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Health Law Journal

A Peer Reviewed Law Journal

A publication of the Health Law Section of the New York State Bar Association

Legal Issues in Operating a Med-Spa in New York State

The Intersection of Partisan Affiliation, Political Polarization and COVID-19 Pandemic Response

The Public Health Intersection of COVID-19 and the Obesity Epidemic

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Publication and Editorial Policy

Persons interested in writing for this *Journal* are welcomed and encouraged to submit their articles for consideration. Your ideas and comments about the *Journal* are appreciated as are letters to the editor.

Publication Policy:
All articles should be submitted to:

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Message From the Section Chair

By Anoush Koroghlian-Scott

I am privileged to report on the ongoing work of our Section to support our members, provide professional growth opportunities, address evolving issues in the health care industry, and assure that we continue to offer a wide variety of both practical and thought-provoking educational opportunities.

Virtual Open House

On June 10, shortly after the commencement of my tenure, we held a virtual Open House during which law students, young attorneys, and Section members became acquainted with our Section, its Committees and the opportunities for professional growth that membership offers. It was a great opportunity to meet people in all stages of their careers from all over the world including New York City, Toronto, Florida, Washington, D.C. and Nigeria. Several attendees also expressed interest in our Mentorship Initiative and are now paired with a mentor as a result of the hard work and dedication of Jorge Luis Rivera Agosta and the entire Mentorship Initiative team.

Mentorship Initiative

The Mentorship Initiative kicked off this summer by pairing 10 mentees with their own individual mentor from among our membership. Our mentees are second- and third-year law students, recent graduates and young practicing attorneys. Many have a particular interest in in-house roles; however, most are interested in general guidance as they develop their health law practice and grow in the profession. Shortly after kickoff, the number of mentees grew to 15! The Mentorship Initiative offers our members the opportunity to share their knowledge, wisdom and expertise and continue the Section's tradition of camaraderie and collaboration. mentors engage with their respective mentees monthly and the mentorship team meets separately with Mentors and mentees every two months to solicit feedback to assure smooth operation of the program and participants continue to realize benefits. If you are interested in serving as a mentor or being mentored, please contact Jorge at jlr2245@columbia.edu or Catherine Carl at ccarl@nysba.org.

Recent CLE Programs

In early June, under Mary Beth Morrissey's leadership, a series of three CLE programs addressed historical and emerging issues in the health industry and public health sector. The first of the series "Advocating for the Rule of Law," was designed to inspire lawyers, teachers, journalists, denizens of social media and all citizens to become better advocates for democracy. The second in the series, "Adaptive Governance for Climate Change and Public Health," discussed how our laws and policies need to adapt to address the vulnerabilities in our health care, economic and political structures that became apparent during the pandemic as we confront the emerging implications of climate change on public health and environmental law and policy. The final program "Immigration Advocacy: Perspective of Health Law, Psychology and Social Work," covered immigration advocacy in the context of the needs of immigrants, refugees, and asylum seekers before, during and after the pandemic. Panel members discussed the strength of interdisciplinary collaboration among attorneys, psychologists, and social workers. All programs were recorded, archived, and are available on-demand on our Section website. Thank you all for all your hard work to make this series a great success.

Annual Meetings

Thanks to Mary Beth Morrissey and members of the planning committee, the program for our annual Fall Meeting is evolving to include a wide array of topics and current issues to be presented by corresponding experts in the field. The meeting will be divided into two half-day sessions in late October, early November. I am also pleased that Margie Davino and Daniel Weinstein will serve as co-chairs of the Annual Meeting. Both programs are sure to be a great success, offering valuable educational opportunities.

Looking Ahead

This year we are starting the process of establishing a health law curriculum, starting with the core competencies for health lawyers practicing in New York State. The curriculum will consist of a variety of programs starting at the fundamental level. Topics covered at the fundamental level may be developed into more advanced substantive courses over time through the annual meetings, committee meetings and events, and other stand-alone programs. All programs may be archived in our online library and made available to our members as part of the practice resources made available by our Section. We will be sure to keep you posted as the process unfolds.

Please Get Involved

Finally, I encourage you all to get involved at whatever level works for you. There are so many ways to get

involved and take advantage of the benefits the Section offers:

- Join a committee: we have numerous substantive committees that can serve as a resource or professional development opportunity for your practice.
- Be a Mentor or a Mentee.
- Participate in the Section's On-Line Community where you can post questions or request referrals from health law experts statewide.
- Write an article for the *Health Law Journal*; you may be able to earn CLE credit.
- Plan a Webinar; contribute to the curriculum; volunteer to be a speaker.
- Attend the annual Fall Meeting or the Annual Meeting.
- Encourage a colleague to get involved.

I am looking forward to a year filled with robust educational opportunities and building on our professional relationships to support one another in our careers, and share best practices, war stories and our collective wisdom.

I invite you to reach out to share your insight, ideas to help expand our membership and improve our programs, or to just say "hello."

Warm Regards,

Anoush

NEW YORK STATE BAR ASSOCIATION

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Articles should be submitted in electronic format (pdfs are NOT acceptable), along with biographical information.

REQUEST FOR ARTICLES

In the New York State Courts

By Leonard M. Rosenberg

SDNY Addresses Pleading Standards Under FCA Whistleblower Provision

Beckles-Canton v. Lutheran Social Services of New York, Inc., 2021 WL 3077460 (S.D.N.Y., July 20, 2021). Plaintiff Sanayi Beckles-Canton sued her former employer under the anti-retaliation provision of the False Claims Act (FCA), alleging that she was terminated in retaliation for reporting defendant's misuse of federal funds from the "Head Start" program administered by the Department of Health and Human Services (HHS). In a detailed opinion, Judge Katherine Polk Failla addressed the complicated and evolving landscape of pleading standards under the FCA's whistleblower provision and found that plaintiff alleged a viable retaliation claim.

Defendant Lutheran Social Services of New York, Inc. is a non-profit organization operating early childhood learning centers for low-income children. Defendant's education centers are primarily funded by HHS' Head Start program. As a result, defendant must comply with various federal regulations related to accounting procedures and fiscal control. In her capacity as defendant's Director of Family Services, plaintiff was responsible for overseeing defendants' education centers throughout the Bronx, Brooklyn, and Manhattan, and was tasked with ensuring appropriate recordkeeping and reviewing certain financial reports prepared by subordinates. In May 2017, plaintiff allegedly discovered that defendant was backdating receipts for the purchase of educational supplies, in a fraudulent effort to fully expend the funds received from Head Start—which would ensure that defendant's budget was not decreased for the next fiscal year. Plaintiff further alleged that defendant charged a $200 fee for admission to its summer program, which was allegedly funded by Head Start on the condition that it be offered free of charge.

Plaintiff promptly reported these irregularities to defendant's president and CEO, Damyn Kelly, who ensured plaintiff that he would conduct an investigation. Shortly thereafter, in June 2017, defendant's executive director, Khamele McCleod-Cato, allegedly told plaintiff that Kelly had no intention of investigating her allegations. Two months later, in August 2017, plaintiff met with Kelly for a second time, and again expressed concern over defendant's misuse of Head Start funds. According to plaintiff, Kelly responded by encouraging her to "be a team player [and] keep things internal." In the ensuing weeks, McCleod-Cato allegedly became hostile toward plaintiff, and chastised her for complaining directly to Kelly—stating that she had "no authority" to do so. Plaintiff met with Kelly to discuss McCleod-Cato's conduct, but Kelly took no action. By late November 2017, plaintiff learned that defendant had continued its practice of backdating receipts, prompting plaintiff to submit a written complaint to Head Start. Several months later, in February 2018, McCleod-Cato terminated plaintiff's employment. McCleod-Cato alleged that, while attending an annual conference along with defendant's director of program governance and a student's parent, plaintiff falsified car service receipts, assisted the parent in submitting the fraudulent receipts, and "treated" the parent to a dinner. In response, plaintiff denied any involvement with preparing or submitting the parent's receipts and noted that the director of program governance—who was responsible for the parent's attendance at the conference—was never disciplined.

On June 8, 2020, plaintiff filed a complaint in the Southern District, which defendant moved to dismiss. After addressing the general pleading standards under Rule 12(b)(6), the court turned to the FCA's anti-retaliation provision, 31 U.S.C. § 3730(h), which requires a plaintiff to satisfy three elements in order to state a claim: (i) plaintiff must engage in protected activity under the statute; (ii) the employer must be aware of such activity; and (iii) the employer must take adverse action against plaintiff because s/he engaged in the protected activity.

Leonard M. Rosenberg is a shareholder in the firm of Garfunkel Wild, P.C., a full service health care firm representing hospitals, health care systems, physician group practices, individual practitioners, nursing homes and other health-related businesses and organizations. Rosenberg is chair of the firm's litigation group, and his practice includes advising clients concerning general health care law issues and litigation, including medical staff and peer review issues, employment law, disability discrimination, defamation, contract, administrative and regulatory issues, professional discipline, and directors and officers liability claims.

On the first element, the court found that plaintiff sufficiently alleged protected activity. As a threshold issue, the court noted that protected activity under the FCA encompasses "(i) lawful acts done by the employee . . . in furtherance of an action under the FCA, and (ii) other efforts to stop one or more violations of the FCA." While the plaintiff need not actually pursue a *qui tam* action, her conduct must be "directed at exposing a fraud upon the government." Here, the court applied a hybrid subjective/objective test, requiring that "(i) the employee in good faith believes, and (ii) a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud against the government."

Defendant argued that plaintiff's complaints were merely part and parcel of her job responsibilities, which included review of certain financial records, and were not aimed at exposing fraud. But the court was unpersuaded, finding instead that plaintiff's "investigation did not cease with [a] review of her supervisees' records . . . [rather], Plaintiff investigated further . . . [and] reported her findings to Kelly." After being informed that nothing would be done, plaintiff again met with Kelly to discuss the alleged misuse of federal funds, making it "evident that Plaintiff did not merely inform a supervisor of a problem, but rather took additional steps." On that basis, plaintiff satisfied the subjective test. On the objective test, plaintiff alleged a reasonable belief that she was investigating possible FCA violations. In particular, plaintiff provided sufficient factual support for her claim that defendant engaged in "fraudulent and wasteful spending" designed to "prevent Head Start from decreasing [its] budget for the next fiscal year." Plaintiff also "reasonably believed that defendant's practice of charging students who participated in the Head Start program was fraudulent, as defendant was allegedly accepting federal funds on the condition that the program would be free of charge."

Next, the court addressed whether defendant had knowledge of plaintiff's protected activity. In doing so, the court grappled with whether to apply a "heightened standard" of notice, which would require an employee to "overcome the presumption that they are merely acting in accordance with their employment obligations." The court questioned the continued viability of this standard in light of certain 2009 amendments to the FCA, which "broadened the scope" of the whistleblower provision to protect employees who "engaged in efforts to stop an FCA violation, even if [their] actions were not necessarily in furtherance of an FCA claim." Ultimately, the court sidestepped this question, finding that "even were the court to apply this [heightened] standard," it is "unable to discern from the allegations in the complaint whether [Plaintiff's] actions were wholly within [her] responsibilities or involved reporting outside the usual chain of command." Specifically, the court highlighted plaintiff's allegation that McCleod-Cato called complaining to Kelly "a mistake" because plaintiff had "no authority" to do so, thus suggesting that plaintiff's actions "went beyond her duties and circumvented defendant's chain of command." Against this backdrop, the court found that plaintiff's persistent internal reporting was sufficient to put defendant on notice of her protected activity—even if defendant was unaware of plaintiff's external complaint to Head Start.

Finally, the court applied a "but-for causation" standard in assessing whether plaintiff sufficiently alleged retaliatory action. Here, the court focused on the temporal relationship between plaintiff's report and her termination, but acknowledged that there is "no bright line rule to define the outer limits beyond which a temporal relationship is too attenuated to establish a causal relationship [.]" The court defined the relevant time frame as approximately seven months—that is, between plaintiff's August 2017 follow-up meeting with Kelly and her February 2018 termination. The court noted that a seven-month gap is "not prohibitively remote" and is "within the temporal range that the Second Circuit has found sufficient to raise an inference of causation." Notably, this finding was reinforced by "the other surrounding circumstances," including McCleod-Cato's hostile attitude toward plaintiff, Kelly's failure to take any action to curtail McCleod-Cato's conduct, and plaintiff's well-pleaded allegations that the reasons for her termination were merely pretextual. Specifically, plaintiff alleged that (i) defendant never provided any policies or guidelines related to food or transportation expenses during the conference; (ii) the parent attending the conference submitted her own receipts to defendant, and plaintiff was unaware of their contents; (iii) plaintiff was not responsible for the parent's attendance at the conference; and (iv) the employee responsible for the parent's attendance was never disciplined. On these facts, the court found that plaintiff satisfied the "but-for causation" standard, and sufficiently alleged retaliatory action.

Ultimately, accepting plaintiff's allegations as true, the court concluded that plaintiff "alleged a viable retaliation claim under the FCA" and denied defendant's motion to dismiss.

Southern District Invokes First-to-File Bar in Dismissing *Qui Tam* Complaint Based on Claims Asserted in an Earlier Filed Complaint Brought by Different Relators

United States ex rel Mohajer v. Ominicare, Inc., 2021 WL950024 (S.D.N.Y., March 2021) The district court considered defendant Omnicare, Inc.'s motion to dismiss a *qui tam* action brought under the False Claims Act by relators Arash Mohajer and Chris Peterson (referred to in the court's decision as the "Utah Relators") on January 10, 2017. The court granted Omnicare's motion, holding that the Utah Relators' single count alleging Omnicare's violation of the Federal False Claims Act and related violations of various states' false claim analogs were substantially similar to a *qui tam* action commenced in 2015 by a different relator, Uri Bassan.

Both *qui tam* suits allege that between 2010 and 2018, Omnicare consistently dispensed prescription medications to patients in long-term residential facilities based on prescriptions that had expired, run out of refills, or were otherwise invalid. Omnicare then submitted claims for reimbursement to several federal health care programs, Medicare, Medicaid, and TRICARE (which provides prescription drug benefits to members of the military), which contained false information.

Omnicare pharmacies dispense and deliver prescription drugs to residents of long-term care facilities. These include nursing homes, assisted living facilities, and skilled-nursing facilities. Such facilities are tiered based on the level of care they provide to their residents; skilled nursing facilities are at the highest tier as they have providers on staff at all times and are akin to hospitals in that they provide around-the-clock care. As a result, some states permit pharmacies to dispense prescription drugs to residents in skilled nursing facilities based on a prescriber's "chart order," which is consistently reviewed and signed by the skilled nursing facility's attending physician. Such "chart orders" typically do not specify the total quantity of the drug prescribed, or the number of refills authorized. This is based on the understanding that a provider is available to monitor the patient's intake of the drug 24-7. "Chart orders" are therefore considered valid prescriptions in the skilled-nursing facility setting, and pharmacies such as Ominicare servicing skilled-nursing facilities are sometimes permitted to refill prescriptions without a set quantity or a set number of refills allowed.

The allegations against Omnicare, however, concerned its conduct in dispensing drugs to "unskilled" residential facilities, such as assisted living facilities, and independent living facilities. Patients at these facilities are treated like individuals residing at home; they must schedule visits with their own providers to obtain prescriptions. As a result, drugs prescribed to these individuals are limited by either time or quantity, and must be renewed if they expire.

A major aspect of the false claims allegations against Omnicare is that it treated prescriptions for patients living at unskilled facilities as though they were meant for patients at skilled-nursing facilities by consistently refilling them without verifying or confirming whether the prescription had expired or was otherwise invalid. Under the federal health care programs, submitting reimbursements for drugs without a valid prescription constitutes a false claim under both federal and state law.

After the United States intervened in both lawsuits, Omnicare then filed three motions to dismiss, including the one to dismiss the Utah Relators' amended complaint, based on three reasons: (1) the False Claims Act's public-disclosure bar; (2) the government's intervention into the action; and (3) the first-to-file rule.

Under the False Claims Act, only the government may intervene and bring a related action based on the facts of an underlying pending false claims action. According to the court, this statutory language has been given a simple interpretation: "as long as a first-filed complaint remains pending, no related complaint may be filed." The justification for the first-filed bar is to incentivize potential relators to "do their homework" and investigate claims accordingly, and to bring as robust a complaint as possible. "Tag-along relators" are prohibited from sharing in an original relator's recovery, and courts are not required to spend time deciding the merits of their claims.

In analyzing whether a later-filed action is "related" to a first-filed action, courts are limited to considering only the original filed complaint. Amending or supplementing a later-filed complaint cannot save it from the first-to-file bar, because it does not bring a new action, but merely introduces a new complaint to an action already pending. The court noted, however, that its decision in the instant matter would have been the same regardless of whether it considered the Utah Relators original or amended complaint.

Whether a later-filed complaint is "related" is determined by whether the claims in that complaint incorporate the "same material elements of fraud" as the earlier action, regardless of whether it contains additional or somewhat different facts or information.

The focus, according to the court, is on the "essential facts alleged," and whether the first-filed complaint could permit the government to fully investigate the fraud alleged in both the first-filed and later-filed complaints. As such, whether the later-filed complaint has different details is immaterial and the first-filed bar still applies as long as the government knows the essential facts of a fraudulent scheme and has enough information to discover related frauds.

In determining that the Utah Relators' complaint contained the same essential facts as Uri Bassan's complaint, the court noted that among other allegations, both complaints allege that Omnicare obtained reimbursements for dispensations of prescription drugs unsupported by valid prescriptions, and both allege that Omnicare's computer systems played an "integral" part in its fraudulent scheme. The court also recognized that both complaints focused on Omnicare's actions regarding the number of refills allowed in its computer systems so that pharmacies were enabled to continuing dispensing drugs after the prescriptions expired, and how both complaints detailed how Omnicare's computer systems allowed for the continued dispensations.

The court also held that the inclusion of additional or more specific details in a later-filed *qui tam* complaint does not alter the analysis of whether that complaint "relates" to the first. According to the court, "relatedness" is not a difficult threshold to meet, and focuses on whether a "later complaint alleges a fraudulent scheme the government already would be equipped to investigate based on the first complaint." According to the court, the focus is on the fraud itself, and not the specific details about how the

scheme was carried out. "If a scheme had a defined fraudulent object and was orchestrated through substantially similar means, involving substantially the same actions, then complaints uncovering the schemes are related." Accordingly, the court held that both the complaints alleged the same fraudulent scheme in which Omnicare filed false claims to the government by manipulating its computer systems to allow the consistent and unchecked dispensing of drugs without a valid prescription.

Following the dismissal of the Utah Relators' sole federal claim, the court considered their remaining 25 state-law claims, which were brought pursuant to various states' False Claims Act analogs. According to the court, the only basis under which the court could take cognizance of the remaining state-law claims was by supplemental jurisdiction.

In rejecting the notion that there was federal question jurisdiction over these claims, the court recognized simply that such claims did not "arise under" the laws of the United States. The court also rejected its subject matter jurisdiction over the remaining state-law claims based on diversity jurisdiction due to the complete diversity between the Utah Relators and Omnicare, and an amount in controversy over $75,000. The court noted that diversity jurisdiction for federal subject matter purposes exists only between "citizens" of the several states and in *qui tam* actions, states—which are the real parties in interest—are not citizens. The court also held that for diversity jurisdiction, the Utah Relators' citizenship is equally irrelevant since they are not the real parties in interest.

Additionally, the court recognized that every court has held that a claim arising under an analogous state false claims statute cannot be removed to federal court. According to the court, since only claims over which a federal court would have original jurisdiction can be removed, it follows that federal district courts only have supplemental jurisdiction over state-law *qui tam* claims.

As a result, the court held that in a *qui tam* suit involving both state and federal claims, once the federal claims are dismissed, a court no longer has original jurisdiction pursuant to the False Claims Act and may then decline to exercise supplemental jurisdiction over those state-law claims related to the federal claim. The court did just that, recognizing that it was appropriate to decline to exercise supplemental jurisdiction over the state claims in the instant case because they were already pending in the earlier-filed complaint by Uri Bassan, and according to the court, "there was no need" to have two sets of relators pursuing state law claims.

District Court Invokes Public Disclosure Bar in Dismissing *Qui Tam* Suit

United States ex rel. CKD Project, LLC v. Fresenius Medical Care Holdings, Inc, 2021 WL 3240280 (E.D.N.Y. July 30, 2021). Under the False Claims Act (FCA), an individual is permitted to sue on behalf of the government for FCA violations. The person who brings the action is the relator. In this case, the relator, CKD Project, LLC, is an LLC formed for the sole purpose of bringing suit against Fresenius Medical Care Holdings, Inc. ("Fresenius"), an outpatient dialysis provider. The relator alleged that Fresenius violated the Anti-Kickback Statute (AKS) by paying physicians to refer their dialysis patients to Fresenius locations. The relator alleged that Fresenius would acquire controlling interests in dialysis clinics, and while physician-owners would continue to hold a minority interest in the clinics, Fresenius would pay remuneration that "far exceeded" the value of any tangible clinic assets. These above-market value payments were alleged to induce doctors to refer patients to Fresenius clinics.

The relator filed an Amended Complaint asserting four claims under the FCA, which included two AKS violations, conspiracy to violate the FCA, and a "reverse false claims" cause of action. Fresenius moved to dismiss. The magistrate issued a report that recommended that the court dismiss the complaint based on the "public disclosure bar." The "public disclosure bar" provides for the dismissal of an action or claim "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . unless . . . the person bringing the action is an original source of the information."

To determine whether the claims fell under the public disclosure bar, the magistrate undertook a two-step inquiry. First, to decide whether "the substance of [the] relator's claim has been disclosed prior to the filing of his suit," and second, if such disclosures had been made, whether "the relator can be considered an 'original source.'" The relator argued that the public disclosure bar did not apply to its complaint and that even if it did, the relator fell under the "original source" exception. The court rejected these objections.

First, the magistrate determined that the substance of the relator's claims had been disclosed in the 2013 Form 20-F that Fresenius filed with the Securities and Exchange Commission. In that form, Fresenius states that the dialysis centers are "joint ventures in which [Fresenius] hold[s] a controlling interest and one or more hospitals, physicians or physician practice groups hold a minority interest." The court noted that the form even indicates that the transaction may not fall under AKS's safe harbor protections, and may be found to be in violation of the AKS. The relator argued that the public disclosure bar did not apply because the fraud itself was not disclosed in the 2013 Form 20-F. However, the court determined that such disclosure was not necessary because the 2013 Form 20-F "offers sufficient details 'to set the government squarely upon the trail of the alleged fraud.'"

Next, the magistrate determined whether the relator qualified as an "original source." The magistrate considered this under the pre-2010 FCA and the post-2010 FCA standards. Under the pre-2010 FCA standard, an original source needed to have "direct and independent knowl-

edge" of the alleged fraud. The magistrate found that the relator was not an original source, since it was an entity formed for the sole purpose of bringing the action and that it acquired its information from an unidentified third party. Thus, the relator could not have either direct or independent knowledge of the alleged fraud. Under the post-2010 FCA standard, an original source must have "knowledge that is independent of and materially adds to the publicly disclosed allegations." To do this, the information must substantially or considerably add to the public information—it cannot merely add detail or color to that information. The magistrate determined that the complaint made minimal contributions, if any, and that it merely added color to the public information. Thus, under both FCA standards, the relator was not an original source. The court adopted the magistrate's recommendation and dismissed the relator's claims for FCA violations.

The magistrate then addressed the relator's FCA conspiracy claim. To maintain this claim, the relator must allege that Fresenius conspired with one or more persons to have a false or fraudulent claim paid by the United States and that one or more conspirators performed an act to effect the conspiracy's object. The magistrate determined that the conspiracy claims were "sparsely pled" and coextensive with the relator's FCA violation claims. Since the relator failed to state a cause of action for FCA violations, the magistrate recommended the dismissal of the conspiracy claims as well, which Judge Conan adopted. Finally, the magistrate addressed the relator's "reverse false claims" claim. In order to state this claim, the relator must allege that Fresenius made a false record or statement at a time that Fresenius had a presently existing obligation to the government, such as a duty to pay money or property. The magistrate recommended and the court ruled that the public disclosure bar required dismissal of this claim as well.

The Second Circuit Court of Appeals Joins the First, Fourth and Seventh Circuits in Holding That Under the Expanded Definition of "Disability" Under the ADA Amendment Act, a Short-Term Injury Can Qualify as an Actionable Disability Under the ADA.

Hamilton v. Westchester County, 2021 WL 2671311, 20-1058 (PR) (2d Cir., June 30, 2021). Plaintiff commenced suit in the Southern District of New York, asserting violations of 42 U.S.C. § 1983 ("Section 1983") and Title II of the Americans with Disabilities Act of 1990 (ADA), against defendant-appellees Westchester County (the "county") and certain County officials ("county defendants"), along with Correct Care Solutions, LLC and Dr. Raul Ulloa (the "Medical Defendants"). Plaintiff alleged deliberate indifference and failure to accommodate his disabilities.

Both sets of defendants moved to dismiss plaintiff's claims, which motions the district court granted. The Second Circuit noted that the district court's sole basis for dismissing plaintiff's ADA claim against the county defendants was that plaintiff failed to allege a plausible qualifying disability under the ADA, as he only alleged the existence of temporary injuries.

On appeal, the Court of Appeals vacated the district court's opinion and order to the extent it dismissed plaintiff's ADA claim against the county defendants and remanded for further proceedings as to the ADA claim only. In so doing, the court found that the district court erred in categorically excluding short-term injuries from qualifying as a "disability" under the ADA. As a matter of first impression, the Second Circuit held that plaintiff's knee injuries could qualify as a disability under the ADA, notwithstanding they are temporary in nature, based upon the expanded definition of "disability" under the ADA Amendments Act (ADAAA).

By way of background, plaintiff alleged that on August 21, 2018, while playing basketball in the recreational yard at the jail, plaintiff stepped onto a crumbled piece of concrete, dislocating his knee and tearing his meniscus. He subsequently received medical treatment at the Westchester Medical Center, where medical providers placed him in a "knee stabilizer" and recommended he receive an immediate MRI. The contractor responsible for treating plaintiff at the jail disregarded this recommendation, which allegedly caused plaintiff's injury to "settle." The contractor, instead, replaced plaintiff's knee stabilizer with an elastic ace bandage, which failed to keep plaintiff's knee in alignment and resulted in severe pain.

Following his injury, plaintiff purportedly used crutches to ambulate. He experienced both numbness and throbbing pain while navigating through the jail with his crutches and found it difficult to move around in his housing unit and cell, which, similar to the courtyard, had cracked and damaged concrete flooring. A lack of accessibility ramps within the housing unit further prevented plaintiff from going outside for recreational activities. Within the housing unit itself, inmates who wished to bathe needed to climb over a two-and-a-half-foot step to access the shower stalls. Plaintiff allegedly experienced excruciating pain while navigating this step. Once inside the stalls, plaintiff purportedly endured further difficulties while bathing himself as the stalls lacked rails and/or benches, and plaintiff had to stand with his crutches. A lack of mats to provide traction on the slippery floors of the shower stalls further exacerbated plaintiff's hardship while bathing. Lastly, plaintiff alleged that following his injury, he underwent strip searches after two family visits. As the areas where the strip-searches occurred lacked both benches and rails for an inmate to use while undressing and dressing, plaintiff had to stand on his injured knee, causing him further pain.

Based on plaintiff's grievances, the Second Circuit found that plaintiff sufficiently alleged that the county had notice of (1) the damaged flooring in the courtyard, (2) the poor conditions of plaintiff's housing unit, and (3) the two-and-a-half-foot step into the slippery shower stalls.

The Second Circuit then turned to whether plaintiff's injuries could qualify as a disability under the ADA and first looked to the statute itself. Specifically, Title II of the ADA provides that "no 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 be subjected to discrimination by any such entity." Prior to the passage of the ADAAA, courts narrowly construed the definition of "disability" under the ADA. The Second Circuit noted that in enacting the ADAAA, Congress explicitly intended to overrule this narrow interpretation of an ADA-qualifying disability.

As such, the ADAAA provides that "[t]he term 'substantially limits' shall be construed broadly in favor of expansive coverage, to the maximum extent permitted by the terms of the ADA," and "is not meant to be a demanding standard." Moreover, "substantially limits" is to be "interpreted and applied to require a lower degree of functional limitation" than the standard required prior to the ADAAA. The statute further relaxed the temporal requirements for establishing a "disability"; under the implementing regulations, "disabilities" shorter than six months in duration can now be actionable under the ADA. 28 C.F.R. § 35.108(d)(ix).

The county defendants argued that a plaintiff does not satisfy the ADA's "substantial limitation" component where an impairment is entirely short term and relied on two non-precedential Second Circuit rulings. The court rejected that argument, finding that the statute does not suggest there is any duration that is too short to qualify.

Supreme Court Holds That a Valid Medical Order for Life-Sustaining Treatment (MOLST) Should Transfer With a Patient From a Hospital Setting to a Psychiatric Setting

In re Greater Binghamton Health Center, 2021 WL 3201404 (Sup. Ct., Broome Cty., July 23, 2021). On December 24, 2020, petitioner, Greater Binghamton Health Center (GBHC), a psychiatric facility, sought court approval of a Medical Order for Life-Sustaining Treatment (MOLST) for Mr. H., a resident of GBHC. Alternatively, GBHC sought the transfer to GBHC of an existing MOLST executed by United Health Services Wilson Hospital (UHS) on behalf of Mr. H. while he was a patient at USH.

The petition alleged that from October 17, 2020 through October 23, 2020, Mr. H. was admitted to UHS for aspiration pneumonia and on October 22, 2020, UHS executed a MOLST on Mr. H.'s behalf. Mr. H. subsequently returned to and resumed residency at GBHC. At the time GBHC filed its petition, Mr. H. was terminally ill, approaching the end of his life and lacked capacity to make health care decisions on his own behalf.

During a January 7, 2021 hearing on this matter, the court heard testimony from Dr. Lizeth Diaz, who indicated that she considered Mr. H. terminally ill and without any expectation of retaining capacity or an improved medical condition. Dr. Diaz testified that USH, which executed the MOLST during Mr. H.'s admission at the hospital, determined in Mr. H's best interest, to establish him as a "do not resuscitate" patient.

Based on Dr. Diaz's testimony, the court determined, on the record, that the evidence supported the implementation of the MOLST at GBHC. The court, however, found that it was unclear whether any statutory or regulatory basis existed to permit the court to order the implementation of the MOLST via a transfer of USH's existing MOLST to GBHC, a non-hospital setting. The court reserved decision and provided the parties with an opportunity to brief this issue.

Mr. H. died on February 6, 2021, during the pendency of this matter and before party submissions were complete. Although Mr. H.'s death rendered GBHC's application moot, the court resolved to decide the controversy presented by the petition given the likelihood of recurrence.

In evaluating the issue, the court looked to the Family Health Care Decisions Act (FHCDA), signed into law on March 16, 2010, for guidance. The FHCDA establishes a decision-making process for patients placed in a nursing home or hospital setting who lack decision-making capacity and advanced directives. The court specifically analyzed FHCDA sections regarding the Determination of Incapacity and Interinstitutional Transfers. The court noted, *inter alia*, that pursuant to the FHCDA, when

> a patient with an order to withhold or withdraw life-sustaining treatment is transferred from a mental hygiene facility to a hospital or from a hospital to a different hospital, any such order or plan shall remain effective until an attending practitioner first examines the transferred patient, whereupon an attending practitioner must either: 1. Issue appropriate orders to continue the prior order or plan; or 2. Cancel such order, if the attending practitioner determines that the order is no longer appropriate or authorized.

As the FHCDA itself is silent as to the transfer of a patient's MOLST from a hospital to a mental hygiene facility, the court looked to the bill jacket to the FHCDA, and to the New York State Department of Health (DOH) for additional guidance. Notably, in guidance provided on its website, the DOH provides that a signed MOLST form should be "transported with patients as they travel to different health care settings."

Based on the above, the court determined that the transfer of a valid MOLST from a hospital setting to a psychiatric setting is permissible. In the instant matter, had Mr. H. survived, the MOLST should have traveled with him from GBHC back to a hospital setting.

Third Department Upholds Revocation of Physician's Medical License Based on Conviction for Accepting Bribes To Send Patient Blood Samples To A Lab

Savino v. Zucker, 140 N.Y.S. 3d 326, 190 A.D. 3D 1243 (3d Dep't, 2021). Petitioner Thomas Savino, M.D. commenced an Article 78 proceeding to review ruling by the Administrative Review Board for Professional Medical Conduct that affirmed a Hearing Committee's determination to revoke his medical license.

In 2018, petitioner was convicted of various federal crimes as a result of his acceptance of cash bribes in exchange for referring his patients' blood specimens to a laboratory services company. Due to his conduct, petitioner was sentenced to 48 months in prison, ordered to pay fines totaling $100,000, and required to forfeit the proceeds of his crimes. Following his conviction, the Office of Professional Medical Conduct commenced an expedited referral proceeding against him, charging him with professional misconduct due to his federal conviction. A Hearing Committee of the State Board for Professional Medical Conduct revoked petitioner's medical license. Petitioner appealed to the Administrative Review Board (ARB), which was operating with only four members at the time. The ARB affirmed the Hearing Committee's revocation of petitioner's medical license.

