system that yields the best educated people in the world."²⁸⁶ Considering this, schools should be funded and empowered as necessary to support its students when concerns such as food security are at issue. However, such institutions should act as collaborative partners with existing small business and nonprofit initiatives and programs, such as mobile food and produce projects, in the interest of public health and safety and social justice.

Disparities Associated with Home Schooling and Online Learning

The Governor's mandate across businesses and academic institutions to cease in-person operations and function remotely, including remote learning, has had a multifaceted impact on households and individuals throughout the State. Parents have been forced to assume a hands-on teaching role for courses of which they may not be well versed, using technologies with which they might be unfamiliar, while also working from home remotely with employer expectations of high productivity. For households lead by front-line workers unable to work from home and single parent households, the burden can be unbearable logistically and emotionally. Considering the vastly diverse composition of our households today, caution must be taken to not discount or ignore the far-reaching implications of a fully technological and business framework. Caretakers and employees are required to not only have the necessary technological equipment to appropriately meet school and work requirements, but the technological and financial resources to

²⁸⁴ Madina Toure and Sally Goldenberg, *Cuomo Defends Decision To Keep Schools Open, But Pressure Mounts*, POLITICO NEW YORK, Apr. 15, 2020, https://www.politico.com/states/new-york/albany/story/2020/03/15/cuomo-defends-decision-to-keep-schools-open-but-pressure-mounts-1267129 (last accessed Apr. 24, 2020).

²⁸⁵ New York State Council on Children & Families, KWIC Indicator: Children Receiving Free or Reduced-price School Lunch - Public Schools, https://www.nyskwic.org/get_data/indicator_profile.cfm?subIndicatorID=52 (last accessed Apr. 24, 2020); Paul Berger and Lee Hawkins, *Gov. Cuomo Wants to Shut New York City's Public-School System*, WSJ, Mar. 15, 2020, https://www.wsj.com/articles/pressure-mounts-to-shut-new-york-citys-school-system-bars-and-restaurants-11584290883 (last accessed Apr. 24, 2020).

²⁸⁶ NEW YORK STATE EDUCATION DEP'T, About NYSED, http://www.nysed.gov/about (last visited Apr. 24, 2020).

support, such as internet. Many households positioned to operate remotely prior to the pandemic still experience the need to purchase necessary office supplies and develop home office and study spaces for work and student learning. We must remember that many others do not have that luxury.

Technology has the ability to facilitate equality through increased access to otherwise inaccessible resources or further stratify us within society as a result of its potentially prohibitive costs for equipment and internet, in addition to the potential need for training.²⁸⁷ Here, there is greater risk of stratification than the potential for equality that must assessed and progressively resolved through collaborative public/private efforts. State, local and community leaders must ensure that vulnerable households needing economic or educational support are identified and supported to not only ensure that academic and professional requirements are able to be met, but academic and professional competency and growth are experienced and not hindered unfairly by this experience due socioeconomic status, disability, or any other factor. Individuals with disabilities must be provided the opportunity to receive ongoing education and services, whether via technological or in-person direct case services with sufficient protective measures, to safeguard them from being marginalized and ultimately harmed for the duration of this pandemic and going forward.

On April 4, 2020, the New York Times published an article entitled, "College Made Them Feel Equal. The Virus Exposed How Unequal Their Lives Are." This speaks to the fact that these issues of inequality permeate all academic and professional levels, and thus must be pondered and remedied as we evaluate and adapt our societal framework to withstand the present pandemic and look ahead to the future. On April 20, 2020, SUNY's chancellor announced the distribution of over 8,800 laptops and chromebooks to students to ensure that they are able to complete their spring coursework. Efforts such as this, with the provision of ancillary resources as needed, will help ensure the safety of our students at all levels and in all communities, while also enhancing their ability to more easily transition to remote learning and achieve academic regardless socioeconomic status.

Many of our students, especially those in colleges and professional institutions, are experiencing disappointment and fear as a result of separation from friends and loved ones; delayed special events and graduations; altered coursework and grading rubrics; postponed and cancelled state and national examinations; withdrawn opportunities and deteriorating job markets. Thus, every effort must be made to provide a strong foundation of resources, guidance and support from which our educational leaders, families and students can build and thrive despite the challenges faced, with social equity and justice in mind.

Essential Health Care Services Workers

Generally, health care services workers are deemed essential workers under Governor Cuomo's EOs.²⁹⁰ However, not all health care services are deemed essential in a public health emergency crisis such as the coronavirus pandemic. For instance, routine dental care, elective joint replacements, non-emergent podiatric care are not deemed essential health care services during this crisis which demonstrates "a fundamental priority shift from routine, patient-centric health care services to providing the best care

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²⁸⁷ Suzanne Woolley, Nikitha Sattiraju, Scott Moritz, *U.S. Schools Trying to Teach Online Highlight a Digital Divide*, BLOOMBERG, Mar. 26, 2020, https://www.bloomberg.com/news/articles/2020-03-26/COVID-19-school-closures-reveal-disparity-in-access-to-internet.

²⁸⁸ Nicholas Casey, *College Made Them Feel Equal. The Virus Exposed How Unequal Their Lives Are*, N.Y. TIMES, Apr. 4, 2020, https://www.nytimes.com/2020/04/04/us/politics/coronavirus-zoom-college-classes.html.

²⁸⁹ Press Release, SUNY, Chancellor Johnson Announces Distribution of Over 8,800 Laptops and Chromebooks to Students in Need to Complete their Spring Semester Coursework, Apr. 20, 2020, https://www.suny.edu/suny-news/press-releases/04-2020/4-20-20/index.html.

²⁹⁰ See Essential Workers EO, Appendix F.

possible to the largest numbers of victims" of the virus.²⁹¹ As non-essential health care services are put on pause, many duly qualified health care services personnel become part of the scarce resources that are reallocated and reassigned to best protect the public's health as health care institutions and facilities assess their relative capacity to manage patient surges arising from a major public health crisis. Other health care providers may travel to different jurisdictions to assist where the incidence of COVID-19 is concentrated; they may be reassigned to roles and responsibilities not within their current contracts or delineation of privileges; or they may be asked to perform outside the boundaries of their traditional scope of practice. These contractual and regulatory frameworks within which and the laws governing the manner in which licensed health care workers practice must be relaxed to allow health care institutions and facilities to incrementally increase clinical staff and resources, establish stand-by pools of providers, and re-deploy non-essential clinical staff to address patient influx greater than current capacity. Likewise, individual health care providers must be assured that by accepting such reassignments they are not unduly exposed to personal professional liability otherwise applicable under normal patient-centric standards of care.

State Licensure

The New York State Education Law governs licensure requirements and scope of practice for licensed health care services providers. Such laws restrict state licensed health care services providers from crossing state lines even in response to a public health emergency. Licensed providers risk investigation, prosecution, and discipline including, but not limited to, exclusion from participation in Medicare and Medicaid, for practicing in a state without a valid license. Likewise, even retirees who have allowed their license registrations to expire risk investigation, prosecution and discipline for professional misconduct for practicing in the state without a current registration. ²⁹³

Recognizing state licensure as a significant barrier to interjurisdictional movement of health care service workers to meet the public health needs in areas of concentrated incidence of COVID-19, Governor Cuomo's EO 202.5 effectively waived these laws to permit such cross jurisdictional coverage. ²⁹⁴ More recently, EO 202.18 further relaxed these laws to allow physicians, physician assistants, registered nurses, licensed practical nurses, nurse practitioners, licensed master social workers, licensed clinical social workers and other similarly licensed or registered practitioners in good standing in any province or territory of Canada to practice in New York without civil or criminal penalty related to lack of licensure or registration. EO 202.18 further relaxed state laws governing laboratory and pharmacy practitioners to allow flexibility in the provision of those essential services for a designated time period during the pandemic.

Credentialing Requirements

Health care organizations and payors of health care services are required by federal and state law to assure that certain health care providers (e.g., physicians, dentists, podiatrists, physician assistants, nurse practitioners) undergo a robust clinical and economic credentialing process to verify licensure, character and competence to practice medicine and receive reimbursement.²⁹⁵ Such processes typically take months to complete. Waivers of these laws coupled with organizations' expedited credentialing processes permit

²⁹¹ James G. Hodge, Jr., Dan Hanfling, and Tia P. Powell, *Practical, Ethical, and Legal Challenges underlying Crisis Standards of Care*, J. L. MED. & ETHICS, Spring 2012, at 51 citing Institute of Medicine, Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response (2012).

²⁹² Health care services providers include physicians, physician assistants, registered nurses, licensed practical nurses, and nurse practitioners, whose scope of practice is defined under New York State Education Law §§ 6524, 6542, 6905, 6906, and 6902, respectively.

²⁹³ See N.Y. ED. LAW §§ 6530 and 6509 (defining "professional misconduct" with respect to licensed health care services providers); (See also Chapter on Business Contracts, Insurance and Risk Management for additional discussion.).

²⁹⁴ See EXECUTIVE ORDER 202.5, Continuing Temporary Suspension and Modification of Laws Relating to the Disaster Emergency, Mar. 18, 2020. https://www.governor.ny.gov/news/no-2025-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency (accessed Apr. 16, 2020).

