



NEW YORK STATE
BAR ASSOCIATION

COVID-19 RESOLUTIONS

November 7, 2020

The Resolutions appearing with this report were adopted by the House of Delegates on November 7, 2020.

NEW YORK STATE BAR ASSOCIATION COVID-19 RESOLUTIONS

Approved by House of Delegates: November 7, 2020

The following Resolutions, as clarified and revised, have been approved by the New York State Bar Association (NYSBA) House of Delegates (HOD) on November 7, 2020.

Please note that the full Health Law Section COVID-19 Report remains available at the links below:

<https://nysba.org/app/uploads/2020/09/Health-Law-Section-COVID-19-Report-September-20-2020.pdf>

<https://nysba.org/healthlawsectioncovid19/>

Resolution #1

Public Health Legal Reforms

The seriousness and magnitude of the present COVID-19 pandemic are unprecedented over the course of the last hundred years by any measure - the number of lives lost, the number of people afflicted with serious COVID-19 illness and the complications of pre-existing co-morbidities, the risks to health care workers and other frontline and essential workers, disruptions to businesses and the New York State (“the State”) economy, impacts upon employment and family life, and the profound trauma, losses and bereavement persons, families, communities, especially communities of color, have suffered and continue to suffer. Public health law and preparedness play an essential role in addressing disasters and emergencies. New York, like the rest of the country, was unprepared to deal with the pandemic. The report of the Health Law Section recommends reforms to public health law addressing identified gaps in the law to strengthen the preparedness and capacities of the State both during the present and in future pandemics, and to protect the public’s health.

The New York State Bar Association recommends: State Government to:

A.1.(a) Enact a **state emergency health powers act** addressing gaps in existing laws in New York, drawing upon the Model State Emergency Health Powers Act (MSEHPA), developed by the Center for Law and Public Health at Georgetown and John Hopkins Universities (2001), and other sources as appropriate;

A.1.(b) Adopt **crisis standards of care** addressing gaps in existing laws in New York, drawing upon the Crisis Standards of Care, developed by the Institute of Medicine (2012); The Arc, Bazelon Center for Mental Health Law, Center for Public Representation and Autistic Self Advocacy Network Evaluation Framework for Crisis Standard of Care Plans (Evaluation Framework); and other sources as appropriate.

Resolution #1 (continued)

A.1.:

A.1.(c) Provide comprehensive workforce education and training in the implementation of the above state emergency health powers act and crisis standards, including proper use and disposal of PPE and other equipment;

A.2.(a) Appoint and maintain a core team of emergency preparedness experts to review evidentiary sources and draft legislation to strengthen emergency preparedness planning; and

A.2.(b) Evaluate the public benefit and costs of laws and/or regulations waived during the COVID-19 emergency, and the Executive Orders and emergency regulations issued in response to the COVID-19 emergency and consider eliminating or amending those laws and/or regulations, as appropriate.

B.1.(a) Adopt **resource allocation guidelines** addressing gaps in existing laws in New York, drawing upon the New York State Task Force on Life and the Law 2015 Report, Ventilator Allocation Guidelines, the Evaluation Framework, and other sources as appropriate;

B.1.(b) Issue emergency regulations mandating all providers and practitioners follow the ethics guidelines, and ensure:

- i. the needs of vulnerable populations, including persons and communities of color, older adults and nursing home residents, persons with disabilities, persons who are incarcerated, and immigrants, are met in a non-discriminatory manner in the implementation of emergency regulations and guidelines;
- ii. provision of palliative care to all persons as an ethical minimum to mitigate suffering among those who are in institutional, facility, residential, or home care settings during the COVID-19 crisis;
- iii. provision of education and training to physicians, health care practitioners, and institutional triage and ethics committees; and
- iv. 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.

B.2. Amend the New York State Public Health Law: Article 29-C “Health Care Proxy,” to require in the case of a State Disaster Emergency Declaration:

B.2.(a) at least one, rather than two, witnesses, or

B.2.(b) attestation by a notary public in person or remotely;

Resolution #1 (continued)

B.2:

B.2.(c) adoption of legislation or regulation as necessary to implement:

- i. procedural requirements for remote witnessing and execution of a health care proxy;
- ii. specific language to be included in the attestation of the notary public;
- iii. that the services of a witness and a notary public be made available by the facility where the individual executing the health care proxy is being treated; and
- iv. that the services of a witness and notary public be provided to institutionalized individuals without charge and regardless of their ability to pay.

B.3. Nothing contained in the Resolutions herein calls for consideration of any proposed change to New York Law as to authority to terminate treatment over the objection of a patient or the patient's surrogate.

Resolution #2

Legal Reforms in Care Provision, Congregate and Home Care, Workforce and Schools

The New York State Bar Association recommends: State Government to:

A.1. Evaluate the public benefit and costs of continuing the following laws and/or regulations which were waived by executive orders, for possible repeal and/or amendment:

A.1.(a) Ability to Exceed Certified Bed Capacity for Acute Care Hospitals: 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.

A.1.(b) Temporary Changes to Existing Hospital Facility Licenses Services and the Construction and Operation of Temporary Hospital Locations and Extensions: 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.

A.1.(c) Anti-Kickback and Stark (AKS) Law Compliance during the COVID-19 Emergency: New York State to 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.

Resolution #2 (continued)

A.2.:

A.2. Congregate Care and Home Care: Ensure, as applicable to all congregate settings and residents thereof, and recipients of home care, including:

A.2.(a) Older Adults, Persons with disabilities, Persons with disabilities in Residential Facilities or Group Homes, Persons confined in Psychiatric Centers, Nursing Home and Adult Care Facilities Residents, and Nursing Home Providers and Adult Care Facilities Operators:

- i. 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;
- ii. Adequate provision of PPE;
- iii. Adequate levels of staffing;
- iv. Adequate funding of employee testing;
- v. Consistent and timely tracking and reporting of case and death data;
- vi. Adoption of non-discriminatory crisis standards and ethics guidelines;
- vii. Recognition and honoring of Older New Yorkers' and New Yorkers' with disabilities right to health and human rights, including rights to be free from abuse and neglect and to care in the most integrated setting, as protected under federal law and international conventions; and
- viii. 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.

A.2.(b) Persons incarcerated and correctional facilities and care: Ensure:

- i. Adequate access of persons incarcerated to COVID-19 testing, medical care and mental health and supportive services;
- ii. COVID-19 testing of correctional staff and adequate provision of gloves, masks and other protective equipment;
- iii. Release to the community of older persons and persons with disabilities who are incarcerated or living with advanced illness who do not pose a danger to the community;
- iv. Adequate funding of prison-to-community transitions including access to housing, meals, and supportive services, and non-discriminatory access to employment opportunities; and

Resolution #2 (continued)

A.2.(b):

- v. Recognition and honoring of the right to health and human rights of persons who are incarcerated, as protected under international conventions.

A.2.(c) Immigrants in detention facilities: In its exercise of state 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 ensure:

- i. Reduction of risk of the spread of COVID-19 among immigrants being held in detention centers, and recognition and honoring of immigrants' right to health and human rights, as protected under international conventions.

A.3. Telehealth: Eliminate restrictions on the provision of care by telehealth and increase reimbursement for services provided via telehealth.

B.1.(a) Prioritize additional childcare funding and implementing novel childcare staffing strategies, such as utilizing staffing firms dedicated to child care to supplement the childcare workforce, to ensure quality childcare services, effective and sustainable facility operations and the health and safety of our children and childcare providers, enabling businesses to effectively reopen with sufficient childcare resources and support;

B.1.(b) Prioritize education and training pertaining to crisis standards to assure all practitioners are supported as they exercise professional medical judgment in triage, treatment and services; and

B.1.(c) Prioritize enhanced employee assistance and other mental health counseling programs to address and mitigate the moral distress suffered by frontline workers under crisis conditions.

B.2. Enhance regulatory oversight, to ensure:

B.2.(a) adequate and non-discriminatory allocation of resources to persons and communities of color and vulnerable populations in conformity with state and federal laws;

B.2.(b) equitable access of persons and communities of color and vulnerable populations to health and mental health services in conformity with state and federal law, including palliative care as an ethical minimum to mitigate suffering among those persons who remain in institutional, facility, residential or home care settings, or are hospitalized during the COVID-19 crisis; and

Resolution #2 (continued)

B.2.:

B.2.(c) provision of PPE and testing to essential workers at highest risk in delivering essential services to vulnerable populations.

B.3. Monitor conformity with state and federal laws barring discrimination.

Resolution #3

COVID-19 Vaccine and Virus Testing: Legal Reforms and Guidelines

The authority of the State to respond to a public health threat and public health crisis is well-established in constitutional law and statute. In balancing protection of the public's health and civil liberties, the Public Health Law recognizes our interdependence, and that a person's health, or her/his/their lack of health, can and does affect others. This is particularly true for communicable and infectious diseases. Since the discovery of the smallpox vaccine in 1796, vaccines have played a crucial role in preventing the spread of dangerous and often fatal diseases. The New York Public Health Law mandates several vaccinations for students at school-age up through post-secondary degree educational levels, and for health care workers. The Public Health Law also mandates treatment for certain communicable diseases, such as tuberculosis.

The New York State Bar Association recommends:

To protect the public's health, it would be useful to provide guidance, consistent with existing law or a state emergency health powers act as proposed in Resolution #1, to assist state officials and state and local public health authorities should it be necessary for the state to consider the possibility of enacting a vaccine mandate. A vaccine must not only be safe and efficacious; it must be publicly perceived as safe and efficacious. Diverse populations, including people of color, older adults, women, and other marginalized groups, must be represented in clinical trials. The trials also must follow rigorous protocols that will establish a vaccine's safety and efficacy through expert consensus of the medical and scientific communities.¹

¹ The National Academies of Sciences, Engineering and Medicine is an example of a recognized organization of medical and scientific experts that assists U.S. policymakers, such as in planning for equitable allocation of COVID-19 vaccines.

It is noted further that nothing in this Resolution or the underlying Report should be regarded as suggesting that emergency use authorization should be considered in determinations concerning any immunization requirement.

Resolution #3 (continued)

State Government to:

A.1. Ensure Access to Virus Testing: Establish a coordinated statewide plan for Virus Testing to ensure:

A.1.(a) frontline health care workers are prioritized in access to rapid diagnostic testing; and

A.1.(b) the most vulnerable individuals from health status and essential business/employee standpoint have equitable access to rapid diagnostic testing.

A.2. Adopt Ethical Principles Guiding Equitable Allocation and Distribution: Once available, a vaccine should first be equitably allocated and distributed based upon widely accepted ethical principles including maximizing benefit to the society as a whole through reducing transmission and morbidity and mortality; recognizing the equal value, worth and dignity of all human persons and human lives; mitigating suffering, health inequities and disparities; and ensuring fairness and transparency in decision making. Health care workers and other essential workers most endangered by COVID-19 and populations at highest risk must be afforded priority access to a vaccine.

A.3. Encourage Public Acceptance and Educational Programs: Efforts must be made to encourage public acceptance. Public health authorities should build on existing systems and infrastructures including community-based organizations and networks. The campaign must acknowledge distrust in communities of color from a history of medical exploitation. Efforts should include linguistically and culturally competent educational and acceptance programs, and stakeholder community engagement strategies, to build public trust, widely encouraging vaccine uptake and addressing vaccine hesitancy.

A.4. Take Steps to Protect the Public's Health and Consider Mandate As May Be Necessary to Reduce Risks of Transmission and Morbidity and Mortality: Our state and nation have suffered terrible losses from COVID-19. As of September 3, 2020, 186,000 Americans, including 26,000 New Yorkers, have lost their lives. Unemployment has been at the highest levels since the Great Depression. Numerous businesses have closed.

Should the level of immunity be deemed insufficient by expert medical and scientific consensus to check the spread of COVID-19 and reduce morbidity and mortality, a mandate and state action should be considered, as may be warranted, only after the following conditions are met and as a less restrictive and intrusive alternative to isolation, subject to exception for personal medical reasons:

A.4.(a) evidence of properly conducted and adequate clinical trials;

A.4.(b) reasonable efforts to promote public acceptance;

Resolution #3 (continued)

A.4.:

A.4.(c) fact-specific assessment of the threat to the public health in various populations and communities; and

A.4.(d) expert medical and scientific consensus regarding the safety and efficacy of a vaccine and the need for immunization.

Enforcement of any immunization requirement should be along the lines of current New York law.

**NEW YORK STATE BAR ASSOCIATION
HEALTH LAW SECTION
COVID-19 REPORT
May 14, 2020
*Revised September 20, 2020***

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

TABLE OF CONTENTS

EXECUTIVE SUMMARY	5
I. PUBLIC HEALTH LAW FRAMEWORK.....	7
INTRODUCTION	7
LEGAL REFORMS	7
CRISIS STANDARDS OF CARE.....	8
PROVIDER AND COMMUNITY ENGAGEMENT	9
ADOPTION AND COMMUNICATION OF CONSISTENT METHODS OF RESOURCE ALLOCATION	10
CONTINUOUS PERFORMANCE IMPROVEMENT	10
PROVIDER EDUCATION ABOUT THE CSC	10
CONSTITUTIONAL PROTECTIONS AND CIVIL LIBERTIES	11
II. ETHICAL ISSUES IN THE MANAGEMENT OF COVID-19.....	12
INTRODUCTION	12
ALLOCATION OF LIFE-SAVING EQUIPMENT	12
<i>Virus Testing</i>	12
<i>PPE</i>	13
<i>Ventilators and Other Scarce Equipment</i>	13
WITHDRAWAL, DNR, AND FUTILITY	15
BALANCING OF AUTONOMY VERSUS PROTECTION OF PUBLIC HEALTH	17
ESSENTIAL SERVICES	19
MEDICAL RESEARCH	19
<i>Ethical Considerations</i>	19
<i>Incapacitated subjects</i>	19
<i>Sharing of Data and Specimen</i>	20
<i>Health Care Workers as Study Subjects</i>	20
III. PROVIDER SYSTEMS AND ISSUES.....	20
INTRODUCTION	20
PURCHASING NECESSARY SUPPLIES FOR HOSPITALS AND OTHER HEALTH CARE PROVIDERS DURING A STATE OF EMERGENCY	20
ABILITY TO EXCEED CERTIFIED BED CAPACITY FOR ACUTE CARE HOSPITALS	22
LIMITATION ON RESIDENT HOURS WORKING IN ACUTE CARE HOSPITALS.....	23
TEMPORARY CHANGES TO EXISTING HOSPITAL FACILITY LICENSED SERVICES, AND THE CONSTRUCTION AND OPERATION OF TEMPORARY HOSPITAL LOCATIONS AND EXTENSIONS	23
ISSUES IN LONG-TERM CARE, RESIDENTIAL AND HOME HEALTH CARE, AND CORRECTIONAL AND DETENTION FACILITIES: HUMAN RIGHTS CRISIS.....	25
<i>Older Adults, Nursing Home Providers and Nursing Home Residents:</i>	27
<i>Persons with Disabilities in Residential Facilities or Group Homes:</i>	27
<i>Inmates and Correctional Facilities:</i>	28
<i>Immigrants in Detention Facilities:</i>	28
ANTI-KICKBACK AND STARK LAW COMPLIANCE DURING THE COVID-19 EMERGENCY	28
EXPANDED USE OF TELEHEALTH DURING THE COVID-19 EMERGENCY	33
TESTING DURING PANDEMIC.....	34
IV. BUSINESS/CONTRACTS/RISK MANAGEMENT.....	35
INTRODUCTION	35

POTENTIAL LIABILITY FOR BREACH OF CONTRACT DURING CORONAVIRUS PANDEMIC	36
FORCE MAJEURE.....	37
COMMON LAW DOCTRINES: FRUSTRATION OF PURPOSE AND IMPOSSIBILITY	38
NEW YORK’S UNIFORM COMMERCIAL CODE SECTION 2-615	38
PAYCHECK PROTECTION PROGRAM	39
IMMUNITY.....	39
<i>Federal Immunity Declarations in Response to COVID-19</i>	39
<i>New York State-Specific Immunity Declarations in Response to COVID-19</i>	42
HIPAA PRIVACY RULE	43
WORKPLACE LIABILITY EXPOSURE	44
<i>Employment Practices</i>	44
<i>Workplace Safety</i>	45
V. WORKFORCE ISSUES ASSOCIATED WITH COVID-19	45
INTRODUCTION TO WORKFORCE	45
ALLOCATION OF HUMAN RESOURCES.....	46
ESSENTIAL AND NON-ESSENTIAL BUSINESS CATEGORIZATION	47
EMPLOYER WORKPLACE CONSIDERATIONS.....	47
EMPLOYEE BENEFITS.....	49
SICK LEAVE, PAID TIME-OFF (PTO), UNEMPLOYMENT.....	49
<i>The Family First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief and Economic</i>	49
<i>Security Act (CARES Act)</i>	49
<i>WARN – Worker Adjustment and Retraining Notifications</i>	49
<i>Sick Leave and Paid Time-Off (PTO), Paid Family Leave Benefits</i>	49
<i>Unemployment Benefits</i>	50
SCHOOLS AND CHILD CARE.....	52
<i>Child Care</i>	54
<i>Public and Private Schools, Colleges, and Universities</i>	56
<i>Operational Uniformity across Academic Institutions</i>	57
<i>Entanglement of the School System, Food Security, and Health Care</i>	57
<i>Disparities Associated with Home Schooling and Online Learning</i>	58
ESSENTIAL HEALTH CARE SERVICES WORKERS.....	59
<i>State Licensure</i>	60
<i>Credentialing Requirements</i>	60
<i>Scope of Practice Principles</i>	61
<i>Education and Training to Crisis Standards of Care</i>	61
EMPLOYEES’ RIGHTS	61
<i>Safe Workplace</i>	62
<i>Protection against Retaliation</i>	63
<i>Discrimination</i>	63
VI. VACCINATION.....	64
VII. VULNERABLE POPULATIONS AND ISSUES OF EQUITY AND DISCRIMINATION: A CALL	
FOR SOCIAL JUSTICE.....	67
HEALTH CARE WORKERS AND ESSENTIAL SERVICES.....	68
ACTION STEPS	69
VIII. CONCLUSION.....	70
IMPROVING PREPARATION FOR NEXT PUBLIC HEALTH EMERGENCY.....	70
EVALUATION OF LAWS AND REGULATIONS POST-PANDEMIC	70
APPENDIX A	
NEW YORK STATE BAR ASSOCIATION HEALTH LAW SECTION LETTER TO GOVERNOR	
CUOMO, MARCH 26, 2020	72
APPENDIX B	

UNIVERSITY OF ROCHESTER MEDICAL CENTER DECISION ALGORITHMS (2015 NYSTFLL GUIDELINES).....	73
APPENDIX C	
HEALTH LAW SECTION PROXY LAW MEMO	74
APPENDIX D	
NEW YORK STATE BAR ASSOCIATION DEPARTMENT OF HEALTH PROPOSED RULEMAKING IN RELATION TO THE RELEASE OF SUBJECT-IDENTIFIED RESEARCH FINDINGS.....	76
APPENDIX E	
STATE SOCIETY ON AGING OF NEW YORK LETTER TO GOVERNOR CUOMO, APRIL 30, 2020 ..	77
APPENDIX F	
GUIDANCE FOR DETERMINING WHETHER A BUSINESS ENTERPRISE IS SUBJECT TO A WORKFORCE REDUCTION UNDER RECENT EXECUTIVE ORDERS.....	78
APPENDIX G	
TASK FORCE RECOMMENDATIONS.....	83
1. PUBLIC HEALTH LAW FRAMEWORK AND LEGAL REFORMS:	83
2. ETHICAL ISSUES IN THE MANAGEMENT OF COVID-19:.....	83
3. PROVIDER SYSTEMS AND ISSUES:.....	84
4. BUSINESS/CONTRACTS/RISK MANAGEMENT	86
5. WORKFORCE	87
6. VACCINATION	87
7. VULNERABLE POPULATIONS AND ISSUES OF EQUITY AND DISCRIMINATION: A CALL FOR SOCIAL JUSTICE 88	
8. EMERGENCY PREPAREDNESS.....	88
APPENDIX H	
NEW YORK STATE BAR ASSOCIATION HEALTH LAW SECTION TASK FORCE MEMBERS, ADVISORS AND EXPERTS.....	90

Executive Summary

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 22,000 New Yorkers have lost their lives to date, based upon New York State Department of Health data, including nursing home and adult care facility COVID-19 related deaths statewide, reported through the period ending May 13, 2020.² While the apex of the pandemic appears to be flattening in New York, deaths are still hovering at an unacceptably high number, and emerging data and evidence suggest heightened risk for young children. 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 and Latinos 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,³ 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, are helping to relieve the stress of front-line workers,

¹ N.Y 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, *Fatalities*, May 14, 2020, <https://covid19tracker.health.ny.gov/views/NYS-COVID19-Tracker/NYSDOHCOVID-19Tracker-Fatalities?%3Aembed=yes&%3Atoolbar=no&%3Atabs=n>; *Nursing Home and ACF COVID Related Deaths Statewide*, May 13, 2020, https://www.health.ny.gov/statistics/diseases/covid-19/fatalities_nursing_home_acf.pdf.

³ UNITED NATIONS, Policy Brief: COVID-19 and the Need for Action on Mental Health, May 13, 2020, https://www.un.org/sites/un2.un.org/files/un_policy_brief-covid_and_mental_health_final.pdf.

and provide critical support to patients and their family members as they confront the assaults of the virus and imminent risk of death.⁴

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-19.⁵ The Health Law Section Task Force began work in early March.⁶

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 13 through April 24, 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.⁷ 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.⁸ 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.

⁴ Dana Lustbader & Sean Morrison, *Palliative Care on the Front Lines of COVID-19*, GNYHA (webinar), Apr. 20, 2020, <https://www.gnyha.org/event/palliative-care-on-the-front-lines-of-covid-19-webinar/>.

⁵ 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.

⁶ 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.

⁷ 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.

⁸ See Task Force Recommendations, Appendix G.

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).⁹

Legal Reforms

Legal reforms have sought to improve planning and response for PHEs through development of legal response capabilities, comprehensive federal and state declarations, and improved classifications of PHEs utilizing modern approaches to react to current threats.¹⁰ 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.¹¹ 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.^{12,13}

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 for 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,¹⁴ developed at the impetus of, and in collaboration with, the NYSBA Public Health Law Committee.

New York State Executive Law Article 2-B,¹⁵ as significantly expanded in April 2020 (Ch. 23, Laws 2020),¹⁶ grants emergency powers to both local heads of government and to the Governor. Epidemics are included in its definition of what is an emergency.¹⁷ 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.¹⁸ If an epidemic cannot be contained by local action,

⁹ JAMES G. HODGE, JR., *PUBLIC HEALTH LAW IN A NUTSHELL*, 227-247 (West Academic Publishing 2014).

¹⁰ 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).

¹¹ See Lawrence O. Gostin et al., *Model State Emergency Health Powers Act*, CENTER FOR LAW AND THE PUBLIC'S HEALTH (Georgetown University 2001), <https://www.ncsl.org/Portals/1/documents/health/modelact.pdf>

¹² See Lawrence O. Gostin & James G. Hodge, *State Public Health Law Assessment Report*, TURNING POINT PUBLIC HEALTH STATUTE MODERNIZATION NATIONAL COLLABORATIVE (2002).

¹³ See *id.*

¹⁴ 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). See <https://app.box.com/s/fabziko9c7uyjmh8e7wy2fo9fmd4prh>

¹⁵ N.Y. EXEC. L. Art. 2-B – State and Local Natural and Man-Made Disaster Preparedness.

¹⁶ Ch. 23, Laws 2020.

¹⁷ N.Y. EXEC. L. §20(2)(B).

¹⁸ N.Y. EXEC. L. §24.

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.¹⁹ As evidenced by the 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.²⁰

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) disaster²¹ -- 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.²²

The Institute of Medicine,²³ 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

¹⁹ 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>.

²⁰ 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 Triage 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.

²¹ 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://commmed.vcu.edu/IntroPH/2012/crisisManagement_IOM.pdf

²² *Id.*

²³ In 2015, the Institute of Medicine was renamed the National Academy of Medicine and is one of the three academies constituting the National Academies of Science, Engineering and Medicine. For more information, please see: <https://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=04282015>

address the need for a surge response.²⁴ 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.²⁵

The development of consensus standards of care can be particularly beneficial to New York State when navigating crises, such as the coronavirus pandemic, because they focus on adherence to ethical and professional standards.²⁶ 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.²⁷ 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.²⁸

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.²⁹ 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, CSC 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 PHE, 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

²⁴ James G. Hodge et al., *Practical, Ethical, and Legal Challenges Underlying Crisis Standard of Care*, J. L. MED. & ETHICS, Spring 2013 at 2.

²⁵ *Id.*

²⁶ *Id.* at 3.

²⁷ *Id.* at 3-4.

²⁸ 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.

²⁹ James G. Hodge et al., *Practical, Ethical, and Legal Challenges Underlying Crisis Standard of Care*, J. L. MED. & ETHICS, Spring 2013 at 5.

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.³⁰ Agreements can ensure consistency with existing New York laws, as well as address specific concerns about resource allocation.³¹

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.³²

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 PHEs, as well as establish legal authority. 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.³³ 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).³⁴ (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.³⁵

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.³⁶

³⁰ 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).

³¹ 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.

³² *Id.*

³³ JAMES G. HODGE, JR., PUBLIC HEALTH LAW IN A NUTSHELL, 227-247 (West Academic Publishing 2014).

³⁴ *Id.* at 4.

³⁵ 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.

³⁶ *Id.* at 1-33-1-34.

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.

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.³⁷ 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, on March 2, 2020, the legislature, 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.³⁸ 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.³⁹ 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.⁴⁰ 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.

³⁷ *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).

³⁸ Wendy Parmet & Michael Sinha, *COVID-19: The Law and Limits of Quarantine*, 15 NEW ENG. J. MED. 28 (2020).

³⁹ *Id.*

⁴⁰ 45 C.F.R. 160 (2012).

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 judicial procedures.⁴¹ 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,⁴² the value of assuring 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 disparities: 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 is needed to ensure: i) frontline health care workers are prioritized in access to testing on the basis of moral obligation; and ii) the most vulnerable New Yorkers from both a health and business operations standpoint have equitable access to testing.⁴³ 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 entities.

⁴¹ 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).

⁴² 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>.

⁴³ 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>.

PPE

The United States is also severely short on PPE for health care workers, such as gowns, face masks, eye protection, and surgical masks,⁴⁴ 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 themselves and others with carefully placed cloth coverings,⁴⁵ health care workers require more advanced N95 respirators because they are intimately and unavoidably exposed to infected people. Those hoarding PPE⁴⁶ 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 scarce equipment for everyone in future waves of the pandemic, as experienced in Italy.⁴⁷ 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 2015,⁴⁸ first issued in 2008, as well as the University of Pittsburgh,⁴⁹ the North Carolina Protocol for Allocating Scarce Inpatient Critical Care Resources in a Pandemic,⁵⁰ Maryland⁵¹ and other states, and the Catholic Health Association of the United States,⁵² follow certain similar patterns. It is of note, however, that the updated 2015 New York Task Force on Life

⁴⁴ 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>.

⁴⁵ 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>.

⁴⁶ 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>.

⁴⁷ 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>.

⁴⁸ 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.

⁴⁹ *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.

⁵⁰ North Carolina Protocol for Allocating Scarce Inpatient Critical Care Resources in a Pandemic, 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>.

⁵¹ *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.

⁵² 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>.

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.⁵³ 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 of scarce ventilator resources calls for re-examination in light of the 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) score⁵⁴ 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 Medicine*⁵⁵ 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,⁵⁶ and the HHS Office of Civil Rights has cautioned that such discrimination on the basis of disability or age is barred by federal law.⁵⁷

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.⁵⁸ 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

⁵³ Mark A. Rothstein, *Should Health Care Providers Get Treatment in an Influenza Pandemic?*, 38 J. L. MED. & ETHICS, 412-419 (2010).

⁵⁴ *Sequential Organ Failure Assessment (SOFA) Score*, MD+CALC, (last accessed Apr. 24, 2020), <https://www.mdcalc.com/sequential-organ-failure-assessment-sofa-score>.

⁵⁵ 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/NEJMs2005114>.

⁵⁶ 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/>.

⁵⁷ 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).

⁵⁸ 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).

Black/African Americans and Latinos,⁵⁹ 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 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

⁵⁹ 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>.

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.⁶⁰ 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 existing bar for individuals to designate health care proxies, such as the recent Executive Order enabling remote witnessing of such legal designations.⁶¹ 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.⁶²

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 care⁶³ 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 Texas⁶⁴ 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.

⁶⁰ 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.

⁶¹ N.Y. EXEC. ORDER No. 202.10, Mar. 23, 2020.

⁶² See Health Care Proxy proposal, Appendix C.

⁶³ 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.

⁶⁴ Michael D. Cantor et al., *Do-Not-Resuscitate Orders and Medical Facility*, 163 (22) ARCH. INTERN. MED. 2689 (2003).

Although an Executive Order has been issued⁶⁵ protecting health care workers from liability for making decisions in accordance with existing law or other executive orders,⁶⁶ 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, and Surrogate's Court Procedure Act section 1750-b,⁶⁷ 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, 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. **More specifically, we recommend that any disaster or emergency crisis-related futility DNR should still be subject to certain procedural protections, for example, (i) futility must be defined narrowly, in terms of effectiveness of restarting the heart, as it is in PHL 2991; (ii) there must be a concurring determination of medical futility by a second practitioner, selected by the facility; (iii) the attending practitioner must notify the patient or, if the patient lacks capacity, the agent/surrogate of the order and the basis for it; (iv) such determinations must be documented in the medical record; and (v) if the order is issued without patient/agent or surrogate consent, there should be a post-issuance medical peer review of the medical support for the futility finding.**

Balancing of Autonomy Versus Protection of Public Health

The second issue concerns the extent to which individual rights and liberty interests⁶⁸ 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 nearly 1.4 million people and resulted in nearly 84,000 deaths.⁶⁹ New York has suffered nearly 22,000 deaths,⁷⁰ primarily in the New York Metropolitan area. Of course, these numbers are changing rapidly, and questions have been raised about the accuracy of official death counts and possible undercounting.⁷¹ As there is presently no vaccine available for COVID-19, the primary resources are the ability to test for its presence, the use of personal protective equipment (PPE) to reduce transmission, clinical support equipment, such as ventilators to support respiratory function of those with compromised lung capacity, and as of May 1, 2020, the investigational antiviral drug remdesivir, recently approved by the U.S Food and Drug Administration through emergency authorization.⁷² Many regions have only

⁶⁵ 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>

⁶⁶ N.Y. PHL Art. 30-D, <https://www.nysenate.gov/legislation/laws/PBH/3082>

⁶⁷ **Reference to MHL Art. 47 has been struck from Section II of the Report.**

⁶⁸ *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).

⁶⁹ CTR. FOR DISEASE CONTROL AND PREVENTION, CORONAVIRUS DISEASE 2019, *Cases in the U.S.*, (last updated May 14, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>.