Petitioner claimed that the ARB was not properly constituted because it did not have its full statutory compliment of five members. The court noted that although the ARB it did not have its full statutory complement of five members as specified by Public Health Law Section 230-c(2), it acted with a quorum, and thus, was legally constituted by virtue of General Construction Law Section 42 and prior case law.

The court noted that when reviewing the penalty determination of the ARB, it applied a "highly deferential standard of review," and would disturb the ARB's penalty only if it was "so disproportionate to the offense as to be shocking to one's sense of fairness." The court held that given the seriousness of petitioner's crimes and his failure to accept responsibility for his actions, it was unable to determine that the Hearing Committee's revocation of his medical license was "shocking to one's sense of fairness."

The court also rejected petitioner's contention that other physicians convicted of similar crimes may have received a lesser penalty than licensure revocation as irrelevant, holding that "each case must be judged on its own peculiar facts and circumstances."

Finally, the court acknowledged that while the record reflected that some members of the ARB were in favor of reducing the penalty imposed by the Hearing Committee, a majority of the four members could not reach a consensus as to the degree of any such reduction in penalty. Accordingly, the court held that since "a majority consensus could not be achieved," there was no error in the ARB's determination to leave the penalty imposed by the Hearing Committee and found no violations of petitioner's due process rights as a result.

Appellate Division Holds That Seller of Skilled Nursing Facility Is Entitled To Receive Post-Sale Proceeds of the Universal Settlement With Department of Health

Founders Pavilion, Inc., v. Pavilion Operations, LLC, 192 A.D. 3d 1575, 145 N.Y.S. 3d (4th Dep't, 2021). The issue before the Fourth Department was whether the buyer or seller of a skilled nursing home facility was entitled to the funds received pursuant to the universal settlement agreement between the State of New York and the state's nursing facilities, and to determine who is liable for the amounts owed as a result of overpayments by the state.

Founders Pavilion, Inc. executed an asset purchase agreement (APA) with Pavilion Operations, LLC to sell a skilled nursing home facility (the "facility"). The APA established which assets and liabilities of the facility would be retained by the seller or transferred to the buyer. The APA stated that seller would retain funds received post-sale as a result of Medicaid rate appeals arising from services rendered prior to the effective date of the APA. The APA further provided that liability for overpayments would be retained by the party who provided the services resulting in the overpayment.

An audit conducted by the Office of the Medicaid Inspector General (OMIG) found that the facility had been overpaid approximately $165,000 for services rendered during both seller's and buyer's operation of the facility.

The Appellate Division ruled that the seller was entitled to the universal settlement funds, but there remained questions of fact regarding who is liable for overpayments. The court first analyzed the universal settlement agreement, which stated that the entire amount of settlement funds was allocated in exchange for cessation of pending rate appeals arising from the state's prior reimbursement methodology. The court then noted that it was undisputed that the only relevant pending rate appeals regarding the prior reimbursement methodology had been filed by the seller, that those appeals arose from services provided by the seller during the period when it owned the facility, and that the APA stated that the seller was entitled to those sums, notwithstanding the fact that the funds were received after the sale.

The APA also stated that a party is liable for overpayments caused by its own acts or omissions, but does not define what constitutes an "act or omission" under the relevant clause. The court ruled that because there was a reasonable basis for a difference of opinion regarding the interpretation of this clause, a question of fact remained regarding liability for overpayments.

Legislating in a Pandemic: What 2021 May Signal for Health Care Policymaking in New York State

By James W. Lytle

This issue of the *Health Law Journal* typically includes a summary of the health care-related legislation passed by the New York State Legislature during its session, which usually concludes in June or early July, when this issue's articles are finalized. For those interested in scanning the products of the 2021 legislative session, feel free to skip ahead: a summary of the health-related legislation is included below. Given the extraordinary interplay of the pandemic, politics and policymaking over the past year, providing some context and background on this legislative session may be helpful.

In short, both in spite of and because of 2021's unique political and policy environment—the pandemic and its aftermath, the national racial reckoning, the rise and fall of Governor Andrew Cuomo, the polarized state of the nation, and longstanding economic and social issues that the public health crisis exacerbated—this year may mark the beginning of a renewed role for the Legislature in health-policy making and a restructured relationship between the legislative and executive branches in New York.

Overview of 2021 Legislative Session

When the COVID-19 pandemic descended on New York State with its full fury in early 2020, it not only seriously tested the resilience of the New York State health care system; it also severely challenged the capacity of New York State health policy makers to respond effectively to the public health emergency. As the pandemic shut down or significantly impacted private economic activity in New York, it also profoundly impacted the operation of New York State government as well. State agencies sought to continue their work virtually and health care policymakers found themselves in a sustained 24/7 crisis mode for weeks and months on end, which undoubtedly contributed to the significant exodus of health officials from the upper reaches of the executive branch of state government.[1]

The legislative branch was also profoundly affected by the crisis. Unable to meet in public session and witnessing the spread of the virus to its own membership and leadership, the Legislature limped through much of 2020, passing less than half as many bills as usual, and largely left the management of the pandemic and its social and economic consequences to the governor. The 2020 legislative session yielded only 414 bills that passed both houses, compared to 935 bills in 2019 and those bills resulted in only 387 new laws (or "chapters") signed by the governor, compared to 758 in 2019.[2]

As legislative activity dwindled, executive actions more than filled the void. After issuing an executive order declaring an emergency on March 7, 2020, the governor issued over 100 extensions and modifications of that order during the course of the emergency.[3] Extraordinary executive authority was sought, granted and exercised, and Governor Cuomo became a national figure, praised for his calm, compassionate and rational response to the public health crisis that was featured in his nearly daily televised briefings. The governor's handling of the early months of the crisis led to a huge spike in his approval ratings—from 44% in February, 2020 to 71% in March, 2020, just one month later, when 87% of New Yorkers specifically approved of his handling of the pandemic[4]—and earned him an Emmy Award for his television updates[5] and a book deal on his handling of the crisis,[6] later acknowledged to include a $5 million advance.[7] Both before and after the results of the presidential election became clear, Governor's Cuomo's national visibility naturally led to speculation on potential roles that he might play in the Biden administration.[8]

2021 has proven to be a very different year. The Legislature continued to do its work—including hearings, committee meetings, debating and voting—in a hybrid fashion, with some legislators present in Albany and others participating remotely, even as the public (including lobbyists) remained excluded from access to the state Capitol. But the Legislature had become more comfortable with its pandemic procedures and proved to be far more productive in 2021. The legislative output more than doubled: from the 414 bills passing both houses in 2019 to 892 in 2021.

Moreover, the Legislature reasserted itself in the health care policy making arena, focusing particularly on a host of issues surrounding COVID-19 and nursing homes. In August of 2020, the Senate and the Assembly held a two-day, 22 hour joint hearing on residential health care facilities and COVID-19.[9] After referencing Governor Cuomo's comment that the virus spread "like fire in dry grass" within nurs-

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ing homes, one legislator described the hearing's purpose as an attempt "to determine who lit the match and why the fire fanned out." From the beginning, questions were raised over whether the nursing home fatalities were being properly reported: a successful Freedom of Information lawsuit,[10] a report by the Attorney General[11] and the admission by the governor's staff in a conference call with key legislators[12] confirmed that nursing home deaths were understated by approximately 50%. Controversy raged, as well, over a Department of Health policy issued on March 25, 2020 that required nursing homes to admit COVID-19-positive patients:[13] according to the Attorney General's report, the subsequently rescinded policy "may have contributed to increased risk of nursing home resident infection, and subsequent fatalities."[14]

More than any other health care policy issue, the nursing home controversy emboldened the Legislature to assume a more active and, at times, contentious role and led to a host of nursing home reform proposals that were described in the prior issue of this *Journal*[15]—the results of which are described below in the listing of long-term care bills that ultimately passed both houses. The controversy over whether the Administration properly reported nursing home fatalities is among several issues that became the focus of an investigation by the Attorney General, along with, most notably, a series of allegations of sexual harassment by the governor, which ultimately led to his resignation. [16]

Lessons from the 2021 Legislative Session

While the nursing home issue prompted the most forceful response by the Legislature, the engagement by the Legislature on a whole host of other policy issues is reflected by the long list of bills that were passed by both houses during 2021. The over 80 bills on a wide array of health and human services topics summarized below may signal the re-emergence of a more co-equal participation in policy making that the Legislature was intended to play.

A few observations on the output of the 2021 legislative session might help place these bills in context:

- ***Rescinding emergency authority and reasserting legislative prerogatives:*** Almost exactly one year after the issuance of the governor's first emergency executive order on the pandemic, the Legislature repealed the 2020 law[17] that had granted the governor extraordinary authority to address the crisis and established new procedures to ensure greater legislative engagement and oversight over any emergency actions that the governor might take.[18] Likewise, after the Legislature agreed to grant immunity for health care facilities and practitioners for services rendered during the COVID-19 emergency in the 2020 budget, the Legislature fine-tuned that grant of immunity just a few months later[19] to narrow its scope[20] and then, in 2021, repealed the immunity provision altogether.[21] While the emergency was nearing its end in any case, these more recent legislative actions reflect pent up concern within the Legislature over whether the balance of authority had shifted too dramatically to the executive during the pandemic and signaled that the Legislature was prepared to reassert its constitutional prerogatives. Ironically, when the governor officially declared the end of the emergency on June 24, there was concern among various economic sectors in New York over the abrupt cessation of various emergency orders that had actually provided some welcome flexibility during the pandemic—including everything from facilitating telehealth to permitting cocktails to go.[22]
- ***Responding to national racial reckoning with renewed focus on equity and racial justice.*** Given the events of the last year, it is not surprising that several bills passed this year reflected concern over the disparate impact of state policies on people of color in New York. Perhaps most notably, the cannabis legalization and regulation scheme enacted by the Legislature contained a substantial reinvestment component to compensate communities that felt the brunt of marijuana criminalization. As noted below, a bill was passed that heightens certificate of need (CON) scrutiny of the impact of a proposed project or transaction on improving health equity and reducing health disparities, while other bills mandated a study on the effects of racial and ethnic disparities on infant mortality and a review of how racial and economic disparities may impact on rates of asthma.
- ***Finding a balance between the more progressive and more moderate members of the Democratic majorities in both houses:*** Much has been made of the potential schisms in the national Democratic party between its more progressive members and more moderate representatives. The ideological friction between the two wings of the party boiled over publicly in New York during the budget process in New York earlier this year. By the end of the session, the progressives succeeded in enacting tax increases on wealthier New Yorkers and finally legalizing adult use marijuana—while, at the same time, a proposal to establish a single payor health care system in New York, the centerpiece of the progressive's health care agenda, continued to languish, despite amassing sufficient numbers of sponsors to pass it in both houses.
- ***Health care workforce issues predominate:*** Just as the larger economy has found it challenging to recruit and retain a robust labor force as we emerged from the pandemic, longstanding workforce issues, exacerbated by the COVID-19 emergency, have become a central focus of policymakers. Long-delayed legislation to impose staffing ratios in nursing homes was finally enacted in the aftermath of reports on understaffing during the pandemic.[23] While the hospitals were spared rigid staffing ratios, legislation mandating a formal clinical staffing committee, with nursing and direct care staff representation, was passed by both houses. Two joint

hearings were held by the Senate Health, Aging and Labor Committees to examine issues relating to the nursing home and home care workforces, while advocates and provider representatives from the behavioral health and developmental disabilities services world have been seeking urgent legislative assistance in addressing their workforce issues.

- ***Reasserting the legislative role in broader health care policymaking:*** More broadly, many of the bills that passed both houses reflect what appears to be a renewed interest by the Legislature in engaging more directly with longer term health care policy issues. Long before the pandemic, the executive has been in the health care policy driver's seat, reflected in recent years through the Medicaid Redesign Team activities, the shepherding of massive federal waiver requests and the implementation of the ACA, with little or no real involvement by the Legislature. While it remains to be seen if an under-resourced Legislature can become a full partner in health care policy-making, a number of the bills passed this session reflect a renewed interest in doing so, including legislation to "reimagine" long term care, to review the delivery of primary care in response to the COVID-19 pandemic, and to undertake focused studies on infant mortality, asthma, and insurance coverage of childbirth, among others noted below. A bill was also passed by both houses (not reflected in the health care-specific bills summarized below) that establishes a goal of reducing childhood poverty in half and seeks to hold the Executive accountable for progress toward that goal[24]—which may prove to be a harbinger of future legislative approaches to enhance its policy-setting and oversight roles.

The following list reflects most of the bills passed by both houses in the health and human services arena, organized into somewhat arbitrary categories. Those that have already been signed into law are noted by a reference to their **chapter number.** To check on whether a bill has been enacted, you can access the status of any legislation by clicking the home tab at the Legislative Bill Drafting Commission site at http://public.leginfo.state.ny.us/navigate.cgi?NVMUO:

Hospitals

Hospital Clinical Staffing Committees (A108-B Rivera/S1168-A Gunther; **Chapter 155**): The bill requires general hospitals, by next January, to establish clinical staffing committees, comprised of nursing, direct care staff, and administrators, that will be responsible for the development and implementation of staffing plans to be submitted to the Department of Health (DOH) by July 1 of each year. In addition, the bill would also create an independent advisory commission to evaluate staffing levels and to report on its findings by October 31, 2024, and every three years thereafter.

Emergency or Disaster Treatment Protection Act Repeal (A3397 Kim/S5177 Biaggi; **Chapter 96**): This bill repealed (as of April 6, 2021) the Emergency or Disaster Treatment Protection Act, which had been passed as part of the 2020-21 Budget and provided immunity to certain health care facilities and professionals during the COVID-19 public health emergency.

Antimicrobial Resistance Prevention and Education Act (S2191 Kavanagh/A5847 Woerner): This bill would require nursing homes and hospitals to establish and implement an antimicrobial stewardship and training program in accordance with federal and state requirements.

Pre-Term Labor Care and Information (S1303 Salazar/A1254 Bichotte Hermelyn; **Chapter 66**): The bill requires hospitals to adopt emergency treatment protocols for expectant mothers including those in pre-term labor, and that such protocols be compliant with EMTALA and eliminates a 2020 requirement that hospitals distribute certain educational information to any expectant mother who presents at the hospital during pregnancy.

Distribution of Sickle Cell Disease Information (A6429-B Hyndman/S5506-B Sanders): The bill would require DOH to design, and hospitals to distribute, an informational packet on sickle cell disease.

Newborn Screening (A4572 Gottfried/S4316 Rivera): The bill would add glucose-6-phosphate dehydrogenase deficiency to the list of conditions for which all newborns must be screened.

Essential Support Person for Hospitalized Individuals with Disabilities (S1035-A Addabbo/A4685-A Pheffer Amato): This bill would require general hospitals to allow essential support persons to accompany individuals with disabilities during the duration of that individual's hospitalization and would ensure that the essential support person could accompany the individual even during a state disaster emergency or pandemic.

Long-Term Care

Nursing Home Staffing Levels (A7119 Gunther/S6346 Rivera; **Chapter 156**): As of January 1, 2022, this legislation will require that nursing homes provide at least 3.5 hours of nursing care per resident day, of which at least 2.2 hours must be provided by certified nurse aides (CNAs) and at least 1.1 hours by a registered nurse (RN) or licensed practical nurse (LPN). This proposal follows the enactment of provisions in the state budget that required nursing homes to spend 70% of their revenue on direct resident care, including at least 40% on resident-facing staffing, subject to even higher thresholds if care provided through staffing agencies.

Requirements for Resident Transfers and Voluntary Discharge (Ch. 80 of the Laws of 2021): This legislation establishes additional requirements for the transfer, discharge, and voluntary discharge of residents from nursing homes,

largely consistent with federal requirements. Prior to initiating a transfer or discharge, facilities are required to use best efforts to secure appropriate placement. If a facility seeks to transfer or discharge a resident to the home of another individual, the facility is required to obtain written consent from both the resident and individual and provide a comprehensive discharge plan. A chapter amendment (S.6204 Rivera/A.7018 Hevesi, **Chapter 138**) was signed that would clarify that in the event a resident seeks a voluntary transfer or discharge, the facility must document the reason the resident is seeking a transfer or discharge.

Nursing Home Resident Bill of Rights and LTC Ombudsman Contact Information (S4377 May/A6222 Wallace): This bill would require DOH to make available to nursing homes the Nursing Home Resident's Bill of Rights in the six most common non-English languages and require facilities to publicly post these versions and make them available to residents upon request. The legislation would also require that facilities prominently post in residents' rooms and disseminate to residents/families the contact information for the Long-Term Care Ombudsman Program.

Nursing Home Disclosure Requirements (S6767 Rivera/A7517 Gottfried, **Chapter 141**): This bill would require nursing home operators to publicly disclose: the rates charged by the facility for residency and services by nongovernmental payer source; all individuals with an ownership interest in the operator of the facility; the name and business address of any landlord of the facility; and a summary of its contracts for goods and services.

Transparency of Violations (S3185 Skoufis/A5848 Wallace, **Chapter 344**) This legislation would require residential health care facilities, as part of the admissions process, to disclose to potential residents and their family members the website where a list of complaints, citations, violations, and penalties taken against the facility can be found.

Publication of Nursing Home Ratings (S553 Sanders/A2037 Dinowitz): This legislation would require that the most recent overall CMS rating of every nursing home be prominently displayed on the home page of DOH's website and at each nursing home facility's website.

LTC Ombudsman Program Reform Act (S612-B May/A5436-B Clark): This legislation would reform the Long-Term Care (LTC) Ombudsman program to allow for staff and volunteers of the program to report issues directly to DOH and to notify ombudsman staff and volunteers when inspections are being conducted or complaints are received at their assigned facilities.

LTC Ombudsman for MLTC Participants (A7022 Wallace/S6740 May, **Chapter 202**): The legislation would extend the authorization of the Long-Term Care Ombudsman Program to advocate on behalf of managed long-term care (MLTC) participants until December 31, 2023.

Reimagining Long-Term Care Task Force (S598-B May/A3922-A Cruz): This bill would establish a task force to study the state of both home-based and facility-based long-term care services in New York, and to make recommendations on potential improvements to long-term care services and on the challenges generated by the COVID-19 pandemic. The report on the COVID-19 pandemic issues would be due December 1, 2021, with the full study due May 1, 2022.

Absentee Voting for Nursing Home Residents (S1644 Cooney/A6220 Lunsford, **Chapter 279**): Between now and December 1, 2021, this bill would require the Board of Elections to mail or deliver absentee ballots to voters residing in nursing homes and would prohibit inspectors from physically delivering ballots in-person.

Personal Caregivers in Nursing Homes and ACFs (S614-B May/A1052-B Bronson, S6203 May/A6966 Bronson, **Chapters 89 and 108**): This bill allows designated personal caregivers and compassionate care visitors at nursing homes and Adult Care Facilities (ACFs) during a declared state or local public health emergency. DOH issued an emergency regulation on June 1, 2021 to implement this legislation, but with the expiration of the public health emergency on June 25, the provisions of this legislation and implementing regulations are currently not in effect. It is anticipated that DOH will issue further guidance related to visitation in nursing homes and ACFs.

ACF Quality Assurance Plans (S1784A Skoufis/A5846 Kim): This bill would require ACFs to include infection control as a component of their quality assurance plan and to create a quality improvement committee. The committee must meet at least every six months to review findings from monitoring the facility's quality assurance plan and the effectiveness of its corrective action policies. The committee must include the administrator or operator of the facility, the resident council president, and employee representation from each area of operation.

Hospice Beds for Inpatient Services (A4594-A Gottfried/S5506-A Hinchey, **Chapter 193**): The bill would authorize hospice residences to use all certified beds for inpatient services that require medical intervention, expanding the current statutory limit of 25% of hospice inpatient beds. This bill would make permanent the Executive Order allowing for 100% of a hospice residence's beds to be used as general inpatient care.

Nursing Home Energy Audits and Disaster Preparedness (A7662 Anderson/S7102 Addabo, **Chapter 125**): The bill would extend the authorization for DOH to conduct energy audits and disaster preparedness reviews of nursing homes until July 1, 2024.

Elder Abuse Multidisciplinary Team (S6528 Persaud/A7634 Cruz, **Chapter 223**): This bill would create the Elder Abuse Enhanced Multidisciplinary Team Program, consisting of teams across the State to provide a coordinated response to complex cases of elder abuse, including financial exploitation, physical abuse, sexual abuse and neglect.

Scheduling of Competency Exams for Home Care Workers (A4662-A Burdick/S1201-A Harckham): This bill would require DOH to maintain a schedule of when they will offer competency exams to qualified home care workers residing outside of New York, and to make the schedule available on the Department's website and accessible by the public.

Social Adult Day Services (S6526 May/A7499 Barnwell, **Chapter 296**): This bill, at the request of the State Office for the Aging (SOFA), would amend the definition of social adult day services to authorize their provision to "functionally impaired individuals" in congregate, community, or a home setting pursuant to a person-centered service plan.

Consumer Directed Personal Assistance Services: As part of enacted budget, Legislature modified the fiscal intermediary (FI) procurement process by requiring DOH to make additional awards to FIs that met certain requirements (including county size, services to I/DD individuals or to racial and ethnic minorities, operating since 2012, not-for-profit status and minority- or women-owned.

Primary Care

Study on Delivery of Primary and Urgent Care (A5713 Fall/S6375 Savino): The bill would require DOH to conduct a study of the delivery of primary care, retail clinics, urgent care centers, federally qualified health centers (FQHCs), and other ambulatory care services in New York State in response to the COVID-19 pandemic. It excludes ambulatory surgery centers (ASCs) and office-based surgery practices from the study. The study would examine the impact of the providers on the delivery, quality, accessibility, and cost of ambulatory health care and include recommendations to improve the delivery, quality, accessibility, and cost of ambulatory health care services. During the study, clinics, urgent care centers, or other ambulatory practices would be required to give a 30-day notice to DOH and locally elected officials before a closure, relocation, or decertification.

Plasma Donation Centers (A228 Gottfried/S2119 Rivera): This bill would establish Source Plasma Donation Centers and would authorize these centers to collect source plasma in compliance with federal law. The donation center would be authorized to employ personnel that would be able to perform total protein tests using digital refractometers, in compliance with federal requirements.

Midwifery Birth Centers (A259-A Gottfried/S1414-A Rivera): This bill would require DOH to approve the establishment of a midwifery birth center that meets that standards of an accrediting organization that specializes in accrediting midwifery birth centers.

Health Planning

Health Equity Assessment for CON Applications (S1451-A Rivera/A191-A Gottfried): The bill would require certain CON applications to include a health equity impact assessment of the proposed project, which will consider how a project will improve access to health care services, improve health equity, and reduce health disparities, with a focus on the medically underserved. The assessment must be prepared by an independent entity and include the meaningful engagement of public health experts, organizations representing the applicant's employees, community leaders and residents of the applicant's service area. An assessment would be required for applications for the construction, establishment, change in operator, merger, acquisition, or substantial reduction, expansion, or addition of a service of a hospital, nursing home, or diagnostic and treatment center.

Heightened CON Review for Ownership of Nursing Homes (S 4893-A Rivera/A5684-A Gottfried, **Chapter 102**) This legislation enhances the Certificate of Need (CON) review process for nursing home establishment and change of ownership applications, including the consideration of past violations at other facilities by owners or related owners, and establishes public notice requirements related to CON applications under review. It requires DOH to provide notice of a nursing home CON application to the Long-Term Care Ombudsman within 30 days of acknowledgment of the application, and the Ombudsman is provided the opportunity to submit a recommendation on the application to DOH and the Public Health and Health Planning Council (PHHPC). It also amends the existing character and competence requirements for nursing home establishment applications to require each individual and entity of the applicant to specify every nursing home in which the individual or entity has held a controlling interest in the last seven years and the nature of that interest. PHHPC is precluded from approving an application unless it finds that each nursing home, including those located outside of New York, in which an individual or entity held a controlling interest in the last seven years, demonstrated a consistently high level of care.

PHHPC Membership (S869 Hoylman/A986 Gottfried, **Chapter 42):** This bill amends legislation passed last year that increased the membership of the Public Health and Health Planning Council (PHHPC). As a result, PHHPC will continue to have 24 members, but maintains the requirement that at least two members be representatives of consumer advocacy groups that advocate for low- and moderate-income health care consumers.

Health Professions

Oral Medication by Optometrists (S1519 Bailey/A1921 Paulin): This legislation would authorize optometrists to prescribe 10 oral medications—six antibiotics, two antiviral medications, and two antiglaucoma medications. Optometrists who are certified to use oral medications would be required to complete an additional 18 hours of continuing education in systemic disease and therapeutic treatment, which would be in addition to the 36 hours of continuing education that are currently required of all optometrists during the triennial registration period.

Practice of Applied Behavioral Analysis (A3523-A Peoples-Stokes /S1662-B Skoufis) This legislation would expand the scope of practice of licensed behavior analysts in New York to allow treatment of individuals with behavioral health conditions recognized in the Diagnostic and Statistical Manual (DSM) published by the American Psychiatric Association—and not just those with a diagnosis of autism or related disorders.

Mandatory Prescribing of Opioid Antagonists (A336-A Braunstein/S2966-A Harckham): This bill would require practitioners prescribing an opioid for the first time each calendar year to also prescribe an opioid antagonist if: (a) the patient has a history of substance use disorder; (b) the dose or cumulative prescriptions result in 90 morphine milligram equivalents or higher per day; or (c) the patient has concurrent use of opioids and benzodiazepine. This requirement would not apply to prescriptions of an opioid in a general hospital, nursing home, Article 31 facility, or to a patient enrolled in hospice.

Extension of Mental Health Practitioner Practice Exemption (A7405-A Bronson/S6431-A Brouk, **Chapter 159**): This bill would extend for one year the permission currently granted to certain mental health practitioners to diagnose. Those practitioners include licensed marriage and family therapists, licensed master social workers, licensed clinical social workers, and school psychologists. The authority to diagnose will remain in place until June 24, 2022.

Expansion of Pharmacist Immunizations (S4807-A Stavisky/A6476-A Hyndman): The bill would make permanent the authorization for pharmacists, pursuant to a patient-specific order or non-specific patient regimen, to administer immunizations for influenza to patients two or older, and for Hepatitis A, Hepatitis B, HPV, measles, mumps, rubella and COVID-19 to patients 18 or older. Further, pursuant to a determination by DOH, the bill authorizes pharmacists to administer additional immunizations recommended by the CDC to patients 18 and older.

Nurse Practitioners: As part of budget, the Nurse Practitioner Modernization Act was extended for one year through June 30,2022.

Medicaid, Medicaid Managed Care, Managed Long-Term Care and Child Health Plus

Medicaid Managed Care Pharmacy Reimbursement (S6603 Skoufis/A7598 Gottfried): This bill would require DOH to reduce administrative fees paid to Medicaid Managed Care (MMC) plans in order to increase reimbursement rates to retail pharmacies and would require MMC plans to pay pharmacies at the same rate as Medicaid Fee for Service (FFS) for dispensing fees and ingredient cost. Plans and their pharmacy benefit managers (PBMs) would be required to allow any retail pharmacy to participate in a plan network if the pharmacy accepts the Medicaid reimbursement rate and would be unable to limit a patients' ability to choose to receive medications from a non-mail order pharmacy of choice.

Medicaid Managed Care Coverage of Medication Assisted Treatment (A2030 Rosenthal/S649-A Harckham): The bill would require MMC plans to cover all buprenorphine products, methadone, and long acting naltrexone (Vivitrol) for detoxification or maintenance treatment of a substance use disorder, when prescribed according to generally accepted national professional guidelines. The bill would repeal the current MMC requirement that prohibited the use of prior authorization for formulary forms of medication prescribed for the treatment of substance use disorder and would require coverage for medication that is both on and off the plan's formulary.

Managed Care Notice of Consumer Assistance (S886 Rivera/A985 Gottfried, **Chapter 129**): The bill clarifies that legislation enacted last year, which required MMC plans to include information regarding the independent Consumer Assistance Program and Substance Use Disorder and Mental Health Ombudsman on all notices of adverse determinations, grievances, and appeals, applies to written and electronic notices.

Child Health Plus (CHP) Coverage of Ostomy Supplies (A783 Cahill/S577 Sanders): The bill would require CHP coverage of ostomy supplies and equipment.

CHP Network Participation Requirements (A1523 Pretlow/S2212 Sepulveda): The bill would prohibit CHP plans from denying or limiting the provision of health care services by a provider under CHP if the provider refuses to participate in a commercial health care network maintained by the organization.

Medicaid Coverage for Licensed Clinical Social Workers (S6576 Savino/A7187 Bronson): This bill would add services provided by licensed clinical social workers for coverage under Medicaid and allow such providers to bill Medicaid directly for services provided.

Medicaid Coverage for Licensed Mental Health Practitioners (S6575 Savino/A6323 Bronson): This bill would add services provided by licensed mental health practitioners for coverage under Medicaid and allow such providers to bill Medicaid directly for services provided.

Review of Medicaid Rates for Ambulette Transportation (A7240 Gottfried/S6542 Kaplan): The bill would require the Commissioner of Health to review reimbursement by the Medicaid program for ambulette transportation to ensure rate adequacy.

School Based Health Centers (S2127 Rivera/A1587 Gottfried): The bill would provide School Based Health Centers (SBHCs) with the choice of operating under Medicaid FFS or participating in MMC. The bill would further provide for the sharing of health data for individuals receiving services from SBHCs via standardized memoranda of understanding developed by DOH.

Telehealth: As part of enacted budget, the Legislature removed restrictions on distant and originating sites and included certified peer recovery advocates as authorized telehealth providers in Medicaid.

Health Insurance

Notice of Partial Approval or Denial of Medical Claims (S2008-B Jackson/A1677-A Gottfried): This bill would require insurers and health maintenance organizations (HMOs) to notify policyholders when a claim is denied or partially approved and the specific reasons for the denial or partial approval.

Extension of Hospital Contract Cooling Off Period (A7659 Buttenschon/S6801 Rivera, **Chapter 181**): This bill would extend the statutory requirement for hospitals and managed care organizations, whose provider contracts are about to expire, to abide by the terms of that contract for an additional two months from the effective date of the termination or non-renewal and would require notice to enrollees within 15 days of the commencement of the two-month period.

Coverage of Early Intervention (S5560 Reichlin-Melnick/ A5339 Paulin): This bill would establish a Covered Lives Assessment (CLA) for the coverage of Early Intervention (EI) services, replacing the current claims-based reimbursement structure whereby health plans cover medical services related to EI. The bill would collect $40 million on an annual basis, to be delivered on a proportional basis to municipalities to pay EI claims and remove the obligation for insurers to pay for EI services.

Stop Loss Coverage and Municipal Consortia (A6245-A Woerner/S5581 Breslin, **Chapter 406**): The bill would authorize stop loss, catastrophic and reinsurance coverages to remain in effect for small groups, if such coverage were in effect prior to 2015, despite a general prohibition that prevents insurers from selling stop loss coverage to groups with between 51 and 100 members. The legislation would also allow municipalities and schools districts that are currently members of municipal consortia to continue those arrangements without applying insurance provisions applicable to small groups to these consortia.

Study on Insurance Coverage for Childbirth (S4827 Salazar/A7315 Jackson): This bill would require the Department of Financial Services (DFS), in consultation with DOH, to conduct a review of covered benefits related to childbirth under all health policies and Medicaid policies in New York State. The report would examine: to what extent policies exceed ACA requirements; the current average length of stay coverage periods for surgical and vaginal deliveries; the average and range of reimbursements to physicians and licensed midwives for labor and surgical or vaginal deliveries; the current range of out-of-pocket expenses for deliveries; the extent to which plans provide expanded coverage for complications with childbirth; the extent to which insurers cover neo-natal care expenses if related to surgical delivery; the extent to which maternity services are covered for dependents under age 26; and the extent to which plans consider pregnancy an event that qualifies women for special enrollment periods.

Prescription Drug Benefits

Explanation of Pharmaceutical Benefits (A3516 McDonald/ S7075 Breslin): This bill would require insurers and managed care plans to include pharmaceutical expenses in the Explanation of Benefits (EOBs) provided to an insured in response to any filed claim.

Mid-Year Formulary Changes (A4668 Peoples-Stokes/ S4111 Breslin): The bill would restrict the ability of health insurers to adjust their prescription drug formulary during a plan year. Except under limited circumstances, it would prohibit insurers from removing a drug from a formulary, change the tiers of a drug, or add utilization management restrictions during the plan year. The insurer may remove a drug from the formulary or impose utilization management restrictions during the plan year if the drug is no longer approved by the FDA, and will permit a drug to be moved into another cost sharing tier if an AB-rated generic or interchangeable biological is added to the formulary at the same time. It requires an insurer to provide notice to policyholders of the intent to remove a prescription drugs from a formulary or coinsurance requirements in the upcoming plan year, 30 days prior to the open enrollment period.

Mail Order Prescriptions (S3566 Breslin/A5854-A Joyner): The bill would require health plans to reimburse retail pharmacies for prescription drugs regardless of whether the retail pharmacy is in the plan's specialty pharmacy network or whether the retail pharmacy can meet the plan's terms and conditions for participation.