²⁹⁵ 42 CFR § 482.22; PuB. H. LAW §§ 2805-j and 2805-k; 10 NYCRR 405.4, 405.5, 405.14, 405.19, and 405.22.

health care organizations to honor the credentialing processes of other health care institutions outside their jurisdictions or within the same health care system to facilitate the swift interjurisdictional movement of health care services workers to meet public health needs in a crisis and avoid unnecessary delays due to lengthy credentialing processes. The Centers for Medicare and Medicaid appropriately waived some applicable Conditions of Participation processes to allow for physicians whose privileges will expire to continue to practice and for new physicians to be able to practice before full medical staff/governing body review required by credentialing processes. Likewise, Governor Cuomo's EO 202.5 waives New York state laws requiring a robust credentialing process to permit hospital staff who are privileged and credentialed to work in a hospital or health care facility in any other state to practice in a hospital or health care facility in New York State. To further protect licensed health care providers from individual liability, many health care organizations and facilities are adopting disaster privileging policies to complement their existing medical staff disaster privileging processes established by their medical staff bylaws to address corresponding risk associated with such waivers.²⁹⁶

Scope of Practice Principles

The scope of practice for each type of health care services worker is governed by the New York State Education Law. 297 Licensed and registered practitioners are not permitted to practice outside their respective statutory and regulatory scope of practice. The Nurse Practice Act limits registered nurses' ability to practice independently outside the scope of physician-ordered treatment regimen or other pre-approved clinical protocols.²⁹⁸ The scope of practice of certain licensed health care practitioners working in health care institutions and facilities is further defined by their respective delineation of clinical privileges. Allied health professionals, such as physician assistants, although permitted to diagnose, treat and prescribe independently, may not practice outside the scope of practice of their respective supervising physician who is required to provide certain oversight.²⁹⁹ The incremental expansion of clinical staff, establishment of stand-by pools and intra-system cross coverage arrangements may require licensed practitioners to be assigned administrative and/or clinical duties and responsibilities beyond their regulatory or contractual scope of services. Credentialed providers that typically provide elective medical care may be re-deployed to provide services beyond their delineation of privileges as Executive Orders "pause" elective and other non-essential health care services. EOs issued by Governor Cuomo in New York have waived certain limitations on scope of practice. For instance, EO 202.10 waived oversight requirements allowing physician assistants and advanced practice registered nurses with certain higher educational degrees to practice without otherwise necessary physician oversight during the public health crisis.³⁰⁰ The relaxation of these oversight requirements makes it easier to reallocate essential providers as needs eb and flow during the crisis.

Education and Training to Crisis Standards of Care

During a public health emergency such as the coronavirus pandemic, as the standard of care shifts from traditional patient-centric standards to crisis standards of care, health care services workers must be educated and trained on the medical-legal implications of CSC. Consistent application of CSC is essential to give assurances to health care services providers who will be asked to exercise their professional clinical judgment to save as many lives as possible, sometimes to the detriment of individual patients where

²⁹⁶ See also discussion pertaining to negligent credentialing, *infra*, Section IV, Business Contracts, Insurance and Risk Management.

²⁹⁷ N.Y. ED. LAW, Title VIII.

²⁹⁸ See N.Y. ED. LAW § 6905 (requirements to qualify for a license as a registered professional nurse).

²⁹⁹ See N.Y. Ed. Law §§ 6540-6548; N.Y. Pub. H. Law §§ 3700-3704; 10 NYCRR 94.2 (relating to the licensure and scope of duties of physician assistants).

³⁰⁰ See Executive Order 202.10, "Continuing Suspension and Modification of Laws Relating to the Disaster Emergency." 23 Mar. 2020. https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency (last accessed Apr. 16, 2020).

practitioners are taught "first, do no harm." As the standard of care shifts, practitioners need to be assured that their decisions pertaining to triage, allocation of medical equipment, supplies and medications are consistent with generally accepted CSC adopted during a crisis. CSC will further require general practitioners, not often trained in palliative care, to offer palliative care interventions to manage symptoms and mitigate suffering in the face of shortages of vital health care equipment such as ventilators.

Employees' Rights

Even in the face of a pandemic, employees rights must be balanced with those of the public health needs. The safety of society's workforce is vital to the public's health. Mandatory shelter-in-place and work from home policies are designed to keep non-essential employees and perhaps the most vulnerable workers out of harm's way during the public health emergency. Essential workers that must report to work to assure essential resources, services and goods remain available and accessible are being asked to put their own health and welfare at risk for the greater public good. Employers must assure that they implement enforceable pervasive safety measures to effectively protect their employees on the front lines. The Occupational Safety and Health Administration ("OSHA") and the Centers for Disease Control and Prevention ("CDC") have issued guidance for employers to their employees remain safe in the workplace during the current coronavirus pandemic. These measures are guidance only and do not necessarily have the effect of law. Notwithstanding, general OSHA requirements to provide a safe workplace remain in full force and effect. Governor Cuomo's EO 202.16 similarly requires all essential business employers to provide masks to employees in the workplace who have direct contact with customers or the general public. Such directive is enforceable by local governments or law enforcement pursuant to Public Health Law, section 12 or 12-b.

Safe Workplace

As essential businesses continue to operate in the face of a public health crisis, employers must continue to assure a safe workplace for their employees. The most relevant OSHA requirements applicable to the prevention of occupational exposure to COVID-19 are as follows:

- The General Duty Clause requires employers to furnish to each worker "employment and a place of employment, which are free from recognized hazards that are causing or are likely to cause death or serious physical harm." COVID-19 presents a threat where persons gather together. Employers need to assure adequate social distancing in the workplace as essential workers interact with each other, customers and the general public. Meetings should be conducted virtually using appropriate video/audio conferencing mechanisms when available or in large conference rooms that permit adequate distance between and among attendees.
- OSHA's Personal Protective Equipment (PPE) standards for general industry require employees to
 "use gloves, eye and face protection, and respirators when necessary. When respirators are
 necessary, employers must implement a comprehensive respiratory protection program in
 accordance with the Respiratory Protection standard."³⁰³
- OSHA's Bloodborne Pathogens standard applies to "occupational exposure to human blood and other potentially infectious materials that typically do not include respiratory secretions." ³⁰⁴ However, they offer guidance for the control of infectious disease such as COVID-19.

³⁰¹ See discussion in Ethics Issues in the Management of COVID-19, infra.

³⁰² Occupational Safety and Health (OSH) Act of 1970, 29 USC 654(a)(1).

^{303 29} CFR 1910.134.

³⁰⁴ 29 CFR 1910.1030.

Compliance with these standards can prove to be difficult during a public health emergency such as the coronavirus pandemic due to scarce resources such as hand sanitizer, masks and other cleansing products. The health care services workforce is accustomed to using universal precautions which are the set of infection control practices used for all patient care to protect healthcare workers from infection and prevent the spread of infection from patient to patient. Universal precautions include proper hand hygiene, use of PPE, respiratory hygiene including cough etiquette principles, proper cleaning and disinfecting the environment, equipment, devices and laundry. Non-health care essential services workers are not necessarily educated, trained or otherwise familiar with such extensive precautions. As a result, essential workers outside the health industry and their respective constituents may be faced with unnecessary risk of exposure or general fear despite good faith efforts to adopt applicable precautions.

Despite good faith efforts of employers of health care services employees and other essential services employees to educate their workforce on the implementation of CSC and the use of appropriate PPE consistent with CDC and OSHA guidance, there are members of the essential workforce that fear coming to work or interacting with customers or the public during the coronavirus pandemic. Do essential business employees and essential health care services employees have a right to choose to stay home and/or selfquarantine or refuse to provide health care to patients who have not been tested for the virus? If so, under what circumstances do or should they have that right?³⁰⁶ Such tension between employees' rights and their role in assuring essential goods and services remain available and accessible during the public health crisis inevitably arise. Employers engaged in providing essential goods and services to the public in times of such public health crises must be prepared to have an abundance of PPE available and examine their operational processes to minimize risk to their workforce and demonstrate genuine concern for their welfare such as limiting the number of employees within the workplace, hypervigilant efforts to keep surfaces clean and disinfected, social distancing protocols when dealing with co-workers and constituents, and temperature checks to assure the workforce remains symptom-free while on at the worksite. In addition, employers may consider offering incentives to come to work such as hazard pay and alternative housing to protect families of health care services workers who may be putting their families at risk if they return home.

Protection against Retaliation

Health care services workers are keenly aware of the need for adequate PPE and other operational adjustments necessary to minimize unnecessary employee exposure during the coronavirus pandemic. In the event of a shortage of PPE, given the prevalence of social media communications, employers should be careful not to curtail employees' rights to free speech as employees voice concerns over equipment shortages and other weaknesses in our societal response to the pandemic. Health care services workers are accustomed to reporting their concerns as part of continuous performance improvement programs as mandated by New York State laws.³⁰⁷ Employers must be receptive to employees' concerns, especially in times of crisis to demonstrate the mutual care and concern for those individuals who are putting their own safety at risk to care for the public's health. The Public Health Law affords confidentiality and immunity for those who report and/or participate in any investigation of an incident or other concerns.³⁰⁸ Similarly, OSHA prohibits employers from retaliating against workers for raising concerns about safety and health conditions.³⁰⁹ Additionally, "OSHA's Whistleblower Protection Program enforces the provisions of more

³⁰⁵ Standard Precautions for All Patient Care, CDC, Jan. 26, 2016, https://www.cdc.gov/infection.control/basics/standard-precautions.html.