⁷⁰ NEW YORK STATE, Department of Health, COVID-19 Tracker, *Fatalities*, May 12, 2020, <https://covid19tracker.health.ny.gov/views/NYS-COVID19-Tracker/NYSDOHCOVID-19Tracker-Fatalities?%3Aembed=yes&%3Atoolbar=no&%3Atabs=n>; *Nursing Home and ACF COVID Related Deaths Statewide*, May 11, 2020, https://www.health.ny.gov/statistics/diseases/covid-19/fatalities_nursing_home_acf.pdf.

⁷¹ Sarah Kliff & Julie Bosman, *Official Counts Understate the Official U.S. Coronavirus Death Toll*, N.Y. TIMES, Apr. 7, 2020, <https://www.nytimes.com/2020/04/05/us/coronavirus-deaths-undercount.html>.

⁷² See, U.S. FOOD & DRUG ADMIN., CORONAVIRUS (COVID-19) UPDATE: FDA ISSUES EMERGENCY USE AUTHORIZATION FOR POTENTIAL COVID-19 TREATMENT, May 1, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment>.

enough tests for those who must be hospitalized,⁷³ hospital systems are creating makeshift PPE out of trash bags,⁷⁴ 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.⁷⁵ 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,⁷⁶ 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.⁷⁷ There are recent New York City Health Department reports of an inflammatory illness affecting children that may possibly be related to COVID-19.⁷⁸ Moreover, the younger 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.⁷⁹ 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 that the executive orders putting New York on PAUSE⁸⁰ and urgent campaigns to get us to stay home are ethically warranted. However, more draconian measures, such as quarantine with penalties as issued in China,⁸¹ 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.

⁷³ *New Coronavirus Testing Guidelines*, NYC Health and Hospitals, <https://www.nyhealthandhospitals.org/coronavirus-testing-guidelines/>.

⁷⁴ 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_.

⁷⁵ *COVID-19 Projections*, INS. FOR HEALTH METRICS & EVALUATION, <https://Covid19.healthdata.org/united-states-of-america>, (last visited Apr. 17, 2020).

⁷⁶ *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).

⁷⁷ 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>.

⁷⁸ J. Goldstein, *15 Children Are Hospitalized With Mysterious Illness Possibly Tied to COVID-19*, N.Y. TIMES, May 8, 2020, https://www.nytimes.com/2020/05/05/nyregion/children-Kawasaki-syndrome-coronavirus.html?campaign_id=16&emc=edit_ml_20200508&instance_id=18295&nl=well-family®i_id=70461562&segment_id=26869&te=1&user_id=a25ad6bf8443b5ca142cd1840c7794d2; NYC HEALTH DEPARTMENT, 2020 Health Alert #13: *Pediatric Multi-System Inflammatory Syndrome Potentially Associated with COVID-19*, <https://www1.nyc.gov/assets/doh/downloads/pdf/han/alert/2020/covid-19-pediatric-multi-system-inflammatory-syndrome.pdf>

⁷⁹ See *Jacobson v Massachusetts*, 197 U.S. 11 (1905).

⁸⁰ NEW YORK STATE, *New York State on Pause: 10 Point Plan*, Mar. 22, 2020, <https://coronavirus.health.ny.gov/new-york-state-pause>.

⁸¹ Hilary Brueck et al., *China Took at Least 12 Strict Measures to Control the Coronavirus. They Could Work for the U.S. but Would Likely Be Impossible to Implement*, BUSINESS INSIDER, Mar. 24, 2020, <https://www.businessinsider.com/chinas-coronavirus-quarantines-other-countries-arent-ready-2020-3#the-country-postponed-non-urgent-medical-care-and-moved-many-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.

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.⁸² However, studies suggest that social distancing and mitigation strategies reduce the community spread of COVID-19 and concomitant mortality.⁸³ 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.⁸⁴ 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,⁸⁵ as well as not allowing either profit motive or fear to drive unjust or reckless trial development.⁸⁶ 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

⁸² 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>.

⁸³ 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-risk-factors-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.

⁸⁴ 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-new-york-state-pause-executive-order>.

⁸⁵ 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/>.

⁸⁶ 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/>.

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.⁸⁷

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.

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.

⁸⁷ 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.

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.⁸⁸ Over 23,000 complaints were filed as of April 21, 2020.⁸⁹ 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.⁹⁰

In New York, the Department of Consumer and Worker Protection (“DCWP”) promulgated an emergency Rule under the City’s Consumer Protection Law⁹¹ 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.⁹² 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.”⁹³

In the absence of any violation of the antitrust laws,⁹⁴ 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 face masks. New York General Business Law Sec. 396-r⁹⁵ 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.

⁸⁸ See FEDERAL TRADE COMMISSION, *Coronavirus (COVID-19) Consumer Complaint Data*, <https://www.ftc.gov/coronavirus/complaint-data>.

⁸⁹ 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>.

⁹⁰ See 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>.

⁹¹ N.Y.C. ADMIN. CODE § 20-701(b).

⁹² 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>.

⁹³ *Id.*

⁹⁴ 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.

⁹⁵ N.Y. GBL §396-r.

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.⁹⁶

In the 1974, the National Health Planning and Resources Development Act⁹⁷ 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.

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 contraindicated, and the CON process does not contemplate situations involving temporary need. Presently, Governor Cuomo’s Executive Order 202.1⁹⁸ accomplishes that goal by providing waivers of section 401.3 and section 710.1 of Title 10 of the NYCRR,⁹⁹ 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 202.10.¹⁰⁰

⁹⁶ 10 NYCRR §441.60.

⁹⁷ PUB. L. NO. 93-641, 42 U.S.C. §§300k et seq.

⁹⁸ 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>.

⁹⁹ 10 NYCRR §§401.3, 710.1.

¹⁰⁰ 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>.

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.¹⁰¹

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 202,¹⁰² 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 NYCRR¹⁰³ 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 202.10.¹⁰⁴

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.

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 2803,¹⁰⁵ and DOH regulations at 10 NYCRR sections 400, 401, 405, 409, 710, 711 and 712,¹⁰⁶ 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

¹⁰¹ 10 NYCRR §405.4(b)(6).

¹⁰² N.Y. EXEC. ORDER No. 202, Mar. 7, 2020, <https://www.governor.ny.gov/news/no-202-declaring-disaster-emergency-state-new-york>.

¹⁰³ 10 NYCRR §405.

¹⁰⁴ 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>.

¹⁰⁵ N.Y. PHL §2803.

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

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 202,¹⁰⁷ 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 202.10,¹⁰⁸ 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 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 applicable body.

We recommend continuation of the waiver provided under Executive Orders 202.1¹⁰⁹ and 202.10¹¹⁰ of state requirements that would restrict the ability of hospitals to reconfigure and expand operations as necessary to deal with the PHE.

¹⁰⁷ N.Y. EXEC. ORDER No. 202, Mar. 7, 2020, <https://www.governor.ny.gov/news/no-202-declaring-disaster-emergency-state-new-york>.

¹⁰⁸ 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>.

¹⁰⁹ 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>.

¹¹⁰ 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>.

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 (ACFs), 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.¹¹¹

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-19.¹¹² It also prohibited nursing homes from requiring a hospitalized resident who was determined medically stable to be tested for COVID-19 prior to admission or readmission.¹¹³ The Department of Health issued a nearly identical advisory for ACFs.¹¹⁴ The foregoing mandates may have substantially contributed to increased risk of spread of infection in nursing homes and adult care facilities. It is also worthy of note that during the same period these mandates were in effect and until more recently, nursing homes continued to have much more limited access to PPE emergency stockpiles than hospitals. 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.

An Executive Order (EO) issued on May 10, 2020¹¹⁵ imposes new requirements on nursing homes and ACFs and rescinds the nursing home directives as referenced in the preceding paragraph.

The May 10th EO No. 202.30, as applicable to Nursing homes and ACFs, mandates the following and imposes penalties for non-compliance:

¹¹¹ 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.

¹¹² NYS DOH Advisory: Hospital Discharges and Admissions to Nursing Homes, Mar. 25, 2020, previously available at: https://coronavirus.health.ny.gov/system/files/documents/2020/03/doh_Covid19_nhadmissionsreadmissions_032520.pdf, page no longer available.

¹¹³ *Id.*

¹¹⁴ NYS DOH Advisory: Hospital Discharges and Admissions to Adult Care Facilities, Apr. 7, 2020, available at: https://coronavirus.health.ny.gov/system/files/documents/2020/04/doh_covid19_acfreturnofpositiveresidents_040720.pdf.

¹¹⁵ N.Y. EXEC. ORDER No. 202.30, May 10, 2020, <https://www.governor.ny.gov/news/no-20230-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency>.

- ❑ Testing of all personnel including employees, contract staff, medical staff, operators and administrators pursuant to a written plan filed with the Department of Health (DOH) no later than May 13, 2020;
- ❑ Reporting of all positive test results to DOH by 5 pm the day following receipt of test results;
- ❑ Filing of Certificate of Compliance with EO 202.30 and all other directives of DOH and Commissioner of Health no later than May 15, 2020; and
- ❑ Suspension or revocation of operating certificate if failure to comply with EO 202.30 or any other regulations or directives; financial penalties of \$2,000 per violation per day, including repeat violation penalty of \$10,000 per violation per day.

The following provisions of EO 202.30 are applicable to hospital discharges to nursing homes only, and not ACFs:

- ❑ Art. 28 hospitals cannot discharge a patient to a nursing home unless the nursing home first certified that is able to properly care for such patient; and
- ❑ Art. 28 hospitals cannot discharge a patient to a nursing home without first performing a diagnostic COVID-19 test and obtaining a negative result.

On May 11, 2020, DOH issued a Dear Administrator Letter¹¹⁶ providing guidance on these new requirements. Nevertheless, there are many questions about how the above directives will be operationalized and more broadly, whether nursing homes and ACFs can reasonably comply with the mandates given the lack of access to COVID-19 testing and limited resources. Employee rights are also an area ripe for legal challenges.

In addition to the recent mandates referenced above, 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.¹¹⁷ 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.¹¹⁸ CMS has issued new guidance

¹¹⁶ N.Y.S. DEP'T OF HEALTH, ACF DAL #20-14, NH-20-07 Required COVID-19 Testing for all Nursing Home and Adult Care Facility Personnel, May 11, 2020, available at:

https://www.health.ny.gov/professionals/hospital_administrator/letters/2020/docs/dal_20-14_covid_required_testing.pdf.

¹¹⁷ 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>.

¹¹⁸ 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/>.

tightening nursing home COVID-19 reporting requirements.¹¹⁹ 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 amount 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 correctional¹²⁰ 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 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 ensure:

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;¹²¹
2. Adequate provision of personal protective equipment (PPE);
3. Adequate levels of staffing;
4. Adequate funding of employee testing, as required under Executive Order 202.30;
5. Consistent and timely tracking and reporting of case and death data;
6. Adoption of non-discriminatory crisis standards and ethics guidelines;
7. Recognition and honoring of Older New Yorkers' right to health and human rights, as protected under international conventions; and
8. 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 ensure:

¹¹⁹ CMS, Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, Ref: QSO-20-26-NH, Apr. 19, 2020, <https://www.cms.gov/files/document/qso-20-26-nh.pdf>.

¹²⁰ 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/>.

¹²¹ 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>.

1. 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;
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 non-discriminatory 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.

Inmates and Correctional Facilities:

Governor, NYS Department of Corrections and NYC Department of Corrections, to ensure:

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
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:

In its exercise of its police powers in the COVID-19 public health emergency, New York State, in cooperation with federal agencies, must take step, similar to those outlined above, to ensure:

1. Reduction of risk of the spread of COVID-19 among immigrants being held in detention centers.¹²²

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

During the 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 statutes ("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.

¹²² 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>.

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.¹²³ 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.”¹²⁴ 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.¹²⁵ While the statute is interpreted broadly,¹²⁶ there are various narrow regulatory exceptions, called “safe harbors,” for practices recognized as beneficial.¹²⁷

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.¹²⁸ The Stark law prohibits the submission, or causing the submission of claims that violate the prohibitions.¹²⁹ The Stark law also has certain regulatory exceptions for practices and arrangements that are sufficiently and strictly tailored as to avoid impropriety of referrals.¹³⁰

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.¹³¹

In addition, these providers also face federal False Claims Act (“FCA”) liability,¹³² which imposes civil (and potentially criminal¹³³) liability on persons who knowingly submit false or fraudulent claims for reimbursement to government health care programs.¹³⁴ 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.¹³⁵

¹²³ 42 U.S.C. § 1320a-7b(b).

¹²⁴ 42 C.F.R. § 1001.951.

¹²⁵ *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985).

¹²⁶ *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).

¹²⁷ See 42 U.S.C. 6 1320a-7b(b)(3); 42 C.F.R. § 1001.952.

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

¹²⁹ *Id.*

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

¹³¹ 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>.

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

¹³³ 18 U.S.C. § 287.

¹³⁴ 31 U.S.C. §3729-33.

¹³⁵ 18 U.S.C. § 3730(b), (c) & (d).

Note that with available treble damages, plus more than \$22,000 per false claim,¹³⁶ 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.¹³⁷

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.¹³⁸ 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.¹³⁹ 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.¹⁴⁰

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 PHE caused by COVID-19 through a waiver and attendant guidance.¹⁴¹ 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,

¹³⁶ 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>.

¹³⁷ 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).

¹³⁸ N.Y. ED. LAW §§ 6530(18) & (19); N.Y. Social Services Law § 366-d.

¹³⁹ N.Y. PHL §§ 238-a - 238-e.

¹⁴⁰ N.Y. STATE FINANCE LAW § 187-194.

¹⁴¹ 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>.

- ☐ 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.

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 PHE.

The OIG simultaneously issued a "message from leadership on minimizing burdens on providers."¹⁴² 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."¹⁴³ "[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."¹⁴⁴ 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."¹⁴⁵ The latter comment may well be a feature of defenses of direct and certainly FCA *qui tam* claims concerning conduct during the PHE.

¹⁴² DEP'T OF HEALTH & HUMAN SVCS, OFFICE OF INSPECTOR GENERAL, *Message From Leadership On Minimizing Burdens On Providers*, Mar. 30, 2020, <https://oig.hhs.gov/coronavirus/letter-grimm-03302020.asp>.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

Subsequently, on April 3, the OIG responded explicitly to the CMS Stark waiver of March 30.¹⁴⁶ 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.¹⁴⁷ 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.¹⁴⁸

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.¹⁴⁹

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 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.

¹⁴⁶ 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>; DEP'T OF HEALTH & HUMAN SVCS, OFFICE OF INSPECTOR GENERAL, *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>.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

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 of reimbursement, have stunted the growth of telehealth and delayed its implementation.

The federal telehealth statute¹⁵⁰ 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.¹⁵¹ Additionally, only eligible practitioners¹⁵² could provide Medicare telehealth services. In New York,¹⁵³ state law allows a wide range of professionals¹⁵⁴ to deliver services through telehealth in New York, to patients located in a wide range of originating sites, including in the patient’s own home.¹⁵⁵ In February 2019, however, in a Special Medicaid Telehealth,¹⁵⁶ 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,”¹⁵⁷ 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

¹⁵⁰ 42 U.S.C. § 1395m(m).

¹⁵¹ 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).

¹⁵² 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 dietitians and nutritional professionals, and certified registered nurse anesthetists.

¹⁵³ N.Y. PHL § 2999-dd(1); N.Y. SOC. SERVS. LAW § 367-u(2).

¹⁵⁴ 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 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.

¹⁵⁵ *Id.*, § 2999-cc (3).

¹⁵⁶ 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.

¹⁵⁷ Coronavirus Preparedness and Response Supplemental Appropriations Act, Pub. L. § 116-123, Mar. 6, 2020, <https://www.congress.gov/116/plaws/publ123/PLAW-116publ123.pdf>.

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).¹⁵⁸ 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 PHE.¹⁵⁹ These changes allowed for Medicare reimbursement for the delivery of 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, 2020,¹⁶⁰ 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 duration of the New York State COVID-19 emergency.¹⁶¹ 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.”

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 may have prevented further spread of disease. But why only temporary? Through 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.”¹⁶²

¹⁵⁸ Coronavirus Aid, Relief, and Economic Security Act, PUB. L. § 116-136, Mar. 27, 2020, <https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf>.

¹⁵⁹ 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/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>.

¹⁶⁰ 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>

¹⁶¹ 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

¹⁶² N.Y. PHL § 580.

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 58-1¹⁶³ prevents research laboratories from reporting their results to individual patients.¹⁶⁴

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.

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-a¹⁶⁵ to suspend that portion of NYS PHL § 580¹⁶⁶ 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."¹⁶⁷ 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

¹⁶³ 10 NYCRR § 58-1.

¹⁶⁴ 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.

¹⁶⁵ N.Y. EXEC. L. § 29-a.

¹⁶⁶ N.Y. PHL § 580.

¹⁶⁷ 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>.

trigger successful business interruption claims.¹⁶⁸ 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.¹⁶⁹

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.¹⁷⁰ These provisions provide some relief for consumers, but do not address the 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.¹⁷¹ 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."¹⁷² 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 PHE; (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.¹⁷³

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

¹⁶⁸ 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).

¹⁶⁹ Jim Sams, *Some Insurance Regulators Skeptical About Business Interruption Claims*, CLAIMS JOURNAL, Apr. 27, 2020, (Last accessed May 3, 2020).

¹⁷⁰ 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).

¹⁷¹ 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/#72fd565489 (Last accessed 04/30/2020).

¹⁷² *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).

¹⁷³ 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.

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.

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.¹⁷⁴ 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.”¹⁷⁵ 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.”¹⁷⁶ 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*.”¹⁷⁷

Some contracts may include “epidemic” as a specific example of a *force majeure* event.¹⁷⁸ 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.¹⁷⁹

¹⁷⁴ *Kel Kim v. Central Mkts.*, 70 N.Y.2d 900, 902 (1987).

¹⁷⁵ *Constellation Energy Servs. of N.Y. v. New Water St.*, 146 A.D.3d 557, 558 (1st Dept. 2017).

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ 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”).

¹⁷⁹ See *Kel Kim*, 70 N.Y.2d 900 at 903.

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.”¹⁸⁰ 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.”¹⁸¹ “Moreover, the impossibility of performance must be produced by an unanticipated event that could not have been foreseen or guarded against in the contract.”¹⁸² “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.”¹⁸³

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 first place.¹⁸⁴ 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.”¹⁸⁵ 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.”¹⁸⁶ 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.”¹⁸⁷ 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.¹⁸⁸

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.”¹⁸⁹ Moreover, a party cannot rely on supervening government action if he or she brought about the

¹⁸⁰ *Id.* at 902.

¹⁸¹ *Id.*

¹⁸² *Id.*

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

¹⁸⁴ *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).

¹⁸⁵ *Id.*

¹⁸⁶ RESTATEMENT (SECOND) OF CONTRACTS § 265 (comment).

¹⁸⁷ UCC § 2-615, Official Comment 1.

¹⁸⁸ UCC § 2-615(b).

¹⁸⁹ UCC § 2-615, Official Comment 11.

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.”¹⁹⁰

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.

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.¹⁹¹ As such funding has been depleted quickly due to overwhelming response, additional funds have been granted through an amendment to the CARES Act.¹⁹² 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,¹⁹³ 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

¹⁹⁰ *Id.*

¹⁹¹ 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>.

¹⁹² 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>.

¹⁹³ 42 U.S.C. § 201 et seq.

Security Act¹⁹⁴ 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 facilities¹⁹⁵ 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.¹⁹⁶

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.¹⁹⁷ 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 PHE declared by the U.S. Health and Human Services.

¹⁹⁴ 42 U.S.C. § 301 et seq.

¹⁹⁵ EMERGENCY MEDICAL TREATMENT & ACTIVE LABOR ACT, 42 U.S.C. § 1395dd.

¹⁹⁶ CMC, CMS Declaration of Waivers under 1135, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers> (last visited Apr. 22, 2020).

¹⁹⁷ *See id.*

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 PHE, on January 31, 2020, the U.S. HHS Secretary issued a declaration under PREP.¹⁹⁸ 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.¹⁹⁹ 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.²⁰⁰ The medical countermeasures include the following: any antiviral, other drug, biologic, diagnostic, other device or vaccine used to treat, diagnose, cure, prevent or mitigate COVID-19 or any virus mutating therefrom; or any device used in the administration of such product and the components and materials of same.²⁰¹

Since 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”).²⁰² 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 not 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 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.²⁰³

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.²⁰⁴ 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.²⁰⁵ To file for compensation under CICP, claimants must submit their requests for same within one (1) year of receipt of the

¹⁹⁸ 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).

¹⁹⁹ See 85 C.F.R.15198.

²⁰⁰ 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).

²⁰¹ See *id.*

²⁰² 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/prep-act-advisory-opinion-april-14-2020.pdf>.

²⁰³ See *id.* at 4.

²⁰⁴ 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).

²⁰⁵ Frequently Asked Questions For Individual Requesters/Recipients, Health Resources & Services Administration, <https://www.hrsa.gov/cicp/faq/requesters.html> (last visited Apr. 23, 2020).

countermeasure.²⁰⁶ 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.²⁰⁷ 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
- ☐ 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.²⁰⁸

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.²⁰⁹ 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

²⁰⁶ See *id.*

²⁰⁷ N.Y. PHL § 2805-k.

²⁰⁸ See N.Y. EXECUTIVE ORDER No. 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).

²⁰⁹ N.Y. ED. L., Art. VIII.

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.²¹⁰

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 facility at which the services are provided. Article 30-D of the Public Health Law,²¹¹ 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.²¹²

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.²¹³ 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), health 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.²¹⁴

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.”²¹⁵ There is also an exception that allows covered

²¹⁰ 42 U.S.C. § 1320a, 42 C.F.R. § 1003.810, Failure to report to NPDB may result in significant Civil Monetary Penalties.

²¹¹ N.Y. PUB. H. L. § 3080 et seq.

²¹² N.Y. PUB. H. L. § 3082.

²¹³ See 45 C.F.R. § 160 et seq.

²¹⁴ See 45 C.F.R. § 160.103; see also 45 C.F.R. 164.500 et seq.

²¹⁵ See 45 C.F.R. 164.512(b)(i) and (b)(iv).

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-19.²¹⁶

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.”²¹⁷ 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.²¹⁸ 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 information on COVID-19 status, but the hospital should refrain from also providing information about that patient’s surgical history and other unrelated medical conditions, absent a reason for doing so.²¹⁹

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”).²²⁰ The March Bulletin references the exceptions discussed above, and provides examples of how those exceptions apply.²²¹

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

²¹⁶ See 45 C.F.R.164.510(b).

²¹⁷ See 45 C.F.R.164.512(j).

²¹⁸ 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).

²¹⁹ See *id.*

²²⁰ 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).

²²¹ See *id.*

that prohibit discrimination in the workplace.²²² 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.²²³

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.

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.²²⁴ 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.²²⁵ 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

²²² 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 seq; Americans with Disabilities Act of 1990, 42 U.S.C. ch. 126 § 12101 et seq; 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 §§ 2601-2654.

²²³ Worker Adjustment and Retraining Notification Act of 1988, 29 U.S.C. §§ 2101-2109.

²²⁴ 28 U.S.C. § 2461.

²²⁵ 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).

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.²²⁶ 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 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.”²²⁷ 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 inseparable symbiotic relationship between businesses, schools, workforce, and transportation, while clearly stating that one cannot reopen independent of the others.²²⁸ This section highlights the tight interconnections among 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.²²⁹ 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.²³⁰ This mandate, though

²²⁶ See N.Y. EXEC. ORDER No. 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).

²²⁷ See N.Y. EXEC. ORDER Nos. 202.6; 202.13; Appendix F.

²²⁸ 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).

²²⁹ See N.Y. EXEC. ORDER No. 202.4, Mar. 17, 2020.

²³⁰ See Empire State Dev., Guidance for Determining Whether a Business Enterprise is Subject to a Workforce Reduction Under Recent Executive Orders, Apr.19, 2020, <https://esd.ny.gov/guidance-executive-order-2026> (last visited Apr. 23, 2020).

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. As New York State prepares to reopen and embrace the “new normal,” it is important to reflect on the past, identify and acknowledge the lessons learned as the emergency period continues to unfold, and commit to embracing an innovative future.

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.)
- ☐ 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. 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 uncharted 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 of the PPE provided by certain hospitals during the PHE. The hospitals' perspective is that the PPE was compliant with guidance during the pandemic.²³¹

In light of the recent release of federal guidelines for reopening businesses,²³² it is important that public health considerations remain at the foundation of any decision-making associated with business operations to mitigate spread.²³³ On May 4, 2020, Governor Cuomo announced four core factors that the State intends to monitor to determine which regions can re-open.²³⁴ Such considerations include the number of new infections, health care capacity, diagnostic testing capacity, and contact tracing capacity.²³⁵ Furthermore, businesses are required to document and put in place new safety precautions upon reopening to mitigate risk of virus spread.²³⁶ Such precaution requirements include the following:

- ☐ Workplace hours and shift design must be adjusted as necessary to reduce density in the workplace;
- ☐ Social distancing protocols must be enacted;
- ☐ Non-essential travel for employees must be restricted;
- ☐ All employees must be required to wear masks if in frequent contact with others;
- ☐ Strict cleaning and sanitation standards must be implemented;
- ☐ A continuous health screening process must be enacted for individuals to enter the workplace;
- ☐ Cases must be traced, tracked and reported on an ongoing basis; and
- ☐ Liability processes must be developed.

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. Considering this, such policies and procedures must not only be established, but implemented consistently and uniformly on an ongoing basis to ensure such efforts are worthwhile and have the long-term effect desired.

²³¹ The case against one of the hospitals was dismissed on May 1, 2020. The cases against the other hospital are proceeding. Proskauer Rose LLP represents the hospitals 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.

²³² THE WHITE HOUSE, Guidelines: Opening 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.

²³³ 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>.

²³⁴ Governor Cuomo Press Conference, *Amid Ongoing COVID-19 Pandemic, Governor Cuomo Outlines Additional Guidelines for When Regions Can Re-Open*, May 4, 2020, available at: <https://www.governor.ny.gov/news/amid-ongoing-covid-19-pandemic-governor-cuomo-outlines-additional-guidelines-when-regions-can>.

²³⁵ *Id.*

²³⁶ *Id.*

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.²³⁷

WARN – Worker Adjustment and Retraining Notifications

The FFCRA and the CARES Act do not alter the provisions of the Worker Adjustment and Retraining Notification statutes.²³⁸ 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.²³⁹ 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.²⁴⁰ 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.²⁴¹

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-19.²⁴² The provisions outline categories of eligible businesses, employee salary ranges, paid family

²³⁷ N.Y. Legis. 25 (2020), 2020 Sess. Law News of N.Y. Ch. 25 (S. 8091) (McKINNEY'S).

²³⁸ 29 U.S.C. §2101(a).

²³⁹ 20 C.F.R. § 639.4.

²⁴⁰ 29 U.S.C. § 2102(b)(2)(B).

²⁴¹ 29 U.S.C. § 2107(b)(3).

²⁴² 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,

leave or disability benefit eligibility standards and guaranteed job protections granted to individuals under the law.²⁴³ 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.²⁴⁴ 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-19.²⁴⁵ 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.²⁴⁶ 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 childcare 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.²⁴⁷

The U.S. Department of the Treasury, the IRS, and the U.S. Department of Labor have collaborated to provide small and mid-sized 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.²⁴⁸ Even so, the extraordinary impact of these benefits is notable. As of May 3, 2020, there were over 170,000 confirmed cases of novel coronavirus, 43,045 hospitalizations, and approximately 13,536 deaths associated with the virus in New York City alone.²⁴⁹ 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.²⁵⁰ For the week of April 25, 2020, the total

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

²⁴³ *Id.*

²⁴⁴ *Id.*

²⁴⁵ *Id.*

²⁴⁶ See U.S. DEP’T OF LABOR, Families First Coronavirus Response Act: Employee Paid Leave Rights (2020), <https://www.dol.gov/agencies/whd/pandemic/ffcr-employee-paid-leave> (Last accessed Apr. 12, 2020).

²⁴⁷ *Id.*

²⁴⁸ *Id.*

²⁴⁹ NEW YORK CITY HEALTH, COVID, COVID-19: DATA, (May 3, 2020), <https://www1.nyc.gov/site/doh/covid/covid-19-data.page>.

²⁵⁰ 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,

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.²⁵¹ In New York, unemployment applications spiked 16,000 percent.²⁵² 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.²⁵³ 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.²⁵⁴ 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.²⁵⁵ 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).²⁵⁶ 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.²⁵⁷

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;

<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).

²⁵¹ 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).

²⁵² 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%).

²⁵³ See U.S. DEP’T OF LABOR, Families First Coronavirus Response Act: Questions and Answers (2020), <https://www.dol.gov/agencies/whd/pandemic/ffcr-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>.

²⁵⁴ 18 N.Y. LAB. LAW § 500 et. seq.

²⁵⁵ NEW YORK STATE, Know Your Rights, <https://coronavirus.health.ny.gov/know-your-rights#insurance>; N.Y. EXEC. ORDER No. 202.1, Mar. 7, 2020, https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/EO_202_1.pdf.

²⁵⁶ *Id.*

²⁵⁷ *Id.*

- 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.²⁵⁸ 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 2020.²⁵⁹ However, Governor Cuomo soon thereafter stated that no decision had been made regarding closing schools or opening businesses in New York City or the State.²⁶⁰ As previously noted, the Governor believes in the deep interconnection between business and school operations, and thus determines that they must open in concert.²⁶¹ On May 7, 2020, Governor Cuomo signed an Executive Order extending the closure of schools statewide for the remainder of the school year.²⁶² School districts are required to continue established alternative instructional options, distribution of meals, and child care, while prioritizing services for children of essential workers.²⁶³ 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 importantly, social justice. In an effort to address some of these challenges in a targeted fashion, the Governor has partnered with the

²⁵⁸ 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>.

²⁵⁹ *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).

²⁶⁰ 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).

²⁶¹ 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 Apr. 20, 2020).

²⁶² N.Y. Exec. Order No. 202.28, <https://www.governor.ny.gov/news/no-20228-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency> (last accessed May 8, 2020).

²⁶³ *Id.*

Gates Foundation to develop a blueprint to reimagine education in the “new normal”²⁶⁴ and has established New York’s Reimagine Council²⁶⁵ to prepare for reopening. Key considerations include:²⁶⁶

- ❑ How can we use technology to provide more opportunities to students no matter where they are;
- ❑ How can we provide shared education among schools and colleges using technology;
- ❑ How can technology reduce educational inequality, including English as a new language student;
- ❑ How can we use technology to meet educational needs of students with disabilities;
- ❑ How can we provide educators more tools to use technology;
- ❑ How can technology break down barriers to K-12 and Colleges and University to provide greater access to high quality education no matter where the student lives; and
- ❑ Given ongoing social distancing rule, how can we delay classroom technology, like immersive cloud virtual classrooms learning, to recreate larger class or lecture hall environments in different locations?