Pharmacy Benefit Manager Licensure and Fiduciary Obligations (A1396 Gottfried/S3762 Breslin): The bill would require the registration, licensure, and comprehensive regulation of Pharmacy Benefit Managers (PBMs). PBMs would be required: (1) to perform services in the best interests of the covered individual, and the health plan or provider; (2) hold and receive all funds for the health plan or provider "in trust"; (3) pass through all income received from pricing discounts, rebates or any other benefits received by the PBM; and (4) provide access to all financial and utilization information of the PBM. In addition, the bill establishes a private right of action for individuals and providers to sue a PBM for legal or equitable relief to enforce these provisions.

Note also: **Medicaid Managed Care Pharmacy Reimbursement and Medicaid Managed Care Coverage of Medication Assisted Treatment** in *Medicaid* section above.

Disability Advocacy

Office of the Advocate for People with Disabilities (A3130 Steck/S1836 Skoufis): This bill would [re-]establish the Office of the Advocate for People with Disabilities within

the Department of State. The office will be tasked with advising and assisting agencies in the development of policies to help support and meet the needs of individuals with disabilities.

Developmental Disabilities Advisory Council (A7358-A Abinanti/A6293-A Mannion): The bill would alter the appointment process for members of the Developmental Disabilities Advisory Council. Previously, all 33 appointments were made by the governor. Under this proposal, the Senate Majority Leader and the Assembly Speaker would each have eight appointees, the Minority Leaders would each have one appointee and the governor would be authorized to appoint 15 members of the council.

Note also **Essential Support Person for Hospitalized Individuals with Disabilities** in ***Hospitals*** section. ***Mental Health*** *and* ***Addiction Services***

Suicide Prevention and Mental Health Crisis Hotline (S6194-B Brouk/A7177-B Gunther) This bill would create the 988-crisis hotline center in New York for responding to individuals experiencing a mental health crisis. The hotline will be staffed with suicide prevention and mental health crisis counselors, mobile crisis teams, crisis receiving services, stabilization services, and other services. Oversight of the suicide prevention and crisis service activities will be shared by the Department of Public Service, the Office of Mental Health (OMH) and the Office of Addiction Services and Supports (OASAS).

Discharge Materials for Risk Protection Orders (A1005-A Paulin/S5434-A Harckham): This bill would require mental health facilities to provide patients and an authorized representative of patients with information about seeking an extreme risk protection order. An extreme risk protection order would prevent the individual from purchasing a firearm; such order would also allow law enforcement officials to confiscate any firearms owned by that individual.

Opioid Settlement Lockbox (S7194 Rivera/A6395-B Woerner, **Chapter 190):** This bill creates an opioid settlement fund and advisory board to ensure that any future opioid settlement funds be put into a "lockbox" dedicated to improve and expand treatment and recovery services for individuals struggling with addiction, and maintained separate from the state general fund. The bill limits the use of funds to prevention, treatment, harm reduction and recovery services related to substance use disorder and co-occurring mental illnesses.

Council for Treatment Equity (S679-A Harckham/A1927-A Rosenthal): The bill would establish the council for treatment equity within the office of addiction services and supports. Treatment equity is defined in the legislation as "achieving the highest level of substance use disorder services for all people and shall entail focused efforts to address avoidable inequalities by equalizing those conditions for substance use disorder services for those that have experienced injustices and socioeconomic disadvantages." The council is tasked with working with OASAS, with stakeholders and representatives of vulnerable populations to set priorities to achieve treatment equity in racial and ethnically diverse areas in the state.

Personal Tax Donation for Substance Use Disorder Education (S4086 Hinchey/A6553 McDonald): This bill would amend Tax Law to allow individuals to donate to the Substance Use Disorder Recovery Fund when filing their state taxes. Monies contributed to the fund would be made available to the Office of Addiction Services and Supports for the purpose of making grants to organizations providing education, prevention, treatment, or recovery services to those suffering from substance abuse disorders.

Workgroup on Frontline Worker Trauma (A1250 Gunther/S1301 Brouk, **Chapter 33**): The bill requires the Commissioner of Mental Health to convene a workgroup to focus on trauma-informed care and the needs and services available to frontline workers. The workgroup is required to issue a report by December 1, 2021 that identifies tools and resources for employers to support employee wellness and a referral mechanism for connecting frontline workers with behavioral health supports and services.

Intellectual/Developmental Disabilities

OPWDD Statewide Comprehensive Plan (S6277 Mannion/A7690 Abinanti, **Chapter 412**) This bill would require the Office for People with Developmental Disabilities (OPWDD) to prepare a statewide comprehensive plan for persons with mental disabilities that would include data related to age, race or ethnicity, residence type, and the primary language spoken by each recipient of services. It will also require the plan to provide the number of individuals receiving services and the average per-recipient cost to the Medicaid program.

OPWDD Care Demonstration Program (S4998 Mannion/S5364 Gunther): The bill would establish a care demonstration program by OPWDD to include community-based care options such as community habilitation, in-home respite, pathways to employment, supported employment, and community prevocational services.

Pharmacy

Online Directory for Distributors of Opioid Antagonists (S6044 Harckham/A128 Rosenthal): This bill would establish an online directory of all distributors of opioid antagonists (naloxone) to the public, including pharmacies, prevention programs and not-for-profits, available on the DOH website. The directory is required to be searchable based on the address of each distributor, contact information, hours of operation, insurance providers accepted, and special populations served.

Insulin Workgroup (S4000 Rivera/A5460 Joyner, **Chapter 134**): The legislation repeals the Insulin Demonstration Program and replaces that program with an Insulin

Workgroup convened by the Commissioner of Health in consultation with the Superintendent of DFS charged with exploring options available to increase access to insulin for state residents who are uninsured or ineligible for publicly funded health insurance, and dependent on insulin to manage diabetes. The workgroup will submit a report on expanding health care coverage to these individuals, addressing barriers to information regarding costs in the insulin supply chain, identifying actions that might be taken to hold manufacturers accountable for price increases and transparency in drug pricing, exploring options for increasing affordability for uninsured and underinsured New Yorkers, and creating opportunities for the state to engage with insulin manufacturers in public/private partnerships to provide affordable access to insulin to those lacking access to the drug. The law also allows for emergency refills of insulin.

Public Health

Cannabis Legalization and Regulation (S854-A Krueger/A1248-A Peoples-Stokes, **Chapter 92**): The bill established a new Cannabis Law and a new Office of Cannabis Management for the regulation of adult use cannabis, authorized the establishment of a regulated and taxed cannabis industry and initiated several social and economic justice initiatives.

COVID-19 Immunity for Health Care Facilities/Personnel (A3397 Kim/S5177 Biaggi, **Chapter 96**): The bill repealed provisions enacted in 2020 that provided immunity to health care personnel and facilities for care provided during the COVID pandemic emergency.

Organ Delivery Vehicles (A96-A Gunther/S4071-A Kennedy): This bill would establish a system allowing certain qualifying vehicles owned and operated by organ procurement organizations for the purpose of transporting human organs and/or medical personnel for the purpose of organ recovery or transplantation to use emergency lights and sirens while doing so.

Expanded Portals for Organ Donor Registration (A6392 Peoples-Stokes/S5973 Hinchey): This bill would provide opportunities for New Yorkers to elect to become organ donors when engaging with the mybenefits.ny.gov website, the Higher Education Services Corporation student financial aid portal or when filing certain tax documents electronically.

Education Programs for Donation of Postnatal Tissue (S3209 Salazar/A182 Gunther, **Chapter 284**): This bill would amend the Health Care and Wellness Education and Outreach program to allow New York State to conduct education and outreach regarding the donation of postnatal tissues and fluids by adding these to the list of conditions and health care opportunities that are included under this program.

Air Ambulance Transportation of Blood (S4085-A Hinchey/A2561-B Woerner): This bill would allow air ambulance services meeting FDA standards to store and distribute blood and blood products at their facilities, as well as to provide transfusion services while transporting patients.

Bone Marrow Registry Information (A989 Solages/A865 Benjamin, **Chapter 31**): The bill requires DOH, in consultation with practitioners and other bone marrow donation and transplant experts, to develop a printable bone marrow donation and registry information for the DOH website.

Study on Racial and Ethnic Disparities on Infant Mortality (S879 Benjamin/A988 Solages; **Chapter 46**): This law was passed to provide DOH additional time to conduct the study on the effects of racial and ethnic disparities on infant mortality. The report is now due on June 23, 2022.

Lyme and Tick-Borne Disease Awareness Campaign (S4089 Hinchey/A6888 Barrett): This bill would direct the Commissioner of Agriculture and Markets, in consultation with the Commissioner of Health, to develop a public awareness campaign regarding Lyme disease and other tick-borne illnesses.

Program for Students with Sudden Cardiac Arrest (A2388-B Aubry/S1016-B Gaughran): This bill would require the Commissioner of Education, in conjunction with the Commissioner of Health, to develop information on the recognition of the signs and symptoms of sudden cardiac arrest and communicate such information to schools and to students participating in interscholastic sports participation. The State Education Department would be directed to promulgate regulations to require students exhibiting symptoms of sudden cardiac arrest to be pulled from athletic activities and not be permitted to return without written permission of a licensed physician. The bill would also require teachers coaching athletics to have instruction in recognizing the signs of cardiac arrest and sudden cardiac arrest.

Education on Reproductive Health Conditions Affecting Fertility (A5979-A Walker/S6957 Brouk, **Chapter 248**): This bill would amend the Health Care and Wellness Education and Outreach program to allow New York State to conduct education and outreach regarding reproductive health conditions that affect female fertility by adding these to the list of conditions and health care opportunities the state may address under this program.

Pelvic Examination Information (S210-B Persaud/A5489-B Solages, **Chapter 272**): This bill would require DOH in consultation with health professionals to develop an informational pamphlet regarding pelvic exams for patients undergoing such exams.

Asthma Study (S646-B Sanders/A2670-B Hyndman): This bill would require the Commissioner of Health to conduct a study and report on the incidence of asthma in all cities and towns in New York State with a population of 90,000 or greater. The report would require an analysis of high-risk neighborhoods examining disparities in income, race and ethnicity, public and private housing, proximity to major

sources of air pollution and an evaluation of the effectiveness of existing medical facilities in each city.

Autism Detection Funding (A1953 Cruz/S2911 Parker): This bill would create within the Autism Spectrum Disorders Advisory Board an autism education and mapping program, established to promote screening and detection of autism, public education, counseling, and referral services, and to map locations of occurrence of the condition. The program would create a series of grants to approved organizations, within amounts appropriated, to advance these goals.

Lymphedema and Lymphatic Diseases Research Grants Program (A333 Rosenthal/S4868 Kennedy): This bill would create a system of competitive research grants under the Lymphedema and Lymphatic Disease Research Grants Program. The bill authorizes the program to administer grants, from available appropriations, to biomedical research institutions conducting direct research related to lymphedema and lymphatic diseases. The amount of each grant would be limited to $50,000 and would be awarded on a competitive basis.

Not-for-Profit Corporations

Voting Requirements for Authorizing Merger or Dissolution (A213 Paulin/S3265 Comrie, **Chapter 321**): The bill would require a two-thirds majority vote of the directors present at the time of the vote, if a quorum is present at that time (as opposed to current simple majority of a quorum of the board) for a proposed merger, consolidation, or dissolution of the corporation.

NFP Reporting and Donor Privacy (S4817-A Krueger/A1141-A Paulin): The bill would eliminate the requirement for charitable organizations, which are already required to file annual financial statements with the Attorney General's Charities Bureau, to file the same annual financial statements with the Department of State—a requirement that was enacted last year and that went into effect on January 1, 2021. In addition, the bill seeks to protect from disclosure, under the Freedom of Information Law (FOIL), the names, addresses and phone numbers of donors to 501(c)(3) not-for-profit organizations by prohibiting the publication of financial disclosure records without redacting this information.

Endnotes

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12. J. McKinley and L. Ferré-Sadurni, *New Allegations of Cover-Up by Cuomo Over Nursing Home Virus Toll*, New York Times, February 12, 2021.
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15. J. Lytle, *COVID-19, Nursing Homes and the Legislative Response*, NYSBA Health Law Journal, v.26, no.2, pp. 15-18.
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17. Chapter 23 of the Laws of 2020.
18. Assembly Bill No. 5967 (Heastie)/Senate Bill No. 5357 (Stewart-Cousins), Chapter 71 of the Laws of 2021.
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In the New York State Agencies

By Francis J. Serbaroli and Caroline B. Brancatella

Drug Take Back

Notice of Adoption. The Department of Health added Subpart 60-4 and amended section 80.51 of Title 10 N.Y.C.R.R. to implement the State's drug take back program to provide for the safe disposal of drugs. Filing Date: February 24, 2021. Effective Date: March 10, 2021. *See* N.Y. Register March 10, 2021.

Investigation of Communicable Disease; Isolation and Quarantine

Notice of Emergency Rulemaking. The Department of Health amended Part 2, section 405.3 and added section 58- 1.14 to Title 10 N.Y.C.R.R. to control communicable diseases. Filing Date: March 2, 2021. Effective Date: March 2, 2021. *See* N.Y. Register March 17, 2021.

Service Day Duration

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-10.5 of Title 14 N.Y.C.R.R. to assist providers in maintaining capacity to operate during the public health emergency. Filing Date: March 8, 2021. Effective Date: March 24, 2021. *See* N.Y. Register March 24, 2021.

Behavior Health Services for Foster Kids in Congregate Facilities, Elimination of Room Isolation and Operation De-escalation Rooms

Notice of Adoption. The Office of Children and Family Services amended sections 441.4, 441.17, 441.22 and 442.2 of Title 18 N.Y.C.R.R. to include behavior health services for foster kids in congregate facilities and eliminate room isolation and operation de-escalation rooms. Filing Date: March 15, 2021. Effective Date: March 31, 2021. *See* N.Y. Register March 31, 2021.

Office of Pharmacy Benefits

Notice of Adoption. The Department of Financial Services added Part 450 (Regulation 219) to Title 11 N.Y.C.R.R. to establish the Office of Pharmacy Benefits and rules for the Drug Accountability Board. Filing Date: March 19, 2021. Effective Date: April 7, 2021. *See* N.Y. Register April 7, 2021.

Public Adjusters

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Part 25 (Regulation 10) of Title 11 N.Y.C.R.R. to update the rule regarding public adjusters, including to conform to Chapter 546 of the Laws of 2013. *See* N.Y. Register April 7, 2021.

Medical Consents

Notice of Proposed/Emergency Rulemaking. The Office for People With Developmental Disabilities amended section 633.11 of Title 14 N.Y.C.R.R. to assist providers in administering the COVID-19 vaccine. Filing Date: March 22, 2021. Filing Date: March 22, 2021. Effective Date: March 22, 2021. *See* N.Y. Register April 7, 2021.

Prohibition of Fireworks

Notice of Emergency Rulemaking. The Department of Health added Subpart 9-4 to Title 10 N.Y.C.R.R. to prohibit the use of fireworks. Filing Date: March 30, 2021. Effective Date: March 30, 2021. *See* N.Y. Register April 14, 2021.

Residential Treatment Facility Leave of Absence

Notice of Emergency/Proposed Rulemaking. The Office of Mental Health amended Parts 576 and 578 of Title 14 N.Y.C.R.R. to update requirements for leave of absence in RTFs; Implement State Plan Amendments effective 7/1/18. Filing Date: March 24, 2021. Effective Date: March 24, 2021. *See* N.Y. Register April 14, 2021.

Rules Governing the Procedures for Adjudicatory Proceedings Before the Department of Financial Services

Notice of Emergency Rulemaking. The Department of Financial Services added section 2.19 to Title 23 N.Y.C.R.R. to specify that the Department of Financial Services may conduct administrative hearings by videoconference. Filing Date: April 1, 2021. Effective Date: April 1, 2021. *See* N.Y. Register April 21, 2021.

Compiled by Francis J. Serbaroli and Caroline B. Brancatella. Serbaroli is a shareholder in the Health & FDA Business Group of Greenberg Traurig's New York office. He is the former Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and is the former Chair of the Health Law Section. Brancatella is of counsel in the Health & FDA Business Group of Greenberg Traurig's Albany office, where she focuses her practice on health care issues, including regulatory, contracting, transactional, and compliance matters. Prior to joining the firm, she clerked for the Honorable Cynthia M. Rufe of the Eastern District of Pennsylvania.

Revise Requirements for Collection of Blood Components

Notice of Emergency Rulemaking. The Department of Health amended Subpart 58-2 of Title 10 N.Y.C.R.R. to facilitate the availability of human blood components while maintaining safety. Filing Date: April 6, 2021. Effective Date: April 6, 2021. *See* N.Y. Register April 21, 2021.

Annual Prevocational Assessment

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-10.4 of Title 14 N.Y.C.R.R. to allow such assessments to be conducted at a location specified by OPWDD. Filing Date: March 31, 2021. Effective Date: April 21, 2021. *See* N.Y. Register April 21, 2021.

Medical Consents

Notice of Adoption. The Office for People With Developmental Disabilities amended section 633.11 of Title 14 N.Y.C.R.R. to assist providers in administering the COVID-19 vaccine. Filing Date: April 12, 2021. Effective Date: April 28, 2021. *See* N.Y. Register April 28, 2021.

Medication Regimen Review

Notice of Adoption. The Office for People With Developmental Disabilities amended Parts 633.16 and 633.17 of Title 14 N.Y.C.R.R. to make technical corrections to align with current regulation allowing for an annual medication regimen review or more frequently. Filing Date: April 12, 2021. Effective Date: April 28, 2021. *See* N.Y. Register April 28, 2021.

Reimbursement of Waiver Services

Notice of Adoption. The Office for People With Developmental Disabilities amended Subpart 641-1, sections 635-4.4 and 635- 10.4 of Title 14 N.Y.C.R.R. to conform OPWDD waiver services to the federally approved waiver agreement. Filing Date: April 20, 2021. Effective Date: May 5, 2021. *See* N.Y. Register May 5, 2021.

Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 N.Y.C.R.R. to waive copayments, coinsurance, and annual deductibles for essential workers for in-network outpatient mental health services. Filing Date: April 27, 2021. Effective Date: April 27, 2021. *See* N.Y. Register May 12, 2021.

Meeting Space in Transitional Adult Homes

Notice of Emergency/Proposed Rulemaking. The Department of Health amended section 487.13 of Title 18 N.Y.C.R.R. to establish criteria for suitable meeting space to ensure privacy in conversations and a requirement to submit a compliance plan to the Department. Filing Date: April 21, 2021. Effective Date: April 21, 2021. *See* N.Y. Register May 12, 2021.

Name Change for the Physically Handicapped Children's Program (PHCP)

Notice of Adoption. The Department of Health amended Parts 11, 46 and 85 of Title 10 N.Y.C.R.R. to change the

name of the PHCP to Children and Youth with Special Health Care Needs Support Services Programs. Filing Date: April 23, 2021. Effective Date: May 12, 2021. *See* N.Y. Register May 12, 2021.

Comprehensive Psychiatric Emergency Programs

Notice of Adoption. The Office of Mental Health amended Parts 590 and 591 of Title 14 N.Y.C.R.R. to provide clarify and provide uniformity relating to CPEPs and to implement chapter 58 of the Laws of 2020. Filing Date: May 4, 2021. Effective Date: May 5, 2021. *See* N.Y. Register May 19, 2021.

Establishment of Youth Assertive Community Treatment (ACT)

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Part 508 of Title 14 N.Y.C.R.R. to include children in the populations eligible to receive ACT and other conforming changes. *See* N.Y. Register May 19, 2021.

Medical Consents

Notice of Withdrawal. The Office for People With Developmental Disabilities withdrew its notice of proposed rulemaking regarding medical consents from consideration. The notice of proposed rulemaking was published in the State Register on April 7, 2021. *See* N.Y. Register May 19, 2021.

Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of Emergency Rulemaking. The Department of Financial Services added section 52.16(q) to Title 11 N.Y.C.R.R. to waive cost-sharing for in-network telehealth services. Filing Date: May 5, 2021. Effective Date: May 5, 2021. *See* N.Y. Register May 26, 2021.

Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of Emergency Rulemaking. The Department of Financial Services amended section 52.16(p) to Title 11 N.Y.C.R.R. to waive cost-sharing for in-network visits and laboratory tests necessary to diagnose the novel coronavirus (COVID-19). Filing Date: May 5, 2021. Effective Date: May 5, 2021. See N.Y. Register May 26, 2021.

Surrogacy Programs and Assisted Reproduction Service Providers

Notice of Emergency Rulemaking. The Department of Health added Subpart 69-11 to Title 10 N.Y.C.R.R. to license and regulate surrogacy programs. Filing Date: May 17, 2021. Effective Date: May 17, 2021. *See* N.Y. Register June 2, 2021.

COVID-19 Confirmatory Testing

Notice of Emergency Rulemaking. The Department of Health amended section 405.11 and added sections 77.13, 77.14 and 415.33 to Title 10 N.Y.C.R.R. to require confirmatory COVID-19 testing in several settings to improve case statistics and contact tracing. Filing Date: May 14, 2021. Effective Date: May 14, 2021. *See* N.Y. Register June 2, 2021.

Nursing Home Case Mix Rationalization

Notice of Adoption. The Department of Health amended section 86-2.40(m) of Title 10 N.Y.C.R.R. to authorize the Department of Health to change the case mix acuity process for all nursing homes. Filing Date: May 17, 2021. Effective Date: June 2, 2021. *See* N.Y. Register June 2, 2021.

Reducing Biannual Testing of Adult Care Facility Staff

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 487.9, 488.9, and 490.9

COMMITTEES

Committee on Attorney Professionalism

Award for Attorney Professionalism

This award honors a member of the NYSBA for outstanding professionalism – a lawyer dedicated to providing service to clients and committed to promoting respect for the legal system in pursuit of justice and the public good. This professional should be characterized by exemplary ethical conduct, competence, good judgment, integrity and civility.

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of Title 18 N.Y.C.R.R. to remove the requirement for biannual testing of adult care workers. *See* N.Y. Register June 2, 2021.

Hospice Residence Rates

Notice of Proposed Rulemaking. The Department of Health proposed amending section 86-6.2 of Title 10 N.Y.C.R.R. to authorize the Medicaid rate of payment to increase the Hospice Residence reimbursement rates by 10 percent. *See* N.Y. Register June 2, 2021.

Stroke Services

Notice of Proposed Rulemaking. The Department of Health proposed amending section 405.34(g) of Title 10 N.Y.C.R.R. to modify the transition period for existing stroke centers to allow the Department to extend the three year transition period, if necessary. *See* N.Y. Register June 2, 2021.

Managed Care Organizations (MCOs)

Notice of Proposed Rulemaking. The Department of Health proposed amending section 98-1.11(e) of Title 10 N.Y.C.R.R. to maintain the contingent reserve requirement at 7.25% through 2022 applied to Medicaid Managed Care, HIV SNP & HARP programs. *See* N.Y. Register June 2, 2021.

Labeling Requirements Concerning Vent-Free Gas Space Heating Appliances

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 71 of Title 10 N.Y.C.R.R. to adjust the current labeling requirements for unvented gas space heating appliances. *See* N.Y. Register June 2, 2021.

Cannabinoid Hemp

Notice of Revised Rulemaking. The Department of Health proposed adding Part 1005 to Title 10 N.Y.C.R.R. to create a licensing framework for cannabinoid hemp processors and cannabinoid hemp retailers. *See* N.Y. Register June 2, 2021.

Applied Behavior Analysis

Notice of Revised Rulemaking. The Department of Health proposed adding section 505.39 to Title 18 N.Y.C.R.R. to include Applied Behavior Analysis in the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) benefit. *See* N.Y. Register June 2, 2021.

Notice to Employees Concerning Termination of Group and Health Insurance Policies, Etc.

Notice of Adoption. The Department of Financial Services amended Parts 55, 62, 89, 136, 216 and 218; repealed Subpart 65-3; and added new Subpart 65-3 to Title 11 N.Y.C.R.R. to make technical changes; comport with statutes; update office addresses; correct citations; etc. Filing Date: May 19, 2021. Effective Date: June 9, 2021. *See* N.Y. Register June 9, 2021.

Designated Services

Notice of Revised Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 830 of Title 14 N.Y.C.R.R. to set-forth the minimum regulatory requirements for certified programs to seek an Office designation. *See* N.Y. Register June 16, 2021.

Personal Caregiving and Compassionate Caregiving Visitors in Nursing Homes (NH's) and Adult Care Facilities (ACF's)

Notice of Emergency Rulemaking. The Department of Health amended section 415.3 of Title 10 N.Y.C.R.R. and added section 485.18 to Title 18 N.Y.C.R.R. to require NH's and ACF's to establish policies and procedures relating to personal caregiving and compassionate caregiving visitors. Filing Date: June 1, 2021. Effective Date: June 1, 2021. *See* N.Y. Register June 16, 2021.

Repeal and Amendment to Outdated Rate Regulations

Notice of Adoption. The Office for People With Developmental Disabilities amended Part 621, Subpart 641-2; repealed sections 641-2.2, 641-2.10, 676.11, 680.12, 690.7; and added section 681.14 to Title 14 N.Y.C.R.R. to repeal and amendment to outdated rate regulations. Filing Date: June 1, 2021. Effective Date: June 16, 2021. *See* N.Y. Register June 16, 2021.

Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of Emergency Rulemaking. The Department of Financial Services added sections 52.17(d) and 52.18(h) to Title 11 N.Y.C.R.R. to clarify application of Insurance Law sections 3217-h and 4306-g. Filing Date: June 4, 2021. Effective Date: June 4, 2021. *See* N.Y. Register June 23, 2021.

Hospital Non-Comparable Ambulance Acute Rate Add-On

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.15 of Title 10 N.Y.C.R.R. to prevent duplicate claiming by Article 28 hospitals for the ambulance add-on regarding participation in the program. Filing Date: June 14, 2021. Effective Date: June 14, 2021. *See* N.Y. Register June 30, 2021.

General Provisions Applicable to All OASAS Programs

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 800 of Title 14 N.Y.C.R.R. to identify those provisions that are required of all OASAS certified, funded or otherwise authorized programs. *See* N.Y. Register July 7, 2021.

Patient's Rights in OASAS Programs

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 815 of Title 14 N.Y.C.R.R. to set-forth the minimum regulatory requirements for patient rights in OASAS cer-

tified, funded or otherwise authorized programs. *See* N.Y. Register July 7, 2021.

Brokers, Agents and Certain Other Licensees—General

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Part 20 of Title 11 N.Y.C.R.R. to set forth classes licensees must complete to fulfill part of the 15 hour credit hours required by Insurance Law, art. 21. *See* N.Y. Register July 7, 2021.

Billing for Day Program Duration

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-10.5 of Title 14 N.Y.C.R.R. to allow providers of day habilitation and site-based prevocational services to bill for day program duration with greater flexibility. Filing Date: June 16, 2021. Effective Date: July 7, 2021. *See* N.Y. Register July 7, 2021.

Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of Emergency Rulemaking. The Department of Financial Services amended section 52.76 of Title 11 N.Y.C.R.R. to require immediate coverage, without cost-sharing, for COVID-19 immunizations and the administration thereof. Filing Date: June 25, 2021. Effective Date: June 25, 2021. *See* N.Y. Register July 14, 2021.

Independent Dispute Resolution for Emergency Services and Surprise Bills

Notice of Adoption. The Department of Financial Services amended Part 400 of Title 23 N.Y.C.R.R. to require notices and consumer disclosure information related to surprise bills and bills for emergency service to be provided. Filing Date: June 23, 2021. Effective Date: August 18, 2021. *See* N.Y. Register July 14, 2021.

Enterprise Risk Management and Own Risk and Solvency Assessment

Notice of Adoption. The Department of Financial Services amended Part 82 (Regulation 203) of Title 11 N.Y.C.R.R. to require an entity subject to the rule to describe its ERM function in its enterprise risk report, among other things. Filing Date: June 23, 2021. Effective Date: August 18, 2021. *See* N.Y. Register July 14, 2021.

Enforcement of Social Distancing Measures

Notice of Emergency Rulemaking. The Department of Health amended Part 66 of Title 10 N.Y.C.R.R. to control and promote the control of communicable diseases to reduce their spread. Filing Date: June 23, 2021. Effective Date: June 23, 2021. *See* N.Y. Register July 14, 2021.

Hospital Personal Protective Equipment (PPE) Requirements

Notice of Emergency Rulemaking. The Department of Health amended section 405.11 of Title 10 N.Y.C.R.R. to ensure that all general hospitals maintain a 90-day supply of PPE during the COVID-19 emergency. Filing Date: June 24, 2021. Effective Date: June 24, 2021. *See* N.Y. Register July 14, 2021.

Nursing Home Personal Protective Equipment (PPE) Requirements

Notice of Emergency Rulemaking. The Department of Health amended section 415.19 of Title 10 N.Y.C.R.R. to ensure that all nursing homes maintain a 60-day supply of PPE during the COVID-19 emergency. Filing Date: June 24, 2021. Effective Date: June 24, 2021. *See* N.Y. Register July 14, 2021.

Surge and Flex Health Coordination System

Notice of Emergency Rulemaking. The Department of Health added sections 1.2, 700.5, Part 360; amended sections 400.1, 405.24, 1001.6 of Title 10 N.Y.C.R.R.; and amended sections 487.3, 488.3 and 490.3 of Title 18 N.Y.C.R.R. to provide authority to the Commissioner to direct certain actions and waive certain regulations in an emergency. Filing Date: June 24, 2021. Effective Date: June 24, 2021. See N.Y. Register July 14, 2021.

COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel

Notice of Emergency Rulemaking. The Department of Health added Subpart 66-4 to Title 10 N.Y.C.R.R. to require nursing homes and adult care facilities to conduct ongoing COVID-19 vaccinations of their residents and personnel. Filing Date: June 24, 2021. Effective Date: June 24, 2021. *See* N.Y. Register July 14, 2021.

Telehealth Services

Notice of Emergency Rulemaking. The Department of Health added Part 538 to Title 18 N.Y.C.R.R. to ensure continuity of care of telehealth services provided to Medicaid enrollees. Filing Date: June 25, 2021. Effective Date: June 25, 2021. *See* N.Y. Register July 14, 2021.

Rate Setting for Residential Habilitation in Community Residences and for Non-State Providers of Day Habilitation

Notice of Adoption. The Department of Health amended Subpart 86-10 of Title 10 N.Y.C.R.R. to amend rate methodologies limiting payments to IRA providers to conform to provisions in an approved waiver. Filing Date: June 23, 2021. Effective Date: July 14, 2021. *See* N.Y. Register July 14, 2021.

Public Water Systems

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 5-1 of Title 10 N.Y.C.R.R. to correct typographic and minor technical errors to obtain primacy for the implementation of Federal drinking water regulations. *See* N.Y. Register July 14, 2021.

New York State Fraud, Abuse, and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health Medicaid Decisions[1]

Compiled by Margaret M. Surowka

Richmond Center for Rehabilitation and Specialty (Decision after Hearing, January 28, 2021, Natalie Bordeaux, ALJ) *and* Healthcare & Kings Harbor Multicare Center (Decision after Hearing, January 28, 2021, Natalie Bordeaux, ALJ)

Appellants are residential health care facilities that challenged audit findings by the New York State Office of the Medicaid Inspector General (OMIG). Both providers were represented by the same counsel, and challenged audit findings based on Medicaid reimbursements being paid without being reduced by partial or full Net Available Monthly Income (NAMI). Each of the providers also challenged the imposition of interest for the same reasons. In each case, Administrative Law Judge (ALJ) Bordeaux's decision was based on the same reasoning. As to OMIG's determination to recover Medicaid Program overpayments for appellants' failure to deduct residents' NAMI amounts, ALJ Bordeaux found appellants' arguments to be without merit. ALJ Bordeaux's decision began with the basic concept that an overpayment is "any amount not authorized to be paid under the Medicaid Program" and that payment of the monthly rate is to be reduced by the residents' NAMI. In both cases, the facilities argued that since there were "uncollected" and "uncollectible" NAMI amounts for residents, the amounts should be considered "bad debt," which should be offset and credited to the facility. In making the argument, appellants argued that Medicare policy reimburses providers for a portion of deductibles and coinsurance that is deemed uncollectible.

The ALJ rejected the relevancy of these Medicare cost policies, and made clear that appellants' cost arguments had no place in the claims audits at issue, as these arguments are only relevant to a rate adjustment. The ALJ recited counsel for appellants' failed attempt to annul an OMIG claims audit by claiming it is entitled to a credit for uncollected NAMI in *Concourse Rehabilitation & Nursing Center, Inc. v. Shah*, 161 A.D.3d 669 (1st Dep't 2018), and noted that none of the cases cited supported the argument that Medicaid is required to reimburse Medicaid providers for uncollected or uncollectible NAMI funds. In fact, in the only case cited by ALJ Bordeaux as relevant to the issue, *Florence Nightingale Nursing Home v. Perales*, 782 F.2d (2d Cir. 1986), the Second Circuit expressly found that "Congress devised the Medicaid Program with the intention not to reimburse providers for costs not covered by Medicaid. Since Medicaid payments to nursing homes must be reduced by NAMI amounts, an unpaid NAMI (even if uncollectible) is ergo not reimbursable by the New York State Medicaid Program." *See* Richmond Center Decision at 10, Kings Harbor Decision at 10. As such, both appellants failed to establish that the OMIG's determination of overpayment was incorrect.