³⁰⁶ Health care providers treating patients in hospitals or other places of public accommodation where there is adequate availability of PPE must be cognizant of their risk of violating federal and state anti-discrimination laws and licensure requirements not to abandon patients when refusing to treat patients, especially those patients requiring emergency care and treatment for conditions other than COVID-19. *See* chapter discussing Contracts, Liability and Risk Management.

³⁰⁷ See N.Y. Pub. H. Law § 2805-1.

³⁰⁸ See N.Y. Pub. H. Law § 2805-m.

³⁰⁹ Occupational Safety and Health Act of 1970, 29 USC 660(c).

than 20 industry-specific federal laws protecting employees from retaliation for raising or reporting concerns about hazards or violations."³¹⁰

Discrimination

The Americans with Disabilities Act of 1990 ("ADA")³¹¹ is a civil rights law that prohibits discrimination based upon disability. Among other provisions, it prohibits employers from making disability-related inquiries and requiring medical examinations of employees, except under limited circumstances. A "medical examination" is a procedure or test that seeks information about an individual's physical or mental impairment or health.³¹² Whether a procedure is a medical examination under the ADA is determined by considering factors such as whether the procedure or test involves the use of medical equipment; whether it is invasive; whether it is designed to reveal the existence of a physical or mental impairment; and whether is it given or interpreted by a medical professional. During employment, the ADA prohibits employee disability-related inquiries or medical examinations unless they are job-related and consistent with business necessity where an employer has a reasonable belief, based upon objective evidence, that an employee will pose a direct threat due to a medical condition. Objective evidence under CSC principles would require that public health authorities set forth those objective parameters for such employee testing to assure a safe work environment for all workers. For instance, health care workers may be required by their employers to submit to a temperature check prior to entering the workplace to assure they do not present a direct threat to patients and staff.³¹³ "Direct Threat" is an important concept during the COVID-19 pandemic where individual's rights often cede to that of the public's health. During a pandemic, employers should rely on the latest CDC and state or local public health standards. While the EEOC recognizes that public health recommendations may change during a crisis and differ between states, employers are expected to make their best efforts to obtain public health advice that is contemporaneous and appropriate for their location, and to make reasonable assessments of conditions in their workplace based on this information.³¹⁴

Further, employers should be mindful of their obligation to assess on a case by case basis employees' requests for leave as a reasonable accommodation under the ADA. Employees suffering from certain medical conditions may have a legitimate basis to support a request for leave or an extension of leave until the risk(s) associated with COVID-19 subsides. Employers who neglect to conduct such case by case analyses may risk exposure to allegations of unlawful discrimination or wrongful termination and the protracted litigation that may ensue long after the crisis abates.³¹⁵

VI. Vaccination

When a vaccine becomes available, there will be a majority of Americans who want the vaccination.³¹⁶ However, some Americans may push back on the COVID-19 vaccination for religious, philosophical or personal reasons.³¹⁷ Nonetheless, for the sake of public health, mandatory vaccinations for COVID-19 should be required in the United States as soon as it is available. Mandatory vaccinations are supported by

³¹⁰ Occupational Health & Safety Administration, Safety and Health Topics/COVID-19, U.S. DEP'T OF LABOR, http://www.osha.gov/SLTC/COVID-19/standards.html.

³¹¹ 42 USC § 12101 et. Seq.

³¹² 42 USC § 12112 (d).

 $^{^{313}}$ Id

³¹⁴ See Guidance of the CDC and public health authorities as of March 2020, the COVID-19 pandemic meets the direct threat standard, http://www.eeoc.gov/facts/pandemic flu.html.

³¹⁵ See Arnold v. Pfizer, Inc., 970 F.Supp.2d 1106, Oregon Dist. Ct. (Sept. 9, 2013).

³¹⁶ CENTERS FOR DISEASE CONTROL AND PREVENTION, *National Center for Health Statistics: Immunization* (2018) https://www.cdc.gov/nchs/fastats/immunize.htm (70.4% of children aged 19-35 months receiving all 7 major vaccines).
317 *Prince v. Massachusetts*, 321 U.S. 158, 167 (1944); *Cruzan by Cruzan v. Director Missouri Dept. of Health*, 497 U.S. 261, 262 (1990); *Phillips v. City of New York*, 775 F.3d 538, 542 (2d. Cir. 2015); *Caviezel v. Great Neck Public Schools*, 739 F.Supp.2d 273, 274-75 (E.D.N.Y. 2010) (*affin'd by Caviezel v. Great Neck Public Schools* 500 Fed.Appx. 16 (2d Cir. 2012).

the authority of the state police power when the vaccinations are necessary to protect the health of the community. The Constitutional challenges under the religious freedom clause under the First Amendment and under the substantive due process clause of the Fourteenth Amendment have failed, when the individual interests are not strong enough to outweigh the public benefit. The strong enough to outweigh the public benefit.

In New York State, the courts have found that religious, personal or "unsupported...medical literature" arguments persuasive. ³²¹ Healthcare workers ³²² and parents of unvaccinated children ³²³ have unsuccessfully challenged compulsory vaccination on administrative law grounds – questioning the NYS and NYC Department of Health's authority in mandating flu and measles vaccinations, as well as challenging the regulations as arbitrary and capricious. The courts found the policies mandating that healthcare workers be vaccinated for influenza, and children vaccinated for measles during an outbreak, were not arbitrary and capricious and the regulations were promulgated under proper authority. ³²⁴ Further, on June 13, 2019, the religious exemption for vaccinating school-attending children was repealed. ³²⁵ The gravity of COVID-19 presents compelling justification for State legislatures and Congress to mandate a COVID-19 vaccination.

The U.S. Department of Health and Human Services developed the National Vaccine Program, to assist with vaccination production, distribution and education.³²⁶ It also annually issues a National Vaccine Plan.³²⁷ The National Vaccine Program addressed the development of a COVID-19 vaccine in its February 2020 meeting.³²⁸

Before the COVID-19 outbreak, a bill was introduced to federally mandate vaccination for school children.³²⁹ Since the COVID-19 outbreak began, additional bills and resolutions have been introduced by

³²⁷ 42 U.S.C. §300aa-1 (2020). U.S. Dept. of Health & Human Services National Vaccine Program, The National Vaccine Program Office Mid-Course Review of the 2010 National Vaccine Plan, https://www.hhs.gov/sites/default/files/nvpo-midcourse-review-final.pdf.

³¹⁸ See generally Jacobson v. Massachusetts, 197 U.S. 11 (1905).

³¹⁹ See Cruzan by Cruzan, 497 U.S. at 278 (citing Jacobson, 197 U.S. at 24-30). Prince, 321 U.S. at 167. Phillips, 775 F.3d at 542. Cavizel, 739 F.Supp.2d at 274-75.

³²⁰ C.F. v. New York City Dept. of Health and Mental Hygiene, 2019 NY Slip Op. 31047, at 4-6 (Apr. 18, 2019) (administrative ruling) (NYC Dept. of Health and Mental Hygiene regulation requiring any person who lives or works in "designated zip codes" to be vaccinate for MMR (measles)).

³²¹ See Cruzan by Cruzan, 497 U.S. at 262. Prince, 321 U.S. at 167. Phillips, 775 F.3d at 542. Cavizel, 739 F.Supp.2d at 274-75. C.F., 2019 NY Slip. Op. 31047, at 4-6.

³²² Spence v. Shah, 136 A.D.3d 1242, 1246 (App. Div. 3d 2016) (NYS Department of Health did not exceed their power and the regulation requiring healthcare workers to receive an influenza vaccination or wear a face mask was not "arbitrary, capricious, irrational or contrary to law").

³²³ Garcia v. New York City Dept. of Health and Mental Hygiene, 31 N.Y.3d 601, 621 (N.Y. 2018) (NYC Dept. of Health and Mental Hygiene was acting "...pursuant to its legislatively-delegated and long-exercised authority to regulate vaccinations" of children for influenza).

³²⁴ See Garcia, 31 N.Y.3d at 621, Spence, 136 A.D.3d at 1246, C.F., 2019 NY Slip. Op. 31047, at 4-6.

³²⁵ PUB. H. LAW § 2164(9) (repealed June 13, 2019).

³²⁶ 42 U.S.C. §300aa-1 (2020).

³²⁸ U.S. Dept. of Health & Human Services National Vaccine Program, *February 13-14, 2020 NVAC Meeting, Agenda* https://www.hhs.gov/vaccines/nvac/meetings/2020/02-13/index.html (in the 1:15pm slot, Dr. Alan Embry presented the Coronavirus Vaccine Development: Opportunities and Potential Pitfalls https://www.hhs.gov/sites/default/files/nvac_feb2020_day1_panel2.pdf).

