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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

Meeting the Challenges of a Post-*Roe* World—Commentary from a Hospital Counsel Perspective

Franchise Regulations in the Context of the MSO Model

An Overview of the Office of Medicaid Inspector General's Proposed Medicaid Fraud, Waste, and Abuse Prevention Regulations

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A Message From the Section Chair

Hello, colleagues!

It is my pleasure, as the chair of the Health Law Section, to welcome you to this edition of the *Health Law Journal*. And I am especially pleased to note that, after two long years of virtual meetings and events, 2022 has been the year we finally started getting back to business in person.

In September, we gathered for an informal get-together to welcome fall at the home of one of our Section members. Great food, great company, great weather and a friendly bocce competition made for a memorable day. Many thanks to Karen Gallinari for her gracious hospitality. In November, we recognized the accomplishments of Assemblymember Richard Gottfried, New York's longest-serving legislator, at an in-person conference at New York University. There, we learned about the Assemblymember's contributions in the areas of health care access, civil liberties, health care decision-making, and health care oversight during his 52-year tenure in public service. We are grateful to Anoush Koroghlian-Scott, Lisa Hayes, Mary Beth Morrissey, Mark Ustin, Jim Dering, Robert Swidler, Danielle Holley Tangorre, Hermes Fernandez, Jim Lytle and all our speakers—and of course to Assemblymember Gottfried—for their contributions to an enlightening and entertaining day. After the conference, we gathered on a rooftop deck to unwind. It was good to renew old acquaintances and make new friends.

In January, we look forward to returning to an in-person format for our Annual Meeting in January at the New York Hilton Midtown. Our program chairs are planning a full day of informative programs addressing hot topics and emerging issues of interest to New York health law practitioners. We will meet in the morning for our customary committee breakfasts, convene for a morning of educational sessions, break for lunch to elect new officers and to network, then reconvene for more programing in the afternoon. It has been rewarding to see the engagement and participation of Section members from many practice settings across the State. We hope you will join us.

This issue of the *Health Law Journal* continues in our Section's tradition of addressing cutting-edge health law issues and their impact in New York. In "License to Heal: The State of Telehealth vs. Telehealth of the States," the author explores the history of telehealth, describes its use during the pandemic, and identifies regulatory trends that may affect its use in the future. In "Franchise Regulations Within the Context of the MSO Model," the author addresses the potential impact of franchise regulations on management service organizations in the context of their efforts to comply with the corporate practice of medicine doctrine. This issue includes a commentary from a hospital counsel on the impact of the decision in *Dobbs* on the efforts of practitioners seeking to offer safe and effective care to those who seek it. This issue also includes a summary of proposed regulations from the Office of the Medicaid Inspector General addressing Medicaid fraud, waste and abuse prevention.

One of the best ways to learn more about a specific health law subject area is to join one of our committees—we have nearly a dozen—and to collaborate with other members in monitoring and influencing the laws that affect your practice. In recent months, we have invigorated our leadership with the installation of new committee chairs and co-chairs. Learn more about our committees here: https://nysba.org/committees/health-law-section/.

We hope you will get involved, stay involved, and encourage others to join you. I look forward to seeing you soon at an upcoming event.

Jane Bello Burke
Chair, Health Law Section

In the New York State Courts

By Dayna B. Tann and Marc A. Sittenreich

Eastern District of New York Dismisses Constitutional and Title VII Challenge to the New York State COVID-19 Vaccine Mandate for Health Care Workers

Does 1-2 v. Hochul, No. 21 Civ. 5067, 2022 WL 4637843 (E.D.N.Y. 2022). On Aug. 26, 2021, the New York State Department of Health adopted an emergency regulation, codified at 10 N.Y.C.R.R. § 2.61 ("§ 2.61" or the "Mandate"), which requires hospitals, nursing homes, and other covered entities to ensure that their patient- and staff-facing workers are "fully vaccinated" against COVID-19. The state's Public Health and Health Planning Council (PHHPC), which issued the rule, released a Regulatory Impact Statement stating that the Mandate was driven by a 10-fold increase in cases of COVID-19 in less than two months, 95% of which were attributable to the Delta variant of the virus. The PHHPC found that the presence of unvaccinated personnel in health care facilities posed "an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications." In line with those findings, § 2.61 contained only a limited medical exemption—and no religious exemption—to the vaccination requirement.

Plaintiffs are five anonymous health care workers, employed by New York Presbyterian Healthcare System, Inc., Trinity Health, Inc., and Westchester Medical Center Advanced Physician Services, P.C. (collectively, the "Private Defendants"), who objected to the vaccination requirement on religious grounds. All of the Private Defendants amended their policies in order to comply with § 2.61 and, as a result, denied Plaintiffs' religious exemption requests or revoked exemptions that had been granted under their pre-existing vaccination policies.

On Sept. 10, 2021, Plaintiffs filed suit against Gov. Kathy Hochul and former Commissioner of Health Howard Zucker (collectively, the "State Defendants"), as well as the Private Defendants, in the U.S. District Court for the Eastern District of New York. Plaintiffs alleged that the Mandate violates the Free Exercise Clause of the First Amendment and the Equal Protection Clause of the Fourteenth Amendment and is preempted by Title VII of the Civil Rights Act of 1964. Plaintiffs also brought Title VII claims against the Private Defendants, alleging that they failed to accommodate Plaintiffs' religious beliefs by denying their requests for religious exemptions or revoking exemptions that had previously been granted. Finally, Plaintiffs brought conspiracy claims against all Defendants under 42 U.S.C. § 1985(3). Defendants moved to dismiss.

The court first addressed Plaintiffs' First Amendment claim. It began its analysis with a discussion of the Supreme Court's landmark ruling in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) and multiple subsequent decisions that stand for "the principle that governments have the power to enact mandatory vaccination policies to protect the public health in the face of a public health emergency." The court went on to explain that the Free Exercise Clause "does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability'" simply because it requires conduct that violates his or her faith.

Reviewing the Mandate, the court found it to be "neutral on its face" because § 2.61 does not reference religion and applies to "all persons employed or affiliated with a covered entity" who have the potential to expose patients, residents, or co-workers to COVID-19, except for those individuals for whom the vaccine is medically contraindicated. The court also held that Plaintiffs had cited "no evidence to suggest that the state's purpose in enacting Section 2.61 was to suppress or discriminate against the exercise of religion," as opposed to "protecting the public" from "exposure to a highly contagious and potentially fatal infection." The court noted that the PHHPC's decision not to include a religious exemption in the Mandate was consistent with multiple other vaccine mandates imposed on New York State health care workers, such as the requirement to be immunized against measles and rubella, which similarly lack a religious exemption.

Likewise, the court found the Mandate to be generally applicable. The court asserted that a law is not generally applicable if it "prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way" or provides a "mechanism for individual exemptions." Plaintiffs alleged that by permitting medical exemptions but not religious exemptions, the State Defendants treated "comparable" secular conduct more favorably than religious conduct and undermined their alleged interest in public safety by allowing medically exempted, unvaccinated workers to remain in their patient- and staff-facing roles. The court rejected this argument, finding it "self-evident that requiring an employee to be vaccinated even if the employee has a documented medical condition that makes vaccination unsafe would not promote the interest in protecting healthcare workers" or "avoiding staffing shortages." The court further rejected Plaintiffs' claim that the Mandate "creates a system of individualized exemptions," as § 2.61 provides "objective standards" for workers seeking a medical exemption, including a "certification from a physician or certified nurse practitioner attesting that they have a pre-existing health condition that renders the vaccination detrimental to their health, in accordance with generally accepted medical standards."

Given its determination that the Mandate is a neutral law of general applicability, the court applied rational basis review to Plaintiffs' First Amendment claim. The court found that "Section 2.61 easily meets this standard," and dismissed Plaintiffs' claim, in light of the extraordinary public health crisis caused by the COVID-19 pandemic.

For the same reasons, the court dismissed Plaintiffs' Equal Protection Clause claim. The court held that workers with medical contraindications to the COVID-19 vaccine are "not similarly situated" to religious objectors to the Mandate. The court also explained that "a law subject to an equal protection challenge" is analyzed under rational basis review where it "does not violate [the plaintiffs'] free exercise of religion."

The court then dismissed Plaintiffs' claim that the Private Defendants violated Title VII by purportedly failing to offer them reasonable religious accommodations. As a threshold matter, the court held that Plaintiffs' Title VII claim was subject to dismissal because they conceded that they had not exhausted their administrative remedies before the U.S. Equal Employment Opportunity Commission. The court went further, however, to rule that Plaintiff's Title VII claim "fail[ed] on the merits." The court observed that the "sole 'accommodation'" sought by Plaintiffs was "a religious exemption from the vaccine requirement." This accommodation "would impose an undue hardship on the Private Defendants"—and thus need not be provided—"because it would require them to violate state law." The court was also persuaded that exempting Plaintiffs from the vaccination requirement would impose undue hardship on the Private Defendants insofar as it would "expose vulnerable patients and nursing home residents, as well as other healthcare workers, to the COVID-19 virus."

The court then turned to Plaintiffs' claim that § 2.61 violates the Supremacy Clause of the U.S. Constitution. Plaintiffs argued that the Mandate "abolished the entire accommodation process under Title VII for religious objectors" to the vaccination requirement. The court first explained the Supremacy Clause is not the source of any substantive rights and does not create a federal cause of action. To the extent that Plaintiffs intended to make a federal preemption challenge to the Mandate, the court held that their claim still failed as a matter of law. The court asserted that Plaintiffs improperly "conflate[d] exemption with accommodation." While § 2.61 prohibits blanket religious exemptions to the vaccination requirement—which Plaintiffs sought—it "does not foreclose all opportunity for Plaintiffs to secure a reasonable accommodation under Title VII."

Finally, the court denied Plaintiffs' conspiracy claim under 42 U.S.C. § 1985(3). The court held that Plaintiffs could not maintain a cause of action for conspiracy because they had "not alleged a violation of the law."

[*Editors' Note: Garfunkel Wild, P.C. represented Defendant Westchester Medical Center Advanced Physician Services, P.C. in the* Does 1-2 *action*]

Appellate Division Reinstates Attorney General's Petition Against Wholesale Distributor for Price Gouging on the Sale of Lysol During the COVID-19 Pandemic

People by James v. Quality King Distributors, Inc., 209 A.D.3d 62 (1st Dep't 2022). Respondent Quality King Distributors, Inc. ("Quality King") is a wholesale distributor of various consumer products, including Lysol disinfectant, to national and local retailers. In February and March 2020, the New York State Attorney General (the "Attorney General") received consumer complaints regarding the price of Lysol at retailers who had purchased the product from Quality King. Pursuant to its authority to investigate and remediate price gouging under General Business Law (GBL) § 396-r and Executive Law § 63(12), the Attorney General sent a cease-and-desist letter to Quality King demanding that it stop charging excessive prices for disinfectants and later requested purchase and sale data.

In May 2020, the Attorney General commenced a special proceeding in the Supreme Court, New York County, alleging that Quality King engaged in price gouging for Lysol spray canisters. The Attorney General contended that there was an "abnormal disruption of the market for Lysol products" on Jan. 31, 2020, when the U.S. Department of Health and Human Services declared a public health emergency resulting from COVID-19, and that Quality King "unjustifiably sold the Lysol product for unconscionably excessive prices" after that date. These allegations were founded on Quality King's purchase and sale data, which demonstrated that prices were repeatedly raised despite relatively stagnant costs, resulting in an approximately 75% increase in gross profit margins between November 2019 and March 2020. The Attorney General sought injunctive relief, an accounting, restitution, disgorgement of profits, and a civil penalty.

Quality King interposed an answer to the petition and moved to dismiss. The Supreme Court denied and dismissed the petition, finding that despite "isolated instances of price increases," Quality King did not "uniformly raise [its] prices" in a way that would suggest the use of any unfair leverage, abuse of bargaining power, or unfair means. Furthermore, the court found that the "abnormal disruption in the market" occurred on March 7, 2020, not Jan. 31, 2020; that there was not a "gross disparity" between Quality King's pricing of the Lysol product before and after that date; and that Quality King demonstrated that it faced its own increase in costs for the Lysol product during that time period. Both parties appealed.

The Appellate Division, First Department began its analysis with an overview of GBL § 396-r. To establish a claim for a violation of that statute, the Attorney General must show: (1) an "abnormal disruption of the market for a particular good or service"; (2) that "the good or service was vital and necessary for the health, safety and welfare of consumers"; and (3) that "the alleged price gouger sold (or offered to sell) the vital and necessary good or service for an unconscionably excessive price, which is established by showing an unconscionably extreme amount of excess in price, an exercise of unfair leverage or unconscionable means, or both." Moreover, to establish a *prima facie* price gouging claim, the Attorney General must demonstrate either that there was a "gross disparity" between the price of the good immediately before and after the abnormal disruption or that the amount charged for the goods "grossly exceeded the price at which the same or similar goods . . . were readily obtainable by other consumers in the trade area." A party accused of price gouging may assert, as an affirmative defense, that the increased prices were justified by additional costs not within its control.

Turning to the merits, the Appellate Division determined that the "abnormal disruption of the market for the Lysol product" occurred on Feb. 26, 2020, when the U.S. Centers for Disease Control and Prevention warned that they expected to see community spread of COVID-19 in the United States. The court observed that GBL § 396-r(2) provides a "disjunctive" list of events that may cause an abnormal market disruption, including, among other things, a "national or local emergency," and that a "declaration of a state of emergency by the governor" is not required. The court found that as of Jan. 31, 2020—the date proposed by the Attorney General—the risk of COVID-19 had "not yet graduated to a national emergency" within the meaning of the statute. On the other hand, the appellate court rejected the date selected by the Supreme Court—March 7, 2020, when then-Governor Cuomo declared a state disaster emergency—because the national emergency began on an earlier date. The court reasoned that employing the later date "would be improper in light of the remedial nature of the price-gouging statute, and because it would potentially permit a period of price-gouging to go unchecked."

Next, the court held that the Lysol product was "vital" and necessary" for purposes of GBL § 396-r. The court stated that "consumers in the first several months of 2020 had good reason to believe that the virus could be killed if a surface were treated with a disinfectant," and thus the Lysol product was, "in the eyes of consumers, of the utmost importance and absolutely needed to address the terrible danger posed by COVID-19."

Then, the court reviewed the purchase and sale data in the record and found "several instances" where there was a "gross

disparity" between the price of Lysol immediately before and after the abnormal market disruption on Feb. 26, 2020. As different prices were charged to different retailers, the court held that each transaction for the Lysol product after that date must be compared to the price charged to the same customer in the usual course of business before the disruption occurred.

Having held that the Attorney General established all three elements of a claim for violation of GBL § 396-r, the Appellate Division reversed the dismissal of the petition and remanded to the Supreme Court for further proceedings. The Appellate Division also noted that the Supreme Court may order an accounting or an evidentiary hearing to assess the extent of any monetary remedies that may be warranted.

Finally, the Appellate Division considered, and rejected, Quality King's contention that certain terms in GBL § 396-r are unconstitutionally vague. The court stated that a statute is "impermissibly vague," and thus violates the Due Process Clause, if it "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits" or if it "authorizes or even encourages arbitrary and discriminatory enforcement." Economic regulations, however, are entitled to a "relaxed vagueness test" because businesses "can be expected to consult relevant legislation in advance of action." Thus, an economic regulation is invalid only where it is "so vague and indefinite as really to be no rule or standard at all." Using that relaxed test, the court concluded that the challenged provisions of GBL § 396-r are sufficiently clear. Although the statute does not provide a "quantitative metric" as to whether a price is "unconscionably excessive or unconscionably extreme," the court asserted that the "absence of such a metric . . . does not affect the statute's constitutionality."

Appellate Division Rejects DOH Methodology for Review of Medical Marijuana License Application

Hudson Health Extracts, LLC v. Zucker, 206 A.D.3d 1515 (3d Dep't 2022). In 2014, New York passed the Compassionate Care Act (the "Act") to regulate the state's medical marijuana industry. The Act established extensive criteria for the Commissioner of Health (the "Commissioner") to consider when evaluating applications for licensure to manufacture and dispense approved medical marijuana products. Among other factors, the Commissioner must consider the applicant's ability to "maintain effective control against diversion of marihuana [and] properly carry on the manufacturing or distributing activity for which [licensure] is sought," along with whether the applicant possesses "sufficient land, buildings, and equipment to properly carry on the activity described in the application." The Act called for initial approval and registration of five organizations, after which the Commissioner maintained discretion to grant additional licenses.

In April 2015, the Department of Health (DOH) solicited applications with the goal of approving up to five new licenses. Petitioner was one of 43 applicants. The DOH conducted an intricate review process, during which it scored applicants in 11 separate categories. For some categories the DOH used a simple pass/fail system, and for others it employed a 0-3 point scale. The DOH then weighted each category to develop a final score. Ultimately, Petitioner ranked 13th among the 43 applicants, resulting in the denial of its application.

An Administrative Law Judge (ALJ) sustained the denial on appeal, ruling that the DOH used a rational scoring methodology and that the underlying evidence supported the DOH's denial of Petitioner's application. Petitioner commenced an Article 78 proceeding after the Commissioner adopted the ALJ's recommendation in full. The Supreme Court transferred the Article 78 proceeding to the Appellate Division, Third Department, pursuant to CPLR 7804(g).

Petitioner did not challenge the underlying evidence, but rather the methodology used by the DOH to score the "financial standing" section of its application, which comprised 9.6% of its overall score. Specifically, Petitioner argued that it was in a superior financial position than other applicants but received the same score because the DOH failed to conduct a substantive examination of its financial disclosures.

On review, the Third Department applied the well-established standard that "an agency's action is arbitrary and capricious when it is taken without sound basis in reason or regard to the facts." In doing so, the court emphasized that the governing DOH regulations require consideration of whether an applicant "can produce sufficient quantities of approved medical marihuana products as necessary to meet the needs of certified patients" and is "ready, willing, and able to properly carry on the activities set forth" in the regulations. The court found that both considerations "necessarily require an accounting of the applicant's financial wherewithal."

The court then detailed the three-step methodology utilized by the DOH to assign "financial standing" scores. The first two steps required applicants to submit financial disclosure forms, namely: (1) "a financial statement setting forth all elements and details of any business transactions connected with the application"; and (2) "the most recent certified financial statement of the applicant . . . including a balance sheet as of the end of the applicant's last fiscal year and income statements for the past two fiscal years." The DOH scored these submissions on a pass/fail basis, with applicants receiving two points (i.e., a passing score) for submission of both required disclosure forms. According to testimony from the DOH's program director, a third step in the scoring process called for a substantive, independent review of the applicant's financial disclosures. Evidently, the DOH did not implement this third step with respect to Petitioner's application.

Despite this omission, the ALJ upheld the DOH's decision, reasoning that "the highest score given any applicant . . . was a raw score of 2 points when the application contained both financial statements," and that neither the statute nor governing regulations "required [the DOH] to rank an applicant higher if the applicant could demonstrate that it possessed superior financial resources." Thus, despite Petitioner's balance sheet indicating "that it was in a superior financial position to that of many other applicants—amassing approximately $18.6 million in assets toward the endeavor," Petitioner did not establish that it was entitled to a higher score than other applicants. In other words, mere submission of the required financial disclosure forms entitled an applicant to two points, with no upward or downward adjustments based on the substantive data contained therein.

The Third Department rejected the ALJ's analysis because it "completely fail[ed] to account for part 3"—that is, the substantive financial review described by the DOH's program director. The court likewise rejected the Commissioner's argument that the DOH regulations do not expressly require a substantive financial review, finding not only that the DOH "create[d] a scoring methodology that directly contemplated such a review," but that "the regulations also implicitly do so by requiring DOH to consider whether the applicant is able to" produce sufficient quantities of approved products and is "ready, willing, and able" to perform. Therefore, the court held, "[t]o simply reason that an applicant gets [two points] for attaching the required financial statements, regardless of the information contained therein, ignores the need to substantively evaluate the applicant's actual financial standing—*i.e.*, the capacity and wherewithal to implement the program in accordance with DOH's own regulations."

Accordingly, the court held that the DOH's "determination regarding the financial standing portion of Petitioner's application [was] arbitrary and capricious and must be annulled." With respect to the appropriate remedy, the court denied Petitioner's request to award three points for financial standing, which, based on the DOH's weighting system, would have placed Petitioner in the top five applicants and automatically entitled Petitioner to a license. Instead, "given the technical and specialized nature of the program at issue, and mindful of the agency's expertise in this area," the court remitted the matter to the DOH to perform a "substantive financial review" and "issue a new determination as to Petitioner's financial standing score, as well as any related change to its overall score, and whether to grant Petitioner a license."

UnitedHealth Defeats Class Action Alleging It Was Required to Pay Facility Fees for Medical Office-Based Surgeries

Med. Soc'y of the State of N.Y. v. UnitedHealth Group, Inc., No. 16 Civ. 5265, 2022 WL 4234547 (S.D.N.Y. Sept. 14, 2022). Two organizations—the Medical Society of the State of New York and the Society of New York Office Based Surgery Facilities—and one New York City medical practice brought a class action lawsuit in the U.S. District Court for the Southern District of New York against UnitedHealth Group Inc. and related entities (collectively, "United"). Plaintiffs alleged that United was required, under the terms of its health benefits plans and the Employee Retirement Income Security Act of 1974 (ERISA), to pay "facility fees" to out-of-network physicians who perform surgeries at their own medical offices, but failed to do so. Following a five-day bench trial held in February 2022, and the submission of post-trial briefs, the court found in favor of United on all counts.

United administers multiple ERISA-governed health benefit plans, the majority of which are self-funded by the plan sponsor. Although the terms of those plans vary somewhat, they all distinguish between "facilities" and "physician offices." In most of United's plans, only hospitals and "alternate facilities" are entitled to collect facility fees, and "physician's office services" is listed as a separate coverage item. None of the plans expressly states that a physician's office is a "facility" entitled to separate facility fees.

Furthermore, all of United's plans employ one of two reimbursement methodologies for out-of-network providers—(1) a percentage of the Medicare rate or (2) a percentage of the "reasonable and customary" charges for the services at issue—and neither allows for payment of a separate facility fee to a physician's office for an office-based procedure. Under Medicare's rules, physicians are paid a "global professional fee," which includes, for office-based surgeries, compensation for the physician's "practice expense" of, among other things, supplies and overhead costs. When the surgery is performed at a hospital or ambulatory surgical center, the global professional fee is reduced to reflect that these costs are borne by the facility and not by the practice. Likewise, when United's plan calls for reimbursement at a percentage of "reasonable and customary charges," United estimates the practice expense based on a "professional charge database" and includes that expense as part of a global professional fee for office-based surgeries.

In or about 2005, United became aware that some physician's offices were using the "facility code" when billing their claims in order to collect a facility fee. United's in-house counsel testified that this prompted a review of its plans and applicable law to determine whether such fees should be paid.

United confirmed that none of its plans required it to pay a facility fee to a physician's office and that no client plan sponsor had ever requested that United do so. As a result, United changed its standard claim adjudication process to flag these charges and deny the facility fee absent proof of facility licensure. And, in 2007, when New York enacted new legislation addressing office-based surgeries, United considered that law and concluded that it did not require the payment of facility fees to physician's offices.

Plaintiffs brought a class-wide claim against United for declaratory and injunctive relief, alleging United "systematically violated ERISA by failing to adequately review the plans to determine whether facility fees should be paid to physician offices for office-based surgeries." The medical practice also separately asserted a claim under ERISA for the payment of more than $1.5 million in facility fees.

The court began its analysis with the legal standard on ERISA claims. When the administrator is granted discretionary authority to interpret the terms of the plan, the denial of benefits may be overturned only if it is arbitrary and capricious. Moreover, ERISA's Claim Procedures Regulation requires plan administrators to "'establish and maintain reasonable procedures' for processing benefit claims, including 'administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents.'" As such, the court needed to "determine whether United's procedures were reasonable, according deference to determinations as to which United may exercise its discretion."

Addressing the class-wide claim, the court held that Plaintiffs failed to meet their burden to prove that United's procedures were unreasonable. The court found that United sufficiently reviewed the plan terms, implemented reasonable systems designed to ensure that coverage determinations were made in accordance with those terms, and sufficiently explained to Plaintiffs why they were denied facility fee claims submitted for office-based procedures. The court also held that United's conclusion that Plaintiffs were not entitled to facility fees was reasonable, as none of the plans at issue expressly required United to pay facility fees to physician's offices and many clearly precluded it. The court found that United's determination was consistent with Medicare conventions, the practices of other insurers, and New York law.

Having ruled against Plaintiffs on the class-wide claim, the court turned to the New York City medical practice's individual claim for ERISA benefits. Because the practice was not a licensed facility under Article 28 of the New York Public Health Law, the court held that it was not entitled to facility fees from United for the surgeries performed at its office.

Whistleblower Claim Alleging that McKesson's Free Business Management Tools Constituted Illegal Kickbacks to Oncology Practices Is Dismissed With Leave to Replead

United States, ex. rel. Hart v. McKesson Corp., No. 15 Civ. 903, 2022 WL 1423476 (S.D.N.Y. May 5, 2022). A former employee of McKesson Corporation ("McKesson") filed a *qui tam* lawsuit against the company and related subsidiaries in the U.S. District Court for the Southern District of New York, alleging that McKesson offered business-management tools exclusively to oncology practices committed to purchasing a significant portion of their drugs from McKesson, in violation of the Anti-Kickback Statute (AKS).

McKesson sells pharmaceuticals, medical supplies, and other services to health care providers. As alleged in the complaint, McKesson Specialty Health, a business unit of McKesson, generated its largest line of its revenue from the oncology business. As a part of this business, McKesson offers commitment programs in which oncology practices must commit to buy a certain volume of their oncology drugs from McKesson. In turn, McKesson provides the oncology practices free use of two of McKesson's business-management tools—the Margin Analyzer (which, among other things, allowed the oncology practice to compare the reimbursement rates of interchangeable drugs) and the Regimen Profiler, (which allowed the oncology practice to calculate the profit margins for the entire course of treatment, including non-drug costs).

Plaintiff-Relator sued on behalf of the federal government and multiple states, asserting that McKesson's policy of offering the tools exclusively to commitment program members violated the AKS, a criminal statute that makes it illegal to knowingly and willfully offer or pay remuneration for items or services reimbursable by a federal health care program. Plaintiff-Relator asserted that any claims for reimbursement submitted to the government in connection with this policy were "false" under the False Claims Act (FCA), a federal law that imposes civil liability for knowingly submitting a false or fraudulent claim to the government.

McKesson moved to dismiss, contending that Plaintiff-Relator's complaint was deficient in three respects: (1) it failed to plausibly allege that the business-management tools constituted remuneration; (2) it failed to plausibly allege that McKesson acted with the required scienter; and (3) it failed to plead the fraudulent scheme with particularity. The court granted McKesson's motion to dismiss, holding that Plaintiff-Relator failed to allege the element of scienter, but afforded Plaintiff-Relator leave to amend the complaint.