As to interest, appellants argued that the interest both prior to issuance of the Audit Report and after the Final

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Audit Report could not be applied to the audits pursuant to 18 N.Y.C.R.R. § 518.4(e), which states: "No interest will be imposed upon any inpatient facility established under article 28 of the Public Health Law as a result of an audit of its costs for any period prior to the issuance of a notice of determination, nor for a period of at least 90 days after issuance of such notice." The ALJ rejected this regulatory argument since the audits at issue were claims audits and not an audit of appellants' costs. As such, the ALJ affirmed OMIG's determination as to overpayments and interest in both matters.

Maplewood Assisted Living (Decision After Hearing, March 3, 2021, Natalie J. Bordeaux, ALJ)

Appellant is an Assisted Living Program (ALP) located in Canton, New York. OMIG conducted an audit of Medicaid billings for ALP services for the period of January 1, 2014 through December 31, 2016. The Final Audit Report determined that 77 claims contained at least one error in nine categories of disallowances, resulting in sample overpayments of $79,322.84. For six of the nine categories, OMIG extrapolated the disallowances but only took the actual dollar value for three of the nine disallowances. OMIG sought recoupment of $437,927 in overpayments. Appellant contested two of the nine categories of disallowances, including: (1) Failure to Complete Annual Performance Evaluation (which was not extrapolated); and (2) Plan of Care Not Updated as Required (which was extrapolated). Appellant also contested OMIG's determination to extrapolate any findings.

As to the disallowances for Failure to Complete Annual Performance Evaluations for its staff, appellant argued that its Home Health Care Staff Supervisory Visit should suffice for an annual performance evaluation of staff, as the supervisory visit is more comprehensive that its standard annual evaluation. ALJ Bordeaux disagreed, and noted that the regulatory requirements applicable to annual assessments must include at least one home visit, but that the home visit alone does not satisfy the requirement for an overall evaluation of all aspects of the employee's performance for the entire year. As such, OMIG's disallowances for this category of findings were upheld.

As to the second category contested by appellant, Plan of Care Not Updated as Required, OMIG indicated that it would accept either an updated plan of care for each resident at least every six months or documents in any format that would show the original plan of care was timely reviewed every six months and encompassed the date of service. As evidence of its review, appellant submitted progress notes noting that a plan of care was reviewed with no changes necessary or that the patient had a six-month check up with no new orders. ALJ Bordeaux indicated that without accompanying documentation indicating that the actual plans of care were reviewed, the evidence provided by appellant was insufficient. As such, the disallowances in this category were affirmed.

Finally, appellant argued that it was punitive and inappropriate to extrapolate any of the findings. The ALJ disagreed. In the decision, ALJ Bordeaux stated that OMIG had the authority to extrapolate all of the audit findings, and the fact that OMIG only extrapolated some of the findings indicated that it was not acting punitively, especially considering appellant had an error rate of 77%. The ALJ also accepted OMIG's position that it only extrapolated the audit findings that were directly related to patient care, and did not extrapolate the findings that were personnel issues or only indirectly related to patient care. As such, appellant failed to overcome the presumption of validity of the sampling methodology for extrapolation, and OMIG's determination as to the overpayments and extrapolation were affirmed.

David M. Poole (Decision After Hearing, March 8, 2021, John Harris Terepka, ALJ)

Appellant operates a non-emergency medical transportation service, which includes both ambulette and livery, and does business in Central New York as F&T Transportation. At issue in this appeal was a data-match audit of Medicaid claims for transportation services for the audit period of January 1, 2012 through December 31, 2015. The Final Audit Report contained disallowances in three categories including: (1) Transportation Claims for Ambulette Services with Unqualified/Disqualified Driver's License for Date of Service (*i.e.*, 19-A certification); (2) Transportation Claims for Ambulette Services with Incorrect/Missing Driver's License for Date of Service; and (3) Transportation Claims with Incorrect/Missing Vehicle License Plate for Date of Service. The largest finding, with more than $136,000 in claims, was Transportation Claims for Ambulette Services with Incorrect/Missing Driver's License for Date of Service.

In its response to OMIG's Draft Audit Report, appellant included contemporaneous documentation including trip logs which identified the driver, driver's license number, vehicle, and plate number for nearly every one of the disallowed claims. OMIG rejected all such proof and relied on its data showing that the claim information was missing or incorrect. Noting that this was a system match audit of claims and not a field audit, OMIG's position was that the contemporaneous documentation, which was not a part of the claims submissions, was irrelevant. Appellant noted that it had no reason to be aware of any errors on the claims since the claims were all paid. As to the finding that the drivers on the claim form were not Article 19-A certified, appellant submitted driver logs which identified the actual drivers for the claims at issue, as well as documentation showing that those drivers were 19-A certified. In response, OMIG admitted that the basis for the findings was not only that the driver was not 19-A certified, but also that the driver who performed the trip was not the driver identified on the claims. In fact, OMIG admitted that it did not verify the certification status of those drivers appellant identified as the actual drivers.

In the decision, ALJ Terepka noted that OMIG failed to amend its findings to change the reason for the disallowances and since the appellant's documentation substantiated the 19-A certification for most services at issue, the disallowances should be reversed. As to the majority of the findings, which were based on an incorrect or missing driver's license number or vehicle license plate number on the claim forms, the ALJ noted that the information was blank on the claim forms submitted to the Medicaid Program, yet the claims were not denied, and were instead paid. ALJ Terepka rejected appellant's initial argument that this information was submitted on its claims forms, and that the data was "lost" by the Department of Health, as appellant was unable to present evidence to rebut the accuracy of the department's data. Next, the ALJ noted that the requirement obligating providers to include license numbers on claims forms was not based on a specific regulation, but was instead based on Medicaid Program policy. Appellant had, however, submitted documentation for the license and vehicle number for all but 48 disallowed claims in response to OMIG's Draft Audit Report.

ALJ Terepka noted that the Medicaid Program paid the claims despite having an edit in place that was meant to reject such claims, thereby ignoring its own claiming requirement and leaving the provider without any notice of the error so that it could be corrected. This being said, the ALJ rejected the argument that OMIG had created a "trap" for providers with its inconsistent use of edits, and noted that the "existence or functioning of 'edits' is irrelevant to appellant's obligation to demonstrate its entitlement to payment. The Medicaid Program is not required to have them in place, or if it does, to use them consistently, nor is the Medicaid Program obligated to advise provider which edits are in place." *See* Decision at 19.

The ALJ did, however, determine, consistent with a line of cases addressing the use of "system match" audits, that OMIG cannot refuse to consider the provider's contemporaneous documentation produced by it to demonstrate its entitlement to payment. Simply put, in these circumstances, "it is unreasonable to demand restitution where no attempt to take advantage of the Medicaid Program is apparent and the provider demonstrates on audit that it is able to fully comply with the requirement to prepare, maintain and produce cotemporaneous documentation demonstrating its entitlement to payment." *See* Decision at 21. In reaching this conclusion, ALJ Terepka made clear that the determination was not merely based on the fact that the services were in fact provided and there was no harm to the Medicaid Program, or that the errors were "inadvertent" or "technical." Instead, the determination was based on the fact that appellant timely produced contemporaneous documentation justifying the claims. The overpayment amount in the Final Audit Report was therefore reduced to $5,475.97, the amount of the claims for which there was no submission of documentation to withdraw the findings.

New York State Attorney General Press Releases

Compiled by Mary Connolly, Jennifer Cruz, Dena DeFazio, and Bridget Steele[2]

Attorney General James Teams With Federal Prosecutors to Make Dental Clinics Agree to Pay $2.7 Million for Alleged Use of Unsterilized Tools—May 25, 2021—The Office of the Attorney General's (OAG's) Medicaid Fraud Control Unit (MFCU), working with the United States Attorney's Office (USAO) in the Western District of New York and Pennsylvania, reached an agreement with the Upper Allegheny Health System for allegedly treating patients with unsterilized tools. A former employee alleged that between April 1, 2010 and May 31, 2015, Upper Allegheny Health System billed Medicaid for services performed with dental handpieces that had not been heat sterilized between uses—a violation of New York State and Federal laws. The Centers for Disease Control and Prevention (CDC) and the American Dental Association also require heat sterilization of dental handpieces after each use due to the health risks posed by using unsterilized tools. Upper Allegheny Health System will pay a total of $2.7 million in damages to the United States, New York, and Pennsylvania, with New York receiving $1.4 million in damages. https://ag.ny.gov/press-release/2021/attorney-general-james-teams-federal-prosecutors-make-dental-clinics-agree-pay-27.

Attorney General James Announces Arrest of Long Island Man for Fraudulently Obtaining Disability Benefits—May 20, 2021—A Huntington man allegedly fraudulently collected over $200,000 in disability benefits from the Social Security Administration, despite continuing to earn income as the president and owner of a limousine company and training as a bodybuilder. His 2013 claim for disability benefits stated that a fall left him in severe pain and unable to work in any capacity. He maintained his eligibility for disability benefits through 2020, despite extensive documentation online of his bodybuilding transformation beginning in 2017. The man was charged with one count of Grand Larceny in the Second Degree, a class C felony, and one count of Offering a False Instrument for Filing in the First Degree, a class E felony. https://ag.ny.gov/press-release/2021/attorney-general-james-announces-arrest-long-island-man-fraudulently-obtaining.

Attorney General James Leads Coalition in Support of HHS Effort to Undo Trump-Era Health Care Rule—May 17, 2021—Attorney General (AG) James, as a part of a coalition of 23 attorneys general, co-led by California AG Rob Bonta, sent a comment letter to the U.S. Department of Health and Human Services (HHS) to praise the agency's proposed rule to undo the Trump-era Title X "gag rule." The Title X program was created to fund family planning, counseling, access to contraceptives, and screenings for high blood pressure, anemia, diabetes, sexually transmitted diseases, and cervical and breast cancers. The Trump-era rule resulted in the loss of over 1,200 Title X clinics and a decrease in the number of clients served by 60%, with low-income, uninsured, and racial and ethnic minorities being the most

impacted groups. The new rule would allow Title X clinics to provide referrals for abortions, and will remove the requirement that pregnant patients be provided referrals for prenatal care when not requested, as well as the physical and financial separation of Title X funded services from abortion care. The Supreme Court has dismissed two cases which challenged the Trump-era regulation as the HHS is working to enact the new rule. AG James and Bonta were joined by the attorneys general of Colorado, Connecticut, Delaware, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, Wisconsin, and the District of Columbia in sending the letter. https://ag.ny.gov/press-release/2021/attorney-general-james-leads-coalition-support-hhs-effort-undo-trump-era-health.

Attorney General James Urges Congress to Pass Black Maternal Health Momnibus Act—May 6, 2021—AG James and a coalition of 21 attorneys general sent a letter to Congress urging the passage of the Black Maternal Health Momnibus Act of 2021 in an effort to combat the disproportionately high maternal mortality rates among Black women in New York and across the nation. The mortality rate of Black mothers is three to four times higher than white mothers, due to different factors such as preexisting conditions, socioeconomic status, lack of health insurance, and implicit bias and discrimination in the health care system. The Act aims to address this inequality by ensuring women have access to equitable care at all stages of pregnancy by, among other efforts, providing funding to community-based maternal health organizations and state programs, improving maternal health care for individuals with mental health conditions, substance use disorders, and those who are incarcerated, enhancing postpartum care, promoting maternal health innovation, and increasing access to education services for mothers. The Act would also allow state attorneys general to better protect their residents against race-based discrimination within the health care system. AG James was joined by the attorneys general of Colorado, Connecticut, Delaware, Hawaii, Illinois, Iowa, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Pennsylvania, Rhode Island, Virginia, Washington, Wisconsin, and the District of Columbia in sending the letter. https://ag.ny.gov/press-release/2021/attorney-general-james-urges-congress-pass-black-maternal-health-momnibus-act.

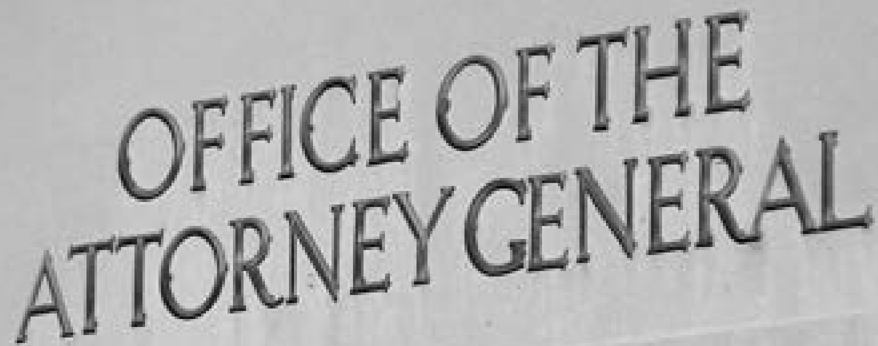
Attorney General James Stops Harassment at Manhattan Planned Parenthood Health Center—April 30, 2021—The OAG reached an agreement prohibiting two anti-choice protestors from entering a designated "buffer zone" around the main entrance to Planned Parenthood of Greater New York Manhattan Health Center. In her statement, AG James maintained that her office will protect women's reproductive rights and health care. https://ag.ny.gov/press-release/2021/attorney-general-james-stops-harassment-manhattan-planned-parenthood-health.

Attorney General James Applauds Biden-Harris Administration's Efforts to End Title X "Gag Rule"—April 14, 2021—In a press release, AG James praised the Biden-Harris Administration for taking action to rescind and replace the Trump administration's Title X rule which prevented health care providers who collect certain federal funds from counseling or making referrals for abortions. In her statement, AG James maintained that the Biden-Harris Administration's decision to replace the Trumpera rule "underscores their commitment to protecting reproductive rights of patients across the nation." https://ag.ny.gov/press-release/2021/attorney-general-james-applauds-biden-harris-administrations-efforts-end-title-x.

Attorney General James Issues Alert Urging New Yorkers to Report Unlawful Vaccine Charges—April 9, 2021—The OAG has issued a consumer alert to New Yorkers regarding the novel coronavirus 2019 (COVID-19) vaccine. The consumer alert reminds New York consumers that COVID-19 vaccinations are free of charge, and that any individual who was charged for the vaccine should report it to the OAG immediately. https://ag.ny.gov/press-release/2021/attorney-general-james-issues-alert-urging-new-yorkers-report-unlawful-vaccine.

Attorney General James Challenges Tennessee's Restrictive Abortion Law—April 8, 2021—New York's AG, along with a coalition of 20 of the nation's attorneys general, filed an amicus brief in *Bristol Regional Women's Center v. Slatery*, in support of a group of Tennessee abortion providers. The coalition of attorneys general are supporting the providers' challenge of Tennessee's waiting-period law, which requires a 48-hour waiting period for abortion services. In the brief, the coalition urged the U.S. Court of Appeals for the Sixth Circuit to uphold the district court's ruling, and argues that the waiting-period law is not reasonably related to the aim of ensuring informed consent and imposes serious burdens on those seeking medical care. AG James was joined by the attorneys general of California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, Virginia, Washington, and the District of Columbia in filing the amicus brief. https://ag.ny.gov/press-release/2021/attorney-general-james-challenges-tennessees-restrictive-abortion-law.

Attorney General James Scores Victory for Thousands of Elderly New Yorkers—March 30, 2021—The OAG reached an agreement with Life Alert Emergency Response, Inc. to resolve allegations of violations of New York's General Business Law § 391-l. The law requires a company to inform consumers orally, or in the written agreement, of their right to terminate the contract within seven days. Life Alert Emergency Response, Inc.'s 36-month monitoring service contract, which was signed by many New York seniors, failed to include the cancellation notification, as required by state law. The negotiated agreement will al-



low more than 5,500 New York consumers to cancel their current contracts with the company before the end of the 36-month contracts they signed. https://ag.ny.gov/press-release/2021/attorney-general-james-scores-victory-thousands-elderly-new-yorkers.

Attorney General James Warns New Yorkers to Remain Alert Against COVID-19 Vaccine and Stimulus Scams—March 30, 2021—New York AG Letitia James issued an alert to New Yorkers encouraging them to remain vigilant against potential scams related to the COVID-19 public health crisis. The alert advised of scams which focus on vaccine eligibility, as well as stimulus payments related to the pandemic. According to the alert, fraudsters are imitating the Internal Revenue Service (IRS) and other federal agencies in an effort to access consumers' personal information by promising access to additional stimulus payments, the ability to skip vaccine lines, and other needed services. New Yorkers who believe that they have been the victim of a scam are encouraged to contact the OAG to file a complaint. https://ag.ny.gov/press-release/2021/attorney-general-james-warns-new-yorkers-remain-alert-against-covid-19-vaccine.

Attorney General James Applauds Legislature for Repealing Nursing Home Immunity Provision—March 24, 2021—AG James released a statement in response to the New York State Legislature's repeal of the nursing home immunity provision, applauding "the Legislature for taking this critical action and ensuring that no one can evade potential accountability for the devastating loss of life that occurred in New York's nursing homes." Her statement followed a report released by the OAG in January of 2021 regarding the Office's ongoing investigations into nursing homes' responses to the COVID-19 pandemic. The OAG has been investigating nursing homes throughout New York State since March of 2020, based on allegations of patient neglect and other conduct that may have jeopardized residents' and employees' health and safety. https://ag.ny.gov/press-release/2021/attorney-general-james-applauds-legislature-repealing-nursing-home-immunity.

Attorney General James Calls on Facebook and Twitter to Stop Spread of Anti-Vaxxer Coronavirus Disinformation—March 24, 2021—AG James and a coalition of 12 attorneys general have asked Facebook and Twitter to take stronger measures to stop the spread of COVID-19 vaccine disinformation being spread by anti-vaxxers on their social media platforms. The coalition of attorneys general issued a letter to Facebook's Chief Executive Officer (CEO), Mark Zuckerberg, and Twitter's CEO, Jack Dorsey, urging the immediate and full enforcement of company guidelines against vaccine misinformation. The letter alleges that a small number of individuals without medical expertise are spreading false information regarding the safety of the COVID-19 vaccines, the misinformation has threatened to undermine vaccine acceptance and harm recovery, and that the platforms have been used to disproportionately target people of color. The letter also cites specific examples of instances where Facebook and Twitter have failed to enforce their existing guidelines. AG James joined the attorneys general from Connecticut, Delaware, Iowa, Massachusetts, Michigan, Minnesota, North Carolina, Oregon, Pennsylvania, Rhode Island, and Virginia in sending the letter. https://ag.ny.gov/press-release/2021/attorney-general-james-calls-facebook-and-twitter-stop-spread-anti-vaxxer.

Attorney General James Helps Secure Nearly $190 Million from Medical Device Manufacturer That Endangered Women's Health—March 23, 2021—AG James, as part of a coalition of 48 attorneys general, have secured nearly $188.6 million from Boston Scientific Corporation, a medical device manufacturer. The settlement resolves allegations of deceptive marketing of Boston Scientific Corporation's transvaginal mesh products that allegedly endangered the health of women. Transvaginal surgical mesh is a synthetic woven fabric that is implanted in the pelvic floor through the vagina to treat common health conditions, and involves the risk of serious complications, with thousands of women allegedly suffering serious complications resulting from the devices. The allegations resolved in the settlement stem from a multistate investigation that found that the companies violated state consumer protections laws by misrepresenting the devices' safety and effec-

tiveness, and failing to sufficiently disclose risks associated with the devices' use. Along with the monetary settlement, the agreement provides injunctive relief and requires Boston Scientific Corporation to engage in certain marketing, training, and clinical trial reforms. New York will receive $6,346,944 from the settlement agreement. https://ag.ny.gov/press-release/2021/attorney-general-james-helps-secure-nearly-190-million-medical-device.

Attorney General James Disappointed in Purdue Plan—March 16, 2021—AG James released a statement regarding the plan filed by Purdue Pharma in the United States Bankruptcy court, stating: "I am disappointed in this plan. While it contains improvements over the proposal that Purdue announced and we rejected in September 2019, it falls short of the accountability that families and survivors deserve." https://ag.ny.gov/press-release/2021/attorney-general-james-disappointed-purdue-plan.

Attorney General James Holds American Medical Collection Agency Responsible for 2019 Data Breach—March 11, 2021—A bipartisan coalition of 41 attorneys general, including New York's AG, have reached an agreement with Westchester County debt collection agency Retrieval-Masters Creditors Bureau d/b/a American Medical Collection Agency that resolves a multistate investigation into the company's 2019 data breach. The breach exposed the personal information—including Social Security numbers, payment card information, and, in some instances, names of medical tests and diagnostic codes—of up to 21 million individuals. American Medical Collection Agency filed for bankruptcy as a result of the breach, but the company received permission from the bankruptcy court to settle with the multistate coalition. The company also filed for dismissal of the bankruptcy on December 9, 2020. https://ag.ny.gov/press-release/2021/attorney-general-james-holds-american-medical-collection-agency-responsible-2019.

Attorney General James Provides $2.4 Million to Brooklyn Substance Abuse Treatment Programs—March 03, 2021—In 2019, the OAG dissolved a New York not-for-profit organization that provided substance use disorder treatment services. The dissolution was based on findings that its owner defrauded the Medicaid Program and exploited individuals living in substance use disorder transitional housing. In addition to the dissolution, a New York Supreme Court order also allowed the OAG to distribute organizational assets for use by other substance use disorder treatment programs. As such, more than $2.4 million from the dissolution was provided to the Brooklyn Community Foundation to fund these treatment programs throughout Brooklyn. https://ag.ny.gov/press-release/2021/attorney-general-james-provides-24-million-brooklyn-substance-abuse-treatment.

Attorney General James Announces Indictment of Rochester Doctor for Manslaughter in Opioids Overdose Death—February 19, 2021—A New York physician was indicted for Manslaughter in the Second Degree and other felonies related to the overdose death of a patient. The primary care physician allegedly prescribed a lethal mix of opioids and other controlled substances that resulted in the overdose death of a 55-year-old patient whom the physician supposedly knew struggled with addiction. The physician was also charged with two counts of Reckless Endangerment in the First Degree as related to two patients, six counts of Criminal Sale of a Prescription for a Controlled Substance or of a Controlled Substance by a Practitioner or Pharmacist for over prescribing high doses of powerful opioid pain killers, and Health Care Fraud in the Fourth Degree for allegedly causing Medicare, through its contractor Cigna Medicare Healthcare Rx, to pay for the medically unnecessary prescriptions that ultimately contributed to the patient's overdose death. The top charge against the physician is a class C felony, with a maximum sentence of five to 15 years imprisonment. https://ag.ny.gov/press-release/2021/attorney-general-james-announces-indictment-rochester-doctor-manslaughter-opioids.

Attorney General James Continues Fight to Maintain Safe Access to Reproductive Health Care During COVID-19 Pandemic—February 12, 2021—AG James led a multistate coalition of 23 attorneys general in filing an amicus brief in support of the plaintiffs' request for a preliminary injunction in *American College of Obstetricians and Gynecologists et al. v. FDA et al.*, as they seek to ensure patients' safe access to medication abortions and miscarriage treatment via telehealth, all in an effort to minimize the risk of exposure to COVID-19. Prior to the COVID-19 global pandemic, the Food and Drug Administration (FDA) required patients to appear in-person in a clinical setting to receive a drug known as mifepristone for an early abortion. This requirement was halted via injunction last summer, allowing patients to receive the drug without risk of exposure to COVID-19. The coalition seeks to extend these protections while COVID-19 continues to be a threat to patient health, and argued that the drug should be readily accessible via telehealth and mail delivery, so as to not potentially expose patients to COVID-19 by requiring unnecessary travel. https://ag.ny.gov/press-release/2021/attorney-general-james-continues-fight-maintain-safe-access-reproductive-health.

Attorney General James Files Lawsuit to End Harassment of Women Entering Manhattan Planned Parenthood Health Center—February 9, 2021—AG James filed a federal lawsuit against two anti-choice protesters, which alleged repeated violations of federal, state, and local clinic access laws stemming from obstructive and violent actions against patients, escorts, and health center staff at a Planned Parenthood location in New York City. The two protestors were charged with blocking access to Planned Parenthood of Greater New York's Manhattan Health Center, threatening those entering with violence, and other intimidating and disruptive behavior that allegedly presented a direct risk to the health and safety of patients and staff. The lawsuit also alleges that during the first peak of the COVID-19 pandemic in New York City, these individuals weaponized the threat of the virus to further intimidate

and interfere with the local Planned Parenthood's operations. The claims were brought under the federal Freedom of Access to Clinic Entrances Act, the New York State Clinic Access Act, and the New York City Access to Reproductive Health Care Facilities Act, all of which prohibit obstructing access to reproductive health clinics. https://ag.ny.gov/press-release/2021/attorney-general-james-files-lawsuit-end-harassment-women-entering-manhattan.

New York State Office of the Medicaid Inspector General Update

Compiled by Dena M. DeFazio

UPDATE: Queens Pharmacy Owner Sentenced to Three-Year Prison Term for Health Care Fraud and Illegal Opioid Distribution—May 27, 2021—https://omig.ny.gov/news/2021/update-queens-pharmacy-owner-sentenced-three-year-prison-term-health-care-fraud-and.

OMIG's Investigative Efforts Help Lead to Arrest and Indictment of NYC Pharmacy Owner—March 17, 2021—https://omig.ny.gov/news/2021/omigs-investigative-efforts-help-lead-arrest-and-indictment-nyc-pharmacy-owner.

Endnotes

1. Please note that these decisions are summarized after they are posted on the Department of Health's website, which is often many months after the date of the decision.
2. The editor wishes to thank Barclay Damon LLP summer associates, Kaitlynn Chopra and Theresa Oliver, who assisted in the summaries of these press releases.

PUBLICATIONS

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Editors:
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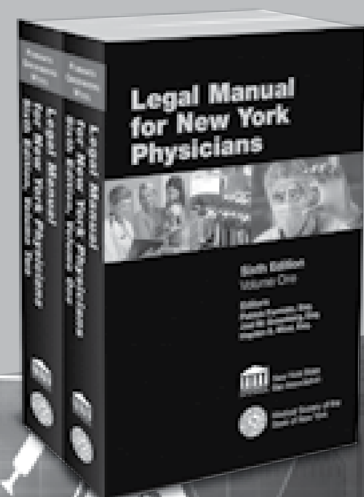

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By Cassandra DiNova

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Cassandra DiNova is an associate attorney of Rivkin Radler LLP, part of their Health Services Group.

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For Your Information

By Claudia O. Torrey

Summer 2021 will be in our collective "rear-view mirror" by the time this issue is published; trusting the readership enjoyed a safe and pleasant Fourth of July holiday, with best wishes that the rest of your summer was peaceful! The following items may be of interest:

1) On June 26, 2021, New York State Attorney General Letitia James announced[1] an agreement with Johnson & Johnson (J&J) regarding the sale and production of opioids; the parent company of Janssen Pharmaceuticals, the agreement promises to deliver up to $230 million to New York State. The agreement requires J&J to potentially pay $30 million more in the first year if the New York State "powers at be" can get an opioid settlement fund signed into law. The agreement also bars J&J and all its subsidiaries, successors, and predecessors from manufacturing or selling opioids in New York State, with acknowledgement by J&J to exit the national opioid business.

   Around July 7, 2021, 15 states (including New York) reached an agreement[2] with Purdue Pharma ("Purdue"), maker of the prescription painkiller OxyContin—cradle of the opioid crisis. The states dropped their collective opposition to Purdue's bankruptcy reorganization plan, and the Sackler family, owners of Purdue, is slated to release many documents and pay dearly. Sackler payment is not only monetarily, but they are also forbidden to seek naming rights to such entities as museums and hospitals. Time will tell how this all "shakes" out!

2) In the previous *Health Law Journal*,[3] I mentioned the scientific technological tool for editing genes known as CRISPR-Cas9.[4] This author noted that such a tool may prove enlightening for COVID-19, as well as for other medical abnormalities.[5] It has recently come to light that there has been an international group of scientists busily working on this potential advancement.[6] The group comprises scientists from Iran, Portugal, Poland, the United States, Ukraine, Azerbaijan, and Turkey.*

3) All "humor aside," the traditional toilet as we know it is a potential public health concern! In the book *Pipe Dreams: The Urgent Global Quest to Transform the Toilet*, author Chelsea Ward (an award-winning science journalist) asserts that about two billion people in the world lack access to proper sanitation situations. Toilets and other waste water treatment concerns consume a lot of water and energy while flushing away components that might make fuel and fertilizer. According to Ms. Ward, the toilet, as well as other tools Americans rely on to remove/process bodily waste, is not available to many people across the globe. Thus, we end up with "massive infrastructure requiring upfront investment, large operating costs, constant electricity, and expertise—not a particularly appropriate reality for many cities and towns in the world.

Endnotes

1. www.ag.ny.gov/press-release/June 26, 2021.
2. Jan Hoffman, *15 States Reach a Deal With Purdue Pharma Advancing a $4.5 Billion Opioids Settlement*, www.nytimes.com/Jan-Hoffman/July 10, 2021.
3. Claudia O. Torrey, *For Your Information*, New York State Bar Association Health Law Journal, 2021, Vol. 26, No. 2, p. 31.
4. www.livescience.com/AparnaVidyasgar/April 21, 2018.
5. *Supra* note 3.
6. www.americanchemicalsociety.com/10.1021/acssensors.0c02312.

*An interesting sidenote, the 2021 Scripps National Spelling Bee Champion, 14-year old Zaila Avant-garde, is very interested in CRISPR and gene editing (among her many talents).

Claudia O. Torrey is a charter member of the Health Law Section.

Legal Issues in Operating a Med-Spa in New York State

By Andrew M. Knoll

Introduction

Med-spas have garnered significant interest among physicians in recent years. It is an opportunity to earn extra money outside of the constraints of third-party payers, as well as performing a service that can be enjoyable and satisfying.

There is no legal definition of a med-spa. It is commonly thought of as a cosmetic practice that provides treatments typically offered at lay spas (e.g., skin peels) as well as those treatments that are medical procedures (e.g., Botox and fillers).

Offering Spa Services in a Medical Practice

The practice of medicine is broadly defined in New York. It is defined as "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition."[1] Accordingly, many cosmetic and aesthetic treatments that do not require a professional license[2] could still come within the definition of medicine as treating a "deformity or physical condition."[3] A physician can certainly incorporate a med-spa-type practice in her office and hire non-typical employees such as aestheticians to perform treatments within their scope of practice (e.g., laser hair removal).[4] There are two important caveats if a physician is considering opening a med-spa within his or her practice. First, if not a dermatologist or plastic surgeon, consult with your malpractice insurance carrier to ensure coverage. Typically the carrier will require documentation of training but then will underwrite the practice. Second, treat the encounter as a medical encounter even if it is not and write a medical progress note. Regulators such as the Office of Professional Medical Conduct (OPMC) will likely not waive the requirement "to maintain a record for each patient which accurately reflects the evaluation and treat-

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The author wishes to thank Bruce Wood, Esq. for reviewing the manuscript and making helpful comments.

ment of the patient"[5] even if the treatment is one that is legally permissible to be performed by a layperson.

Ironically, NYSED will not authorize a professional entity such as a P.C. or PLLC to be formed with the words "Med Spa" included in the name.[6] A search of the Department of State website revealed 55 active entities using the name "Med Spa" (or similar), all of which are business entities[7] which, as discussed below, would not be authorized to perform medical procedures.

Scope of Practice Issues

Just because the spa services are being offered within a medical practice does not mean the physician can delegate any procedure to anyone. Medical spa services all fall within the scope of practice of a physician, nurse practitioner (N.P.) and a physician assistant (P.A.). Of note with regard to a P.A., the supervising physician must also be qualified and competent to perform the procedure.[8] This issue is important because it is professional misconduct to either (1) permit, aid or abet "an unlicensed person to perform activities requiring a license" or (2) delegate "professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified, by training, by experience, or by licensure, to perform them."[9]

A common question I am asked is what is the scope of practice for a nurse—either a registered nurse (R.N.) or licensed practical nurse (L.P.N.)—in performing med-spa-type services. The general rule, with minor exception, is that nurses execute patient-specific orders issued from a physician, N.P. or P.A. The ordering provider must first examine the patient; i.e., there cannot be so-called "standing orders," more formally known as non-patient specific orders. Following such an examination and order, the Nursing Board has stated that these services fall within a nurse's scope of practice:

> (1) Light treatments, such as topical photodynamic Therapy (PDT); infrared light; magenta light; UVB light and UVS light; (2) Skin Peels/Removal of the superficial dermal layer . . .; (3) Non-ablative lasers (intense pulsed light, long pulsed dye laser, sclerotherapy for telangiectasia, laser hair removal or tattoo removal and non-invasive radio frequency procedures); and (4) Injections (using FDA approved products) such as Botox, absorbable dermal fillers and sclerotherapy of superficial veins.[10]

The Nursing Board further stated that micro-needling and PDO threading were not within the R.N.'s scope of practice[11] and that any procedures performed by an L.P.N. needs the personal supervision (i.e., in direct line of sight during the procedure) of the ordering provider or the R.N.[12]

Aestheticians are licensed by the Department of State, not the Education Department.[13] The practice of aesthetics is defined as:

> providing for a fee, or any consideration or exchange, whether direct or indirect, services to enhance the appearance of the face, neck, arms, legs, and shoulders of a human being by the use of compounds or procedures including makeup, eyelashes, depilatories, tonics, lotions, waxes, sanding and tweezing, whether performed by manual, mechanical, chemical or electrical means and instruments but shall not include the practice of electrology.[14]

Their regulations expressly state that an aesthetician cannot practice medicine or nursing.[15] Furthermore, an aesthetic practice (i.e., a spa owned by a business entity) cannot "permit the practice of medicine [or nursing] at its business location without appropriate licensure therefor."[16] Appropriate licensure would be either: (a) the medical practice being entirely separate and simply leasing space and services from the spa, or (b) authorization as an Article 28 facility. Clearly, no spa owned by a business entity would go through the considerable expense of NYSDOH Certificate of Need (CON) approval. The regulation, however, does not prohibit (and does not apply to) an aesthetician performing services under the direct supervision of a physician or R.N. "when performed within the direct employ of and on the premises of a medical facility."[17] When read as a whole, an aesthetician can be employed by a physician and perform procedures in the physician's office, but such procedures cannot be those that require either a medical or nursing license.