As the Gates Foundation collaboration and New York’s Reimagine Council progress forward toward a revitalized and stronger New York, it is essential that health care practitioners and public health experts are proactively integrated in future discussions in light of the significant impact health has on positive education outcomes.

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.²⁶⁷ 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.²⁶⁸ Almost 1.5 million children receive free or reduced lunch through the public school system.²⁶⁹ In regards to child care, there are approximately 17,000 day care centers throughout New York State.²⁷⁰ Despite having a total capacity of over 630,000 children across centers, child care shortages are an ongoing issue throughout the state.²⁷¹ 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

²⁶⁴ Governor Cuomo Press Conference, Video, Audio, Photos & Rush Transcript: Amid Ongoing COVID-19 Pandemic, Governor Cuomo Announces Collaboration with Gates Foundation to Develop a Blueprint to Reimagine Education in the New Normal, May 5, 2020, <https://www.governor.ny.gov/news/video-audio-photos-rush-transcript-amid-ongoing-covid-19-pandemic-governor-cuomo-announces-19> (last accessed May 8, 2020).

²⁶⁵ Governor Cuomo Press Conference, Amid Ongoing COVID-19 Pandemic, Governor Cuomo Announces Members of the Reimagine Education Advisory Council, May 8, 2020, <https://www.governor.ny.gov/news/amid-ongoing-covid-19-pandemic-governor-cuomo-announces-members-reimagine-education-advisory> (last accessed May 8, 2020).

²⁶⁶ Governor Cuomo Press Conference, Video, Audio, Photos & Rush Transcript: Amid Ongoing COVID-19 Pandemic, Governor Cuomo Announces Collaboration with Gates Foundation to Develop a Blueprint to Reimagine Education in the New Normal, May 5, 2020, <https://www.governor.ny.gov/news/video-audio-photos-rush-transcript-amid-ongoing-covid-19-pandemic-governor-cuomo-announces-19> (last accessed May 8, 2020).

²⁶⁷ State Univ. of New York, Fast Facts, Jan. 2019, <https://www.suny.edu/about/fast-facts/> (last visited Apr. 19, 2020).

²⁶⁸ 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).

²⁶⁹ 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.

²⁷⁰ OFFICE OF CHILDREN AND FAMILY SERV., New York State 2017 Child Care Demographics (2017).

²⁷¹ *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 childcare facilities).

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).²⁷² 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 childcare programs.²⁷³ 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 childcare services offerings throughout the State are woefully inadequate and prohibitively costly due to inadequate funding, limited staff²⁷⁴ and a stringent regulatory framework related to adult-child ratios, training and experience, inspections, and employee eligibility requirements.²⁷⁵

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 childcare providers with public health and operations related updates.²⁷⁶ To date, OCFS has been collecting information from licensed and registered providers via surveys to determine “whether they have openings in their childcare program, and if they have the capacity and desire to serve more children than their established capacity.”²⁷⁷ Furthermore, surveys were distributed to determine parent or caregiver need.²⁷⁸ OCFS advises that child care *may* be available based on the responding party’s “job, employer, number of children, and financial need.”²⁷⁹ 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.²⁸⁰ Since then various stakeholders have started initiatives to ensure that health care workers, first responders and front-line workers have access to child care.²⁸¹ In

²⁷² 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).

²⁷³ See 18 N.Y.C.R.R. § 413.2.

²⁷⁴ 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 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>.

²⁷⁵ *Id.*

²⁷⁶ 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>).

²⁷⁷ OFFICE OF CHILDREN AND FAMILY SERV., Coronavirus Information (COVID-19) News and Updates, Survey on Child Care Program Openings, Mar. 25, 2020, <https://ocfs.ny.gov/main/news/COVID-19/#t1-Letters-to-Child-Care-Providers> (last accessed Apr. 20, 2020).

²⁷⁸ *Id.*

²⁷⁹ *Id.*

²⁸⁰ Letter from New York State Ed. Dep’t, Mar. 17, 2020; N.Y. EXEC. ORDER No. 202.4, Mar. 17, 2020.

²⁸¹ 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 County, 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.

recognition of the shortage of childcare workers and the significant impact potential infection could have on maintaining sufficient manpower, Governor Cuomo also altered background check requirements for childcare workers.²⁸²

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.²⁸³ Additionally, it is uncertain whether all frontline 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.²⁸⁴ The issue is whether there is a sufficient number of healthy, trained, and experienced child care workers available to support the workforce as the State's battle against the pandemic continues, and we begin phasing in the workforce.²⁸⁵ 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 remain available through September 30, 2021 to "prevent, prepare for, and respond" to the COVID-19 health emergency.²⁸⁶ The CARES Act also includes appropriations for Head Start, while reducing State cost-sharing contributions.²⁸⁷ Although these appropriations do not direct funding towards increasing access to childcare services to frontline workers, they provide States with increased flexibility to develop childcare programs for these workers if warranted.²⁸⁸ 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 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.²⁸⁹ 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

Dist., Childcare for Essential Emergency Workforce Personal, Mar. 20, 2020, <https://www.ichabodcrane.org/2020/03/20/emergency-responder-health-worker-child-care/> (last accessed Apr. 21, 2020).

²⁸² N.Y. EXEC. ORDER No. 202.13, Mar. 29, 2020.

²⁸³ 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).

²⁸⁴ Identifying Caregivers for Children Unaccompanied and/or Unsupervised Due to the Hospitalization of their Primary Care Giver, NYC Children Emergency Guidelines, Apr. 9, 2020.

²⁸⁵ Lillian Mongeau, *Coronavirus is Closing Day Cares; Child Care Providers Worry They May Never Reopen*, USA TODAY, 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).

²⁸⁶ Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat 281 (2020).

²⁸⁷ *Id.*

²⁸⁸ See 45 C.F.R. 98.16(aa) (incorporating use of block grant funding to be used to assist with child care 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 Apr. 12, 2020).

²⁸⁹ 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).

COVID-19 pandemic.”²⁹⁰ The income level for eligibility is less than 300 percent of the federal poverty level, which is \$78,600 for a family of four.²⁹¹ The funding may be used to cover existing care arrangements or to establish a new one.²⁹² Funding will also provide child care providers critical resources, such as masks, gloves, diapers, baby wipes, baby formula and food, with childcare resource and federal agencies receiving grants of approximately \$600 per provider.²⁹³ As childcare resource and referral agencies, childcare 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 childcare workers, while still maintaining a welcoming and nurturing environment.

In regard to workforce, New York should consider granting staffing firms dedicated to child care 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, childcare specific staffing firms could provide fully qualified and pre-screened teachers, assistant teachers and site directors for childcare centers, preschools, and before & after school programs on an on-demand, same day, short-term, long-term, or permanent basis.²⁹⁴ 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 childcare workforce stability within local communities on a routine and emergency basis, while also ensuring 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;²⁹⁵ the significant reliance on schools for food security for a large population of students;²⁹⁶ structural and economic disparities across academic institutions and students associated with home schooling and online learning;²⁹⁷ disparities associated with alternative grading systems within institutions and the modification,²⁹⁸ postponement and/or cancellation of institutional, state and/ or

²⁹⁰ *Id.*

²⁹¹ *Id.*

²⁹² *Id.*

²⁹³ *Id.*

²⁹⁴ Child Care Careers, About Us, http://www.childcarecareers.net/about_us (last visited Apr. 23, 2020).

²⁹⁵ 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).

²⁹⁶ Council On Children & Families: Kids’ Well-Being Indicators Clearinghouse, *Supra* at note. 7.

²⁹⁷ 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>.

²⁹⁸ 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>.

professional examinations;²⁹⁹ the short-term and long-term impacts associated with the postponement and/or cancellation of graduation and other related ceremonies;³⁰⁰ uncertainty regarding the timeline for reopening schools³⁰¹ 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 were disoriented and frustrated in the absence of strong direction from the State regarding school closures in the early phase of the pandemic.³⁰² 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 child care, 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.

Entanglement of the School System, Food Security, and Health Care

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.³⁰³ 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 to third-party entities. Furthermore, many schools have school-based health centers which offer primary health care services within the school environment.³⁰⁴ Beyond providing first aid, emergency care and other services to individuals and students within the building, the center also provides diverse services, such as primary care and preventative health services (physical exams, required school health services, medical care for chronic illness and disease and referrals to specialty care), mental health services on site or by referral, health education, drug and alcohol abuse

²⁹⁹ 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).

³⁰⁰ 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>.

³⁰¹ Dixon, et al, *supra*.

³⁰² 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).

³⁰³ 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).

³⁰⁴ NEW YORK STATE DEP’T OF ED., School-Based Health Centers, available at: <https://www.schools.nyc.gov/school-life/health-and-wellness/school-based-health-centers> (last accessed May 8, 2020)

counseling, dental services, and age-appropriate teen reproductive health services.³⁰⁵ Considering this, expanded partnerships with health care entities, such as federally qualified health centers, should be established to ensure access to such critical health services for children and youth. This proposal is not intended to suggest that school systems be excluded from providing such benefits entirely, but rather calls attention to 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.”³⁰⁶ 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 led 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 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.³⁰⁷ Here, there is greater risk of stratification than the potential for equality that must be 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 to 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 care services with sufficient protective measures, to safeguard them from being marginalized and ultimately harmed for the duration of this pandemic and going forward. The failure to provide appropriate evidence-based supports and services typically provided through schools could have long-term unintended consequences, such as regression. As New York seeks to become more

³⁰⁵ *Id.*

³⁰⁶ NEW YORK STATE DEP’T OF ED., About NYSED, <http://www.nysed.gov/about> (last visited Apr. 24, 2020).

³⁰⁷ 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>.

technologically advanced in the area of education, the provision of technological hardware, software, communication devices, and other assistive technology which promote inclusive distant learning, while sheltering in place and beyond, could facilitate student access to the same educational opportunities as other students.

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.”³⁰⁸ 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.³⁰⁹ 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.³¹⁰ 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 possible to the largest numbers of victims” of the virus.³¹¹ 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.

³⁰⁸ 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>.

³⁰⁹ 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>.

³¹⁰ See Essential Workers EO, Appendix F.

³¹¹ 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).

State Licensure

The New York State Education Law governs licensure requirements and scope of practice for licensed health care services providers.³¹² 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.³¹³

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.³¹⁴ 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.³¹⁵ Such processes typically take months to complete. Waivers of these laws coupled with organizations' expedited credentialing processes permit 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.³¹⁶

³¹² 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.

³¹³ 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.).

³¹⁴ See N.Y. EXEC. ORDER No. 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).

³¹⁵ 42 C.F.R. § 482.22; PUB. H. LAW §§ 2805-j and 2805-k; 10 NYCRR 405.4, 405.5, 405.14, 405.19, and 405.22.

³¹⁶ See also discussion pertaining to negligent credentialing, *infra*, Section IV, Business Contracts, Insurance and Risk Management.

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.³¹⁷ 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.³¹⁸ 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.³¹⁹ 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.³²⁰ The relaxation of these oversight requirements makes it easier to reallocate essential providers as needs ebb and flow during the crisis.

Education and Training to Crisis Standards of Care

During a PHE 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 practitioners are taught "first, do no harm."³²¹ As the standard of care shifts, practitioners need to be assured that their decisions pertaining to triage and to 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 PHE. 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

³¹⁷ N.Y. ED. LAW, Title VIII.

³¹⁸ See N.Y. ED. LAW § 6905 (requirements to qualify for a license as a registered professional nurse).

³¹⁹ 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).

³²⁰ See N.Y. EXEC. ORDER No. 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).

³²¹ See discussion in Ethics Issues in the Management of COVID-19, *infra*.

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.”³²² 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.”³²³
- OSHA’s Bloodborne Pathogens standard applies to “occupational exposure to human blood and other potentially infectious materials that typically do not include respiratory secretions.”³²⁴ However, they offer guidance for the control of infectious disease such as COVID-19.

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.³²⁵ 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

³²² Occupational Safety and Health (OSH) Act of 1970, 29 U.S.C. 654(a)(1).

³²³ 29 C.F.R.1910.134.

³²⁴ 29 C.F.R.1910.1030.

³²⁵ Standard Precautions for All Patient Care, CDC, Jan. 26, 2016, <https://www.cdc.gov/infection-control/basics/standard-precautions.html>.

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 self-quarantine 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?³²⁶ 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.³²⁷ 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.³²⁸ Similarly, OSHA prohibits employers from retaliating against workers for raising concerns about safety and health conditions.³²⁹ Additionally, "OSHA's Whistleblower Protection Program enforces the provisions of more than 20 industry-specific federal laws protecting employees from retaliation for raising or reporting concerns about hazards or violations."³³⁰

Discrimination

The Americans with Disabilities Act of 1990 ("ADA")³³¹ 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.³³² 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

³²⁶ 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.

³²⁷ See N.Y. PUB. H. LAW § 2805-l.

³²⁸ See N.Y. Pub. H. Law § 2805-m.

³²⁹ Occupational Safety and Health Act of 1970, 29 U.S.C. 660(c).

³³⁰ 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>.

³³¹ 42 U.S.C. § 12101 et. Seq.

³³² 42 U.S.C. § 12112 (d).

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.³³³ “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.³³⁴

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.³³⁵

VI. Vaccination

When a vaccine becomes available, there will be a majority of Americans who want the vaccination.³³⁶ However, some Americans may push back on the COVID-19 vaccination for religious, philosophical or personal reasons.³³⁷ *After testing and as supported by scientific evidence*, once a *safe and effective* COVID-19 vaccine becomes available, the NYSBA Health Law Section recommends:³³⁸

- That a vaccine subject to scientific evidence of safety and efficacy be made widely available, and widely encouraged, and if the public health authorities conclude necessary, required, unless a person's physician deems vaccination to be clinically inappropriate; and
- Steps to ensure a planned vaccination program:
 - (a) Rapid mass vaccination achieved through equitable distribution;
 - (b) Prioritizing health care workers and individuals at highest risk for complications and virus transmission to others if inadequate vaccine supply; and

³³³ *Id.*

³³⁴ 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.

³³⁵ See *Arnold v. Pfizer, Inc.*, 970 F.Supp.2d 1106, Oregon Dist. Ct. (Sept. 9, 2013).

³³⁶ 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).

³³⁷ *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) (*affm’d by Caviezel v. Great Neck Public Schools* 500 Fed.Appx. 16 (2d Cir. 2012).

³³⁸ This recommendation has been revised consistent with amendments to the language voted on by the NYSBA Executive Committee on June 12, 2020.

(c) Linguistically and culturally competent vaccine educational and acceptance program.³³⁹

Mandatory vaccinations are supported by the authority of the state police power when the vaccinations are necessary to protect the health of the community.³⁴⁰ 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.³⁴¹ In New York State, the courts have found religious, personal or “unsupported...medical literature”³⁴² arguments unpersuasive.³⁴³ Healthcare workers³⁴⁴ and parents of unvaccinated children³⁴⁵ 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.³⁴⁶ Further, on June 13, 2019, the religious exemption for vaccinating school-attending children was repealed.³⁴⁷ 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.³⁴⁸ It also annually issues a National Vaccine Plan.³⁴⁹ The National Vaccine Program addressed the development of a COVID-19 vaccine in its February 2020 meeting.³⁵⁰

Before the COVID-19 outbreak, a bill was introduced to federally mandate vaccination for school children.³⁵¹ Since the COVID-19 outbreak began, additional bills and resolutions have been introduced by

³³⁹ Schaffer DeRoo S, Pudalov NJ, Fu LY. Planning for a COVID-19 Vaccination Program. *JAMA*. Published online May 18, 2020. doi:10.1001/jama.2020.8711

³⁴⁰ See generally *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

³⁴¹ 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.

³⁴² *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 vaccinated for MMR (measles)).

³⁴³ 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.

³⁴⁴ *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”).

³⁴⁵ *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).

³⁴⁶ 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.

³⁴⁷ PUB. H. LAW § 2164(9) (repealed Jun. 13, 2019).

³⁴⁸ 42 U.S.C. §300aa-1 (2020).

³⁴⁹ 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>.

³⁵⁰ 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).

³⁵¹ 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

the 116th Congress regarding vaccination and immunization.³⁵² They include resolutions by the House and Senate, supporting the GAVI Alliance, which supports vaccines and immunizations in developing countries.³⁵³

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.³⁵⁴ Others support wide-spread vaccination across the United States.³⁵⁵ These include bills offering wide-spread vaccination programs that are subsidized by the federal government for seniors and children.³⁵⁶ In the “Protecting Seniors Through Immunization Act of 2019,” the Medicare program will encourage and provide free

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 Hirono on Jun. 13, 2019); Pandemic 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).

³⁵² 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).

³⁵³ 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).

³⁵⁴ 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).

³⁵⁵ 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).

³⁵⁶ 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).

vaccinations to seniors already covered.³⁵⁷ 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.³⁵⁸ Given these proposals, vaccination distribution and funding will likely be heavily influenced by Congress.

The devastating 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.”³⁵⁹ 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 under-resourced 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.³⁶⁰ Data reported during the current crisis document higher numbers of COVID-19 positive cases and higher mortality rates among

³⁵⁷ Protecting Seniors Through Immunization Act of 2019, S.1872, 116th Cong. (introduced by Sen. Mazie 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).

³⁵⁸ Vaccinate All Children Act of 2019, H.R. 2527, 116th Cong. (introduced on May 3, 2019 by Rep. Frederica Wilson).

³⁵⁹ 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, Apr. 16, 2020, <https://www.thehastingscenter.org/ethics-and-evidence-in-the-search-for-a-vaccine-and-treatments-for-COVID-19/>.

³⁶⁰ Aaron van Dorn, Rebecca E. Cooney & Mariam L. Sabin, *COVID-19 exacerbating inequalities in the US*, 395.

Black/African Americans and other marginalized and socioeconomically disadvantaged groups.³⁶¹ 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 groups,³⁶² as well as across the five boroughs.³⁶³ 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.³⁶⁴ While federal law bars such discrimination,³⁶⁵ 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.³⁶⁶ 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 Developmental 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,”³⁶⁷ which echoes that of the New York State Department of Education.³⁶⁸ 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.”³⁶⁹ The failure to do such could potentially result in the suspension or limitation of a provider’s operating certificate.³⁷⁰ 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

³⁶¹ *Id.*; COVID-19 exacerbating inequalities in the US, LANCET, Vol. 395, Apr. 18, 2020; Yancy CW, COVID-19 and African Americans, JAMA, Published online Apr. 15, 2020, doi:10.1001/jama.2020.6548.

³⁶² 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 Apr. 16, 2020, <https://www1.nyc.gov/assets/doh/downloads/pdf/imm/COVID-19-deaths-race-ethnicity-04162020-1.pdf>.

³⁶³ 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>,

³⁶⁴ 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.

³⁶⁵ 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>.

³⁶⁶ 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.

³⁶⁷ NEW YORK STATE OFFICE FOR PEOPLE WITH DEVELOPMENTAL DISABILITIES, *supra* note 4.

³⁶⁸ THE STATE EDUCATION DEPARTMENT, *Additional Guidance on Statewide School Closures Due to Novel Coronavirus (COVID-19) Outbreak in New York State*, Mar. 17, 2020.

³⁶⁹ NEW YORK STATE OFFICE FOR PEOPLE WITH DEVELOPMENTAL DISABILITIES, *COVID-19 Guidance for Providers on Essential Business*, Mar. 20, 2020.

³⁷⁰ N.Y. EXEC. ORDER No. 202.5, Mar. 18, 2020.

by health insurance. Moreover, the temporary expansion of Title 1 of the Family and Medical Leave Act (FMLA)³⁷¹ and adoption of “The Emergency Paid Sick Leave Act” under The Families First Coronavirus Response Act³⁷², 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.³⁷³ 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.³⁷⁴

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.³⁷⁵ 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 ensure:

- ❑ 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;

³⁷¹ 29 U.S.C. § 2601 *et. seq.*

³⁷² Families First Coronavirus Response Act, Public Law No. 116-127 (Mar. 18, 2020) (*to be added as* 29 U.S.C. §§ 2601 *et. seq.*). Paid Leave Under the Families First Coronavirus Response Act, 85 Fed. Reg. 19,326 (Apr. 6, 2020).

³⁷³ N.Y. EXEC. ORDER No. 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>.

³⁷⁴ See generally Mary Beth Walsh, *The Top 10 Reasons Children With Autism Deserve ABA*, 1 BEHAVIOR ANALYSIS PRACTICE 72-79 (2011).

³⁷⁵ See generally Valerie Blake, J.D., M.A., *When Is a Patient-Physician Relationship Established?*, AMERICAN MEDICAL ASSOCIATION JOURNAL OF ETHICS (May 2012).

- 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.

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.”³⁷⁶

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,³⁷⁷ IOM’s Crisis Standards of Care, as applicable, equipment allocation guidelines,³⁷⁸ 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.³⁷⁹ 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.³⁸⁰ 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 have been waived during the pandemic 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-19 world. At the New York State level, some scope of practice requirements, CON requirements and

³⁷⁶ LAWRENCE O. GOSTIN, *GLOBAL HEALTH LAW* 72 (Har. Univ. Press 2014).

³⁷⁷ 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).

³⁷⁸ See discussion *infra*, Section II of this Report, Ethical Issues in the Management of COVID-19.

³⁷⁹ National Governors Association, Executive Committee, <https://www.nga.org/governors/ngaleadership/>.

³⁸⁰ CMS, CMS list of Coronavirus Waivers & Flexibilities, available at: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.

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.

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 Association Health Law Section Letter to Governor Cuomo, March 26, 2020

COVID-19 New York Public Health Emergency and Disaster Conditions: Call for Essential Crisis Standards in New York

APPENDIX B

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

2015 Ventilator Allocation Guidelines, NYS Task Force

University of Rochester 2015 Updated Ventilator Allocation Flow Diagrams

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, cannot 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

Proposed Rule by the NYSBA Health Law Section

Proposal 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

COVID-19 New York Public Health Emergency and Disaster Conditions: Call for Equitable Allocation of Scarce Resources to Older Adults and Non-Discriminatory Crisis Standards

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)³⁸¹

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 in-person 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

³⁸¹ 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>.

- ☐ public water and wastewater
- ☐ telecommunications and data centers
- ☐ airlines/airports
- ☐ 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:

- ☐ construction is for, or your business supports, roads, bridges, transit facilities, utilities, hospitals or healthcare facilities, homeless shelters, or public or private schools;
- ☐ construction is for affordable housing
- ☐ construction is necessary to protect the health and safety of occupants of a structure;
- ☐ 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;
- ☐ construction is for projects in the energy industry
- ☐ construction is for existing (i.e. currently underway) projects of an essential business; or
- ☐ 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. 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 ensure: 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: New York State Department of Health or Governor to consider:

- i. Establishing a coordinated statewide plan that ensures: frontline health care workers are prioritized in access to rapid diagnostic testing; and further, the most vulnerable individuals from health status and essential business/employee standpoint have equitable access to rapid diagnostic testing.

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 ensure:
 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;³⁸²
 2. Adequate provision of PPE;
 3. Adequate levels of staffing;
 4. Adequate funding of employee testing, as required under Executive Order 202.30;
 5. Consistent and timely tracking and reporting of case and death data;
 6. Adoption of non-discriminatory crisis standards and ethics guidelines; and
 7. Recognition and honoring of Older New Yorkers' right to health and human rights, as protected under international conventions; and
 8. 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 ensure:
 1. Access of persons with disabilities to adequate COVID-19 testing and appropriate medical care, mental health and other supportive services, including appropriate day

³⁸² 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 non-discriminatory 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 ensure:
- 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: 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 ensure:
- 1. Reduction of risk of the spread of COVID-19 among immigrants being held in detention centers.³⁸³

(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

³⁸³ 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 childcare 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

When a vaccine becomes available, there will be a majority of Americans who want the vaccination.³⁸⁴ However, some Americans may push back on the COVID-19 vaccination for religious, philosophical or personal reasons.³⁸⁵ *After testing and as supported by scientific evidence*, once a *safe and effective* COVID-19 vaccine becomes available, the NYSBA Health Law Section recommends:³⁸⁶

³⁸⁴ 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).

³⁸⁵ *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) (*affm'd by Caviezel v. Great Neck Public Schools* 500 Fed.Appx. 16 (2d Cir. 2012)).

³⁸⁶ This recommendation has been revised consistent with amendments to the language voted on by the NYSBA Executive Committee on June 12, 2020.

- That a vaccine subject to scientific evidence of safety and efficacy be made widely available, and widely encouraged, and if the public health authorities conclude necessary, required, unless a person's physician deems vaccination to be clinically inappropriate; and
- Steps to ensure a planned vaccination program:
 - (a) Rapid mass vaccination achieved through equitable distribution;
 - (b) Prioritizing health care workers and individuals at highest risk for complications and virus transmission to others if inadequate vaccine supply; and
 - (c) Linguistically and culturally competent vaccine educational and acceptance program.³⁸⁷

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

- (a) Enhance regulatory oversight, to ensure:
 - 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.

³⁸⁷ Schaffer DeRoo S, Pudalov NJ, Fu LY. Planning for a COVID-19 Vaccination Program. *JAMA*. Published online May 18, 2020. doi:10.1001/jama.2020.8711.

- (b) Re-evaluate the public benefit and costs of reinstating laws which have been waived during COVID-19.

APPENDIX H

New York State Bar Association Health Law Section Task Force Members, Advisors and Experts

Hermes Fernandez, *Health Law Section Chair*

Members of Task Force

Mary Beth Quaranta Morrissey, Esq., PhD, MPH, *Task Force Chair*

Jane Bello Burke, Esq.

Kathleen M. Burke, Esq.

Veda Collmer, Esq.

Karen Gallinari, Esq.

Edward S. Kornreich, Esq.

Anoush Koroghlian-Scott, Esq.

Thomas G. Merrill, Esq.

Brendan S. Parent, Esq.

Nathan G. Prystowsky, Esq.

Salvatore J. Russo, Esq.

Jennifer M. Schwartzott, Esq.

Mishka A. Woodley, JD, LLM

Advisors to the Task Force:

Thomas V. Caprio, MD, MPH, MS, CMD, HMDC, FACP, AGSF, FAAHPM

Christopher Comfort, MD

Larry Faulkner, Esq.

Allie Gold, Esq.

Roshni D. Persaud, Esq.

Donna Seminara, MD, MACP

Samuel J. Servello, JD, LLM

Attorney, law clerk and law student, and other volunteers:

Patrick Benjamin

John D. Clopper, Esq.

Marissa Cohen

Morgan Dowd

Michele Korkemaz-Christie

Martha Mahoney

Kerianne Morrissey

Matthew Pappalardo

Ivelina V. Popova, Esq.

Daniel S. Weinstein

We thank the following esteemed members of the bar, scholars and ethicists who served as experts and provided generous assistance and consultative support to the Task Force:

Linda Fentiman, JD, LLM

Joseph J. Fins, M.D., M.A.C.P., F.R.C.P.

Professor Lawrence O. Gostin

James Hodge, Jr., JD, LLM

Beth Roxland, JD, M.Bioethics

Robert Swidler, Esq.



NEW YORK STATE BAR ASSOCIATION **BUSINESS LAW SECTION**

October 1, 2020

To: Kathy Baxter
Members of the House of Delegates
From: Business Law Section

Re: Health Law Section Report on COVID-19

The NYSBA Business Law Section writes in support of the Report and Recommendations of the Health Law Section Task Force on COVID-19 (the “Report”), and urges the House of Delegates to approve the proposed Resolutions implementing aspects of the Report at its November 2020 meeting. The Report is an extraordinary, thorough, and well-considered analysis of the steps needed to combat, control, and ultimately overcome the COVID-19 pandemic, while giving appropriate consideration to the disproportionate impact of the pandemic on minority and disadvantaged populations, to the ethical considerations and difficult decisions to be made when healthcare resources and testing are insufficient to meet the needs of all, and to the public health needs of the State and the nation.

From the perspective of business lawyers, it is apparent to us that the recovery of the economy, the full re-opening of businesses and, indeed, their very health and survival, depend on success in controlling the coronavirus. Until the employees, customers, and other stakeholders of our business clients feel comfortable returning to normal economic activity, the economy will continue to be hamstrung, economic activity will be reduced, and unemployment will remain at unprecedented levels. Even as New York State has begun to permit reopening, we see a continued reluctance of employees to return to work and customers to return to in-person purchasing of goods and services, even where such activity is permitted.

The recommendations of the Health Law Section set forth in the Report provide a framework for New York State to move forward.

Resolution # 1 addresses public health legal reforms and emergency preparedness, and ethical issues including allocation of life-saving equipment, and virus testing. We believe these recommendations give careful consideration to the difficult ethical issues raised when the pandemic demand for health care exceeds what is available and take proper care to ensure that “the needs of vulnerable populations, including persons and communities of color, older adults and nursing home residents, persons with disabilities or who are incarcerated, and immigrants, are met in a non-discriminatory manner in the implementation of emergency regulations and guidelines,” resulting in appropriate resolution of the issues in a manner calculated to help medical providers deal with a potential resurgence of crisis demands for medical care.

Resolution # 2 provides for several constructive recommendations. With respect to medical providers, the resolution calls for continuation of waivers and executive orders relating to capacity issues and resident hours; steps relating to nursing homes and older adults, incarcerated persons and detained immigrants; and encouragement of telehealth care.

In addition, it calls for consideration of ways to supplement the childcare workforce; and regulatory oversight to ensure adequate and non-discriminatory allocation of resources and equitable access to

health and mental health services for persons and communities of color and vulnerable populations. The Business Law Section considers these steps particularly important to the development of public confidence in the safety of returning to normal economic activities as employees and consumers, and to the ability to turn to childcare options and re-opened schools without fear for the well-being of children, without which many will be unable to return to the workforce.

Resolution #3 calls for

- a coordinated statewide plan for virus testing, prioritizing front-line health care workers and the most vulnerable individuals
- vaccine development where safety and efficacy are established through expert consensus after rigorous clinical trials that include representation of diverse populations
- ethical, equitable allocation and distribution of vaccines
- steps to encourage public acceptance of a safe and effective vaccine,
- and finally, consideration of mandatory vaccination (subject to medical exemptions), by state and local governments for populations identified by state or local public health authorities, if the level of vaccination is “deemed insufficient to check the spread of COVID-19 and reduce morbidity and mortality, after due consideration of the expert medical and scientific consensus regarding the safety and efficacy of a vaccine and the need for required inoculation, including i) evidence of properly conducted and adequate clinical trials, ii) reasonable efforts to promote public acceptance, and iii) fact-specific assessment of the threat to the public health in populations and communities”

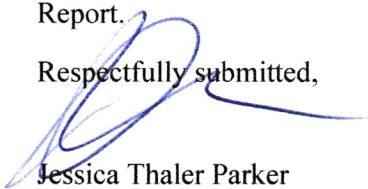
While this recommendation has drawn some opposition, we believe that these prerequisites to mandatory vaccination – safety and effectiveness as determined by expert consensus after appropriate clinical trials, and need, as determined levels of vaccination in relevant populations after efforts to promote public acceptance – are sufficient to avoid any infringement of civil liberties and personal autonomy. In New York, these decisions would generally be made at the county level.