The court explained that because Plaintiff-Relator's FCA claim was based on a violation of the AKS, Plaintiff-Relator was required to satisfy the pleading requirements for

both statutes. On the issue of scienter, the parties disputed what mental state is required to allege a "willful" violation. Plaintiff-Relator argued that he must plead only "that the defendant willfully committed an act that violated the AKS," while McKesson argued that willfulness requires McKesson to have acted "with an intent to do something unlawful." The court held that the term "willful" required Plaintiff-Relator to plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful, although he need not allege that McKesson acted with specific knowledge of the AKS. Applying this standard, the court agreed with McKesson that Plaintiff-Relator failed to plead willfulness. While the complaint alleged that McKesson generally knew giving remuneration to induce purchases was illegal, the factual allegations—including that McKesson operated the alleged policy openly and took no action to conceal the purported fraudulent scheme—belied Plaintiff-Relator's contention that McKesson knew its policy violated the law. The court therefore held that dismissal was required.

The court also evaluated—and rejected—McKesson's other motion to dismiss arguments. The court held that Plaintiff-Relator sufficiently alleged that the free tools constituted remuneration under the AKS because he pleaded facts establishing that they had "substantial value" to customers "apart from the products offered by McKesson." Likewise, the court held that the tools' value was not "virtually meaningless" without McKesson's products and specifically noted that the complaint alleged that at least one customer sought access to the tools after ending its commitment program. Furthermore, the court declined McKesson's request to take judicial notice of other entities' free tools, which McKesson claimed were comparable, since McKesson was not simply asking the court to acknowledge the tools' existence, but was asking for a factual determination that the tools were similar. The court held that this argument was inappropriate on a motion to dismiss.

Lastly, with regard to the submission of claims to the government, McKesson argued that Plaintiff-Relator needed to allege specific false claims that were submitted. The court disagreed, finding that a plaintiff need only plead: (1) facts sufficient to support an inference that false claims were submitted; and (2) that the information capable of identifying those claims is peculiarly within the defendant's knowledge. The court held that Plaintiff-Relators' allegations, which included details from the records made available during his employment at McKesson, met this pleading standard because they suggested McKesson knew that its customers were routinely submitting claims to Medicare and other federal health care programs.

Second Circuit Upholds FOIA Redactions to Documents Submitted in Connection with New Drug Application, Finding Sufficient Evidence of Foreseeable Harm to Submitter's Commercial or Financial Interests

Seife v. U.S. Food & Drug Admin., 43 F.4th 231, 234 (2d Cir. 2022). In 2007, Sarepta Therapeutics, Inc. ("Sarepta") submitted an Investigational New Drug Application to the FDA for Exondys 51, a drug developed by Sarpeta to treat Duchenne muscular dystrophy (DMD), a fatal neuromuscular disease that affects young and adolescent males. On September 19, 2016, following a nine-year approval process in which Sarepta submitted tens of thousands of documents, the U.S. Food and Drug Administration (FDA) granted accelerated approval for the drug.

In December 2016, Plaintiff-Appellant Charles Seife, a science writer and journalism professor, submitted a request to the FDA and the U.S. Department of Health and Human Services (HHS) pursuant to the Freedom of Information Act (FOIA), seeking documents submitted by Sarepta as part of the approval process. At the same time, Seife requested expedited processing on his FOIA request. On December 21, 2016, the FDA denied Seife's request for expedited processing. Plaintiff-Appellant appealed that denial administratively and, on April 25, 2017, the FDA denied his appeal.

On May 25, 2017, Seife filed suit against the FDA and HHS in the U.S. District Court for the Southern District of New York, challenging the denial of expedited processing and what was "tantamount to a constructive denial of his FOIA request." After Seife moved for partial summary judgment on his expedited processing claim, the FDA granted his request, and the parties agreed to a schedule for producing documents responsive to a "narrowed FOIA request." Thereafter, the FDA produced approximately 45,000 pages to Seife, but redacted some pages pursuant to FOIA exemptions. On September 15, 2017, Sarepta moved to intervene as a defendant, which the district court granted.

Seife challenged certain redactions that the FDA made to those documents under Exemption 4 of the FOIA, which shields from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." The parties submitted cross-motions for summary judgment regarding those redactions. On October 6, 2020, the district court granted Defendants' motion for summary judgment and denied Seife's motion for summary judgment. The district court concluded that Defendants demonstrated that the redacted information fell within Exemption 4 and met the additional requirement, set by the FOIA Improvement Act of 2016 (FIA), that an agency shall withhold information under the FOIA only if it "foresees that

disclosure would harm an interest protected by an exemption" or if disclosure is "prohibited by law." Seife appealed.

The U.S. Court of Appeals for the Second Circuit began its analysis by discussing the "two primary competing district court interpretations of the interests protected by Exemption 4": (1) "the submitter's economic or business interests"; and (2) "the information's confidentiality—that is, its private nature." Although Seife did not dispute that the redacted information fell within the scope of Exemption 4, he urged the court to adopt the first approach, contending that to "meet the additional burden imposed by the FIA," an "agency must show harm through 'diminution in the economic value of a submitter's intangible property' calculated in the same way as monetary damages." Defendants argued that such showing was unnecessary, in line with the second approach, asserting that the interest protected by Exemption 4 is "the confidentiality of the information itself."

The Second Circuit held, as a matter of first impression for the appellate courts, that "the interests protected by Exemption 4 of FOIA are the commercial or financial interests of the submitter in information that is of a type held in confidence and not disclosed to any member of the public by the person to whom it belongs." The court first parsed the language of Exemption 4 and asserted that its "plain text . . . indisputably protects confidential information" and "contemplates harm specifically to [the] commercial or financial interests" of the submitter. Thus, an agency can meet the foreseeable harm requirement of the FIA by showing foreseeable commercial or financial harm to the submitter upon release of the information in question.

Upon review of the record, the court concluded that Defendants presented sufficient evidence to establish foreseeable harm to Sarepta's commercial or financial interests. Specifically, Sarepta's declarations described how the information could be "used to develop studies" for similar drugs, be "used in competitors' head-to-head trials," or inform competitors "as to Sarepta's future clinical endpoint research." The court asserted that Seife failed to present any evidence to rebut defendants' showing of foreseeable harm, finding that "at most" he challenged "the degree of commercial or financial harm to Sarepta, rather than that such harm would result."

District Court Upholds New York City COVID-19 Vaccine Mandate for Department of Education Staff and City Employees Working in a School Setting

Kane v. de Blasio, No. 21 Civ. 7863, 2022 WL 3701183 (S.D.N.Y. Aug. 26, 2022). In August 2021, the New York City Commissioner of Health and Mental Hygiene (the "Commissioner") issued an order requiring Department of Education (DOE) staff, along with other city employees and contractors working in person in school settings, to provide proof of vaccination against COVID-19, or proof that they are on track to become fully vaccinated: (a) by Sept. 27, 2021, or (b) prior to beginning their employment (the "Mandate").

On Sept. 1, 2021, the United Federation of Teachers Local 2, AFT, AFL-CIO (UFT) filed a Declaration of Impasse and entered into arbitration with the City and the Board of Education of the City of New York (BOE), challenging the lack of religious exemptions to the Mandate. On Sept. 10, 2021, the City, the BOE, and the UFT reached an agreement that provided a procedure for seeking religious exemptions. Under this agreement, religious exemption requests were required to be documented in writing by a religious official. Exemption requests would be denied where the religious official had spoken publicly in favor of the vaccine; where documentation was readily available (e.g., from an internet source); or where the objection was personal, political, or philosophical in nature.

Plaintiffs filed suit in the U.S. District Court for the Southern District of New York, alleging that the Mandate violated their constitutional rights. Plaintiffs then sought preliminary injunctive relief, which the district court denied. On appeal, the Second Circuit found that Plaintiffs were unlikely to succeed on their argument that the Mandate is facially unconstitutional, but found merit to their "as applied" challenges and ordered a central citywide panel to reconsider their religious exemption requests adhering to the standards of Title VII of the Civil Rights Act of 1964, rather than the criteria set forth in the UFT arbitration agreement. The citywide panel subsequently reviewed the claims of the named Plaintiffs and generally determined that it would be an undue hardship, under Title VII, for the DOE to allow unvaccinated teachers to enter school buildings.

On Feb. 14, 2022, Defendants moved to dismiss Plaintiffs' complaint for failure to state a claim. In line with other courts that have upheld COVID-19 vaccine mandates, the court granted Defendants' motion and dismissed the action in its entirety.

Plaintiffs first alleged that the Mandate violated the First Amendment's Free Exercise clause. The court asserted that in order to prevail on a Free Exercise clause claim, a plaintiff must establish that the object of the challenged law is to infringe upon or restrict practices because of their religious motivation, or that its purpose is the suppression of religion or religious conduct. By contrast, the Free Exercise clause does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability. Where the government seeks to enforce a law that is neutral and of general applicability, it need only demonstrate a rational basis for its enforcement, even if enforcement of the law incidentally burdens religious practices.

The court noted that Plaintiff's arguments lacked merit because the Second Circuit had already found, on appeal of their motion for a preliminary injunction, that the Mandate is facially neutral and generally applicable. While Plaintiffs took the position that the Mandate had the "express purpose of inflicting special disability against minority religious viewpoints," the court determined there was no such evidence of "animus." Rather, the court found that the clear objective of the Mandate is to reduce the spread of COVID-19 in New York City schools and permit them to remain open. The court also rejected Plaintiffs' argument that the Mandate is not generally applicable based on exemptions carved out of the City's private employer vaccination mandate, as that was a separate mandate that applied to an entirely different group of people. Furthermore, the court rejected Plaintiffs' contention that the DOE's process for applying for individual exemptions requires strict scrutiny, because the citywide panel was instructed to adjudicate the exemption requests in accordance with the Title VII standard.

The court then held that rational basis review applied to Plaintiffs' claim. As it found that the DOE articulated a rational and compelling basis for the Mandate—namely, to allow schools to continue in person safely—Plaintiffs' Free Exercise Clause claim failed. The court also dismissed Plaintiffs' Establishment Clause claim, holding that it was "nothing more than a repackaging of plaintiffs' free exercise claims." The court likewise dismissed Plaintiffs' claim under the Equal Protection Clause, finding that they did not point to any "similarly situated persons who have been treated differently."

Next, the court turned to Plaintiffs' claim that the Mandate violated their substantive and procedural rights under the Due Process Clause. The court rejected Plaintiffs' substantive due process challenge because: (1) the Second Circuit and the Supreme Court have consistently recognized that the Constitution embodies no fundamental right that would render vaccine requirements imposed in the public interest, in the face of a public health emergency, unconstitutional; and (2) Plaintiffs cannot demonstrate that the state action was "so egregious, so outrageous, that it may fairly be said to shock the contemporary conscience . . . even were it accompanied by full procedural protection." Similarly, the court dismissed Plaintiffs' procedural due process challenge because there was no protected liberty interest at stake, adequate notice was provided, and any alleged deprivation could be fully remedied through the grievance procedures provided for in a collective bargaining agreement or through an Article 78 proceeding.

Finally, the court found that the Mandate was not unconstitutional as applied to Plaintiffs. The court noted that two Plaintiffs had their requests for religious accommodations granted and that five failed to avail themselves of the DOE process for seeking an exemption. The remaining Plaintiffs' claims were reviewed by the citywide panel. While Plaintiffs claimed that the citywide panel simply "rubber-stamped" their previous denials in "bad faith," the court determined that such assertions were insufficient to state a claim and contradicted by the record, which showed that the citywide panel reversed the denial of one Plaintiff's request. Moreover, all but one denial was based on a determination that the request presented an "undue hardship" because Plaintiffs, as school teachers, could not physically be in a classroom while unvaccinated without presenting a risk to the student population. The court found that the citywide panel's findings satisfied the requirements of Title VII because it appropriately determined that Plaintiffs' inability to teach their students safely in person imposed more than a *de minimis* cost on the DOE.

District Court Dismisses FMLA Claim by Employee Who Failed to Meet Hours Requirement as a Result of Wrongful Termination

Varecka v. CSX Transp., Inc., No. 21 Civ. 876, 2022 WL 1750700 (W.D.N.Y. May 31, 2022). Plaintiff is an employee of CSX Transportation, Inc. (CSX) who has a serious health condition and was granted intermittent leave under the Family and Medical Leave Act (FMLA). In 2018, CSX accused plaintiff of abusing his FMLA leave to take off time around holidays and terminated his employment. Plaintiff challenged his termination in arbitration pursuant to a collective bargaining agreement (CBA), resulting in two decisions where he was ordered to be reinstated and made whole. Following his reinstatement, Plaintiff again applied for FMLA leave, which CSX rejected because Plaintiff had not worked the requisite number of hours in the preceding year.

Plaintiff brought a putative class action against CSX in the U.S. District Court for the Western District of New York, alleging that CSX interfered with his and other employees' rights under the FMLA. Plaintiff claimed that the reason why he did not meet the criteria for FMLA leave is because of his wrongful termination. According to Plaintiff, CSX used the delay in the CBA arbitration process to its advantage in order to deny FMLA requests made by him and all similarly situated employees. CSX moved to dismiss, contending that Plaintiff failed to plead that he was an eligible employee under the FMLA.

The court noted that this case presented an issue of first impression in the Second Circuit: whether hours an employee would have worked but for a wrongful termination should count toward FMLA eligibility upon reinstatement. Under the FMLA, an eligible employee is one who has "been employed for at least 12 months . . . and for at least 1,250 hours of service with such employer during the previous 12-month period." Given the lack of binding authority, the court turned to FMLA's statutory and regulatory scheme to determine whether Plaintiff met the "hours of service" threshold to qualify as an "eligible employee." The court observed that the FMLA regulations provide only "one limited circumstance" where hours that an employee "'would have worked" are expressly credited: when an employee returns from military service covered by the Uniformed Services Employment and Reemployment Rights Act.

The court then looked to the Fair Labor Standards Act (FLSA) to determine Plaintiff's "compensable hours of work." The court noted that while the FLSA does not define "hours of service," its basic principle is that employees are entitled to compensation only for "physical or mental exertion" that is "controlled or required by the employer" for the benefit of its business. Conversely, the court noted, periods in which an employee is "completely relieved from duty and which enables them to use their time for their own purposes are not hours worked" under the FLSA. The court found that "these definitions appear to exclude hours Plaintiff would have worked between his termination and reinstatement from counting as 'hours of service' under the FMLA."

After discussing relevant case law from the First and Sixth Circuits, the court turned to two Second Circuit decisions addressing "two analogous issues." In the first of those cases, *Woodford v. Community Action of Greene County, Inc.*, the Second Circuit struck down a FMLA regulation providing that an employee lacking the minimum work hours to qualify for leave could still be deemed eligible if the employer incorrectly confirmed his or her eligibility or failed to provide timely notice of his or her ineligibility. The Second Circuit held that this regulation impermissibly expanded the scope of the FLSA and was thus contrary to the express intent of Congress, but it nonetheless held that the FMLA "leaves space" for rulemaking that may cure noncompliance with notice requirements by "creating a right of estoppel." In a subsequent case, *Kosakow v. New Rochelle Radiology Associates, P.C.*, the Second Circuit held that an employer may be estopped from challenging an employee's eligibility for leave because of the employer's misconduct in failing to post FMLA-required notices. The Second Circuit found that even if the plaintiff did not meet the 1,250-hour eligibility requirement, "nothing prevents a court from exercising its equitable estoppel powers to estop a party from raising a particular claim or defense."

In light of the *Woodford* and *Kasakow* decisions, the court held that Plaintiff could succeed only if he establishes "all of the elements" of an equitable estoppel claim. As Plaintiff did not plead those elements, the court granted CSX's motion to dismiss. Although Plaintiff did not ask to amend his complaint, the court afforded him the opportunity to make a motion for leave to amend consistent with its ruling.

Dayna B. Tann and **Marc A. Sittenreich** are partners at Garfunkel Wild, P.C., a full-service health care law firm representing hospitals, health systems, physician groups, individual providers, nursing homes, and other health-related businesses and organizations. Both Tann and Sittenreich are members of the firm's litigation practice group. Their respective practices focus on general commercial and health care litigation and arbitration, including breach of contract and business tort claims, payer-provider reimbursement disputes, employment actions, disability discrimination and accommodation claims, dissolution proceedings, and physician practice disputes.

In the Legislature

By Michael A. Paulsen

As of this writing, the 2022 general election is well underway for statewide, state legislative, and congressional seats, following a chaotic redistricting process. With uncertainty during the primary season on what state and congressional maps would be used, lawmakers are running in newly drawn districts that were established by a court-appointed special master, rather than the redistricting maps that were approved by the Legislature in February. Despite these changes to the election process, the Assembly is expected to remain overwhelmingly under Democratic control and the Senate is also expected remain under Democratic control, although the historic supermajority following the 2020 elections may not be secure.

While the outcome of the general election is unlikely to significantly alter the balance of power in Albany, the issues related to health care policy in New York are likely to remain the same. Looking forward, we expect the following health care issues to be under consideration during the upcoming New York state legislative session:

Health Care Leadership

The most significant change for the 2023 legislative session will occur in the Assembly, since the former Assembly Health Committee chair, Richard Gottfried, retired at the end of 2022 after serving in this post for 35 years, and in the Assembly since 1970. This article could not attempt to capture and reflect on the impact that Mr. Gottfried has had on New York's health care delivery system, as many articles published during his final legislative session have more appropriately covered. In fact, the Health Law Section fall meeting was dedicated to covering the *Impact of NYS Assembly Health Committee Chair Richard Gottfried on New York's Health Care Delivery System*. At a minimum, it is widely recognized that his departure will have a significant impact on the development of health policy in New York going forward. As of this writing, a successor for the position has not been announced.

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Health Care Staffing

Despite significant investments last year in the health care workforce (home care minimum wage increase) and bonuses (Health Worker Bonus Program) designed for recruitment and retention, health care staffing shortages continue to significantly impact the industry, with some providers having to reduce services due to the shortage. Temporary contract labor has increased strikingly as a percent of total workforce expenses, and has been a main driver of operating losses at health care providers. It is expected that additional efforts to address the shortage will be under consideration in 2023, including efforts to increase the supply of health care professionals, loan repayment programs, and additional scope of practice reforms to allow licensed professionals to undertake additional functions under supervision.

Health Care Provider Licensure

While many of the Executive Orders issued during the COVID-19 pandemic have expired, Executive Order (EO) 4, continuing the Declaration of a Statewide Disaster Emergency Due to Healthcare Staffing Shortages, remains in effect. This EO provides flexibilities for health care providers, including allowing certain licensed out-of-state and foreign health care providers to practice in New York. As this licensure flexibility has assisted the COVID-19 response as well as the current staffing shortages, it will be difficult for the governor to allow it to expire without any other licensure mechanisms in place. Last year, the governor proposed adopting provisions of law allowing the state to enter both the Interstate Medical Licensure Compact (IMLC) and the Nurse Licensure Compact (NLC), as well as a process to issue temporary permits for high need health care professionals to practice in New York while their applications for licensure are pending. While not enacted, it is expected that these proposals, as well as others addressing health care provider licensure, will be under consideration again in 2023.

HCRA

The New York State Health Care Reform Act (HCRA) is due for reauthorization in the Fiscal Year (FY) 24 budget cycle as it is due to expire 2023. HCRA is a major component of New York's health care financing system, with receipts and spending totaling more than $6.5 billion that are used to fund

a multitude of health care initiatives, including a significant portion of the offset Medicaid costs in the General Fund. While three-year extenders are typical for extending HCRA, with similar extensions adopted in 2008, 2011, 2014, 2017, and 2020, each HCRA reauthorization provides an opportunity for the legislature to rethink the broader HCRA policy and modify the revenue raising and/or spending components of HCRA. While there is no indication that major changes to HCRA are under consideration (and the Medicaid budget is not projected to have a significant deficit), HCRA provides a mechanism to redirect or increase health care spending in certain areas. As the state continues to focus on health equity and addressing health care disparities, using a greater percentage of HCRA may provide a mechanism to further support these initiatives.

Reproductive Health

In 2022, the Legislature adopted a portfolio of reproductive health protection related bills designed to protect out-of-state patients traveling to New York for reproductive health services and New York practitioners providing services to out-of-state patients. However, lawmakers failed to come to an agreement on a constitutional amendment to secure certain reproductive rights in New York's Constitution. Members of the Legislature remain focused on continuing to enhance the provider protections for reproductive health services and it is expected that these issues will be central to budget and session priorities.

Health Care Provider Finances

Health care providers face continued pressures stemming from the pandemic, including lower utilization, increased agency staffing, and permanent premium labor costs. Both historically financially stable and distressed health care providers continue to face these financial pressures in the near-term. While the FY23 enacted budget included capital and operational investments for health care providers, including a 1% increase in Medicaid reimbursement, many health care providers face continued financial pressures as federal financial support for pandemic response runs dry. It is expected that providers will continue to seek increased reimbursement under Medicaid to address increased costs.

Single Payor

The future of the New York Health Act, originally authored and sponsored by Assemblyman Gottfried, is unclear, at least for 2023, with his departure from the legislature. While the bill has a significant number of cosponsors who remain, Assemblyman Gottfried served as the champion for the bill and the broader concept of single payor for New York. It is anticipated that it may take time for new leadership on the bill, especially in the Assembly, to coalesce before it is under active consideration again.

Health Care Planning

The legislature previously adopted a requirement that certain Certificate of Need (CON) applications 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 medically underserved groups in the applicant's service area. This requirement takes effect for CON applications submitted after June 2023. While health equity was always a focus of New York's health planning system, it is expected to take a larger role in the review of individual applications, and could drive further legislative involvement in New York's health delivery system.

In the New York State Agencies

By Caroline B. Brancatella

Prescription Refills

Notice of Adoption. The Department of Health amended § 505.3(d)(2) of Title 18 N.Y.C.R.R. to limit Medicaid FFS prescriptions to a maximum of 12 fills within one year from the date the prescriber initiates a prescription. Filing Date: May 24, 2022. Effective Date: June 8, 2022. *See* N.Y. Register June 8, 2022.

Relating to the Certification, Operation and Reimbursement of Clinic Treatment Programs Serving Adults and Children

Notice of Proposed Rule Making. The Office of Mental Health proposed amending Part 599 of Title 14 N.Y.C.R.R. to align certain programs with the State Plan Amendment. *See* N.Y. Register June 8, 2022.

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

Notice of Adoption. The Department of Financial Services amended Part 52 of Title 11 N.Y.C.R.R. to provide additional minimum standards for the content of health insurance identification cards in accordance with federal law. Filing Date: May 31, 2022. Effective Date: July 15, 2022. *See* N.Y. Register June 15, 2022.

COVID-19 Reporting and Testing

Notice of Emergency Rule Making. The Department of Health added §§ 2.9 and 2.62 to Title 10 N.Y.C.R.R. to require COVID reporting in schools and to permit the commissioner to issue testing determinations in certain settings. Filing Date: May 27, 2022. Effective Date: May 27, 2022. *See* N.Y. Register June 15, 2022.

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

Notice of Adoption. The Department of Financial Services added § 2.19 to Title 23 N.Y.C.R.R. to specify that administrative hearings are held by videoconference unless a determination is made to hold the hearing in-person. Filing Date: June 7, 2022. Effective Date: June 22, 2022. *See* N.Y. Register June 22, 2022.

Prevention of COVID-19 Transmission by Covered Entities

Notice of Adoption. The Department of Health added § 2.61; amended §§ 405.3, 415.19, 751.6, 763.13, 766.11, 794.3, and 1001.11 of Title 10 N.Y.C.R.R.; and amended §§ 487.9, 488.9, and 490.9 of Title 18 N.Y.C.R.R. to require covered entities to ensure their personnel are fully vaccinated against COVID-19 subject to certain exemptions. Filing Date: June 8, 2022. Effective Date: June 22, 2022. *See* N.Y. Register June 22, 2022.

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

Notice of Emergency Rule Making. The Department of Financial Services added § 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: June 13, 2022. Effective Date: June 13, 2022. *See* N.Y. Register June 29, 2022.

Repeal of Limits on Administrative Expenses and Executive Compensation

Notice of Proposed Rule Making. The Department of Health proposed repealing Part 1002 of Title 10 N.Y.C.R.R. to Repeal of Limits on Administrative Expenses and Executive Compensation. *See* N.Y. Register June 29, 2022.

Establishes Crisis Stabilization Centers

Notice of Adoption. The Department of Mental Health added Part 600 to Title 14 N.Y.C.R.R. to establish standards for a Crisis Stabilization Center which provides a full range of psychiatric and substance use services. Filing Date: June 13, 2022. Effective Date: June 13, 2022. *See* N.Y. Register June 29, 2022.

Gender Identity and Expression

Notice of Proposed Rule Making. The Office for People with Developmental Disabilities proposed amending § 633.4 of Title 14 N.Y.C.R.R. to ensure people are treated with dignity and respect. *See* N.Y. Register June 29, 2022.

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

Notice of Emergency Rule Making. The Department of Financial Services added § 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: June 15, 2022. Effective Date: June 15, 2022. *See* N.Y. Register July 6, 2022.

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

Amended Notice of Adoption. The Department of Financial Services added § 2.19 to Title 23 N.Y.C.R.R. to specify that administrative hearings are held by videoconference unless determination is made to hold the hearing in-person. Filing Date: June 21, 2022. Effective Date: July 06, 2022. *See* N.Y. Register July 6, 2022.

Medicaid Program Fraud, Waste and Abuse Prevention

Notice of Proposed Rule Making. The Office of Medicaid Inspector General proposed repealing Part 521; and added Part 521 to Title 18 N.Y.C.R.R. to establish requirements for providers to detect and prevent fraud, waste, and abuse in the Medicaid Program. *See* N.Y. Register July 13, 2022.

Charges for Professional Health Services

Notice of Emergency Rule Making. The Department of Financial Services amended § 68.1 and Appendix 17–C of Title 11 N.Y.C.R.R. to establish schedules of maximum permissible charges for professional health services payable as no-fault insurance benefits. Filing Date: June 30, 2022. Effective Date: June 30, 2022. *See* N.Y. Register July 20, 2022.

Public Water Systems

Notice of Proposed Rule Making. The Department of Health proposed amending Subpart 5-1 of Title 10 N.Y.C.R.R. to correct typographical errors and inconsistencies with the CFRs to obtain primacy enforcement authority under Safe Drinking Water Act. *See* N.Y. Register July 20, 2022.

Masking Requirements in All OASAS Certified/ Funded/ Otherwise Authorized Settings

Notice of Emergency Rule Making. The Office of Alcoholism and Substance Abuse Services added Part 808 to Title 14 N.Y.C.R.R. to prevent the ongoing threat to public health of the spread of COVID-19 in OASAS settings. Filing Date: July 11, 2022. Effective Date: July 11, 2022. *See* N.Y. Register July 27, 2022.

Notice of Expiration

The following notice has expired and cannot be reconsidered unless the Office of Alcoholism and Substance Abuse Services publishes a new notice of proposed rulemaking.