³²⁹ Recognizing the importance of vaccinations and immunizations in the United States, H.Res.179, 116th Cong. (introduced by Rep. Adam Schiff on Mar. 5, 2019). A resolution recognizing the importance of vaccinations and immunizations in the United States, S.Res.165, 116th Cong. (agreed to in the Senate on Apr. 11, 2019). Vaccinate All Children Act of 2019, H.R. 2527, 116th Cong. (introduced on May 3, 2019 by Rep. Frederica Wilson). VACCINES Act of 2019, H.R.2862, 116th Cong. (introduced by Rep. Kim Schrier on May 21, 2019). Vaccine Awareness Campaign to Champion Immunization Nationally and Enhance Safety Act of 2019, S.1619, 116th Cong. (introduced by Sen. Gary C. Peters on May 22, 2019). Protecting Seniors Through Immunization Act of 2019, S.1872, 116th Cong. (introduced by Sen. Mazie K. Hirono on Jun. 13, 2019). Pandemic

the 116th Congress regarding vaccination and immunization.³³⁰ They include resolutions by the House and Senate, supporting the GAVI Alliance, which supports vaccines and immunizations in developing countries.³³¹

Some of the remaining pending federal bills and resolutions provide immediate insurance coverage for treatment of COVID-19, including a vaccination when one becomes available.³³² Others support widespread vaccination across the United States.³³³ These include bills offering wide-spread vaccination programs that are subsidized by the federal government for seniors and children.³³⁴ In the "Protecting Seniors Through Immunization Act of 2019," the Medicare program will encourage and provide free vaccinations to seniors already covered.³³⁵ The "Vaccinate All Children Act of 2019" will require vaccinations for every student at a public elementary and secondary school to be vaccinated in order to receive federal grants, with only medical exemptions allowed.³³⁶ Given these proposals, vaccination distribution and funding will likely be heavily influenced by Congress.

and All-Hazards Preparedness and Advanci

and All-Hazards Preparedness and Advancing Innovation Act of 2019, S.1379, 116th Cong. (became law on June 24, 2019 as Public Law 116-22). Supporting Older Americans Act of 2020, H.R.4334, 116th Cong. (introduced by Rep. Suzanne Bonamici on Sept. 16, 2019). Protecting Seniors Through Immunization Act of 2019, H.R. 5076, 116th Cong. (introduced by Rep. Donna Shalala on Nov. 13, 2019).

³³⁰ See, e.g., Take Responsibility for Workers and Families Act, H.R. 6379, 116th Cong. (introduced Mar. 23, 2020 by Rep. Nita Lowey). Ensuring Coverage in Public Health Emergencies Act of 2020, H.R. 6317, 116th Cong. (introduced by Rep. Lloyd Doggett on Mar. 23, 2020). Ensuring Treatment for Covid Act, S.3564, 116th Cong. (introduced by Sen. Robert P. Casey, Jr. on Mar 22, 2020). Care for COVID-19 Act, H.R.6311, 116th Cong. (introduced by Rep. Raul Ruiz on Mar. 19, 2020). Rapid Coverage of COVID-19 Vaccine Act of 2020, H.R. 6299, 116th Cong. (introduced Mar. 19, 2020 by Rep. Joe Courtney). Ensuring Coverage in Public Health Emergencies Act of 2020, S.3536, 116th Cong. (introduced by Sen. Robert P. Casey, Jr. on Mar. 19, 2020). Rapid Coverage for Coronavirus Vaccines Act, S.3505, 116th Cong. (introduced by Sen. Doug Jones on Mar. 17, 2020). Ensuring Access to COVID-19 Preventive Care Act of 2020, H.R. 6231, 116th Cong. (introduced by Rep. Larry Bucshon on Mar. 12, 2020). Ensuring Affordable COVID-19 Preventive Care Act of 2020, H.R. 6222, 116th Cong. (introduced by Rep. Janice Schakowsky on Mar. 12, 2020). Care for COVID-19 Act, S.3442, 116th Cong. (introduced by Sen. Cory A. Booker on Mar. 11, 2020). Coronavirus Vaccine Act, S.3370, 116th Cong. (introduced by Sen. Edward Markey on Mar. 2, 2020). Protecting Americans from Seasonal Influenza Act of 2020, H.R.5729, 116th Cong. (introduced by Rep. Rick Larsen on Jan. 30, 2020).

³³¹ A resolution supporting the role of the United States in helping save the lives of children and protecting the health of people in developing countries with vaccines and immunization through GAVI, the Vaccine Alliance, S.Res.511, 116th Cong. (introduced by Sen. Marco Rubio on Feb. 27, 2020). Supporting the role of the United States in helping save the lives of children and protecting the health of people in poor countries with vaccines and immunization through the GAVI Alliance, H.Res.861, 116th Cong. (introduced by Rep. Betty McCollum on Feb. 21, 2020).

³³² Ensuring Coverage in Public Health Emergencies Act of 2020, H.R. 6317, 116th Cong. (introduced by Rep. Lloyd Doggett on Mar. 23, 2020). Ensuring Treatment for Covid Act, S.3564, 116th Cong. (introduced by Sen. Robert P. Casey, Jr. on Mar 22, 2020). Care for COVID-19 Act, H.R.6311, 116th Cong. (introduced by Rep. Raul Ruiz on Mar. 19, 2020). Ensuring Coverage in Public Health Emergencies Act of 2020, S.3536, 116th Cong. (introduced by Sen. Robert P. Casey, Jr. on Mar. 19, 2020). Rapid Coverage of COVID-19 Vaccine Act of 2020, H.R. 6299, 116th Cong. (introduced Mar. 19, 2020 by Rep. Joe Courtney). Rapid Coverage for Coronavirus Vaccines Act, S.3505, 116th Cong. (introduced by Sen. Doug Jones on Mar. 17, 2020). Ensuring Affordable COVID-19 Preventive Care Act of 2020, H.R. 6222, 116th Cong. (introduced by Rep. Janice Schakowsky on Mar. 12, 2020). Ensuring Access to COVID-19 Preventive Care Act of 2020, H.R. 6231, 116th Cong. (introduced by Rep. Larry Bucshon on Mar. 12, 2020). Care for COVID-19 Act, S.3442, 116th Cong. (introduced by Sen. Cory A. Booker on Mar. 11, 2020).

³³³ Recognizing the importance of vaccinations and immunizations in the United States, H.Res.179, 116th Cong. (introduced by Rep. Adam Schiff on Mar. 5, 2019). A resolution recognizing the importance of vaccinations and immunizations in the United States, S.Res.165, 116th Cong. (agreed to in the Senate on Apr. 11, 2019).

³³⁴ Vaccinate All Children Act of 2019, H.R. 2527, 116th Cong. (introduced on May 3, 2019 by Rep. Frederica Wilson). Protecting Seniors Through Immunization Act of 2019, S.1872, 116th Cong. (introduced by Sen. Mazie K. Hirono on Jun. 13, 2019). Protecting Seniors Through Immunization Act of 2019, H.R. 5076, 116th Cong. (introduced by Rep. Donna Shalala on Nov. 13, 2019).

³³⁵ Protecting Seniors Through Immunization Act of 2019, S.1872, 116th Cong. (introduced by Sen. Mazie K. Hirono on Jun. 13, 2019). Protecting Seniors Through Immunization Act of 2019, H.R. 5076, 116th Cong. (introduced by Rep. Donna Shalala on Nov. 13, 2019).

³³⁶ Vaccinate All Children Act of 2019, H.R. 2527, 116th Cong. (introduced on May 3, 2019 by Rep. Frederica Wilson).

The devasting impact of COVID-19 has led to the call for solutions that will help return our society to normalcy, elevating the importance of ensuring scientists and legislators move cautiously but quickly to provide vaccines and treatments. The history of unsuccessful attempts to challenge mandatory vaccinations may reduce the extent of opposition. As Hastings Center scholars have said, to avoid, "COVID-19 interventions [joining] the list of others that entered the clinic on the basis of limited or contested evidence of effectiveness and then harmed patients or proved to be ineffective[, strategies] can be developed to minimize this from happening, but they will only work with commitment from scientists, physicians, policymakers, patients, and the general public." Deliberate, reasoned attention to such strategies is imperative.

VII. Vulnerable Populations and Issues of Equity and Discrimination: A Call for Social Justice

An often overlooked set of legal and ethical issues in the context of the COVID-19 crisis and crisis conditions concerns the impact of the crisis on vulnerable populations, especially with respect to the heightened precarity of such populations as a result of the present crisis and the serious threats the crisis poses to health and mental health, well-being, and post-crisis recovery and resilience.

The public health law perspective is well suited to the examination of issues of equity across diverse populations and communities in New York during the crisis, assessing the responsiveness of the law to the needs of all persons and communities across settings, including communities of color, vulnerable persons such as older adults and persons with disabilities, and all those who are isolated, home-bound or living in residential, correctional or detention facility settings, as well as vulnerable health care workers in underresourced communities.

As framed in Part I of the report, public health law effects a shift from person-centered clinical care to community and population health, and the social and economic determinants of health, such as education, neighborhood, income, race and ethnicity, food insecurity, and access to health and mental health services.