From NYSED's perspective, an aesthetician would be an unlicensed person, no different from a medical assistant. The NYS Board for Medicine published guidance on the scope of practice of unlicensed persons, including medical assistants, originally in April 2010 and updated in December 2019.[18] The guidance lists non-exhaustive examples of permitted and prohibited tasks. In general, an unlicensed person cannot perform any task that (1) requires medical judgment or decision making; (2) is invasive;[19] or (3) administers medication by any route.

The question, of course, is what this means in practical terms given the prevalence of med-spas where both medical and non-medical procedures are performed. While New York has not explicitly given guidance in this area, other states have, and have used the stratum corneum layer of the skin as the defining boundary between medical and non-medical procedures; i.e., an aesthetician cannot perform a procedure that goes deeper than the stratum corneum.[20] Accordingly, in the absence of express guidance, it is, in my opinion, both reasonable and defensible to use this boundary as delineating the scope of practice of an aesthetician in New York. This would permit treatments such as superficial chemical peels,[21] but not micro-needling.

In summary, a professional entity such as a P.C. or PLLC may provide med-spa services performed by individuals within their scope of practice. Delegating services to individuals who are not licensed to perform such services is professional misconduct in New York.

Prohibition Against the Corporate Practice of Medicine

Further problems arise where a business owned by an aesthetician seeks to hire a so-called "medical director" and perform medical procedures within its business. This violates the Corporate Practice of Medicine doctrine (CPOM) and would also constitute impermissible fee splitting.[22]

CPOM is a common law doctrine based on the Education Law statutes and regulations that prohibit a layperson from owning or controlling a medical practice.[23] More accurately it should be called the Corporate Practice of the Professions, as it applies to all professional licensees and would be applicable with any licensed professional, including a nurse practitioner.

While violating CPOM is unlawful, its violation is not professional misconduct per se. However, the sharing of money that is naturally inherent in such a relationship is. Education Law § 6530(19) makes it professional misconduct to permit laypersons to share in the fees for professional services. The statute goes on to state: "This prohibition shall include any arrangement or agreement whereby the amount received in payment for furnishing space, facilities, equipment or personnel services used by a licensee constitutes a percentage of, or is otherwise dependent upon, the income or receipts of the licensee from such practice[.]" Thus if the medical director is paid a percentage of collections on medical treatments such as Botox, for example, 45%, that is no different than if the medical practice paid the business entity 55% of its collections and would violate the statute.

NYSED has provided guidance on its website regarding CPOM.[24] Specifically, a business entity, such as a spa owned by an aesthetician, is prohibited from "provid[ing] professional services to the public; exercis[ing] any judgment over the delivery of professional services; hav[ing] employees who offer professional services to the public; hold[ing] itself out as offering professional services; or shar[ing] profits or split fees with licensed professionals."[25] It may provide non-professional services, such as management and support services, provided that it does not violate any of the prohibitions above.[26]

PC/MSO Model

A business setup that would comply with CPOM and is in common practice could be based on the professional corporation/medical services organization (PC/MSO) model.[27] In the PC/MSO model, the MSO, which may be owned by laypersons, provides business services, such as space, support services, administrative services, billing, lay employees, etc. to the P.C. The P.C. hires the licensed professionals and provides the medical services.

Consider the following hypothetical. Aesthetics, LLC ("Aesthetics") wants to offer med-spa services. It cannot simply hire a medical director and give Botox under its corporate umbrella so it contracts with John Doe, M.D., P.C. (PC). PC intends to use an N.P. to perform the medical services. The parties enter into a written Space Use and Support Services Agreement whereby, for a fair market fee, PC will utilize the space and administrative assistance of Aesthetics. This fee will not be based on the profits or a percentage of collections of PC. There will be signage and statements on Aesthetics literature and website that all medical procedures are performed by the PC.

Assume a client/patient ("client") comes to Aesthetics and asks for laser hair removal (non-medical), a superficial chemical peel (non-medical), and Botox (medical). Aesthetics' aestheticians perform the laser hair removal and chemical peel. PC's N.P. injects the Botox. Best practice would be to generate two separate bills but I believe (albeit it has never been tested) that Aesthetics could offer one bill as a convenience to client and collect the entire fee so long as it acts as a pass-through for PC and disburses the money without any markup or administrative fee. In that case, the money needs to be scrupulously accounted for in order to demonstrate to regulators there is no fee splitting. It should not be treated as a credit and offset against the MSO fees. For example, if client's total bill is $2,000 and the Botox was $600, Aesthetics would collect the $2,000, there would be an invoice from PC to Aesthetics for $600 and either a check or electronic transfer from Aesthetics to PC showing payment of the $600. As I stated above, this model has not been tested but is, in my opinion, legally defensible. This is also an oversimplification of the arrangement. An individual wishing to enter into such an arrangement should consult counsel because, as the old saying goes, the devil is in the details. This is none truer than in the highly regulated world of health care.

Enforcement Actions

As stated above, failure to properly structure the arrangement or delegating procedures to individuals outside their scope of practice can be professional misconduct. On April 13, 2021, Dr. Ann Marie Harman was disciplined by the Board for Professional Medical Conduct (BPMC) for doing just that.[28]

Dr. Harman was disciplined "on referral" from the Virginia Board of Medicine (VBOM) because it is professional misconduct in New York to have been disciplined by a sister state.[29] However, the basis for the discipline also has to be a predicate for discipline in New York. In this case the equivalent to the Virginia misconduct statute was permitting, aiding, or abetting an unlicensed person to perform activities requiring a license in violation of Education Law § 6530(11).[30] In cases resolved by Consent Order and Agreement (COA), as was done in that case, the facts in the

BPMC COA are scant but more detail can be seen in the underlying Virginia Consent Order.[31]

The VBOM alleged that Dr. Harman wrote "standing orders" for an R.N. to assess patients, determine the procedures to be performed, inject Botox and fillers, and perform follow up assessments.[32] Dr. Harman had minimal personal involvement with the med-spa but was appointed its medical director and paid $1,000 per month.[33] Dr. Harmon admitted to professional misconduct, was reprimanded and assessed a fine.[34]

As of the date that this article was written, BPMC has not initiated direct published disciplinary action against any physicians in New York for impermissible delegation or fee splitting in the operation of a med-spa. However, in my private discussions with senior OPMC personnel I have been told that med-spas are an area of concern and, in my professional opinion, it is only a matter of time before a med-spa operating in New York is directly investigated and subsequently prosecuted for professional misconduct for violating the rules discussed above as occurred in the Dr. Harman case in Virginia.

Conclusion

Involvement with or operating a med-spa in New York implicates a number of regulatory issues for health care professionals, including scope of practice rules, CPOM prohibitions, and illegal fee splitting. A licensed professional who violates these rules is at risk of professional discipline. A physician, P.A., or N.P. who wishes to establish a med-spa or is offered a position as a so-called medical director of an aesthetic practice should consult experienced health care counsel before entering into such an arrangement.

Endnotes

1. Education Law § 6521.
2. In this article "professional license" will refer to a license issued by the State Education Department (NYSED) pursuant to Title VIII of the Education Law. Aestheticians and cosmetologists are licensed, but their licenses are issued by the Department of State. *See* G.B.L. § 401(1).
3. For example, a person desiring laser hair removal arguably suffers from hirsutism, ICD-10 Diagnosis Code L68.0.
4. Interestingly, laser hair removal is within an aesthetician's scope of practice because it is within anybody's scope of practice. It is entirely unregulated in New York. Bills have been offered to regulate laser hair removal as an aesthetic practice, but have not been enacted. *See e.g.*, 2017 Senate Bill 6088, seeking to amend G.B.L § 400 to include laser hair removal as a regulated practice within the scope of esthetics.
5. Education Law § 6530(32). The exception would be if the aesthetic practice is entirely separate from the medical practice. There it could be argued that the aesthetic practice is not within OPMC's jurisdiction. Legal separation is required and physical separation is recommended. This is a complicated issue so consultation with knowledgeable legal counsel is recommended.
6. Email, NYSED @ OPCORP@nysed.gov., dated June 23, 2021 (on file with the author).
7. N.Y. Department of State, Division of Corporations, Entity Search, https://apps.dos.ny.gov/publicInquiry/EntityListDisplay (last accessed June 23, 2021).
8. *See* Education Law § 6542(1) ("a physician assistant may perform medical services, but only when under the supervision of a physician and only when such acts and duties as are assigned to him or her ***are within the scope of practice of such supervising physician***.") (emphasis added). While a physician's legal scope of practice, as defined in the statute, is broad, OPMC takes the position that the physician must be competent to perform the procedure that he or she supervises. *See* 8 N.Y.C.R.R. § 29.1(b)(9) (which makes it professional misconduct by "performing professional responsibilities which the licensee knows or has reason to know that he or she is not competent to perform").
9. Education Law § 6530(11), (25). While the phrase is disjunctive, OPMC interprets the statute to mean that training and experience is not sufficient competency for responsibilities that require licensure.
10. Email, N.Y. Nursing Board at NURSEBD@nysed.gov, dated July 25, 2019 (on file with the author).
11. *Id.*
12. Email, N.Y. Nursing Board at NURSEBD@nysed.gov, dated April 27, 2017 (on file with the author). Functionally, this substantially limits the cost effectiveness of utilizing L.P.N.s in a Med-Spa.
13. G.B.L. § 401(1). N.Y. uses the term "esthetician" rather than the more commonly seen "aesthetician," which will be used in this article.
14. G.B.L. § 400(6).
15. 19 N.Y.C.R.R. § 160.27(c), (d).
16. *Id.*
17. § 160.27(f).
18. NYSED Office of the Professions, *Utilization of Medical Assistants*, http://www.op.nysed.gov/prof/med/medmedicalassistants.htm (last accessed June 18, 2021).
19. *Id.* There is an exception to the prohibition against invasive procedures for phlebotomy, but that would not be applicable here.
20. *See e.g.*, 225 ILCS 410/3A-1 (defining esthetics as treatments limited to the stratum corneum); D.C. Code § 3-1201.02(7)(A)(iv) (providing that any procedure deeper than the stratum corneum is within the scope of practice of medicine); S.D. Codified Laws § 36-15-2.2(1) (providing that the practice of esthetics is limited to non-invasive skin procedures and defining non-invasive to be confined to the non-living cells of the stratum corneum).
21. For example, Connecticut defines a chemical peel that utilizes a chemical agent that exceeds 30% concentration and has a pH lower than 3.0 as an invasive medical procedure. Conn. Gen. Stat. § 19a-903c(a)(2).
22. *See* Education Law § 6530(19).
23. *See, e.g., United Calendar Mfg. Corp. v. Huang*, 94 A.D.2d 176, 180 (2d Dep't 1983); *State v. Abortion Information Agency, Inc.*, 69 Misc. 2d 825, 828-29 (Sup. Ct. N.Y. Co. 1971).
24. NYSED Office of the Professions, Corporate Entities, "Introduction," http://www.op.nysed.gov/corp/# (last accessed June 18, 2021).
25. *Id.*
26. *See id.*
27. "PC" refers to a professional corporation, but could be a PLLC. "MSO" means Management Services Organization or Medical Services Organization and is the management company.
28. *In re Ann Marie Harman, M.D.*, https://apps.health.ny.gov/pubdoh/professionals/doctors/conduct/factions/PhysicianDetailsAction.action?finalActionId=13048 (last accessed June 18, 2021).
29. Education Law § 6530(9)(d).
30. *See* endnote 28, *supra.*
31. Available at http://www.dhp.virginia.gov/Notices/Medicine/0101045774/0101045774Order09242020.pdf (last accessed June 18, 2021).
32. *Id.* at ¶ 2.a.
33. *Id.* at ¶ 4.
34. *Id.* at ¶ 2, Order ¶¶ 1, 2.

REPORT

The New York State Bar Association Emergency Task Force on Mandatory Vaccination and Safeguarding the Public's Health

Report approved by the New York State Bar Association's Executive Committee on August 27, 2021

The New York State Bar Association (NYSBA) Emergency Task Force on Mandatory Vaccination and Safeguarding the Public's Health ("Task Force") provides below an Executive Summary of the Task Force's Recommendations for purposes of facilitating the Executive Committee's review and discussion of such recommendations at the Executive Committee meeting scheduled for tomorrow. The Resolutions adopted by the NYSBA House of Delegates on November 20, 2020 are also attached hereto for your ease of reference.

Please also note the following minor revisions to the Report:

- The Public Employers section of the Report has been revised to reflect Mayor de Blasio's reversal of his previous "vaccinate-or-test" requirement for New York City educators and new requirement that all New York City educators be vaccinated (*See* page 48).
- The recommendation on access to vaccination for immigrants in civil immigration detention in New York has been collapsed into one recommendation for purposes of parsimony and clarification (*See* page 49).

Executive Summary

1. **NYSBA urges all NYSBA members** to be fully vaccinated against COVID-19. In fact, NYSBA urges all lawyers to be fully vaccinated. NYSBA calls on every bar association within the State and nation to urge their members to be fully vaccinated.
2. **NYSBA urges all employers** to require that their employees be fully vaccinated subject to medical exemptions or other recognized exceptions under applicable law. In this regard, NYSBA also urges all employers that have the capabilities to provide vaccines on-site, and to provide paid time-off for any employee who may suffer from temporary side-effects in the days post-vaccine. NYSBA is now requiring all its employees to be vaccinated as outlined below and urges all law firms to do the same.
3. **NYSBA recognizes the herculean efforts of health care workers thus far.** We have heard the calls from health care workers that New Yorkers and all Americans take steps to stop the spread of COVID-19. Health care workers must lead. Health care workers must be vaccinated. NYSBA endorses the State Department of Health Order and the NYS Public Health and Health Planning Coun-

cil emergency regulations requiring that the health care workers and personnel of all hospital, nursing home and other covered entities be vaccinated. NYSBA calls upon health care employers not covered by the DOH Order and emergency regulations to require that their patient-facing workforces be fully vaccinated against the vaccine. NYSBA also calls upon health care professional associations to urge that their members be fully vaccinated their members be fully vaccinated.

4. **NYSBA recommends to the State Legislature, State Government officials and departments/offices:**

   A. **Recommend** that actions, which were approved by the NYSBA House of Delegates on November 20, 2020 (attached hereto), be taken unless already implemented, including Public Health Legal Reforms and Legal Reforms in Care Provision, Congregate and Home Care, Workforce and Schools; and further that COVID Vaccine and Virus Testing Legal Reforms and Guidelines be fully implemented.

   B. **Recommend to the Honorable Kathleen M. Hochul as Governor and/or local governments:**

   Mandate that: (1) all state and local employees be masked during work hours when in the presence of others, (2) the Office of General Services require that only vaccinated (unless exempted and regularly tested) and masked individuals should be allowed to provide services under state contracts, and (3) each State Department and Office prepare a plan for fostering vaccination and masking in connection with regulation of the activities for which they are responsible;

   Encourage businesses as permitted by law to require all individuals as a condition of entry and presence on their property: (1) either proof of vaccination or the results of a test within the past 24 hours showing that the individual is COVID-free and (2) the wearing of a mask.

   C. **Recommend to the Department of Corrections** that immediate access to vaccination be provided in all correctional settings, as well as public health protections including masking and testing.

   Recommend to state, county, municipal or unit of local government, or officer, employee or agent of government that immediate access to vaccination be provided to all immigrants being held in civil immigration detention in New York, including pregnant women, and require that such access to vaccination be a condition of any contract with private contractors operating detention facilities in New York; or take steps necessary to terminate or not renew immigration detention agreements with U.S. Immigration and Customs Enforcement in New York State or its private contractors for purposes of civil immigration detention, and ensure all persons currently detained under such agreements have immediate access to vaccination and all other public health protections.

   Recommend to the Commissioner/Department of Education, to require that all individuals applying or reapplying for a license under the Education Law, to provide proof of vaccination unless the individual provides documentation acceptable to the Department that he or she is an exempted individual. The good faith of the Department in making that determination should be presumed. The licensees would include without limitation physicians, physician assistants, surgical assistants, pharmacists, nurses and nurse practitioner, midwives, psychologists, social workers, mental health practitioners, respiratory therapists, respiratory therapy technicians, and clinical laboratory technologists, and for the DOE to recommend to school boards that school employees be vaccinated and at all times while on school property, be masked: and **Recommend to Department of State and Department of Financial Services** the same vaccination requirement for any occupational license.

   Recommend to the Department of Motor Vehicles, to work with the Department of Health and each county to make vaccines available at each DMV location. In much of the state, DMV registration takes place at County Clerk offices.

5. **NYSBA urges that higher education institutions** require that their students and workforces be fully vaccinated.

6. **NYSBA recognizes the legitimate calls of teachers for safe teaching environments in schools.** NYSBA also recognizes the need for children to return safely to schools. As a part of those safe teaching environments, NYSBA calls upon all teachers, aides, support staff and schools administrators to be fully vaccinated. NYSBA also calls upon the State Legislature to require COVID-19 vaccination for elementary school-age children when a vaccine becomes available and is approved by regulators and public health authorities.

   NYSBA recommends to educational institutions, to: (1) require vaccination as a condition of teaching, registration as a middle or high school or college student or volunteer except in those cases where the teacher or student provides documentation convincing to the educational institution that he or she is an exempted individual and in that case require regular testing no less than weekly; and (2) require each teacher, student and volunteer to wear a face covering or mask acceptable to the educational institution over the individual's nose and mouth for the entire time that the individual is on the education institution's premises or conducting business on behalf of the educational institution.

7. **NYSBA recommends that businesses require proof of vaccination or negative test in last 24 hours for entry.**

8. **<u>NYSBA concludes that the law permits all these steps.</u>**
9. **<u>NYSBA calls for a strong, multi-faceted campaign to encourage vaccine acceptance, using people, places and message likely to be effective.</u>**

Final Report

Emergency Task Force on Mandatory Vaccination and Safeguarding the Public's Health

I. Introduction

The New York State Bar Association Emergency Task Force on Mandatory Vaccination and Safeguarding Public Health ("Task Force"), appointed end of July 2021 by New York State Bar Association (NYSBA) President T. Andrew Brown, builds on the considerable work done in 2020 and 2021 by NYSBA task forces appointed by bar leadership, including the 2020 Health Law Section COVID-19 Task Force[1] and the 2020 Long Term Care Task Force.[2] The establishment of the present Task Force responds to the ongoing Severe Acute Respiratory Syndrome Coronavirus 2 (a/k/a "COVID-19" or the "virus") or COVID-19 public health crisis unfolding in New York, heightened in recent weeks by the spread of the Delta variant and possibly other variants in the ensuing weeks and months. In keeping with the overall NYSBA mission to educate the public about the law and serve the public interest, the goals of the Task Force are to provide the most current information on legal and policy issues relevant to the public health threat in New York as guided by New York Law, and make policy recommendations that prioritize safeguarding the public's health consistent with scientific evidence. Central to these goals is advocating for equity and elimination of health disparities in the allocation and distribution of vaccines and access to immunization, building of community relationships and provision of community education to help address vaccine hesitancy and support uptake, and strengthening immunization and public health infrastructures.

II. Structural Contexts and Public Health Environment

It is important to understand the larger contexts of the COVID-19 experience in New York as a backdrop to consideration of the Task Force recommendations. First and foremost, the 2020-2021 COVID-19 pandemic and the threats it poses to the public's health have been driven by longstanding pre-existing structural inequities and well-documented health disparities across diverse populations. Such inequities and disparities have contributed to the disproportionate impact COVID-19 has had upon people of color, indigenous peoples, and vulnerable populations including nursing home residents and others who are institutionalized, and persons with co-morbidities and who are homeless or living with disabilities or serious mental illness.[3] Systemic racism and social and economic determinants of health such as educational attainment, income inequality, poverty, lack of insurance or underinsurance, housing and food insecurity, and neighborhood or place are among the varied contexts of which policymakers need to remain mindful in weighing policy options for mitigating vaccine hesitancy and increasing vaccine uptake. A history of exploitation of people of color and distrust of government, ideological polarization, and inflammatory debates about liberty and civil rights have influenced attitudes toward vaccination and the variable public understanding of science, public health and vaccine mandates. The emergence and recent spread of the Delta variant have compounded the threat to the public's health for both those who are unvaccinated and vaccinated who remain at risk. Finally, widespread distress from isolation and loneliness[4] has created an urgent need for mental health and psychosocial services even among those who have not been directly affected by the pandemic. The heightened individual and collective trauma experienced in the pandemic environment calls for expansion of trauma-informed care. For example, in some cases nursing home residents have experienced the trauma and detrimentality of long-term isolation as a result of state policies restricting visitation. Such policies may have also violated nursing home residents' human rights.

Advancing Equity and Eliminating Health Disparities

Social and economic determinants of health, pre-existing inequities, and racial and ethnic disparities have created enormous challenges in the current pandemic environment. An important part of the policy process in developing recommendations for COVID-19 vaccination in the face of an ongoing serious threat to the public's health is understanding how such inequities and disparities influence attitudes toward and access to vaccination. The problem of access is also a complex structural one and calls for systems-level changes including strengthening immunization and public health infrastructures at all levels of government.[5]

The Centers for Disease Control (CDC) has created a site on *Health Equity and Promoting Fair Access to Health* that identifies the following factors influencing vaccine access and acceptance: Education, income and wealth inequalities; employment access and conditions; racism and other forms of discrimination; health care access inequities; transportation; neighborhood; and distrust resulting from past racist practices such as medical exploitation and experimentation.[6] Developing and implementing strategies for community outreach, including culturally appropriate education and identifying community champions, are essential to advancing equitable access to vaccination and eliminating health disparities in the contexts of the pandemic, and go hand-in-hand with vaccination mandates. Writing in *Health Affairs*, Moucheraud, Guo and Macinko (2021) conclude, "The interconnectedness of trust in institutions and associations with vaccine attitudes should be considered carefully in the context of policy making and messaging, particularly during a pandemic" (p. 1222).[7] This overarching context of building trust is key to increasing vaccine access and acceptance contemporaneously with implementing vaccine mandates in New York.

III. Constitutional Landscape

American law protects the right of each individual to their own pursuit of a good life, to the extent that it does not unreasonably interfere with another's pursuit. The COVID-19 pandemic demonstrates the tension between promotion of individual rights and protection of common good. The U.S. Constitution enables us to tip the scale to protect public health, but only so far as necessary. The Fourteenth Amendment provides, ". . . No state shall make or enforce any law . . . nor shall any State deprive any person of life, liberty, or property without due process of the law . . . ."[8] The Due Process Clause protects the fundamental rights and substantive liberty interests of individuals from government interference.[9] The court will review *substantive* rights protected under the Due Process clause under the rational basis standard of review where the state must show a legitimate state interest that is reasonably related to the law.[10]

The United States Supreme Court has held that a person has a *substantive* liberty interest in refusing unwanted medical treatment.[11] However, this substantive right is not absolute nor fundamental—". . . the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint."[12] Because the substantive liberty interest in refusing unwanted medical treatment is not a fundamental right, the court will use the highly deferential rational basis standard of review for state infringement on said right.[13] If the state's regulations are "reasonable regulations established directly by legislative enactment as will protect the public health and the public safety," the infringement on individual liberty will be held constitutional.[14]

At the Constitution's ratification, the States did not relinquish their authority to enact "health laws of every description" under their broad police powers.[15] The States' police power has not been specifically defined, but it does have limitations.[16]

Here, states acting under their police powers have taken action to respond to the COVID-19 pandemic that has swept the globe. Measures, such as quarantining, mandatory masks, limiting the number of people who may congregate, and mandatory vaccinations for participation in school, the workplace, and other social activities have burdened coveted individual liberties protected by the Constitution, such as free speech, free exercise, right to travel, voting, and abortion.[17] The court has upheld said burdens on liberty because they are outweighed by the states' legitimate interest in protecting the welfare of its citizens and the community from the spread of the deadly COVID-19 virus.[18] Moreover, absent going beyond the police power where a law has no reasonable relation to the states' interest, a court will not second guess the decisions of the legislature based on experts and science.[19]

In *Jacobson*, the court upheld the Massachusetts law imposing *compulsory* vaccination without exception to prevent the spread of the smallpox virus.[20] Many states, employers, and universities are now imposing mandatory vaccination as a prerequisite for participation.[21] It follows that states' measures that are less restrictive than those in *Jacobson* are a constitutional exercise of their police powers.[22]

Religious Exemption

The circumstances with which the court has been most concerned regarding the states' protective measures as a valid exercise of their police powers is in the realm of the fundamental right of free exercise under the First Amendment. As a starting point, the Supreme Court has held, ". . . the right of free exercise does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)'".[23]

The court has only departed from the test of neutral and general applicability in circumstances where the law is, ". . . a religiously motivated action . . . in conjunction with other constitutional protections."[24] When a law falls short of neutrality and general applicability, the standard of review is strict scrutiny requiring the state to show "a compelling governmental interest and must be narrowly tailored to advance that interest" for the law to survive.[25]

The court has further explained, while states are free under the political process to afford religious accommodations to generally applicable regulations, it is not constitutionally required to provide such an exemption.[26] However, if the state does grant individual exceptions, but excludes a religious exemption, the court will review such action as not neutral and subject to strict scrutiny standard of review.[27]

In the present circumstances of the states' efforts to contain the spread of the COVID-19 virus, the right to free exercise, "does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death."[28] The courts, consistent with this precedent, have upheld regulations that are neutral and generally applicable while invalidating laws that have impermissibly targeted religious exercise.[29] Moreover, consistent with the legislative right to afford accommodations that are not constitutionally required, the court has upheld the legislative decision of New York to repeal an exemption from vaccination on religious grounds.[30]

Implications in Current Pandemic

Given the ongoing threat of COVID-19, particularly with new variants replicating, it is constitutional for the states to act under their police powers to take measures necessary to control the spread of the virus. In so doing, the states may constitutionally mandate vaccination for participation in social, educational, and employment contexts. As explained, states are free to carve out accommodations, such as religious or medical exemptions, but are not consti-

tutionally required.[31] State elected officials must protect the welfare of their citizens. These duties are carried out under the authority of state police powers. Unless it is shown that the states have stepped beyond their police powers, or have "impermissibly targeted" religion, such measures will be found constitutional.[32]

IV. Employer Mandates

Employers are permitted to require employees to be vaccinated for COVID-19 before physically entering the workplace or engaging in other client/customer/patient activities, with certain exceptions. The Equal Employment Opportunity Commission (EEOC) has blessed such a requirement, subject to the employer's compliance with the reasonable accommodation provisions of Title VII and the Americans with Disabilities Act (ADA).[33] The Department of Justice, in a July memorandum, has similarly opined that a vaccination requirement as a condition of employment, even if such vaccine was approved under Emergency Use Authorization, is permissible. To date, the only federal court to decide this issue has agreed with the DOJ.[34] Likewise, a vaccination requirement as a condition of employment would not run afoul of any express prohibition under New York State Human Rights Law (NYSHRL), again subject to an employer's obligation to engage in a reasonable accommodation analysis.[35]

In most cases, unionized private employers cannot unilaterally implement a vaccination requirement as such a requirement would be a mandatory subject of bargaining with the union.[36] If an employer has a broad management rights clause or other specific grant of authority within its collective bargaining agreement, it might be able to implement without the union's consent, but this would be a rare case. An employer could implement such a requirement if it reached a bargaining impasse with the union (even without the union's agreement), but implementation at impasse brings on a host of practical and legal obstacles. Weekly COVID-19 testing requirements would be subject to the same analysis and, in most cases, not permitted without notice and bargaining.[37]

In order to comply with state and federal law, an employer imposing a vaccination requirement as a term of employment is obligated to reasonably accommodate an employee who is unable to receive the vaccine because of a disability or a sincerely-held religious belief. Under the NYSHRL (which is slightly broader in its definition than Title VII), a disability is defined as "a physical, mental or medical impairment resulting from anatomical, physiological, genetic or neurological conditions which prevents the exercise of a normal bodily function or is demonstrable by medically accepted clinical or laboratory diagnostic techniques."[38] In virtually all cases, documentation from a health care provider that an employee is unable to receive the vaccine because of a medical condition will qualify as a disability. This would include medical conditions that are pregnancy-related, although pregnancy itself is not considered a disability under the ADA[39] and recent CDC guidance urges that pregnant women receive the vaccine.[40] Regarding requests for religious accommodation, the EEOC has advised employers that they "should ordinarily assume that an employee's request for religious accommodation is based on a sincerely-held religious belief."[41] However, if an employer has some objective basis for questioning the sincerity or the practice, it may request additional supporting information, such as written material describing the belief, the employee's explanation of his or her religious belief, or statements/documents from third-parties, including a religious leader, about the employee's beliefs or practices.[42] Without more, an employee's reluctance, non-religious objection to a vaccination, or medical opinion that a vaccine is not necessary would not entitle an employee to a reasonable accommodation.

Under state and federal law, employers must offer accommodation to those with a medical/disability or religious exemption if it does not pose an undue hardship to the employer or pose a direct threat to the health and safety of others in the workplace. In New York, undue hardship is defined as "an accommodation requiring significant expense or difficulty (including a significant interference with the safe or efficient operation of the workplace or a violation of a bona fide seniority system)."[43] Examples of an accommodation might include requiring a mask, permitting entry only after a negative COVID-19 test, remote work, changing an employee's schedule, leave of absence, or any combination therein. However, the law does not require that an employer remove any essential function of an employee's job as an accommodation. If an employer determines that an employee cannot perform the essential functions remotely or cannot grant other accommodation without causing undue hardship, then an employer may place that employee on an unpaid leave until such time as the accommodation is possible or, if leave is not an option, terminate the employee.

Health Care Workers

Mandatory vaccinations for health care workers have long been the policy of health care organizations, which courts have consistently upheld. New York State requires that all persons who work at hospitals,[44] nursing homes,[45] diagnostic and treatment centers,[46] certified home health agencies and programs,[47] licensed home care services,[48] and hospices[49] be vaccinated against measles and rubella. New York State requires employees of health care facilities, including hospitals, diagnostic and treatment centers and hospices, to be vaccinated against influenza or wear a surgical or procedure mask during "flu season," i.e., when influenza is prevalent as determined by the New York State Commissioner of Health.[50] Employees and residents of long-term care facilities, adult homes, adult day health care facilities, and enriched housing programs must receive an influenza vaccination annually.[51]

In accordance with those precedents, on August 16th, 2021, the State Department of Health announced that all hospital and long-term care workers must be vaccinated by

September 27, 2021. On August 26, the NYS Public Health and Health Planning Council adopted emergency regulations requiring all health care workers and personnel of covered entities including hospitals, nursing homes, hospices and community-based health care programs and agencies to be fully vaccinated. The regulations allow certain medical exemptions but eliminate religious exemptions.

The policy and practice of mandatory vaccination for health care workers have withstood constitutional challenges in court. In 2016, for example, the Appellate Division in New York held that New York State had not exceeded its power and the regulation requiring health care workers to receive an influenza vaccination or wear a face mask was not "arbitrary or capricious, irrational or contrary to law.[52]

Universities and Schools

Courts have consistently recognized the "broad discretion of state power required for the protection of the public health"[53] to mandate vaccinations for elementary school students[54] and universities.[55] According to the National Conference of State Legislatures, all fifty states and the District of Columbia have laws requiring students to be vaccinated before attending school.[56] In New York State, for example, every student entering or attending public, private or parochial school must be vaccinated against diphtheria, tetanus, pertussis, measles, mumps, rubella, poliomyelitis, hepatitis B and varicella.[57] College, university and students attending post-secondary institutions in New York (registered for 6 or more credit hours) must demonstrate proof of immunity against measles, mumps and rubella subject to exemptions on medical and religious grounds.[58]

Exemptions from state-mandated vaccination vary from state to state: all fifty states allow for medical exemptions from school immunization requirements; 44 states and Washington D.C. grant religious exemptions; 15 states allow philosophical exemptions for children whose parents object to immunizations because of personal, moral or other beliefs; and there are currently no states that require children to receive COVID vaccination for school entry.[59] It should be noted that many states, including New York, align their vaccine requirements in accordance with recommendations from the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.[60] There are six states that do not allow non-medical (i.e. religious and philosophical/personal) exemptions to school mandated vaccinations: Maine, Connecticut, New York,[61] West Virginia, Mississippi and California.[62] Although New York State continues to provide medical exemptions for public school age students, the religious exemption was repealed in 2019[63] in response to a severe measles outbreak. A recent challenge to the repeal in the New York State Appellate Division by parents who, prior to the repeal, had been granted religious exemptions, was rejected.[64] In observing that "the sole purpose of the repeal is to make the vaccine requirement generally available to the public at large in order to achieve herd immunity", the court held that "given the significant public health concern, the repeal is supported by a rational basis and does not violate the Free Exercise Clause."[65] New York State law, however, continues to provide medical and religious exceptions to immunization mandates for students enrolled in colleges, universities and other post-secondary institutions.[66]

Klaassen v. The Trustees of Indiana University appears to be the first decision issued by a U.S. court regarding the constitutionality of a university's COVID-19 vaccine mandate policy. The District Court for Northern Indiana addressed the question of whether the University acted constitutionally in mandating the COVID-19 vaccine for its students, and the court upheld the University's mandate.