> (i) General provisions applicable to all OASAS programs: I.D. No. ASA-27-21-00009-P. Proposed on July 7, 2021. Expired on July 7, 2022. *See* N.Y. Register July 27, 2022.

Nursing Home Minimum Direct Resident Care Spending

Notice of Revised Rule Making. The Department of Health added § 415.34 to Title 10 N.Y.C.R.R. to enforce that every RHCF shall spend a minimum of 70% of revenue on direct resident care and 40% of revenue on resident-facing staffing. *See* N.Y. Register Aug. 10, 2022.

Minimum Staffing Requirements for Nursing Homes

Notice of Revised Rule Making. The Department of Health amended §§ 415.2 and 415.13 of Title 10 N.Y.C.R.R. to require minimum staffing levels for nursing homes. *See* N.Y. Register Aug. 10, 2022.

Requirements for the Establishment, Incorporation and Certification of Providers of Addiction Services

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services proposed amending Part 810 of Title 14 N.Y.C.R.R. to update outdated and stigmatizing language and to clarify processes of the certification process for providers and applicants. *See* N.Y. Register Aug. 17, 2022.

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

Notice of Revised Rule Making. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 N.Y.C.R.R. to apply disclosure requirements to dental and vision and hold issuers responsible for inaccurate network status information. *See* N.Y. Register Aug. 17, 2022.

Investigation of Communicable Disease

Notice of Emergency Rule Making. The Department of Health amended Part 2, § 405.3; and added § 58-1.14 to Title 10 N.Y.C.R.R. to control communicable disease. Filing Date: July 28, 2022. Effective Date: July 28, 2022. *See* N.Y. Register Aug. 17, 2022.

Registration of Pharmacy Benefit Managers

Notice of Adoption. The Department of Financial Services added Part 451 (Regulation 221) to Title 11 N.Y.C.R.R. to establish registration and first annual reporting requirements for pharmacy benefit managers. Filing Date: Aug. 16, 2022. Effective Date: Aug. 31, 2022. *See* N.Y. Register Aug. 31, 2022.

Pharmacy Benefits Bureau

Notice of Adoption. The Department of Financial Services amended Part 450 (Regulation 219) of Title 11 N.Y.C.R.R. to establish the Pharmacy Benefits Bureau and revise the rules for the Drug Accountability Board. Filing Date: Aug. 16, 2022. Effective Date: Aug. 31, 2022. *See* N.Y. Register Aug. 31, 2022.

Mandatory Face Coverings in OPWDD Settings

Notice of Emergency Rule Making. The Office for People with Developmental Disabilities added § 633.26 to Title 14 N.Y.C.R.R. to protect public health. Filing Date: Aug. 15, 2022. Effective Date: Aug. 15, 2022. *See* N.Y. Register Aug. 31, 2022.

Face Coverings for COVID-19 Prevention

Notice of Emergency Rule Making. The Department of Health added § 2.60 to Title 10 N.Y.C.R.R. to control and promote the control of communicable diseases to reduce their spread. Filing Date: Aug. 19, 2022. Effective Date: Aug. 19, 2022. *See* N.Y. Register Sept. 07, 2022.

Certification of the Facility Class Known as Individualized Residential Alternative

Notice of Emergency Rule Making. The Office for People with Developmental Disabilities amended § 686.16 of Title 14 N.Y.C.R.R. to increase IRA capacity in cases of emergent circumstances. Filing Date: Aug. 23, 2022. Effective Date: Aug. 23, 2022. *See* N.Y. Register Sept. 07, 2022.

General Purpose

Notice of Emergency Rule Making. The Office for People with Developmental Disabilities amended § 686.3 of Title 14 N.Y.C.R.R. to increase IRA capacity in cases of emergent circumstances. Filing Date: Aug. 23, 2022. Effective Date: Aug. 23, 2022. *See* N.Y. Register Sept. 07, 2022.

Patient Rights in OASAS Programs

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 815 of Title 14 N.Y.C.R.R. to establish patient rights and provider obligations regarding patient rights in OASAS programs. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

Residential Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 819 of Title 14 N.Y.C.R.R. to establish rules and expectations for providers of residential services. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

Withdrawal and Stabilization Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 816 of Title 14 N.Y.C.R.R. to establish rules and expectations for providers of withdrawal and stabilization services. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

Residential Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 820 of Title 14 N.Y.C.R.R. to establish rules and expectations for providers of residential services. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

General Provisions Applicable to All Programs Certified, Funded or Otherwise Authorized by OASAS

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 800 of Title 14 N.Y.C.R.R. to include general provisions applicable to all programs certified, funded or otherwise authorized by OASAS. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

Residential Rehabilitation Services for Youth

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 817 of Title 14 N.Y.C.R.R. to establish rules and expectations for providers of residential rehabilitation services for youth. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

Inpatient Rehabilitation Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 818 of Title 14 N.Y.C.R.R. to establish rules and expectations for providers of inpatient rehabilitation services. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

Outpatient Programs

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 822 of Title 14 N.Y.C.R.R. to establish rules and expectations for providers of outpatient services. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

Incident Reporting Requirements at All Certified, Licensed, Funded, or Operated Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 836 of Title 14 N.Y.C.R.R. to establish rules and expectations for incident reporting at all OASAS programs and services. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

Designated Services and License Endorsements

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 830 of Title 14 N.Y.C.R.R. to establish designated services and license endorsements and associated rules and expectations for providers. Filing Date: Aug. 30, 2022. Effective Date: Oct. 01, 2022. *See* N.Y. Register Sept. 14, 2022.

Telehealth Services

Notice of Adoption. The Department of Health amended §§ 505.17, 533.6 and 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: Aug. 29, 2022. Effective Date: Sept. 14, 2022. *See* N.Y. Register Sept. 14, 2022.

Covid-19 Masking Program

Notice of Emergency Rule Making. The Office of Mental Health added Part 556 to Title 14 N.Y.C.R.R. to implement Covid-19 Mask Program. Filing Date: Aug. 26, 2022. Effective Date: Aug. 26, 2022. *See* N.Y. Register Sept. 14, 2022.

Certified Residential Opportunities

Notice of Adoption. The Office for People with Developmental Disabilities added Subpart 636-3 to Title 14 N.Y.C.R.R. to provide equity in opportunities for certified residential housing. Filing Date: Aug. 30, 2022. Effective Date: March 14, 2023. *See* N.Y. Register Sept. 14, 2022.

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

Notice of Emergency Rule Making. The Department of Financial Services added § 52.76(b) to Title 11 N.Y.C.R.R. to require immediate coverage, without cost-sharing, for COVID-19 immunizations and the administration thereof. Filing Date: Sept. 09, 2022. Effective Date: Sept. 9, 2022. *See* N.Y. Register Sept. 28, 2022.

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

Notice of Adoption. 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: Sept. 15, 2022. Effective Date: Sept. 28, 2022. *See* N.Y. Register Sept. 28, 2022.

Early Intervention Program

Notice of Proposed Rule Making. The Department of Health proposed amending Subpart 69-4 of Title 10 N.Y.C.R.R. to conform existing program regulations to federal regulations and state statute, as well as to provide additional clarification. *See* N.Y. Register Sept. 28, 2022.

Repeal of Collection of Source Plasma

Notice of Proposed Rule Making. The Department of Health proposed repealing § 58-2.14 of Title 10 N.Y.C.R.R. to repeal the Collection of Source Plasma. *See* N.Y. Register Sept. 28, 2022.

Source Plasma Donation Centers

Notice of Proposed Rule Making. The Department of Health proposed adding Subpart 58-4 to Title 10 N.Y.C.R.R. to distinguish source plasma donation centers as a separate regulatory entity from blood banks. *See* N.Y. Register Sept. 28, 2022.

Private Duty Nursing (PDN) Services to Medically Fragile Adults

Notice of Proposed Rule Making. The Department of Health proposed amending § 505.8 of Title 18 N.Y.C.R.R. to increase PDN fee-for-service reimbursement for nursing services provided to medically fragile adults. *See* N.Y. Register Sept. 28, 2022.

COVID-19 Vaccination Program

Notice of Adoption. The Office of Mental Health added Part 557 to Title 14 N.Y.C.R.R. to implement a COVID-19 vaccination program in OMH Operated or Licensed Hospitals. Filing Date: Sept. 08, 2022. Effective Date: Sept. 08, 2022. *See* N.Y. Register Sept. 28, 2022.

Telehealth Expansion

Notice of Adoption. The Office of Mental Health amended Part 596 of Title 14 N.Y.C.R.R. to establish regulations regarding the expansion of telehealth. Filing Date: Sept. 12, 2022. Effective Date: Sept. 13, 2022. *See* N.Y. Register Sept. 28, 2022.

Surge and Flex Health Coordination System

Notice of Emergency Rule Making. The Department of Health added §§ 1.2, 700.5, Part 360; amended §§ 400.1, 405.24, 1001.6 of Title 10 N.Y.C.R.R. to provide authority to the commissioner to direct certain actions and waive certain regulations in an emergency. Filing Date: Sept. 20, 2022. Effective Date: Sept. 20, 2022. *See* N.Y. Register Oct. 05, 2022.

Hospital and Nursing Home Personal Protective Equipment Requirements

Notice of Emergency Rule Making. The Department of Health amended §§ 405.11 and 415.19 of Title 10 N.Y.C.R.R. to ensure that all general hospitals and nursing homes maintain a 60-day supply of PPE during the COVID-19 emergency. Filing Date: Sept. 20, 2022. Effective Date: Sept. 20, 2022. *See* N.Y. Register Oct. 05, 2022.

Maximum Contaminant Levels

Notice of Proposed Rule Making. The Department of Health proposed amending Subpart 5-1 of Title 10 N.Y.C.R.R. to adopt Maximum Contaminant Levels (MCLs) for four (4) additional per- and polyfluoroalkyl substances (PFAS). *See* N.Y. Register Oct. 05, 2022.

Training Flexibilities

Notice of Emergency Rule Making. The Office for People with Developmental Disabilities added § 633.27 to Title 14 N.Y.C.R.R. to provide flexibilities in training requirements. Filing Date: Sept. 15, 2022. Effective Date: Sept. 15, 2022. *See* N.Y. Register Oct. 05, 2022.

COVID-19 Vaccines

Notice of Adoption. The Office for People with Developmental Disabilities added § 680.14 to Title 14 N.Y.C.R.R. to require vaccinations in certain OPWDD settings. Filing Date: Sept. 20, 2022. Effective Date: Oct. 05, 2022. *See* N.Y. Register Oct. 05, 2022.

Erratum

Notice of Proposed Rule Making, Early Intervention Program, ID No. HLT-39-22-00020-P, published in the Sept. 28, 2022 issue of the State Register inaccurately indicated that public comment will be accepted until five days after the last scheduled public hearing. Public comment for this proposed rule, however, will be accepted for 60 days after (the Sept. 28th) publication of the Notice. *See* N.Y. Register Oct. 12, 2022.

Licensure and Practice of Nursing Home Administration

Notice of Proposed Rule Making. The Department of Health proposed amending Part 96 of Title 10 N.Y.C.R.R. to clarify and update the nursing home administrator licensure program. *See* N.Y. Register Oct. 12, 2022.

Medical Respite Program (MRP)

Notice of Proposed Rule Making. The Department of Health proposed adding Part 1007 to Title 10 N.Y.C.R.R. to establish procedures for review and approval of applications from a not-for-profit corporation to be certified as an MRP operator. *See* N.Y. Register Oct. 19, 2022.

Compiled by **Caroline B. Brancatella**. Ms. Brancatella is of counsel in the Health and 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, Caroline clerked for the Honorable Cynthia M. Rufe of the Eastern District of Pennsylvania. The assistance of Franklin A. Carcamo, in preparing these summaries is gratefully acknowledged.

New York State Fraud, Abuse, and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health Medicaid Decisions

Compiled by Dena M. DeFazio

Queens Center for Rehab and Residential Health care (Decision After Hearing, August 5, 2022, Ann Gayle, ALJ)

Appellant is a 179-bed residential health care facility (RHCF) in Whitestone, New York. The New York State Office of the Medicaid Inspector General (OMIG) initiated a review of payments for Medicaid recipients who resided at the RHCF from Feb. 1, 2007 through Jan. 31, 2011. In both its draft and final audit report, OMIG identified overpayments in the amount of $340,797.39, including interest, representing four areas of overpayments. After issuing the final audit report but before hearing, OMIG agreed to remove 83 retroactive net available monthly income (NAMI) claims in the amount of $17,002.41, including interest, reducing the total overpayment amount to $323,794.98. Additionally, appellant withdrew its challenge to three of the four audit findings, but continued to challenge the interest charged on all four findings.

The only overpayment finding contested at hearing related to Medicaid reimbursements being paid without being reduced by partial or full NAMI. At hearing, Appellant asserted that it was entitled to Medicaid reimbursements for bad debts it experienced from uncollected resident NAMIs, and that the bad debts loss should be applied to offset the overpayments identified in the audit. Administrative Law Judge (ALJ) Gayle rejected these arguments as inconsistent with both regulations and Medicaid program reimbursement methodology. Appellant's next argument, that is should be reimbursed for bad debts stemming from good-faith collection efforts, was also rejected. According to ALJ Gayle, Appellant confused Medicaid cost-based reimbursement with fee-for-service reimbursement, and by doing so, Appellant was incorrectly attempting to hold the Medicaid Program responsible for amounts that are the patient's responsibility. *See* 18 N.Y.C.R.R. § 517.3(a)–(b). Appellant's arguments related to cost reporting and the rate setting processes were also rejected as irrelevant to the hearing, which dealt with an audit of specific fee-for-service claims submitted by the RHCF, rather than per diem reimbursement rate setting.

Appellant's arguments based on an action commenced in 2012 arguing the issues raised at hearing were also rejected by ALJ Gayle. *See Concourse Rehab. & Nursing Ctr., Inc. v. Shah*, 161 A.D.3d 669 (1st Dep't 2018), *lv denied*, 32 N.Y.3d 904 (2018). Despite Appellant's assertions related to the Appellate Division's decision in the proceeding, the court dismissed the action because Appellant had not availed itself of the administrative remedies available, and did not address the ability to write-off bad debts related to residents' NAMI or OMIG's treatment of uncollectible NAMI debt. Even though these arguments were not addressed in the *Concourse* decision, the ALJ concluded that they were meritless and irrelevant to the fee-for-service overpayments identified in the audit. ALJ Gayle also acknowledged that Appellant's counsel raised the same "uncollected NAMI" arguments in prior Medicaid Program and OMIG audit-related administrative hearings, and the arguments were found to be without merit. As no new or materially different facts or arguments were raised that were not addressed and decided in the previous decisions, the ALJ determined that the arguments were meritless. Therefore, as Appellant did not dispute that it submitted claims to the Medicaid Program that included the NAMI amounts that were the residents' responsibility, ALJ Gayle found that Appellant failed to prove that OMIG's disallowances should be reversed. *See* 18 N.Y.C.R.R. § 519.18(d).

Appellant's remaining arguments at hearing were related to OMIG's imposition of interest on the overpayment findings. Specifically, Appellant argued that OMIG incorrectly imposed interest from the date of the overpayments pursuant to 18 N.Y.C.R.R. § 518.4(b)–(c), instead of from the date the audit report was issued pursuant to 18 N.Y.C.R.R. § 518.4(e). ALJ Gayle rejected this argument, concluding that it attempted to confuse audits of cost reports with fee-for-service audits, and that interest was properly charged based on the regulations applicable to fee-for-service audits.

Appellant also asserted that the interest assessments were incorrect because it may not have actually received the overpayments until weeks after the dates recorded in the Department of Health's (DOH) payment records. ALJ Gayle rejected this argument, concluding that Appellant failed to offer any specific evidence to rebut the presumption of accuracy afforded to OMIG's records or to dispute the interest calculation's accuracy. *See* 18 N.Y.C.R.R. § 519.18(f). Appellant's attempt to shift the burden to OMIG by asserting that OMIG could have reviewed Appellant's financial records to determine when payment on the claims were made was re-

jected. Moreover, these arguments could neither be raised nor considered at hearing, as they were not raised in response to the draft audit report. *See* 18 N.Y.C.R.R. § 519.18(a).

Finally, ALJ Gayle rejected Appellant's argument that interest should not be imposed on RHCFs for audits of cost reports, concluding that the same contentions had been correctly rejected in previous administrative hearings. Therefore, OMIG's determination to seek recoupment of overpayments in the amount of $323,794.98 was affirmed.

Catholic Managed LTCS MLTC (Decision, August 2, 2022, John Harris Terepka, ALJ)

Appellant requested a hearing to appeal OMIG's determination to recover overpayments. OMIG requested a decision on the issue of whether Appellant's hearing request was timely. Appellant did not submit evidence or argument in response to OMIG's request for a determination.

OMIG's final audit report was issued on Jan. 27, 2022, and Appellant received the report on Feb. 1, 2022. Appellant did not request a hearing until April 14, 2022, more than 60 days after the date of OMIG's written determination. *See* 18 N.Y.C.R.R. § 519.7(a). Prior to requesting a hearing, Appellant communicated with OMIG's auditors in February and March of 2022 seeking an extension of time before initiation of recoupment of the overpayment. ALJ Terepka concluded that these communications did not constitute a request for a hearing and did not extend the time to submit a request, as questions pertaining to initiating recovery of any overpayment before a hearing is requested or held are unrelated to the requirements for requesting a hearing. *See West Midtown Mgm't Grp. v. State of N.Y.*, 31 N.Y.3d 533 (2018). As Appellant's request for a hearing was not submitted until Feb. 14, 2022, the ALJ held that DOH lacked jurisdiction to grant the request.

Ashu Sachdev (Decision After Hearing, July 18, 2022, Natalie J. Bordeaux, ALJ)

Appellant is a dental provider enrolled in the Medicaid program. Appellant procured a certified Electronic Health Record (EHR) system to qualify for an initial payment from the EHR Technology Incentive Program for 2016. On Oct. 14, 2018, Appellant submitted an application—including a certification that the meaningful use objectives required for payment in a year subsequent to the initial year of payment had been met—for payment for the 2017 payment year under the program. On audit, OMIG reviewed Appellant's compliance with the EHR Technology Incentive Program's requirements and determined that Appellant was not eligible to receive an incentive payment for the 2017 payment year due to Appellant's failure to produce documentation to support the meaningful use objectives/measures attestation.

On audit, OMIG found that Appellant failed to meet the EHR Technology Incentive Program objective of protecting electronic protected health information (ePHI), as Appellant failed to provide documentation supporting Appellant's affirmation that a security risk analysis had been conducted. At hearing, Appellant asserted that Appellant's office met the objective by using certified EHR technology to encrypt information, taking measures to safeguard log in information, updating software, and installing security cameras and an alarm system in the office. ALJ Bordeaux rejected Appellant's argument based on federal regulations requiring eligible professionals to take and document certain specific steps in order to meet the security risk analysis requirement. *See* 42 C.F.R. §§ 164.308(a)(1), 495.22(e)(1). The objective's requirements were not satisfied by the process Appellant described, as well as the lack of corresponding documentation.

Moreover, no documentation was provided to support Appellant's attestation that the clinical decision support objective had been met. The ALJ noted that clinical quality measures are patient-specific and based on each patient's health. Although OMIG would have accepted a letter or screen shots from Appellant's software vendor identifying five clinical decision support interventions enabled during the reporting period to satisfy the objective, Appellant failed to provide this documentation, despite the fact that other dental providers were able to do so when asked. Appellant's arguments that clinical decisions were based on digital x-rays and visual inspections, and that the information and resulting treatment plans were stored in the EHR software, were rejected as insufficient to meet the objective's requirements.

As to the computerized provider order entry measure, eligible professionals under the EHR Technology Incentive Program are required to use computerized provider order entry for medication, laboratory, and radiology orders. Appellant attested to qualifying for an exclusion from this objective, which is available to providers who write fewer than 100 medication, laboratory, and radiology orders during an EHR reporting period. *See* 42 C.F.R. § 495.22(3)(ii)(B). On audit, OMIG determined that Appellant did not qualify for an exclusion from the third measure, which required more than 30% of radiology orders during the EHR reporting period to be recorded using computerized provider order entry, as Appellant's meaningful use dashboard showed that radiology services were ordered 562 times, and none were entered into the EHR software. *See* 42 C.F.R. §§ 495.22(e)(3)(1), (ii)(A). At hearing, Appellant argued that the measure was not applicable because the radiology services were performed in-house, using Appellant's own equipment. ALJ Bordeaux rejected this argument, finding that providers who perform radiology procedures themselves are not exempted from the computerized provider order entry requirement. As such, Appellant failed to qualify for an exclusion from this objective.

The next objective, patient-specific education resources, pertained to the obligation to use clinically relevant information from certified EHR technology to identify and provide patient-specific education resources. *See* 42 C.F.R. § 495.22(e)(6)(i). Although Appellant attested to being excluded from meeting this objective because Appellant had no office visits, Appellant's EHR software dashboard indicated that 273 patients were seen during the reporting period. Appellant's argument that the exemption applied because Appellant is a dentist and only provides patients with treatment, not consultation, was rejected as unsupported by applicable law. According to ALJ Bordeaux, the meaningful use of EHR technology requirements apply to all professional services rendered by an eligible professional for which payment is made, and Appellant incorrectly attested to being excluded from this requirement as there is no exclusion for treatment of a patient. *See* Social Security Act § 1848(k)(3), (o); 42 C.F.R. § 495.2(a).

Similarly, Appellant argued that an exclusion from the secure electronic messaging objective applied due to Appellant not having any office visits during the reporting period. *See* 42 C.F.R. §§ 495.22(e)(9)(ii)(A)(3), (B). Specifically, Appellant asserted that dental appointments do not constitute office visits, and that the exclusion from the objective was appropriate because Appellant only communicated with patients in-person based on the belief that electronic communications do not further Appellant's practice. ALJ Bordeaux rejected these arguments, noting that the purpose of the EHR Technology Incentive Program was to improve the quality of patient care through the electronic exchange of health care information, and that Appellant's arguments did not establish that OMIG erred in its determination that Appellant did not qualify for an exclusion from the objective. *See* Social Security Act § 1848(o)(2).

Appellant's argument that the certified EHR technology had been used to its capacity for a dental practice, and as such, the meaningful use objectives and measures had been satisfied to the extent possible for a dental practice was also rejected by ALJ Bordeaux. Relying on the fact that nearly 100 of the 180 dental providers reviewed for compliance with the objectives had passed their audits, the ALJ concluded that dental providers are capable of demonstrating satisfaction of the meaningful use requirements. Finally, Appellant's argument that the overpayment should be pro-rated to account for Appellant's satisfaction of some of the objectives and measures was rejected, as the applicable regulations did not permit incentive payments to be apportioned.

Therefore, OMIG's overpayment finding in the amount of $8,500 was affirmed as Appellant failed to demonstrate that all criteria required to obtain an incentive payment under the EHR Technology Incentive Program had been met.

Rite Surgical Supplies Inc. (Decision, July 14, 2022, Kimberly A. O'Brien, ALJ)

Appellant was a medical supply company in Brooklyn, New York. OMIG conducted an audit and sought restitution of Medicaid program overpayments. OMIG's determination was communicated to Appellant by a final audit report dated April 3, 2015. The issue before ALJ O'Brien was whether appellant's request for a hearing had been abandoned.

On or around May 13, 2015, appellant's counsel requested a hearing on the overpayment findings, and a subsequent request to adjourn dated Aug. 5, 2015 was granted. The matter was taken off of the administrative hearing calendar in March of 2017 in anticipation of settlement. In 2021, OMIG contacted Appellant's counsel, who confirmed that representation of Appellant had been withdrawn in or around 2019. At that time, OMIG requested that the matter be put back on the hearing calendar. A notice dated June 9, 2022 advised Appellant that the hearing had been rescheduled to July 13, 2022. Appellant failed to appear for the hearing and did not request to have the hearing rescheduled. As such, Appellant's request for a hearing was deemed abandoned.

University Nursing Home (Decision After Hearing, July 11, 2022, Ann Gayle, ALJ)

Appellant is a 46-bed RHCF in Bronx, New York. OMIG initiated a review of payments for Medicaid recipients who resided at the RHCF from Oct. 1, 2010 through Nov. 30, 2012, and identified overpayments in the amount of $22,234.80, including interest, related to residents' NAMI and incorrect rate codes. After the final audit report was issued but before hearing, OMIG agreed to remove one NAMI overpayment, which adjusted the overpayment finding to $20,903.35, including interest. Additionally, Appellant withdrew its challenge to the incorrect rate code audit finding, but continued to oppose the NAMI-related finding and the interest charged on the overpayments.

At hearing, Appellant challenged OMIG's audit finding that Medicaid reimbursements were paid without being re-

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duced by partial or full NAMI. First, Appellant asserted that it was entitled to Medicaid reimbursements for bad debts it experienced from uncollected resident NAMIs, that debt is an item that can be included in the facility's cost report and calculation of its Medicaid reimbursement, and that the bad debts loss should be applied to offset the overpayments identified in the audit. ALJ Gayle rejected these arguments as inconsistent with both regulations and Medicaid program reimbursement methodology. Moreover, Appellant failed to demonstrate how it made good-faith efforts to obtain payment from the residents before seeking the contributions from the Medicaid Program. Appellant's reliance on *Eden Park Health Services v. Axelrod*, 114 A.D.2d 721 (3d Dep't 1985), was misplaced, as the Third Department's decision did not support Appellant's assertion that unpaid NAMI is bad debt that may be applied to offset overpayments identified in fee-for-service claim audits. According to ALJ Gayle, Appellant was attempting to incorrectly hold the Medicaid Program responsible for amounts that are the patient's responsibility. *See* 18 N.Y.C.R.R. § 517.3(a)–(b). Appellant's arguments related to the cost reporting and rate setting processes were also rejected as irrelevant to fee-for-service claim audits, and the assertion that a regulatory reference to Medicare principles of reimbursement recognizing unpaid NAMI as bad debt overrides contrary state and federal laws, was found to be without merit and explicitly contradicted by regulation. *See* 10 N.Y.C.R.R. § 86-2.17(a).

Appellant's arguments based on a 2012 action arguing the issues raised at hearing were rejected by ALJ Gayle. *See Concourse Rehab. & Nursing Ctr., Inc. v. Shah*, 161 A.D.3d 669 (1st Dep't 2018), *lv denied*, 32 N.Y.3d 904 (2018). Contrary to Appellant's assertions, the action was dismissed by the court due to Appellant's failure to avail itself of the administrative remedies available, and neither the ability to write-off bad debts related to residents' NAMI nor the treatment of uncollectible NAMI debt by OMIG were addressed by the Appellate Division. Nevertheless, the ALJ concluded that Appellant's bad debt claims were meritless and irrelevant to the fee-for-service overpayments identified in the audit. Appellant did not dispute OMIG's findings that claims which included NAMI amounts that were the residents' responsibility were submitted to the Medicaid Program, and hearing testimony did not establish that OMIG's determination was incorrect. ALJ Gayle also acknowledged that Appellant's counsel raised the same "uncollected NAMI" arguments in prior Medicaid Program and nursing home audit-related administrative hearings, and the arguments were found to be without merit. As no new or materially different facts or arguments were raised that were not addressed and decided in the previous decisions, Appellant's arguments were again found to be without merit.