Notably, these determinations are not legal questions, but scientific and medical ones. The development of “herd immunity” to the coronavirus – which we believe will be critical to full resumption of the economy – requires 60% or more of the population to be immune to the virus, whether from prior exposure, natural immunity, or vaccination. This may be achievable without mandatory vaccination, should enough people voluntarily obtain vaccines. But if that does not happen, the threat to the public health from unvaccinated individuals cannot be accepted. One’s civil liberties do not extend to a right to threaten the health of others, such as those too young, too old, or otherwise medically unable to be vaccinated. As the adage goes, your freedom to swing your fist stops at my nose.

Mandatory vaccination requirements were instrumental in eliminating smallpox, and, as recently as last year, the ability to require vaccination was critical to the successful battle to stop the outbreaks of measles in Brooklyn and in Rockland County. If such steps are determined to be necessary to stop the spread of COVID-19, then they must be undertaken.

For all of these reasons, the Business Law Section urges the House of Delegates to approve the Report.

Respectfully submitted,



Jessica Thaler Parker
Secretary

DRAFT

MEMORANDUM

TO: Thomas J. Richards, Esq.
Deputy General Counsel
New York State Bar Association

FROM: Jonathan B. Fellows, Esq.
Chair, Commercial and Federal Litigation Section

DATE: September 8, 2020

RE: Report and Recommendations of the NYSBA Health Law Section Task Force on COVID-19

This memorandum is submitted in response to the request for comments from NYSBA Sections on the Report of the Health Law Section Task Force on COVID-19 (the “Report”).

The leadership of the Commercial and Federal Section received the Report following the June meeting of the House of Delegates. The Report was called to the attention of our Section Members at the July 1, 2020, meeting of the Section’s Executive Committee. The Section’s representatives in the House of Delegates reported on the discussions of the Report and the proposed resolutions in the House of Delegates at our July 1 Executive Committee meeting. The Section’s leadership has received only minimal response from our members since our July 1 meeting.

Much of the Report and the accompanying recommendations appear to be outside the purview of the Commercial and Federal Litigation Section. The Report does include in section IV a discussion of “Business/Contracts/Risk Management” that discusses force majeure, frustration of purpose, impossibility and section 2-615(a) of the Uniform Commercial Code.

Resolution Number 4 proposed by the Executive Committee of the Health Law Section suggests that the Legislature consider amendments to UCC § 2-615(a) in connection with commercial disputes arising from the Pandemic. The leadership of the Commercial and Federal Litigation Section believes that our State's Commercial Division courts, and the federal courts in our State can resolve commercial disputes arising out of the Pandemic using existing common law doctrines and the existing UCC without the need for legislation.

Health Law Section COVID 19 Report -
Comments of the Committee on Disability Rights

Date: August 17, 2020

Introduction

On May 14, 2020, the Health Law Section of the New York State Bar Association issued its COVID 19 Report. The Report was the product of a Task Force conceived by the past President of the New York State Bar Association (NYSBA), Hank Greenberg, and appointed by past Section Chair Hermes Fernandez.¹ The Task Force was charged with examining the legal issues presented by the pandemic.² The work of the Task Force is to be commended. The Report is thorough and well researched. It covers the following subject areas; Public Health Law Framework, Ethical Issues in the Management of COVID 19; Provider Systems and Issues; Business Contracts/Risk Management; Workforce Issues Associated with COVID - 19; Vaccination, and Vulnerable Populations and Issues of Quality and Discrimination. At Appendix G of the Report recommendations are found tracking each subject area addressed in the Report. The Health Law Section has also drafted four (4) Resolutions related to the Report that will be presented to the NYSBA House of Delegates at their November 2020 meeting.³ The substantive comments of the Committee on Disability Rights are a product of a sub-committee formed by the Disability Rights Committee, approved by

¹ Health Law Section (hereinafter "COVID") Report, p 2.

² *id.*

³ The draft resolutions as shared with our Committee are attached as Addendum [A] to this Comment.

a vote of the Committee and were informed following several meetings with members of the Health Law Section.⁴

Our Committee was pleased to see attention focused on vulnerable populations, as well as issues around quality of care and discrimination in the delivery of care. However, the Task Force membership was notably lacking people who identify as having disabilities or advocacy groups for people with disabilities. People with disabilities, including residents of nursing facilities and other congregate care settings, have been devastated by the Coronavirus. Yet voices of this critical constituency were not heard in the Task Force's recommendations.

The Task Force stated that the New York State Bar Association needs to do all that it can to “advocate for the removal of legal and regulatory obstacles that hinder health care providers’ ability to fully respond to the challenges of the pandemic.”⁵ Our members believe this statement affords too much deference to the State and health care providers at the expense of vulnerable populations they serve.⁶ “Legal and regulatory obstacles” were created to protect people, and any proposals to waive these protections should be subjected to more serious scrutiny.

⁴ The Disability Rights Committee acknowledges Mary Beth Morrissey, Robert Swidler and Brendan Parent of the Health Law Section who met with Committee members to address various concerns our Committee raises in this Comment. In particular, Mary Beth Morrissey was very generous with her time and met with Committee members on three separate occasions. Substantive edits to the Report were agreed to following these meetings and as further described in this Comment.

⁵ COVID Report, p 16.

⁶ For example, the COVID Report at page 11 recommends permitting physicians to make decisions regarding life-sustaining treatment over the objection of family members and urges override of several existing laws, including article 47 of the Mental Hygiene Law. Article 47 provides for the Mental Hygiene Legal Service. The Service is a state agency mandated to provide protective legal services to patients and residents of mental hygiene facilities.

Furthermore, our members strongly disagree with this Report's conclusion that skilled nursing facilities (SNFs) need to be defended from "inaccurate media reports" relating to the conditions at these facilities.⁷ From our perspective, the perils experienced by residents of SNFs and their families during this pandemic are the product of years of neglect well known to both New York State and to the industry.⁸ The Report does not recognize the chronic understaffing of SNFs is largely caused by the under-compensation of caregivers. We note this may be driven by inadequate Medicaid reimbursement, but also observe that nursing facilities are in many cases operated by for-profit entities whose objective is to remain profitable. Our Committee believes that: 1) the Report has missed an opportunity to recommend greater oversight and quality assurance throughout the entire health care system, but especially SNFs, adult homes and residential mental health facilities; 2) there is a need for more effective enforcement as well as additional mandatory requirements relating to emergency preparedness, and 3) there should be mandatory minimum staffing requirements.

⁷ COVID Report p 22. The context for comment at page 22 of the Report focused largely on communication with families during the pandemic. However, the point our Committee makes is that long-standing sub-standard conditions at SNFs and other long term care facilities are well documented (see <https://nursinghome411.org>). The State agency charged with the oversight of nursing facilities, the New York State Department of Health, has failed to sufficiently inspect, investigate and sanction this sector. Chronic understaffing should not be accepted as a given and is inexcusable and our Committee urges study of the Safe Staffing and Quality Care Act by the NYSBA (S.1032/A.6571).

⁸ See Richard Mollott, Nursing Homes were a Disaster Waiting to Happen, <https://www.nytimes.com/2020/04/28/opinion/coronavirus-nursing-homes.html#:~:text=Nursing%20Homes%20Were%20a%20Disaster%20Waiting%20to%20Happen.and%20lax%20standards%20were%20widespread%20and%20well%20known> . While the Committee agrees with the COVID Report that there needs to be greater resources devoted to increasing staffing in congregant care settings, there must be concurrent and after-the-fact accountability for how that money is spent, especially by for-profit entities.

We appreciate this opportunity to offer the Task Force our comments. Our members are composed of attorneys in the public sector and the private bar. Our members include attorneys with disabilities, and they practice in wide areas of law. Our comments below do not address every topic covered by the Report and focus, instead, on several discrete issues.

Comments

1. Public Health Law Framework and Legal Reforms

The COVID Report recommends that the Department of Health (or through it the Task Force on Life and the Law) review and consider enactment into New York Law of the Model State Emergency Health Powers Act (“MSEHPA”). This may be ill-considered and we urge re-examination of the recommendation. In 2002 the New York State Legislature considered adopting the Model Act, but the effort failed.⁹ We mention three issues for consideration:

- The Model Act fails to provide for adequate checks and balances. The lack of checks and balances could have serious consequences for individuals' freedom, privacy, and equality. Public health authorities make mistakes, and politicians abuse their powers; there is a history of discriminatory use of the quarantine power against particular groups of people based on race and national origin, for example. The Act permits a governor to declare a state of emergency unilaterally and without judicial oversight, fails to provide modern due process procedures for quarantine and other emergency powers, it lacks adequate compensation for seizure of assets, and contains no checks on the power to order forced treatment and vaccination.

⁹ See testimony of NYCLU expressing concerns about the Model Act. <https://www.nyclu.org/en/publications/testimony-model-state-emergency-health-powers-act> - last accessed July 5, 2020

- The impetus for the Model Act was bioterrorism, but the Act goes well beyond that framework. The Act includes an overbroad definition of “public health emergency” that sweeps in HIV, AIDS, and other diseases that clearly do not justify quarantine, forced treatment, or any of the other broad emergency authorities that would be granted under its provisions.¹⁰
- The Model Act lacks privacy protections. It requires the disclosure of massive amounts of personally identifiable health information to public health authorities, without requiring basic privacy protections and fair information practices that could easily be added to the bill without detracting from its effectiveness in quelling an outbreak. And the Model Act would undercut existing protections for sensitive medical information. That not only threatens to violate individuals' medical privacy but undermines public trust in government activities.

The COVID Report also recommends 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 Department of Health (or through it The Task Force on Life and the Law). We observe that The Arc of the United States, The Bazelon Center for Mental Health Law, the Center for Public Representation and the Autistic Self Advocacy Network on April 8, 2020 published a 6-point disability framework to assess Crisis Standards of Care and other health care allocation criteria. It does not appear to us that the Task Force adequately considered the disability framework for

¹⁰ “Public Health emergency” is defined under the Act as an occurrence or imminent threat of an illness or health conditions caused by bioterrorism, epidemic or pandemic disease, or novel and highly infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or permanent or long-term disability. Such illness or health condition includes, but is not limited to, an illness, or health condition resulting from and natural disaster (Model Act Section 104 [l]).

crisis standards of care plans in its Report and we recommend that they be included.¹¹

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

The COVID Report urges avoiding criteria that discriminate on the basis of disability in the allocation of scarce health care resources such as ventilators. However, COVID Report endorses adoption of the 2015 Ventilator Allocation Guidelines released by the Task Force on Life and the Law. On April 7, 2020, Disability Rights New York filed a complaint with the federal Department of Health and Human Services alleging that the 2015 Allocation Guidelines contain serious gaps that discriminate against people with pre-existing disabilities in violation of the Americans with Disabilities Act (42 U.S.C. 12101 *et seq*) and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794).¹² Advocates highlighted the following concerns about the guidelines: (1) they do not retain the presumption that all patients who are eligible for ICU services during ordinary circumstances remain eligible for ICU services in a pandemic; (2) they contain exclusion criteria based on age, disabilities and other factors; (3) they do not ensure that all patients receive individualized assessments by clinicians based upon the best available objective medical evidence; (4) they do not ensure that no one is denied care based upon

¹¹ http://www.bazelon.org/wp-content/uploads/2020/04/4-9-20-Evaluation-framework-for-crisis-standards-of-care-plans_final.pdf - last accessed August 16, 2020.

¹² DRNY is a Protection and Advocacy System specifically authorized to pursue legal, administrative and other appropriate remedies to ensure the protection of, and advocacy for, the rights of individuals with disabilities (42 U.S.C. 15043[a][2][A][i] and New York State Executive Law 558 [b]). The DRNY OCR complaint referenced in the text of this comment is attached as an Addendum [B] for ease of reference.

stereotypes, assessments of quality of life or judgments about a person's "worth" or the presence of absence of disabilities other factors; and (5) while it is appropriate to evaluate the possibility of a person's survival in allocation decisions, the guidelines do not mandate that the considerations must be based upon the prospect of surviving the condition for which the treatment is designed -in this case COVID-19. In other words, individuals with pre-existing conditions are completely disadvantaged in a triage situation prior to considering any symptoms that result from COVID-19.

From our Committee's perspective there are very troubling conclusions in the COVID Report, as well, regarding medical futility. In this regard at page 12 of the COVID Report it is stated that challenges may arise when a patient's advance directive conflicts with, or a surrogate decision-maker disagrees with, the decision of doctor to withdraw or withhold care. In such cases, the COVID Report recommends that if a doctor with the concurrence of another opines that treatment is futile, there should be no legal constraints on the issuance of a do-not-resuscitate order. In the same section of the COVID Report it is recommended that a number of essential statutory protections for vulnerable people be overridden, including Surrogate's Court Procedure Act (SCPA) 1750-b and article 47 of the Mental Hygiene Law, providing for the functions, powers and duties of the Mental Hygiene Legal Service.¹³

¹³ SCPA 1750-b is a discrete health care decision making statute for individuals with developmental disabilities (See Christy Coe, *Beyond Being Mortal, Safeguarding the Rights of People with Developmental Disabilities to Efficacious Treatment and Dignity at the End of Life*, 88 Oct N. Y.

The Committee must take issue with these recommendations. SCPA 1750-b, in particular, has proven to be an important statutory safeguard to ensure that people with developmental disabilities who may lack capacity to make their own health care decisions have potential life sustaining treatment withdrawn consistent with statutory standards.¹⁴ The Mental Hygiene Legal Service, as well as mental hygiene facility directors, have an important role to perform under SCPA 1750-b and during the COVID-19 pandemic, pledged their resources to be available whenever needed to meet statutory mandates.¹⁵ The Report cites no example where the mandates of SCPA 1750-b could not be fulfilled during the pandemic to ensure that health care decisions for this most vulnerable population were made with full regard for the dignity of the individual in accordance with statutory requirements. While members of the Committee are aware those procedures were utilized by some providers, there are questions whether the process was appropriately utilized by others.

St. B. J 8 (2016). MHLS informs the Committee that during the pandemic health care providers have largely been able to comply with the statute and MHLS and mental hygiene facility directors have expedited their review processes and made staff available after hours and on weekends. Our Committee also notes that following meetings with the Health Law Section members, it was agreed that the reference to article 47 of the Mental Hygiene Law would be removed from the text of the Report. The Health Law Section members also agreed to make other edits to their Report as reflected in Addendum [C] to this Comment. While the Committee appreciates the Health Law Section revisiting their Report and making these substantive changes, our Committee still does not endorse or agree with the recommendations surrounding "no benefit/medically futile" DNR orders.

¹⁴ See *e.g.*, not 11, Coe article. Our Committee observes that SCPA 1750-b is not a setting specific health care decision making statute, in contrast to the FHCDA, and is not limited to do-not-resuscitate orders. Thus, the COVID Report's recommendation that 1750-b be suspended during a pandemic is dramatically overbroad and has wide ranging implications beyond hospitals and for the range of life sustaining treatment elections for people with developmental disabilities, not just resuscitation.

¹⁵ See <https://molst.org/covid-19-guidance/opwdd-individuals/>

3. Additional Considerations

The Committee offers the following additional concerns relative to the Report.

- A. There is no mention of people confined in psychiatric centers during the pandemic. Media reports explained the impact of the virus on state hospitals, particularly the Rockland Psychiatric Center in Orange County.¹⁶ Also, inpatient beds were closed in psychiatric hospitals licensed by the Office of Mental Health (OMH) operated by Public Health Law article 28 hospitals to create additional beds for a potential COVID surge. For example, the Health Alliance campus in Ulster County closed its inpatient psychiatric unit during the crisis.¹⁷ It is our understanding that that all hospitals in New York State have 30% of their beds available reserved in case New York State experiences another COVID-19 surge. The National Alliance on Mental Illness New York State (NAMI -NYS) reports that many hospitals are disproportionately targeting psychiatric beds and services for reduction or elimination in order to meet the mandate.¹⁸ There is no guarantee that these beds will return post COVID-19; in fact, our Committee members are concerned that many of these psychiatric beds and units will not reopen, thus adversely impacting communities that depend on these essential acute care psychiatric services.
- B. There should be stronger recommendations for the release of disabled inmates at heightened risk and termination of imprisonment for minor parole violations.
- C. Mandatory vaccination has helped to eradicate lethal disease world-wide but raises serious bioethical issues and has had a disturbing history for people with disabilities. Our Committee is of the view that

¹⁶ See, *New York Times*: <https://www.nytimes.com/2020/04/24/nyregion/coronavirus-new-york-psychiatric-hospitals.html?action=click&module=Top%20Stories&pgtype=Homepage>

¹⁷ See, *Kingston Daily Freeman*:
https://www.dailyfreeman.com/news/local-news/lawmakers-push-for-return-of-inpatient-mental-health-services-to-ulster-county/article_f7954ac8-b31a-11ea-b080-6b51947f8e2f.html?utm_campaign=socialflow&utm_medium=social&utm_source=facebook.com&utm_content=fb-freeman&fbclid=IwAR1vyypsT_qwVfq2lrkvCVCgGLaYzeFbOmnOZHSe6YWT1FXWGgp7rrDRYGUQ

¹⁸ <https://www.naminys.org/nys/media/> - last accessed July 5, 2020

these critical issues should be acknowledged, if not addressed, in the Report before making such a recommendation.¹⁹

- D. In the section on page 23 relating to the rights of people with developmental disabilities, we note the sentence recommending that there be "oversight of residential facilities and group homes and programs to assure nondiscriminatory management of persons with disabilities during the COVID-19 crisis conditions." We are not aware of a similar call for oversight of either hospitals or nursing homes/adult homes despite the broad immunity granted to them from suit. All vulnerable populations need the protection of oversight and protection against discrimination and we wholeheartedly support measures to insure same occur.
- E. Commencing at page 18 of the Report is a narrative relating to the recommendation to relax limits on the number of beds certified for particular facility. Our Committee agrees with this recommendation. However, it seems to us that the Health Law Section/Task Force is missing an opportunity to demand further examination of the vast differences in resources between various hospitals in New York City. For example, Central Brooklyn and other parts of the City have been severely impacted in terms of their access to tertiary care facilities and the hospitals in these neighborhoods are vastly underfunded compared to the more prosperous systems in Manhattan and Westchester and Long Island. There needs to be a long-term evaluation of how beds have been allocated, along with a commitment to ensuring that COVID funding go to those facilities which were most impacted and had the highest number of patients. This should be done before the next wave of COVID infection strikes our communities.
- F. While our Committee appreciates the call for greater resources for community-based services, there also needs to be a clear recommendation that the size of facilities, such as nursing facilities and other congregate care settings be sharply reduced. In addition, for reasons of personal dignity as well as preventing the spread of infection, the practice of designing or certifying facilities that require people to share rooms and bathrooms needs to be reconsidered and provision needs to be made for downsizing all facilities.

¹⁹ See reporting on Hepatitis B experiments on Willowbrook class members and the human challenge vaccine trials. <https://www.forbes.com/sites/leahrosenbaum/2020/06/12/willowbrook-scandal-hepatitis-experiments-hideous-truths-of-testing-vaccines-on-humans/#6764a13d279c>. See also, 2009 NYCLU letter against forced vaccination of health care workers during the H1N1 crisis: https://www.nyclu.org/sites/default/files/releases/Flu_Letter_DOH_10.13.09.pdf

- G. The passage of the Emergency Disaster Treatment Protection Act ("EDTPA") conferred complete immunity from liability on health care facilities during the COVID-19 crisis. In the opinion of our Committee, without clear standards on the allocation of scarce resources and the perception of immunity, the rights of vulnerable patients are quite capable of being disregarded under the current crisis regime. Further immunity should not be awarded to providers unless it is linked with a requirement that providers adhere to standards of care that are clear and enforceable.²⁰
- H. There needs to be additional examination of the State response to the needs of people with developmental disabilities. In our opinion, the Office for People with Developmental Disabilities (OPWDD) lacked clear policies on containment at the outset of the pandemic and the Issuance of policies and guidance was too slow to prevent spread of infection.
- I. We recommend a strong independent professional ombudsperson in medical facilities including nursing homes and assisted living with direct administrative access and the imprimatur of DOH. The position would be funded by the facilities and discipline/termination could only occur with the consent of DOH. This would facilitate a local and independent surrogate/advocate for patients, residents and families concerning the futility/immunity issues as well as staff concerning matters of patient/resident care.
- J. We further recommend whistleblower protection for healthcare workers, regardless of position or whether classified as employees, per diem or independent contractor. Particularly in times of severe budget deficits, it is imperative that staff be empowered to complain, similar to complaints about discrimination, and be protected from retaliation.

²⁰ See May 28, 2020 letter to United States Senate Majority and Minority leaders from national and state stakeholder groups strongly opposed to granting immunity to nursing homes during the COVID crisis. The letter is attached as an Addendum [b]to this Comment. Our Committee acknowledges that the New York State subsequently adopted legislation that served to claw back the broad immunity protections in the EDTPA (L. 2020, Ch, 34). We are informed that the Health Law Section will, in fact, withdraw its proposed Resolution 4 from consideration by the HOD given the 2020 chapter amendment referenced above.

Further, we offer these comments in relation to people with developmental disabilities, in particular, to illustrate the devastating impact of the virus on this population. First, OPWDD guidance issued did not address all critical issues. In this regard, it is important to recognize that how policies are developed in New York State. DOH has primary responsibility and OPWDD, by necessity, was required to interpret guidance as it was issued by DOH. This often caused delay in developing OPWDD-specific guidance with a negative impact upon people receiving services, providers and families. As an example of this, visitation at hospitals was suspended by DOH without considering how this suspension impacted people with disabilities who often rely on family and staff support when they are hospitalized. Considerable advocacy was required for DOH to recognize this need and visitation policies were amended.²¹

In addition, DOH policies for congregate care settings were an imperfect fit in some cases for the OPWDD service delivery system. For example, there are a considerable number of people who live independently in apartments supported by

²¹ We observe in relation to this issue, as well, that DOH and OPWDD failed to seek Appendix K emergency funding in connection with the Medicaid Home and Community Based Services waiver to cover staff to accompany persons with developmental disabilities to hospitals when admitted for inpatient care and treatment . See <https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/home-community-based-services-public-health-emergencies/emergency-preparedness-and-response-for-home-and-community-based-hcbs-1915c-waivers/index.html> - last accessed August 16, 2020.

OPWDD services and supports. DOH policies for congregate care settings impacted the ability of people in apartments to return to community life when the Governor began to relax COVID restrictions in phases.

Finally, we advance the following non-exclusive list of observations from members of our Committee who advocate for people in the OPWDD system regarding the OPWDD coronavirus response: (i) there was a lack of flexibility to permit creative and necessary solutions; (ii) minimal resource support undermined infection control, specifically with respect to personal protective equipment (PPE) for residents and staff; (iii) there was insufficient COVID testing available for residents and staff; (iv) there was a failure of communication; for example, exclusive dependence on OPWDD website caused issues because there were broken links during the crisis making it difficult to navigate and locate resources. There was also no plain language communication to individuals with developmental disabilities and their families and no foreign language translation of guidance documents; (v) difficulties were identified in completing MOLST forms so as to assure a person's right to dignity in an end of life situation. Solutions were developed to address these issues, but valuable time was lost in the process;²² and (vi) there were no protocols in place to address the needs of 21 year old students with disabilities transitioning to adult care services in the OPWDD system from school placements under the auspices of the New York State Education

²² Advocates worked with OPWDD to ensure that its health care decision making web page was updated to include resources for securing concurring options and contact information for Mental Hygiene Legal Service staff in every county. <https://opwdd.ny.gov/providers/health-care-decisions> - last accessed August 16, 2020.

Department. Many of these children are still languishing in educational placements unable to access adult services from OWPDD.

4. **Further Recommendations**

- A. At least one representative from this Committee should be appointed to the Health Department COVID Task Force or another as may be created by the NYSBA to address the serious issues posed by the pandemic and ensure that there is a disability perspective included in the NYSBA response.
- B. As mentioned earlier in this comment, our community urges caution regarding extending immunity to nursing facility operators and other providers of service as a pandemic response.²³ If immunity is part of any pandemic response, the provider should have the burden of proof to demonstrate that there was more than satisfactory compliance with all applicable regulatory standards of care requirements including needed state mandated staffing levels.
- C. Our Committee recommends that the Health Law Section consider the June 23, 2020 petition of the Americans Civil Liberties Union and other stakeholders to the federal Department of Health and Human Services which in detail explains how the federal response to the Coronavirus crisis has been wholly inadequate to ensure the safety and welfare of people with disabilities living in nursing homes and other congregate care settings. A copy of the ACLU petition is an addendum [C] to this Comment.
- D. Our Committee urges the NYSBA to make a strong statement in its COVID Report that the model of care must change for people who currently reside in congregate care settings to ensure that a second wave of the coronavirus or another pathogen does not devastate our most vulnerable citizens. Regulatory agencies on the Federal and State level, particularly the Department of Health and Human Services and the New York State Department of Health must confront the crisis in nursing facilities and other congregate settings for people with disabilities by (i) requiring true transparency and accountability in terms of data collection and reporting; (ii) reducing the census in facilities by diverting admissions and transitioning people to community living; and (iii) protecting the residents and staff who remain by

²³ See note 20 and letter referenced with argument against immunity. As noted there, subsequent legislation did impact considerably the scope of immunity previously authorized under the EDTPA (L. 2020, Ch. 34).

ensuring that there are adequate supplies of PPE, regular testing, robust infection control protocols and adequate compensation for essential workers.

E Relative to the proposed Health Law Section Resolutions our Committee observes:

Resolution 1 recommends the Department of Health (DOH), (or through it, the NYS Task Force on Life and the Law(NYSTFLL)), review and consider: Enactment into New York Law of the Model State Emergency Health Powers Act (MSEHPA), developed by the Center for Law and Public Health at Georgetown and John Hopkins Universities (2001), as informed by the Columbia University Center for Health Policy Gap Analysis (2008), and as otherwise updated. As explained in this Comment, the Committee does not recommend enactment of MSEHPA in New York State as the Act is currently drafted (*see infra*, pages 4-5). Further study is required.

Resolution 1 also recommends adoption of the Crisis Standards of Care developed by the Institute of Medicine. As explained in this Comment, the Task Force did not, in our opinion, adequately consider the disability framework for crisis standards of care plans. There is certainly room to find consensus, here, however. For example, the Health Law Section members who met with the Disability Rights Committee shared an article that could provide a framework for the more detailed analysis the Committee recommends (*see* Michelle Mello, *et.al.*, Respecting Disability Rights - Toward Improved Crisis Standards of Care, New England Journal of Medicine, July 30, 2020. The authors pose 6 guideposts to follow when considering health care allocation criteria: (1) do not use categorical exclusions (especially based on disabilities or diagnosis); (2) do not use perceived quality of life; (3) use hospital survival and near term prognosis; (4) when people have their own ventilators for use at home they should not be allocated to other patients; (5) designate triage officers and train on disability rights; and (6) include disability advocates in policy development and dissemination of information (*see also*, The Bazelon Center for Mental Health Law, the Center for Public Representation and the Autistic Self Advocacy Network 6-point disability framework to assess Crisis Standards of Care and other health care allocation criteria are cited at footnote 11 of this Comment and merit consideration.

Resolution 2 speaks to several issues concerning long term care facilities, including the need for adequate staffing. The Committee recommends that the Report be amplified to address the Safe Staffing and Quality Care Act (S.

1032/A.3691-A). The NYSBA should study the bill and take a position as to whether the bill warrants adoption.²⁴

Resolution 3 relates to vaccines. Our Committee refers to its comment on pages 9-10, *infra*.

Our Committee does not endorse Resolution 4 (immunity) but understands that the Health Law Section will withdraw this resolution.

Conclusion

The Health Law Section took on a difficult assignment addressing the legal and ethical implications of the COVID 19 crisis. Our comments are offered to provide a disability perspective on the crisis and the State's response.

Joseph Ranni, Esq.

Alison Morris, Esq., Co-Chairs

The Committee gratefully recognizes the substantial efforts of former Committee Co-Chair Sheila Shea in the preparation of this response.

²⁴ Among other things, the Act requires acute care facilities and nursing homes to implement certain direct-care nurse to patient ratios in all nursing units; sets minimum staffing requirements; requires every such facility to submit a documented staffing plan to the department on an annual basis and upon application for an operating certificate; requires acute care facilities to maintain staffing records during all shifts; authorizes nurses to refuse work assignments if the assignment exceeds the nurse's abilities or if minimum staffing is not present; requires public access to documented staffing plans; imposes civil penalties for violations of such provisions; establishes private right of action for nurses discriminated against for refusing any illegal work assignment. As reported in the media, DOH has now issued a report pushing back against this bill. See <https://champ.gothamist.com/champ/gothamist/news/state-health-department-pushes-back-against-bill-would-mandate-more-nurses> - last accessed August 16, 2020.

ADDENDUM A

NYSBA HOUSE OF DELEGATES COVID-19 RESOLUTIONS

Resolution #1

Recommendations

A. Public Health Legal Reforms and Emergency Preparedness

- A. 1. Recommend the Department of Health (DOH), (or through it, the NYS Task Force on Life and the Law(NYSTFLL)), review and consider:
- (a) Enactment into New York Law of the **Model State Emergency Health Powers Act** (MSEHPA), developed by the Center for Law and Public Health at Georgetown and John Hopkins Universities (2001), as informed by the Columbia University Center for Health Policy Gap Analysis (2008), 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.
- A. 2. Recommend DOH review and consider:
- (a) Appoint and maintain a core team of emergency preparedness experts to review evidentiary sources and draft legislation to strengthen emergency preparedness planning;
 - (b) Re-evaluate the public benefit and costs of reinstating laws waived during COVID-19.

Resolution #1 (continued)

B. Ethical Issues: Ethics Guidelines including Allocation of Life-Saving Equipment, and DNR/Futility and Virus Testing

B.1. Recommend DOH, NYSTFLL, or Governor review/consider:

- (a) NYSTFLL 2015 Report, “Ventilator Allocation Guidelines,” and adopt the policy as is, or as amended; and
- (b) Issue emergency regulations mandating all providers and practitioners follow the ethics guidelines, and ensure:
 - i. the needs of vulnerable populations, including persons and communities of color, older adults and nursing home residents, persons with disabilities or who are incarcerated, and immigrants, are met in a non-discriminatory manner in the implementation of emergency regulations and guidelines;
 - ii. 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;
 - iii. provision of education and training to physicians, health care practitioners, and institutional triage and ethics committees; and
 - iv. 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.

B.2. Recommend amendment of the New York State Public Health Law: Article 29-C “Health Care Proxy,” to require in the case of a State Disaster Emergency Declaration:

- (a) at least one, rather than two, witnesses, or
- (b) attestation by a notary public in person or remotely.