COVID-19 has tragically resulted in the heightening of precarity among those who are already vulnerable and marginalized, such as older persons, members of communities of color or low-income communities, inmates, immigrants, nursing home and assisted living facility residents, persons who are homeless, persons with disabilities, and rural-dwelling community members. Health disparities across these groups, including among health care workers who are members of such groups, are well documented.³³⁸ Data reported during the current crisis document higher numbers of COVID-19 positive cases and higher mortality rates among Black/African Americans and other marginalized and socioeconomically disadvantaged groups.³³⁹ New York City Department of Health data show rates of cases, hospitalizations and deaths by race/ethnicity group, reflecting stark disparities across Black/African American, Hispanic/Latino, White and Asian

³³⁷ Karen J. Maschke & Michael K. Gusmano, *Ethics and Evidence in the Search for a Vaccine and Treatments for COVID-19*, The Hastings Center, Bioethics Forum (April 16, 2020), https://www.thehastingscenter.org/ethics-and-evidence-in-the-search-for-a-vaccine-and-treatments-for-COVID-19/.

³³⁸ Aaron van Dorn, Rebecca E. Cooney & Mariam L. Sabin, COVID-19 exacerbating inequalities in the US, 395.

³³⁹ *Id.*; COVID-19 exacerbating inequalities in the US, LANCET, Vol. 395, April 18, 2020; Yancy CW, COVID-19 and African Americans, JAMA, Published online April 15, 2020, doi:10.1001/jama.2020.6548.

groups,³⁴⁰ as well as across the five boroughs.³⁴¹ Crisis conditions of scarce resources, such as PPE, dialysis machines, and ventilators, also heighten the precarity of vulnerable individuals who are more likely to have advanced illness, and therefore less likely to access life-saving measures based on certain crisis standard of care plans that use allocation criteria risking discrimination. ³⁴² While federal law bars such discrimination, ³⁴³ forms of persistent discrimination and racism that remain embedded in our social structures, and less visible in non-emergency circumstances, are more prominently foregrounded in the crisis conditions of the COVID-19 emergency.

Health Care Workers and Essential Services

Strategic initiatives and efforts are desperately needed, in addition to increased access to protective equipment and testing to protect immuno-compromised or otherwise high-risk populations who work on the front lines. Statistically, a disproportionate number of older, minority and immigrant populations with limited access to quality health care work in low-paying front-line jobs deemed "essential" in the midst of the crisis, including direct service workers.³⁴⁴ As we plan to reopen the economy, we must consider a way to protect individuals on the front lines identified by health care providers as very high-risk individuals based on their health status and underlying health conditions in the interest of the health of the individual, public health as a state and local community, and mitigating fatalities nationally.

We are confronted too with the social and ethical problem of access to health care and education for some of our most vulnerable populations, such as individuals with disabilities, especially as related to direct care services. The Office for People with Disabilities (OPWDD) has issued guidance stating that Direct Support Professionals (DSPs) are "essential and integral employees to OPWDD's provision of services" which is "especially true during this public health emergency," which echoes that of the New York State Department of Education. The Department further clarified that agencies which provide services to individuals with developmental disabilities and are operated, certified, authorized or funded by OPWDD are exempt and "should remain in operation to the extent necessary to provide those services." The failure to do such could potentially result in the suspension or limitation of a provider's operating certificate. However, some patients and students who receive therapies in their homes and schools are not receiving such critical direct care services, despite them being prescribed by a physician and covered by health insurance. Moreover, the temporary expansion of Title 1 of the Family and Medical Leave Act (FMLA)³⁴⁹ and adoption of "The Emergency Paid Sick Leave Act" under The Families First Coronavirus

³⁴⁰ Age-adjusted rates of lab confirmed COVID-19 nonhospitalized cases, estimated non-fatal hospitalized cases, and patients known to have died 100,000 by race/ethnicity group as of April16, 2020,

https://www1.nyc.gov/assets/doh/downloads/pdf/imm/COVID-19-deaths-race-ethnicity-04162020-1.pdf.

³⁴¹ NEW YORK CITY DEPARTMENT OF HEALTH, Rates by Borough of positive cases per 100,000 people in each borough, https://www1.nyc.gov/site/doh/Covid/COVID-19-data.page#download,

³⁴² Ari Ne'eman & Sam Bagenstos, Evaluation Framework for Crisis Standard of Care Plans, Apr. 8, 2020, http://thearc.org/wp-content/uploads/2020/04/Evaluation-framework-for-crisis-standards-of-care-plans-4.9.20-final_4-14-20.pdf.

³⁴³ 42 U.S.C. §§ 2000 et. seq.; HHS Office for Civil Rights in Action, Bulletin: Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19), (Mar. 28, 2020), https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf.

³⁴⁴ NEW YORK STATE OFFICE FOR PEOPLE WITH DEVELOPMENTAL DISABILITIES, *Direct Support Professionals Defined As Essential Employees* (Mar. 18, 2020). *See also* Dorn, *supra* note 1.

³⁴⁵ NEW YORK STATE OFFICE FOR PEOPLE WITH DEVELOPMENTAL DISABILITIES, *supra* note 4.

³⁴⁶ THE STATE EDUCATION DEPARTMENT, Additional Guidance on Statewide School Closures Due to Novel Coronavirus (COVID-19) Outbreak in New York State (Mar. 17, 2020).

³⁴⁷ NEW YORK STATE OFFICE FOR PEOPLE WITH DEVELOPMENTAL DISABILITIES, *COVID-19 Guidance for Providers on Essential Business* (Mar. 20, 2020).

³⁴⁸ NEW YORK STATE, Exec. Order 202.5 (Mar. 18, 2020).

³⁴⁹ 29 U.S.C. § 2601 et. seq.

Response Act³⁵⁰, do not provide relief for families who must care for vulnerable adult children who are unable to attend adult day care facilities due to government shut-downs.

Thus, anecdotal evidence suggests lack of uniformity in access to services, such as therapeutic interventions for individuals with autism, in response to the implementation of "New York State on Pause," enacted by Governor Cuomo, which are designed to minimize the transmission of the COVID-19 virus through social distancing and business closures.³⁵¹ Some providers may be unsure as to whether the OPWDD exemption applies to them, especially if the provider serves the disabled community but is not a licensed OPWDD provider, while others may opt to not provide services in light of the pandemic. Whichever is the case, interruption of such services for even short periods of time, let alone the duration of the pandemic's "PAUSE" period, significantly increases the risk of adverse outcomes when such services are necessary to maintain physiological and emotional stability, while facilitating health and social progress.³⁵²

The scope of this issue is expansive as it also impacts our young and adult patients and minor students residing in schools for the developmentally disabled or other TBI programs where they would otherwise receive physical and occupational therapy, and other services essential to their unique physical and mental needs. Considering this, it is imperative that any clarification necessary to ensure that exempt providers are operating in accordance with OPWDD guidance be published. Furthermore, providers not regulated by the OPWDD, but are otherwise exempt, should be advised to continue to serve any patients with which a treatment relationship has been established, if able, or refer the patient elsewhere to prevent patient abandonment.³⁵³ This is critical from not only a professional but ethical standpoint, and in the best interest of public health.

Action Steps

In sum, the COVID-19 crisis has illuminated the social structural inequities in the health systems and put the most vulnerable populations and communities of color, including vulnerable health care workers, at the highest risk. The Task Force urges action steps, including appropriate regulatory oversight, to assure:

- adequate and non-discriminatory allocation of resources to vulnerable populations and communities of color;
- equitable access of vulnerable populations to health and mental health services, including palliative care as an ethical minimum to mitigate suffering among those vulnerable persons who remain in residence or institutionalized in nursing homes, assisted or independent living facilities or group homes, or are hospitalized during the COVID-19 crisis, especially when desired equipment or other resources are not available;
- provision of PPE to essential health care workers at highest risk in delivering essential services to vulnerable populations; and
- monitoring conformity with federal laws barring discrimination.

³⁵⁰ Families First Coronavirus Response Act, Public Law No. 116-127 (Mar. 18, 2020) (*to be added as* 29 U.S.C. §§ 2601 *et. seg.*). Paid Leave Under the Families First Coronavirus Response Act, 85 Fed. Reg. 19,326 (Apr. 6, 2020).

³⁵¹ NEW YORK STATE, Exec. Order 202.8 (Mar. 20, 2020) https://www.governor.ny.gov/news/no-2028-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency. *See also* NEW YORK STATE, *Governor Cuomo Signs the 'New York State on PAUSE' Executive Order* (Mar. 20, 2020) https://www.governor.ny.gov/news/governor-cuomo-signs-new-york-state-pause-executive-order.

³⁵² See generally Mary Beth Walsh, The Top 10 Reasons Children With Autism Deserve ABA, 1 BEHAVIOR ANALYSIS PRACTICE 72-79 (2011).

³⁵³ See generally Valerie Blake, J.D., M.A., When Is a Patient-Physician Relationship Established?, AMERICAN MEDICAL ASSOCIATION JOURNAL OF ETHICS (May 2012).

We call for urgent attention to these issues both in the context of the current crisis, as well as through long-term health policy planning. In the words of our esteemed colleague and public health law scholar Lawrence O. Gostin, we must settle for no less than a fully unburdened, "global health with justice." 354

VIII. Conclusion

The preceding Sections of this Report contain a number of specific recommendations which may be found in summary form in Appendix F. The following observations present overarching recommendations to further strengthen both New York State's emergency preparedness capabilities and its general delivery of health care.