Appellant's remaining arguments at hearing were related to OMIG's imposition of interest on the overpayment findings. Specifically, Appellant argued that OMIG incorrectly imposed interest from the date of the overpayments pursuant to 18 N.Y.C.R.R. § 518.4(b)–(c), instead of from the date the audit report was issued pursuant to 18 N.Y.C.R.R. § 518.4(e). ALJ Gayle rejected this argument, concluding that it attempted to confuse audits of cost reports with fee-for-service audits, and that interest was properly charged based on the regulations applicable to fee-for-service audits.

Appellant also asserted that the interest assessments were incorrect because it may not have actually received the overpayments until weeks after the dates recorded in the DOH's payment records. ALJ Gayle rejected this argument due to Appellant's failure to offer any specific evidence to rebut the presumption of accuracy afforded to OMIG's records or to dispute the interest calculation's accuracy. *See* 18 N.Y.C.R.R. § 519.18(f). Instead, Appellant's attempt to shift the burden to OMIG by asserting that OMIG could have reviewed Appellant's financial records to determine when payment on the claims were made was rejected. Moreover, Appellant's arguments related to the accuracy of the payment dates and interest assessments could not be considered at hearing, as Appellant failed to raise the challenges in response to OMIG's draft audit report. *See* 18 N.Y.C.R.R. § 519.18(a).

Finally, ALJ Gayle rejected Appellant's argument that interest should not be imposed on RHCFs for audits of cost reports, concluding that the contention had been rejected in previous administrative decisions. Therefore, OMIG's determination to seek recoupment of overpayments in the amount of $20,903.35 was affirmed.

Angels In Your Home, LLC (Decision After Hearing, June 8, 2022, Natalie J. Bordeaux, ALJ)

Appellant is a licensed home care services agency (LHCSA) and a home and community based services (HCBS)/traumatic brain injury waiver (TBI Waiver) provider. OMIG initiated an audit of medical and fiscal records supporting claims for HCBS TBI Waiver services paid by the Medicaid Program from Jan. 1, 2013 through Dec. 31, 2015, and reviewed 100 randomly sampled TBI Waiver services claims paid during the audit period. OMIG identified 12 disallowance categories representing 79 claims with at least one error. The disallowed payments totaled $14,861.31, and using extrapolation, OMIG determined that the overpayment received by Appellant was $2,391,420. After issuing the final audit report but prior to hearing, OMIG removed its findings in one of the disallowance categories, resulting in a reduction of the total extrapolated overpayment to $2,376,559.

At hearing, Appellant contested all of the remaining disallowances, as well as OMIG's determination to extrapolate the overpayment findings. The first disallowance category, TBI Training Not Completed—Home and Community Support Services (HCSS), pertained to TBI Waiver providers' obliga-

tion to comply with three training components: (1) basic orientation training; (2) service specific training; and (3) annual training. *See* HCBS NYS DOH Medicaid Waiver for Individuals with TBI Program Manual (TBI Program Manual), § VIII (Apr. 2009). Pursuant to this requirement, HCSS staff must attend basic orientation training and service specific training prior to providing any Medicaid billable service. *See id.*, § VI.

On audit, OMIG identified 54 instances wherein HCSS were performed by staff who allegedly lacked adequate documentation to show that both types of training were completed before the dates of service in the claims sample. Appellant asserted that the disallowances were improper because the HCSS staff received training to become a personal care aide or a home health aide, and that this training was sufficient to justify Appellant's right to receive payment for the HCSS in the sampled claims. ALJ Bordeaux rejected this argument, indicating that these types of training were prerequisites to HCSS training and were insufficient for HCSS training purposes. *See id.*

The ALJ also rejected Appellant's argument that OMIG incorrectly assumed that other documented trainings did not contain the elements of TBI Waiver basic orientation and service specific training, and concluded that these other trainings are distinct and unrelated to TBI Waiver Program-related training. Pointing to the TBI Program Manual's requirement that providers include documentation of all Program-related training in each employee's file, ALJ Bordeaux found that Appellant failed to offer documentation showing that the employees who completed other training received basic orientation for the TBI Waiver Program at the same time. *See id.*, § VIII. Based on the lack of documentation explicitly showing that the required training was completed for each employee identified in the sampled claims, OMIG lacked a reason to conclude that the other training provided by Appellant met all of the TBI Waiver Program requirements applicable to HCSS staff. Appellant's argument that OMIG's search for, and scrutiny of, sign-in sheets and other documents demonstrating compliance with the training requirements was not rooted in specific requirements was rejected, and ALJ Bordeaux found that the documents reviewed were based on the specific requirements set out in the TBI Program Manual. *See id.* The ALJ also noted that OMIG received adequate documentation of training for the employees providing HCSS services in the remaining sampled claims, and to the extent that documentation other than what was specifically required by the Manual was considered, Appellant was offered a further opportunity to show compliance with the requirements.

The third, eighth, and twelfth disallowances categories involved similar issues. First, the third disallowance category—Failure to Complete Required HCSS In Service Training—related to the TBI Waiver Program requirement obligating HCSS staff to attend six hours of in-service education annually, including Program-specific training. *See id.*, § VI. The disallowances in this category were upheld. Next, the eighth disallowance category pertained to services performed by unqualified HCSS staff, and was based on OMIG's finding that Appellant failed to document required training for HCSS staff members who rendered billed services for certain sampled claims. ALJ Bordeaux affirmed OMIG's determination to disallow these claims. OMIG's overpayment findings for the twelfth disallowance category—TBI Training not Completed—Service Coordinator—were also upheld.

The second disallowance category at issue at hearing—Failure to Complete Health Requirements—related to the applicable LHCSA regulations pertaining to health requirements. Pointing to the regulatory requirements which obligate LHCSAs to ensure the health status of all new personnel is assessed and documented prior to assuming patient care duties, OMIG concluded that documentation for certain sampled claims did not include health assessments that occurred before the dates of service subject to audit. *See* 10 N.Y.C.R.R. § 766.11(c). Specifically, the applicable regulations require an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test, and annual assessments thereafter for all personnel prior to employment or affiliation, unless the personnel has no clinical or patient contact responsibilities. *See* 10 N.Y.C.R.R. § 766.11(d)(4). At hearing, ALJ Bordeaux concluded that the relevant claims were properly disallowed, as TB test results for several HCSS staff members were not included in Appellant's documentation for certain sampled claims. Moreover, although TB test results were provided for some of the sampled claims, the ALJ concluded that the claims were properly disallowed as the results were read by a licensed practical nurse (LPN), despite this task being outside of a LPN's scope of practice. *See* N.Y. Educ. Law § 6902(2); N.Y. St. Dep't of Educ.—Off. of Professions, Nursing Practice Alerts and Guidelines, PPD Protocol (June 2009). Finally, the last disallowance in this category was affirmed, as Appellant was unable to provide documentation showing that a HCSS provider who had previously tested positive for TB received clinical follow-up, as required by regulation. *See* 10 N.Y.C.R.R. § 766.11(d)(4).

Disallowance category five related to missing documentation of services provided. ALJ Bordeaux upheld OMIG's findings in this category, concluding that Appellant failed to provide documentation describing how HCSS staff assisted the TBI Waiver Program participant and how the assistance related to the participant's care plan, and failed to substantiate the total number of hours billed through service documentation.

Next, the sixth disallowance category pertained to billed services that were not included in the service plan. Pointing to federal regulations, the ALJ stated that TBI Waiver Program services may only be furnished in accordance with a plan of

care approved by DOH, and only those services that are provided by a DOH-approved provider and included in the service plan will be reimbursed. *See* 42 C.F.R. § 441.301(b)(1)(i); TBI Program Manual, § VI. ALJ Bordeaux upheld the disallowances in this category, concluding that for some sample claims, Appellant was not the authorized service provider for the services billed, and for others, Appellant failed to provide supporting documentation that included a listing of the participant's approved waiver services, which impeded Appellant's ability to establish that the services billed were rendered in accordance with the participant's approved plan of care.

OMIG's findings for the seventh and ninth disallowance categories were similarly affirmed by the ALJ. The seventh disallowance category—Failure to Conduct Required Criminal History Check—and ninth disallowance category—Missing Documentation of Nursing Supervision Visit—were also upheld.

The tenth category of disallowances—Failure to Obtain Authorized Practitioner's Signature Within Required Time Frame—was also upheld, as the supporting documentation for one of the sampled claims demonstrated that the medical order was not effectuated within six months of the date of service billed. *See* 10 N.Y.C.R.R. § 766.4(a), (c). Similarly, another disallowance in this category was upheld due to Appellant's failure to provide OMIG with a medical order encompassing the billed dates of service. Finally, OMIG's finding in the eleventh disallowance category—Billed More Hours Than Documented—was upheld for one sampled claim as the Medicaid program was billed for nine service hours, but the HCSS staff member only documented providing eight hours of services.

At hearing, Appellant made a variety of broader arguments, in addition to the disallowance-specific responses and arguments. First, Appellant asserted that it was unable to produce requested documentation to OMIG because numerous documents were stolen by former employees in 2015. ALJ Bordeaux rejected Appellant's argument, noting that Appellant alleged in governmental filings and various communications that the removed or copied files did not include files related to home care services. Moreover, Appellant had not notified OMIG's Self-Disclosure Unit of the alleged documentation loss in 2015, and did not provide the notification until the audit at issue was commenced. Next, Appellant's arguments that the standards set forth in Chapter 3 of the Medicare Program Integrity Manual regarding loss of documentation should be considered was also rejected, as the Centers for Medicare and Medicaid Services' (CMS) Medicaid Integrity Program manual was the operative document. Finally, ALJ Bordeaux concluded that Appellant's attempts to establish mitigating circumstances to justify the lack of supporting documentation were insufficient to waive the Medicaid Program's record keeping requirements. Pointing to the fact that Appellant did not attempt to identify the documentation that it believed was removed by the former employees, the ALJ concluded that Appellant's arguments improperly shifted the burden of proof to OMIG.

Next, Appellant asserted that disallowances based on the TBI Program Manual, rather than regulation or statute, were improper. ALJ Bordeaux rejected this argument, finding that DOH has the authority to make rules, regulations, and official directives that are necessary to implement its regulations, and that providers are required to comply with them. *See* 18 N.Y.C.R.R. § 504.3(i); *PSSNY v. Pataki*, 58 A.D.3d 924 (3rd Dept. 2009); *Lock v. N.Y. State Dep't of Social Servs.*, 220 A.D.2d 825 (3rd Dept. 1995). Since the TBI Program Manual did not contradict or add significantly to the payment conditions set forth in regulation, OMIG's reliance on the Manual was proper.

Appellant also argued that OMIG's determinations were improper since the Medicaid Program already remitted payment for the claims, and as such, Appellant should have been permitted to correct claims and justify them on audit with contemporaneous documentation. ALJ Bordeaux rejected this argument and found that Appellant's reliance on *Chelsea Express Transportation, Inc.* (Decision After Hearing, May 24, 2019, William J. Lynch, ALJ) was misplaced, as the current audit identified issues with supporting documentation for paid claims, and was not an audit wherein OMIG found that submitted claims contained clerical errors. Additionally, Appellant's arguments citing *Statewide Ambulette Service Inc.* (Decision After Hearing, Oct. 28, 2015, John Harris Terepka, ALJ) were also rejected as irrelevant as OMIG did not determine to sanction Appellant pursuant to 18 N.Y.C.R.R. Part 515. Finally, ALJ Bordeaux found that Appellant was precluded from raising an argument that the period audited by OMIG overlapped with a Sept. 23, 2015 LHCSA survey, as the issue had not been raised before the hearing was commenced. Nevertheless, the ALJ determined that the LHCSA survey did not review the same aspects of Appellant's operations, and OMIG's disallowances were unrelated to the previously surveyed items.

At hearing, Appellant also challenged OMIG's determination to extrapolate the audit findings to the universe of claims, and asserted that the extrapolation of the audit findings did not comport with CMS' guidelines, as stated in Chapter 8 of the Medicare Program Integrity Manual. The ALJ rejected this argument, concluding that the Medicare Program Integrity Manual is not binding authority in audits of Medicaid Program claims, and that the Manual provides that a failure to follow its guidelines does not necessarily affect the validity of statistical sampling or the projection of an overpayment. *See* Medicare Program Integrity Manual § 8.4.1.1.

Each of the arguments presented by Appellant's expert witness were also rejected by ALJ Bordeaux. Finally, Appellant's

arguments challenging OMIG's use of the March 9, 2018 audit protocol applicable to dates of service before Sept. 1, 2017, rather than the previous protocol revised July 3, 2015, was rejected. According to the ALJ, OMIG's decision to follow the audit protocol in effect when the audit was conducted, rather than when the claims were paid, was appropriate and within its discretion. Overall, ALJ Bordeaux found that Appellant failed to overcome the assumption of validity afforded to OMIG's statistical sampling methodology. As such, the overpayment findings and extrapolation were affirmed.

Wesley Gardens Corporation (Decision After Hearing, May 31, 2022, Jean T. Carney, ALJ)

OMIG conducted an audit of the Medicaid rates paid to Appellant, a RHCF, from Jan. 1, 2012 through Dec. 31, 2015. The audit consisted of a review of Appellant's records supporting the capital portion of its cost report RHCF-4 for the calendar years of Jan. 1, 2010 through Dec. 31, 2013. OMIG identified an overpayment of $302,472, and Appellant objected to three of OMIG's audit findings.

At hearing, Appellant challenged audit finding 1(d), which related to the capitalization of costs for the installation of a new boiler into Appellant's heating system in 2011. When one of the three boilers at Appellant's RHCF failed prematurely in 2011, Appellant decided to remove and replace the failed boiler. On audit, OMIG disallowed the depreciation costs reported by Appellant for the installation. At hearing, ALJ Carney considered whether Appellant showed that OMIG erred in disallowing the replacement of the portion of the heating system as a capital cost. In reaching the overpayment determination, OMIG viewed the heating system as a whole (three boilers working together to provide heat to the RHCF) and determined that pursuant to DOH regulations applicable to RHCFs, the replacement constituted a repair, rather than an expenditure that could be capitalized. Specifically, repairs are defined in regulation as the "restoration of a capital asset to full capacity, or a contribution thereto, after damage, accident, or prolonged use, without increase in its previously estimated service life or productive capacity." 10 N.Y.C.R.R. § 451.230(a).

Appellant argued that the new boiler was a capital expenditure and that it was proper to treat it as a depreciable asset until the decision was made to dispose of it from an accounting perspective. Citing the regulatory requirements applicable to capital expenditures, ALJ Carney determined that replacing the boiler neither added to nor increased the heating system's capacity, and instead, only restored the system to its former full capacity. *See* 10 N.Y.C.R.R. § 451.46. Moreover, although the project did increase the heating system's overall efficiency, there was a lack of evidence to support Appellant's argument that the project increased the system's service life or productive capacity, which was particularly true in light of the fact that Appellant later replaced the entire heating system in 2014. As such, ALJ Carney concluded that OMIG's determination to disallow depreciation for the new boiler as a capital cost was reasonable.

In regards to audit finding 1(e), ALJ Carney considered whether Appellant showed that OMIG erred in disallowing the undepreciated amount of the heating system equipment that was disposed of two years after being installed as a capital cost. In 2013, Appellant found that one of the three boilers was at risk of failing, and decided to replace the entire heating system—including the boiler that was installed in 2011—with a more efficient hot water heating system. Based on the finding that the new boiler was a repair, rather than a depreciable asset, the ALJ concluded that OMIG's disallowance was reasonable, as replacing the heating system in 2014 was not a loss on disposal of a depreciable asset.

Finally, ALJ Carney considered whether Appellant showed that OMIG erred in disallowing abandoned project planning costs as capital costs. In 2003, Appellant submitted a Certificate of Need application to DOH seeking approval to renovate and expand the RHCF by adding a tower and creating a parking lot. Appellant obtained survey drawings and plans, but construction never began due to the RHCF's location in a historic district requiring approval from the local preservation board. The project was subsequently abandoned in 2011 due to the lack of project approval from the preservation board. At this time, Appellant had accrued $85,285 in planning costs associated with the abandoned project, and these costs were written off and included in Appellant's 2013 cost reports. Appellant also requested to amortize the planning costs over three years, and the amortized portions were included in its 2013 and 2015 cost reports, resulting in duplicate write-offs.

Noting that there are no Medicaid Program regulations that address planning costs, ALJ Carney relied on relevant Medicare Program regulations which allow abandoned project costs to be considered operating costs, so long as the project was intended to expand or renovate the nursing home. *See* 10 N.Y.C.R.R. § 86-2.17(a). Relying on these regulations, the ALJ concluded that the project planning costs were allowable under the operating component of Appellant's rate, rather than the capital component, since the project included adding an addition to the RHCF that would allow the number of beds on each floor to be reconfigured. Appellant asserted that the Bureau of Residential Health Care Reimbursement (BRHCR) had granted its rate appeal and adjusted the rates to allow the abandoned project costs, and as such, OMIG should not disallow them on audit. ALJ Carney rejected this argument, as rates set by the BRHCR are considered provisional until they are audited by OMIG. *See* 10 N.Y.C.R.R. § 86-2.7. As such, Appellant did not show that OMIG erred in disallowing the abandoned project costs.

As Appellant failed to meet its burden of proving that OMIG erred in disallowing depreciation for the new boiler as a capital cost, disallowing the loss on disposal as a capital cost, and disallowing the abandoned project costs, OMIG's determination to seek recoupment of overpayments from Appellant was affirmed.

New York State Attorney General Press Releases

Compiled by Samuel Chubb, Jamie Dughi Hogenkamp, and Bridget Steele

Attorney General James Acts To Protect Access to Reproductive Health Care at Major New York Pharmacies—August 30, 2022—Attorney General (AG) James sent letters to CVS and Walgreens in response to reports that store employees in other states refused customers birth control, condoms, emergency contraceptives, and/or other medications related to reproductive health. AG James' letter reminded CVS and Walgreens that denying these prescribed or over-the-counter medications or products is illegal in any of their more than 1,000 locations in New York, and that the harassing, embarrassing, and shaming behavior by employees reported in other states would be a violation of New York's Public Health and Civil Rights Laws. Finally, AG James' letter requested additional information on the pharmacies' policy allowing pharmacists to step away from filling prescriptions that they have a moral objection to. As the policy seemingly infringes upon the rights of New Yorkers, the requested information would provide clarity on how the policy works in practice.

https://ag.ny.gov/press-release/2022/attorney-general-james-acts-protect-access-reproductive-health-care-major-new.

Attorney General James Applauds Google for Improving Search Results for Individuals Seeking Abortion Care—August 25, 2022—AG James applauded Google for committing to updating Google Maps search results to label facilities that provide abortion care, including distinguishing these facilities from misleading anti-abortion clinics known as crisis pregnancy centers (CPCs). The changes will help individuals locate the reproductive health care facilities they need.

https://ag.ny.gov/press-release/2022/attorney-general-james-applauds-google-improving-search-results-individuals.

Attorney General James Fights To Protect Access to Reproductive Health Care and Emergency Abortion Care—August 16, 2022—AG James and the AG of California, as the co-leaders of a multistate coalition, joined 21 attorneys general in filing two amicus briefs in U.S. district courts in Idaho and Texas. The briefs argue that the states' near total bans on abortion conflict with the federal Emergency Medical Treatment and Labor Act (EMTALA), which requires hospitals to treat any patient's emergency medical condition, including providing abortion care, to stabilize serious jeopardy to the patient's health.

https://ag.ny.gov/press-release/2022/attorney-general-james-fights-protect-access-reproductive-health-care-and.

Attorney General James Sues CVS for Harming New York Safety Net Hospitals and Clinics by Diverting Millions From Underserved Communities—July 28, 2022—AG James filed suit against CVS Health Corporation (CVS) alleging unfair business practices that undermined the goal of the 340B program to provide savings via federal subsidies for prescriptions in safety net hospitals and clinics. The lawsuit alleges that by requiring safety net hospitals to contract with a CVS subsidiary to process federal subsidy claims, the company violated New York antitrust laws resulting in financial losses to the hospitals. The suit seeks injunctive relief, hospitals' lost revenue and other incurred costs, and civil penalties for unfair and illegal business practices.

https://ag.ny.gov/press-release/2022/attorney-general-james-sues-cvs-harming-new-york-safety-net-hospitals-and-clinics.

Attorney General James Condemns Texas AG for Endangering Lives of Pregnant People—July 14, 2022—AG James issued a statement admonishing the Texas AG for his lawsuit challenging the Biden administration's rule regarding maternal life-saving abortions in medical emergencies.

https://ag.ny.gov/press-release/2022/attorney-general-james-condemns-texas-ag-endangering-lives-pregnant-people.

Attorney General James Releases Written Testimony From Public Hearing on New York's Mental Health Crisis—July 11, 2022—AG James released written testimony from government officials, health care providers, community organizations, and impacted New Yorkers who detailed mental health issues including a lack of psychiatric care beds for adults and children, stigmatized perceptions of mental illness, criminalization of mental illness, inadequate Medicaid reimbursement rates, a lack of long-term care options, and long wait times for those seeking care. AG James also seeks to hear from those who have experienced issues accessing emergency care for an acute psychiatric condition.

https://ag.ny.gov/press-release/2022/attorney-general-james-releases-written-testimony-public-hearing-new-yorks-mental.

Attorney General James Uncovers Evidence That Teva Pharmaceuticals Lied to Evade Accountability for Opioid Crisis in New York—July 11, 2022—AG James filed a motion alleging Teva Pharmaceuticals USA's parent company made significant and intentional misrepresentations to the Office of Attorney General (OAG) and the court. The OAG uncovered evidence that refutes prior sworn testimony that led to the parent company's dismissal from the OAG's opioid

litigation. The OAG seeks to vacate the dismissal to examine the parent company's real role, in an effort to ensure the judgment against Teva Pharmaceuticals USA is paid.

https://ag.ny.gov/press-release/2022/attorney-general-james-uncovers-evidence-teva-pharmaceuticals-lied-evade.

Attorney General James Recoups $122,000 for Consumers Charged for Expedited COVID-19 Tests That Were Late—July 7, 2022—The OAG has recovered $122,014 in fees from Clear 19 Testing LLC, which were charged to 692 consumers. The recovery was related to COVID-19 test results that were received more than two hours, and in some cases days or weeks, after the promised 24-hour time frame.

https://ag.ny.gov/press-release/2022/attorney-general-james-recoups-122000-consumers-charged-expedited-covid-19-tests.

Attorney General James' Statement on New Efforts To Protect Abortion and Strengthen Gun Control—July 1, 2022—AG James issued a statement recognizing New York's quick response to preserve the right to abortion and enact protective gun violence measures in the wake of decisions from the U.S. Supreme Court.

https://ag.ny.gov/press-release/2022/attorney-general-james-statement-new-efforts-protect-abortion-and-strengthen-gun.

Attorney General James Calls on Google To Address Dangerous Amplification of Fake Pregnancy Centers—June 29, 2022—In a letter to Google, AG James called on the company to correct "abortion" search results in Google Maps to list only those facilities that offer abortion services. AG James expressed grave concerns that the results could lead those seeking abortions to CPCs because CPC websites may misrepresent that they provide abortion services, but they, in fact, exist only to discourage the practice.

https://ag.ny.gov/press-release/2022/attorney-general-james-calls-google-address-dangerous-amplification-fake.

Attorney General James, National Law Firms, and Reproductive Rights Groups Launch Hotline for Abortion Legal Service—June 28, 2022—AG James announced the launch of a legal hotline as part of the new Pro Bono Task Force on Reproductive Health, a group including 24 national law firms and eight reproductive rights organizations. The hotline—which is available in New York's 12 most commonly spoken languages—is free to anyone seeking legal information and advice about abortions in New York, those seeking to travel to New York to obtain an abortion, healthcare providers, and others providing support. The hotline number is (212) 899-5567.

https://ag.ny.gov/press-release/2022/attorney-general-james-national-law-firms-and-reproductive-rights-groups-launch.

Attorney General James Joins National Coalition of Attorneys General to Reaffirm Commitment To Protecting Access to Abortion Care—June 27, 2022—AG James joined 22 attorneys general in a statement condemning the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*. In a joint statement, the attorneys general reaffirmed their commitment to support and expand access to abortion care nationwide.

https://ag.ny.gov/press-release/2022/attorney-general-james-joins-national-coalition-attorneys-general-reaffirm.

Attorney General James Issues Advisory Reminding New Yorkers Abortion is Legal and Protected in New York State—June 24, 2022—AG James issued an advisory in multiple languages to remind New Yorkers that abortion remains legal in New York. According to the advisory, the New York Reproductive Health Act, passed in 2019, guarantees access to abortion care, prohibits discrimination and harassment for reproductive decision-making, guarantees the confidentiality of abortion services, and requires insurers to provide coverage for abortion. The statement also notes that New York provides public funding for abortion.

https://ag.ny.gov/press-release/2022/attorney-general-james-issues-advisory-reminding-new-yorkers-abortion-legal-and.

Attorney General James Issues Statement on U.S. Supreme Court Decision—June 24, 2022—AG James issued a statement after the U.S. Supreme Court issued its decision to overturn *Roe v. Wade*. Her statement denounced the ruling as a "vicious, dangerous, and deliberate attack on our most basic freedom as humans" and vowed "to protect [New Yorkers] right to make decisions about their own bodies."

https://ag.ny.gov/press-release/2022/attorney-general-james-issues-statement-us-supreme-court-decision.

Attorney General James Secures $58.5 Million From Top Opioid Manufacturer Mallinckrodt for Fueling Opioid Crisis—June 16, 2022—AG James announced an agreement with drug manufacturer Mallinckrodt PLC for its role in New York's opioid crisis. The $58.5 million agreement resolves claims that the company used deceptive and misleading marketing practices to encourage opioid use.

https://ag.ny.gov/press-release/2022/attorney-general-james-secures-585-million-top-opioid-manufacturer-mallinckrodt.

Attorney General James Recovers $26.8 Million From Drug Manufacturer Mallinckrodt for Medicaid Fraud—June 16, 2022—In a statement regarding the recovery of $26.8 million from drug manufacturer Mallinckrodt PLC and its U.S. subsidiary, Mallinckrodt ARD, LLC (collec-

tively, "Mallinckrodt"), for allegedly cheating Medicaid requirements which help offset rising drug prices, AG James announced the resolution of claims against the distributor for defrauding the state's Medicaid Program and violating the New York State False Claims Act. The alleged fraud started in 2013 and extended to all 50 states, Washington D.C., Puerto Rico, and the federal government, and involved Mallinckrodt allegedly taking advantage of the FDA's approval of the drug Acthar by claiming it was a new medication, which allowed it to ignore Medicaid reimbursement guidelines in order to extract higher prices for the medication. Acthar was first introduced into the market in 1952. The settlement agreement resolves all claims on behalf of all 50 states, Washington D.C., Puerto Rico, and the federal government between January 2013 through June 2020.

https://ag.ny.gov/press-release/2022/attorney-general-james-recovers-268-million-drug-manufacturer-mallinckrodt.