B.3. Recommend the DOH or Governor review and consider: Establishing a coordinated statewide plan for Virus Testing to ensure:

- (a) frontline health care workers are prioritized in access to rapid diagnostic testing; and
- (b) the most vulnerable individuals from health status and essential business/employee standpoint have equitable access to rapid diagnostic testing.

Resolution #2

Recommendations

A. Providers

A.1. Amend New York Law:

Purchasing Necessary Supplies: 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. REMOVE/ENACTED INTO LAW

A.2. Continue Waivers and Executive Orders (See also Immunities):

(a)Ability to Exceed Certified Bed Capacity for Acute Care Hospitals: 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.

(b)Limitation on Resident Hours Working in Acute Care Hospitals: 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.

(c)Temporary Changes to Existing Hospital Facility Licenses Services and the Construction and Operation of Temporary Hospital Locations and Extensions: 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.

(d) **Anti-Kickback and Stark (AKS) Law Compliance during the COVID-19 Emergency:** New York State to 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.

A.3. Older Adults, Nursing Home Providers and Nursing Home Residents: Governor, DOH, DOH Bureau of Long Term Care and State Office for Aging to ensure:

(a)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;

(b)Adequate provision of PPE;

(c)Adequate levels of staffing;

(d)Adequate funding of employee testing, as required under Executive Order 202.30;

Resolution #2 (continued)

- (e) Consistent and timely tracking and reporting of case and death data;
- (f) Adoption of non-discriminatory crisis standards and ethics guidelines; and
- (g) Recognition and honoring of Older New Yorkers' right to health and human rights, as protected under international conventions: and
- (h) 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.

A.4. Persons incarcerated and Correctional Facilities and Care: Governor, NYS Department of Corrections and NYC Department of Corrections, to ensure:

- (a) Adequate access of persons incarcerated to COVID-19 testing, medical care and mental health and supportive services;
- (b) COVID-19 testing of correctional staff and adequate provision of gloves, masks and other protective equipment;
- (c) Release to the community of older persons who are incarcerated or living with advanced illness who do not pose a danger to the community;
- (d) Adequate funding of prison-to-community transitions including access to housing, meals, and supportive services, and non-discriminatory access to employment opportunities; and
- (e) Recognition and honoring of the right to health and human rights of persons who are incarcerated, as protected under international conventions.

A.5. Immigrants in Detention Facilities: Governor, DOH or other state agencies:

In its exercise of state 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 ensure:

- (a) Reduction of risk of the spread of COVID-19 among immigrants being held in detention centers

A.6. Telehealth

Governor or DOH to review and consider:

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

Resolution #2 Continued:

B: Workforce, Schools, Child Care and Disproportionate Impact upon Communities of Color and Vulnerable Populations

B.1. Governor, Board of Regents or Department of Education:

- (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.
- (b) 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.
- (c) Consider granting staffing firms dedicated to childcare 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.
- (d) 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.
- (e) 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.

B.2. Governor or DOH or other state agencies: Enhance regulatory oversight, to ensure:

- (a) adequate and non-discriminatory allocation of resources to persons and communities of color and vulnerable populations;
- (b) equitable access of persons and communities of color and vulnerable populations to health and mental health services, including palliative care as an ethical minimum to mitigate suffering among those 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;
- (c) provision of PPE to essential health care workers at highest risk in delivering essential services to vulnerable populations; and

(d) monitoring conformity with federal laws barring discrimination.

Resolution #3

REVISED 8-4-20 Vaccine Mandate Recommendation

After testing, including testing among diverse vulnerable populations, and as supported by scientific evidence, once a safe and effective COVID-19 vaccine becomes available, the NYSBA Health Law Section recommends;

A.1. That a vaccine subject to scientific evidence of safety and efficacy be made widely available, and widely encouraged, and if the public health authorities conclude necessary, required, unless a person's physician deems vaccination to be clinically inappropriate.

A.2. Steps to ensure a planned vaccination program:

(a) Rapid mass vaccination achieved through equitable distribution;

(b) Prioritizing access to vaccines for health care workers and individuals at highest risk for complications and virus transmission to others if inadequate vaccine supply based on consensus guidelines for equitable distribution and considerations of systemic racism, social and economic determinants of health including income, employment, place, neighborhood, food insecurity and fact-specific findings of public health threat; and

(c) Linguistically and culturally competent vaccine educational and acceptance program.
(Schaffer DeRoo S, Pudalov NJ, Fu LY. Planning for a COVID-19 Vaccination Program. *JAMA*. Published online May 18, 2020. doi:10.1001/jama.2020.8711)

Resolution #4

Recommendations

A. COVID-19 Qualified Legal Immunities for Providers and Practitioners

3.A.1. Patient Care Immunities: Federal and NYS Governments:

Provide/extend criminal and civil immunity for physicians, nurses and other health care practitioners and Article 28 facilities **related to provision of care to patients in connection with the COVID-19 disaster emergency** (excluding willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm). **THIS WOULD COVER ANY CARE PROVIDED UNDER THE UMBRELLA OF THE DISASTER EMERGENCY, NOT JUST CARE TO COVID-19 PATIENTS.**

3.A.2. Ethics Guidelines Immunities: Governor or DOH :

(a)waive/suspend certain NYS laws to provide/extend immunity from civil and criminal liability to providers and practitioners who follow the ethics guidelines (excluding willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm); and

(b)direct all state agencies to interpret and apply the law and regulations in a way to support compliance with the ethics/triage guidelines. **THIS IMMUNITY COVERS PATIENT CARE FOR PATIENTS WITH OR WITHOUT COVID-19 DUE TO SCARCITY/TRIAGE ARISING IN PANDEMIC.**

3.A.3. DNR/Medical Futility Immunities: Governor, DOH, or Amend Law: provide/extend immunity from criminal and civil immunity for physicians, nurses and other health care practitioners and Article 28 facilities, when the following steps are taken (excluding willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm):

(a)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;

b) a second practitioner concurs with the determination; and

c) 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. **HERE AGAIN THIS IMMUNITY COVERS PATIENT CARE FOR PATIENTS WITH OR WITHOUT COVID-19 und**

B. COVID-19 Business of Health Care Immunities:

3.B.1. Anti-Kickback and Stark Laws: New York State:

Resolution #4 continued:

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.

3.B.2. Vendors: New York State:

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.

C. COVID-19 Regulatory Waiver Immunities: New York State:

3C. Provide/extend immunity from civil and criminal liability for practitioners and providers related to acts or omissions under regulatory waivers, such as would be applicable to credentialing, licensure, registration, and scope of practice, during the COVID-19 declared emergency and disaster (excluding willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm). **SAME HERE. OPERATIVE LANGUAGE IS THE COVID-19 DECLARED DISASTER EMERGENCY.**

ADDENDUM B

UNITED STATE DEPARTMENT OF
HEALTH AND HUMAN SERVICES

DISABILITY RIGHTS NEW YORK,

Complainant,

OCR CASE NO:

-against-

COMPLAINT

NEW YORK STATE DEPARTMENT OF
HEALTH

Respondent.

PRELIMINARY STATEMENT

1. In November 2015 the New York State Task Force on Life and the Law (“Task Force”) and the New York State Department of Health (“NY DOH”) published Ventilator Allocation Guidelines (“Guidelines”) in order to provide guidance on how to “ethically allocate limited resources (i.e. ventilators) during a severe influenza pandemic while saving the most lives.” *Ventilator Allocation Guidelines* (New York State Task Force on Life and the Law, New York State Department of Health, Nov. 2015).
2. Howard A. Zucker, New York State Commissioner of Health, stated that the Guidelines “provide an ethical, clinical, and legal framework to assist health care providers and the general public in the event of a severe influenza pandemic.” *Id.* “Letter from the Commissioner of Health.”
3. Upon information and belief, the Guidelines are being reviewed and potentially revised by the Department of Health in order to ensure they best effectuate their goals as stated above.

4. The Guidelines, as written, contain serious gaps which discriminate against people with preexisting disabilities and place them in potentially life-threatening positions in violation of the Americans with Disabilities Act (“ADA”), 42 U.S.C. § 12101, *et seq.*, and Section 504 of the Rehabilitation Act of 1973 (“Section 504”), 29 U.S.C. § 794, *et seq.*
5. The Guidelines, as written, will have the unintended consequence of disproportionately disqualifying many people with disabilities from ventilator access simply because they have underlying conditions that may intensify symptoms and slow recovery, which violates both the ADA and Section 504.
6. On March 26, 2020, Disability Rights New York (“DRNY”) sent a letter to Andrew Cuomo, Governor of the State of New York, requesting that the New York State Department of Health (“NY DOH”) issue clear guidance regarding the potential for discrimination against people with disabilities seeking medical care during the COVID-19 pandemic.

JURISDICTION

7. The Office of Civil Rights of the United States Department of Health and Human Services has subject matter jurisdiction over claims of discrimination against State health care agencies as well as programs and activities to whom the Department provides federal assistance.

PARTIES

8. Disability Advocates, Inc. is an independent non-profit corporation organized under the laws of the State of New York. Disability Advocates, Inc. is authorized to conduct business under the name Disability Rights New York (“DRNY”).

9. DRNY is a Protection and Advocacy system (“P&A”), as that term is defined under the Developmental Disabilities Assistance and Bill of Rights Act (“DD Act”), 42 U.S.C. § 15041 *et seq.*, the Protection and Advocacy for Individuals with Mental Illness Act of 1986 (“PAIMI Act”), 42 U.S.C. § 10801 *et seq.*, and the Protection and Advocacy of Individual Rights Act (“PAIR Act”), 29 U.S.C. § 794e *et seq.* with offices in the State of New York located at: 25 Chapel Street, Suite 1005, Brooklyn, NY 11201; 725 Broadway, Suite 450, Albany, NY 12208; and 44 Exchange Blvd., Suite 110, Rochester, NY 14614.
10. As New York State’s Protection & Advocacy system, DRNY is specifically authorized to pursue legal, administrative, and other appropriate remedies or approaches to ensure the protection of, and advocacy for, the rights of individuals with disabilities. 42 U.S.C. § 15043(a) (2)(A) (i); N.Y. Exec. Law § 558(b).
11. Pursuant to the authority vested in it by Congress to file claims of abuse, neglect, and rights violations on behalf of individuals with disabilities, DRNY brings claims on behalf of individuals with disabilities who are currently seeking or may seek acute medical care during the COVID-19 pandemic.
12. New York State is a public entity as defined by 42 U.S.C § 12131(1)(A).
13. New York State operates the New York State Department of Health (“NY DOH”).
14. NY DOH is a program or activity of New York State pursuant to 28 C.F.R. § 35.130.
15. NY DOH has a mission to protect, improve and promote the health, productivity and well-being of all New Yorkers, and is responsible for issuing guidance to healthcare providers pursuant to its mission.
16. NY DOH is located at Corning Tower at the Empire State Plaza in Albany, NY 12237.

STATEMENT OF FACTS

New York State Ventilator Allocation Guidelines

17. The NY DOH is “empowered to issue voluntary, non-binding guidelines for health care workers and facilities; such guidelines are readily implemented and provide hospitals with an ethical and clinical framework for decision-making.” *Ventilator Allocation Guidelines*, p. 8.
18. “A pandemic that is especially severe with respect to the number of patients affected and the acuity of illness will create shortages of many health care resources, including personnel and equipment. Specifically, many more patients will require the use of ventilators than can be accommodated with current supplies.” *Id.* at 1.
19. “To ensure that patients receive the best care possible in a pandemic, a patient’s attending physician does not determine whether his/her patient receives (or continues) with ventilator therapy; instead a triage officer or triage committee makes the decision.” *Id.* at 5.
20. “While the attending physician interacts with and conducts the clinical evaluation of a patient, a triage officer or triage committee does not have any direct contact with the patient. Instead, a triage officer or triage committee examines the data provided by the attending physician and makes the determination about a patient’s level of access to a ventilator.” *Id.*
21. “This role sequestration allows the clinical ventilator allocation protocol to operate smoothly. The decision regarding whether to use either a triage officer or committee is left to each acute care facility (i.e., hospital) because available resources will differ at each site.” *Id.*

22. NY DOH's Guidelines provide that "an allocation protocol should utilize clinical factors only to evaluate a patient's likelihood of survival and to determine the patient's access to ventilator therapy." *Id.*
23. For the ventilator allocation protocols, "there are three steps: (1) application of exclusion criteria, (2) assessment of mortality risk, and (3) periodic clinical assessments ("time trials")" conducted by a patient's attending physician. *Id.* at 6.
24. "In Step 1, patients who do not have a medical condition that will result in immediate or near-immediate mortality even with aggressive therapy are eligible for ventilator therapy." *Id.*
25. Step 1 applies the "List of Exclusion Criteria for Adult Patients Medical Conditions that Result in Immediate or Near-Immediate Mortality Even with Aggressive Therapy," which includes: "Cardiac arrest: unwitnessed arrest, recurrent arrest without hemodynamic stability, arrest unresponsive to standard interventions and measures; trauma-related arrest; Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy; Traumatic brain injury with no motor response to painful stimulus; Severe burns: where predicted survival $\leq 10\%$ even with unlimited aggressive therapy; Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy." *Id.* at 57.
26. "In Step 2, patients who have a moderate risk of mortality and for whom ventilator therapy would most likely be lifesaving are prioritized for treatment." *Id.* at 6.
27. "In Step 3, official clinical assessments at 48 and 120 hours after ventilator therapy has begun are conducted to determine whether a patient continues with this treatment." *Id.*

28. "Triage decisions are made based on ongoing clinical measures and data trends of a patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy." *Id.*
29. "Thus, the guiding principle for the triage decision is that the likelihood of a patient's continuation of ventilator therapy depends on the severity of the patient's health condition and the extent of the patient's medical deterioration. In order for a patient to continue with ventilator therapy, s/he must demonstrate an improvement in overall health status at each official clinical assessment." *Id.*
30. "At Steps 2 and 3, a triage officer/committee examines a patient's clinical data and uses this information to assign a color code to the patient. The color (blue, red, yellow, or green) determines the level of access to a ventilator." *Id.*
31. "Blue code patients (lowest access/palliate/ discharge) are those who have a medical condition on the exclusion criteria list or those who have a high risk of mortality and these patients do not receive ventilator therapy when resources are scarce." *Id.* at 6-7.
32. "[I]f more resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may be eligible for ventilator therapy." *Id.* at 7.
33. "Red code patients (highest access) are those who have the highest priority for ventilator therapy because they are most likely to recover with treatment (and likely to not recover without it) and have a moderate risk of mortality." *Id.*

34. “Patients in the yellow category (intermediate access) are those who are very sick, and their likelihood of survival is intermediate and/or uncertain. These patients may or may not benefit (i.e., survive) with ventilator therapy. They receive such treatment if ventilators are available after all patients in the red category receive them.” *Id.*
35. “Patients in the green color code (defer/discharge) are those who do not need ventilator therapy.” *Id.*
36. “In some circumstances, a triage officer/committee must select one of many eligible red color code patients to receive ventilator therapy. A patient’s likelihood of survival (i.e., assessment of mortality risk) is the most important consideration when evaluating a patient.” *Id.*
37. “However, there may be a situation where multiple patients have been assigned a red color code, which indicates they all have the highest level of access to ventilator therapy, and they all have equal (or near equal) likelihoods of survival. If the eligible patient pool consists of *only adults* or *only children*,¹ a randomization process, such as a lottery, is used each time a ventilator becomes available because there are no other evidence-based clinical factors available to consider. Patients waiting for ventilator therapy wait in an eligible patient pool.” *Id.* (emphasis in original).
38. “In addition, there may be a scenario where there is an incoming red code patient(s) eligible for ventilator therapy and a triage officer/committee must remove a ventilator

¹ “Because of a strong societal preference for saving children, the Task Force recommended that *young age* may be considered as a tie-breaking criterion in limited circumstances. When the pool of patients eligible for ventilator therapy includes both adults and children (17 years old and younger), the Task Force determined that when all available clinical factors have been examined and the probability of mortality among the pool of patients has been found equivalent, only then may young age be utilized as a tie-breaker to select a patient for ventilator therapy.” *Ventilator Allocation Guidelines*, p. 5.

from a patient whose health is not improving. In this situation, first, patients in the blue category (or the yellow category if there are no blue code patients receiving ventilator therapy) are vulnerable for removal from ventilator therapy if they fail to meet criteria for continued ventilator use.” *Id.*

39. “If the pool of ventilated patients vulnerable for removal consists of *only adults* or *only children*, a randomization process, such as a lottery, is used each time to select the (blue or yellow) patient who will no longer receive ventilator therapy.” *Id.* (emphasis in original).
40. “A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list. However, if all ventilated patients are in the red category (i.e., have the highest level access), *none* of the patients are removed from ventilator therapy, even if there is an eligible (red color code) patient waiting”. *Id.* (emphasis in original).
41. “Patients who have a medical condition on the exclusion criteria list or who no longer meet the clinical criteria for continued ventilator use receive alternative forms of medical intervention and/or palliative care. The same applies to patients who are eligible for ventilator therapy but for whom no ventilators are currently available.” *Id.*
42. “Alternative forms of medical intervention, such as other methods of oxygen delivery and pharmacological antivirals, should be provided to those who are not eligible or waiting for a ventilator.” *Id.*

ADA and Section 504 Implications Due to Implicit Bias

43. In creating the Guidelines, “the Task Force concluded that an allocation protocol should utilize clinical factors only to evaluate a patient’s likelihood of survival and to determine the patient’s access to ventilator therapy.” *Id.* at 5.
44. However, in its March 26, 2020, letter DRNY expressed urgent concern that hospitals and medical providers would not act in accordance with the non-discrimination mandates of the ADA and Section 504 and solely utilize clinical factors unless they were explicitly instructed to be aware of potential implicit bias against persons with disabilities.
45. While the Task Force bases its definition of “survival” on the short-term likelihood of survival of the acute medical episode, *id.* at 55, without explicit instruction on frequent implicit bias against the disability community, people with disabilities are likely to be disproportionately categorized as having a condition that falls into the “exclusion criteria” simply because they have underlying conditions which may intensify symptoms and slow recovery.
46. During Step 2 of the triage process, the Task Force states that the Sequential Organ Failure Assessment (“SOFA”) system should be used. *Id.* at 57.
47. A SOFA score, which is used to track a person’s status during an intensive care stay adds points based on clinical measures of function in six key organs and systems: lungs, liver, brain, kidneys, blood clotting, and blood pressure. *Id.* at 58.
48. Using SOFA, each variable is measured on a zero to four scale, with four being the worst score. A perfect SOFA score, indicating normal function in all six categories, is 0; the worst possible score is 24 and indicates life-threatening abnormalities in all six systems.
Id.

49. While a SOFA score is based solely on clinical factors and does not take into account personal values or subjective judgments, individuals with preexisting conditions are by default going to receive higher (worse) SOFA scores than individuals without disabilities, meaning these individuals with disabilities will be less likely to receive life-saving care.
50. Individuals with disabilities may live day-to-day without any complications, but with a condition that presents abnormalities in one or more of the six key organs and systems measured using SOFA.
51. These individuals would be disadvantaged in a triage situation prior to considering any symptoms that result directly from COVID-19.
52. The Task Force Acknowledges this fact: “For most patients who are sick with only influenza and have no other comorbidities, the single organ failure is limited to their lungs, which gives them a low SOFA score. However...a patient may also have a comorbidity(s) that affects another organ system(s) which will increase his/her SOFA score.” *Id.* at 59.
53. In its March 26, 2020, letter DRNY requested that the following be included in any updated guidance NY DOH provides to healthcare practitioners in order to avoid potentially discriminatory outcomes:
- a. Treatment allocation decisions must be made based on individualized determinations, using current objective medical evidence, and not based on generalized assumptions about a person’s disability.
 - b. Treatment allocation decisions cannot be made based on misguided assumptions that people with disabilities experience a lower quality of life, or that their lives are not worth living.

- c. Treatment allocation decisions cannot be made based on the perception that a person with a disability has a lower prospect of survival. While the possibility of a person's survival may receive some consideration in allocation decisions, that consideration must be based on the prospect of surviving the condition for which the treatment is designed—in this case, COVID-19—and not other disabilities.
 - d. Treatment allocation decisions cannot be made based on the perception that a person's disability will require the use of greater treatment resources. Reasonable modifications must be made where needed by a person with a disability to have equal opportunity to benefit from the treatment.
54. Without this guidance, NY DOH would allow inevitable implicit biases against people with disabilities to gravely impact their access to potentially life-sustaining care.

Denial of Equal Access to Acute Healthcare Services

55. In its March 26, 2020, letter, DRNY also described the spreading fear of accessing acute healthcare among chronic ventilator users as a result of the Guidelines.
56. Chronic ventilator users contacted DRNY to state that they are afraid to seek acute medical care if they become ill during the COVID-19 pandemic because the Guidelines allow their personal, every-day ventilator to be re-allocated to another individual who is deemed higher priority per the Guidelines. These individuals have also expressed a fear of forcible extubation, which would likely result in death.
57. While some chronic ventilator users in New York live in facilities, thousands of other live independently in the community, realizing the ideal embodied in the right of a person with a disability to live with the greatest autonomy and independence possible.

58. “The Task Force concurred that community-dwelling persons should not be denied access to their ventilators and the Guidelines are only applied to these patients upon their arrival at an acute care facility,” *id.* at 42, which leaves chronic ventilator users who live in the community afraid to seek any type of medical care.
59. The chilling effect described above comes from the Task Force’s determination that “ventilator-dependent chronic care patients are subject to the clinical ventilator allocation protocol only if they arrive at an acute care facility for treatment. Once they arrive at a hospital, they are treated like any other patient who requires ventilator therapy.” *Id.* at 5.
60. “All acute care patients in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical ventilator allocation protocol. Ventilator-dependent chronic care patients are only subject to the clinical ventilator allocation protocol if they arrive at an acute care facility.” *Id.* at 6.
61. The Task Force acknowledged that “to triage patients in chronic care facilities once the Guidelines are implemented may theoretically maximize resources and result in more lives saved, [it] conflicts with the societal norm of defending vulnerable individuals and communities.” *Id.* at 41. However, it inexplicably withdraws this “defense” the moment a vulnerable individual seeks necessary acute medical care. *Id.*
62. Further, while “[p]atients using ventilators in chronic care facilities are not subject to the clinical protocol,” chronic ventilator users who live and thrive in our communities have no such sense of security in their personal assistive technology and are not afforded the access to daily medical care that individuals in facilities have. *Id.* at 40.
63. Perhaps most inexplicably, the Task Force acknowledges the danger its Guidelines pose:
- Chronically ill patients are vulnerable to the pandemic, and chronic care facilities should be able to provide more intensive care on site as part of the

general emergency planning process of expanding care beyond standard locations. These facilities should implement procedures that would treat these patients onsite as much as possible so that only urgent cases are sent to acute care facilities. Barriers to transfer are appropriate and likely during a phase in which acute care hospitals are overwhelmed.

However, this approach may be problematic because it may not provide equitable health care to person with disabilities, *and may place ventilator-dependent individuals in a difficult position of choosing between life-sustaining ventilation and urgent medical care.* Some argued that this strategy was contrary to the aim of saving the most lives because denying ventilator therapy to a ventilator-dependent person is different from denying the ventilator to someone who has a high probability of mortality who might have qualified for a ventilator under non-pandemic circumstances. Thus, *if the ventilator is removed from a person known to depend upon it, s/he will not survive, regardless of the reason requiring hospitalization.*

The Task Force examined the alternative approach, which requires assessing all intubated patients, whether in acute or chronic care facilities, by the same set of criteria. This method does not violate the duty to steward resources and subjects all patients, not just the acutely ill, to a modified medical standard of care. Depending on the design of the criteria, the result might be likely fatal extubations of stable, long-term ventilator-dependent patients in chronic care facilities. The proposed justification for such a strategy is that more patients could ultimately survive if these ventilators were instead allocated to the previously healthy individuals of the influenza pandemic. *This strategy, however, makes victims of the disabled. This approach fails to follow the ethical principle of duty to care and could be construed as taking advantage of a very vulnerable population. More patients might survive, but they would be also different types of survivors, i.e., none of the survivors would be from the disabled community.* The Task Force concluded that such a strategy relies heavily upon ethically unsound judgments based on third-party assessments of quality of life.....

Furthermore, if chronic care patients become so ill that they must be transferred to an acute facility, they may not be eligible for ventilator therapy and lose access to the ventilator at that point. The ventilator may eventually enter the wider pool without prospectively triaging these patients at chronic care facilities. Therefore, the ventilators in chronic care facilities should remain there for *the chronically ill, who are likely to have severely limited access to ventilators in acute care facilities,* which offers an appropriate balance between the duties to care and to steward resources wisely.

Id. at 41-42 (emphasis added).

64. Despite this acknowledgement, and the statement that they examined “the alternative approach,” the Task Force fails to even consider providing guidance that does not, under any circumstances, remove a chronic ventilator user from their ventilator without another device being readily available for their use. This is the only acceptable approach.

65. While few could imagine a justification for taking life-sustaining insulin injections from one Type-1 diabetic and providing it to another Type-1 diabetic with a better triage score, NY DOH has made an analogous decision for chronic ventilator users who live in the community and seek acute medical care.

66. In its effort to treat everyone equally, the Task Force seemingly accepts the inevitable deaths of chronic ventilator users:

While a policy to triage upon arrival may deter chronic care patients from going to an acute care facility for fear of losing access to their ventilator, it is unfair and in violation of the principles upon which this allocation scheme is based to allow them to remain on a ventilator without assessing their eligibility. Distributive justice requires that all patients in need of a certain resource be treated equally; if chronic care patients were permitted to keep their ventilators rather than be triaged, the policy could be viewed as favoring this group over the general public.

Id. at 42.

67. Such a conclusion is against decades of case law and public policy surrounding the ADA and Section 504. Reasonable accommodations will necessarily require that an entity treat an individual with a disability differently, but such differences are necessary to achieve society’s equal opportunity goals, and allow individuals with disabilities to enjoy the same benefits and services as their non-disabled peers.

68. DRNY requested that the Guidelines contain explicit guidance to healthcare providers that a chronic ventilator user should never be removed from ventilation support for reasons of rationing.

69. A chronic ventilator user should never be disconnected from ventilation support without a new device being readily available for their use.

70. Without explicit changes in the Guidelines to state that such actions are never acceptable, NY DOH is discriminatorily preventing chronic ventilator users from seeking acute healthcare services in violation of federal law.

FIRST CLAIM FOR RELIEF
TITLE II OF THE AMERICANS WITH DISABILITIES ACT
42 U.S.C. § 12101, et seq.

71. DRNY incorporates by reference each and every allegation contained in the foregoing paragraphs as if specifically alleged herein.

72. Title II of the ADA states, in pertinent part:

[N]o qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or subjected to discrimination by any such entity. 42 U.S.C. § 12132.

73. A “public entity” includes state and local government, their agencies, and their instrumentalities. 42 U.S.C. § 12131(1).

74. NY DOH was, at all times relevant to this action, and currently is a “public entity” within the meaning of Title II of the ADA.

75. NY DOH provided and provides “services, programs [and] activities” through their office. 28 C.F.R. § 35.130.

76. The term “disability” includes physical and mental impairments that substantially limit one or more major life activities. 42 U.S.C. § 12102(2).

77. A “qualified individual with a disability” is a person “who, with or without reasonable modification to rules, policies or practices ... meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by a public entity.” 42 U.S.C. § 12131(2).

78. People with disabilities who seek acute medical care in New York State are qualified individuals under the ADA.

79. NY DOH’s Guideline violate Title II of the ADA and its implementing regulations by authorizing or failing to forbid actions that:

- a. Deny a qualified individual with a disability the benefits of the services, programs, or activities of a public entity because of the individual’s disability. 42 U.S.C. § 12132.
- b. “Aid or perpetuate discrimination against a qualified individual with a disability by providing significant assistance to an agency, organization, or person that discriminates on the basis of disability in providing any aid, benefit, or service to beneficiaries of the public entity's program.” 28 C.F.R. § 35.130(b)(1)(v).
- c. “[L]imit a qualified individual with a disability in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.” 28 C.F.R. § 35.130(b)(1)(vii).
- d. “[D]eny a qualified individual with a disability the opportunity to participate in services, programs, or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.” 28 C.F.R. § 35.130(b)(2).

- e. “Directly or through contractual or other arrangements, utilize criteria or other methods of administration: (i) That have the effect of subjecting qualified individuals with disabilities to discrimination on the basis of disability; (ii) That have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the public entity's program with respect to individuals with disabilities; or (iii) That perpetuate the discrimination of another public entity if both public entities are subject to common administrative control or are agencies of the same State.” 28 C.F.R. § 35.130(b)(3).
- f. Fail to “make reasonable modifications in policies, practices, or procedures when the modifications are necessary to avoid discrimination on the basis of disability, unless the public entity can demonstrate that making the modifications would fundamentally alter the nature of the service, program, or activity.” 28 C.F.R. 35.130(b)(7).
- g. “Impose or apply eligibility criteria that screen out or tend to screen out an individual with a disability or any class of individuals with disabilities from fully and equally enjoying any service, program, or activity, unless such criteria can be shown to be necessary for the provision of the service, program, or activity being offered.” 28 C.F.R. 35.130(b)(8).

80. As a result of NY DOH’s acts and omissions, individuals with disabilities seeking acute medical care in New York State have and will continue to be denied equal access to the benefits of the services, programs and activities of the healthcare system adhering to the NY DOH Guidelines.

SECOND CLAIM FOR RELIEF
SECTION 504 OF THE REHABILITATION ACT OF 1973
29 U.S.C. § 794

81. DRNY incorporates by reference each and every allegation contained in the foregoing paragraphs as if specifically alleged herein.
82. Section 504 provides, in pertinent part that “no otherwise qualified individual with a disability in the United States... shall, solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” 29 U.S.C. § 794(a).
83. NY DOH was, at all times relevant to this action, and is currently a recipient of federal financial assistance within the meaning of Section 504.
84. NY DOH provided and provides a “program or activity” where “program or activity” is described as “all operations of a department, agency, special purpose district or other instrumentality of a State or of a local government.” 29. U.S. C. § 794(b)(1)(A).
85. A disability is defined as “a physical or mental impairment that substantially limits one or more major life activities of such individual.” 29 U.S.C. § 705(9)(B) citing 42 U.S.C. § 12102(1)(A).
86. People with disabilities who seek acute medical care in New York State are qualified individuals under Section 504.
87. NY DOH’s Guideline violate Section 594 by authorizing, or failing to forbid, actions that:

- h. Exclude from participation in, deny the benefits of, or otherwise subject individuals to discrimination on the basis of disability. 29 U.S.C. § 794(a); 45 C.F.R. §§ 84.4(a), 84.52(a)(1); 28 C.F.R. § 41.51(a).
- i. Deny qualified persons with a disability the opportunity to participate in or benefit from the aid, benefit, or service. 45 C.F.R. § 84.4(b)(1)(i); 28 C.F.R. § 41.51(b)(1)(i).
- j. Afford qualified persons with a disability an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded to others. 45 C.F.R. §§ 84.4(b)(1)(ii), 84.52(a)(2); 28 C.F.R. § 41.51(b)(1)(ii).
- k. Limit individuals with a disability in the enjoyment of rights, privileges, advantages and opportunities enjoyed by others receiving an aid, benefit, or service. 45 C.F.R. §§ 84.4(b)(1)(vii), 84.52(a)(4); 28 C.F.R. § 41.51(b)(1)(vii).
- l. Use criteria or methods of administration that have the effect of subjecting qualified persons to discrimination on the basis of disability, or that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of a program or activity with respect to persons with disabilities. 45 C.F.R. §§ 84.4(b)(4) and 84.52(a)(4); 28 C.F.R. § 41.51(b)(3).