Improving Preparation for Next Public Health Emergency

COVID-19 has proven that city, state and federal emergency preparedness efforts, which were enhanced after 9/11, are insufficient for an extreme public health crisis. The Task Force recommends that Governor Cuomo keep a core team of experts in place to review the MSEHPA, the Columbia University Center for Health Policy Gap Analysis, ³⁵⁵ IOM's Crisis Standards of Care, as applicable, equipment allocation guidelines, ³⁵⁶ and each of the emergency orders needed to manage COVID-19. This team could be charged with drafting legislation to combine the essential provisions of these useful resources.

Legislation in New York, and other states which have not yet adopted the MSEHPA and the CSC, would facilitate the immediate activation of most if not all of the emergency orders which have been needed to manage COVID-19.

Further, Governor Cuomo will soon become the Chair of the National Governors Association.³⁵⁷ In that role, New York will be well placed to facilitate a coordination of efforts across the states. Effective state coordination will place each state in a position to be less vulnerable to inadequate federal action.

Evaluation of Laws and Regulations Post-Pandemic

For the purposes of assuring a post-pandemic legal environment that serves the public well, we also call for evaluation of the state and federal laws and regulations that have been waived during the pandemic. CMS has provided a convenient list of the federal and state COVID-19 waivers. In the post-COVID 19 world, both government and health care providers will face enormous financial pressure. Before being automatically reinstated, laws and regulations that were waived, should be critically re-evaluated in terms of benefit to the public, as well as the costs and administrative and enforcement burdens to government. For instance emergency waivers relating to EMTALA, HIPAA and 42 CFR Part 2, and federal fraud and abuse laws have elements that could be continued in the post-Covid world. At the New York State level, some scope of practice requirements, CON requirements and directives to managed care organizations should be reviewed before waivers and directives are lifted. In short, this emergency provides an opportunity to re-test waived regulations for new circumstances.

³⁵⁴ LAWRENCE O. GOSTIN, GLOBAL HEALTH LAW 72 (Har. Univ. Press 2014).

³⁵⁵ Benjamin Mason Meier & Jocelyn Getgen, *Gap Analysis: Comparing the Model State Emergency Health Powers Act with Corresponding New York State And New York City Statutory Authority*, CENTER FOR HEALTH POLICY, Columbia University (2008).

³⁵⁶ See discussion infra, Section II of this Report, Ethical Issues in the Management of COVID-19.

³⁵⁷ National Governors Association, Executive Committee, https://www.nga.org/governors/ngaleadership/.

³⁵⁸ CMS, CMS list of Coronavirus Waivers & Flexibilities, available at:

https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

It is evident through the progress in "flattening the curve" achieved to date that employers, employees, and community members at large in the State of New York are committed to working hard to maintain and ultimately re-strengthen our economy while keeping public health, safety and community values at the forefront of their efforts. If we continue to commit ourselves to pressing forward in a united fashion and reaching beyond the racial, socioeconomic, geographic and political barriers that often seek to divide us, our communities and the State of New York can not only heal but be transformed and strengthened in a fashion beyond our comprehension.

APPENDIX A

New '	York State	Bar Assoc	ciation Healt	th Law Sect	tion Letter to G	overnor Cuomo,	March 26.	2020

APPENDIX B
University of Rochester Medical Center Decision Algorithms (2015 NYSTFLL Guidelines)

APPENDIX C

Health Law Section Proxy Law Memo

TO: Howard Zucker, MD, Commissioner, NYSDOH

Megan Baldwin, Assistant Secretary, Executive Chamber

FROM: NYSBA Health Law Section

RE: Health Care Proxy Barriers and Solutions

The New York State Bar Association (NYSBA) Health Law Section was pleased to learn about Executive Order 202.14, which should make it much easier for most people to complete a health care proxy when two witnesses are not physically present. However, it is not enough to help the most vulnerable, those who have no one to witness or have only one person, or those who don't have access to, can not use, or cannot be taught to use technology.

Therefore, the NYSBA Health Law Section supports additional urgently needed reforms to ensure that people are able to complete valid health care proxies.

In the midst of the coronavirus pandemic, we have learned that many patients want to complete health care proxies, but cannot as there are no available witnesses given the social distancing and quarantine requirements. We have also heard from clinicians that many patients have no advance directives, especially as hospitals continue to become overwhelmed. There is little doubt that similar problems must exist in other facilities, such as nursing homes.

It is critically important that patients have the ability to complete health care proxies, but existing legal barriers will still prevent some people, despite EO 202.14, from doing so.

Urgent measures are needed, either legislatively or through Executive Order, to address this concern, including:

- Removing the two-witness requirement and requiring only one witness.
- If no witnesses are available, provide the option of requiring only a notary public signature.
- If a notary is used, allowing an audio-visual notarization as the Governor's Executive Order 202.7 now allows for other notary services.
- Allowing for individuals who do not have access to the technology which enables them to accomplish video conference witnessing, to have a valid health care proxy if the patient communicates auditorily to two witnesses the name of their health care agent and possible alternate(s). The communication to the witnesses does not need to be simultaneous, and can happen at separate times. Such witnesses' contact information shall be stated in the document and such witnesses shall be willing to confirm they heard the principal express their wishes if contacted by a health care facility.
- All the above would include the I/DD population, but required capacity determination should remain in effect.
- Accelerating the effective date regarding the amendments to PHL 29-CCC on physician assistants (currently June 17, 2020) regarding MOLST forms which it is possible, but unclear, that Executive Order 202.10 now does.

Implementing these measures will make it more likely that patients will get health care and treatment that they want and need, and make it easier for health care professionals to both know the health care wishes of their patients.

Others who are experts in the field, doctors, lawyers and organizations which work with people on advance care planning and specifically health care proxies, also support the urgent need for the reforms proposed. These include among others, those listed below.

Patricia A. Bomba, MD, MACP, FRCP Vice President & Medical Director, Geriatrics, Excellus BlueCross BlueShield Chair, MOLST Statewide Implementation Team MOLST & eMOLST Program Director Chair, National Healthcare Decisions Day NYS Coalition

Carla Braveman
President & CEO
Hospice and Palliative Care Association of New York State

Thomas V. Caprio, MD, MPH, MS Director, Finger Lakes Geriatric Education Center Chief Medical Officer, UR Medicine Home Care & Hospice University of Rochester Medical Center

CaringKind

Maggie Carpenter, MD, HMDC Nightingale Medical

Sarah Egan, MD Hospice and Palliative Medicine Brooklyn, NY

David N. Hoffman, Esq. Compliance Officer Carthage Area Hospital and Claxton-Hepburn Medical Center

Robert Milch, MD, FACS Professor, Clinical Surgery University at Buffalo Jacobs School of Medicine

New York Legal Assistance Group (NYLAG)

Volunteers of Legal Service

APPENDIX D

New York State Bar Association Department of Health Proposed Rulemaking in Relation to the Release of Subject-Identified Research Findings

APPENDIX E
State Society on Aging of New York Letter to Governor Cuomo, April 30, 2020

APPENDIX F

GUIDANCE FOR DETERMINING WHETHER A BUSINESS ENTERPRISE IS SUBJECT TO A WORKFORCE REDUCTION UNDER RECENT EXECUTIVE ORDERS (enacted to address the COVID-19 Outbreak)³⁵⁹

ESSENTIAL BUSINESSES OR ENTITIES, including any for-profit or non-profit, regardless of the nature of the service, the function they perform, or its corporate or entity structure, are not subject to the inperson restriction. *Essential Businesses must continue to comply with the guidance and directives for maintaining a clean and safe work environment issued by the Department of Health (DOH) and every business, even if essential, is strongly urged to maintain social distancing measures to the extent possible.*

This guidance is issued by the New York State Department of Economic Development d/b/a Empire State Development (ESD) and applies to each business location individually and is intended to assist businesses in determining whether they are an essential business. With respect to business or entities that operate or provide both essential and non-essential services, supplies or support, only those lines and/or business operations that are necessary to support the essential services, supplies, or support are exempt from the workforce reduction restrictions.

State and local governments, including municipalities, authorities, and school districts, are exempt from these essential business reductions, but are subject to other provisions that restrict non-essential, in-person workforce and other operations under Executive Order 202.

For purposes of Executive Order 202.6, "Essential Business," shall mean businesses operating in or as:

1. Essential health care operations including

- research and laboratory services
- hospitals
- walk-in-care health clinics and facilities
- emergency veterinary, livestock medical services
- senior/elder care
- medical wholesale and distribution
- home health care workers or aides for the elderly
- doctor and emergency dental
- nursing homes, residential health care facilities, or congregate care facilities
- medical supplies and equipment manufacturers and providers
- licensed mental health providers
- licensed substance abuse treatment providers
- medical billing support personnel
- emergency chiropractic services
- physical therapy, prescribed by medical professional
- occupational therapy, prescribed by medical professional

2. Essential infrastructure including

- public and private utilities including but not limited to power generation, fuel supply, and transmission
- public water and wastewater
- telecommunications and data centers
- airlines/airports

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³⁵⁹ Please note that the content below represents an abridged version of content noted on the following Empire State Development website, https://esd.ny.gov/guidance-executive-order-2026.