Attorney General James To Hold Public Hearing on New York's Mental Health Crisis—June 14, 2022—AG James announced an in-person hearing to examine the accessibility of mental health care for New Yorkers, to be held on June 22, 2022. According to the statement, approximately 400 inpatient psychiatric beds have been eliminated in New York State and either converted to COVID-19 related beds, general medical use beds, or completely taken out of commission. Additionally, there were less than 5,000 adult short-term inpatient psychiatric beds in hospitals across the state in 2022, and only 274 psychiatric beds for children and adolescents.

https://ag.ny.gov/press-release/2022/attorney-general-james-hold-public-hearing-new-yorks-mental-health-crisis.

Attorney General James Reaches Agreement With Verizon To Prevent Legionnaire's Disease—June 14, 2022—AG James announced an agreement with Verizon Wireless ("Verizon") which resolved public health violations caused by Verizon's cooling tower locations throughout the state. The agreement requires the company to take swift and comprehensive action to prevent the spread of Legionnaires' disease in the state. Legionnaires' disease is a harmful form of pneumonia that is contracted by inhaling water droplets that contain Legionella bacteria, and cooling towers are considered a significant source of public exposure to the disease. As part of the agreement, Verizon will adopt official policies and procedures to ensure full, ongoing compliance with applicable laws and will pay a $118,000 penalty for the violations.

https://ag.ny.gov/press-release/2022/attorney-general-james-reaches-agreement-verizon-prevent-legionnaires-disease.

Attorney General James Provides $13.6 Million to Consumers Who Were Denied Mental Health Care Coverage—May 20, 2022—AG James announced a settlement with UnitedHealthcare resolving a lawsuit filed by the OAG in August of 2021 for violations of New York's Behavioral Health Parity Law (originally enacted as "Timothy's Law" in 2006) and the federal Mental Health Parity and Addiction Equity Act of 2008. The suit alleged that UnitedHealthcare denied outpatient psychotherapy coverage for thousands of its members. The settlement allows for direct payments to patients across the country, with more than $8 million to be paid to New Yorkers with behavioral health conditions who were denied care in 2021. UnitedHealthcare also paid $725,000 directly to consumers who had been impacted by its illegal practices.

https://ag.ny.gov/press-release/2022/attorney-general-james-provides-136-million-consumers-who-were-denied-mental.

CONSUMER ALERT: Attorney General James Provides Guidance To Protect the Digital Privacy of People Seeking Abortion Care—May 13, 2022—In an announcement related to abortion rights, AG James provided guidance to protect the privacy of individuals seeking abortion care and to prevent unwanted digital tracking and data sharing. The announcement provided five steps individuals can take to protect their information and prevent third-parties from accessing information about their reproductive health, as well as resources consumers can access in the event that an individual believes they are being tracked when trying to obtain abortion care.

https://ag.ny.gov/press-release/2022/attorney-general-james-takes-action-expand-abortion-access.

Attorney General James Takes Action To Expand Abortion Access—May 9, 2022—Efforts taken by the New York State legislature to establish a state program providing financial resources to abortion providers in New York were highlighted in an announcement by AG James. The Reproductive Freedom and Equity Program was designed to provide funding for abortion providers and non-profit organizations to help increase access to care-related funding for uncompensated and uninsured abortion care, and to provide resources to support the needs of individuals accessing care. The announcement highlighted the U.S. Supreme Court's likely elimination of federal rights to abortion, and emphasized the need for additional support for abortion services given the increase in individuals traveling to New York for the service and other reproductive health care.

https://ag.ny.gov/press-release/2022/attorney-general-james-takes-action-expand-abortion-access.

Attorney General James Calls for State Constitutional Amendment for Abortion—May 7, 2022—AG James issued

a statement supporting the New York State Constitution's amendment to ensure the right to abortion.

https://ag.ny.gov/press-release/2022/attorney-general-james-calls-state-constitutional-amendment-abortion.

Attorney General James and Mayor Adams Fight Opioid Crisis With First of $256 Million in Payments for New York City—April 21, 2022—AG James announced that New York City has received $88.9 million to fund opioid treatment and prevention across all five boroughs. The funds are the first round of payments from the $1.5 billion settlement agreements between the OAG and various opioid manufacturers and distributors. The first payments came from settlements with opioid distributors AmerisourceBergen Corporation ("AmerisourceBergen"), Cardinal Health, Inc. ("Cardinal Health"), and McKesson Corporation ("McKesson"). Later this year, New York City will receive additional payments from the settlements with Endo Health Solutions ("Endo"), Janssen Pharmaceuticals ("Janssen"), and Allergan. Over the course of the payout period, New York City is set to receive up to $256 million.

https://ag.ny.gov/press-release/2022/attorney-general-james-and-mayor-adams-fight-opioid-crisis-first-256-million.

Attorney General James Distributes First Funds From Historic Opioid Settlements to Westchester and the Hudson Valley—April 20, 2022—AG James announced that the City of Yonkers, Hudson Valley, and Westchester County have received more than $16.7 million in the first round of payments from the $1.5 billion settlements between the OAG and various opioid manufacturers and distributors. The first payments came from settlements with opioid distributors AmerisourceBergen, Cardinal Health, and McKesson. Later this year, Yonkers, Hudson Valley, and Westchester County will also receive payments from the settlements with Endo, Janssen, and Allergan, as well as funds from the New York State Opioid Settlement Fund, managed by the New York State Office of Addiction Services and Supports (OASAS). Over the course of the payout period, Hudson Valley and Westchester will receive up to $95 million in total.

https://ag.ny.gov/press-release/2022/attorney-general-james-distributes-first-funds-historic-opioid-settlements-3.

Attorney General James Distributes First Funds From Historic Opioid Settlements to Southern Tier —April 20, 2022—AG James announced that the Southern Tier has received more than $4.8 million in the first round of payments from the $1.5 billion settlements between the OAG and various opioid manufacturers and distributors. The first payments came from settlements with opioid distributors AmerisourceBergen, Cardinal Health, and McKesson. Later this year, the Southern Tier will also receive payments from the settlements with Endo, Janssen, and Allergan, as well as funds from the New York State Opioid Settlement Fund, managed by OASAS. Over the course of the payout period, the Southern Tier will receive up to $26.7 million in total.

https://ag.ny.gov/press-release/2022/attorney-general-james-distributes-first-funds-historic-opioid-settlements-2.

Attorney General James Distributes First Funds From Historic Opioid Settlements to North Country—April 20, 2022—AG James announced that the North Country has received more than $2.6 million in the first round of payments from the $1.5 billion settlements between the OAG and various opioid manufacturers and distributors. The first payments came from settlements with opioid distributors AmerisourceBergen, Cardinal Health, and McKesson. Later this year, the North Country will also receive payments from the settlements with Endo, Janssen, and Allergan, as well as funds from the New York State Opioid Settlement Fund, managed by OASAS. Over the course of the payout period, the North Country will receive up to $14.5 million in total.

https://ag.ny.gov/press-release/2022/attorney-general-james-distributes-first-funds-historic-opioid-settlements-north.

Attorney General James Distributes First Funds From Historic Opioid Settlements to Long Island—April 19, 2022—AG James announced that Long Island has received more than $46.9 million in the first round of payments from the $1.5 billion settlements between the OAG and various opioid manufacturers and distributors. The first payments came from settlements with opioid distributors AmerisourceBergen, Cardinal Health, and McKesson. Later this year, Long Island will also receive payments from the settlements with Endo, Janssen, and Allergan, as well as funds from the New York State Opioid Settlement Fund, managed by OASAS. Over the course of the payout period, Long Island will receive up to $228 million in total.

https://ag.ny.gov/press-release/2022/attorney-general-james-distributes-first-funds-historic-opioid-settlements-long.

Attorney General James Distributes First Funds From Historic Opioid Settlements to Capital Region—April 19, 2022—AG James announced that the Capital Region has received more than $5.7 million in the first round of payments from the $1.5 billion settlements between the OAG and various opioid manufacturers and distributors. The first payments came from settlements with opioid distributors AmerisourceBergen, Cardinal Health, and McKesson. Later this year, the Capital Region will also receive payments from the settlements with Endo, Janssen, and Allergan, as well as funds from the New York State Opioid Settlement Fund, managed by OASAS. Over the course of the payout period, the Capital Region will receive up to $32 million in total.

https://ag.ny.gov/press-release/2022/attorney-general-james-distributes-first-funds-historic-opioid-settlements-1.

Attorney General James Distributes First Funds From Historic Opioid Settlements to Finger Lakes Region—April 19, 2022—AG James announced that the Finger Lakes Region has received more than $9 million in the first round of payments from the $1.5 billion settlements between the OAG and various opioid manufacturers and distributors. The first payments came from settlements with opioid distributors AmerisourceBergen, Cardinal Health, and McKesson. Later this year, the Finger Lakes Region will also receive payments from the settlements with Endo, Janssen, and Allergan, as well as funds from the New York State Opioid Settlement Fund, managed by OASAS. Over the course of the payout period, the Finger Lakes Region will receive up to $53 million in total.

https://ag.ny.gov/press-release/2022/attorney-general-james-distributes-first-funds-historic-opioid-settlements-finger.

Attorney General James Distributes First Funds From Historic Opioid Settlements to Central New York—April 19, 2022—AG James announced that Central New York has received more than $6.3 million in the first round of payments from the $1.5 billion settlements between the OAG and various opioid manufacturers and distributors. The first payments came from settlements with opioid distributors AmerisourceBergen, Cardinal Health, and McKesson. Later this year, Central New York will also receive payments from the settlements with Endo, Janssen, and Allergan, as well as funds from the New York State Opioid Settlement Fund, managed by OASAS. Over the course of the payout period, Central New York will receive up to $36.8 million in total.

https://ag.ny.gov/press-release/2022/attorney-general-james-distributes-first-funds-historic-opioid-settlements-0.

Attorney General James Distributes First Funds From Historic Opioid Settlements to Western New York—April 19, 2022—AG James announced that Western New York has received more than $12.8 million in the first round of payments from the $1.5 billion settlements between the OAG and various opioid manufacturers and distributors. The first payments came from settlements with opioid distributors AmerisourceBergen, Cardinal Health, and McKesson. Later this year, Western New York will also receive payments from the settlements with Endo, Janssen, and Allergan, as well as funds from the New York State Opioid Settlement Fund, managed by OASAS. Over the course of the payout period, Western New York will receive up to $75 million in total.

https://ag.ny.gov/press-release/2022/attorney-general-james-distributes-first-funds-historic-opioid-settlements.

Attorney General James Urges CDC To Adopt Stronger Opioid Prescription Guidelines—April 19, 2022—In a letter to the Centers for Disease Control and Prevention ("CDC"), AG James urged the adoption of strong opioid prescription guidelines. The letter was submitted as part of the public comment period for the Proposed Clinical Practice Guideline for Prescribing Opioids–United States, 2022, 87 Fed. Reg. 7838 (Feb. 10, 2022), Docket No. CDC–2022–0024. AG James' letter recommends that the CDC's official guidelines: (1) clearly warn prescribers to exercise caution when increasing an opioid dosage beyond 50 MME per day; (2) advise prescribers to offer naloxone, the overdose-reversal drug, to all patients taking at least 50 MME of opiates per day; (3) direct doctors to review their patients' prescription drug monitoring program data at least every three months; (4) encourage the use of non-opioid pain therapies and ensure coverage by insurers; (5) publicly recognize the limited evidence to support the usefulness of opioids for the treatment of chronic pain; and (6) publicly acknowledge that pain is undertreated and untreated in women and people of color, and encourage prescribers to address potential biases in clinical decision-making.

https://ag.ny.gov/press-release/2022/attorney-general-james-urges-cdc-adopt-stronger-opioid-prescription-guidelines.

New York State Office of the Medicaid Inspector General Update

Compiled by Dena M. DeFazio

Governor Hochul Launches Health Care Worker Bonus Program—August 3, 2022—https://omig.ny.gov/news/2022/governor-hochul-launches-health-care-worker-bonus-program.

OMIG Assists in Investigation That Leads to Indictment of Long Island Physician in Alleged $1 Million Medicaid Kickback Scheme—August 2, 2022—https://omig.ny.gov/news/2022/omig-assists-investigation-leads-indictment-long-island-physician-alleged-1-million.

UPDATE: New York City Doctor Convicted of Medicaid, Medicare Fraud Scheme—July 19, 2022—https://omig.ny.gov/news/2022/update-new-york-city-doctor-convicted-medicaid-medicare-fraud-scheme.

Compliance Programs, Self-Disclosure, and Medicaid Managed Care Fraud, Waste and Abuse Prevention Programs Proposed Regulations To Be Published in the State Register on July 13, 2022—July 7, 2022—https://omig.ny.gov/news/2022/compliance-programs-self-disclosure-and-medicaid-managed-care-fraud-waste-and-abuse.

In the Journals

Compiled by Jeff Ehrhardt

A compendium of citations to recent topics published in health law journals

A Reconceptualization of Website Accessibility Under the ADA: Resolving the Inter-Circuit Conflict Post-Pandemic, Jonathan Lazar & David Ferleger, 39 Santa Clara High Tech. L.J. 63 (2022-2023).

Abortion Rights and Disability Equality: A New Constitutional Battleground, Allison M. Whelan & Michele Goodwin, 79 Wash. & Lee L. Rev. 965 (2022).

Alienation, Commodification, and Commercialization: A Feminist Critique of Commercial Surrogacy Agreements Through the Lens of Labor Exploitation and U.S. Organ Donation Law, Isa Elfers, 33 Hastings J. Gender & L. 151, 153 (2022).

Body Revolution in Comparative Perspective: Promoting Equality Through Adoption of New Theory of Bodiliness, Arseny Shevelev, Georgy Shevelev, 55 UIC L. Rev. 615, 616 (2022).

Certificates of Public Advantage and Hospital Mergers, Christopher Garmon & Kishan Bhatt, 65 J.L. & Econ. 465 (2022).

Commercialization of Your DNA Privacy Regulations Lagging for Companies Collecting Genetic Data, Jayla E. Harvey, N.J. Law., August 2022, at 38.

Considerations for Self-Disclosure: Who, What, Where and When? Guidelines for Compliance Professionals, Gabriel Imperato, 24 J. Health Care Compliance 19 (2022).

Defining Privacy of Biometric Information Legislative Approaches to Growing Use of Biometrics in Our Society and What It Means for Businesses, Brett R. Harris & Natalie Moszczynski, N.J. Law., August 2022, at 16.

Does Malpractice Liability Promote Patient Safety? A Methodological Excursion, Michael J. Saks, Stephan Landsman, 62 Jurimetrics J. 397 (2022).

Ensuring Compliance Officer Independence of Legal Counsel, Robbi-Lynn Watnik, 24 J. Health Care Compliance 13 (2022).

Free-Exercise Arguments for the Right to Abortion: Reimagining the Relationship Between Religion and Reproductive Rights, Olivia Roat, 29 UCLA J. Gender & L. 1 (2022).

Health Care Fraud, Abby Rickeman, Kathryn DeMallie, Todd Kowalski, Sabrina Parisi, Brynne Peluso, & Ryan Thomas, 59 Am. Crim. L. Rev. 975 (2022).

Honoring the Public Trust: Curbing the Bane of Physician Sexual Misconduct, Kunal K. Sindhu et. al., 9 J.L. & Biosciences 1 (2022).

How Far We Have Not Come: An Empirical Comparison of Federal and State Mental Health Legislation, Martyna Sawicka, 64 Ariz. L. Rev. 571 (2022).

In Congress, Rare Bipartisan Support for Mental Health Legislation, Hilary Jochmans, N.Y. State Bar J., September/October 2022, at 54.

Manipulating the Prescription Drug Market: Spiking Prices, Inducing Demand, and Costs to the Public, Katherine Drabiak, 23 DePaul J. Health Care L. 20 (2022).

Normalizing Reproductive Genetic Innovation, Myrisha S. Lewis, 74 Admin. L. Rev. 481 (2022).

Optimizing Ethics Engagement in Research: Learning from the Ethical Complexities of Studying Opioid Use in Pregnancy, Seema K. Shah et. al., 50 J.L. Med. & Ethics 339, 340 (2022).

Pandemic Response Through Whole Person Care: The Intersection of Physical and Mental Health and the Law, Jennifer Kinsley Smith, Esq, Elizabeth J. Lattner, MA, Allison Kreiner, MD, & Edward J. Kilbane, MD, MA, Keyvan Ravakhah MD, MBA, 31 Annals Health L. & Life Sci. 115 (2022).

Paying Employees for Referring Healthcare Business, Kim C. Stanger & Allison Kjellander, 24 J. Health Care Compliance 33 (2022)

Prepare for Battle: Understanding and Responding to the CMS Audit Contractor Enforcement Landscape, Anna M. Grizzle & Lauren Gaffney, 24 J. Health Care Compliance 5 (2022).

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Jeff Ehrhardt is an associate in the health services and commercial litigation practice groups at Rivkin Radler LLP.

Proving a Violation of the False Claims Act Through Deliberate Ignorance, Joel D. Hesch, 17 Liberty U.L. Rev. 3 (2022).

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The Public Health Turn in Reproductive Rights, Rachel Rebouché, Prac. Law., October 2022, at 3.

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Value-Based Activities Compensation: Can We Throw Fair Market Value Out the Window?, Robert A. Wade & Jane Sitorius, 24 J. Health Care Compliance 5 (2022).

Voluntary Registries to Support Improved Interaction Between Police and People Living with Dementia, Heather M. Ross (FNa1) et. al., 50 J.L. Med. & Ethics 348, 349 (2022).

We Shouldn't Need Roe, Carliss Chatman, 29 UCLA J. Gender & L. 81 (2022).

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For Your Information

By Claudia O. Torrey

According to the Commonwealth Fund[1] (CF), the effect of climate change on health breaks down into six main categories: physical health, mental health, costs, equity, access, and quality.[2] The floods, heat wave(s), hurricanes, and wildfires, etc. that we have seen over the last several months in the United States exact a devastating toll on communities, as well as exacerbate existing inequities.[3]

The CF states that more than 5 million deaths are attributed each year to abnormally hot and cold weather. Physical health abnormalities such as exhaustion, heat stroke, cardiovascular and respiratory illness resulted in 1.8 million deaths globally in 2019, and more than 600 excess deaths in one week in the states of Oregon and Washington during the June 2021 Pacific Northwest heat wave.[4]

The impact of climate change on mental health is harder to quantify than on physical health, but is no less acute.[5] The trauma and loss due to geographic displacement from floods, heat, and drought can trigger stress, depression, anxiety, and posttraumatic stress disorder. Needless to say, the costs of air pollution, bad water, and other climate change fallouts are high (think about our health care professionals).[6]

The inequity of climate change deepens preexisting inequities on the most vulnerable such as children, older adults, people with disabilities, people experiencing homelessness, and low-income individuals.[7] Extreme climate events stress hospitals and other facilities with power outages, damaged roads and/or transit systems. For example, in 2012 when Hurricane Sandy struck New York City, Bellevue Hospital (which serves 500,000 patients annually) was forced to temporarily close and move patients elsewhere.[8] Thus, access and quality yield the strain of climate change variables. The United States has a lot on its proverbial current platter as to tackling the ever-evolving climate change and its effect on health.

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

Endnotes

1. Shanoor Seerva, Lovisa Gustafson, and Melinda K. Abrams. *The Impact of Climate Change on our Health and Health Systems*, Commonwealth Fund, May 2022, https://doi.org/10.26099/49re-ky81.
2. *Id.*
3. *Id.*
4. *Id.*
5. *Id.*
6. *Id.*
7. *Id.*
8. *Id.*

Meeting the Challenges of a Post-*Roe* World—Commentary From a Hospital Counsel Perspective

By Laura M. Alfredo

In *Dobbs v. Jackson Women's Health Organization,* the U.S. Supreme Court held, "the authority to regulate abortion is returned to the people and their elected representatives." States are wielding that authority at breakneck pace, which is not surprising given the extreme politicization of abortion services.

What is noteworthy is the intensifying conflict between states that oppose abortion and states that support it, and the ways they are using and exploring legislation to try to regulate abortion access across state lines. As David Cohen, Greer Donley, and Rachel Rebouche observe in their draft *Columbia Law Review* article, "The New Abortion Battleground," this may have grave consequences for our system of federalism over time.[1]

But for the lawyers I work with, who represent hospitals and health systems, the immediate task is preventing patients and providers from being caught in the crossfire. Hospital counsels are undaunted by the challenge because they and their clients have a singular mission—ensuring safe and effective care to all those who seek it.

As of the time of this writing, no states have enacted laws to criminalize or create liability for out-of-state parties acting in accordance with their own state's laws while providing abortion services to residents of other states. There are, however, several states considering such measures, and there is a lot of generalized commentary—and generalized anxiety—about the prospect of this trend taking hold.

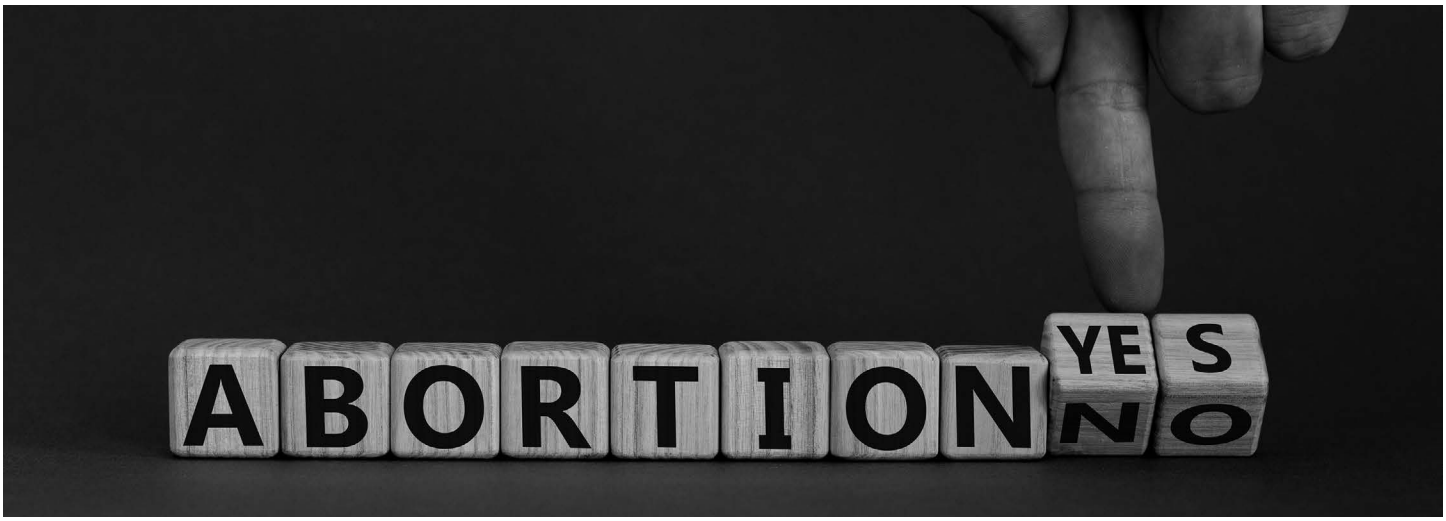
There is a growing list of issues stemming from the largely untested[2] question of how far a state can go in exporting criminal or civil liability for violation of its abortion laws. The areas and questions include:

- Graduate medical education (what are the consequences for entering into an affiliation agreement to provide required abortion training to medical or surgical residents based in a state that has outlawed the service?).
- The integrity and privacy of patient information (should abortion services be documented differently, and can such information be reliably isolated from the rest of the record given that our health information systems are set up to favor broad information sharing?).
- Reimbursement (should hospital financial assistance plans be modified to account for out-of-state patients, including those from states prohibiting health insurance coverage for abortions?).
- Boundaries around telemedicine (in medication abortion, should patients be constrained to ingest all medication in the state where abortion is permissible to minimize liability for the prescriber?).
- Employer health plans (should coverage for reproductive health care or travel be modified for employees in states where abortion is restricted or banned?).
- And how much of the risk and uncertainty should be passed on to the patient as part of a waiver or the "informed consent" process?

Health lawyers are skilled at navigating the crossroads of law and policy: Health care delivery is intensively regulated at the state and federal level and increasingly controversial. The COVID-19 pandemic is only one example of the dynamic tension that draws many lawyers to this specialty.

What is different now is the risks are largely unknown. Pre-*Dobbs* state laws that prohibit or restrict abortion, including so-called "trigger" laws meant to go into effect upon the repeal of *Roe*, will be applied in a very different political and legal context than that in which they were enacted, with uncertain results. The legal challenges to those laws are very much in play.[3] Also, some states are considering other options to expand their laws' reach, such as Missouri, which considered a measure to regulate abortion services across their borders through adoption of the Texas approach of deputizing private citizens to sue out-of-state providers who allegedly violate their state's abortion laws,[4] and South Carolina, which considered legislation that would criminalize providing information about abortion to a pregnant woman by any mode of communication.[5] The National Right to Life Committee (NRLC) has provided guidance to such states in the form of model legislation that would create criminal and civil liability for, among other things, giving instructions over the phone or Internet on accessing illegal abortions and transporting minors for illegal abortions under certain circumstances, regardless of where the abortion takes place.[6]

In the absence of federal legislation defining the parameters of legal abortion, which is politically infeasible, the Biden



administration's efforts[7] to untangle this morass through administrative guidance and regulations, while important, will only add to the legal wrangling. For example, the Department of Health and Human Services' July 11 letter to health care providers[8] stating that the Emergency Medical Treatment and Active Labor Act (EMTALA) requires providers to perform an abortion if it is necessary to stabilize a patient experiencing an emergency medical condition—and thus could be used as a legal defense to certain state actions—was swiftly met with a lawsuit by the Texas attorney general.[9] Coming on the heels of the Texas action was the federal government's challenge[10] to Idaho's abortion law on the grounds that it conflicts with EMTALA. The courts in those cases have issued conflicting rulings on each plaintiff's request for emergency injunctive relief.[11]

Among the many commentators on the *Dobbs* effect are those who think the concerns are overblown, such as the NRLC's general counsel, who called certain questions about the new risks "ridiculous scaremongering," and those who assert that the sky is not only falling, but about to land on our heads.

It is best to focus on the task at hand.

Given that women's health care needs will not wait for lawyers and judges to provide answers, what can a state like New York do to stave off the understandable chilling effect of this legal uncertainty and help its providers care for out-of-state patients?

New York has already taken several steps. Gov. Kathy Hochul recently signed into law a package of bills that includes measures to protect New York providers performing legal abortions from out-of-state subpoenas and other demands,[12] prohibit malpractice insurers[13] and licensing authorities[14] from acting against New York providers solely because they provide abortions that are legal in New York, and give providers the right to countersue parties who sue them for violating other states' abortion laws.[15] Governor Hochul has also announced grants to expand provider capacity and access to abortion services, as well as enhance security at health care facilities.