88. As a result of NY DOH's acts and omissions, individuals with disabilities seeking acute medical care in New York State have and will continue to be excluded from participation in, denied the benefits of, and subjected to discrimination from the healthcare system adhering to the NY DOH Guidelines.

PRAYER FOR RELIEF

WHEREFORE, DRNY requests relief as set forth below:

1. Issue a declaratory judgment that NY DOH's Ventilator Allocation Guidelines have subjected and continue to subject people with disabilities seeking acute healthcare in New York State to discrimination in violation of Title II of the ADA and Section 504.
2. Direct the NY DOH to issue new Ventilator Allocation Guidelines that do not discriminate against people disabilities seeking acute healthcare in New York State.
3. An award of reasonable attorneys' fees and costs; and
4. Such other further relief as deemed just and proper.

DATE: April 7, 2020
Albany, NY

DISABILITY RIGHTS NEW YORK
Complainant

/s/ Jessica Barlow

Jessica Barlow
Jessica.Barlow@drny.org

/s/ Sarah Smith

Sarah Smith
Sarah.Smith@drny.org

725 Broadway, Suite 450
Albany, NY 12207-5001
(518) 432-7861 (voice)

ADDENDUM C

NYSBA Health Law Section Report: Withdrawal, DNR, and Futility Section (pp.15-17)

Please see clarifying language changes below:

1.Reference to PHL Article 47 (*sic - should be MHL*) has been struck from this section (bottom of p. 16). The amended language now reads:

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 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, to issue a do-not-resuscitate order based on a determination that resuscitation would be “medically futile,” as defined in PHL 2961.12.

2. The following clarifying language has been added to this section, specifying futility DNR procedural protections:

Any disaster or emergency crisis-related futility DNR should still be subject to certain procedural protections, e.g., (i) futility must be defined narrowly, in terms of effectiveness of restarting the heart, as it is in PHL 2991; (ii) there must be a concurring determination of medical futility by a second practitioner, selected by the facility; (iii) the attending practitioner must notify the patient or, if the patient lacks capacity, the agent/surrogate of the order and the basis for it; (iv) such determinations be documented in the medical record; and (v) if the order is issued without patient/agent or surrogate consent there should be a post-issuance medical peer review of the medical support for the futility finding.

3. The following language clarifies the position of the NYSBA Health Law Section on risks of potential discrimination in triage or futility DNR decisions:

The NYSBA Health Law Section recommendations to New York State to adopt uniform statewide ethics/triage guidelines, and issue emergency regulations to assure implementation of such guidelines, explicitly address that any such guidelines must be in full conformity with federal and state civil rights laws barring discrimination on the basis of disability or age.

More specifically, triage and futility DNR protocols must protect persons with physical and intellectual disabilities from discrimination. Such protocols must explicitly prohibit consideration of a disabled patient's quality of life.

We clarify further that the recommendations made by the NYSBA HLS also call for full review of the 2015 New York State Task Force on Life and the Law (NYSTFLL) Ventilator Guidelines. The NYSTFLL should be reconvened or reconstituted and charged with conducting such review and in particular, ensuring that new or revised guidelines protect persons with disabilities from discrimination in the allocation of scarce resources during the present COVID-19 crisis conditions or in future pandemics.

Finally, the Health Law Section Report and recommendations call for priority attention to pre-existing inequities and disparities, heightened during the pandemic, that have had a disproportionate impact upon older adults, persons with disabilities, persons and communities of color, persons who are homeless and hungry, persons incarcerated, and immigrants refugees and asylum seekers, as well as other vulnerable, marginalized and excluded groups.



New York State Bar Association

One Elk Street, Albany, New York 12207 • 518/463-3200 • <http://www.nysba.org>

Mirna M. Santiago, Esq.
Co-Chair, Committee on Diversity & Inclusion

Violet E. Samuels, Esq.
Co-Chair, Committee on Diversity & Inclusion

September 10, 2020

To: The Health Law Committee Task Force on Covid-19

Re: The Task Force on Covid-19's Report and Recommendations

The Committee on Diversity and Inclusion declines to take a position—pro or con—with respect to the Health Law Task Force's Covid-19 report and the recommendations contained therein. However, the Committee does wish to set forth certain concerns raised by our Committee members in response to the report and we request that such matters be discussed and resolved prior to a vote being taken on the report and recommendations of the Task Force by the House of Delegates.

With respect to the recommendation of the Task Force that covid-19 vaccines be made mandatory for the general population as a public health mandate, it is the Committee's recommendation that such discussion be tabled until such time as a vaccine is actually available; until then, it is our position that such discussion and recommendation is premature.

If the discussion is not tabled, we note the following:

The efficacy and safety of the likely vaccine has not been proven. In fact, it has been reported that the vaccine will be granted an "emergency use" exemption,¹ so as to be put on the market before Phase III trials are completed.² Per the U.S. Food and Drug Administration (FDA), it has created a special emergency program for possible coronavirus therapies, which includes vaccines. The FDA's Coronavirus Treatment Acceleration Program (CTAP) "uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful."

In other words, the FDA will allow the inoculation of actual patients prior to determining whether the vaccine is helpful, harmful or ineffective. Typically, a vaccine would not be put to market until it has completed Phase III of clinical trials. Phase III in vaccine trials is when the vaccine is given to thousands of diverse people so as to test for efficacy and safety in a cross-section of the population.³ While different races of people do not differ biologically, environmental and other factors can cause differences in how diverse people react to therapeutics, including vaccines. This phenomenon has been scientifically documented with flu

¹ <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>

² <https://www.cnbc.com/2020/08/30/fda-willing-to-fast-track-coronavirus-vaccine-before-phase-three-trials.html>

³ <https://www.cdc.gov/vaccines/basics/test-approve.html>

vaccines.⁴ There is concern that the vaccine is being “fast tracked” for political purposes and is being made available before the election, notwithstanding the failure to complete the phases required for efficacy and safety. This is particularly concerning in light of the reports that there is not sufficient diversity in the participants in the current trials, notwithstanding that “racial minorities experience disproportionately higher rates of Covid-19 infection, hospitalization and death[.]”⁵

In addition, there is concern about enforcement of a “mandatory” vaccine. Where will the rollout begin? Who will be mandated to get the vaccine first? During this pandemic, we have already seen disproportionate policing of social distance and quarantining as against people of color.⁶ What penalties will be imposed against those people who decline to be inoculated?

Last, the United States government has a history of experimenting on people of color. From Colonial times to present, doctors “would often try new ideas on white patients when they hoped that the experiment would help the person in question; [but] they would use [people of color] as subjects when the point of the research was to benefit others.”⁷ Here, there is a probability that the vaccine may not—at least, initially—prove safe or efficacious. The fear is that a mandatory vaccine will be forced upon already vulnerable populations (people of color and/or the poor)⁸ and the findings will be used to benefit the white population (who will receive a version of the vaccine perfected through human trials on people of color who were mandated to receive it first).

In summary, while the Committee on Diversity and Inclusion does not presently either support or oppose the report and recommendations of the Health Law Committee Covid-19 Task Force, we do respectfully request that our concerns be reviewed and responded to by the Task Force prior to a vote by the House of Delegates.

Sincerely,

Mirna M. Santiago and Violet E. Samuels
Co-Chairs, Committee on Diversity and
Inclusion

cc: Executive Committee
House of Delegates

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5325335/>

⁵ <https://www.medicalnewstoday.com/articles/researchers-call-out-lack-of-diversity-in-covid-19-clinical-trials>

⁶ <https://www.nytimes.com/2020/05/07/nyregion/nypd-social-distancing-race-coronavirus.html>

⁷ <https://time.com/4746297/henrietta-lacks-movie-history-research-oprah/>

⁸ <https://www.nbcnews.com/news/nbcblk/covid-19-vaccine-will-only-work-if-trials-include-black-n1228371>

MEMORANDUM

TO: Health Law Section COVID-19 Task Force

FROM: Executive Committee, Food, Drug & Cosmetic Law Section

DATE: October 5, 2020

RE: Comments on COVID-19 Task Force's Revised Resolution No. 3, "COVID-19 Vaccine and Virus Testing Legal Reforms"

The Executive Committee of the Food, Drug & Cosmetic Law Section (the "FD&C Law Section") of the New York State Bar Association ("NYSBA") submits these comments (the "Comments") on the Revised Resolutions of the NYSBA Health Law Section's COVID-19 Task Force, dated September 18, 2020, which will be submitted to NYSBA's House of Delegates for review, consideration and formal action on November 7, 2020. The Health Law Section has proposed these Revised Resolutions in connection with a revised report (the "Report") issued by the Health Law Section's COVID-19 Task Force, dated September 20, 2020.¹ The FD&C Law Section distributed an earlier version of the Report to its members for comment and received no comments.

The FD&C Law Section will address the Health Law Section's proposed Revised Resolution No. 3, "COVID-19 Vaccine and Virus Testing Legal Reforms" ("Revised Resolution No. 3") regarding vaccination, as FD&C Law Section members have a degree of expertise with respect to legal issues concerning vaccines. The FD&C Law Section believes that the remaining

¹ The COVID-19 Task Force issued the original Report on May 15, 2020 and a prior revised version of the Report was issued on July 1, 2020.

Resolutions proposed by the Health Law Section are not within the particular legal expertise of FD&C Law Section members and should be addressed by other Sections with more relevant expertise. Revised Resolution No. 3 is attached hereto as Appendix A.

The FD&C Law Section of the NYSBA appreciates the tremendous amount of work done under severe time constraints by the Health Law Section and its COVID-19 Task Force on the Report, and the amendments to the original draft Resolutions with respect to mandatory vaccinations. The FD&C Law Section wishes to express its thanks to the Task Force and, in particular, Hermes Fernandez, Esq., past Health Law Section Chair, and Mary Beth Quaranta Morrissey, Esq., the Task Force Chair, for the work done on the Report and Resolutions. In addition to preparing the Report, the Task Force held two dialogues regarding the Resolutions, and Dr. Morrissey repeatedly made herself available to discuss them.

The FD&C Law Section provides the comments below on Revised Resolution No. 3 and also proposes further revisions to Revised Resolution No. 3, which the FD&C Law Section believes are consistent with the Task Force's description of Revised Resolution No. 3 at the dialogue held on September 29, 2020. The proposed revisions to Revised Resolution No. 3 are attached hereto as Appendix B.

The Elimination of the Previously Proposed Vaccination Mandate Should be Made Clear

During discussions with the Task Force following the issuance of the Revised Resolutions, the Task Force made clear that the Revised Resolutions do not advocate enactment of a vaccination mandate, but instead seek to provide guidance setting forth issues that must be addressed before state and local government officials and public health authorities consider the possibility of a government mandate. The FD&C Law Section agrees with the NYSBA

Committee on Diversity and Inclusion that a resolution endorsing enactment of a vaccine mandate for the general population would have been premature since a COVID-19 vaccine has not yet been approved by the United States Food and Drug Administration (“FDA”) or been deemed to be safe and effective by the medical and scientific community. The FD&C Law Section also believes that NYSBA lacks the necessary scientific and medical expertise to recommend a mandatory vaccine when there is no existing vaccine that has been shown to be safe and effective, and that the NYSBA can make its most effective contributions to our nation’s efforts to combat the coronavirus pandemic by focusing on the wide range of legal issues involved, where NYSBA has relevant expertise.

The initial Report received significant media coverage for calling for nationwide mandatory vaccinations as soon as a COVID-19 vaccine becomes available. See, e.g., “State Bar Group Calls for ‘Mandatory’ COVID-19 Vaccinations, Regardless of Objections,” *New York Law Journal*, May 28, 2020;² “New York State Bar Committee Recommends Mandatory COVID Vaccine,” *National Review*, June 4, 2020.³ Particularly in light of the substantial publicity surrounding the initial Report, the FD&C Law Section believes it is important that Revised Resolution No. 3 make clear that the Health Law Section is no longer advocating a nationwide, state-wide or local vaccine mandate, but is instead proposing to set forth legal guidance as to the circumstances when it may be appropriate for state and local officials and public health authorities to consider the possibility of a government mandate.

² Available at: <https://www.law.com/newyorklawjournal/2020/05/28/state-bar-calls-for-mandatory-covid-19-vaccinations-regardless-of-objections/>.

³ Available at: <https://www.nationalreview.com/corner/n-y-state-bar-committee-recommends-mandatory-covid-vaccine/>.

Clarification and Definition Required as to When a Vaccine is Deemed Safe and Effective

The FD&C Law Section applauds Resolution No. 3's clear recognition that "[a] vaccine must not only be safe and efficacious; it must be publicly perceived as safe and efficacious." Revised Resolution No. 3 provides that "trials also must follow rigorous protocols that will establish a vaccine's safety and efficacy through expert consensus of the medical and scientific communities." Revised Resolution No. 3 references "due consideration of the expert medical and scientific consensus regarding the safety and efficacy of a vaccine," including "evidence of properly conducted and adequate clinical trials." Yet neither the Report nor Revised Resolution No. 3 suggest where the "expert medical and scientific consensus" should come from. Thus, it is unclear whether permission to "allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN [Chemical, Biological, Radiological, Nuclear] threat agents when there are no adequate, approved, and available alternatives"⁴ pursuant to the FDA's Emergency Use Authorization ("EUA") process would constitute sufficient "due consideration of the expert medical and scientific consensus regarding the safety and efficacy of a vaccine" to provide a basis for enactment of a vaccination mandate under Resolution No. 3.

The FD&C Law Section believes that Revised Resolution No. 3 requires further clarification and definition on the critical issues of when a COVID-19 vaccine will be deemed to be safe and effective and which entities should be making that determination. Would the FDA's

⁴ Emergency Use Authorization, FDA, available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#abouteuas>.

normal vaccine approval process automatically be sufficient to permit state and local government officials and public health authorities to consider mandatory vaccination laws? Or would something more be required to establish a “medical and scientific consensus”?

The typical vaccine approval process is a three-part process as follows: During Phase I, small groups of people receive the trial vaccine. In Phase II, the clinical study is expanded and the vaccine is given to people with characteristics (such as age and physical health) similar to those for whom the new vaccine is intended. In Phase III, the vaccine is given to thousands of people and tested for efficacy and safety, after which the FDA review team will review all of the information submitted to evaluate whether the studies show that the vaccine is safe and effective for the proposed use.⁵ Multiple reports have indicated that the federal government and private companies have been working feverishly to expedite development, approval, and distribution of a COVID-19 vaccine as quickly as possible. The FDA has created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program (“CTAP”).⁶ This effort is certainly appropriate and laudable given the staggering loss of human life, with more than 200,000 Americans already dead from COVID-19. The FDA has indicated that a COVID-19 vaccine likely will be granted an EUA, which would allow such a vaccine to be administered to patients before completion of Phase III clinical trials. According to the FDA’s website, CTAP “uses every available method to move new treatments to patients as quickly as possible, *while at the same time finding out whether they are helpful or harmful*” (emphasis added). Thus, the FDA would allow a vaccine permitted under an EUA to be used on human

⁵ Available at <https://www.cdc.gov/vaccines/basics/test-approve.html>

⁶ Available at: <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>.

patients before it makes a determination that the vaccine is helpful, ineffective or harmful (i.e., safe and effective).

The FD&C Law Section recommends that Resolution No. 3 be further revised to identify a non-exhaustive list of recognized medical and scientific communities, such as the National Academies of Science, Engineering and Medicine, to which state and local government officials and public health authorities may look to determine whether a COVID-19 vaccine has been shown to be safe and effective. In light of reports of recent political pressure affecting COVID-19 guidelines and recommendations⁷, such assessments and determinations must be clearly untainted by political considerations. Aside from safety and efficacy concerns, this is important for the vaccine to attain public acceptance and consensus. While the FD&C Law Section appreciates the urgent need to develop a safe and effective vaccine, there is a clear tension between expediting delivery of a vaccine and ensuring that it is safe and effective and will not cause harmful side effects. The FD&C Law Section is unaware of a single instance in which the EUA process has ever been used to expedite mandated inoculation of the general population. Particularly in the current environment, the Report wisely recommends “deliberate, reasoned attention” to strategies to avoid mandating COVID-19 vaccines approved on the basis of limited or contested evidence of effectiveness which harm patients or prove to be ineffective. Consistent with this “deliberate, reasoned” approach, the FD&C Law Section believes that Resolution No. 3 should be further revised to clarify that issuance of an EUA by the FDA, standing alone, is not a sufficient basis upon which to consider imposition of a vaccination mandate in the absence of an

⁷ “White House Blocks New Coronavirus Vaccine Guidelines,” *New York Times*, October 5, 2020. Available at <https://www.nytimes.com/2020/10/05/us/politics/coronavirus-vaccine-guidelines.html?referringSource=articleShare>

expert consensus of the medical and scientific communities establishing the vaccine's safety and efficacy, among a number of other factors which should also be considered.

Need for Greater Diversity in Clinical Trials

Revised Resolution No. 3 appropriately discusses the need to include “people of color” in the clinical trials. Scientists recommend that the patient population at least mirror the actual percentage of the population (indeed the National Institute of Health has suggested that the Black and Latino population should be overrepresented). This is especially important given that those communities have been found to be far more likely to be hospitalized with, and die from COVID-19 than other groups, and in light of the Report's recommendation that those communities be given priority in receiving any approved vaccine.

Constitutionality of State and Federal Mandatory Vaccine Laws

There is a strong likelihood of massive litigation challenging the constitutionality of any vaccination mandate on various grounds. Indeed, individuals and groups filed legal and constitutional challenges to mask mandates and stay-at-home executive orders, and it is reasonable to anticipate additional challenges if a state or other regulatory authority enacts a vaccine mandate at any level. Given the current lack of any national consensus regarding a coronavirus vaccine, it is also reasonable to anticipate the possibility of protests and violent confrontations between those who refuse to get vaccinated and those who may be required to enforce any mandate, as the country has already seen with businesses seeking to enforce existing mask mandates.

The FD&C Section has reviewed existing case law on the constitutionality of state and local vaccination mandates and agrees with the Report that mandatory vaccinations have been

upheld as constitutional exercises of the state's police power to protect public health, and that challenges to the exercise of that authority have been rejected by the courts. All fifty states have laws requiring certain vaccines for students, with exemptions for medical reasons. As the Report notes, in 2019, New York repealed the religious exemption for vaccinating school-attending children (Report at 65), although many other states continue to include a religious exemption in their existing vaccination mandates.

States have the right to enact mandatory vaccination laws to protect public health. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (upholding constitutionality of mandatory vaccination law for smallpox). The Court in *Jacobson* recognized that “the police power of a State must be held to embrace reasonable regulations enacted by the legislature to protect public health and safety,” *id.* at 25, and that individual liberties under the Constitution do “not import an absolute right in each person to be, at all times and in all circumstances, wholly free from restraint.” *Id.* at 26. The Court recognized that “a community has the right to protect itself against an epidemic of disease which threatens the safety of its members” and that “the rights of an individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.” *Id.* at 29. A state law requiring mandatory vaccinations would be constitutional unless it “has no real or substantial relation to protecting public health” or is “a plain, palpable invasion of rights secured by the fundamental law.” *Id.* at 31. The mere fact that the vaccine is not fully effective for all and that it may cause side effects does not render mandatory vaccine laws unconstitutional. The Court in *Jacobson* concluded that mandatory vaccines are constitutional provided they contain an exception where vaccination would jeopardize a person's health.

Relying on *Jacobson*, the Supreme Court has previously concluded it is within the police power of a state to provide for compulsory vaccinations, rejecting constitutional challenges. *Zucht v. King*, 260 U.S. 174 (1922). The Supreme Court has upheld the state’s power to issue laws protecting public health even where such laws restrain individual rights and religious liberties. See, e.g., *Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944) (noting that “the right to practice religion freely does not include liberty to expose the community to communicable disease”).

Jacobson remains good law. Chief Justice Roberts cited *Jacobson* earlier this year, concurring in declining a religious institution’s attempt to enjoin, on First Amendment free exercise grounds, a California executive order issued to address the coronavirus pandemic, which restricted large public gatherings, including religious services. *South Bay United Pentecostal Church v. Newsom*, 590 U.S. ___, 140 S.Ct. 1613 (2020). Chief Justice Roberts gave great deference to State officials, noting that “[w]hen those officials ‘undertake[] to act in areas fraught with medical and scientific uncertainties,’ their latitude ‘must be especially broad.’” *Id.* at ___, 140 S.Ct. at 1613,

Significantly, the decision in *South Bay United Pentecostal Church* was 5-4, with Justice Ruth Bader Ginsburg in the majority declining to enjoin the executive order. Given the high probability that coronavirus litigation will again make its way to the Supreme Court, the scope of *Jacobson v. Massachusetts* may well be addressed by the Supreme Court again soon, with a newly-confirmed Supreme Court Justice as the swing vote. It is possible that the Supreme Court may be more receptive to challenges to vaccination mandates that fail to include a religious exemption.

There are some significant potential distinctions between the vaccination mandate upheld in *Jacobson* in 1905 and any potential vaccination mandate that may be considered today, which could have an impact on any efforts to apply *Jacobson* to any COVID-19 vaccination mandate that may be enacted. The smallpox vaccine at issue in *Jacobson* had been “accepted by the mass of the people, as well as by most members of the medical profession... and in most civilized nations for generations.” *Jacobson*, 195 U.S. at 34-35. By contrast, a premise of the Report -- that a majority of Americans will want a COVID-19 vaccine when it becomes available (Report at 64) -- may no longer be accurate today, just a matter of months after the Report was first written. A recent study indicated that the percentage of people who said they would get the vaccine if it were available today is now just over 50 percent. Pew Research Center, “US Public Now Divided over Whether to Get COVID-19 Vaccine.”⁸

In addition, the penalty for non-compliance with the vaccine mandate in *Jacobson* was a \$5 fine, equivalent to roughly \$150 today. Neither the Report nor Revised Resolution No. 3 address how any COVID-19 vaccination mandate might be enforced. The FD&C Law Section assumes that Revised Resolution No. 3 does not contemplate a vaccination mandate that would be enforced by forcible physical compulsion, and that enforcement might take the form of a fine, as in *Jacobson*, or conditioning participation in education or government programs upon compliance or creation of other incentives for compliance.

Revised Resolution No. 3 refers to the possibility of state and local governments mandating vaccinations for unspecified “populations identified by the state and local health authorities.” Elsewhere, Revised Resolution No. 3 states that “[h]ealth care workers and other

⁸ Available at: <https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine>.

essential workers most endangered by COVID-19 and populations at highest risk must be afforded priority access to a vaccine.” There is a substantial difference between affording vulnerable segments of the population priority access to a vaccine and mandating that they receive it. Particularly in the absence of a strong consensus as to the safety and efficacy of a vaccine, imposing a mandatory vaccine on certain communities could cause additional complications in enforcement, raising potential ethical issues and providing bases for additional legal challenges.

The Report alludes to the possibility of a federal vaccination mandate, stating that “the gravity of COVID-19 presents compelling justification for State legislatures *and Congress* to mandate a COVID-19 vaccination.” Report at 65 (emphasis added). Although the Report addresses the constitutionality of a vaccine mandate under a State’s police power, the Report does not discuss the constitutionality of a potential federal vaccine mandate.

Questions exist as to whether Congress’s enumerated powers include the power to require vaccination. Indeed, the Supreme Court has held that “the regulation of health and safety matters is primarily, and historically, a matter of local concern.” *Hillsborough Cnty. v. Automated Med. Labs.*, 471 U.S. 707, 719 (1985). Congressional authority to regulate interstate commerce does not permit Congress to compel individual action. *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (Commerce Clause does not give Congress the power to command individuals to purchase insurance). Federal regulatory agencies cannot act beyond Congressional authority. The FDA does not have authority to mandate vaccines or to require states to mandate vaccines. While the Centers for Disease Control’s Advisory Committee on Immunization Practices may make recommendations about vaccines, it does not have the authority to mandate vaccines. Inasmuch as Revised Resolution No. 3 does not propose a federal

mandate and the Report does not address the issue of a federal mandate in detail, we do not believe a detailed analysis of the constitutionality of a potential federal mandate is necessary here.

The FD&C Law Section appreciates the opportunity to provide these comments on Revised Resolution No. 3 and also appreciates the Task Force's consideration of the proposed Revisions to Revised Resolution No. 3, attached hereto as Appendix B.

Appendix A

Resolution #3

COVID-19 Vaccine and Virus Testing Legal Reforms

The authority of the State to respond to a public health threat and public health crisis is well-established in constitutional law and statute. In balancing protection of the public's health and civil liberties, the Public Health Law recognizes our interdependence, and that a person's health, or her/his/their lack of health, can and does affect others. This is particularly true for communicable and infectious diseases. Since the discovery of the smallpox vaccine in 1796, vaccines have played a crucial role in preventing the spread of dangerous and often fatal diseases. The New York Public Health Law mandates several vaccinations for students at school-age up through post-secondary degree educational levels, and for health care workers. The Public Health Law also mandates treatment for certain communicable diseases, such as tuberculosis.

The New York State Bar Association recommends:

A vaccine must not only be safe and efficacious; it must be publicly perceived as safe and efficacious. Diverse populations, including people of color, older adults, women, and other marginalized groups, must be represented in clinical trials. The trials also must follow rigorous protocols that will establish a vaccine's safety and efficacy through expert consensus of the medical and scientific communities.

State Government to:

A.1. Ensure Access to Virus Testing: Establish a coordinated statewide plan for Virus Testing to ensure:

A.1.(a) frontline health care workers are prioritized in access to rapid diagnostic testing; and

A.1.(b) the most vulnerable individuals from health status and essential business/employee standpoint have equitable access to rapid diagnostic testing.

A.2. Adopt Ethical Principles Guiding Equitable Allocation and Distribution: Once available, a vaccine should first be equitably allocated and distributed based upon widely accepted ethical principles including: maximizing benefit to the society as a whole through reducing transmission and morbidity and mortality; recognizing the equal value, worth and dignity of all human persons and human lives; mitigating suffering, health inequities and disparities; and ensuring fairness and transparency in decision making. Health care workers and other essential workers most endangered by COVID-19 and populations at highest risk must be afforded priority access to a vaccine.

A.3. Encourage Public Acceptance and Educational Programs: Efforts must be made to encourage public acceptance. Public health authorities should build on existing systems and infrastructures including community-based organizations and networks. The campaign must

Resolution #3 (continued)

acknowledge distrust in communities of color from a history of medical exploitation. Efforts should include linguistically and culturally competent educational and acceptance programs, and stakeholder community engagement strategies, to build public trust, widely encouraging vaccine uptake and addressing vaccine hesitancy.

A.4. Take Steps to Protect the Public's Health, and As May Be Necessary, Consider Vaccine Mandate to Reduce Risks of Transmission and Morbidity and Mortality:

Our state and nation have suffered terrible losses from COVID-19. As of September 3, 2020, 186,000 Americans, including 26,000 New Yorkers, have lost their lives. Unemployment has been at the highest levels since the Great Depression. Numerous businesses have closed.

Should the level of vaccination be deemed insufficient to check the spread of COVID-19 and reduce morbidity and mortality, after due consideration of the expert medical and scientific consensus regarding the safety and efficacy of a vaccine and the need for required inoculation, including i) evidence of properly conducted and adequate clinical trials, ii) reasonable efforts to promote public acceptance, and iii) fact-specific assessment of the threat to the public health in populations and communities, appropriate action as warranted would need to be taken to permit the state and local governments to mandate vaccination for populations identified by state or local public health authorities, subject to exception for personal medical reasons.

Appendix B

Proposed Revisions to Revised Resolution #3

COVID-19 Vaccine and Virus Testing Legal Guidelines

Deleted: Reform

The authority of the State to respond to a public health threat and public health crisis is well-established in constitutional law and statute. In balancing protection of the public's health and civil liberties, the Public Health Law recognizes our interdependence, and that a person's health, or her/his/their lack of health, can and does affect others. This is particularly true for communicable and infectious diseases. Since the discovery of the smallpox vaccine in 1796, vaccines have played a crucial role in preventing the spread of dangerous and often fatal diseases. The New York Public Health Law mandates several vaccinations for students at school-age up through post-secondary degree educational levels, and for health care workers. The Public Health Law also mandates treatment for certain communicable diseases, such as tuberculosis.

The New York State Bar Association recommends:

To protect public health, it would be useful to provide guidance, consistent with existing law, to assist state and local elected officials and public health authorities in identifying conditions that must be met before it may be appropriate for them to consider the possibility of enacting a vaccine mandate. A vaccine must not only be safe and efficacious; it must be publicly perceived as safe and efficacious. Diverse populations, including people of color, older adults, women, and other marginalized groups, must be represented in clinical trials. The trials also must follow rigorous protocols that will establish a vaccine's safety and efficacy through expert consensus of the medical and scientific communities as may be reflected in the assessments and determinations of recognized organizations of medical and scientific experts such as the National Academies of Science, Engineering and Medicine. Permitting an Emergency Use Authorization by the U.S. Food and Drug Administration, standing alone, is not a sufficient basis upon which to consider imposition of a vaccination mandate in the absence of an expert consensus of the medical and scientific communities establishing the vaccine's safety and efficacy, among other factors which should be considered.

Deleted: ¶

Formatted: Font: (Default) Times New Roman, 12 pt, Not Bold

Formatted: Font: (Default) Times New Roman, 12 pt, Not Bold

Formatted: Font: (Default) Times New Roman, 12 pt, Not Bold

State Government to:

A.1. Ensure Access to Virus Testing: Establish a coordinated statewide plan for Virus Testing to ensure:

A.1.(a) frontline health care workers are prioritized in access to rapid diagnostic testing; and

A.1.(b) the most vulnerable individuals from health status and essential business/employee standpoint have equitable access to rapid diagnostic testing.

A.2. Adopt Ethical Principles Guiding Equitable Allocation and Distribution: Once available, a vaccine should first be equitably allocated and distributed based upon widely accepted ethical principles including: maximizing benefit to the society as a whole through reducing transmission and morbidity and mortality; recognizing the equal value, worth and dignity of all human persons and human lives; mitigating suffering, health inequities and disparities; and ensuring fairness and transparency in decision making. Health care workers and other essential workers most endangered by COVID-19 and populations at highest risk must be afforded priority access to a vaccine.