The decision responds to a preliminary injunction motion to prevent the implementation of the mandate, therefore it does not represent a final disposition of the case, but it may serve as an important bellwether for other colleges and universities seeking to implement similar vaccine mandate policies.

The court acknowledged that Indiana University's policy has real implications. Specifically, students could be deprived of attending the university without being vaccinated or qualifying for an exemption. Eight students sued the University because of its vaccination mandate and because of the extra requirements of masking, testing, and social distancing that apply to those who receive an exemption. "They asked the court to enter a preliminary injunction – an extraordinary remedy that requires a strong showing that they will likely succeed on the merits of their claims, that they will sustain irreparable harm, and that the balance of harms and the public interest favor such a remedy."[67]

The court denied the students' motion, noting that students still had options with respect to the vaccine mandate, which applied for the Fall 2021 semester only. Students could choose to take the vaccine, apply for a religious exemption, apply for a medical exemption, apply for a medical deferral, take a semester off, or attend another university.

The court recognized the students' significant liberty to refuse unwanted medical treatment, however, the court held that the Fourteenth Amendment permits the University to implement a reasonable vaccination policy meeting due process requirements in the legitimate interest of public health for its students, faculty and staff.

Most recently, Justice Amy Coney Barrett denied students' challenge to Indiana University's vaccine mandate without comment.[68]

Public Employers

Although private employers generally have great latitude when deciding whether to implement vaccine mandates for employees, public employers have the additional consideration of the Taylor Law. The Taylor Law, officially entitled the Public Employees' Fair Employment Act, is codified as Article 14 of the Civil Service Law. Enacted in 1967, the Taylor Law governs labor relations between pub-

lic employers and public employees in New York State. The Taylor Law is administered by the Public Employment Relations Board (PERB).

As public employers, school districts and public universities in New York State have the duty to negotiate with certified or recognized employee organizations (labor unions) regarding mandatory subjects of bargaining. There is an open legal question as to whether a public employer's decision to require COVID-19 vaccination/testing is a mandatory subject of bargaining. There is little precedent from PERB regarding employee vaccinations generally, and it does not appear that we currently have any PERB decisions regarding the COVID-19 vaccine. Even if it is not a mandatory subject of bargaining, and vaccination/testing is something that can be unilaterally imposed by the employer, it is likely that the effects/impact of the employer's decision upon the union members must be negotiated. It must also be noted that medical exemptions and religious exemptions must be taken into account unless the employer is a covered entity subject to the emergency regulations recently adopted by the NYS Public Health and Health Planning Council mandating vaccination for all health care workers and personnel and eliminating religious exemptions.

V. Discussion of Strategies

Increasing the rate of vaccination will require a variety of actions. Vaccine resistance has arisen on multiple accounts: The speed with which the vaccines have been developed; a pre-existing anti-vaccine movement; politics; distrust of the medical establishment; a belief that "it can't happen to me;" and an uncompromising emphasis on personal liberty. To meet these varied rationales, responses must be a mix of carrots and sticks, as well as campaigns of education and persuasion. In addition, conversations with hard-to-reach communities in a spirit of cultural humility must continue through engagement with trusted community leaders.

The carrots thus far have taken a variety of forms. First and foremost is connecting vaccination to protection from the virus itself. For many, that has been enough. Others have responded to various minor incentives: lottery tickets, baseball tickets, movie passes. New York City Mayor DeBlasio has recently proposed $100 payments to those who complete a full vaccine regimen.[69]

Some responses are a mix of carrot and stick. The denial of the ability to travel across borders was a stick, and returning this ability through "vaccine passports"—proof of vaccination—is a carrot. This concept has been extended beyond travel to entertainment and public gathering forums including concerts and sports matches.

The sticks are extending to college attendance. The New York State University system has announced that fall attendance will require proof of vaccination. Many of the State's private universities have announced similar policies.[70]

In the face of the Delta variant, employers are beginning to require proof of vaccination. Employer mandates are supported by guidance from the U.S. EEOC and a recent U.S. Department of Justice advisory.[71] Both the State and City of New York have now announced requirements for full vaccination or a literal stick—weekly nasal swab testing. The Governor went further, announcing that all patient-facing State employees must be fully vaccinated. A number of private employers have made similar announcements.

Continued incentives and mandates must comply with state and federal law and be supported. Public accommodations—stores, restaurants, theaters, stadiums, etc.—should be encouraged to require proof of vaccination, and explicitly authorized to do so if necessary. Public and private employers, especially health care providers, also should be encouraged to require proof of vaccination, and explicitly authorized to do so.

For incentives and mandates to be most effective, hearts and minds must be changed to willingly accept vaccination. The experience of illness and death will alter the risk/reward calculation for some. Other minds may change through interaction with influencers. The influencers may be, or at least appear to be, apolitical, such as Olivio Rodrigo's outreach to young adults. Previous studies have demonstrated that respected celebrities and cultural icons have significant impact on public health behaviors and attitudes.[72] What could be accomplished if our cultural icons used the same level of expertise to influence vaccination acceptance that is used to sell car insurance or Tostitos?

Continued efforts must also be made through faith-based and other community groups. Priests, rabbis, imams and ministers must be enlisted with the same energy political candidates use when seeking election. The same is true for trusted community groups and leaders. As extensive as the efforts have been thus far, they have not yet been enough. Particular attention must be paid to Black, Latinx, and Indigenous communities, and their respective political leaders, faith-based leaders, medical and health and mental health professionals, athletes and entertainers all enlisted in the effort.

Political persuasion will be more difficult. There is no denying that COVID-19 has been made a political fault line. Nevertheless, some Republicans, including U.S. Senate Republican Leader Mitch McConnell, have publicly endorsed vaccination. As difficult as it may be, the President should take steps to induce Donald Trump to support vaccination. After all, it was Donald Trump who announced Operation Warp Speed.

Finally, vaccinations must be made physically accessible to those who are unvaccinated. Such efforts have been ongoing. They must continue and be well thought through. They should be tied to acceptance campaigns and in many cases will be local, such as setting up vaccination in a housing site or for outside a health club or concert. Employers can also establish on-site vaccination clinics for their employees.

In sum, there are many steps that can be taken, encouragement, incentives and requirements. The law is not an impediment to their success.

VI. Recommendations

The Task Force recommends a comprehensive and reinvigorated campaign to eradicate Severe Acute Respiratory Syndrome Coronavirus 2 in New York State. The primary way to accomplish the goal is to vaccinate as many people as possible. A companion approach is to require masking of all persons in any indoor venue. The urgent need for strong and decisive action continues. It is imperative that every government unit, business, educational institution, union, and community-based organization recommit as one, to wipe out the virus. Many entities in these constituencies have already implemented on their own creative and effective ways to encourage vaccination and to make the opportunity for vaccination more available.

The Task Force makes a number of recommendations including requiring vaccination for many groups of individuals. In cases where mandating vaccinations is recommended, the law provides there must be "reasonable accommodation" to exempt an individual who provides convincing and acceptable documentation that he or she should be exempted from a vaccine requirement because of either a medical condition or a sincerely held religious belief, practice, or observance (hereinafter "exempt individual"). We believe that in such cases, masking and testing (at minimum weekly) must be required.

Finally, the Task Force calls for priority attention to glaring inequities across diverse populations that have been heightened during the pandemic, including limited access to public health protections for certain groups and subgroups. For example, Miller and colleagues (2021) report in *Health Affairs* that, "Black people in the highest income group experienced an increase of mortality of more than 3.5 times larger than the increase in mortality experienced by the poorest White people" on account of the pandemic (p. 1253).[73]

Strategies for dismantling racism and other structural forces and social determinants of health that have contributed to growing inequities and health disparities, especially for people and communities of color, must be deployed in working with all governmental and non-governmental actors through trusted community leaders and champions. In such contexts, the Task Force recommends that government take immediate steps to make vaccination available to all immigrants, refugees and asylum seekers and their children and families, whether in the community or in detention facilities, and to all persons incarcerated in the State of New York.

1. **NYSBA urges all NYSBA members to be fully vaccinated against COVID-19. In fact, NYSBA urges all lawyers to be fully vaccinated. NYSBA calls on every bar association within the State and nation to urge their members to be fully vaccinated.**

   A. **Recommend to the NYSBA** that a Call to Action be issued to all the members of the Association to be vaccinated, and in turn to encourage their families, friends and colleagues to be vaccinated. This Call to Action is grounded upon the epistemic access of members of the state bar in their privileged position as attorneys in the State of New York *and the cultural humility which they bring to these conversations with other communities*. NYSBA's Call to Action also stands as a model of leadership for other professional communities who are in a position to serve as trusted ambassadors to their constituencies in these vaccination efforts and conversations.

2. **NYSBA urges all employers to require that their employees be fully vaccinated. In this regard, NYSBA also urges all employers that have the capabilities to provide vaccines on-site, and to provide paid time-off for any employee who may suffer from temporary side-effects in the days post-vaccine. NYSBA now requires all its employees to be vaccinated as outlined below, and urges all law firms to do the same.**

   A. **Recommend to employers** to require vaccination for current employees and applicants as a condition of employment when the employee's job requires work to be performed on the employer's premises or to conduct face-to-face business elsewhere on behalf of the employer, subject to medical exemptions and other recognized exceptions under applicable law (e.g., disability/medical- including in some cases, pregnancy- and sincerely held religious beliefs) and further subject to any collective-bargaining obligations. NYSBA will adopt this standard for its employees. NYSBA will urge all law firms to adopt this standard for all their employees.

3. **NYSBA recognizes the herculean efforts of health care workers thus far. We have heard the calls from health care workers that New Yorkers and all Americans take steps to stop the spread of COVID-19. Health care workers must lead. Health care workers must be vaccinated. NYSBA endorses the State Department of Health Order, and the NYS Public Health and Health Planning Council emergency regulations requiring health care workers and personnel of all hospital, nursing home and other covered entities be vaccinated subject to certain medical exemptions but eliminating religious exemptions. NYSBA calls upon health care employers not covered by the emergency regulations to require that their patient-facing workforces be fully vaccinated against the vaccine. NYSBA also calls upon health care professional associations to urge that their members be fully vaccinated.**

Recommend to the Commissioner/Department of Health as applicable;

Direct each county and NYC to develop and im-

plement by September 30th a plan for outreach to unvaccinated residents in their county, in order to encourage—such individuals to be vaccinated and such plans should be placed on the DOH website and include:

1. The particulars of assistance to individuals as to making an appointment and providing transportation for the individual to and from the vaccination site;
2. How vaccines would be made available to, and convenient for, the residents to obtain;
3. Initiatives to encourage vaccination by offering a financial benefit, similar to the NYC MTA's offering a free Metro card for vaccination; and
4. Include the community leaders, groups and organizations, such as schools, houses of worship and faith communities, day care centers, senior citizen centers, YWCAs and YMCAs, health clubs, homeless shelters, theatres or concert venues already enlisted or to be recruited to participate in the effort as Vaccine Champions and to make their locations available as sites for vaccination or to otherwise publicize the availability and location of where vaccines may be obtained.

4. **Recommend to the State Legislature, State Government officials and departments/offices:**

   A. **Recommend** that actions, which were approved by the NYSBA House of Delegates on November 20, 2020 (attached hereto), be taken unless already implemented, including Public Health Legal Reforms, Legal Reforms in Care Provision Congregate and Home Care, Workforce and Schools; and COVID Vaccine and Virus Testing Legal Reforms and Guidelines be fully implemented.

   B. **Recommend to the Honorable Kathleen M. Hochul that as Governor and/or local governments**, she: Mandate that: (1) all State and local employees be masked during work hours when in the presence of others, (2) the Office of General Services require that only vaccinated (unless exempted and regularly tested) and masked individuals should be allowed to provide services under State contracts, and (3) each State Department and Office should prepare a plan for fostering vaccination and masking in connection with regulation of the activities for which they are responsible;

   Encourage businesses to require of all individuals as a condition of entry and presence on their property: (1) either proof of vaccination or the results of a test within the past 24 hours showing that the individual is COVID-free and (2) the wearing of a mask.

   C. **Recommend to the Department of Corrections** that immediate access to vaccination be provided in all correctional settings, as well as public health protections including masking and testing.

   D. **Recommend to state, county, municipal or unit of local government, or officer, employee or agent of government** to that immediate access to vaccination be provided to all immigrants being held in civil immigration detention in New York, including pregnant women, and require that such access to vaccination be a condition of any contract with private contractors operating detention facilities in New York, or terminate or not renew immigration detention agreements with U.S. Immigration and Customs Enforcement in New York State or its private contractors for purposes of civil immigration detention, and take all necessary steps to ensure all persons currently detained under such agreements have immediate access to vaccination and all other public health protections.

   E. **Recommend to the Commissioner/Department of Education**, to require that all individuals applying or reapplying for a license under the Education Law, to provide proof of vaccination unless the individual provides documentation acceptable to the Department that he or she is an exempted individual. The good faith of the Department in making that determination should be presumed. The licensees would include without limitation physicians, physician assistants, surgical assistants, pharmacists, nurses and nurse practitioner, midwives, psychologists, social workers, mental health practitioners, respiratory therapists, respiratory therapy technicians, and clinical laboratory technologists, and for the DOE to recommend to school boards that school employees be vaccinated and at all times while on school property, be masked: and **Recommend to Department of State and Department of Financial Services** the same vaccination requirement for any occupational license.

   F. **Recommend to the Department of Motor Vehicles**, to work with the Department of Health and each county to make vaccines available at each DMV location. In much of the state, DMV registration takes place at County Clerk offices.

5. **NYSBA urges that higher education institutions require that their students and workforces be fully vaccinated.**

6. **NYSBA recognizes the legitimate calls of teachers for safe teaching environments in schools. NYSBA also recognizes the need for children to return safely to schools. As a part of those safe teaching environments, NYSBA calls upon all teachers, aides, support staff and schools administrators to be fully vaccinated. NYSBA also calls upon the State Legislature to require COVID-19 vaccination for elementary school-age children when a vaccine becomes available and is approved by regulators and public health authorities.**

   A. **Recommend to educational institutions**, to: (1) require vaccination as a condition of teaching, registra-

tion as a middle or high school or college student or volunteer except in those cases where the teacher or student provides documentation convincing to the educational institution that he or she is an exempted individual and in that case require regular testing no less than weekly; and (2) require each teacher, student and volunteer to wear a face covering or mask acceptable to the educational institution over the individual's nose and mouth for the entire time that the individual is on the education institution's premises or conducting business on behalf of the educational institution.

7. **Recommend that businesses require proof of vaccination or negative test in last 24 hours for entry.**

   A. **Recommend to businesses**, that, in order for an individual to enter onto and remain on the entity's premises, to require (1) proof either of vaccination or that the individual has been tested for the virus within the prior 24-hour period and found to be virus-free.

8. **NYSBA concludes that the law permits all these steps.**

9. **NYSBA calls for a strong, multi-faceted campaign to encourage vaccine acceptance, using people, places and message likely to be effective.**

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Endnotes

1. NYSBA Health Law Section Task Force. See Resolutions adopted by NYSBA House of Delegates in November 2020; 1-8: https://nysba.org/app/uploads/2021/01/health-Law-Resolutions-and-report-with-cover-approved-November-2020.pdf.
2. NYSBA Nursing Homes and Long Term Care Task Force. *See* Report adopted by House of Delegates in June 2021: https://nysba.org/app/uploads/2021/03/Task-Force-on-Nursing-Home-and-Long-Term-Care-Report-FINAL-approved-6.12.2021.pdf.
3. *Id.*
4. National Academies of Sciences, Engineering, and Medicine. 2020 *Social Isolation and Loneliness in Older Adults: Opportunities for Health Care System*. Washington, DC: The National Academies Press.
5. Shen, A. et al. Ensuring equitable access to COVID-19 vaccines in the US: Current system challenges and opportunities. *Health Affairs*, 40 (1), 62-69. doi: 10.1377/hlthaff.2020.01554.
6. *See* Centers for Disease Control. *Health Equity and Promoting Fair Access to Health.* https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/vaccine-equity.html.
7. Moucheraud, C., Huiying G, & Macinko, J. (2021). Trust in governments and health workers low globally, influencing attitudes toward heath information, vaccines. *Health Affairs*, 40(8), 1215-1224. doi: 10.1377/hlthaff.2020.02006
8. U.S. CONST. amend. XIV § 1.
9. *See Washington v. Glucksberg*, 521 U.S. 702, 720 (1997). The standard of review for a state's infringement on *fundamental* rights, "so rooted in the traditions and conscience of our people," is a heightened level of scrutiny. *See Washington v. Glucksberg*, 521 U.S. at 720 (*citing Snyder v. Massachusetts*, 291 U.S. 97, 105 (1934)); *see generally Loving v. Virginia*, 388 U.S. 1 (1967) (right to marry); *Skinner v. Oklahoma ex rel. Williamson*, 36 U.S. 535 (1942) (right to education and rear children); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (right to contraception); *Roe v. Wade*, 410 U.S. 113 (1973) (right to an abortion).
10. *See Jacobson v. Massachusetts*, 197 U.S. 11 (1904).
11. *See Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 278 (1990) (*citing Jacobson v. Massachusetts*, 197 U.S. 11, 24-30 (1904) ("the Court balanced the individual's liberty interest in declining an unwanted smallpox vaccination with the states interest in preventing disease").
12. *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1904); *Klassen v. Trs. Of Ind. Univ.*, 2021 U.S. LEXIS 22785 (*citing Washington v. Glucksberg*, 521 U.S. at 720-722 (the plaintiffs lack a fundamental liberty interest in refusing vaccination to participate in university education)).
13. *See Jacobson*, 197 U.S. 11.
14. *Id.* 197 U.S. at 25-26.
15. *Id.*
16. *See In Jew Ho v. Williamson*, 103 F. 10 (C.C.D. Cal. 1900) (the court struck down California's action of closing off an area of San Francisco to prevent the spread of the plague because such action was overbroad); *Ex parte Dillon*, 44 Cal. App. 239, 244 (Cal. Ct. App. 1919) (court struck down quarantine in Los Angeles for lack of a reasonable showing inhabitants were infected with a contagious disease).
17. *See Murphy v. Lamont*, 2020 WL 4435167 (D. Conn. Aug. 3, 2020) (upholding restriction on speech); *S. Bay United Pentecostal Church v. Newsom*, 140 S.Ct. (May 29, 2020) (upheld challenge to restriction on the size of religious gatherings); *Page v. Cuomo*, 2020 WL 4589329 (N.D.N.Y. Aug. 11, 2020) (upholding restriction on travel during quarantine); *Republican Nat'l Committee v. Democratic Nat'l Committee*, 140 S.Ct. 1205 (Apr. 6, 2020) (court extending voting deadlines); *In re Abbott*, 954 F.3d 772 (5th Cir. 2020) (court upheld restriction on abortion during emergency exercises of a public health crisis).
18. *Id.*
19. *S. Bay United Pentecostal Church v. Newsom*, 140 S.Ct. 716, 717 (May 29, 2020) (Roberts, J. concurring) ("Our Constitution principally entrusts the safety and the health of the people' to the politically accountable officials of the States . . . when those officials undertake to act in areas fraught with medical and scientific uncertainties their latitude must be especially broad . . . not . . . subject to

second guessing by an unelected federal judiciary which lacks the background, competence, and expertise to asses public health and is not accountable to the people.”).

20. *See Jacobson*, 197 U.S. 11.
21. *See Phillips v. City of New York*, 775 F.3d 538 (2nd Cir. 2015) (court upheld New York chicken pox vaccination requirement for children’s participation in public school was within the states’ police power); *Klassen v. Trs. Of Ind. Univ.*, 2021 U.S. LEXIS 22785 (Indiana University vaccination requirement upheld); *Bridges v. Houston Methodist Hosp.*, 2021 LEXIS 110382 (S.D. Tex. 2021) (court upholds employer vaccination requirement).
22. *Id.*
23. *Employment Div. v. Smith*, 494 U.S. 872, 886 (1990) (*citing United States v. Lee*, 455 U.S. 252, 263 n.3 (19820)). The right to free exercise, “does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.” *Phillip*, 775 F.3d 583 at 543 (*citing Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1994)).
24. *Employment Div.*, 494 U.S. 872 at 887 (*citing Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (right of parents to direct children’s education); *Murdock v. Pennsylvania*, 319 U.S. 105 (1943) (court struck down a tax on religious ideas); *Wisconsin v. Yoder*, 406 U.S. 205 (1972) (court struck down state law requiring Amish children to attend school against parents’ religious beliefs)); *Church of Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520, 533 (1993) (city ordinance prohibiting ritualistic animal sacrifice was found to target religion and violated free exercise clause); *Fulton v. City of Philadelphia*, 141 S.Ct. 1868, (2020) (court struck down as a violation of the free exercise clause a city’s refusal to contract with a religious foster care agency unless they agreed to certify same-sex couples as foster parents).
25. *Id.*
26. *Employment Div.*, 494 U.S. 872 at 890 (“But to say a nondiscriminatory religious-practice exemption is permitted . . . is not to say that it is constitutionally required . . . it may be fairly said to leaving accommodation to the political process will place at a relative disadvantage those religious practices . . . but that unavoidable consequence of democratic government must be preferred . . .”).
27. *See Fulton v. City of Philadelphia*, 141 S.Ct. 1868 (2020).
28. *Phillip*, 775 F.3d 583 at 543 (*citing Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1994)).
29. *See Calvary Chapel Dayton Valley v. Gov. of Nevada et al.*, 591 U.S. (2020) (court denied injunction from Nevada’s restriction on number of people allowed at religious congregations); but *see, S. Bay United Pentecostal Church v. Newsom*, 141 S.Ct. 716 (2021) (court invalidated California’s unequal treatment of religious congregation while allowing other accommodations for entertainment industry); *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S.Ct. 63, 66 (2020) (the Court invalidated New York Governor’s executive order restricting the attendance of religious services as not neutral).
30. *See F.F., as Parent of Y.F. et al., Infants et al. v. State of New York et al.*, 194 AD 3d 80 (2021); See N.Y. Public Health Law § 2164(8); *Employment Div.*, 494 U.S. 872 at 890.
31. *See Employment Div.*, 494 U.S 872.
32. *S. Bay United Pentecostal Church v. Newsom*, 140 S.Ct. 716 (May 29, 2020) (*citing Church of Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520, 534-535 (1993).
33. *See* EEOC, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, at K.1, EEOC.gov, https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws (last updated May 28, 2021).
34. *See Bridges v. Houston Methodist Hosp.*, No. 4:21-cv-01774, 2021 WL 2399994, at *1–2 (S.D. Tex. June 12, 2021), *appeal docketed*, No. 21-20311 (5th Cir. June 14, 2021).
35. Vaccination requirements are not specifically approved by the New York State Division of Human Rights, although the EEOC’s guidance has been adopted by New York City Commission of Human Rights.
36. *See, e.g.*, Virginia Mason Hospital, 357 NLRB 564 (2011).
37. *See, e.g.*, Johnson-Bateman, Co., 295 NLRB 180, 193 (1989).
38. N.Y. Human Rights Law § 292.21
39. EEOC, *supra* note 33, at J.2. “First, pregnancy-related medical conditions may themselves be disabilities under the ADA, even though pregnancy itself is not an ADA disability.”
40. CDC, *Pregnant and Recently Pregnant People*, CDC.gov, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnant-people.html (last updated Aug. 16, 2021), “COVID-19 vaccination is recommended for all people 12 years and older, including people who are pregnant . . . .”
41. EEOC, *supra* note 33, at K.12; 29 CFR § 1605; *see also United States v. Seeger*, 380 U.S. 163, 192 (1965) (construing religious belief broadly, holding it more akin to a “sincere belief” for purposes of religious exemptions for conscientious objectors).
42. EEOC, *supra* note 33, at K.12.
43. N.Y.C. Admin. Code § 8-107(3)(b); 9 N.Y.C.R.R. § 466.11(b)(2).
44. N.Y.C.R.R. Title 10, 405.3.
45. N.Y.C.R.R. Title 10, 415.26.
46. N.Y.C.R.R. Title 10, 751.6.
47. N.Y.C.R.R. Title 10, 763.13.
48. N.Y.C.R.R. Title 10, 766.11.
49. N.Y.C.R.R. Title 10, 794.3.
50. NYS Public Health Law Section 2168. *Regulation for Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel.*
51. NYS Public Health Law Article 21-A *The Long-term Care Resident and Employee Immunization Act.*
52. *Spence v. Shah*, 136 A.D.3d 1242, 1246 (App.Div 3d 2016).
53. *Id.* at 177.
54. *Garcia v. New York City Dept. of Health and Mental Hygiene*, 31 A.D.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).
55. *Klassen v. Trs. Of Ind. Univ.*, 2021 U.S. LEXIS 22785 (The 14th Amendment permits Indiana University to pursue a reasonable and due process of COVID-19 vaccination in the legitimate interest of public health for its students, faculty, and staff).
56. National Conference of State Legislatures, *States with Religious and Philosophical Exemptions from School Immunization Requirements* States With Religious and Philosophical Exemptions From School Immunization Requirements (ncsl.org) (August 7, 2021).
57. New York State Public Health Law Section 2164 and New York Codes, Rules and Regulations (N.Y.C.R.R.) Title 10, Subpart 66-1.
58. NYS Public Health Law Section 2165 and N.Y.C.R.R. Title 10, Subpart 66-2.
59. National Conference of State Legislatures, *States with Religious and Philosophical Exemptions from School Immunization Requirements* States With Religious and Philosophical Exemptions From School Immunization Requirements (ncsl.org) (August 7, 2021).
60. Centers for Disease Control and Prevention, *ACIP Vaccine Recommendations and Guidelines*. (ACIP recommends vaccines when the benefits outweigh the risks for a target population.) https://www.cdc.gov/vaccines/hcp/acip-recs/index.html.
61. NYS Public Health Law Section 2164(8) provides for medical exemptions to immunization for schools and child care programs.
62. National Conference of State Legislatures, *States with Religious and Philosophical Exemptions from School Immunization Requirements* States With Religious and Philosophical Exemptions From School Immunization Requirements (ncsl.org).
63. NYS Public Health Law Section 2164(9) (repealed June 13, 2019).
64. *F.F. v. State of New York* 2021 NY Slip OP 01541 Decided on March 18, 2021.
65. *Id.*
66. NYS Public Health Law Section 2165.
67. *Klaassen v. Trustees of Indiana University*, 1:21-CV-238 DRL, 2021 WL 3073926, at *1 (N.D. Ind. July 18, 2021).

68. *Klaassen v. Trustees of Indiana University*, No. 21-2326, 2021 WL 3281209, (7th Cir. Aug. 2, 2021), *cert. denied*, 594 U.S. _ (U.S. Aug. 12, 2021)(No. 21A15).
69. *See* COVID-19 Vaccine Incentives, https://www1.nyc.gov/site/coronavirus/vaccines/vaccine-incentives.page.
70. *See* What Colleges Require the COVID-19 Vaccine?, Aug. 12, 2021, https://www.bestcolleges.com/blog/list-of-colleges-that-require-covid-19-vaccine/#new-york.
71. EEOC, *supra* note 33, at K.1.
72. Hoffman *et al.*, Celebrities' impact on health-related knowledge, attitudes, behaviors and status outcomes: protocol for a systematic review, meta-analysis and met-regression analysis. Syst. Rev. 2017; 6: 13. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5251292/.
73. Miller *et al.*, (2021). Estimated Mortality Increases During The COVID-19 Pandemic By Socioeconomic Status, Race And Ethnicity. *Health Affairs*, *40*(8), 1252-1260. doi: 10.1377/hlthaff.2021.00414.

Appendix A

New York State Bar Association COVID-19 Resolutions

Approved by House of Delegates: November 7, 2020

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

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.

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 nondiscriminatory 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;

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.

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

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

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]

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;

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

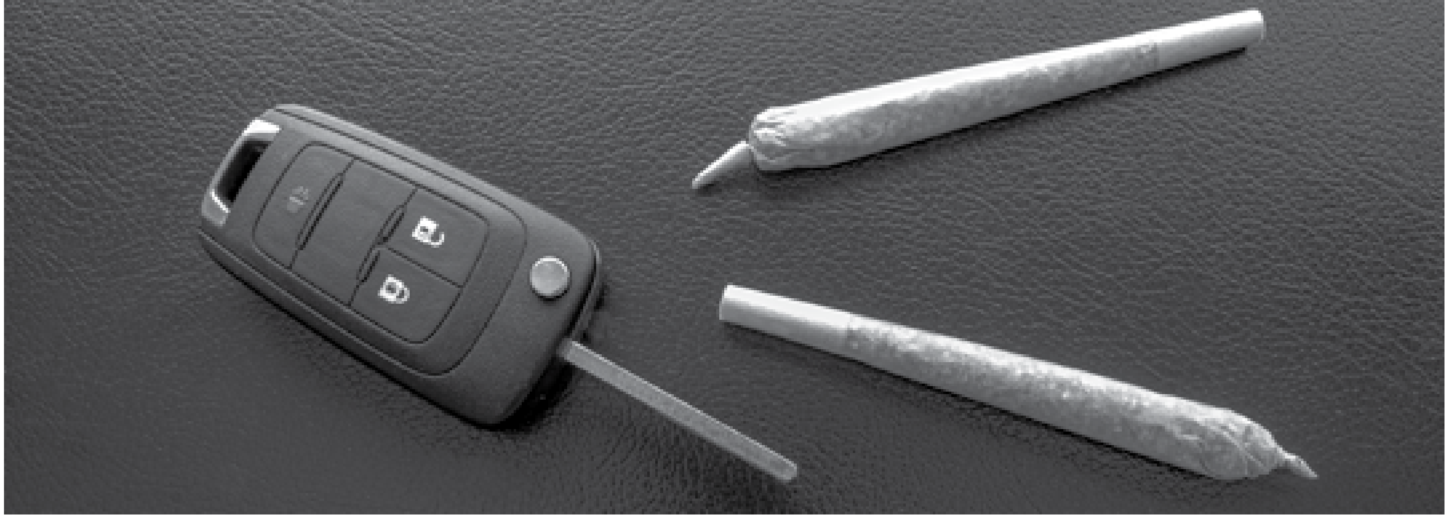
A.4.(d) expert medical and scientific consensus regarding the safety and efficacy of a vaccine and the need for immunization.

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

Endnotes

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.



Oral Fluids and Breathalyzers Fail as Detection Tools for Cannabis-Related Driving Impairment

By Ari P. Kirshenbaum, Mishka Woodley, Brendan S. Parent, Andy Kaplan, Chris Lewis and Brent A. Moore

Abstract

Traffic fatalities are preeminent among the public health threats associated with cannabis use. Public safety thus requires law enforcement to identify impaired drivers. Oral solutions and breathalyzer tests are attractive tools for detecting cannabis impairment amongst drivers due to their known effectiveness in identifying alcohol and drug impairment. Consequently, these tests are among the most widely available and used means of roadside detection. However, current psychopharmacological science strongly suggests that these biomarker tests are neither consistent nor reliable when cannabis detection is at issue. These identified deficiencies in oral solution and breathalyzer testing mechanisms are especially problematic since different legal standards for enforcing against cannabis impairment while driving are employed across the United States.

Many of these standards not only encourage but require the use of scientifically unsupported cannabis-impairment tests by law enforcement agencies for efficiency purposes. Continued use of these tests in conjunction with existing legal standards will likely lead to over-prosecution, and do not appear best suited to protect public health or promote individual rights. Law and policymakers concede that technological advancements and research specific to roadside testing mechanisms is still limited and requires time and further collection of data. In effort to address such concerns, some states are focused on expanded research and law enforcement training, such as New York. Inconsistent and unreliable roadside testing has grave implications for populations of individuals that some cannabis legalization provisions are intended to benefit. Thus, to ensure social equity and justice it is critical that lawmakers, policymakers, and law enforcement professionals alike strategically establish and implement the necessary mechanisms to protect against unwarranted arrests and over-prosecution.