And New York Attorney General Letitia James has established a hotline for patients and providers seeking information about their legal rights to access and provide abortions. The attorney general's task force is co-led by the law firm Paul Weiss and the Center for Reproductive Rights and includes several national law firms and reproductive rights organizations.[16] It includes the provision of some *pro bono* legal services to providers and patients.

These measures are extremely important. New York, as a declared abortion safe harbor and leader in supporting reproductive rights, should also be prepared to address access and equity issues as part of its response to *Dobbs.*

This should include further enhancing New York providers' ability to participate in telemedicine. The state should join the Interstate Medical Licensure Compact (IMLC). As Cohen and his colleagues note, increasing membership in the IMLC would expand access to abortion services by allowing abortion-supportive states to pool resources to address heightened demand in their states. The IMLC is also good policy: The pandemic has proven telemedicine is an effective way to increase access to certain high-demand health care needs, including behavioral health. New York should also address some of the infrastructure and technology needs of its citizens. While the federal government has the primary role in building infrastructure, the state should explore how to make data for video telemedicine more accessible for low-income patients while also making permanent certain telehealth flexibilities.

Outside of telemedicine, New York could also do more to raise awareness among patients and providers about the interplay between federal and state health care privacy laws. This should include helping providers understand the new provi-

sions for out-of-state subpoenas and information requests. Organizations like mine stand ready to help hospitals and health systems educate their staff on workflows that will support implementation of the new laws and avoid inadvertent disclosures to out-of-state parties that could cause harm to patients and providers alike.

Finally, and especially in a state renowned for its high liability costs, New York should be prepared to establish a defense fund for any provider or health care delivery organization facing a legal challenge solely because they provided an abortion that is legal in New York to a woman from another state. While this would not supplant the work of the dedicated law firms committed to providing *pro bono* services, it could be a backstop to the extent those services prove insufficient to meet long-term needs.

In this time of profound uncertainty, supporting reproductive rights means supporting those who are willing and able to perform abortions safely and legally. That work has only just begun.

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Endnotes

1. David Cohen, Greer Donley, and Rachel Rebouche, *The New Abortion Battleground,* 123 Columbia Law Review (forthcoming, 2023).
2. In considering the question of how far states may go in legislating extraterritorially, certain commentators have pointed to *Bigelow v. Virginia*, 421 U.S. 809 (1975), as a potentially dispositive case. A managing editor of a Virginia newspaper was convicted of violating a Virginia statute prohibiting the encouraging of an abortion after he published a New York City organization's advertisement offering to arrange low-cost placements of women with unwanted pregnancies in New York hospitals and clinics. In reversing the conviction, the court stated that, "[a] State does not acquire power or supervision over another State's internal affairs merely because its own citizens' welfare and health may be affected when they travel to the other State …" Other commentators, including Cohen, *et al* (at p. 19 of their draft article) have cautioned against relying too strenuously on *Bigelow*, which could easily be revisited by the current Supreme Court.
3. *See Abortion is banned or severely limited in a number of states. Here's where things stand*, CNN Politics, Aug. 26, 2022, https://www.cnn.com/2022/08/25/politics/where-abortion-banned-states-court-legal-challenges/index.html.
4. House Bill 2012, https://house.mo.gov/Bill.aspx?year=2022&code=R%20&bill=HB%202012.
5. Senate Bill 1373, 2021-2022 Bill 1373: Abortion—South Carolina Legislature Online (scstatehouse.gov).
6. *See* NRLC Post-*Roe* Model Abortion Law, https://www.nrlc.org/wp-content/uploads/NRLC-Post-Roe-Model-Abortion-Law-FINAL-1.pdf.
7. President Biden has issued two Executive Orders on abortion: July 8, 2022, and Aug. 3, 2022 directing his administration to take certain actions to strengthen abortion rights and access.
8. https://www.hhs.gov/sites/default/files/emergency-medical-care-letter-to-health-care-providers.pdf; *see also* corresponding update to Centers for Medicare and Medicaid Services' State Surveyors' Manual, https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/reinforcement-emtala-obligations-specific-patients-who-are-pregnant-or-are-experiencing-pregnancy-0.
9. https://www.texasattorneygeneral.gov/sites/default/files/images/executive-management/20220714_1-0_Original%20Complaint%20Biden%20Admin.pdf.
10. https://www.justice.gov/opa/press-release/file/1523481/download.
11. https://storage.courtlistener.com/recap/gov.uscourts.txnd.365015/gov.uscourts.txnd.365015.73.0.pdf (in *Texas v. Becerra*¸granting Texas's request for preliminary injunction against HHS EMTALA guidance and letter, applicable only to providers in Texas including the plaintiffs in the case) and https://www.courthousenews.com/wp-content/uploads/2022/08/usa-vs-idaho-abortion-law-memorandum-decision-and-order.pdf (in *US v. Idaho*, granting US request for preliminary injunction against Idaho's criminal abortion law to the extent it conflicts with EMTALA).
12. Legal Protections for Abortion Service Providers, A.10372-A/S.9077-A, https://www.nysenate.gov/legislation/bills/2021/a10372.
13. Prohibits medical malpractice insurance companies from taking any adverse action against a reproductive health care provider who provides legal reproductive health care, A.9718-B/S.9080-B, https://www.nysenate.gov/legislation/bills/2021/A9718.
14. Prohibits professional misconduct charges against health care practitioners for providing reproductive health services to patients who reside in states where such services are illegal, A.9687-B/S.9079-B, https://www.nysenate.gov/legislation/bills/2021/A9687.
15. Establishes a cause of action for unlawful interference with protected rights, A.10094-A/S.9039-A, https://www.nysenate.gov/legislation/bills/2021/A10094.
16. https://ag.ny.gov/reproductivehealth#hotline.

A License To Heal: The State of Telehealth vs. Telehealth of the States

By Jonathan Fenster

Introduction

For Maki Inada, receiving the news that her lung cancer had recurred amidst a global pandemic was almost too much to bear.[1] Living in upstate New York where she teaches biology at Ithaca University, Maki knew that she was in for a brutal commute when she was directed to the world-famous Dana-Farber Cancer Institute in Boston, to be treated by its expert oncology team.[2] One silver lining for Maki during this challenging time was the advancement and implementation of telehealth services in response to the COVID-19 pandemic.[3] The concept of telehealth was neither new nor novel at the time of the coronavirus breakout in 2020.[4] However, the utilization and ubiquity of telehealth was drastically altered as a result of it.[5] The practical benefits of telehealth during the pandemic were obvious. Physicians were able to treat and monitor their patients when stay-at-home orders were in place without worrying about spreading the virus in an office setting.[6] Additionally, numerous regulations that had stagnated the use of telehealth in the past were paused due to the emergency situation.[7] Most important, state licensure laws that prohibited physicians from treating patients in a state in which they were not licensed were waived, allowing physicians to treat patients across the country through telehealth.[8] As a result, Maki was able to conduct her postoperative and oncology appointments via video conference from her home instead of having to travel to Boston.[9]

However, in June 2021, the waivers were rolled back and Dana-Farber informed Maki that to continue to receive its telehealth treatment, she would have to be physically located in the same state as the hospital.[10] Instead of driving five and a half hours from her home in Ithaca to Dana-Farber, Maki would drive three and half hours to the Massachusetts state line and pull over to the side of the road to conduct her telehealth visits from her car to spend less time away from her child.[11]

Experts agree that telehealth is here to stay, and that a new regulatory framework needs to be implemented to ensure safety, transparency, and convenience for both patients and physicians.[12] Scholars and academics have argued what that potential framework should look like, but it is clear to all that forcing patients like Maki to travel to such lengths to receive treatment that can be offered via telehealth at her home is both impractical and outdated.[13] The difficulty that policymakers face in addressing this issue is in balancing numerous complex relationships and motivations. The states want to control and regulate health care practiced in their locale, rural patients want more access to health care, and physicians and patients want to be sure that telehealth is both safe and effective.[14]

The first part of this article will delve into the history of telehealth and how it works. The second part will discuss the state licensure laws prior to the pandemic, changes made in response to the pandemic, and the regulations presently in place. The third part will address several issues that arise when using telehealth including: (1) whether a physician-patient relationship can be formed through telehealth; (2) the standard of care owed to patients treated through telehealth; and (3) whether physicians can prescribe medications via telehealth. The fourth part of the article will analyze four trending regulatory proposals to ensure the efficacy of telehealth, and discuss the benefits and dangers of each. The fifth part will propose a new regulatory framework that views telehealth differently depending on whether the patient and physician began their relationship in person. The proposal suggests that telehealth should be considered the same as the regular practice of medicine if the patient was initially treated by the doctor in person. In such circumstances the patient-physician relationship has been clearly established, and the physician has been provided with much more medical information than what can be provided through a screen. In such a case, once the physician-patient relationship has been established in person, the relationship should be allowed to continue via telehealth, irrespective of the location of the patient. In doing so, states will maintain control over the industry without having to worry about online-only doctors practicing in other locations, while allowing patients to receive health care out of the state. However, if the physician and patient did not establish a physician-patient relationship in person, telehealth should still be permitted, but in a more limited capacity.

As we will see, in some states, the practice of telehealth is not viewed as the practice of medicine; instead, it is almost considered to be another field with different rules and regulations. In such an environment, physicians would be held to a different standard of care, have different prescribing capabilities, and would likely have to charge a much lower fee. This will allow rural patients to receive access to a form of health care that they are in desperate need of, while appeasing state

licensing boards who don't have to worry about unfettered telehealth, all while ensuring its safety and efficacy.

What Is Telehealth and How Has It Evolved?

The History of Telehealth

Telehealth is defined as "[T]he use of electronic information and telecommunications technologies to support long-distance clinical healthcare, patient and professional health-related education, public health, and health administration."[15] As technology progressed, the utilization of telehealth evolved. In the 1940s, aside from giving medical advice over the phone, the first real iteration of telehealth was conceived by radiologists who electronically transferred scans to one another, in two towns 24 miles apart.[16] Then in the 1960s the National Aeronautics and Space Administration (NASA) needed a way to monitor the health of astronauts during missions to the moon and developed the Integrated Medical and Behavioral Laboratories and Measurement Systems (IMBMLS) to allow a seamless transfer of health data from space.[17] In the 21st century, the Veterans Association (VA) has been using telehealth systems to provide health care to veterans who have a difficult time making it to their physicians.[18] Additionally, with the advent of the internet and mobile applications, companies like MDLive and Teleadoc began providing remote consultations for patients via video conferences or phone calls.[19] Still, significant hurdles hindered the widespread use of telehealth for the greater public.[20]

The Evolution of Telehealth

The original motivation for institutionalizing telehealth was to provide health care access to rural communities that were faced with shortages of local health care professionals.[21] It has been estimated that nearly 80 million people live in "shortage areas" where physicians, medical staff, and health care specialists are scarce, inevitably leading to a less healthy population.[22] Telehealth provides an opportunity to bridge this health gap by delivering premier health care to rural communities remotely. But even the greatest advocates and believers of telehealth could not have imagined the shifting parameters that have allowed its proliferation.[23] As the pandemic forced individuals to stay at home, industries got creative and turned to companies like Zoom to continue their work virtually.[24] The health care industry was no different. This shift was just the push that telehealth needed to exhibit its beneficial use and dismantle the preconceived notions that both stigmatized and stymied its concept as inferior care.[25] Additionally, many of the regulations, restrictions, and limitations on telehealth were paused, allowing patients to seek medical care from physicians across the nation.[26] Research has shown that telehealth use has increased 38-fold from the pre-COVID-19 baseline.[27] Furthermore, venture capital investment in the first half of 2021 totaled $14.7 billion, which is nearly twice the investment in all of 2019.[28] Many speculate that the pandemic has been telehealth's tipping point, and that we are on the precipice of a new medical frontier.[29] Although the propagation of telehealth is an exciting and positive development, there are still numerous issues to address to ensure that the technology is regulated properly.

State Licensure Laws: Pre-Pandemic, Pandemic, Post-Pandemic

Pre-Pandemic

State medical boards are delegated with the authority to regulate medical practices in their state, and therefore, are the issuers of physician licenses.[30] Such licenses limit a physician's practice to provide treatment to residents that are in that state.[31] This is because "states have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions."[32] In essence, licensure regulations are "consumer protection" laws implemented to protect residents of a particular state.[33] Aside from ensuring quality control of their physicians and protecting their constituents, by relinquishing their licensure powers, states would suffer economic loss from licensing fees and revenues while saturating the market for their physicians by allowing out-of-state physicians to practice telehealth on their patients.[34] Theoretically, it is possible for physicians to obtain licenses from other states, in addition to the states in which they are already licensed, however, such a process is costly and time-consuming.[35] Even in states that have implemented exceptions and compacts for out-of-state physicians, telehealth expansion had been stagnant, as providers understood the impractical components and financial risks.[36] Finally, if a physician practices without a license, states can pursue civil and criminal liability suits.[37]

Pandemic

Secretary of Health and Human Services Alex Azar declared a public health emergency after confirming cases of COVID-19 on Jan. 31, 2020.[38] As the country grappled with and prepared for many possible scenarios, numerous decisions regarding health care were made.[39] Among other things, stay-at-home orders were implemented, and as a result citizens were unable to access the medical care they needed.[40] Physicians, state medical boards, and legislators realized that the use of telehealth would limit the risk of exposure and spread of the virus, and therefore governors implemented broad waivers of the in-state licensure requirements allowing individuals to receive telehealth care across the country, irrespective of their location.[41]

At the federal level, several agencies regulate different aspects of telehealth. The Office for Civil Rights (OCR), which is responsible for the protection of personal health information and the enforcement of the Health Insurance Portability and Accountability Act (HIPAA), only permitted certain secure video platforms to be used for telehealth prior to COVID-19, however, once the pandemic hit, it permitted "every communication technology," including platforms like FaceTime and Zoom.[42] In addition to loosening privacy regulations, the Centers for Medicare and Medicaid Services (CMS) waived many of its own limitations to allow providers to practice remote care across state lines and to bill and collect for telehealth services commensurate with in-person visits. [43] These waivers increased the weekly use of telehealth services from 13,000 beneficiaries before the pandemic to 1.7 million during the pandemic.[44] Lastly, the Drug Enforcement Administration (DEA) waived the prohibition of prescribing controlled substances via telehealth, even without an in-person visit.[45]

The federal waivers did not supersede state guidelines, and therefore states had to lift their own regulations as well. Nearly all states waived their licensure regulations and allowed providers with equivalent licenses to practice in their state.[46] Additionally, many states waived in-person prescribing requirements.[47] Many states also waived written informed consent requirements, allowing it to be accomplished verbally.[48]

Post-Pandemic

In July 2020, CMS Administrator Seema Verma wrote:

> With these transformative changes unleashed over the last several months, it's hard to imagine merely reverting to the way things were before. As the country re-opens, CMS is reviewing the flexibilities the administration has introduced and their early impact on Medicare beneficiaries to inform whether these changes should be made a permanent part of the Medicare program.[49]

Additionally, 30 U.S. legislators sent a bipartisan letter to Senate Majority Leader Mitch McConnell (R-KY) and Senate Minority Leader Chuck Schumer (D-NY) in June 2020, asking Congress to permanently adopt some of the temporary telehealth provisions set forth at the beginning of the pandemic.[50] President Biden has been extremely supportive of the telehealth push, and on March 14, 2022, signed into law the $1.5 trillion Consolidated Appropriations Act of 2022 (the Omnibus Bill), extending many of the aforementioned waivers.[51] It is unclear what will happen once the extension ends, however, clear guidelines will need to be conveyed especially in light of new abortion laws in which patients and physicians will have to determine whether the issue of telehealth and state licensure laws will play a role in the prescription of abortion pills via telehealth.

Establishing a Physician-Patient Relationship, The Standard of Care, and Prescribing Practices in the Realm of Telehealth

Physician-Patient Relationship

For a physician to provide treatment to a patient, the physician must first establish a physician-patient relationship.[52] One challenge with telehealth is determining when the physician-patient relationship takes effect.[53] In general, in order for such a relationship to be established, there must be a two-way communication, the physician must agree to treat the patient, and the patient must agree to be treated by the physician.[54]

In New York, a mere telephone call from a physician to a patient can be enough to establish a physician-patient relationship.[55] Similarly, in Arkansas, the physician-patient relationship can be formed through any audio-video interaction.[56] However, in states like Georgia and Texas, even though a physician-patient relationship can be performed via telehealth, an in-person follow-up visit is required.[57] Rural states including Idaho, Nebraska, North Dakota, West Virginia, and Wyoming have all allowed the formation of a physician-patient relationship to be established via two-way video conference.[58] However, Florida is silent "with respect to the modality required to establish the physician-patient relationship."[59] The American Medical Association (AMA) has suggested that in order to establish a physician-patient relationship, a face-to-face meeting should occur prior to the rendering of telehealth services.[60] The concern for allowing the physician-patient relationship to be formed via telehealth is that it will be difficult to confirm and authenticate the patient and physician and it will be difficult to obtain necessary consent.[61]

Standard of Care

Another question to address is the standard of care to which physicians should be held to when rendering treatment via telehealth. In general, the standard of care takes into consideration the circumstances and the physician's specialty.[62] In malpractice cases, it is medical experts who explain what the standard of care should have been.[63] When it comes to telehealth, some states view it as a tool to practice medicine, while others view it as its own form of medicine.[64] For example, California, Florida, and Kentucky all view the telehealth standard of care as "a tool in medicine practice, not a form of medicine," and therefore, the standard of care should be the same as the regular practice of medicine during an in-person visit.[65] However, in Hawaii, the standard of care for telehealth providers is that of a "non-in-person consultation," which is ultimately a lower standard of care, taking into account some of the limitations of performing an exam remotely.[66] While

many states have not addressed the standard of care for telehealth services, it is clear that a uniform model among the states will not be established.

Prescribing Practices

Historically, state regulations required face-to-face encounters between patients and physicians in order to prescribe medication. However, in *Teladoc, Inc. v. Texas Medical Board*, a Texas court found that requiring in-person visits in order to prescribe patients would violate the Sherman Antitrust Act[67] because it would effectively prohibit telehealth services.[68] In response, many states have loosened their requirements and now allow physicians to prescribe drugs to patients via telehealth.[69]

Federally, the Ryan Haight Act requires the dispensation of controlled substances pursuant to a valid prescription obtained through an in-person evaluation.[70] If the telehealth visit occurs at a particular facility, for example a hospital or a clinic, the physician can prescribe remotely.[71] There is also an exception to the general requirement for an in-person evaluation: prescribing of controlled substances is allowed if the telehealth provider registers with the DEA and receives training before prescribing remotely.[72] However, the DEA has yet to establish such a registration process and, therefore, the mechanism has not been implemented.[73] During the COVID-19 pandemic, the Ryan Haight restrictions were paused, and physicians have been able to prescribe controlled substances via telehealth.[74] On Oct. 13, the public health emergency is set to end, and it is unclear whether there will be another extension or permanent implementation of these waivers.

Four Proposed Solutions and Why None Will Be Implemented

As policymakers consider legislation to facilitate the use of telehealth, physicians and academics agree that licensure reforms will be essential in enabling the increased use of this technology.[75] While states may be motivated to maintain the status quo and preserve their control, some argue that the expansion of large national and regional health systems has expanded the scope of health care markets beyond state lines.[76] Furthermore, the absurdity of having individuals cross state borders to attend primary care visits from their cars, in order to be in the same state as their physician, has already been discussed.[77] It has also been argued that state licensing boards are focused on protecting their physicians from competition and collecting licensing fees, rather than working to ensure the safety of their patient population.[78] This was seen when the Federal Trade Commission sued the North Carolina State Board of Dental Examiners in 2014 for violating antitrust laws when the board arbitrarily prohibited non-dentists from providing teeth-whitening services.[79] In response to many of the aforementioned concerns, numerous proposals have been suggested.

Compact

The first proposal is to keep the current in-state licensure system while making it easier for physicians to get licensed out of state. In 2017, under the Interstate Medical Licensure Compact, 29 states agreed that physicians can complete a single application to expedite the approval of licensure from other states in the compact. [80] For $700, individual physicians can join the compact and obtain a license from each participating state for a small fee.[81] However, as of now, only 0.4% of all eligible physicians have joined the compact.[82] It is possible that if the fees are lowered and the remaining states join the compact that more doctors would join. This proposal is unlikely to become reality because there seems to be little incentive for physicians to join the compact as many states are not part of the compact, and the fees and administrative burdens remain high. Similarly, there is no incentive for states to relinquish their control over the competition and agree to such a proposal as they want to maintain their long-history of state-based disciplinary authority and limit competition from out-of-state providers.

Reciprocity

A second proposal would be to implement a system of reciprocity where states would allow their own state-licensed physicians to practice in each other's state.[83] This would be similar to the bar reciprocity that lawyers use to practice in other states. In 2013, Rep. Devin Nunes proposed the Tele-Med Act that would have allowed Medicare providers to provide telehealth services to Medicare beneficiaries and permanently implemented reciprocity.[84] Again, this proposal seems unlikely to come into practice for the same reasons mentioned above; states are not going to be willing to relinquish their long history of control over the health care industry, competition from out-of-state providers, and the profits that are generated from licensure boards.

Federal Licensure

A third approach would be to implement a federal license to practice medicine. Senator Tom Udall proposed a bill on Jan. 31, 2012, that would create a dual licensure process; in addition to receiving a state license, physicians can apply for a national license as well. In another form, this system would just abolish the concept of state licensing and create a single federal licensure system, as physicians would have no reason to receive licenses from the states. However, "such a policy may be impractical, since it overlooks more than a century of experience with state-based licensure systems" and dismisses the role that boards play in disciplinary activity.[85] For the rejections seen in the first two proposals, states will never agree to such a model because they won't want to relinquish control

of their disciplinary authority. Additionally, physicians will be nervous to allow such a system where competition will be much more fierce if patients in their area can see physicians on an opposite coast.

The Practice of Medicine Is Based on the Physician's Location

A fourth, and most novel proposal, would be to license the practice of medicine based on where the physician is located rather than where the patient is. This model was recently introduced by Senators Ted Cruz (R-Texas) and Marsha Blackburn (R-Tenn.) on April 15, 2020, in the Equal Access to Care Act[86] as a way to increase access during the COVID-19 crisis. This model is sheltered from the criticisms of the first three proposals because states would maintain their control over the physicians and physicians will not have to worry about out-of-state doctors competing for their patients. However, this law is extremely unlikely to be enacted because it challenges long standing systems of regulating medical practice. One of the main purposes of requiring patients to be in the same state as the physician is to grant the states with the power to protect their patients. The bill has been temporarily authorized until the end of the emergency declaration.

Although the aforementioned proposals are unique and somewhat helpful, they are unrealistic. Therefore, a new framework is needed.

A Novel Solution: Distinguishing Telehealth Based on an Initial In-Person Consultation

In order to alleviate the concerns regarding the future of telehealth, it is clear that a new regulatory framework will be necessary. Taking into account the needs of patients, physicians, and states is complex and will be difficult to balance. This article proposes a solution that can appease all parties while ensuring the safety and efficacy of this exciting breakthrough in healthcare.

The Initial In-Person Requirement

The proposed solution will adapt some elements of the AMA's telehealth policy recommendations and convert them into policy.[87] Under this legislation, patients and physicians will have to conduct an initial in-person check-up prior to the rendering of future telehealth services. Once the initial consultation is complete, under this proposal, the patient can access unfettered telehealth services across state lines. This is because the initial consultation will create a physician-patient relationship according to state standards, and by doing so, the future telehealth visits can be considered a continuation of that initial visit.

From the states' perspective, this will relieve concerns about patient identification, physician identification, and consent, because each has already been confirmed at the initial visit. Additionally, requiring an initial in-person visit effectively allows the states to maintain their licensure requirements. States will preserve their regulatory control over the industry as well as the economic incentives appropriated from their licensing fees. Under these circumstances, states should have no problem considering the telehealth visits as a continuation of the initial in-person visit. In practice, this simply means that the states will waive the in-state licensure requirement after the initial in-person visit.

For physicians, requiring an in-person initial consultation will assuage their fears of online-only physicians competing for their patients and saturating their market. Medically speaking, physicians will also be more comfortable providing future recommendations and diagnosis via telehealth once they have examined the patient in person.[88] Studies show that "physicians remain conservative in their view of telehealth's effectiveness compared with in-person care."[89] Additionally, under this approach, it makes sense that physicians will be able to continue prescribing medications via telehealth, because it is just a continuation of their initial in-person visit. What follows is that the standard of care during follow-up telehealth visits must be commensurate with the standard of care during in-person visits. This will allow insurance companies to pay the same amount for telehealth visits as in-person visits, as they are doing currently because of the pandemic, incentivizing physicians to use the technology. This will be relieving for patients who can be confident in their treatment going forward, as the equal compensation will help ensure that highly skilled, experienced physicians will be willing and able to provide telehealth services. Under this proposal, telehealth will be considered "a tool of medicine" that is used to continue treating the patient after an in-person visit.[90]

Note that there are two issues within this proposal that would need to be addressed. First, there needs to be a limit as to how long the telehealth visits would be a "continuation" of the initial in-person examination. It certainly wouldn't make sense to allow an in-person visit that took place 10 years ago to continue through telehealth under this theory. Therefore, physicians and legislators must come up with a practical and medically appropriate timeframe that renders the initial visit effective for the future follow-up visits. A simple, once-a-year, in-person examination may be appropriate and hopefully not too burdensome for patients.

The second issue with this proposal is that it contradicts one of the main purposes of telehealth; to increase health care access to rural Americans. Requiring an initial in-person examination is counterintuitive and much too onerous for the individuals who need telehealth the most. Therefore, under this proposal, an exception must be implemented.

The Exception: Hawaii Five-0

If it is too taxing or impractical for an initial in-person visit to take place, patients should still be able to utilize this technology and have access to health care. Therefore, there must be circumstances in which the in-state licensure requirement can be waived. An exception based on Hawaii's definition of telehealth will help establish a system that provides health care to those that cannot be seen initially in-person. Hawaii's telehealth regulation states:

> Treatment recommendations made via telemedicine, including issuing a prescription via electronic means, shall be held to the same standards of appropriate practice as those in traditional physician-patient settings *that do not include a face-to-face visit* but in which prescribing is appropriate, including on-call telephone encounters and encounters for which a follow-up visit is arranged.[91]

Under this framework, telehealth can never be treated as "in-person" care. Rather, it will be held to the standards of a non "face-to-face" visit. This means that although a physician-patient relationship can be formed and prescribing practices will be permitted, the quality of care, and consequently the standard of care, will be lower because it is often difficult for physicians to glean the necessary patient information through a screen.[92] Sacrificing the "in-person" standard of care is a worthy compromise if it will finally provide rural patients with access to healthcare that has been lacking.

In order for this exception to be effective, it should include a geographical limitation. For example, patients can only use this mode of telehealth when the closest health care provider for their needs is over an hour away by car.