- commercial shipping vessels/ports and seaports
- transportation infrastructure such as bus, rail, for-hire vehicles, garages
- hotels, and other places of accommodation

3. Essential manufacturing including

- food processing, manufacturing agents including all foods and beverages
- chemicals
- medical equipment/instruments
- pharmaceuticals
- sanitary products including personal care products regulated by the Food and Drug Administration (FDA)
- telecommunications
- microelectronics/semi-conductor
- food-producing agriculture/farms
- household paper products
- defense industry and the transportation infrastructure
- automobiles
- any parts or components necessary for essential products that are referenced within this guidance

4. Essential retail including

- grocery stores including all food and beverage stores
- pharmacies
- convenience stores
- farmer's markets
- gas stations
- restaurants/bars (but only for take-out/delivery)
- hardware, appliance, and building material stores
- pet food
- telecommunications to service existing customers and accounts
- delivery for orders placed remotely via phone or online at non-essential retail establishments; provided, however, that only one employee is physically present at the business location to fulfill orders

5. Essential services including

- trash and recycling collection, processing, and disposal
- mail and shipping services
- laundromats and other clothing/fabric cleaning services
- building cleaning and maintenance
- childcare services
- bicycle repair
- auto repair
- automotive sales conducted remotely or electronically, with in-person vehicle return and delivery by appointment only
- warehouse/distribution and fulfillment
- funeral homes, crematoriums and cemeteries
- storage for essential businesses
- maintenance for the infrastructure of the facility or to maintain or safeguard materials or products therein
- animal shelters and animal care including dog walking, animal boarding

- landscaping, but only for maintenance or pest control and not cosmetic purposes
- designing, printing, publishing and signage companies to the extent that they support essential businesses or services
- remote instruction or streaming of classes from public or private schools or health/fitness centers; provided, however, that no in-person congregate classes are permitted

6. News media

7. Financial Institutions including

- banks or lending institution
- insurance
- payroll
- accounting
- services related to financial markets, except debt collection

8. Providers of basic necessities to economically disadvantaged populations including

- homeless shelters and congregate care facilities
- food banks
- human services providers whose function includes the direct care of patients in state-licensed or funded voluntary programs; the care, protection, custody and oversight of individuals both in the community and in state-licensed residential facilities; those operating community shelters and other critical human services agencies providing direct care or support

9. Construction

All non-essential construction must safely shut down, except emergency construction, (e.g. a project necessary to protect health and safety of the occupants, or to continue a project if it would be unsafe to allow to remain undone, but only to the point that it is safe to suspend work).

Essential construction may proceed, to the extent that:

- the construction is for, or your business supports, roads, bridges, transit facilities, utilities, hospitals or healthcare facilities, homeless shelters, or public or private schools;
- the construction is for affordable housing
- the construction is necessary to protect the health and safety of occupants of a structure;
- the construction is necessary to continue a project if allowing the project to remain undone would be unsafe, provided that the construction must be shut down when it is safe to do so;
- the construction is for projects in the energy industry
- the construction is for existing (i.e. currently underway) projects of an essential business; or
- the construction work is being completed by a single worker who is the sole employee/worker on the job site.

10. Defense

• defense and national security-related operations supporting the U.S. Government or a contractor to the US government

11. Essential services necessary to maintain the safety, sanitation and essential operations of residences or other businesses including

- law enforcement, including corrections and community supervision
- fire prevention and response
- building code enforcement
- security

- emergency management and response, EMS and 911 dispatch
- building cleaners or janitors
- general maintenance whether employed by the entity directly or a vendor
- automotive repair
- disinfection
- residential moving services

12. Vendors that provide essential services or products, including logistics and technology support, child care and services including but not limited to:

- logistics
- technology support for online services
- childcare programs and services
- government owned or leased buildings
- essential government services
- any personnel necessary for online or distance learning or classes delivered via remote means

13. Recreation

- Parks and other open public spaces, except playgrounds and other areas of congregation where social distancing cannot be abided
- However, golf courses are not essential and cannot have employees working on-premise; notwithstanding this restriction, essential services, such as groundskeeping to avoid hazardous conditions and security, provided by employees, contractors, or vendors are permitted and private operators may permit individuals access to the property so long as there are no gatherings of any kind and appropriate social distancing of six feet between individuals is strictly abided
- Marinas, boatyards, and recreational marine manufacturers, for ongoing marina operations and boat repair/maintenance, where such facilities adhere to strict social distancing and sanitization protocols. Use of such sites for the purposes of personal use or operation of boats or other watercraft is permissible, provided that no establishment offer chartered watercraft services or rentals. Restaurant activity at such sites are limited to take-out or delivery only.

14. Professional services with extensive restrictions

- Lawyers may continue to perform all work necessary for any service so long as it is performed remotely. Any in-person work presence shall be limited to work only in support of essential businesses or services; however, even work in support of an essential business or service should be conducted as remotely as possible.
- Real estate services shall be conducted remotely for all transactions, including but not limited to title searches, appraisals, permitting, inspections, and the recordation, legal, financial and other services necessary to complete a transfer of real property; provided, however, that any services and parts therein may be conducted in-person only to the extent legally necessary and in accordance with appropriate social distancing and cleaning/disinfecting protocols; and nothing within this provision should be construed to allow brokerage and branch offices to remain open to the general public (i.e. not clients).

Restrictions on requesting designation as an essential business:

Pursuant to the Governor's Executive Orders, the following businesses are specifically enumerated as non-essential and are, therefore, unable to request a designation:

• Any large gathering or event venues, including but not limited to establishments that host concerts, conferences, or other in-person performances or presentations in front of an in-person audience;

- Any dine-in or on-premise restaurant or bar service, excluding take-out or delivery for off-premise consumption;
- Any facility authorized to conduct video lottery gaming or casino gaming;
- Any gym, fitness centers, or exercise classes, except the remote or streaming service noted above;
- Any movie theater;
- Any indoor common portions of retail shopping malls with 100,000 or more square feet of retail space available for lease;
- All places of public amusement, whether indoors or outdoors, including but not limited to, locations
 with amusement rides, carnivals, amusement parks, water parks, aquariums, zoos, arcades, fairs,
 children's play centers, funplexes, theme parks, bowling alleys, family and children's attractions;
 and
- Any barbershops, hair salons, tattoo or piercing parlors and related personal care services, including nail technicians, cosmetologists and estheticians, and the provision of electrolysis, laser hair removal services.

APPENDIX G

Task Force Recommendations

The Task Force acknowledges the leadership of New York State Governor Andrew M. Cuomo and Commissioner of Health Howard A. Zucker, M.D., J.D., during the State Disaster Emergency. Governor Cuomo and Commissioner Zucker *inter alia* rapidly and creatively adapted State policies to: (1) prevent the spread of the COVID-19 pandemic, (2) enhance the ability of health care providers to treat and care for persons suffering from COVID-19, and (3) protect health care workers in doing so.

The members of the Task Force recommend the following actions in order to build upon the Governor's and Commissioner's considerable accomplishments to date:

1. Public Health Law Framework and Legal Reforms:

The Department of Health (or through it the Task Force on Life and the Law) to review and consider:

- (a) Enactment into New York Law of the Model State Emergency Health Powers Act (MSEHPA), which was developed by the Center for Law and Public Health and the Public Health at Georgetown and John Hopkins Universities in 2001, as informed by the Columbia University Center for Health Policy Gap Analysis and as otherwise updated; and
- (b) Adoption of the, "Crisis Standards of Care," developed by the Institute of Medicine in 2012, as is, or as otherwise updated and amended, by the New York State Department of Health (or through it The Task Force on Life and the Law).

2. Ethical Issues in the Management of COVID-19:

- (a) Allocation of Life-Saving Equipment: The Task Force on Life and the Law (NYSTFLL) or New York State Department of Health or Governor to:
 - i. NYSTFLL to review and consider whether the 2015 Task Force Report entitled, "Ventilator Allocation Guidelines" requires updating and amendment, including without limitation whether the equipment to be allocated should include hemo-dialysis or other life-saving machines, and recommend that the New York State Department of Health adopt the policy as is, or as amended, and
 - ii. DOH to issue emergency regulations mandating all providers and practitioners follow the ethics guidelines, and assure: 1. the needs of vulnerable populations, including older adults, persons with disabilities, inmates and immigrants, are met in a non-discriminatory manner in the implementation of emergency regulations and guidelines; 2. provision of palliative care as an ethical minimum to mitigate suffering among those who are in institutional, facility, residential, or home care settings during the COVID-19 crisis, especially when access to life-saving measures, desired equipment or other resources are not available; 3. provision of education and training to physicians, health care practitioners, and institutional triage and ethics committees; and 4. provision of generalist-level palliative care education and training for all health care workers and health-related service workers in all settings who are providing supportive care.