Introduction

Implementing methods to detect cannabis-related driving impairment is critical given the number of states joining the movement to legalize or decriminalize use. To date, 36 states, District of Columbia, Guam, Puerto Rico and U.S. Virgin Islands have comprehensive medical marijuana/cannabis programs.[1] Of those states, 16 states, two territories, and the District of Columbia have legalized small amounts of cannabis for recreational/adult-use with New Mexico, New York and Virginia passing legislation as recently as April 2021.[2] Cannabis is the most regularly detected illicit drug in national roadside surveys[3] and driving under the influence of cannabis is preeminent among the public health threats imposed by an increased frequency of use.[4] In some instances, legalization of a cannabis retail market hinges on the availability of a reliable roadside test, and oral-fluid detection has been rejected by state legislature on the basis that it is not reliable as a test for intoxica-

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tion nor predictive of driving impairment.[5] In this article, we review evidence regarding oral fluids and breathalyzers (OF&B) as measures of cannabis-related driving impairment. Although oral fluids may be used to identify a history of cannabis use, utilization of oral fluids as an indication of motor-vehicle operation impairment is scientifically unjustified, legally challengeable, and ethically questionable.

Incomplete Science

The relationship between blood-alcohol concentration (BAC) and neurocognitive and behavioral impairment and intoxication is linear, and nearly a century of science supports the assessment of BAC via breathalyzer and blood sampling for the purpose of enforcement against driving under the influence of alcohol.[6] Given that BAC has been adopted as the legal standard for DUI arrest, expectations run high that a similar biological test can represent intoxication and impairment from cannabis. The *Marijuana Use and Highway Safety Report* published by the Congressional Research Service highlights the complexity of detecting cannabis impairment through standardized tests as compared to alcohol impairment.[7] The report describes alcohol as a "liquid that enters the bloodstream quickly and is metabolized by the body very quickly . . . [so] a person's BAC peaks within an hour after drinking and declines gradually and linearly after that."[8] The report explains that the degree of impairment of various BAC levels is well-established as related to driving but that similar data do not support this connection with tetrahydrocannabinol (THC).[9] THC concentration is known to drop quickly within an hour of use but traces can remain in one's system for weeks after cannabis use.[10]

Current breath and body fluid mechanisms used for cannabis testing fail to have the same degree of scientific support as alcohol. The scientific case against OF&B testing for THC rests on two key points. First, there is arguably poor reliability and questionable validity of OF&B results as indicators of blood concentrations of THC.[11] Second, even if these tests were accurate in predicting blood concentrations, the scientific evidence does not show a direct linear relationship between THC blood concentrations and driving impairment.[12] Hence, a test's ability to accurately predict blood concentrations of THC does not necessarily equate to its ability to accurately assess driver impairment, which is the underlying purpose of the test.

The reliability and validity of OF&B testing is problematic because, contrary to BAC, blood concentration of THC from inhalation (smoking or vaping) can vary across individual users despite similar levels of cannabis consumption.[13] OF&B tests often rely on the detection of residual THC remaining in the mouth and respiratory tract. Yet rate of drug absorption shows substantial variability, and quantitative values of THC metabolites can inaccurately represent the proportion of THC in the blood. Several factors affect the relationship between OF&B and blood THC concentrations separate from cannabis consumption. Specifically, hormonal changes, genetics, systemic disease, and food/beverage consumption can all impact salivary concentrations and thus degrade the reliability of oral fluid testing as a measure of blood concentration.[14] The rate of dissipation of THC in oral fluid can vary substantially, further complicating the relationship between oral fluids and blood concentration.[15] Oral-fluid THC concentrations decline dramatically within the first three hours after use while trace levels above current legal DUI thresholds can be present more than 16 hours since last use, and this is particularly true for chronic users.[16] Thus, frequent users of cannabis are more likely to yield false positive intoxication results. Among the numerous laboratory tests of THC-related cognitive impairments, there is clear evidence that heavy users become tolerant to impairment-producing effects of cannabinoids,[17] despite greater risk of being designated as impaired.[18] Differences in the susceptibility to THC-intoxication due to individual factors, including history of use, represent a significant problem for establishing OF&B criteria for impairment.

Importantly, oral fluid samples taken at roadside have been shown to correlate poorly with observable signs of THC intoxication,[19] and do not accurately measure blood concentration of THC.[20] Overall, cut-off criteria have been found to produce high levels of inaccurate classification, including false positive rates as high as 19%.[21] Oral-fluids tests at roadside have also been shown to be sensitive to the presence of THC stemming from sources peripheral to the direct self-administration of cannabis smoke. For instance, second-hand exposure to cannabis-smoke can affect oral-fluid THC levels but may have little or no intoxication effects. Since the THC detected under these circumstances fails to correspond to blood concentrations,[22] second-hand smoke exposure may lead to arrests for false positive intoxication. Additionally, environmental exposure to cannabis smoke or vapor can also contaminate oral-fluid sampling devices.[23] Even weather conditions have been shown to affect the ability of oral-fluids tests to detect the presence of THC,[24] which calls into question the reliability of these devices across times of day and a wide range of geographical areas.

Compared to saliva tests, breathalyzers have received far less attention from psychopharmacological investigators because of how recently they were developed to address THC intoxication.[25] While they appear to be an attractive tool to use for THC detection because of their common association with accepted means of assessing blood alcohol concentration (BAC), skepticism about their use stems largely from the fact that THC is not eliminated in breath the way that alcohol is. Therefore, detection of THC by breathalyzers is limited by the same findings endemic to oral-fluid testing. Contamination, incongruence with blood concentration, and inconsistent dissipation in the bloodstream prevent breathalyzers from accurately portraying impairments in motor-vehicle operation related to cannabis intoxication. Potential exists for these limitations to be addressed through breathalyzer technological innovation. Such advances in breathalyzer capabilities

would provide much less invasive testing than existing blood or oral solution testing forms, thus mitigating many of the ethical concerns surrounding the collection of genetic material involved in other biomarker analyses.

Even if the reliability of OF&B analyses were improved, impaired driving is not clearly associated with THC blood concentration in a manner that parallels alcohol or opioids. In terms of general cognitive performance, THC in the bloodstream is often inconsistently associated with impairment.[26] For example, in a within-subjects analysis of THC dose, subjects' self-reported feelings of "intoxication" and "confusion" were not correlated with blood levels.[27] Blood concentrations tend to remain high despite rapidly abating cognitive effects of THC well after self-administration.[28] As the National Highway Traffic Safety Administration noted in their 2017 report to Congress:

> A number of States have set a THC limit in their laws indicating that if a suspect's THC concentration is above that level (typically 5 ng/ml of blood), then the suspect is to be considered impaired. This *per se* limit appears to have been based on something other than scientific evidence.

We do not dispute the connection between THC and driving-related impairment. Both epidemiologic and driving-simulator studies indicate that cannabis use increases motor vehicle accident risk.[29] For instance, the Governors Highway Safety Association released a report in October 2018 which denotes that the proportion of Washington State DUI and collision cases increased from 20% to 30% between 2005 and 2014 with the median THC level increasing from 4.0 ng/mL in 2005 to 5.6 ng/mL.[30,31] Furthermore, marijuana-related traffic deaths increased 66% in the four-year average (2013-2016) since Colorado legalized recreational marijuana.[32] Instead, we argue that THC blood concentration levels are poorly correlated with driving skill, and this argument is echoed by driving-simulator studies which demonstrate that the "magnitude of performance impairment" is not correlated with THC levels.[33] Perhaps because of this, there is much disagreement regarding what appropriate toxicity thresholds could or should be.[34] The Governors Highway Safety Association reviewed evidence on increased crash risk and determined that driving while under the influence of THC is a significant public safety threat, and that cannabis differs substantially from alcohol and cannot be measured accurately in breath.[35] Individual differences in metabolism, including but not limited to frequency of use,[36] represent major obstacles for oral-fluid testing, as does the finding that metabolites of THC can be found in oral fluids as a result of indirect environmental exposure.[37] Thus, although cannabis use is clearly associated with greater motor vehicle accident risk, the relationship between existing biological markers of use and driving performance is weak. Careful consideration must be given to the existing legal standards across the country, and to what standards best promote public safety and protect individual rights.

Legal Standards

To date, 16 states, two territories and the District of Columbia have legalized cannabis for adult/recreational use with New York, New Mexico and Virginia passing legalization as recently as April 2021.[38] Yet lawmakers, policymakers, and health care experts agree that testing for cannabis-specific drug impairment remains a challenging endeavor due to technological limitations and the lack of agreement on impairment limits.[39] In October 2020, a cohort of medical societies released a joint statement "to express mutually shared concerns about state governments' efforts to legalize marijuana for recreational use," including impaired driving arrests and increased use among youth.[40] The American Medical Association (AMA) further calls for improved surveillance efforts to ensure available data related to impaired driving to deter such behavior and facilitate social equity in cannabis prohibition and enforcement policies.[41] In light of continuing trends of adult-use cannabis legalization, driving-related impairment testing mechanisms should be consistent, reliable, and scientifically validated.

Marijuana-impaired driving laws in the United States generally fall within three categories: driving under the influence of drugs (DUID), zero tolerance laws, and per se laws.[42] Driving under the influence of drugs is illegal in every state and requires that an officer observe that a driver is impaired and the impairment must result from ingestion of a drug, including cannabis.[43] Zero tolerance laws prohibit any amount of a specified drug in the body, with some states prohibiting THC or a metabolite and others having no metabolite restriction.[44] Per se laws prohibit driving with more than a specified amount of a drug in one's body, similar to alcohol limits.[45] Once law enforcement is able to establish that a driver either reached or exceed the state's legally established limit, the person is automatically deemed impaired.[46] Per se THC limits can range between 1 nanogram and 5 nanograms.[47] This discrepancy speaks to current enforcement disparities in the impairment criteria alone absent the concerns noted regarding the inaccuracy of the roadside testing mechanisms used.[48] Colorado law makes some effort to mitigate the potential prosecutorial harms that may result from limited scientific data. The law provides that "if at such time [a] driver's blood alcohol contained five nanograms or more of [THC] per milliliter in whole blood, as shown by analysis of the defendant's blood, such fact gives rise to a permissible inference that the defendant was under the influence of one or more drugs."[49] The reasonable inference provision permits drivers charged with impaired driving to introduce an affirmative defense that they were not impaired, unlike per se laws.[50] Though the ability to provide an affirmative defense may be beneficial during the prosecutorial period, such provision does not prevent drivers from being unnecessarily charged at the roadside.

As the trend toward cannabis legalization continues, it is unclear which legal standard will best promote public safety and protect individual rights. Per se limits are not

scientifically grounded because no set amount of cannabis in the body is determinative of impairment. This legal standard will result in arrests and prosecutions of some people who are in fact impaired, could miss others who are impaired at lower levels, and will also punish some unimpaired people for risks they did not create due to their cannabis use. Zero tolerance laws would punish far more unimpaired people for risks they did not create, and would be inconsistent with the cultural, political and legal trends toward acceptance of marijuana use. History suggests that over-prosecution related to controlled substances has caused irreparable harms to marginalized populations, which states are strategically attempting to remedy with legalization. Accordingly, DUID laws, requiring determination of actual driving impairment related to drug use will likely be the most just approach to cannabis. This necessitates reliable, consistent, scientifically validated impairment testing tools. Current OF&B cannabis measurement methods are inadequate.

To successfully prosecute on the grounds of driving under the influence of THC, scientific expert testimony must be admitted in order to validate the methods used to test intoxication. Failure to produce expert testimony could result in the dismissal of charges.[51] The *Daubert* Standard for admitting scientific expert testimony has been applied to the use of blood and urine testing of cannabis impairment and some have argued that these methods meet that standard;[52] however, it is unlikely that oral fluid or breathalyzer testing meet this standard. *Daubert*, among other criteria, holds that conclusions from an expert's testimony must (1) be the product of sound scientific methodology, and (2) must rest on a reliable foundation.[53] Extensive research on oral fluids has been conducted, so oral fluids are amenable to testing, have been peer reviewed, and false-positive and false-negative error rates are reported.[54] However, one of the criteria for determining "sound scientific methodology" is whether the known error rate is acceptable.[55] As described above, error estimates for oral fluids are substantial, and methods of fluid sample collection and testing vary considerably. The exact devices used and the timing of oral-fluid sampling during the arrest process are variable across and within law enforcement agencies.[56] For these reasons, OF&B detection tools are not accepted by most states in which cannabis has been decriminalized. *Flannigan et al.* have noted that outcomes of oral fluid tests, in particular, are unreliable:

> Officers who use on-site [oral fluids] devices in this manner are cautioned to consider the results within the totality of the circumstances, not simply rely on the results as a stand-alone basis to make an arrest.[57]

These facts suggest both lack of soundness in methodology for OF&B testing, as well as lack of reliability as required by *Daubert*. It is unlikely that expert testimony arguing that OF&B are dispositive of impairment would thus meet the required evidentiary standard.

On March 28, 2021, New York State Governor Andrew Cuomo, Senate Majority Leader Andrea-Stewart Cousins and Assembly Speaker Carl Heastie announced an agreement on legislation (S.854-A/A.1248-A) to legalize adult-use cannabis that was signed by the Governor Cuomo on March 31, 2021.[58] The proposed legislation includes a number of provisions to address issues associated with impaired driving.[59] The division of state police are required to increase the number of trained and certified drug recognition experts within the state with increased roadside impaired driving enforcement training.[60] Furthermore, the commissioner of health is directed to select one or more higher education research institutions to conduct a controlled research study to evaluate methodologies and technologies for the detection of cannabis-impaired driving.[61] In the meantime, use of cannabis by drivers remains prohibited, effectively serving as a zero tolerance driving policy.[62] The odor of cannabis, the odor of burnt cannabis, possession, or the suspicion of possession of cannabis may not be used as a finding or determination of reasonable cause to believe a crime has been committed. However, such prohibitions do not apply when law enforcement is investigating whether a person is operating a motor vehicle while impaired by drugs or the combined influence of drugs and alcohol.[63]

New York State Vehicle and Traffic Law currently prohibits individuals from operating a motor vehicle while impaired by use of a drug or the combined influence of drugs or of alcohol and any drug or drugs and relies on blood content testing to determine impairment status.[64] This serves as a DUID law, on top of the zero tolerance law described above, and it relies on blood content testing to determine impairment status.[65] Convictions are deemed misdemeanor offenses at a minimum and could result in criminal penalties in the form of a fine of not less than $500, imprisonment in a penitentiary or county jail or both.[66] Second and third offenses could result in felony charges.[67] Existing breath and bodily fluid tools for evaluating cannabis-related impairment are unreliable for assisting in these investigations, yet current law promotes the use of such tools.

Even with appropriate testing, under New York State law one must be merely "impaired" while driving under the influence of drugs, including cannabis, to be guilty of a misdemeanor, whereas one must be intoxicated to be guilty when driving under the influence of alcohol.[68] A person is deemed guilty when it is proved beyond a reasonable doubt that (1) the defendant ingested the drug, (2) the drug ingested is proscribed under Public Health Law Section 3306, (3) after ingesting the drug, the defendant operated a motor vehicle, and (4) while operating the motor vehicle, the defendant's ability to operate was impaired by ingestion of the drug.[69] Under this framework, law enforcement must not only prove impaired driving ability but that such impairment was caused by alcohol, drugs or intoxicating substances.[70] Reports suggest New York lawmakers struggled to determine how to defined marijuana-impaired driving[71] and thus specific impairment remains undefined.[72] Consequently, driving under the influence of marijuana remains

illegal in New York as regulators fulfill the research mandates previously discussed.[73]

The Rocky Mountain High Intensity Drug Trafficking Area (RMHIDTA) prepared a report discussing the impact of marijuana legalization in Colorado and highlighting key approaches to cannabis-impaired driving in other countries.[74] One common approach adopted by a number of countries to address the weaknesses in roadside cannabis-impairment testing is to "use oral fluid testing to identify drivers who have recently used cannabis and measure THC in blood if they fail the oral fluid test."[75] Even so, there is much concern that use of breath tests in conjunction with THC blood level analyses discourage cannabis use instead of functioning as effective public safety mechanisms.[76] Some policymakers suggest that the following research areas should be prioritized: the effects of drug testing on road fatalities and injuries in which alcohol, cannabis and other drugs are detected postmortem; changes in public attitudes towards the acceptability of driving after using cannabis; and changes in cannabis users' perceived risks of being detected if they drive after using cannabis. Furthermore, the cost-effectiveness of cannabis-impaired driving enforcement efforts must be considered as compared to alcohol that appears to have a greater public health impact.[77]

Since cannabis impairment cannot be accurately assessed with currently used OF&B tests, careful consideration must be given to the testing methodologies used and the criteria for enforcement and conviction—especially in states like New York where social and racial justice were critical considerations in the adult-use legalization negotiations. Use of inappropriate testing methodologies and enforcement criteria related to driving could result in continued inequitable treatment of disproportionately impacted populations and communities that the new law intends to proactively remedy.

Civil Liberties Are at Stake

Significant resources have been spent developing oral fluids and breathalyzer tests for cannabis intoxication. Although these tools hold promise in that they may detect a history of cannabis use, many different legal-advocacy groups have argued against their use on civil rights grounds. In line with scientific studies previously cited, the ACLU suggests that roadside saliva tests do not accurately detect the presence of drugs in a person's system or actual impairment.[78]

There are additional ethical concerns that arise from the use of oral fluids that inevitably contain personally identifying genetic information. Police in several states are collecting biological samples from individuals some of whom are not accused or even suspected of particular crimes. The practice of adding oral fluid samples to federal, local or private DNA databases is used as a means for identifying perpetrators in past, or future, crime scenes. The Supreme Court has protected the collection of such samples from arrestees,[79] and there are no laws preventing police from requesting the DNA of individuals to add to databases during instances such as a roadside stop. A request for an oral sample, coming from an officer, can sound like a demand if the citizen is not aware of the right to refuse.[80] Such requests can also be framed with minimal information regarding what will happen to the biological sample in terms of its storage and future use. Since the sample may be used to implicate citizens (or relatives) in future crimes, it exposes individuals to criminal scrutiny without their consent. The samples may also lead to the harassment of innocent people and possibly reveal confidential family information (adoption, incest, children outside of marriage). Additionally, the collection and storage of biological samples inevitably exacerbates the overrepresentation of minorities in criminal investigation because they are more often searched and targeted for sample collection than other groups.[81] Due to sample contamination or poor sample quality, DNA samples are subject to "false inclusion" and can lead to wrongful arrest and incarceration,[82] and it is overwhelmingly difficult for a citizen to remove a biological sample from federal databases.[83] Whether mandated, requested, or surreptitious, a foreseeable ethical problem with oral-fluid THC testing is that its practice would facilitate police collection of DNA samples for forensic databases.[84]

Conclusions

Oral fluids and breathalyzers may have a place in the toolbox of law enforcement to identify a history of cannabis use.[85] However, they are unreliable indicators of THC-related driving impairment and impose significant threats to civil liberty.[86] The *per se* legal standard for cannabis-intoxication while driving promotes the use of unreliable testing methods, and the zero-tolerance standard is inconsistent with the trend toward legalization, both of which will likely lead to over-prosecution. A DUID legal standard is likely the most just approach, which necessitates the development of tools that measure actual cannabis impairment. Furthermore, legal provisions that reasonably provide opportunities for defendants to provide an affirmative defense against impairment charges are critical to mitigate the social unintended consequences that may result from inequitable and/or over-prosecution. Such efforts not only protect the individual rights and liberties discussed above but directly align with the expressed goals of legalization efforts—such as increased revenue, and promoting economic development and social/racial equity—which heavily rely on appropriate and effective enforcement practices to encourage, versus deter, legal purchase and use.

Conflicts of Interest

Kaplan, Kirshenbaum, and Lewis are partners in DriveAbilityVT, LLC, which is a software company devoted toward developing solutions for impairments related to motor-vehicle operation; none received compensation for their work on this article but their work in this field drew their attention to the issues presented in this manuscript. Parent, Moore and Woodley declare no financial, personal, or academic conflicts of interest.

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Assembly Bill S854–A: Marijuana Regulation and Taxation Act

STATE OF NEW YORK

854—A

2021-2022 Regular Sessions

IN SENATE

(Prefiled)

January 6, 2021

EXPLANATION—Matter in italics (underscored) is new; matter in brackets [–] is old law to be omitted.

Introduced by Sens. KRUEGER, BAILEY, BENJAMIN, BIAGGI, BRESLIN, BRISPORT, BROUK, COMRIE, COONEY, GIANARIS, HINCHEY, HOYLMAN, JACKSON, KENNEDY, LIU, MAY, MYRIE, PARKER, RAMOS, RIVERA, SALAZAR, SANDERS, SAVINO, SEPULVEDA, SERRANO—read twice and ordered printed, and when printed to be committed to the Committee on Finance—committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee.

AN ACT in relation to constituting chapter 7-A of the consolidated laws, in relation to the creation of a new office of cannabis management, as an independent entity within the division of alcoholic beverage control, providing for the licensure of persons authorized to cultivate, process, distribute and sell cannabis and the use of cannabis by persons aged twenty-one or older; to amend the public health law, in relation to the description of cannabis; to amend the penal law, in relation to the growing and use of cannabis by persons twenty-one years of age or older; to amend the tax law, in relation to providing for the levying of taxes on cannabis; to amend the criminal procedure law, the civil practice law and rules, the general business law, the state finance law, the executive law, the penal law, the alcoholic beverage control law, the general obligations law, the social services law, the labor law, the family court act, and the vehicle and traffic law, in relation to making conforming changes; to amend the public health law, in relation to the definition of smoking; to amend the state finance law, in relation to establishing the New York State cannabis revenue fund, the New York State drug treatment and public education fund and the New York State community grants reinvestment fund; to amend chapter 90 of the laws of 2014 amending the public health law, the tax law, the state finance law, the general business law, the penal law and the criminal procedure law relating to medical use of marihuana, in relation to the effectiveness thereof; to amend chapter 174 of the laws of 1968 constituting the urban development corporation act, in relation to loans to social and economic equity applicants, providing increased drug recognition awareness and Advanced Roadside Impaired Driver Enforcement training, directing a study designed to evaluate methodologies and technologies for the detection of cannabis-impaired driving, providing for the transfer of employees and functions from the department of health to the office of cannabis management; to repeal certain provisions of the public health law relating to growing of cannabis and medical use of marihuana; to repeal article 221 of the penal law relating to offenses involving marihuana; to repeal paragraph (f) of subdivision 2 of section 850 of the general business law relating to drug related paraphernalia; and to repeal certain provisions of the penal law relating to making conforming changes.

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. This act shall be known and may be cited as the "marihuana regulation and taxation act."

§ 2. Chapter 7-A of the consolidated laws is enacted, to read as follows:

CHAPTER 7-A OF THE CONSOLIDATED LAWS

CANNABIS LAW

ARTICLE 1

SHORT TITLE; LEGISLATIVE FINDINGS AND INTENT; DEFINITIONS

Section 1. Short title.

2. Legislative findings and intent.

3. Definitions.

Section 1. Short title. This chapter shall be known and may be cited and referred to as the "cannabis law."

§ 2. Legislative findings and intent. The legislature finds that 16 existing marihuana laws have not been beneficial to the welfare of the general public. Existing laws have been ineffective in reducing or curbing marihuana use and have instead resulted in devastating collateral consequences including mass incarceration and other complex generational trauma, that inhibit an otherwise law-abiding citizen's ability to access housing, employment opportunities, and other vital services. Existing laws have also created an illicit market which represents a threat to public health and reduces the ability of the legislature to deter the accessing of marihuana by minors. Existing marihuana laws have disproportionately impacted African-American and Latinx communities.

The intent of this act is to regulate, control, and tax marihuana, heretofore known as cannabis, generate significant new revenue, make substantial investments in communities and people most impacted by cannabis criminalization to address the collateral consequences of such criminalization, prevent access to cannabis by those under the age of twenty-one years, reduce the illegal drug market and reduce violent crime, reduce participation of otherwise law-abiding citizens in the illicit market, end the racially disparate impact of existing cannabis laws, create new industries, protect the environment, improve the state's resiliency to climate change, protect the public health, safety and welfare of the people of the state, increase employment and strengthen New York's agriculture sector.

Nothing in this act is intended to limit the authority of any district, government agency or office or employers to enact and enforce policies pertaining to cannabis in the workplace; to allow driving under the influence of cannabis; to allow individuals to engage in conduct that endangers others; to allow smoking cannabis in any location where smoking tobacco is prohibited; or to require any individual to engage in any conduct that violates federal law or to exempt anyone from any requirement of federal law or pose any obstacle to the federal enforcement of federal law.

The legislature further finds and declares that it is in the best interest of the state to regulate medical cannabis, adult-use cannabis, cannabinoid hemp and hemp extracts under independent entities, known as the cannabis control board and the office of cannabis management.

§ 3. Definitions. Whenever used in this chapter, unless otherwise expressly stated or unless the context or subject matter requires a different meaning, the following terms shall have the representative meanings hereinafter set forth or indicated:

1. "Applicant" unless otherwise specified in this chapter, shall mean a person applying for any cannabis, medical cannabis or cannabinoid hemp license or permit issued by the New York State cannabis control board pursuant to this chapter that: has a significant presence in New York State, either individually or by having a principal corporate location in the state; is incorporated or otherwise organized under the laws of this state; or a majority of the ownership are residents of this state. For the purposes of this subdivision, "person" means an individual, institution, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.
2. "Cannabinoid" means the phytocannabinoids found in hemp and does not include synthetic cannabinoids as that term is defined in subdivision (g) of schedule I of section thirty-three hundred six of the public health law.
3. "Cannabinoid hemp" means any hemp and any product processed or derived from hemp, that is used for human consumption provided that when such product is packaged or offered for retail sale to a consumer, it shall not have a concentration of more than three tenths of a percent delta-9 tetrahydrocannabinol.
4. "Cannabinoid hemp processor license" means a license granted by the office to process, extract, pack or manufacture cannabinoid hemp or hemp extract into products, whether in intermediate or final form, used for human consumption.
5. "Cannabis" means all parts of the plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination. It does not include hemp, cannabinoid hemp or hemp extract as defined by this section or any drug products approved by the federal Food and Drug Administration.
6. "Cannabis consumer" means a person twenty-one years of age or older acting in accordance with any provision of this chapter.
7. "Cannabis control board" or "board" means the New York State cannabis control board created pursuant to article two of this chapter.
8. "Cannabis flower" means the flower of a plant of the genus Cannabis that has been harvested, dried, and cured, prior to any processing whereby the plant material is transformed into a concentrate, including, but not limited to, concentrated cannabis, or an edible or topical product containing cannabis or concentrated cannabis and other ingredients. Cannabis flower excludes leaves and stem.

9. “Cannabis product” or “adult-use cannabis product” means cannabis, concentrated cannabis, and cannabis-infused products for use by a cannabis consumer.

10. “Cannabis-infused products” means products that have been manufactured and contain either cannabis or concentrated cannabis and other ingredients that are intended for use or consumption.

11. “Cannabis trim” means all parts of the plant of the genus Cannabis other than cannabis flower that have been harvested, dried, and cured, but prior to any further processing.

12. “Caring for” means treating a patient, in the course of which the practitioner has completed a full assessment of the patient’s medical history and current medical condition.

13. “Certification” means a certification made under this chapter.

14. “Certified medical use” includes the acquisition, cultivation, manufacture, delivery, harvest, possession, preparation, transfer, transportation, or use of medical cannabis for a certified patient, or the acquisition, administration, cultivation, manufacture, delivery, harvest, possession, preparation, transfer, or transportation of medical cannabis by a designated caregiver or designated caregiver facility, or paraphernalia relating to the administration of cannabis, including whole cannabis flower, to treat or alleviate a certified patient’s medical condition or symptoms associated with the patient’s medical condition.

15. “Certified patient” means a patient who is a resident of New York State or receiving care and treatment in New York State as determined by the board in regulation, and is certified under this chapter.

16. “Chief equity officer” means the chief equity officer of the office of cannabis management.

17. “Concentrated cannabis” means: (a) the separated resin, whether crude or purified, obtained from cannabis; or (b) a material, preparation, mixture, compound or other substance which contains more than three percent by weight or by volume of total THC, as defined in this section.

18. “Condition” means having one of the following conditions: cancer, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, amyotrophic lateral sclerosis, Parkinson’s disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington’s disease, post-traumatic stress disorder, pain that degrades health and functional capability where the use of medical cannabis is an alternative to opioid use, substance use disorder, Alzheimer’s, muscular dystrophy, dystonia, rheumatoid arthritis, autism or any other condition certified by the practitioner.

19. “Cultivation” means growing, cloning, harvesting, drying, curing, grading, and trimming of cannabis plants for sale to certain other categories of cannabis license- and permit-holders.

20. “Delivery” means the direct delivery of cannabis products by a retail licensee, microbusiness licensee, or delivery licensee to a cannabis consumer.

21. “Designated caregiver facility” means a facility that registers with the office to assist one or more certified patients with the acquisition, possession, delivery, transportation or administration of medical cannabis and is a: general hospital or residential health care facility operating pursuant to article twenty-eight of the public health law; an adult care facility operating pursuant to title two of article seven of the social services law; a community mental health residence established pursuant to section 41.44 of the mental hygiene law; a hospital operating pursuant to section 7.17 of the mental hygiene law; a mental hygiene facility operating pursuant to article thirty-one of the mental hygiene law; an inpatient or residential treatment program certified pursuant to article thirty-two of the mental hygiene law; a residential facility for the care and treatment of persons with developmental disabilities operating pursuant to article sixteen of the mental hygiene law; a residential treatment facility for children and youth operating pursuant to article thirty-one of the mental hygiene law; a private or public school; research institution with an internal review board; or any other facility as determined by the board in regulation.

22. “Designated caregiver” means an individual designated by a certified patient in a registry application. A certified patient may designate up to five designated caregivers not counting designated caregiver facilities or designated caregiver facilities’ employees.

23. “Designated caregiver facility employee” means an employee of a designated caregiver facility.

24. “Distributor” means any person who sells at wholesale any cannabis product, except medical cannabis, for the sale of which a license is required under the provisions of this chapter.

25. “Executive director” means the executive director of the office of cannabis management.

26. “Form of medical cannabis” means characteristics of the medical cannabis recommended or limited for a particular certified patient, including the method of consumption and any particular strain, variety, and quantity or percentage of cannabis or particular active ingredient, or whole cannabis flower.

27. “Hemp” means the plant Cannabis sativa L. and any part of such plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration (THC) of not more than three-tenths of a percent on a dry weight basis. It shall not include “medical cannabis” as defined in this section.

28. “Hemp extract” means all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers derived from hemp, used or intended for human consumption, for its cannabinoid content, with a delta-9 tetrahydrocannabinol concentration of not more than an amount determined by the office in regulation. For the purpose of this article, hemp extract excludes (a) any food, food ingredient or food additive that is generally recognized as safe pursuant to federal law; or (b) any hemp extract that is not used for human consumption. Such excluded substances shall not be regulated pursuant to the provisions of this article but are subject to other provisions of applicable state law, rules and regulations.

29. “Labor peace agreement” means an agreement between an entity and a labor organization that, at a minimum, protects the state’s proprietary interests by prohibiting labor organizations and members from engaging in picketing, work stoppages, boycotts, and any other economic interference with the entity.

30. “Laboratory testing facility” means any independent laboratory capable of testing cannabis and cannabis products for adult-use and medical-use; cannabinoid hemp and hemp extract; or for all categories of cannabis and cannabis products as per regulations set forth by the state cannabis control board.

31. “License” means a written authorization as provided under this chapter permitting persons to engage in a specified activity authorized pursuant to this chapter.

32. “Licensee” means an individual or an entity who has been granted a license under this chapter.

33. “Medical cannabis” means cannabis as defined in this section, intended for a certified medical use, as determined by the board in consultation with the commissioner of health.

34. “Microbusiness” means a licensee that may act as a cannabis producer for the cultivation of cannabis, a cannabis processor, a cannabis distributor and a cannabis retailer under this article; provided such licensee complies with all requirements imposed by this article on licensed producers, processors, distributors and retailers to the extent the licensee engages in such activities.

35. “Nursery” means a licensee that produces only clones, immature plants, seeds, and other agricultural products used specifically for the planting, propagation, and cultivation of cannabis by licensed adult use cannabis cultivators, microbusinesses, cooperatives and registered organizations.

36. “Office” or “office of cannabis management” means the New York State office of cannabis management.

37. “On-site consumption” means the consumption of cannabis in an area licensed as provided for in this chapter.

38. “Package” means any container or receptacle used for holding cannabis or cannabis products.

39. “Permit” means a permit issued pursuant to this chapter.

40. “Permittee” means any person to whom a permit has been issued pursuant to this chapter.

41. “Practitioner” means a practitioner who is licensed, registered or certified by New York State to prescribe controlled substances within the state. Nothing in this chapter shall be interpreted so as to give any such person authority to act outside their scope of practice as defined by title eight of the education law. Additionally, nothing in this chapter shall be interpreted to allow any unlicensed, unregistered, or uncertified person to act in a manner that would require a license, registration, or certification pursuant to title eight of the education law.

42. “Processor” means a licensee that extracts concentrated cannabis and/or compounds, blends, extracts, infuses, or otherwise manufactures concentrated cannabis or cannabis products, but not the cultivation of the cannabis contained in the cannabis product.

43. “Registered organization” means an organization registered under article three of this chapter.

44. “Registry application” means an application properly completed and filed with the board by a certified patient under article three of this chapter.

45. “Registry identification card” means a document that identifies a certified patient or designated caregiver, as provided under this chapter.