Under this framework, it is unlikely that states and physicians would object to such a practice. First, since this will be a modified, and arguably inferior form of medicine, insurance companies will pay significantly less for the rendering of its services. For many doctors, maintaining an online-only telehealth practice will be economically unfeasible. Therefore, in-person physicians may not worry that their market will be oversaturated. For similar reasons, the states will not have to worry about losing control of the health care industry.

Conclusion

Telehealth is no longer a futuristic abstract idea; it is our new reality. Although the pandemic didn't create telehealth, it did provide an opportunity for its benefits to be displayed on the world scale. Legislators are faced with the difficult task of creating laws that satisfy the needs of multiple players in the health care system, including patients, physicians, and the states. This article proposes a compromise solution that may be palatable to all stakeholders by creating a federal statute that requires an initial in-person visit between the physician and patient. This requirement will: (1) allow states to maintain regulation over the industry; (2) provide doctors with the comfort that their industry will not be over-saturated by online-only physicians; and, (3) provide patients with the comfort that they are receiving quality care. Under this model, if an in-person visit is impossible, an exception to the rule will be made, ensuring that rural patients have adequate access to care. The exception would allow telehealth treatment to be conducted even *without* an initial in-person visit, but this form of telehealth will be considered a modified, and arguably inferior, form of healthcare. Based on Hawaii's telehealth legislation, the standard of care will be lower, and therefore the prices charged will be cheaper. This will alleviate the concerns of the states and physicians while providing a much-needed service to those in dire need of remote health services.

Most importantly, under this proposal patients like Maki Inada will no longer have to worry about driving three and a half hours to the Massachusetts state line to receive cancer treatment from her car.[93] In such a world, Maki would only have to make an initial trip to Boston, and after that, her physicians would be equipped with a tool called telehealth to continue providing her treatment.

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45. COVID-19 Information Page, DIVERSION CONTROL Div., https://remote-communications-during-the-covid-19.html ("On

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49. *See* Verma, *supra* note 44.
50. *See generally,* Letter from Brian Schatz, Senator, U.S. Senate et al. to Mitch McConnell, Majority Leader, U.S. Senate and Charles Schumer, Minority Leader, U.S. Senate (June 15, 2020), https://www.schatz.senate.gov/imo/media/doc/Letter%20to%20leadershipCONNECT%20for%20Health%20Act_06.12.20.pdf.
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52. 6 Med. Malprac. Chklsts. & Disc. Introduction; Scope § 47:15, Westlaw.
53. Lynette Herscha*, Is There a Doctor in the House? Licensing and Malpractice Issues Involved in Telemedicine*, 2 B.U. J. Sci. & TECH. L. 8, 35 (1996).
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57. *Id.*
58. Michael Horner et al., *Liability in the Telehealth Era*, White & Williams Healthcare Alert, https://www.whiteandwilliams.com/resources-alerts-Liability-in-the-Telehealth-Era (2020).
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61. *Supra* note 53.
62. 46 Am. Jur. Proof Of Facts 2D 373, Existence of Physician and Patient Relationship § 2.
63. *Id.*
64. Alexis S. Gilroy et al., *Hot Topics in Telemedicine 2016: Payment Policy, Prescribing, and Practice Standards* 20160627 AHLA Seminar Papers 11 (June 27, 2016).
65. *Id.; see* Ky. Bd. of Md. Licensure, Board Opinion Regarding the Use of Telemedicine Technologies in the Practice of Medicine (June 19, 2014).
66. Laura E.A.Wibberley, *Telemedicine in Illinois: Untangling the Complex Legal Threads*, 50 J. Marshall L. Rev. 885, 912 (2017).
67. Sherman Act, 26 STAT. 209 (1890), 15 U.S.C. §§ 1-4 (1946).
68. *See Teladoc, Inc. v. Tex. Med. Bd.,* 112 F. Supp. 3d 529, 534.
69. *See* Tenn. Comp. R. & Regs. 0880-02-.16(1)(f), (g) (2016) (defining telehealth and technology used in the field) and Ark. code ann. § 17-80-403 (discussing how a relationship is formed via telehealth).
70. Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (2008) (codified in 21 U.S.C.A. §§ 829(e)(2)(A)(i); 42 U.S.C.A. § 1395m(m)(1); 42 C.F.R. § 410.78(a)(3) (2020)) (Ryan Haight was a teenager who was prescribed with a controlled substance online by a physician he had never met, and died as a result of overdose). *See also,* Marlene Maheu, *Telehealth Opioids and Ryan Haight Act: Update*, Telehealth. Org (May 21, 2021), https://telehealth.org/ryan-haight-act/.
71. 21 U.S.C.A. § 831(h).
72. 21 U.S.C.A. § 802(54)(A)-(G).
73. *See* Jeremy Sherer & Amy Joseph, *Physician Law Evolving Trends and Hot Topics: Telehealth*, 32 Health L. 20, 23 (2020).
74. *See supra,* note 70 (as a result of the emergency declaration, the Ryan Haight Act's requirements of in-person prescription has been paused); *see also* https://www.hhs.gov/opioids/sites/default/files/2018-09/hhs-telemedicine-dea-final-508compliant.pdf.
75. Mehrotra,*supra* note 12.
76. *Id.* at 688.
77. *See supra* note 1.
78. Mehrorta*supra* note 12.
79. *See N.C. State Bd. of Dental Exam'rs v. FTC,* 574 U.S. 494. Feb 25, 2015.
80. U.S. State Participation in the Compact, Interstate Med. Licensure Compact, https://www.imlcc.org/.
81. *Id.*
82. Mehrotra*supra* note 12.
83. *Id.*
84. Telemed Act of 2013, H.R. 3077, 113th Cong. (2013-2014) https://www.congress.gov/bill/113th-congress/house-bill/3077/text.
85. Mehrotra*supra* note 12.
86. H.R.688 — 117th Congress (2021-2022), https://www.congress.gov/bill/117th-congress/house-bill/688.
87. *See* "AMA Chart" *supra* note 55.
88. Jenny Cordina et al., *Patients Love Telehealth—Physicians are not so Sure*, Mckinsey and Company, https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/patients-love-telehealth-physicians-are-not-so-sure (2021).
89. *Id.*
90. *Supra*, note 66 (explaining that telehealth is a tool for the practice of regular medicine and not a new form of medicine).
91. *See* Hawaii Telehealth Regulations, §453-1.3 *Practice of Telehealth*. https://www.capitol.hawaii.gov/hrscurrent/vol10_ch0436-0474/HRS0453/HRS_0453-0001_0003.htm. (Emphasis added.).
92. Jenny Cordina et al., *Patients Love Telehealth—Physicians are not so Sure*, Mckinsey and Company, https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/patients-love-telehealth-physicians-are-not-so-sure (2021).
93. Mehrotra,*supra* note 9.

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

August 17, 2022

DHCBS DAL: 22-14

SUBJECT: Licensed Home Care Services Application Changes

Dear Administrator:

Effective April 1, 2020, applications for licensure as a Licensed Home Care Services Agency (LHCSA) are subject to review based on new public need and financial feasibility standards, in addition to the existing character and competence review process. Information regarding the new standards and application process are included in this letter and its attachments.

Background

Part B of Chapter 57 of the Laws of 2018 amended Public Health Law (PHL) Section 3605, Subdivision 4 to require that the Public Health and Health Planning Council (PHHPC) "not approve an application for licensure unless it is satisfied as to: (a) the public need for the existence of the licensed home health care service agency at the time and place and under the circumstances proposed; (b) the character, competence and standing in the community of the applicant's incorporators, directors, sponsors, stockholders, or operators; (c) the financial resources of the proposed licensed home health care service agency and its sources of financial revenues; and (d) such other matters as it shall deem pertinent".

The Department of Health (Department) amended its regulations to include the requirements set forth by law. The regulations were effective on April 2, 2020 and the adopted regulation package can be found as Attachment 1 to this letter.

Public Need Methodology

The public need methodology applies to all applications for licensure submitted on or after April 1, 2020.

- The public need methodology includes a rebuttable presumption of no need for additional LHCSAs in a county if there are five or more LHCSAs actively serving patients within the county as of April 1, 2020. The target date for the Department to determine need has been adjusted to April 1, 2022 and the counties with need are identified in the attached LHCSA County No Need Report.

- A LHCSA applicant can overcome the presumption of no need based on local factors related to an applicant's services or planning area, including, but not limited to:

- the demographics and/or health status of the patients in the planning area or the State, as applicable;
- documented evidence of the unduplicated number of patients on waiting lists who are appropriate for and desire admission to a LHCSA, but who experience a long waiting time for placement;
- the number and capacity of currently operating LHCSAs;
- the quality of services provided by existing agencies;
- the availability and accessibility of workforce;
- personnel and resources dedicated to adding and training additional members of the workforce including committed resources in an organized training program;
- cultural competency of existing agencies; and,
- subpopulations requiring specialty services.

- Applications for licensure based on change of ownership for LHCSAs actively serving at least 25 patients will not be subject to public need review and shall be evaluated only on financial feasibility and the character and competence of the proposed operator, unless the proposed operator seeks to serve patients outside of the agency's approved counties.

- LHCSAs affiliated with an Assisted Living Program (ALP), Program of All-Inclusive Care for the Elderly (PACE), Nurse Family Partnership (NFP), or Continuing Care Retirement Community (CCRC) will be exempt from the public need methodology if the agency exclusively serves patients within those programs. The agency will be subject to the need methodology if they apply to serve patients outside of the specific program. Any exemption will be noted on the agency's license.

Financial Feasibility

The standards for the financial feasibility review will require, at a minimum:

- an examination of the sources of available working capital that the proposed licensed home care services agency operators have, with a minimum requirement equal to at least two months of estimated operating expenses of the agency;

- that the application passes a reasonableness test with respect to the financial capability of the agency or sources for start-up funding; and

- an examination of the financial feasibility of the agency or projections indicating that the agency's revenues, including but not limited to operating revenue, will be equal to or greater than projected expenditures over time.

All applications will be reviewed for character and competence using the existing standards and procedures. Also attached to this letter is a revised application for licensure (Attachment 2), a list of counties and the number of LHCSAs actively serving patients in each county (Attachment 3), and FAQs (Attachment 4).

Questions on the new requirements may be sent to homecareapplications@health.ny.gov

Sincerely,

Carol Rodat, Director
Division of Home and Community Based Services

Attachments: Title 10 NYCRR, Part 765
Revised application for licensure
LHCSA County Presumption of No Need Report
Frequently Asked Questions (FAQs): LHCSA Public Need Methodology and Financial Feasibility Review
Quality Assurance Committee Guidelines

cc: Mark Hennessey
Valerie Deetz

Franchise Regulations in the Context of the MSO Model

By Weston Harty

I. In complying with the corporate practice of medicine, MSOs and professional medical practices risk falling within the expansive reach of franchise regulations

Consumer (i.e., patient) protection in part justifies the existence and enforcement of the corporate practice of medicine doctrine (CPOM) in New York.[1] CPOM's compliance requirements, namely the prohibition of nonprofessionals having ownership interests in a professional entity, in turn, has accelerated the proliferation of management service organizations (MSOs) forming MSO-practice affiliations (MSO groups) as a means of opening the New York health care market to private, nonprofessional investment. Depending on the sophistication and size of the MSO and the parameters of the MSO group relationship, however, an MSO group's legitimate efforts to comply with the CPOM may unintentionally increase the liability risk under an unrelated consumer protection framework: franchise regulations.

Beginning in the 1970s, states enacted franchise laws to combat fraud pervading the franchising industry boom in post-World War II America.[2] Most of these initial franchise acts drew inspiration from securities regulations, viewing a franchise offering as an investment opportunity, and sought to establish a uniform baseline of available information to empower investors (i.e., franchisees) to make informed decisions.[3] The first state-level franchise regulations required certain pre-transaction financial and operating disclosures, a model essentially adopted at the federal level in 1979 with the first iteration of the Federal Trade Commission's (FTC) "Franchise Rule."[4] Though borrowing from the securities regulatory framework, the FTC promulgated the Franchise Rule under its general authority to combat unfair and deceptive trade practices under Section 5 of Federal Trade Commission Act of 1914 (FTC Act).[5] Since the adoption of the FTC Act, most states have deferred to the FTC for franchise regulation, though a minority of states including New York, still maintain, or have since enacted, laws and regulations to supplement the Franchise Rule.[6]

As discussed below, the nature of MSO group relationships—especially the delegation of substantial business functions and trademark[7] licensing—can implicate the broadly drafted franchise regulations existing at the federal and state level. For MSO groups falling under the purview of these regulations, MSOs face both the specter of government enforcement and additional causes of action originating with the practice in the event the MSO group affiliation sours. Each MSO, then, must view both the practice and the patient as a consumer when applying existing consumer protection regulations when structuring an MSO group.[8]

II. Franchise regulations generally apply where a party pays a fee and cedes some control over its business for the right to use a trademark, but New York's regulations are substantially broader

The Franchise Rule aims to remedy bargaining imbalances in franchise relationships through pre-transaction disclosures, but, due to its structure and the FTC's enforcement priorities, there are limited mechanisms to ensure these disclosures are actually made. The New York Franchise Act, as defined below, generally expands the scope and enforcement capacity of the Franchise Rule by: (1) covering more relationships, (2) requiring franchisor registration; and (3) permitting private causes of action.

A. The FTC requires franchisors to provide pre-transaction disclosures to franchisees, and the FTC Act empowers only the FTC to enforce this requirement

Under the Franchise Rule, a "franchise" is any relationship where (1) a franchisor grants the franchisee the right to use the franchisor's trademark in exchange for (2) a fee, where (3) the franchisor exerts "significant" control over, or provides "significant" assistance to, the business of the franchisee.[9]

The FTC interprets the trademark and fee elements in the broadest of terms. To the FTC, a "trademark" is shorthand for any kind of commercial symbol associated with a particular good or service, regardless of protection or registration status, essentially any trade or service mark, logo, or trade dress.[10] Fees, meanwhile, extend beyond express licensing fees and include any kind of compensation, be it rent, security deposits, escrows, training fees, equipment leases, continuing royalties, or other arrangement related to the trademark right.[11] In other words, any transfer of value from the purported licensee to the licensor, regardless of the nomenclature, satisfies the fee element if the franchisee's use of the trademark is in any way contingent upon or related to that value transfer.

The FTC defines the third element less clearly, requiring a more rigorous and nuanced analysis of a given relationship on a case-by-case basis. Levels of control or assistance exist on a continuum without clear demarcation, where "the more

franchisees reasonably rely upon the franchisor's control or assistance, the more likely the control or assistance will be considered 'significant.'"[12] The FTC also seeks to balance the degree of control against legitimate business interests, like the basic steps all licensors must take to protect and perfect their ownership of a given trademark.[13] Indicia of significant control include customer-facing requirements familiar to anyone who has frequented a fast food restaurant, like standardized site design, product offerings, and production techniques.[14] Significant controls also extend to back office control over things like accounting practices and vendor relationships.[15] Indicia of significant assistance are more amorphous, and can include "furnishing management, marketing, or personnel advice," selecting site locations, and "furnishing system-wide networks and websites."[16] As the fee and trademark element each cast extremely wide nets and involve relatively simple yes or no analyses, whether an arrangement constitutes a franchise for federal purposes almost always hinges on whether the franchisor's control or assistance is significant.

For arrangements satisfying its elements, the Franchise Rule implements a pre-transaction disclosure system to combat unfair or deceptive trade practices through the use of the Franchise Disclosure Document (FDD). The Franchise Rule requires the franchisor to provide the FDD sufficiently ahead of a franchise sale to give the franchisee an opportunity to review and ask questions about its contents. The Franchise Rule also specifies the information the franchisor must include in the FDD. In broad strokes, the FDD must contain information regarding the: (1) nature of the franchise system; (2) franchisor's current and projected financial viability; (3) anticipated costs and expenses associated with operating a franchise in the franchisor's system; (4) franchise agreement; and (5) experience and expertise of the franchisor's key personnel.[17]

As outlined above, noncompliance with the Franchise Rule constitutes an unfair and deceptive trade practice under Section 5 of the FTC Act. As such, the FTC has enforcement authority including levying civil penalties bringing claims in federal court for contract rescission and restitution on behalf of the franchisee.[18] The FTC Act offers no private right of action, giving the FTC plenary enforcement authority that the FTC seldom utilizes.[19] The lack of FTC enforcement likely owes to the fact that the financial rewards available for state-level causes of action (whether for common law fraud or under a state franchise regulation) incentivize franchisees to bring private state-level claims rather than rely on the FTC. To wit, a franchisee in a state like North Carolina can bring a private claim under that state's analog to the FTC Act and seek treble damages in addition to the rescission and restitution the FTC could otherwise secure on its behalf.[20]

B. The New York Franchise Act requires each franchisor to register its FDD with the New York Attorney General and empowers the New York Attorney General and franchisees to enforce its requirements

As mentioned above, while many states simply leave franchise regulation to the federal government, a minority of states maintain supplementary schemes. States with their own franchise acts have taken several approaches, which generally range from broadening the scope of regulated franchise relationships,[21] to providing additional registration or filing requirements with state-level agencies,[22] to regulating some aspect of the franchisor/franchisee relationship other than pre-transaction disclosures,[23] or some combination of the above. In substance, the New York Franchise Sales Act (New York Franchise Act)[24] follows the latter path, and captures a broader range of relationships under its purview than the

Franchise Rule and enhances the pre-transaction compliance requirements.

Under the New York Franchise Act, a "franchise" means any arrangement where (1) the franchisee pays a fee (2) for the right to distribute goods or services either (a) pursuant to a business plan "prescribed in substantial part" by the franchisor or (b) "substantially associated" with the franchisor's trademark.[25] The NY Franchise Act mostly aligns its interpretations of these individual elements with the Franchise Rule. For instance, the New York Attorney General (NYAG), the state authority responsible for enforcing the NY Franchise Act, interprets a "marketing plan" as broadly including "operational, managerial, technical or financial guidelines or assistance."[26] Though technically different from the Franchise Rule's notion of "substantial control" or "substantial assistance", the analysis is roughly analogous: a fact—intensive review to determine the degree of the franchisee's dependence on the franchisor. Similarly, trademarks function as shorthand to reference "any commercial symbol" (whether or not protected) associated with the franchisor.[27] A "franchise fee" likewise generally means any kind of payment associated with the franchise relationship, regardless of form.[28]

Where the NY Franchise Act increases its scope relative to the Franchise Rule, then, is not in the definitions of the elements themselves,[29] but by condensing the three element Franchise Rule definition into two.[30] Instead of requiring the presence of *both* the franchisor's substantial control over *and* licensing of its trademark to, the franchisee, the NY Franchise Act requires merely that *either* the franchisor provide a "marketing plan" *or* license its trademark to the franchisee. As a result, business relationships can constitute a franchise in New York even without trademark licensing if the assistance or advice provided by the purported franchisor otherwise constitutes a "marketing plan," or vice versa. The massive increase of scope cannot be understated; except for the specifically enumerated exceptions to the NY Franchise Act, many trademark licensing relationships are technically franchises for the purposes of New York law. Consequently, the NY Franchise Act facially applies to a number of business relationships that are outside the scope of the Franchise Rule, most other state franchise acts, and a common sense, layperson understanding of franchises in general.

In addition, New York requires the franchisor to put the state on notice of the terms of the franchise sale. While the Franchise Rule only requires that the franchisor provide a compliant FDD to the franchisee, New York essentially requires the franchisor to maintain a current copy of its FDD (with a few additional disclosures) on file with the New York attorney general.[31] During the registration process, the New York attorney general has the opportunity to review and comment on the FDD and additional materials prior to approving the franchisor to make franchise offerings in New York. After the initial approval, the franchisor must continue to regularly update its disclosures to maintain a current registration and authorization to continue franchise sales within the state.[32]

The NY Franchise Act, like the Franchise Rule, authorizes government enforcement of its requirements. Similar to the FTC, the New York attorney general can levy civil penalties and seek restitution on behalf of the franchisee.[33] The New York attorney general can also seek to enjoin future franchise sales by the offender and initiate criminal proceedings against a willing and knowing violator.[34] Unlike the Franchise Rule, however, there is also a private cause of action enabling franchisees to seek damages and rescisson of the franchise agreement,[35] though actions under the New York Franchise Act are generally restorative and not punitive in nature (unlike the treble damages that may be available in other states like North Carolina).[36] Where additional malfeasance, like intentional misrepresentations, accompany noncompliance with the NY Franchise Act, a franchisee may have grounds fraud or other causes of action.

III. Though policy leans against government enforcement of franchise regulations against MSOs, private causes of action remain a potential source of liability

As shown below, given the vast breadth of these regulations, an MSO group could constitute a franchise, at least nominally, in both a federal and New York-specific context. MSOs should therefore remain cognizant of the available exceptions and exclusions to the Franchise Rule and New York Franchise Act and, regardless of whether any exceptions or exclusions apply, carefully structure the MSO group relationship to avoid potential liabilities under these statutes and regulations.

A. MSO groups facially meet the definition of a franchise (i) in New York when they involve the payment of a fee in exchange for considerable support services, and (ii) for federal purposes, with the addition of a right to use a trademark

In a typical MSO group relationship, the MSO provides a variety of back-office support services to the practice, as provided in a management, support, administrative, or other non-clinical services contract (ASA) in exchange for a fee. These services optimally encompass all business functions other than the actual practice of medicine[37] (which, due to the CPOM, the MSO legally cannot perform). Typically, the practice will delegate all or some degree of authority to the MSO for: supply and equipment purchasing or leasing; vendor contracting; IT systems (including the electronic medical record (EMR)) licensing and management; office space procurement; developing and implementing marketing strategies

for the practice; recruiting new physician candidates; maintaining the practice's books and records, handling payroll, and processing patient billing and collections; and procuring insurance for the practice and its professional employees. In essence, the practice stands to experience a substantial interruption of its business and perhaps might not profitably operate without the MSO. While the reservation of authority over clinical matters means the MSO does not control the practice for franchise Rule purposes, this degree of assistance is at least arguably "significant" within the FTC's interpretation of the phrase.

The MSO (or an affiliate) may also hold a trademark that it makes available to or requires the practice to use as part of a broader branding strategy. For instance, the MSO may permit, or require, that the practice migrate to web addresses, post signage, and use letterhead bearing or incorporating the MSO's trademark. Where trademark licensing occurs, the fee under the ASA will also be sufficient to constitute a fee for franchise analysis purposes. In sum, many MSO group relationships where the MSO licenses a trademark to the practice could constitute a franchise under the Franchise Rule.[38]

A New York-specific analysis of the MSO group model is even more clear-cut. In New York, remember that franchises form any time one party exchanges a fee for a trademark license or access to a marketing plan. Accordingly, *every time* the MSO couples a trademark license with its services, a franchise will exist, regardless of the nature and degree of its support services. Even where the MSO does not license a trademark, New York's broad view of what constitutes a "marketing plan" (that is, operational, managerial, technical or financial guidelines or assistance), leads to the same conclusion given the extent of support services describe above. And that is before even considering that many MSOs expressly assume control of marketing and advertising as part of the MSO group affiliation.[39] As the MSO's services at least arguably constitute a marketing plan, then, the MSO group relationship could constitute a franchise under the NY Franchise Law as well even absent a trademark license.

B. MSO groups generally do not meet the statutory exclusions to the Franchise Rule and NY Franchise Act

The FTC has promulgated a number of exceptions to the Franchise Rule, and also recognizes a number of exclusions outside the context of its regulations.[40] New York, meanwhile, largely tracks these exceptions and exclusions as codified in the New York Franchise Act.[41] Notably, these exclusions and exemptions do not nullify the general prohibitions on unfair or misleading trade practices, but instead merely exempt the franchisor from pre-transaction disclosure and, in the case of New York, registration with the New York attorney general. In relevant part, this means that fitting under an exclusion or exemption does not insulate the franchisor from liability for fraud or other, similar causes of action.

Although these exemptions and exclusions exist, most are not applicable in the MSO group context,[42] and the limited options that are available are not necessarily practical to rely upon. For example, the Franchise Rule exempts offerings to franchisees having at least a five-year operating history and a net worth in excess of $6,165,000 (subject to adjustments for inflation).[43] While some practices may well fall into this category, practice assets are largely intangibles like goodwill, presenting accurate valuation challenges.

Of more use is the single franchise exemption to the Franchise Rule.[44] This arrangement, as its name implies, refers to situations where the franchisor grants a single license in its trademark.[45] New York's exemption is slightly different, in that it refers to offers directed "to not more than two persons" and also requires the franchisor to be qualified in New York, among other requirements.[46] The upshot, however, is largely the same—a limited offering of franchises. That can be a viable path in some cases, but is not particularly helpful for a larger MSO group because it requires rolling all of the affiliated physicians and practices into one (potentially multistate) professional entity. Qualifying one professional entity in more than one jurisdiction quickly becomes cumbersome if not entirely infeasible while an MSO group may prefer to spread its affiliations over multiple practices to limit risk.

The overall impact is that MSO groups can arguably form franchises under federal and New York law, and these relationships do not neatly fall into existing exclusions or exemptions, potentially exposing MSOs to franchisor liability.

C. The dynamics between practice and MSO in an MSO group does not align with the policy justifications supporting government regulation of franchises

In assessing the risk of franchisor liability, however, we must also consider the MSO group model practically through a prosecutorial lens. As outlined above, franchise regulations generally aim to protect franchisees that are generally placed at a bargaining disadvantage, whether due to their inexperience in the franchise's line of business or the relative fungible nature of the capital they provide. In practice, consider that, to a prospective franchisee, a franchise presents a turnkey business opportunity: the franchisor determines how the franchise will look, where it will be located, what goods or services it will provide, the vendors it will purchase from, and a myriad of other operational know-how that is essential to running the business, as well as the value of the goodwill associated with an established brand. To the franchisor, meanwhile, the franchisees are essentially interchangeable—in a good franchise system, franchisees do not need training, experience, or any-

thing else other than the up-front capital necessary to open the location because of all of the assistance the franchisor is providing.

For MSO groups, the inverse is, to a degree, true. The services that an MSO provides, for example, are by definition ancillary to the nature of the business itself and are not otherwise unique between MSOs. Though necessary for the practice to operate as a business, it is the MSO's services, and not the franchisees, that are more or less fungible. Moreover, while the MSO may possess an established brand identity, it is the practice that often offers the more valuable goodwill through its relationships with its patients. And the practice, of course, could only develop its own patient base if it successfully operated as a business prior to affiliating with the MSO, meaning that the practice theoretically can operate without the MSO's involvement. The relative bargaining positions of the MSO and practice, then, more closely balance each other as opposed to a textbook franchisor-franchisee relationship.[47] This relative balance in bargaining position, in turn, misaligns with the policy justifications for government intervention in the formation of putative franchise relationships, as the practice is less likely to be taken advantage of than an inexperienced investor.