- iii. Governor to: 1. waive or suspend certain NYS laws to protect from civil and criminal liability exposure practitioners who follow the ethics guidelines; and 2. direct all state agencies to interpret and apply the law and regulations in a way to support compliance with the ethics/triage guidelines.
- (b) Withdrawal, DNR and Futility: Amend the New York State Public Health Law:
 - i. Article 29-C "Health Care Proxy," to require in the case of a State Disaster Emergency Declaration: (i) at least one, rather than two, witnesses, or (ii) attestation by a notary public in person or remotely; and
 - ii. to provide criminal and civil immunity for physicians, nurses and other health care practitioners and Article 28 facilities, when the following steps are taken: (1) a practitioner, as defined in Public Health Law Section 2994-a, determines that a patient's resuscitation would be "medically futile" as defined in PHL 2961.12; (2) a second practitioner concurs with the determination; and (3) both practitioners document their determination in the medical record; and in connection therewith, revoke or amend all laws and regulations prohibiting or penalizing such determinations and actions, including without limitation, those set forth on page 12 of this Report.

(c) Virus Testing:

i. Consider establishing a coordinated state-side plan which prioritizes the most vulnerable individuals from health status and essential business/employee standpoint for access to rapid diagnostic testing. Testing individuals with greatest risk of infection due to pre-existing health conditions and working in close proximity with others will help mitigate spread and support public health across the state.

3. Provider Systems and Issues:

- (a) Amend New York Law:
 - i. Purchasing Necessary Supplies:
 - 1. Amend New York General Business Law Section 396-r to include prohibition from exorbitant pricing of all equipment and products of any kind used either in patient care or to protect health care workers from infection.
- (b) Continue Waivers and Executive Orders:
 - i. Ability to Exceed Certified Bed Capacity for Acute Care Hospitals
 - 1. Continue the waiver by the Governor's Executive Orders 202.1 and 202.10 of the DOH regulations governing certified bed restrictions for the pendency of the State Disaster Emergency.
 - ii. Limitation on Resident Hours Working in Acute Care Hospitals

- 1. Continue the Governor's Executive Order 202.10's waiver of NYCRR Article 10, Section 405, limiting resident work hours for the pendency of the State Disaster Emergency.
- iii. Temporary Changes to Existing Hospital Facility Licenses Services and the Construction and Operation of Temporary Hospital Locations and Extensions
 - 1. Continue the waiver provided in Executive Orders 202.1 and 202.10 of the State requirements that restrict the ability of Article 28 facilities to reconfigure and expand operations as necessary, for the pendency of the State Disaster Emergency.
- iv. Anti-Kickback and Stark Law Compliance during the COVID-19 Emergency
 - 1. New York State: Adopt the waivers provided by CMS and the OIG as to the Anti-Kickback and Stark Laws in substantially similar form for the state versions of the Stark Law and AKS during the State Disaster Emergency, each as tailored for the particular statute at issue
- (c) Long Term Care, Residential and Home Care, and Correctional and Detention Facility Settings
 - i. Older Adults, Nursing Home Providers and Nursing Home Residents: Governor, Department of Health (DOH), DOH Bureau of Long Term Care and State Office for Aging to assure:
 - 1. Equitable allocation of scarce resources from the Public Health and Social Services Emergency Fund—established by the CARES Act—to older adults and their health care providers, prioritizing under-resourced long-term care providers;³⁶⁰
 - 2. Adequate provision of PPE;
 - 3. Adequate levels of staffing;
 - 4. Consistent and timely tracking and reporting of case and death data;
 - 5. Adoption of non-discriminatory crisis standards and ethics guidelines; and
 - 6. Recognition and honoring of Older New Yorkers' right to health and human rights, as protected under international conventions: and
 - 7. Adequate resources for the Office of the State Long Term Care Ombudsman, which provides advocacy for nursing home residents and families and helps residents understand and exercise their rights to quality care and quality of life.
 - ii. Persons with Disabilities in Residential Facilities or Group Homes: Governor and Department of Health to assure:
 - 1. Access of persons with disabilities to adequate COVID-19 testing and appropriate medical care, mental health and other supportive services, including appropriate day

³⁶⁰ U.S. SENATE COMMITTEE ON FINANCE, Senator Charles E. Grassley, Chairman, Letter to HHS Secretary Alex Azar and CMS Administrator Verma, Apr. 17, 2020, (asking about the federal response to COVID-19 in nursing homes, group homes, and assisted living facilities, and expressing concerns about testing capacity, data tracking inconsistencies, lack of personal protective equipment (PPE) for nursing home staff, and federal spending transparency), https://www.finance.senate.gov/imo/media/doc/HHSCOVIDLetter17Apr2020Final.pdf.

- services to substitute for community-based day programs that need to be discontinued during a pandemic;
- 2. Adequate and appropriate staffing, of residential facilities and group homes, for both day and evening shifts, and provision of appropriate funding for such staff and for appropriate COVID-19 staff training;
- 3. Access of residential facility and group home staff to adequate testing and appropriate medical care and mental health and other supportive services;
- 4. Oversight of residential facilities and group homes and programs to assure nondiscriminatory management of persons with disabilities during the COVID-19 crisis conditions; and
- 5. Recognition and honoring of persons with disabilities' right to health and human rights, as protected under international conventions.

iii. Inmates and Correctional Facilities: Governor, NYS Department of Corrections and NYC Department of Corrections, to assure:

- 1. Adequate access of inmates to COVID-19 testing, medical care and mental health and supportive services;
- 2. COVID-19 testing of correctional staff and adequate provision of gloves, masks and other protective equipment;
- 3. Release to the community of older inmates and inmates with advanced illness who do not pose a danger to the community;
- 4. Adequate funding of prison-to-community transitions including access to housing, meals, and supportive services, and non-discriminatory access to employment opportunities; and
- 5. Recognition and honoring of inmates' right to health and human rights, as protected under international conventions.

iv. Immigrants in Detention Facilities:

1. In its exercise of its police powers in the COVID-19 public health emergency, New York State must take steps, similar to those outlined above, in cooperation with federal agencies to reduce the spread of COVID-19 among immigrants being held in detention centers.³⁶¹

(d) Telehealth

i. Eliminate restrictions on the provision of care by telehealth and increase reimbursement for services provided via telehealth.

(e) Immunities

i. Adapt Executive Orders to be consistent with Sections of the Public Health Law and include criminal liability, as well as immunity to health care facilities.

4. Business/Contracts/Risk Management

³⁶¹ See Cole J.P Cole, Federal and State Quarantine Isolation Authority, CONGRESSIONAL RESEARCH SERVICE, Oct. 19, 2014, https://www.ncsl.org/documents/statefed/health/FedandStateQIAuth.pdf.

- (a) Consider extending immunity under NY UCC section 2-615(a) to supply chain vendors where specific performance under a contract becomes impracticable due to unforeseen event or good faith compliance with governmental orders or regulations during crisis.
- (b) Adopt CMS 1135 Waivers and afford civil and criminal immunity to permit health care and health care related organizations and individual providers to modify operations to control contagion and manage the public health crisis. Immunity afforded to individual practitioners should extend to treatment of all patients during the crisis, not just acts of omission or commission in the management of COVID-19 since other patients within the health care system are inevitably impacted by the decisions made by these practitioners on the front lines.

5. Workforce

- (a) Provide clear, timely guidance and support to all non-health care businesses and academic institutions to coordinate effective implementation of universal precautions and other workplace safety best practices to facilitate public health and trust, while mitigating disparate conditions during the phase-in process and long-term.
 - i. Consider publicly posting essential/non-essential business operations decisions with an industry-wide impact on the Empire State Development (ESD) website in real time to mitigate confusion and enhance institutional compliance.
 - ii. Consider granting staffing firms dedicated to child care the provider status necessary to enable them to operate in New York State and supplement the childcare workforce in order to ensure the health and safety of our children, while enabling businesses to effectively reopen within sufficient childcare support.
 - iii. Consider education and training pertaining to crisis standards and civil and criminal immunity to assure all practitioners are supported as they exercise professional medical judgment in triage, treatment and services.
 - iv. Consider enhanced employee assistance and other mental health counseling programs to address and mitigate the moral distress suffered by front-line health care workers under crisis conditions.

6. Vaccination

(a) When the efficacy of a COVID-19 vaccine has been confirmed, enact legislation requiring vaccination of each person unless the person's physician deems vaccination for his or her patient to be clinically inappropriate.

7. Vulnerable Populations and Issues of Equity and Discrimination: A Call for Social Justice

- (a) Enhance regulatory oversight, to assure:
 - i. adequate and non-discriminatory allocation of resources to vulnerable populations and communities of color;
 - ii. equitable access of vulnerable populations to health and mental health services, including palliative care as an ethical minimum to mitigate suffering among those

vulnerable persons who remain in institutional, facility, residential or home or care settings, or are hospitalized during the COVID-19 crisis, especially when desired equipment or other resources are not available;

- iii. provision of PPE to essential health care workers at highest risk in delivering essential services to vulnerable populations; and
- iv. monitoring conformity with federal laws barring discrimination.

8. Emergency Preparedness

- (a) Maintain a core team of emergency preparedness experts to review and draft legislation, drawing upon the following evidentiary sources:
 - i. MSEHPA;
 - ii. Columbia University Center for Health Policy Gap Analysis;
 - iii. IOM's Crisis Standards of Care;
 - iv. Allocation of scarce resource guidelines, and
 - v. Emergency orders needed to manage COVID-19.
- (b) Re-evaluate the public benefit and costs of reinstating laws which have been waived during COVID-19.

APPENDIX H

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