A.3. Encourage Public Acceptance and Educational Programs: Efforts must be made to encourage public acceptance. Public health authorities should build on existing systems and infrastructures including community-based organizations and networks. The campaign must acknowledge distrust in communities of color from a history of medical exploitation. Efforts should include linguistically and culturally competent educational and acceptance programs, and stakeholder community engagement strategies, to build public trust, widely encouraging vaccine uptake and addressing vaccine hesitancy.

A.4. Take Steps to Protect the Public's Health, and As May Be Necessary, Consider Vaccine Mandate to Reduce Risks of Transmission and Morbidity and Mortality:

Our state and nation have suffered terrible losses from COVID-19. As of September 3, 2020, 186,000 Americans, including 26,000 New Yorkers, have lost their lives. Unemployment has been at the highest levels since the Great Depression. Numerous businesses have closed.

Should the level of immunity be deemed insufficient by expert medical and scientific consensus to check the spread of COVID-19 and reduce morbidity and mortality, a potential mandate should be considered only after the following conditions are met:

Deleted: vaccination

Deleted: after due consideration of the expert medical and scientific consensus regarding the safety and efficacy of a vaccine and the need for

Deleted: required inoculation,

i) evidence of properly conducted and adequate clinical trials;

ii) reasonable efforts to promote public acceptance;

iii) fact-specific assessment of the threat to the public health in populations and communities,

iv) the expert medical and scientific consensus (as may be reflected in the assessments and determinations of recognized organizations of medical and scientific experts such as the National Academies of Science, Engineering and Medicine) regarding the safety and efficacy of a vaccine and the need for immunization, and

v) consideration of potentially less intrusive alternatives.

State and local governments may then consider whether or not it may be appropriate to take action as warranted to mandate vaccination for populations identified by state or local public health authorities, subject to exception for personal medical reasons. Enforcement of any vaccination mandate that may be enacted would never be through the use of physical compulsion, but could be achieved through various means, including fines for non-compliance, conditioning participation in education upon compliance or creation of incentives for compliance.

Deleted: including

Deleted: ,

Formatted: Indent: First line: 0.5"

Deleted:

Deleted: , and

Deleted: would need to be taken to permit the state and local governments

Deleted: ¶
¶

LSGLS COVID Issues

Overview of the NYSBA Health Law Section Task Force

The Health Law Section 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.

The draft report was issued July 1, 2020 and has a heavy emphasis on health care related issues. The report is broken down into seven sections:

1. Public Health Law Framework
2. Ethical Issues in The Management of Covid-19
3. Provider Systems and Issues
4. Business/Contracts/Risk Management
5. Workforce Issues Associated with Covid-19
6. Vaccination
7. Vulnerable Populations and Issues of Equity and Discrimination: A Call For Social Justice

LSGLS Issues

The Role of Local Public Health Agencies and Officials

Overview of Local Public Health Structure

The State of New York's public health system is two-level system with the State Health Department's supervising the work and activities of the local boards of health and health officers throughout the state, unless otherwise provided by law. The State Department of Health oversees reporting and control of disease, maintains vital records, and promotes the prevention and control of disease.

The State's 57 county health departments and the New York City Department of Health and Mental Health have the major responsibility of providing public health services at the local level. These local health departments provide a variety of services and programs to protect and promote the health of the communities they serve. All local health departments offer core public health services that include assessing the health of the community, disease control and prevention, family health services, and health education.

However, on March 18, 2020, Governor Cuomo issued Executive Order 202.5, which provides in relevant part:

Notwithstanding section 24 of the Executive Law, no locality or political subdivision shall issue any local emergency order or executive order with respect to response of COVID-19 without the approval of the State Department of Health.

While chief executive officers may still declare a local state of emergency, before a local government announces, publicizes, or posts a local emergency order issued pursuant to NYS Executive Law § 24, the NYS Department of Health must approve such order. Local officials may submit written requests for

approval to the Department of Health via email at localordersreview@health.ny.gov. Click [here](#) for the Department of Health's detailed guidance on the procedure for obtaining approval.

While this process served to facilitate a uniform response to the pandemic statewide, it hamstrung the ability of local officials to respond locally.

Enforcement of Public Health Regulations and Orders

The Governor's COVID emergency orders were issued pursuant to the authority under NYS Executive Law Article 2-B. However, unlike Executive Law § 24, which provides a penalty for violating orders issued by local chief executive officers pursuant to a local emergency, there is no analogous penalty for violating an order of the Governor issued as a result of a State declared emergency.

RECOMMENDATION: Amend Executive Law § 29-a to provide that any person who knowingly violates any local emergency order of a chief executive promulgated pursuant to this section is guilty of a class B misdemeanor.

Conducting Essential Government Services and Public Access to Essential Government Services

Local officials are finding themselves in situations where conducting business that is essential for the continuation of municipal operations and complying with the technical procedural requirements of State law is difficult and potentially impossible in light of public health considerations. Particularly problematic, given the nature of the current crisis, is the in-person requirement of the NYS Open Meetings Law.

On March 13, 2020, Governor Cuomo issued Executive Order No. 202.1 in an effort to address the conflict between the requirements of the Open Meetings Law and the Governor's emergency orders limiting gatherings. Specifically, Executive Order No. 202.1 suspends Article 7 of the Public Officers Law (also known as the Open Meetings Law) to the extent necessary to permit any public body to meet and take such actions authorized by law without allowing the public to be physically present at the meeting. The order also authorizes public bodies to meet remotely by conference call or similar service. If a public body restricts in-person access to its meetings or conducts a meeting remotely by conference call or similar service, the public body must provide the public the ability to view or listen to such meetings live and must record and later transcribe such meetings.

Executive Order 202.14 extended Executive Order 202.1 until May 7, 2020. Executive Order 202.28 extended Executive Order 202.1 until June 6, 2020. Executive Order 202.38 further extended Executive Order 202.1 until July 6, 2020. And on July 6, 2020, Executive Order 202.48 extended Executive Order 202.1 through August 5, 2020. On August 5, 2020, the Governor issued Executive Order 202.55 which, in part, extended Executive Order 202.1 through September 4, 2020. On September 4, 2020, the Governor issued Executive Order 202.60 which, in part, extended Executive Order 202.1 through October 4, 2020.

While Executive Order 202.1 provides for conducting meetings remotely, the requirement that the meetings be transcribed has proven to be costly and time-consuming, as well as unnecessary, especially when the recording is made readily available. This has in turn served as a disincentive to conducting meetings remotely.

In addition, last minute extensions of the Executive Orders, either on or close to the date on which each expired, has resulted in meetings being noticed to occur in-person to then be changed at the last minute to remote, and vice versa, resulting in confusion and inconvenience to the public.

Recommendation: The authority to conduct meetings remotely during the pandemic should be made as easy as possible. As a result, the requirement to transcribe meetings should be removed from the Executive Order 202.1 requirement and the Open Meetings Law should be amended to provide the authority to conduct remote meetings during the duration of the pandemic.

Elections

Three major issues have arisen as a result of the pandemic with respect to conducting elections: 1) the circulating of petitions to get on the ballot, 2) the public voting in person, and 3) getting individuals to work as poll inspectors. These activities do not lend themselves to social distancing. As a result, the risk of COVID transmission is an issue. Fear of transmission has created numerous problems in each of these areas of the election process.

Recommendations: The Governor modified petition requirements for this past summer's elections. Additionally, he issued an executive order declaring the threat of COVID as an illness for which individuals could vote by absentee ballot. Both provisions should be extended throughout the duration of the pandemic.

Government Liability

Government officials have been concerned about the potential for liability from the public and also from employees who get sick with COVID by visiting local government offices, using local government infrastructure or services, or working for a local government.

Recommendations: The question of COVID-related liability has been a topic at both the State and federal level. Local governments face a question of liability with respect to employees who contract COVID on the job as well as from individuals who contract COVID while using municipal infrastructure or services. The burden of proving causation serves as a protection for local governments against liability. However, the question of government liability needs to be addressed as the cost of defending against liability lawsuits may be significant, especially during a time when local and state governments are faced with tremendous budgetary shortfalls.

The State should NOT create a presumption that local government officials who contract COVID did so while on the job. To the contrary, the State should enact provisions limiting liability of local governments for COVID injuries; thereby protecting the public fisc and local tax payers.

Consequently, local governments should be immune from civil liability for damages or an injury resulting from exposure of an individual to COVID-19 on the premises owned or operated by the local government, or during an activity managed by the local government. This local government immunity should not apply to:

1. willful misconduct;
2. reckless infliction of harm; or
3. intentional infliction of harm.



Matthew J. Leeds, Esq.
Direct Tel.: (212) 922-9071
Direct Fax: (212) 823-0933
Email: mleeds@ganfershore.com

Hermes Fernandez, Esq.
Chair, Health Law Section
One Elk Street
Albany, New York 12207

Mary Beth Quaranta Morrissey, Esq.
Chair, Health Law Section Task Force
on Covid-19
One Elk Street
Albany, New York 12207

September 22, 2020

Re: New York State Bar Association Health Law Section Covid-19 Report

Dear Mr. Fernandez and Ms. Morrissey:

On behalf of the Executive Committee of the Real Property Section, I have been asked to contact you with some questions about potential further efforts of the Task Force, after the issuance of this excellent Report, as well as to ask if there is anything we can do to help.

We are sure that our membership and the Bar in general greatly appreciate this effort. It is so important and much appreciated that the Task Force was able to draw on collaboration from so many applicable legal and medical disciplines. We are certain that the Report will be a useful tool to Bar leadership as they might be developing policy in this area. At the same time, this comprehensive survey will clearly also be a valuable tool to practitioners who have an opportunity to review it. On behalf of the Section and its membership, thank you for that.

At the same time, as the Report recognizes, it is possible that considerations of the issues dealt with might be re-examined as science and experience develop. We do not know if the Task Force has been asked to anticipate updates taking into account changed future circumstances. Nor is it clear if the full Bar intends to take public positions or make further pronouncements. We assume that such matters await discussion at other levels, including at the House of Delegates.

As real estate lawyers, the members of our Section see much of the day-to-day life that is so greatly affected by the pandemic. Owners, landlords, tenants, lenders, borrowers, management companies and insurance companies would all like to anticipate potential requirements or limitations to be made on how they operate, including the question of whether vaccination would be recommended or mandated, and who, if anybody, would be responsible for the burdens of requiring and policing vaccinations. Should or can government require them? Should or can a building owner? Should or could tenants? We wonder if the insight of the legal and medical professionals on the Task Force might foresee the implications of future vaccinations (or lack of vaccinations) on these considerations.

As to matters of policy and legal practice, it is interesting to note that at a recent meeting of our Section's Executive Committee, the mere fact of the report elicited a few spirited comments, but those were in the context of an informal conversation about various issues. One issue that arose was whether or not the full State Bar could -- or should -- take a position on whether vaccinations should be mandated generally for the population, if and when reliable vaccinations are universally available. Naturally, there are subordinate questions, even if this broadest question were not considered, such as whether the profession could (or should) mandate vaccination of those working in the profession. Further, another step down, is the question of whether as a matter of law office management, a private law practice could (or should) require vaccination for those in its office. In any event, it is anticipated that many will seek advice as to whether the current Covid-19 type precautions should be kept in place if and until universal vaccination is available and/or implemented.

Anybody who reviews the Report will recognize the great value of the material and learning in the suggestions that certain groups should be given priority for what we all hope is an inevitable vaccination program, and if we understand that correctly, for whom vaccination should be mandatory, such as frontline providers and those in healthcare. We also appreciated the summary of the law that has developed in the area of whether vaccinations could be required, particularly with respect to school systems.

It is appropriate to repeat that as of the date of this letter, our Section has not had a comprehensive conversation nor made any recommendations. However, we are interested in guidance of what we should be examining, how we could help the Task Force, and direction as to what kind of feedback from our Section would be of use to the Task Force.

As a form of summary, our current questions include:

1. Is the Task Force expected to update their report?
2. Has the Task Force been asked to and do you intend to deal with the question of whether the Bar Association could or should recommend universal vaccination for the entire population?
3. Are there any insights, requirements or suggestions that the Task Force might have or look to develop as to what the future should hold or might hold for landlords, tenants, mortgagors, borrowers, real property managers or insurance companies regarding how to comport themselves in the world as it is now, or as it might be situated when a vaccine is available? Where could and should options to require vaccination lie? What

parties could or should be responsible for implementation? What could be or should be appropriate enforcement mechanisms or penalties for non-compliance?

4. If not universal in the population, could or should the Bar establish a requirement for those in the legal community?
5. If vaccination is not required at a broader level, as a matter of law office management, could or should individual law offices or firms require vaccination for the population within its office?
6. If vaccination is not universal, should offices anticipate the precaution and expense of continuing current Covid-19 precautions?
7. Is it felt that the Bar Association (i) could or (ii) should take a position on these matters?
8. What can our Section do to help the Task Force? Without being presumptuous, can the Real Property Section provide certain specific questions or viewpoints to the Task Force that would be helpful to any further work?

Certainly, there is no need for you to undertake the effort of a formal reply at this time. However, we would be happy just to talk on the phone informally. For any purposes, you can contact either me at the contact information on this letterhead, or the Chair of the Real Property Section, Ira S. Goldenberg at his office: (914) 997-0999; igoldenberg@goldenbergseker.com. If there will be further effort required, it is likely that our Section will be organizing a working group to consider these matters.

We look forward to any insight you might be able to share, and certainly to any further material that your group is asked to produce.

Very truly yours,



Matthew J. Leeds

cc: Ira S. Goldenberg, Esq.



TRIAL LAWYERS SECTION

Betty Lugo, Esq.

Chair

Pacheco & Lugo, PLLC

To: Karen Gallinari, Chair, NYSBA Health Law Section

William S. Friedlander, Esq.

Vice Chair

From: Betty Lugo, Chair, NYSBA Trial Lawyers Section

Daniel Ecker, Esq.

Treasurer

Christian Soller, Esq.

Secretary

The NYSBA Trial Lawyers Section has reviewed the Health Law Section CoVid-19 report and addendum and submits the following response in opposition to any recommendation to provide immunity and takes no position on the vaccine as it is premature.

Very truly yours,

Betty Lugo, Esq.

The Trial Lawyers Section Legislative Committee has reviewed the report prepared by the Health Law Section as well as its recommendations. The report in sum and substance is excellent; however, our section has a fundamental issue, in general, with any proposal to grant immunity.

A recent Hart Research survey completed in early May, 2020, revealed “there is broad bipartisan opposition to legislation that would give guaranteed immunity.” We are concerned that the guarantee of immunity to hospitals, physicians and health care workers will begin a movement for all businesses and companies to seek legislation granting immunity from lawsuits in cases involving coronavirus infection.

The survey revealed that large majorities of voters thought the guarantee of immunity would result in fewer businesses taking precautions to keep people safe from the virus. The survey concluded “it is a bad idea to guarantee” immunity from coronavirus lawsuits.

Key findings revealed by 64% to 36%, voters opposed giving guaranteed immunity. 72% of Democrats, 64% of Independents and 56% of Republicans opposed giving guaranteed immunity.

There is fear that blanket immunity would cause more consumers and workers to die and further hinder our economic recovery. Proving that a health care provider, hospital, or company acted unreasonably and that those actions caused injury to someone will be a difficult task to prove.

Nursing homes will be the next business seeking immunity, and we are concerned that granting immunity to one group will soon lead other groups to seek the same relief.

Mitch McConnell is in the process of drafting legislation in an attempt to protect the nursing home industry from failure to take reasonable precautions to stop the spread of the virus. Granting immunity is really saying it is more important for business to profit than for nurses, caregivers and patients to be protected.

The Seventh Amendment guarantees the right to trial by jury. The concept of facing a jury trial provides incentives to employees to act responsibly and to take reasonable precautions to protect employees from hazards that are likely to cause death or serious physical harm. Professor David Vladeck, who teaches at the Georgetown University Law Center, said, “to attack the jury system is nothing less than an attack on a core guarantee of the Constitution.”

If immunity is provided under the proposed report and recommendations of the Health Law Section, it is our major concern that this will be “the tip of the iceberg” for a large number of special interest groups to seek immunity and create chaos undermining our legal system.

The Trial Lawyers Section Legislative Committee has unanimously agreed that we should oppose any recommendation made by the Health Law Section to provide immunity as set forth in its report.

The Legislative Committee has not taken any position in regard to the Health Law Section’s proposal requiring mandatory vaccinations. A vaccine has yet to be developed, and without studies to review regarding the efficacy and safety of a vaccine, it is our position that, at best, it is premature to take any position.

Trial Lawyers Legislative Committee
Kevin J. Sullivan (former Section Chair)
Seth M. Rosner
Evan M. Goldberg
Christian J. Soller

Betty Lugo, Esq.
Chair, Trial Lawyers Section
Pacheco & Lugo, PLLC
340 Atlantic Avenue
Brooklyn, NY 11201
(718) 855-3000

To: Health Law Section Task Force COVID -19 Report Committee
From: Trusts and Estates Law Section/Report Review Team
RE: TELS Comment to Health Law Section Report and Resolutions.
Dated: October 2, 2020

The Review team met on several occasions to review the Report and resolutions proposed by the Health Law Section in connection with the COVID-19 Crisis. After a thorough review, we have come to the conclusion that our particular expertise as Trusts and Estates attorneys lends itself to comment in regard to very few specific proposals contained in the Report and the Resolutions, and our comments to those sections are included below. We have, additionally, reviewed the Report prepared by the Elder Law and Special Needs Section (“ELSNS”) and recommend joining with them in their comments as to their reservations in connection with: 1) the treatment of older adults and people with disabilities within the proposals; 2) with regard to the report’s focus on health care providers and government regulators leaving little room for the input of the general public; and 3) with the level of seemingly unmitigated trust being placed in the hands of the Department of Health to evaluate and choose an appropriate course of action.

We further recommend joining the ELSNS in calling for a proposed amendment to the Report and resolutions calling for a provision that any review of potential legislation or regulation by the Department of Health also include appropriate consumer rights groups and that any findings of said review be subject to public comment and/or hearings before implementation.

Regarding specific provisions of the Resolution, the TELS offers comment on item B.2 of Resolution 1:

B.2. Recommend amendment of the New York State Public Health Law: Article 29-C “Health Care Proxy,” to require in the case of a State Disaster Emergency Declaration:

- (a) at least one, rather than two, witnesses, or
- (b) attestation by a notary public in person or remotely.

We recommend support of this provision as we recognize that in a State Disaster Emergency Declaration the ability to secure witnesses for documents is more difficult. We agree that reducing the number of witnesses appropriately balances the reality of a State Disaster Emergency Declaration with maintaining the propriety of the appointment of a health care agent. We however wish to make it clear that we do not support this change outside of a State Disaster Emergency Declaration.



NEW YORK STATE BAR ASSOCIATION

One Elk Street, Albany, New York 12207 • PH 518.463.3200 • www.nysba.org

MEMORANDUM

TO: Kathy Baxter
General Counsel
New York State Bar Association

FROM: Terri A. Mazur
Chair, Women in Law Section

CC: Susan L. Harper, WILS Delegate to House of Delegates
Kim Wolf Price, WILS Alternate Delegate to House of Delegates
Linda Redlisky, WILS Secretary

DATE: October 26, 2020

RE: Comments of Women in Law Section on Health Law Section's Task Force Report and Resolutions on COVID-19

This Memorandum is submitted in response to the request for comments on the Report and proposed Resolutions of the Health Law Section Task Force on COVID-19 (the "Report" and "Resolutions").

The leadership of the Women in Law Section ("WILS" or "Section") received the Report and Resolutions following the June 2020 meeting of the House of Delegates. The Section's representatives to the House of Delegates reported on the discussion about the Report and proposed Resolutions during the House of Delegates meeting. WILS Executive Committee members reviewed the Report and Proposed Resolutions and discussed them extensively during the October 13, 2020 WILS Executive Committee meeting and voted on the Resolutions.

The WILS Executive Committee appreciates the tremendous and thorough efforts of the Health Law Section in preparing the COVID-19 Report and Proposed Resolutions, and thanks the Health Law Section and Task Force for their work. It should be noted that several WILS Executive Committee members expressed their concern that they do not have the substantive expertise to evaluate these proposals. The Section urges the adoption of the Report and Resolutions subject to the following comments and proposed revisions:

Resolution #1: Public Health Legal Reforms

WILS Vote: There was one abstention, all others present voted in favor of Resolution #1, subject to the following comments and proposed revisions:

1. Health Care Proxy: B.2.(a): WILS recommends that: (i) that the number of required witnesses be kept at two witnesses rather than reduced to one because having two witnesses affords the principal greater protection against abuse, and (ii) add an express statement that such witnessing can be done "in person or remotely."

Resolution #2: Legal Reforms in Care Provision, Congregate and Home Care, Workforce and Schools

WILS Vote: There was one abstention, all others present voted in favor of Resolution #2, subject to the following comments and proposed revisions:

1. A.1.(b) Limitation on Resident Hours Working in Acute Care Hospitals: Add a provision that NYSBA recommends exploring ways to increase the number of medical professionals available in Acute Care Hospitals to minimize the need to lift limits on the maximum number of hours professionals can work.
2. A.2.(b): Possible typo - should "Persons incarcerated and correctional facilities and care" be revised to "Persons incarcerated in correctional facilities and care"?
3. While A.2.(b)(ii) states that protective gear be provided to correctional staff, it is not clear whether incarcerated persons are – or should be – provided with any level of protective gear. Accordingly, please add an express statement that PPE or protective gear should be provided to incarcerated persons, a provision parallel to A.2.(b)(ii). This will also help minimize the spread of COVID-19.
4. A.2.(b)(iv) Adequate funding of prison-to-community transitions.: Does this Resolution already reflect the law? If so, what is the purpose of its inclusion here?
5. Immigrants: A.2.(c): Immigrants should all receive the same level of protection against COVID-19 as set forth in A.2.(a) and (b) (including WILS' proposed revision).

Resolution #3: Vaccine and Virus Testing Legal Reforms

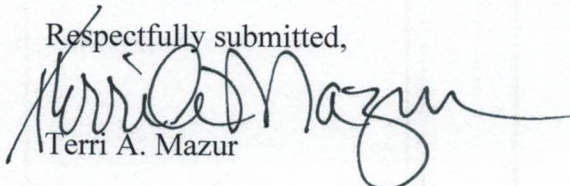
WILS Vote: Provisions A.1 - A.3 were approved.

WILS Vote: Provision A.4 (Vaccine Mandate): the majority approved (one person voted against this provision), subject to the following comments and proposed revisions to clarify the second paragraph of Part A.4 of Resolution #3:

1. This Resolution states that "Should the level of vaccination be deemed insufficient to check the spread of COVID-19 and reduce morbidity and mortality...." WILS requests clarification of and revision to this provision to: (a) identify who will evaluate the situation to determine that the level of vaccination is insufficient; and (b) while this provision states that "due consideration of the expert medical and scientific consensus" will be included, more detail should be provided on the criteria or data that will be used to evaluate that the level of vaccination is insufficient to check the spread of COVID-19 so that the public knows what data will be used to make this decision.

For these reasons, the Women in Law Section recommends that the Proposed Resolutions (and related portions of the Report) be revised as set forth above and then approved by the House of Delegates.

Respectfully submitted,


Terri A. Mazur

MEMORANDUM

To: Health Law Section Covid-19 Report Committee
From: The Elder Law and Special Needs Section
Dated: August 26, 2020
RE: Comments to COVID-19 Resolutions and Health Law Section Report

Embedded herein, please find the comments of the Elder Law and Special Needs Section (“ELSN Section”) regarding the resolutions being posed to the NYSBA House of Delegates in response to the COVID-19 Pandemic¹.

The ELSN Section recognizes and agree with the need to address the critical shortfalls exposed by the COVID-19 Pandemic. However, on behalf of the populations that the ELSN Section serves (namely older adults and people with disabilities and their families) the ELSN Section has a number of reservations both with the general positioning of the report, which has a focus on health care providers and government regulators leaving little room for the input of the general public, and with the level of seemingly unmitigated trust being placed in the hands of the Department of Health to evaluate and choose an appropriate course of action.

In addition to specific commentary offered below, the ELSN Section urges the authors of the Report, the House of Delegates and any body to whom the findings of the Report or the resolutions are referred to carefully consider all perspectives of the proposed relief.

As a general note and proposed friendly amendment to the Report, the ELSN Section suggests that any call for review of potential legislation or regulation by the Department of Health also include appropriate consumer rights groups and that any findings of said review be subject to public comment and/or hearings before implementation.

Our Section’s working group on the subject is available to the authors of the Report at their convenience should they wish to discuss this Memorandum.

NYSBA HOUSE OF DELEGATES COVID-19 RESOLUTIONS

Resolution #1

Recommendations

A. Public Health Legal Reforms and Emergency Preparedness

A. 1. Recommend the Department of Health (DOH), (or through it, the NYS Task Force on Life and the Law (NYSTFLL)), review and consider:

¹ Portions of the proposals on which the ELSN SECTION has chosen to abstain from comment have been removed from this memorandum in the interest in clarity. Subject to our general comments noted above, the ELSN Section takes no position on those items.

The ELSN Section is in support of this resolution to the extent that it calls for the DOH to “review and consider” the Model State Emergency Health Powers Act and Crisis Standards of Care. The ELSN Section believes that clear enumerated guidance should be enacted to prevent arbitrary administration of care and systematic access to limited resources in the time of crisis. However, the ELSN Section shares the Committee on Disability Rights’ concerns that vulnerable populations are not adequately protected by the laws.

(a) Enactment into New York Law of the **Model State Emergency Health Powers Act (MSEHPA)**, developed by the Center for Law and Public Health at Georgetown and John Hopkins Universities (2001), as informed by the Columbia University Center for Health Policy Gap Analysis (2008), and as otherwise updated; and

As best stated by the Committee on Disability Rights², there are three main issues presented by this model legislation that previously failed to pass the legislature.

1. The Model Act fails to provide for adequate checks and balances. The lack of checks and balances could have serious consequences for individuals' freedom, privacy, and equality. Public health authorities make mistakes, and politicians abuse their powers; there is a history of discriminatory use of the quarantine power against particular groups of people based on race, national origin, and age for example. The Act permits a governor to declare a state of emergency unilaterally and without judicial oversight, fails to provide modern due process procedures for quarantine and other emergency powers, it lacks adequate compensation for seizure of assets, and contains no checks on the power to order forced treatment and vaccination.
2. The impetus for the Model Act was bioterrorism, but the Act goes well beyond that framework. The Act includes an overbroad definition of “public health emergency” that sweeps in HIV, AIDS, and other diseases that clearly do not justify quarantine, forced treatment, or any of the other broad emergency authorities that would be granted under its provisions.³
3. The Model Act lacks privacy protections. It requires the disclosure of massive amounts of personally identifiable health information to public health authorities, without requiring basic privacy protections and fair information practices that could easily be added to the bill without detracting from its effectiveness in quelling an outbreak. And the Model Act would undercut existing protections for sensitive medical information. That not only threatens to violate individuals' medical privacy but undermines public trust in government activities.

² Committee on Disability Rights Comments on Health Law Committee’s Covid-19 Report.

³ “Public Health emergency” is defined under the Act as an occurrence or imminent threat of an illness or health conditions caused by bioterrorism, epidemic or pandemic disease, or novel and highly infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or permanent or long-term disability. Such illness or health condition includes, but is not limited to, an illness, or health condition resulting from and natural disaster (Model Act Section 104 [1]).

- (b) Adoption of the, “**Crisis Standards of Care**,” developed by the Institute of Medicine in 2012, as is, or as otherwise updated and amended.

When considering the adoption of Crisis Standards of care, the ELSN Section encourages the DOH to incorporate the 6-point disability framework published on April 8, 2020 by The Arc of the United States, The Bazelon Center for Mental Health Law, the Center for Public Representation and the Autistic Self Advocacy Network.

A. 2. Recommend DOH review and consider:

- (a) Appoint and maintain a core team of emergency preparedness experts to review evidentiary sources and draft legislation to strengthen emergency preparedness planning;
- (b) Re-evaluate the public benefit and costs of reinstating laws waived during COVID-19.

Before taking a position on this sub-resolution, the specific “waived” laws should be identified.

B. Ethical Issues: Ethics Guidelines including Allocation of Life-Saving Equipment, and DNR/Futility and Virus Testing

B.1. Recommend DOH, NYSTFLL, or Governor review/consider:

Again, to the extent that the resolution is to recommend review and consideration of the following ethical allocation guidelines, the ELSN Section is in support. Generally, the ELSN Section understands the need to derive a system to allocate scarce resources. However, the Executive review should consider and address the comments set forth herein.

- (a) NYSTFLL 2015 Report, “Ventilator Allocation Guidelines,” and adopt the policy as is, or as amended; and

We again adopt the comments of the Committee on Disability Rights:

“On April 7, 2020, Disability Rights New York filed a complaint with the federal Department of Health and Human Services alleging that the 2015 Allocation Guidelines contain serious gaps that discriminate against people with pre-existing disabilities in violation of the Americans with Disabilities Act (42 U.S.C. 12101 et seq) and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794).⁴ Advocates highlighted the following concerns about the guidelines: (1) they do not retain the presumption that all patients who are eligible for ICU services during ordinary circumstances remain eligible for ICU services in a pandemic; (2) they contain exclusion criteria based on age, disabilities and other factors; (3) they do not ensure that all patients receive individualized assessments by clinicians based upon the best available objective medical evidence; (4) they do not ensure that no one is denied care based upon stereotypes, assessments of quality of

⁴ DRNY is a Protection and Advocacy System specifically authorized to pursue legal, administrative and other appropriate remedies to ensure the protection of, and advocacy for, the rights of individuals with disabilities (42 U.S.C. 15043[a][2][A][i] and New York State Executive Law 558 [b]). The DRNY OCR complaint referenced in the text of this comment is attached as an Addendum [A] for ease of reference.

life or judgments about a person's "worth" or the presence of absence of disabilities other factors; and (5) while it is appropriate to evaluate the possibility of a person's survival in allocation decisions, the guidelines do not mandate that the considerations must be based upon the prospect of surviving the condition for which the treatment is designed -in this case COVID-19. In other words, individuals with pre-existing conditions are completely disadvantaged in a triage situation prior to considering any symptoms that result from COVID-19.”

(b) Issue emergency regulations mandating all providers and practitioners follow the ethics guidelines, and ensure:

- i. the needs of vulnerable populations, including persons and communities of color, older adults and nursing home residents, persons with disabilities or who are incarcerated, and immigrants, are met in a non-discriminatory manner in the implementation of emergency regulations and guidelines;
- ii. 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;
- iii. provision of education and training to physicians, health care practitioners, and institutional triage and ethics committees; and
- iv. 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.

While the ELSN Section is pleased to see this “catch-all” provision recognizing that vulnerable populations, including the elderly and disabled, are at particular risk under the allocation guidelines, the reviewer must assure that such considerations are meaningfully represented in any adopted guidelines, rules, regulations and law.

B.2. Recommend amendment of the New York State Public Health Law: Article 29-C “Health Care Proxy,” to require in the case of a State Disaster Emergency Declaration:

(a) at least one, rather than two, witnesses, or

(b) attestation by a notary public in person or remotely.