46. “Retail sale” means to solicit or receive an order for, to keep or expose for sale, and to keep with intent to sell, made by any licensed person, whether principal, proprietor, agent, or employee, of any cannabis, cannabis product, cannabinoid hemp or hemp extract product to a cannabis consumer for any purpose other than resale.

47. “Retailer” means any person who sells at retail any cannabis product, the sale of which a license is required under the provisions of this chapter.

48. “Small business” means small business as defined in section one hundred thirty-one of the economic development law, and shall apply for purposes of this chapter where any inconsistencies exist.

49. “Smoking” means the burning of a lighted cigar, cigarette, pipe or any other matter or substance which contains cannabis including the use of an electronic smoking device that creates an aerosol or vapor.

50. “Social and economic equity applicant” means an individual or an entity who is eligible for priority licensing pursuant to the criteria established in article four of this chapter.

51. “Terminally ill” means an individual has a medical prognosis that the individual’s life expectancy is approximately one year or less if the illness runs its normal course.

52. “THC” means Delta-9-tetrahydrocannabinol; Delta-8-tetrahydrocannabinol; Delta-10-tetrahydrocannabinol and the optical isomer of such substances.

53. “Total THC” means the sum of the percentage by weight or volume measurement of tetrahydrocannabinolic acid multiplied by 0.877, plus, the percentage by weight or volume measurement of THC.

54. “Warehouse” means and includes a place in which cannabis products are securely housed or stored.

55. “Wholesale” means to solicit or receive an order for, to keep or expose for sale, and to keep with intent to sell, made by any licensed person, whether principal, proprietor, agent, or employee of any adult-use, medical-use cannabis or cannabis product, or cannabinoid hemp and hemp extract product for purposes of resale.

ARTICLE 2

NEW YORK STATE CANNABIS CONTROL BOARD

Section

7. Establishment of the cannabis control board or “board.”
8. Establishment of an office of cannabis management.
9. Executive director.
10. Powers and duties of the cannabis control board.
11. Functions, powers and duties of the executive director; office of cannabis control.
12. Chief equity officer.
13. Rulemaking authority.
14. State cannabis advisory board.
15. Disposition of moneys received for license fees.
16. Violations of cannabis laws or regulations; penalties and injunctions.
17. Formal hearings; notice and procedure.
18. Ethics, transparency and accountability.
19. Public health and education campaign.
20. Uniform policies and best practices.

Accommodative Residences Utilizing Community Medicaid Exemptions for Older Adults and Persons With Disabilities

By Joseph J. Ranni

Executive Summary

August 12, 2021

The following proposal is the result of a multi-disciplinary pro bono collaboration and is non-proprietary.

PROPOSAL: To facilitate the development of accommodative housing for persons with disabilities regardless of their age. Personal resource preservation and service delivery would occur consistent with existing Community Medicaid, Nursing Home Waiver, Redirection and Avoidance programs. Medicaid savings would occur though small economies of scale and expanded community-based service programs currently existing.

CONCEPT: Small condominium style, community residences with a maximum of 10–12 suites of accommodative design for persons with disabilities to age in place with spouses while preserving the financial resource exemption for primary home ownership consistent with the Community Medicaid Resource Exemption. The Community Medicaid monthly income exemption (and excess income) allows for the payment of monthly common charges for food, utilities with the residence providing common area housekeeping, maintenance, landscaping, and security.

PURPOSE: Provide home ownership in fee simple for individuals from which they would never have to move who are otherwise eligible for congregate care. The community residence would provide maximum independence for residents regardless of physical or mental health limitations throughout the remainder of their lives. As the residence could be in any small town or urban neighborhood, access for family and friends can be maximized. Additionally, existing community supports and services programs can be expanded or modified.

METHOD: Community Medicaid resource and income exemptions would be utilized to allow for the purchase of a residential suite and provide for the monthly expenses. Personal care services would be provided through existing Consumer Directed Personal Assistance Services (CDPAS) or licensed home care services through Managed Long Term Care Plan entities (MLTCP's). Medicaid costs are reduced through smaller shared service delivery economies of scale and nursing home avoidance. Additionally, "overnights" and more fluid care delivery for residents can occur as service delivery would be shared by consumers and homecare workers would be able to provide services to multiple clients. Community-based services can provide for myriad non-care services including companionship, socialization, and oversight.

COMPOSITION: Small community residence condo-like apartments, either stand alone or clustered, consisting of suites directly opening to common interior areas with secure exterior areas accessible from the common area. Suites would be of universal design with private bedroom, accommodative bath, sitting area, and hazard-free kitchenette. The suites could also have two bedrooms such that a parent, child, or caregiver could co-reside. Exterior spaces would include porches and patios, grass and gardens, playground and walkways.

OWNERSHIP: Condominium residence ownership would be in a purpose-built or renovated structure compliant with disability and memory care guidelines. The ownership interest is an exempt resource asset under Community Medicaid eligibility rules. While Medicaid has many rules and some exemptions, preserving assets through home investment is a typical "spend down" strategy in current elder planning to preserve resources in the primary residence otherwise lost pursuant to nursing home Medicaid poverty requirements. Unfortunately, many people live in homes that cannot accommodate their disabilities and must move. Since Community Medicaid allows a principal residence up to $906,000 of equity to be exempt, residences could be simple or complex, and the purchase funds preserved as an exempt resource that can be used for liquidity and a source of funds for monthly expenses. People who are house rich and cash poor will be able to preserve their resources and provide for their future needs. Conversely, people with strong income but no residence can obtain a mortgage and invest in an exempt asset.

Joseph J. Ranni is an attorney in private practice concentrating in disability, elder and civil rights law and litigation who has acted as lead collaborator. He is co-chair of the Disability Rights Committee and a member of the Health Law Section Committee on Long Term Care and Public Health Committee as well as a member of the Elder Law/Special Needs Long Term Care Facilities Reform Legislative Committee. He is also board president of the non-profit Independent Living Inc. which provides community supports and services for people with disabilities in the Hudson Valley.

Residents retain all exclusive ownership rights and responsibilities typical of primary homeownership for their individual condo suite. At any time, the resident can sell their interest as is typical of any condominium interest, though the purchaser would preferably be otherwise eligible for congregate care. Notwithstanding, while the equity may be accessed for any purpose, sufficient balances must be preserved to provide an uninterrupted income stream (ex. SSI, SSDI, pension, 401(k) etc.) such that monthly common charges through the age of mortality plus five years can be paid.

An issue is whether a person should need to be otherwise eligible for congregate care or should or could there be restrictions on transfer. Comments have been between a need for restriction while others believe them unnecessary, pointing out that regardless of how nice this sounds, the environment is necessary not by choice for older adults. Notwithstanding, other disability residences might prefer no restrictions and promote integrated housing.

MONTHLY EXPENSES: People would be responsible for their monthly expenses the same as if they were living in a private residence, though with more amenities. The residence would have a building manager, cook, common area housekeeping, maintenance, security and environmental non-care services. Community Medicaid allows an individual a monthly income exemption of $884 with excess income that can be used for non-Medicaid housing and costs of living. Consequently, the typical Social Security, pension, IRA etc. income can be used to pay a monthly expense that would be utilized for the maximum benefit and at the discretion of the individual. Residences can be complex or simple with different attributes and amenities as people may choose based upon personal resources and preferences. Monthly expenses will vary the same as a retirement community, condo/coop or homeowners' association.

ADDITIONAL EXEMPT RESOURCES: Medicaid has several rules concerning "allowable" exempt resources beyond the home, though the amounts are very low. An individual is allowed assets of only $15,900; with Medicaid-dependent spouse, $23,400; and non-Medicaid spouse is permitted up to $130,380 of assets. Additionally, prepaid burial expenses are exempt. Consequently, while the individual limits are very low, individuals with or without their spouse would be able to maximize benefits through shared expenses.

SERVICE DELIVERY: Currently, people are typically shuffled from home or senior residence to assisted living when they need "hands-on" or "within reach" direct care assistance with at least two Activities of Daily Living (ADL). ADLs include hygiene, dressing, grooming, eating, bathing, continence, transfer, and mobility. After a person loses function in three or more, they are eligible for nursing home care. Typically, memory and mobility/transfer are the primary cause. Regardless, many assisted living and nursing homes don't have memory care units. Whether home or in congregate care, many people will subsequently need palliative or hospice care.

Appropriate service delivery also includes assistance in Instrumental Activities of Daily Living (IADL). While these aren't specifically directed to the mental and bodily functions as are ADLs, they are necessary for an appropriate living environment. IADLs include cooking, cleaning, laundry, finances, and transportation as a few examples.

Whether nursing home, assisted living or aging in place (living home), these supports and services are currently provided through Medicaid programs if a person is eligible and unable to privately pay for the services. People aging in place are likely living in homes they own and using their monthly income for financial support while most people in assisted living or on nursing home Medicaid cannot own a home and are becoming totally impoverished. A tragic corollary effect is that once a person begins that journey they become separated from their spouse physically, financially, and emotionally.

Most people aging in place utilize Community Medicaid and receive ADL/IADL services inside the home through a Managed Long Term Care Plan (MLTCP) and Consumer Directed Personal Assistance Services (CDPAS), which typically contract with licensed homecare. There is often the opportunity to choose among regional MLTCPs that are responsible for performing an assessment and determine services and scheduling. All caregivers are required to be properly trained, licensed if necessary, and compliant with the obligations consistent with any program pursuant to which services are provided.

Services are allocated based upon "hours per day" correlated to need. Requiring more than 12 hours (overnights) is a logistical challenge to remain home and subject to additional Medicaid scrutiny whether a person is "able" to remain home. Notably, this is a financially based rationale as the hours that need to be covered are nighttime hours when a person requires the least care. Smaller service delivery economies of scale can provide for the overnights and provide uniquely tailored service delivery over the course of each day. Additionally, as MLTCPs benefit from providing services to people co-located, there would be the greater potential of obtaining more or enhanced services for a person than would be available at home

Normative activities are those that provide quality of life, companionship, socialization and recreation. While not considered in Medicaid assessments, these are the reasons for living. Appropriate community environments would provide for the integration of ADLs, IADLs and normative activities. This can be accomplished by building upon community networks as an overlay to direct care services.

Telemedicine has expanded exponentially as a result of the pandemic and includes remote health monitoring, immediate access to professionals and coordinated follow-up.

Importantly, the accommodative residence would provide an appropriate environment for hospital/rehabilitation discharge that should reduce the likelihood of readmissions through better outcomes. Beyond the obvious financial savings, quality of life is also improved.

Hospice and palliative care have also advanced such that end-of-life comfort can occur where a person lives. Transfers to a hospice residence occur because of the caring and supportive environment provided. In this proposal an accommodative home would already exist with family, friends and faith close by.

Other potential benefits include mollifying potential offensive behaviors that occur in congregate care. A person would be acclimated to a new environment and routines before mental acuity degenerates. Transfer trauma currently occurs when a person is least capable of adjusting to their sequentially changing living environment, which the proposal eliminates

LICENSING and INSPECTIONS: The residence is providing accommodative design and services that if currently being provided to someone in their home would not need separate licensing. All direct care giving is provided through MLTCP or CDPAS that are licensed or approved entities according to current Community Medicaid regulations. Questions have arisen whether this should be regulated as senior housing, enriched adult home, assisted living facility or simply hospitality industry inspections of food service and common areas. In brief, essential elements of assisted living facilities require case management and care planning which would not be done by the residence, but instead the Community Medicaid licensed professionals as currently exists for people aging in place. The only "services" arguably offered under the regulations is providing limited IADL assistance and facilitating normative activities which are unregulated. Providing a cook, common area housekeeping and limited non-care services are little different than full-service retirement communities or some condo/coop developments with mandatory club charges.

COMMUNITY SUPPORTS and SERVICES: Currently there are broad community supports and services for persons with disabilities across a wide spectrum though far less for older adults with the same or similar types of disability. These include mental health services, peer counseling services, visitation and linking people to other community-based services. There would also be greater access to faith-based services. Notwithstanding, innovative community-based programs are being aggressively developed to address the pandemic crisis for all persons with disabilities regardless of age who seek to avoid institutionalization and receive community supports and services.

A component of Community Medicaid is to create a "partnership" between the MLTCP and "family contribution." However, many families are unable and some unwilling to provide cooperative assistance. Beyond that the smaller economy of scale should offset some of those needs, the residence supplements some IADLs, and community programs can be expanded to provide some of these supportive services as well.

BROAD APPLICATION: While the proposal can be most helpful to the current middle class, there is clear potential for low-income individuals using exempt resources to preserve assets in an exempt property interest and establish a financial base while receiving services. Low- or no-interest loans could be offered to non-profits for build-out or specific purpose grants/subsidies for particular populations as currently exists.

Since the residences are small, they could be built for special purposes for which people may *want* to socialize in their living situation. Whether religious reasons, disability related or just similar interests they can accommodate personal independence of choice for people in need of accommodative housing. There are existing and new policy efforts for greater community integration with other types of affordable or workforce housing into which the concept could easily be incorporated. While the residences can be operated standalone, optimally they would be integrated into every community seamlessly. There is no reason a residence could not be included in a retirement or recreational community as well.

ADDITIONAL FEATURES: To provide the most integrated setting, no more than five residences should be grouped on any building lot unless co-located with other forms of housing with the residence comprising no more than 20% of the total units. There would be a maximum of 12 suites of accommodative design which must at minimum consist of a bedroom, sitting area, kitchenette (hazard-free) and bathroom. The sitting area must be large enough to provide for a pull-out queen bed if no second bedroom. Each suite must open directly to the common area. While the suite entry can be a foyer, it should not be a hallway, though recognizing urban design may require otherwise. Each residence shall maintain common exterior spaces directly accessible from the interior common areas. Each residence should provide freshly prepared meals with food service available a minimum of 12 hours per day and accessible 24/7. Each residence would provide common area security, housekeeping services and premises maintenance. Each residence would provide for all common charges for utilities, water, sewer, maintenance (not including interior suites), and common areas both interior and exterior.

MEDICAID WAIVER OF RECOVERY AS A POSSIBLE INCENTIVE:. New York State Medicaid currently retains a right of recovery against the primary residential resource after the death of the resident and potentially the surviving spouse. Should Medicaid waive such right, and allow the resource to pass to beneficiaries, a significant financial incentive would be created for this type of nursing home avoidance. Recovery is pursued on a county-by-county basis and varies across the state with no uniformity

in rules. Notwithstanding, due to advanced elder law planning techniques, assets actually recovered are very limited relative to the financial burdens upon counties in providing services. The anticipated savings to Medicaid should be substantial relative to waiving the amounts obtained through recovery and the burdens of obtaining same.

WHAT'S THE ASK? This collaboration is for the purpose of advancing a proposal to compel discussion of community-based solutions that can be implemented immediately. Comment and formal consideration are sought from all diverse stakeholders, hopefully with the purpose of advancing and enhancing the potential of creating a unified plan. There is an opportunity to provide better integration and life continuum for persons with disabilities, regardless of age or type, to be and remain an active part of all communities.

A further goal is to create a condominium template and streamline the process to facilitate construction and renovation as soon as possible. This would reduce both planning and development costs. Perhaps there is the potential of providing a method to facilitate expedited local government zoning, planning, and building approval as well.

CONCLUSION: The proposal provides an opportunity for individuals with disabilities regardless of age, whether living in rural or urban settings, to enjoy an appropriate living environment with improved quality of life while having their support and care needs met. Most importantly they will preserve assets and continue to reside in the community with their spouse and never have to move. Lastly, Medicaid will save money though more appropriate economies of scale while also providing more appropriate community-based care.

A Note About the Proposal Development and Collaboration

This proposal is a multi-disciplinary collaboration among legal, elder, disability, health, care service and residential care professionals brought together through personal and professional direct involvement during the pandemic and recognizing the need for systemic response. All have acted in their individual capacities and no association or organization endorsement is represented.

Special thanks is extended to the Interdisciplinary Public Health and Palliative Care Certificate Program, Finger Lakes Geriatric Education Center at University of Rochester Medical Center.

The Intersection of Partisan Affiliation, Political Polarization, and COVID-19 Pandemic Response

By Mary Scouten

Prior to the outbreak of COVID-19 across the world, the United States was already facing extreme political divide, due largely to the partisanship structure of our government.[1] While President Obama, a Democrat, was in office, the division between Republicans and Democrats in fundamental political areas, such as the role of government, social and racial issues, and national security, reached record levels.[2] By the end of Obama's presidency, Gallup Polls reported a 77 point gap between the president's approval among members of his party and Republicans.[3] Those gaps grew even larger when President Trump, a conservative Republican, took office.[4] By Trump's third-year in office, the gap rose to 82 points, "which is the largest degree of political polarization in any presidential year measured by Gallup."[5]

Given the political climate of our country at this time, it is no surprise that our nation quickly turned the spread of the novel coronavirus, COVID-19, into a politicized issue.[6] The first reported case of COVID-19 in the U.S. was on January 21, 2020.[7] By March 11, 2020, the World Health Organization declared COVID-19 a global pandemic.[8] Now, a number of studies show that "partisan affiliation is one of the strongest single predictor of behavior and attitudes about COVID-19, even more powerful than local infection rates or demographic characteristics, such as age and health status."[9] This raises an important question – is this predictor based on genuine political beliefs that fundamentally distinguish the two parties? Or is it a result of the juxtaposition of competing party ideologies and the intense need to be in opposition to the other party?

Historically, the two parties have been separated by their stance on major issues such as social justice, government regulation, and health care policy.[10] Democrats often favor community and social responsibility, government regulation to protect consumers, and strong government involvement in health care, whereas Republicans favor individual liberties and view government involvement as an impediment on those liberties.[11] Additionally, Democrats have consistently reported having greater trust in science than Republicans.[12] Given these stark differences, "it's not exactly news that Democrats and Republicans don't like each other"; however, today we are facing a long-developing trend of loathing the opposite party.[13] This level of hatred is what political scientists call "negative partisanship."[14] Now, nearly one-and-a-half years into the pandemic, "research indicates that many people are looking at [COVID-19] policies they don't like and blaming whichever party they're not part of."[15] Keeping these competing foundational party principles and negative partisanship in mind, this article will consider how it directly relates to both the government and the two political parties' response to COVID-19, specifically with regard to stay-at-home orders and mask mandates.

Scientific studies show that wearing a mask properly reduces a person's exposure to the virus by 65%, whereas double-masking (wearing a surgical mask and a cloth mask) increases the protection up to 83%.[16] Nevertheless, while the Center for Disease Control (CDC) and individual states began to issue mandatory quarantines and stay-at-home orders,[17] mask mandates, and prevention guidelines, President Trump repeatedly downplayed the severity of the highly infectious and deadly disease.[18] In January 2020, Trump told a CNBC reporter that "we have it totally under control. It's one person coming in from China . . . it's going to be just fine."[19] Later in February 2020, Trump said that "[t]he risk to American people remains very low. We have the greatest experts, really in the world, right here."[20] Yet, on a number of occasions, Trump refused to act in a manner appropriate to the magnitude of the emergency, discrediting those very experts he said were the best. Most notably, Trump repeatedly questioned Dr. Anthony Fauci, the leading U.S. official on infectious diseases, in his effort to convince people to wear masks to slow the spread of the disease.[21] Later, on September 30, 2020, Trump held a presidential campaign rally in Minnesota, where he entered and remained on stage unmasked.[22] Just two days later, President Trump announced to the public that he was diagnosed with COVID-19.[23] Tweeting from the military hospital where he was receiving treatment, Trump again downplayed the severity of the disease, writing "[d]on't be afraid of Covid . . . . Don't let it dominate your life."[24] At that time, more than 210,000 people in the United States had died from COVID-19.[25] Despite the scientific evidence backing mask mandates, the death tolls consistently rising, and scientists, ethicists, and doctors all across the U.S. urg-

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ing the public to comply with the federal and state COVID-19 guidelines,[26] a poll conducted in May 2020 showed that Democrats reported being almost twice as likely as Republicans (70% v. 37%) to say they wear a mask "every time" they leave their house.[27]

The wearing of masks quickly "became a catalyst for political conflict, where scientific evidence was viewed through a partisan lens."[28] Mask mandates elicited great anger around the United States, "inciting a nationwide feud about public health, civil liberties, and personal freedom."[29] The mandates soon led to what is now commonly referred to as the "anti-mask" movement among Republicans.[30] The divide between those who wear masks and the "anti-maskers" is increasingly sharp.[31] In interviews in the Midwest and across the U.S., "many people sounded deeply mistrustful of people on the other side and blamed them for the nation's economic and public-health crises."[32] Even during the 2020 presidential campaigns, and just two days before Trump tested positive for COVID-19, former President Trump mocked current President Biden for always wearing a mask.[33]

Notwithstanding the anti-mask movement, Republican-leaning states where economies opened up early and where people are less likely to wear masks saw a sharp increase in positive COVID-19 cases.[34] Then, in August 2021, as the nation addressed the spread of the novel Delta variant, a recent Quinnipiac poll found that while "nearly 60 percent of Americans overall . . . [said] they were concerned about the Delta variant, more than 60 percent of Republicans said they weren't."[35] This ongoing division between the two parties, dating back to the beginning of the pandemic, is consistent with the competing party ideologies and the trend of negative partisanship.

Perhaps what is most alarming is that while President Trump continued to discredit the science and experts that he previously said were the best in the world,[36,37] the support for him by a majority of Republicans did not waiver.[37,38] A study conducted by The Ohio State University revealed that "trust in Trump predicted less concern about the virus."[38] Finally, a poll conducted in October 2020 revealed that "89% of Republicans and GOP-leaning independents who rely most on President Trump and his task force for news about COVID-19 reported that the U.S. has controlled the outbreak as much as it could have."[39]

Despite seemingly unwavering support for President Trump by a majority of Republicans, he delegated to the states most of the responsibility for the COVID-19 response.[40] And although national guidelines have an effect, states hold considerably more power in the United States than the federal government in terms of setting and enforcing public health regulations.[41] State governments have the ability to approach the COVID-19 pandemic by targeting their specific population with public health policy and economic responses.[42] As part of the states' police powers, "state governors have the authority to implement quarantines or lockdowns of their citizens."[43] Unsurprisingly, it follows that "a state's partisan orientation often explains its public health policies, including the timing and duration of stay-at-home orders, bans on social gathering, and mask mandates."[44] In a study conducted by Christos Makridis and Jonathan T. Rothwell, results showed an increased likelihood that Democratic-ran states adopted a state shutdown order and mandatory mask-wearing policy over Republican-ran states.[45]

Given the leadership of the states and the failure of the Trump Administration to present guidelines for the general public to follow, state governors started to receive a lot of praise. In March 2020, Governors of New York, New Jersey, and Connecticut, all Democrats, formulated the same rules for closures, citing that they "were forced to act because of a lack of coordination from the federal government."[46] By July 2020, 93% of Democrats reported trusting their Democratic governors over Trump.[47] At that time, New York's (now former) Democratic governor, Andrew Cuomo, became a standout leader in the nation's COVID-19 response.[48]

New York had its first confirmed COVID-19 case on March 1, 2020[49] and by March 7, 2020, Governor Cuomo declared a statewide disaster emergency.[50] By March 20, 2020, Cuomo "took the most drastic action possible and ordered all nonessential businesses to close statewide."[51] Countless executive orders were to follow, as well as daily COVID-19 briefings broadcasted on every local news network, quickly growing in national popularity.[52] During a six-day period in March 2020, more than 4.7 million people tuned in to watch Cuomo's briefings.[53] Cuomo's swift rise to fame even led to calls for him to run for president, as "#PresidentCuomo" began to trend on Twitter.[54] At that same time, a Siena poll reported that 87% of New Yorkers approved of Cuomo's handling of the pandemic, compared to only 41% who approved of Trump's response to the crisis.[55] Cuomo suddenly became a national figure—a de facto leader in COVID-19 response.[56] At the time, his consistent presence in daily briefings and support for scientific experts' recommendations was just what America was looking for. Known for being a "bully-for-good,"[57] Cuomo's brash and seemingly no-nonsense approach "was a welcomed relief from President Trump's approach to the virus."[58] Continuing to stand out as the nation's leader, in August 2020, Governor Cuomo called the president's handling of the COVID-19 pandemic "the worst government blunder in modern history."[59] And as the pandemic worsened, "the governor's approval rating shot to its highest level since his 2011 inauguration."[60]

Yet, Governor Cuomo, like President Trump, was not without his faults. Governor Cuomo, along with other state leaders, prohibited nursing homes from discriminating against residents based on their COVID-19 infection status, thereby allowing residents to be admitted or return to the nursing home while testing positive for COVID-19.[61] This move by Cuomo received great pushback from the general public; however, this was in March 2020 when the

hospitals in New York City and all across the state were so overwhelmed that "New York's hospital lobby was pleading with Cuomo to issue policy on transfers to nursing homes."[62] Cuomo managed to avoid career-threatening blowback at this time, but then the public learned of what is now known as the nursing home reporting scandal.[63]

Within a matter of days, "one of America's most trusted voices in the COVID-19 pandemic became a political pariah."[64] Cuomo's fall from admiration to demise occurred after reports by New York's Attorney General, Letitia James, alleged that the Cuomo administration had undercounted nursing home deaths by several thousand.[65] A subsequent preliminary investigation conducted by the Attorney General's office, released on January 2021, accused the Cuomo administration of under-reporting deaths by as much as 50%.[66] Cuomo "later acknowledged as much, blaming the lower figure on fears that the Trump Administration would use the data as a political weapon."[67] Yet still, in August 2021, just two days into Cuomo's successor, Gov. Kathy Hochul, taking office, the Hochul administration acknowledged an additional 12,000 deaths from what had previously been reported.[68] Cuomo's "fall from grace is a cautionary tale of the perils of policymaking during a public health crisis."[69] As an elected official entrusted to lead the state in public health policy during a time when political polarization reached unprecedented levels, Cuomo succumbed to political agendas.

Perhaps the most fascinating aspect of the nursing home reporting scandal is how the general public and other state officials were so quick to condemn Cuomo, declaring his failure to report nursing home deaths to be "completely unethical."[70] Government officials should be held to high standards of transparency, which it would be hard to argue Cuomo met. But studies have shown that the ineffective national policies and responses are the biggest drivers of COVID-19 cases in the U.S.[71] And "the costliest errors of the Trump Administration were committed in the pandemic's earliest stages." For example, "eight months into the pandemic, over 80% of U.S. nurses reported to still reusing at least one type of single-use personal protective equipment (PPE) because of the federal government's failure to budget appropriately to supply PPE."[72] Nevertheless, despite an ailing economy and a failed pandemic response, President Trump continued to enjoy strong support among his voters.[73]

So why is it that the general public's response to Governor Cuomo's nursing home policies and failure to report nursing home deaths created such an immediate backlash, while so many of President Trump's failures were written off? Perhaps it is because the political parties that Cuomo, a Democrat, and Trump, a Republican, represent. More Americans say that "the Democratic Party is described well by phrases such as 'governs in an honest and ethical way.'"[74] Cuomo, once known as a "bully-for-good,"[75] was held to those Democratic values. His political downslide is one of moral code violations—lying to cover-up the actual number of nursing home deaths in our state to fulfill a personal political agenda. This unscrupulous leadership, although did not necessarily put the general public at increased risk for exposure to COVID-19, went against those very Democratic values that once resulted in his praise.[76] Trump, on the other hand, has an affinity for conspiracy theories, a characteristic shared by many of his supporters.[77] Those conspiracies regarding COVID-19 have encouraged Americans to disobey public health guidance, putting us all at risk,[78] yet this rhetoric was overlooked because it is consistent with the Republican party's ideologies—such as lack in trust of science and an emphasis on individual liberties.

It would be difficult to prove that a less politically polarized climate, or a more widespread, generalized support of science could change the outcome of the COVID-19 pandemic. However, we have seen first-hand how negative partisanship has shaped the government and each party's response. As time passes, more studies will surely be conducted analyzing political affiliations, government response, and the ultimate outcome of the COVID-19 pandemic. Regardless of those conclusions, the federal and state COVID-19 policies, governmental actor's shortcomings, and the political climate of our nation during this time will unquestionably define our nation's history. It will also provide future leaders with data that can guide them during the next public health emergency. Hopefully at that future time, a more bipartisan approach can be taken.

Endnotes

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The Public Health Intersection of COVID-19 and the Obesity Epidemic

By Megan Edwards

Over the course of the last tumultuous year, infectious disease researchers have discovered much about the pathology and impact of the novel SARS-Cov-2 virus, otherwise known as COVID-19. One such important avenue of research is the impact of COVID-19 on obese and overweight patients. Before the pandemic reached the United States, the country was facing an obesity epidemic.[1] As of 2019, CDC data showed that 12 states have an adult obesity prevalence of at least 35%—an increase from nine states back in 2018.[2] Obesity puts individuals at risk for myriad health issues, including heart disease, stroke, type-2 diabetes, and some kinds of cancers.[3] Importantly, obesity also puts individuals at risk for severe COVID-19.[4] Here we will briefly explore the public health intersections of COVID-19 and obesity.

It is theorized that obese people tend to experience more severe illnesses from COVID-19 because of the way the virus infiltrates the body. COVID-19 binds with receptors on human cells called ACE-2 receptors.[5] These receptors are found in the heart, lungs, kidneys, and the intestines, creating multiple pathways for the virus to infiltrate the body.[6] Preliminary data also shows that these receptors are higher in concentration in adipose tissues—tissue that is found in increased amounts in people living with obesity.[7] Because of the increased number of ACE-2 receptors, and in addition to the immune system's over-response to infection, obese patients face an increased risk for adverse impacts from COVID-19.[8] A recent CDC study of the relationship between COVID-19 and obesity supports this theory of pathology.[9] This study surveyed the 148,494 adults who received a COVID-19 diagnosis at 238 U.S. hospitals between March of 2020 and December of 2020.[10] Of these patients surveyed, 50.8% of them were obese.[11] The study found that obesity was a risk factor for hospitalization, invasive mechanical ventilation, and death.[12]

Given the dangerous relationship between COVID-19 and obese patients, it is unsurprising that obesity has been identified by the CDC as one of the 12 underlying medical conditions that increase the risk of severe illness from

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COVID-19.[13] Accordingly, 29 states included obesity as a condition to receive priority access to the COVID vaccine, while 32 states give priority access to those with severe obesity (BMI of 40+).[14] As obesity is by far the most prevalent high-risk factor for essential workers, access to vaccines is vital for a huge population of Americans.[15]

The priority status for obese patients has generated controversy and backlash. Those who are not obese claim that giving obese people priority for the vaccine is not fair because they are being "rewarded for bad habits."[16] But this outright fat-shaming ignores the realities of what causes obesity, including myriad factors such as genetics, underlying illnesses, trauma, and structural socioeconomic inequalities.[17] Additionally, it has been suggested that listing obesity as a condition for priority vaccine access is a way to serve underserved populations—essentially, obesity is a proxy to reach those who have been traditionally left out when it comes to health initiatives.[18]

People living with obesity have had mixed feelings when it comes to being given priority access to the vaccine. Some obese people are hesitant to take advantage of the priority listing because of public ridicule.[19] Others note that larger people, especially in America, have been discriminated against in general society and in the medical community, and will take advantage of the ability to gain access to a lifesaving vaccine.[20]

As more vaccines have become available, medical professionals have urged every person to get vaccinated—especially those that are immunocompromised or have other health risk-factors such as obesity. All vaccines currently available in the U.S. have shown equal efficacy in patients with obesity and non-obese patients.[21] The vaccines are also effective against the delta variant.[22] Despite this, with the current uptick in COVID cases due to the rise of the delta variant, those breakthrough cases that are occurring are manifesting mostly in patients in high risk categories such as obesity.[23] Unvaccinated communities—those that tend to have high rates of risk factors like obesity—ultimately face the biggest risk from the delta variant.[24] This reality highlights the importance of getting vaccinated and exercising proper COVID safety practices.

In addition to the risk of severe illness, COVID-19 has compounded the issue of obesity in the United States. Early into the pandemic, factors that contribute to obesity were amplified, such as increased periods of low activity and increased caloric intake from processed foods.[25] The pandemic also brought on an increase of socioeconomic hardships.[26] People struggling financially often turn to cheaper, highly processed, readily available, and calorie-dense foods, which contribute to weight gain.[27] Additionally, people quarantining spent more time inside and away from others, leading to increased sedentary periods and less physical activity, which also contribute to weight gain.[28] Adults, children, and even pets have gained weight over the course of the last year.[29]

This health crisis has highlighted the severity of the obesity epidemic. Physicians have recognized that diverse treatment options will be necessary to effectively treat obesity—the "eat less, move more" approach has not sufficed.[30] As the world regains a semblance of normalcy, some doctors suggest the immediate resumption of weight management and bariatric surgeries to combat severe cases of obesity. But beyond these more traditional weight management interventions, treatment innovations must be made to help a wider array of obese patients—especially in the current health climate.[31] Personalized counseling interventions that focus on the individual patients' personal barriers to meaningful lifestyle changes move away from the "one size fits all" approach.[32] Individualized counseling focusing on manageable and actionable changes for each patient—while also establishing an empathetic relationship between physician and patient—has the potential to foster motivation in each patient that results in lasting behavioral lifestyle changes.[33]

Endnotes

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