The ELSN Section supports this and recognizes that in a health care emergency the ability to secure witnesses for documents is frustrated. The ELSN Section believes reducing the number of witnesses appropriately balances the reality of the health care crisis with ensurance of the sanctity of the appointment of a health care surrogate.

Resolution #2

Recommendations

A. Providers

A.2. Continue Waivers and Executive Orders (See also Immunities):

(a)Ability to Exceed Certified Bed Capacity for Acute Care Hospitals: 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.

The ELSN Section agrees with the recommendation that in the circumstances of a statewide emergency, where the need for increased hospital beds is urgently required, that acute care hospitals be allowed 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 during a state of emergency. This will better able these facilities to deliver necessary services to more New Yorkers during temporary periods of increased patient need.

(b)Limitation on Resident Hours Working in Acute Care Hospitals: 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.

The ELSN Section further agrees with the recommendation to continue the waiver of rules related to the number hours a resident can work in an acute care hospital during a state of emergency. The ELSN Section agree with the finding in the report that in ordinary circumstances, limiting the number of hours better serves both the patients and residents; however in the case of a pandemic where the State is looking to retired physicians and professionals from outside of New York State to come in, limiting the number of hours of Residents is both counter-productive to the provision of care unnecessarily putting patient treatment at risk.

(c)Temporary Changes to Existing Hospital Facility Licenses Services and the Construction and Operation of Temporary Hospital Locations and Extensions: 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.

The ELSN Section also agrees with the recommendation of the report to continue the waivers provided in E.O. 202.1 and 202.10, thus allowing acute care hospitals to reconfigure and expand operations as necessary, for the pendency of any declared state of emergency.

A.3. Older Adults, Nursing Home Providers and Nursing Home Residents: Governor, DOH, DOH Bureau of Long-Term Care and State Office for Aging to ensure:

- (a) 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;
- (b) Adequate provision of PPE;
- (c) Adequate levels of staffing;
- (d) Adequate funding of employee testing, as required under Executive Order 202.30;
- (e) Consistent and timely tracking and reporting of case and death data;
- (f) Adoption of non-discriminatory crisis standards and ethics guidelines; and
- (g) Recognition and honoring of Older New Yorkers’ right to health and human rights, as protected under international conventions: and
- (h) 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.

SEE SUB-MEMORANDUM ATTACHED.

A.6. Telehealth

Governor or DOH to review and consider:

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

SEE SUB-MEMORANDUM ATTACHED.

SUB MEMORANDUM RE: LONG TERM CARE FACILITY ISSUES

Introduction:

As attorneys who serve older adults and persons with special needs, the ELSN Section's members are deeply troubled by the rampant spread of COVID-19 and the accompanying high number of deaths that occurred in nursing homes and other long-term care facilities. The Health Law Section COVID-19 Report ("Report") declares "This is not just a matter of a public health emergency, but it is also a human rights crisis."⁵ The ELSN Section agrees with this stark assessment and understand that the Report is focused on the effects of the current pandemic and recommending ways to prepare for the next public health crisis. However, the ELSN Section believes that prior to COVID-19 there was already an existing public health emergency in many nursing homes and long-term care facilities in New York State. The Report should also acknowledge and address that existing emergency and seriously recommend ways to improve quality of care for residents. Many of our clients reside in nursing homes and other long-term care facilities. The facility is their home. The ELSN Section knows firsthand from experiences they have shared with us that there are facilities that strive to provide adequate care and others that do not. The COVID-19 crisis starkly exposed systemic problems in how care and services are provided to residents in a great number of facilities and the failure of the New York State Department of Health to enforce current laws and standards of care.

This tragedy not only requires preparation for the next public health crisis but demands that we address the current state of patient/resident care in nursing homes and other long-term care facilities. There is a dire need for improved patient care that respects the dignity of each resident. The COVID-19 crisis exposed deficiencies in staffing, infection control and protocol, availability of personal protective equipment for residents and staff, testing, visitation by and notice to family members and governmental representatives, and reporting requirements. This crisis also highlighted disproportionately high levels of infection and death among facility residents of color. This moment compels us to ensure that nursing homes and other long-term care facilities meet current statutory and contractual requirements and that those requirements are appropriately enforced. In addition, we must explore legislative initiatives and other reforms to cure current deficiencies and prepare for future challenges. The ELSN Section firmly believes that there needs to be an expansion of community-based benefits and services so that more seniors and those with special needs can remain at home.

In addition to those items outlined in the Report and Resolutions, the ELSN Section is strongly in favor of the following additional policy considerations and proposed actions and would urge the inclusion of same in any discussion of Long-Term Care Facilities.

- NYS Legislature's passage of the Safe Staffing for Quality Care Act.
- Implementation of additional requirements for transparent reporting of data, including specifically tracking and reporting:

⁵ *Health Law Section Report at page 24.*

- COVID-19 infections for residents and staff by adult care facility and nursing home; and
- Inclusion of residents transferred from adult care facility and nursing home who then died at the hospital in COVID-19 facility level death data.
- Development and implementation of policies and protocols aimed to ensure:
 - that resident's rights to visitation by one or more support visitors are not infringed
 - safe infection control measures regarding and during visitation, including but not limited to, staff trained to supervise and enforce such measures;
 - publication of visitation policy and designated patient contact persons;
 - prioritization, with respect to time and frequency of access to residents in end-of-life and other compassionate care situations; and
 - visitation by local long-term ombudsmen and resident advocacy organizations.
- Development and implementation of policies and protocols that support redesign of the institutionalized nursing home model that currently dehumanizes older adults and people with disabilities such as requiring private rooms for all new nursing home builds and operator changes.
- Take actions that support long-term care services and supports in the community. Such actions would facilitate the voluntary transfer/discharge to the community setting instead of forcing a person to remain at risk for contracting COVID-19, abuse, neglect, and various indignities, in an institutionalized setting.

Comments to the Report

The ELSN Section presents these comments in response to the paragraphs of the Report beginning at page 24.

The ELSN Section commends our colleagues for the inclusive list of types of congregate care facilities in this section. The ELSN Section appreciates that home health care settings are included and further believe that with adequate Personal Protective Equipment (PPE) for home care workers, the care at home model is far safer in the time of a pandemic and offers better quality of care overall. The ELSN Section agrees that this is a time of moral imperative demanding immediate attention. The ELSN Section further lauds the reference to the duty of care and duty of non-abandonment to all persons, which is found in the Institute of Medicine's 2012 Crisis Standards of Care. The ELSN Section continues to be a legal watchdog for the elderly and special needs communities; consistently advocating and drawing attention to the fact that many times these populations are not adequately protected by society.

During the COVID-19 pandemic there have been numerous Executive Orders and New York State Department of Health Advisories issued to triage the overwhelming fury the pandemic unleashed on long term care facilities and home health care providers. The Report focuses on the March 25, 2020 New York State Department of Health advisory, prohibiting nursing homes from denying admission or re-admission to a nursing home solely based on a confirmed or suspected

diagnosis of COVID-19 and the similar advisory issued regarding Adult Care Facilities as major contributing factors to the increased spread of the virus in those facilities.⁶

Arguably, while the March 25th NYS Department of Health advisory did contribute to the increased risk of spread of COVID-19 infection in nursing homes as suggested in the Report, nursing homes are not hospitals, and have always had the responsibility to only admit those they can provide care and services to meet that person's individual needs.⁷ The March 25th advisory did not negate that requirement. If a nursing home was short on staff or other resources needed to meet the needs of current residents during the pandemic (or any time), that nursing home had a legal responsibility to not accept patients from the hospital as new residents. A denial of admission to a hospital patient due to not having enough resources is not the same as denying a patient admission based on a confirmed or suspected diagnosis of COVID-19.

A similar point can be made regarding Adult Care Facilities and the NYS Department of Health April 7, 2020 advisory. If an Adult Care Facility could not safely isolate a resident, or that resident's care needs exceeded the licensure of the facility, that facility could have denied readmission to the resident, until that resident's needs could be safely met. Due to the severe undercounting of residents who died from (or contracted) COVID-19 complications in Adult Care Facilities, it is hard to determine the extent the April 7th advisory had on COVID-19 spread in Adult Care Facilities.

In addition to the previously mentioned state advisories, The Report references "other state requirements, which have generally imposed new burdens on under-staffed facilities and administrators during the pandemic..."⁸ It is important to note that nursing homes in New York have been historically understaffed, and the state has not held ownership accountable. The burdens were not on the "institution" but on the residents who suffered from abuse and neglect due to the constant understaffing of nursing homes. Insufficient staffing of nursing homes has always been allowed. New York is one of a minority of states in the country that does not have a minimum staffing law.

"Every day our nursing home residents face conditions that undermine their health and dignity. Countless adult residents are forced to wear diapers because their facilities will not hire sufficient staff to help them get to the bathroom. Thousands of New Yorkers are given dangerous antipsychotic drugs every day because it makes them easier to care for. These drugs have an FDA "Black Box" warning against use on elderly people with dementia because they can

⁶ NYS DOH Advisory: *Hospital Discharges and Admissions to Nursing Homes*, Mar. 25, 2020, previously available at: https://coronavirus.health.ny.gov/system/files/documents/2020/03/doh_Covid19_nhadmissionsreadmissions_032520.pdf, page no longer available.

NYS DOH Advisory: *Hospital Discharges and Admissions to Adult Care Facilities*, Apr. 7, 2020, available at: https://coronavirus.health.ny.gov/system/files/documents/2020/04/doh_covid19_acfreturnofpositiveresidents_040720.pdf.

⁷ https://www.health.ny.gov/facilities/nursing/select_nh/select_nh.htm. Once the patient is medically assessed as appropriate for the NH, "each nursing home is required to develop an admission policy and procedure that is in accordance with State/Fed regulations and does not unlawfully discriminate against applicants. However, NHs have discretion in making admissions decisions and are not required to admit every applicant."

⁸ Report at page 26.

have serious side effects, including heart attacks, strokes, and death. Yet they are used on almost one in five nursing home residents in NY, often as a form of chemical restraint.”⁹

Safe staffing matters and initial research into COVID-19 and its impact on nursing homes shows that nursing homes with higher RN staffing had lower resident deaths from COVID-19.¹⁰ While the New York State Department of Health issued its long overdue report late August 14, 2020 that details the challenges with staffing, there is no question that safe staffing is vital to providing quality care and, as unified, NYSBA must push for the passage of the Safe Staffing for Quality Care Act.¹¹ Nursing homes make a legal and moral promise to provide safe and quality care to each resident they chose to admit. While the state can implement policy that helps boost the workforce, the responsibility to recruit, retain, and properly train staff rests with the nursing home.

The Report at page 25 and 26 states that nursing homes did not have adequate supplies of PPE and that hospitals had more access to emergency stockpiles of this equipment. There is conflicting information regarding these statements. In some cases, as testified to at the August 2020 New York State Assembly and Senate hearings, PPE was stored in administrators’ offices and not distributed to the employee caregivers. It is also important to note that PPE was also scarce at ACF’s, and exceedingly difficult for home care agencies to access through state mechanisms.¹² Nevertheless, the increase in nursing home residents with COVID-19 beginning in March 2020 and the March 25th decision by the New York State Health Department regarding the admission of COVID-19 positive residents highlights what was made evident by the marked increase in COVID-19 cases in these facilities. Namely, that nursing home staff never received adequate PPE training. While the Report discusses the limited access, some facilities had in securing PPE, there is no discussion regarding training staff about how to properly use and dispose of PPE. The testimony during the August hearings conducted by the New York State Senate and Assembly included numerous front-line workers- both registered nurses and certified nursing assistants- who stated that there was in fact PPE available in their facilities but there was no training in how to properly use it. For example, Ira Purks, CNA from Safire Rehabilitation of Northtowns, testified on August 10 about needing training in PPE. Any adequate infection control program must have adequate training as part of its protocol. This should be addressed in any plan to improve infection control.

On July 6, 2020, the New York State Department of Health issued a report entitled “Factors Associated with Nursing Home Infections and Fatalities in New York State During the COVID-19 Global Health Crisis” (“DOH Report”). This report was updated and revised on July 20, 2020. The DOH Report when discussing the March 25th DOH directive states that the peak of admissions of positive residents occurred a week after the peak of nursing home deaths from COVID-19. Therefore, the DOH Report concludes, the March 25th directive was not a decisive factor in the

⁹ Long Term Community Care Coalition, Memo in Support: Safe Staffing For Quality Care Act A02954/S01032.

¹⁰ Yue Li, et al. COVID-19 Infections and Deaths among Connecticut Nursing Home Residents: Facility Correlates” Journal of the American Geriatrics Society, June 18, 2020.

¹¹ A02954/S01032

¹² Testimony of Daniel Ross of Mobilization for Justice (ACF’s), Kathy Lebraio, Pres/CEO NYS Assoc. Health Care Providers, Al Cardillo, Pres/CEO Home Care Assoc. NYS.

mortality rate among nursing home residents based on the timing of admissions and infection. This report states that most of the COVID transmission and infection came in nursing homes came from staff at the facilities as opposed to COVID positive residents. While it is difficult to accurately gauge how transmission was occurring in these facilities, it is clear that nursing home staff members are in constant contact with both residents and other staff. Given the lack of training and distribution regarding PPE in many facilities, it is very difficult to believe that adding more positive residents to a given facility did not contribute to more spread, and that the bulk of transmission was due to COVID positive staff.

The Report states at page 26 that conditions in the nursing homes have been inaccurately represented in media reports. This broad statement is belied both by testimony from families at the recent hearings as well as some of the staff who testified. In addition, the ELSN Section has received firsthand reports from our clients, which corroborate the reports in the media. On August 16, 2020 Newsday published an expose on one facility where families were completely shut out from receiving information on their loved ones.¹³ It was reported that numerous families were simply called and told that their loved one had passed with no further information. (*Id.*) This type of behavior was also exposed in the recent hearings where family members testified to similar practices by nursing homes.

We believe that in late March and into April COVID-19 positive returnees to skilled nursing facilities should have been admitted to a COVID-19-only facility. Using the Javits Center or the USS Comfort would have been a much smarter decision and it would have been easy to manage infection and transmission. In addition, the DOH Report states that there were numerous other nursing homes that were COVID-19 only and available for residents who were deemed COVID-19 positive.

Why weren't positive COVID-19 residents sent to these facilities? Governor Cuomo stated on more than one occasion in his press conferences that nursing homes will "do the right thing" and will not accept residents they cannot keep safe.

Unfortunately, this view does not take into consideration that most nursing homes are private businesses, whether they are deemed non-profit or not, for whom profit is a significant matter. Every "body" that a nursing home loses to another facility is lost revenue- and profits. It is clear the nursing homes were ill prepared to handle the infection rates and could not curtail the spread as evidenced by over 6000 deaths. If the nursing homes were to "do the right thing" they would have acknowledged their inability to keep residents safe. Instead, facilities complained about the lack of PPE and did not advocate for the residents by supporting transfers to COVID-19 only facilities.

Owners and operators of nursing homes and other long-term care facilities are always concerned about profit and that concern can and does get in the way of adequate patient care. Regulating the amounts of money nursing home operators must spend on resident care should be part of any comprehensive reform package. The Report at page 26 refers to "historically low reimbursement rates that threaten the stability of the long-term care sector." However, any discussion about increases in Medicaid/Medicare reimbursement rates should include a discussion

¹³ Newsday, August 16, 2020; Crisis, Care and Tragedy on LI.

about passing regulations that require transparency with respect to how owners and operators are spending money. It seems that if a facility is going to claim that they would go into the red when meeting actual safe staffing levels for example, they should have to show why this is so. Also, a medical loss ratio model similar to the Affordable Care Act or some other method should be implemented to ensure that Medicaid and Medicare dollars are not inappropriately wasted on excessive management fees and other administrative costs.

As far as proof of the degree of concern about profits by operators, here are two examples: First, many nursing homes put “arbitration clauses” in their Admission Agreements limiting a resident’s ability to file a case in court if they have been harmed or injured by negligent care in the facility. Second, many nursing homes put “venue” selection clauses in their Admission Agreements so that if a claim is filed for a Public Health Law violation the claim must be litigated in the County chosen by the nursing home in the Agreement. Many Bronx and Brooklyn based nursing homes have clauses in the Agreements which place venue in Nassau County or Westchester County. Why? Arbitration clauses take away the right to a jury trial. These clauses are *always* buried in the middle of what is a 20 to 30-page agreement and is rarely, if ever, noticed by the signer who is frequently under significant stress at the time. These types of things are meant to increase profits by limiting damage awards for wrongdoing.

Finally, the ELSN Section understands that the issue of safe visitation during this crisis is complex. However, it is clear from this recent experience that prolonged isolation from loved ones causes residents to suffer severe psychological trauma and depression, which exacerbates or causes additional serious conditions. Providing safe visitation even during high infection rates is a problem that can be solved by resources (screening, minimum safe staffing levels, PPE, and proper practices) and a mandate to do it. Seeing loved ones is a matter of freedom that rests on the basic human right of free association. Congregate care facilities are not prisons whose confined inmates have lost this right; they are homes to their residents who crave human contact. Further, keeping watchdogs such as Ombudsmen out of these facilities, only allows dangerous conditions to persist. Based on many accounts, residents died of sheer neglect that went unreported or underreported before and during this pandemic. The ELSN Section suggests adopting safe visitation protocols as part of this mandate.

Our Comments to the Resolutions:

1. We believe the title of the Resolutions should be amended to read:

Older Adults and People with Disabilities, Nursing Home Providers & ACF Operators, and Nursing Home & ACF Residents¹⁴:

2. Paragraph (a) of the Resolution should be revised to read:

¹⁴ The Report at page 27 has a separate section of recommendations for “**Persons with Disabilities in Residential Facilities or Group Homes**” however, there is no final Resolution for this category of facilities. It is not clear why this category of facilities was left out of the final Resolutions. The ELSN Section strongly recommend including final Resolutions regarding these facilities.

(a) Equitable allocation of scarce resources from the Public Health and Social Services Emergency Fund—established by the CARES Act—to older adults, people with disabilities, and their health care providers, prioritizing under-resources long-term care providers, including home care and consumer-directed personal care

3. (c) Adequate levels of staffing:

“Adequate” is not nor has it ever been enough to ensure that nursing home (and adult care facility) residents received the care and services to meet their needs. Nursing homes must be held to the standard of nurse staffing minimums as stated in the Safe Staffing for Quality Care Act. Furthermore, staffing must encompass all nursing home staff, and not focus solely on nursing. Nursing homes must have enough staff to ensure residents have timely and routine access to visitors of their choosing, even if virtually, and there must be enough staff to ensure facility cleanliness, food service, social services, and activities to ensure each resident’s needs are met. As it stands, the ELSN Section cannot support a resolution that uses “adequate” as its benchmark.

4. Paragraph (g) of the Resolution should be revised to read:

(g) Recognition and honoring of older New Yorkers’ and New Yorkers’ with Disabilities right to health and human rights, to be free from abuse and neglect, and to care in the most integrated setting, as protected under federal law and international conventions;

SUB MEMORANDUM RE: TELEHEALTH

The ELSN Section (hereinafter “ELSN Section”) supports the expansion of telehealth services and reimbursement beyond emergency conditions and submits the following comments with respect to the HOD Resolutions.

I. INTRODUCTION:

Based upon our analysis of the statutes and regulations cited in the proposed HOD Resolution, the ELSN Section supports the concept of permanently expanding telehealth services. the ELSN Section agrees that the expansion of coverage pursuant to N.Y. EXEC. ORDER No. 202.1, Mar. 12, 2020 will afford the greatest amount of patients’ access to care beyond emergencies such as the current pandemic. Given the special challenges confronted by the elderly and special needs populations, our goal is to ensure that the standards of care, as well as the protections afforded under the HIPAA regulations are not compromised. While emergencies require leniency in ensuring immediate access to health care, the quest to continue the expansion of telehealth beyond the COVID-19 crisis cannot be at the expense of privacy and thorough medical evaluations and treatment plans. There should be no difference in providing health care to individuals whether they are in-person or utilizing telehealth services. Moreover, individuals receiving Medicaid and Medicare should not be denied coverage because their providers will not be reimbursed under the current guidelines.

With respect to the language offered in the HOD Resolution the ELSN Section has the following comments.

I. WHEN IS TELEHEALTH COVERED BY MEDICARE AND MEDICAID?

Pre-Covid-19 Guidelines:

New York Medicaid Update, Special Edition, Expansion of Telehealth Vol. 35, No. 2, N.Y.S. DEP’T OF HEALTH, Feb. 2019

While NYS Medicaid has expanded coverage of telehealth services, such telehealth services should not be used by a provider if they may result in any reduction to the quality of care required to be provided to a Medicaid member or if such service could adversely impact the member. Telehealth is designed to improve access to needed services and to improve member health. Telehealth is not available solely for the convenience of the practitioner when a face-to-face visit is more appropriate and/or preferred by the member.

The “originating site” requirement was what dictated whether or not Medicare would pay for services via telehealth. Medicare would reimburse fee-for-service treatment if the person were receiving telehealth services in a designated rural area, physician’s office, or a specified health care facility.

Pages 32-33 states to following: “In February 2019, however, in a Special Medicaid Telehealth, 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,”

We recommend the following change: However, in a NYS/DOH Medicaid Update, Special Edition released in February 2019, concerning the expansion of telehealth New York instituted limitations on coverage. With respect to dual individuals (those eligible for both Medicare and Medicaid), “[i]f Medicare covers the telehealth encounter, Medicaid will reimburse the Part B coinsurance and deductible to the extent permitted by state law. If 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.” (See billing guidelines). Although New York had a broader category of what services could be provided and where the origination sites could be, dual eligibles were not covered. On the federal level, Section 102 of the Telehealth Services During Certain Emergency Periods Act of 2020 gives the HHS Secretary authority to waive, among other policies, the geographic and originating site requirements of Section 1834(m) of the Social Security Act (the Act) as he sees fit, without restrictions on the definition of “qualified provider.”¹⁵ The expansion of coverage on the federal level allows dual eligibles to be covered as it expanded coverage under the Medicare program. Should the federal reimbursement rules be scaled back once we are past the current public health emergency, New York should adopt a policy which includes coverage for dual eligibles.

II. DEFINING TELEHEALTH

According to the American Academy of Family Physicians: “Telehealth is different from telemedicine in that it refers to a broader scope of remote health care services than telemedicine. Telemedicine refers specifically to remote clinical services, while telehealth can refer to remote non-clinical services.”¹⁶ “The American Academy of Family Physicians supports expanded use of telemedicine as an appropriate and efficient means of improving health, when conducted within the context of appropriate standards of care.

The CDC Definitions of Telehealth and Telemedicine:

“Telehealth is ‘the use of electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration.’ Often, telehealth is used interchangeably with the terms telemedicine or eHealth. Telehealth, however, is broader than these other terms; telemedicine and eHealth are distinct areas within telehealth. Telemedicine is defined by the Federation of State Medical Boards as ‘the practice of medicine using electronic communication, information technology, or other means between a physician in one location, and a patient in another location, with or without an intervening health care provider.’ The World Health

¹⁵ Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R. 6074)

¹⁶ <https://www.aafp.org/news/media-center/kits/telemedicine-and-telehealth.html>

Organization defines eHealth as ‘the use of information and communication technologies (ICT) for health.’”¹⁷

III. CONTINUING TEMPORARY SUSPENSION AND MODIFICATION OF LAWS RELATING TO THE DISASTER EMERGENCY N.Y. EXEC. ORDER No. 202.1, Mar. 12, 2020

Section 2999-cc of the New York Public Health Law authorizes additional telehealth provider categories 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, pursuant to such limitations as the commissioners of such agencies may determine appropriate. From standpoint of recipients of such services, the greatest issue prior to the COVID-19 pandemic was that access to telehealth was limited by geographic location and whether or not a provider would be reimbursed for providing services. Under the Medicare guidelines, access to telehealth was limited to rural areas. No consideration was taken with respect to homebound individuals. In the cities, care may be readily available, but that does not mean that accessing the care in-person would be possible. For elderly individuals living in walk-up apartments, they might not be able to leave their homes without EMS assisting them. Access-a-Ride is not always reliable, and many times seniors spend hours waiting to be picked up from doctors’ offices. For many older adults, a trip to the doctor is often delayed until an emergency because coordinating getting them to the doctor’s office may be too difficult if they are immobile.

The ELSN Section is concerned as to whether or not a physician or health provider would be able to adequately provide services to someone who is suffering from a disabling condition, such as cognitive impairment, or physical limitations, such as hearing loss. As stated in the Resolution, on March 6, 2020, the federal government enacted the “Telehealth Services during Certain Emergency Periods Act of 2020.” The Act eliminated the “originating site” requirements during public emergencies. As a result, qualified providers would be able to assist patients via telehealth. The providers must have a “pre-existing relationship with the patient.” With respect to offering services to the elderly and special needs population, it is vital that a relationship exist between provider and patient prior to determining whether or not services can be executed through this means.¹⁸ Standards of care must be reviewed in order to address concerns such as the prescribing of medications or evaluating cognitive deterioration must be addressed.

IV. HIPAA PROTECTION MUST REFLECT THE USE OF TECHNOLOGY

Communications modes for telehealth are limited by the HIPAA Privacy, Security and Breach Notification Rules. With COVID-19, HIPAA restrictions along with patient access to in-person treatment were greatly alleviated by the expansion of telehealth. Due to the increased need

¹⁷ <https://www.cdc.gov/phlp/publications/topic/anthologies/anthologies-telehealth.html>.

¹⁸ Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act this section will eliminate the requirement included in the Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R. 6074) that providers or others in their group must have treated the patient in the past three years to provide them with a telehealth service during the ongoing public health emergency. This particular provision would not be appropriate for treatment beyond a public health emergency.

for telehealth, HIPAA regulators are more lenient with respect to communications, as long as a provider uses a non-public facing app advises the patient of privacy, as acts in good faith. If those requirements are met, it appears that a provider could use a non-HIPAA compliant app to provide telehealth. The HHS/OCR announcement specifies that public-facing apps like Facebook Live, Twitch and TikTok are not to be used. The ELSN Section supports the exercise of enforcement discretion for HIPAA regulations under the current conditions, but regulations must be permanently adopted to ensure there is a compliant communications that allows for expanded access to telehealth, while protecting the privacy of patients.

V. PATIENTS' RIGHTS AND CONSENTS

The practitioner shall provide the member with basic information about the services that he/she will be receiving via telehealth and the member shall provide his/her consent to participate in services utilizing this technology. Telehealth sessions/services shall not be recorded without the member's consent. Culturally competent translation and/or interpretation services must be provided when the member and distant practitioner do not speak the same language. If the member is receiving ongoing treatment via telehealth, the member must be informed of the following patient rights policies at the initial encounter.¹⁹ Documentation in the medical record must reflect that the member was made aware of these and other policies described in the NYS/DOH Medicaid Update, Special Edition released in February 2019.

VI. CONCLUSION

During this time of public health crisis, the expansion of telehealth has proven an effective means of treating patients for medical conditions beyond the effects of COVID-19. The ELSN Section recognizes that telehealth affords individuals an opportunity for treatment to individuals who may be too compromised to travel to a provider whether due to physical, cognitive, developmental, or psychological issues. By redefining the rules regarding reimbursement of services provided to dual eligibles, as well expanding the services covered, many more people will have access to proper medical treatment on a regular basis.

¹⁹ NYS/DOH Medicaid Update, Special Edition, released in February 2019, pg.7

From: [David Fischler](#)
To: [Richards, Thomas](#)
Subject: Re: Annotated Copy of Resolutions - Report of Health Law Section - November House of Delegates - September 10 Comment Deadline
Date: Monday, July 13, 2020 9:00:36 PM

Hi Tom,

Thanks for allowing the Committee on Mass Disaster Response the opportunity to comment report from the Health Law Section. We offer the following comment;

Resolution 1:

(b) Adoption of the, “**Crisis Standards of Care**,” developed by the **Institute of Medicine** in 2012, as is, ...

I would note that the IOM changed its name to the National Academy of Medicine in 2015.

Dave

David H. Fischler, Esq.(NY)
10054 Diamond Lake Road
Boynton Beach, FL 33437

631-584-3500
dfischlerlaw@aol.com

On Jun 29, 2020, at 17:00, Richards, Thomas <TRICHARDS@NYSBA.ORG> wrote:

Dear Section and Committee Chairs:

The New York State Bar Association Health Law Section has prepared a report and recommendations on public health issues resulting from the COVID-19 pandemic.

An annotated copy of the Health Law Section COVID 19 Resolutions with cross-referenced footnotes and citations is attached for your review. Links to the full report, addendum, and unannotated resolutions are copied below.

[Report and recommendations of Health Law Section](#)

[Health Law Section Addendum](#)

Resolutions offered by Health Law Section

The report will be presented at the November 7, 2020 meeting of the House of Delegates.

NYSBA sections and committees are requested to review the report and submit any comments by Thursday, September 10. Comments may be sent to trichards@nysba.org. All comments will be shared with the authors of the report and the Health Law Section.

You are invited to contact Karen Gallinari, Health Law Section chair (kgallinari@gmail.com), Mary Beth Morrissey, Health Law Section Task Force chair (mamorrissey@fordham.edu), and Catherine Carl, Health Law Section liaison (ccarl@nysba.org) should you have questions on the report and resolutions.

 **Thomas J. Richards, Esq.** Deputy General Counsel,
Director of Public Interest
New York State Bar Association
One Elk Street, Albany, NY 12207

direct/fax: 518.487.5640 | **main:** 518.463.3200 | **email:** trichards@nysba.org | www.nysba.org

-



From: Richards, Thomas
Sent: Monday, June 15, 2020 3:54 PM
To: NYSBA <NYSBA@nysba.onmicrosoft.com>
Cc: Karson, Scott <skarson@nysba.org>; T. Andrew Brown <abrown@brownhutchinson.com>
Subject: Report of Health Law Section - November House of Delegates - September 10 Comment Deadline

Dear Section and Committee Chairs:

The New York State Bar Association Health Law Section has prepared a report and recommendations on public health issues resulting from the COVID-19 pandemic.

[Report and recommendations of Health Law Section](#)

[Health Law Section Addendum](#)

[Resolutions offered by Health Law Section](#)

The report will be presented at the November 7, 2020 meeting of the House of Delegates.

NYSBA sections and committees are requested to review the report and submit any comments by Thursday, September 10. Comments may be sent to trichards@nysba.org. All comments will be shared with the authors of the report and the Health Law Section.

<image003.jpg> **Thomas J. Richards, Esq.** Deputy General Counsel,
Director of Public Interest
New York State Bar Association
One Elk Street, Albany, NY 12207

direct/fax: 518.487.5640 | **main:** 518.463.3200 | **email:** trichards@nysba.org | www.nysba.org

-

[<image004.jpg>](#)

<Rev 6-29-20 NYSBA Past Presidents Health Law Section resolutions with document requests 6-27-20.pdf><Rev 6-29-20 NYSBA Past Presidents Health Law Section resolutions with document requests 6-27-20.docx>