The greater utility of other consumer protection frameworks available to governmental authorities also affects the likelihood of government enforcement. Specifically, the CPOM, in theory, protects a greater number of consumers than franchise regulations with regard to MSO groups, as patients (the consumer for CPOM purposes) greatly outnumber practices (the consumer for franchise regulation purposes), and the patient is, in any event, the ultimate consumer of health care services. The patient, furthermore, generally lacks expertise in, or sophisticated knowledge of, medicine and relies on the professional judgment of the clinician. Given that CPOM and franchise issues can substantially overlap, the enforcement authority, for instance, the New York attorney general, should favor enforcing the CPOM over franchise regulations given the greater utilitarian benefit. Reality has already borne this out, best exemplified in the New York attorney general's enforcement activity around Aspen Dental. The arrangement, involving individual practice entities separately operating under Aspen Dental's trade dress, plainly constitutes a franchise under the New York Franchise Act.[48] Yet the AG's final Assurance of Discontinuance entirely omits any discussion of franchise law and rests solely on the CPOM and patient protection.[49]

In sum, even though many MSO groups might otherwise meet the definition of a franchise, the policy justifications underlying franchise regulations and greater utility of CPOM enforcement should advise against the FTC or New York attorney general invoking its authority to enforce these regulations against MSO groups.

D. Because private causes of action still exist under the New York Franchise Act, MSOs could face liability as a putative franchisor even absent government enforcement

So, as we've seen, although many MSO group relationships arguably constitute franchises under both federal and New York law, the enforcing agencies lack strong policy justifications to pursue enforcement, especially in light of other enforcement mechanisms that apply to many of the same relationships. That, in total, means MSO groups likely need not lose sleep over government (whether federal or state) enforcement of franchise regulations, but that does not address private causes of action.

Accordingly, MSOs should carefully structure the MSO group to minimize the risk of inadvertently forming an actionable franchise in the event an affiliation with a practice sours. Recall that states and the federal government regulate franchises primarily to combat unfair and deceptive trade practices against the franchisee—things like hidden costs; arbitrarily prescriptive or restrictive operational requirements; or over-promised and under-delivered support. Structuring the MSO group arrangement around these principles, then, can minimize inferences of an actionable franchise.

Due to the aforementioned overlap between CPOM and franchise issues, MSO group arrangements should mitigate this risk already as a natural byproduct of structuring around the CPOM. The practice, for instance, should always retain absolute discretion over clinical decisions or any other act that constitutes the practice of medicine. However, an MSO's services can eat into the autonomy of the practice without violating the CPOM by limiting the autonomy of the practice in a practical sense. For instance, the MSO may receive a delegation to negotiate and bind the practice to payor contracts or secure broader than necessary power of attorney to sign negotiable instruments on behalf of practice. Other fairly common practices like assigning real property leases from the practice to the MSO (to serve as sublandlord to the practice) or having the MSO sublicense the EMR to the practice can also weigh in the favor of finding a franchise relationship by limiting the practice's options if a dispute were to arise. Consider whether the practice has a real option to terminate the ASA in the event of a breach if the MSO has the right to deny the practice's employees entry to the practice's offices or access to the practice's EMR in the event the ASA terminates. The MSO could still, of course, negotiate these kinds of agreements and recommend locations, but the practice should be the signing party.

To be clear, these are policy arguments, and the MSO could still perform the tasks referenced above without guaranteeing franchisor liability in the event the practice ever filed a claim. However, the MSO can distance itself from the type of relationship that the New York Franchise Act seeks to govern if the ASA reserves some degree of authority over non-clinical affairs for the practice. In those cases, borrowing from the federal interpretation, the degree of influence is lessened and more comfortably reflects an administrative service provider than that of a franchisor.

IV. State and federal franchise regulations present a manageable but oft-ignored risk in MSO-practice affiliations

The federal government and several states, especially New York, take an over-inclusive view of franchise relationships and consequently nominally regulate many business relationships that are not commonly understood as, or intended to be, franchises. Looking purely at these regulatory frameworks, some MSO groups could fall also constitute unintentional or inadvertent franchises. Though an MSO group might technically be a franchise, the realities of the MSO-practice dynamic in the MSO group do not squarely align with the policy justifications favoring regulations of franchises in most cases, which minimizes the risk of government enforcement. However, New York's private cause of action under the New York Franchise Act advises structuring the MSO's delegation of authority from the practice around both franchise regulations as well as the CPOM.

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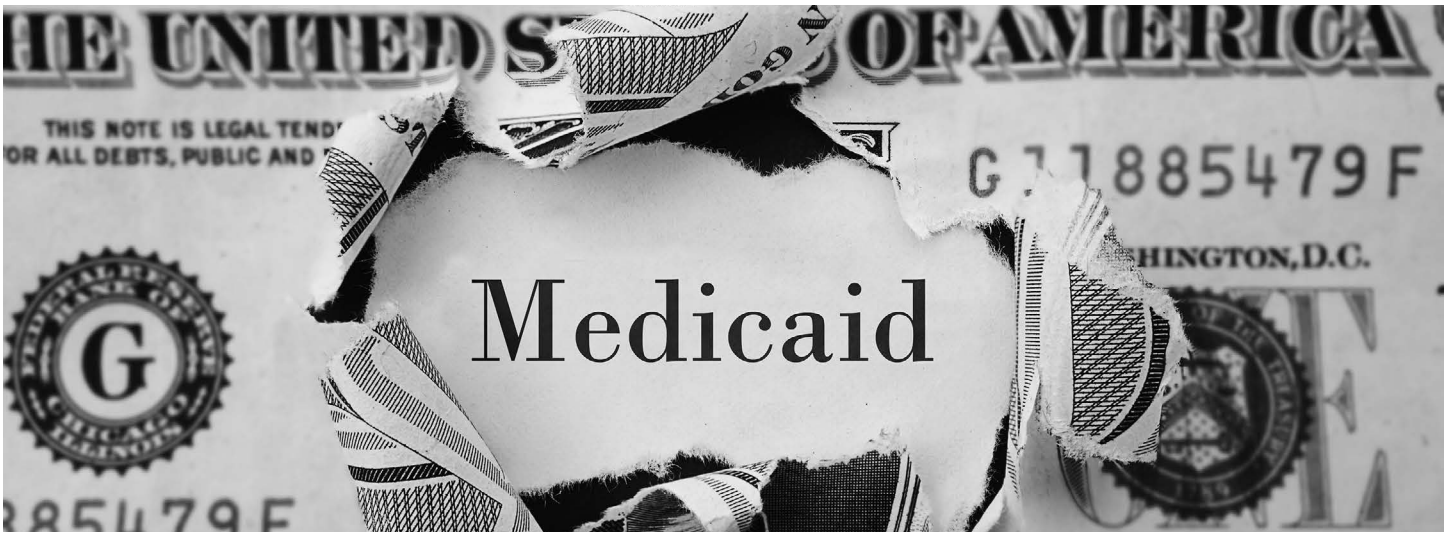
Endnotes

1. *See, generally*, *Carothers, M.D., P.C. v. Progressive Ins. Co.*, 128 N.E.3d 153, 162 (N.Y. 2019).
2. *About the Franchise Investment Law*, California Department of Financial Investment and Protection, https://dfpi.ca.gov/about-the-franchise-investment-law/ (last updated Feb. 7, 2020).
3. *The Accidental Franchise and the New York Restaurateur*, Hospitality Law Committee of the Association of the Bar of the City of New York, https://s3.amazonaws.com/documents.nycbar.org/files/2019516-Franchise_Laws.pdf (April, 2019); *See also* N.Y. Gen. Bus. L. § 680 ("The legislature hereby finds and declares that . . . New York residents have suffered substantial losses where the franchisor . . . has not provided full and complete information regarding the franchisor-franchisee relationship.").
4. *Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunities*; Final Rule, 72 Fed. Reg. 15445 (March 30, 2007).
5. *Id.*
6. *See, generally*, State Pre-Sale Franchise Registration and Disclosure Laws Charts: Overview, Practical Law Commercial Transactions, with P. Loh, B. Smith, and M. Mitcham, Westlaw (November 30, 2021).
7. I use the term "trademark" here, and throughout this article, as a general stand-in for any commercial symbol, design, logo, phrase, or dress associated with a good or service, regardless of registration status.
8. This article will focus on the application of the federal and New York state franchise regulations to the MSO group model. Though, as discussed in this article, New York's franchise regulations are among the broadest in the United States, separate state-level analyses are necessary for each state relevant to a given MSO group.
9. 16 C.F.R. § 436.1(h).
10. *Compliance Guide: Franchise Rule 16 C.F.R. Part 436*, Federal Trade Commission, p. 2 (May 2008), https://www.ftc.gov/system/files/documents/plain-language/bus70-franchise-rule-compliance-guide.pdf.
11. *Id.* at p. 5.
12. *Id.* at p. 2.
13. *Id.* at p. 3.
14. *Id.*
15. *Id.*
16. *Id.*
17. 16 C.F.R. § 436.5.
18. 15 U.S.C. § 57b(b).
19. https://www.foley.com/en/insights/publications/2022/02/ftc-initiates-rare-enforcement-action-burgerim.
20. North Carolina's analog to the FTC Act includes a private cause of action, and prevailing plaintiffs can be awarded treble damages. N.C.G.S. § 75-16. While North Carolina does not independently regulate franchises in most contexts, it does import the federal understanding of unfair and deceptive trade practices from federal jurisprudence.
21. California, for instance, separately incorporates certain petroleum and gasoline production and distribution relationships into the definition of "franchise" in addition to essentially incorporating the Franchise Rule's three-element test. See Cal. Corp. Code § 31005(b).
22. "Registration" and "filing" jurisdictions are industry terms relating to the level of state review. A registration jurisdiction requires state review and approval of the FDD, whereas a filing jurisdiction merely requires filing of the FDD. *Compare* Calif. Corp. Code §§ 31114—16 with Va. Code § 13.1-560.
23. For example, N.J. Stat. § 56:10-4 governs the termination of the franchise relationship, as opposed to the formation of one.
24. N.Y. Gen. Bus. L. §§ 680, *et seq*.
25. N.Y. Gen. Bus. L. § 681(3).
26. 13 N.Y.C.R.R. § 200.1(b).
27. N.Y. Gen. Bus. L. § 681(3)(b).
28. N.Y. Gen. Bus. L. § 681(7); *see also* 13 N.Y.C.R.R. § 200.1(a).
29. Though it could be argued that a "marketing plan" is broader than substantial control or substantial assistance, the difference is functionally negligible in comparison to the merging of elements.

30. It also bears noting that the NY Franchise Act does not apply only to franchises physically located in the state. For instance, if the franchisor is located in New York and extends an offer to an out-of-state person for an out-of-state franchise, the NY Franchise Act would apply. *See A Love of Food I, LLC v. Maoz Vegetarian USA, Inc.*, 70 F. Supp. 3d 376, 393–94 (D.D.C. Sept. 30, 2014).
31. N.Y. Gen. Bus. L. § 683.
32. *Id.*
33. N.Y. Gen. Bus. L. § 689.
34. N.Y. Gen. Bus. L. §§ 690; 692.
35. N.Y. Gen. Bus. L. § 691.
36. N.Y. Gen. Bus. L. § 691(2) (preventing franchisees from brining a claim under the NY Franchise Act if, prior to the franchisee's filing of a claim, the franchisor offered to repay the franchise fee with interest).
37. For instance, all practice standards; patient care decisions; and the hiring, firing, and disciplining of the practice's physician employees.
38. It bears reiterating that without a trademark, a franchise relationship cannot form under the Franchise Rule. As such, not licensing a trademark is seemingly a foolproof work around franchise regulation. However, larger MSOs (i.e., MSOs with a presence in multiple states and which otherwise fall outside of the exclusions and exemptions to follow) typically possess an established trademark with associated goodwill value. Those MSOs presumably, then, would not find avoiding trademark licensing altogether particularly helpful advice. For that reason, I generally assume the presence of a licensed trademark for the purposes of the federal analysis. And, regardless, while a trademark license is necessary for the Franchise Rule, recall that a franchises can exist without a trademark license under the NY Franchise Law.
39. Control over marketing does not, per se, constitute a marketing plan. However, if a MSO is affiliated with multiple practices and utilizes a similar marketing strategy for each practice, or operates a centralized marketing plan for all of the practices, then there is an inference of a cohesive plan. This isn't necessarily the type of cooperative marketing offered in franchise systems (that is, where each franchisee pays a designated fee into a central advertising fund, which the franchisor spends on behalf of all of the franchisees), but the statute does not make a distinction.
40. *See Compliance Guide*, *supra* note 10.
41. N.Y. Gen. Bus. L. § 684.
42. *See, e.g.,* 16 C.F.R. § 436.8(a)(1) (relating to arrangements with fees totaling less than $615); 16 C.F.R. § 436.8(a)(7) (exempting relationships that lack written documents governing the relationship).
43. 16 C.F.R. § 436.8(a)(5)(ii). *See also* N.Y. Gen. Bus. L. § 684(2)(a) (notably, in this case the AG still has the discretion to grant or deny an exemption on a case-by-case basis).
44. This exception is not expressly stated in the FTC's regulations, but is listed in the compliance guide published by the FTC. *See Compliance Guide*, *supra* note 10.
45. *Id.* at p. 16.
46. N.Y. Gen. Bus. L. § 684(3)(c).
47. This is not to say that bargaining power is necessarily equal between an MSO and a practice.
48. *See In re Aspen Dental Management, Inc.*, Assurance of Discontinuance No.: 15-103 (June 15, 2015).
49. *Id.*

An Overview of the Office of Medicaid Inspector General's Proposed Medicaid Fraud, Waste, and Abuse Prevention Regulations

By Jean Krebs and Cody Keetch



Introduction

On July 1, 2022, the New York Office of Medicaid Inspector General (OMIG) published a Notice of Proposed Rulemaking in the New York State Register titled *Medicaid Program Fraud, Waste, and Abuse Prevention*.[1] OMIG proposed these regulations to implement recommendations made by the Department of Health's Medicaid Redesign Team II (described further below). The proposed rules would repeal and replace Part 521 of the Department of Social Services regulations, which address Medicaid provider compliance programs, and make changes related to (1) Medicaid provider compliance programs; (2) Medicaid managed care plan fraud, waste, and abuse prevention programs; and (3) "the obligation to report, return and explain [New York] Medicaid overpayments through OMIG's Self-Disclosure program."[2] In this article, we provide a concise review of the proposed Part 521, which we will refer collectively to as the "Proposed Rules," and examine the impact each proposed rule can have on Medicaid providers and MMCOs alike. We will also provide an overview of the Medicaid Redesign Teams (plural) that have influenced both past and proposed changes to New York's Medicaid program and the laws and rules governing it.

Taking Initiative: The Medicaid Redesign Teams

On Jan. 5, 2011, former Gov. Andrew M. Cuomo issued Executive Order No. 5, which established the first Medicaid Redesign Team (MRT I).[3] MRT I was created to "address underlying health care cost and quality issues in New York's Medicaid program…and develop a multiyear reform plan."[4] MRT I consisted of members that have expertise in areas such as health care delivery, insurance, economics, business, consumer rights, health care workforce, business, and consumer rights.[5] MRT I was tasked with engaging Medicaid program stakeholders to conduct a comprehensive review and make recommendations for redesigning New York's Medicaid program. These include addressing existing programs in New York that resulted in savings to the Medicaid program and improve and target existing regulations that could be revised for the modernization of the Medicaid program. Since its creation, MRT I has developed more than 200 initiatives, all of which seek to implement changes to the way that the Medicaid program provides, reimburses, and manages health care.[6]

The Governor's Fiscal Year 2021 (FY 2021) Budget reestablished the Medicaid Redesign Team (MRT II).[7] MRT II was constituted in part to propel forward those innovations and solutions kickstarted by MRT I. [8] Additionally, MRT II is tasked with generating recommendations for the New York Medicaid program. One component of MRT II's recommendations must address policies that ensure the "efficient and effective use of Medicaid dollars and reduce waste, fraud, and abuse."[9] In support of this goal, the New York Legislature amended § 363-d of the Social Services Law, which addresses Medicaid provider compliance programs. Effective April 1, 2020, this statute's requirements were changed to conform with the federal compliance program requirements, impose monetary penalties for failing to implement a program, re-

quire written compliance policies, and require the designation of a compliance committee, among others.[10] Additionally, the Social Services Law was revised to codify certain components of OMIG's self-disclosure program.[11]

Recommendations to Regulations

The regulations OMIG proposed in the July 1, 2022 New York Register build upon the Social Services Law's existing requirements for Medicaid provider fraud, waste, and abuse prevention. The stated objective of the Proposed Rules is to protect the Medicaid program's fiscal integrity, and to promote provider and Medicaid managed care organization (MMCO) compliance with New York's Medicaid laws, rules, and requirements.[12] Additionally, OMIG contends that the Proposed Rules are necessary to carry out MRT II's initiatives and implement provisions of the State Fiscal Year 2020-2021 enacted budget.[13]

In addition to the Social Services Law, Part 521 of the Department of Social Services regulations contain requirements governing Medicaid provider compliance and provider compliance programs. The Proposed Rules would repeal and replace the current Part 521 in its entirety. The proposed Part 521 goes beyond Medicaid provider compliance program requirements and also addresses MMCO fraud, waste, and abuse prevention, as well as OMIG's self-disclosure program. Tellingly, the proposed Part 521 is titled *Fraud, Waste, and Abuse Prevention*.[14] The remainder of this Article summarizes each of the proposed Subparts.

Subpart 521-1: Compliance Programs

If enacted, Part 521-1 will compel Medicaid providers and Medicaid MCOs to examine and potentially restructure their compliance programs. We highlight and discuss the provisions of Subpart 521-1 below:

Scope and Applicability of Program—§ 521-1.1

Subpart 521 requires certain "required providers" participating in the New York Medicaid program to adopt a compliance plan to detect and prevent fraud, waste, and abuse. The following are deemed required providers and are obligated to comply with this proposed regulation:

- hospitals, nursing homes, residential care facilities, and home care service agencies;
- family care homes and residential treatment facilities for children and youth;
- any managed care provider or managed long term care plan; and
- any other person for whom the Medicaid program is or is reasonably expected to be a "substantial portion of their business operations." "Substantial portion of their business operations" includes persons who have claimed or received at least $1,000,000 a year from the Medicaid program. The current statutory definition sets $500,000 as the threshold.[15]

In the current Part 521 regulations, managed care providers and managed long-term plans are not included in the scope of the required provider definition.[16]

Duties of Required Providers—§ 521-1.3(a)

To receive payment through the Medicaid program, required providers must maintain an effective compliance program. The regulations define an "effective compliance program" as a program that is:

- well-integrated into the company's operations and supported by the highest levels of the organization;
- promotes adherence to the required provider's legal and ethical obligations; and
- designed and implemented to prevent, detect, and correct non-compliance with Medicaid program requirements, such as fraud, waste, and abuse.[17]

The provider must ensure that contracts with contractors, agents, subcontractors, and independent contractors are subject to their compliance program, and if such individuals meet the definition of an affected individual, the contracts must include termination provisions for failure to adhere to the required provider's compliance program requirements.[18] The proposed regulations define affected individuals as "persons who are affected by the required provider's risk areas including the required provider's employees, the chief executive and other senior administrators, managers, contractors, agents, subcontractors, independent contractors, and governing body and corporate officers."[19]

Risk Areas for Providers and Medicaid MCOs—§ 521-1.3(d)

The proposed regulations indicate there are ten risk areas, defined as areas of operation affected by the compliance program, that the compliance program must apply to:

- billings;
- payments;
- ordered services;
- medical necessity;
- quality of care;
- governance;
- mandatory reporting;
- credentialing;

- contractor, subcontractor, agent, or independent contract oversight; and
- other risk areas that are or should reasonably be identified by the provider through "organizational experience."[20]

The regulations define "organizational experience" to include four components, which include the required provider's knowledge, skill, practice, and understanding in operating a compliance program; identification of issues or risk areas; experience, knowledge, skill, practice and understanding of its participation in the Medicaid program; and awareness of issues it should reasonably become aware of for its services.[21]

In the current Part 521, "ordered services" and "contractor, subcontractor, agent, or independent contractor oversight" are not risk areas required to be addressed in a required provider's compliance program. The proposed regulations also add ten additional risk areas for MMCOs to address in their compliance programs. These additional areas of risk include:

- compliance with MMCO's contract terms;
- cost reporting;
- submission of encounter data;
- network adequacy and contracting;
- provider and subcontractor oversight;
- underutilization;
- marketing;
- provision of medically necessary services;
- payments and claims processing; and
- statistically valid services verification.[22]

Certification—§ 521-1.3(f)

Required providers must submit an annual certification to the Department of Social Services that it maintains a compliance program. The required provider must also submit a copy of such certification to each Medicaid MCO with whom the required provider has a provider agreement.[23]

Written Policies of Compliance Program—§ 521-1.4(a)

Required Providers are required to have written policies, procedures, and standards of conduct that govern the compliance program. These policies, procedures, and standards of conduct must cover several topics, including, providing guidance on dealing with compliance issues, descriptions of how compliance issues are investigated and resolved, and include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program. The policies and procedures must be reviewed at least annually.[24]

Compliance Officer and Compliance Committee—§ 521-1.4(b)-(c)

In the current Part 521, a required provider is responsible for designating one employee that is responsible for the compliance program's operation. Now, under the proposed Part 521, required providers must designate a compliance officer who will oversee, monitor, and review the compliance program, implement compliance work plans, and investigate matters related to the compliance program.[25] The compliance officer will also coordinate with a designated compliance committee. The compliance committee will be responsible for, among other things, collaborating with the compliance officer on written policies and procedures, ensuring that the compliance officer is allotted sufficient resources to perform their job, and enacting required modifications to the compliance program.[26]

Compliance Training and Education—§ 521-1.4(d)

Required providers must maintain an annual compliance training and education program for the compliance officer and all Affected Individuals. The training and education must include, at a minimum, a discussion of the following:

- risk areas and organizational experience of the Required Provider;
- written policies, procedures, and standards of conduct related to compliance;
- the role of the compliance officer and compliance committee;
- the obligation of Affected Individuals to report compliance concerns, the procedures for reporting concerns, and the non-intimidation and retaliation policies of the Required Provider;
- disciplinary standards related to the compliance program and fraud, waste, and abuse prevention;
- corrective action plans and response to compliance issues;
- Medicaid program requirements and the required provider's category of services;
- coding and billing requirements and best practices;
- claim development and submission; and
- for Medicaid MCOs only, the fraud, waste, and abuse prevention program requirements of Subpart 521-2.[27]

OMIG Compliance Program Reviews—§ 521-1.5

OMIG may review a required provider's compliance program to determine its compliance with the regulations. OMIG will notify a required provider of its intent to commence a

review, and such notice will include the review period and procedures that will be undertaken to complete the review. Once the review is complete, OMIG will advise the Required Provider if it satisfies the requirements of Part 521 and if the Required Provider needs to correct any deficiencies.[28]

Subpart 521-2: Medicaid Managed Care Fraud, Waste, and Abuse Prevention

Subpart 521-2 is proposed to "establish the requirements, consistent with [Social Services Law], for Medicaid Managed Care Fraud, Waste and Abuse Prevention programs." [29] If enacted, Subpart 521-2 will compel MMCOs to examine and, potentially, restructure their fraud, waste, and abuse prevention strategies.

Definitions—§ 521-2.1 and § 521.2

The regulation defines "abuse" to include practices that are inconsistent with sound fiscal, business, medical or professional practices. These practices could result in the following:

- unnecessary costs to the Medicaid program; and
- payments for services that fall below recognized health care standards or were not medically necessary.[30]

The definition of "fraud" includes the following:

- intentional deceptions or misrepresentations made with knowledge that it could result in an unauthorized benefit; and
- acts that constitute fraud under applicable federal or New York laws, including New York's Medicaid false claims act.[31]

Duties of Medicaid Managed Care Organizations—§ 521-2.3

The below requirements will serve as a minimum standard of a MMCO's fraud, waste, and abuse prevention program, and as such, a MMCO's prevention program may go above and beyond the below requirements:

- **Fraud, Waste, and Abuse Prevention Policies:** MMCOs must adopt and implement policies for the detection and prevention of fraud, waste, and abuse.
- **Record Retention:** In addition to the record retention requirements imposed under a MMCO's contract with the Department of Social Services, MMCOs and their subcontractors must retain all records demonstrating they have adopted, implemented, and operated a fraud, waste, and abuse prevention program satisfying the requirements of this Subpart.
- **Contracts with Third Parties:** MMCOs must ensure that their contracts with contractors, agents, subcontractors, independent contractors, and participating providers specify that such parties are subject to audit, investigation, or review under the MMCO's fraud, waste, and abuse prevention program.[32]

Compliance Program—§ 521-2.4(a)

MMCOs (among other entities) must implement and maintain a compliance program in accordance with Subpart 521-1. Under this Subpart 521-2, MMCOs must ensure that its fraud, waste, and abuse prevention programs are incorporated into its compliance program and otherwise satisfies the requirements of § 521-1.4(a) related to written policies and procedures, compliance officer duties, and training requirements.[33]

Special Investigation Unit—§ 521-2.4(b)

MMCOs with an enrolled population in excess of 1,000 persons or more in any given year, must establish a full-time Special Investigation Unit (SIU).[34] SIUs must identify and investigate cases of potential fraud, waste, and abuse, and in turn, report such cases to OMIG and report potential fraud to the Medicaid Fraud Control Unit (MFCU).[35] An MMCO's SIU must also operate as a separate and distinct unit from any other function or unit of the MMCO.[36]

- **Staffing Requirements:** MMCOs must employ at least one full-time lead investigator and one SIU director. The lead investigator and SIU director must be based in New York and will be responsible for communicating and coordinating with OMIG and MFCU. In addition, MMCOs must employ or utilize existing employees to support the work of the SIU. MMCOs must employ one full-time investigator per 60,000 enrollees, except in the case of a managed long-term care plan, which must employ one full-time investigator per 6,000 enrollees. MMCOs may propose to OMIG alternative minimum staffing levels if such staffing levels would be no less effective than required by this Subpart.[37]
- **SIU Investigator Qualifications:** SIU investigators must either possess: (i) a minimum of 5 years' experience in the healthcare field working in fraud, waste, and abuse investigations and audits, a minimum of 5 years of insurance claims investigation experience or professional investigation experience with law enforcement agencies, or 7 years of professional investigation experience involving economic or insurance related matters; (ii) an associate's or bachelor's degree in criminal justice or a related field; or (iii) employment as an investigator in an MMCO's SIU on or before this Subpart's effective date.[38]
- **SIU Work Plan:** At least annually, SIUs most develop a work plan detailing the activities they plan to complete

that upcoming year. The work plan may be a standalone document or part of the compliance program described in Subpart 521-1.[39]

- **Delegation:** A MMCO may delegate all or part of the functions of the SIU, however, the MMCO will be ultimately responsible for meeting the requirements of this Subpart.[40]

MMCO Audits and Investigations—§ 521-2.4(c)

Through its respective SIUs and in coordination with the MMCOs' compliance officers, MMCOs must audit, investigate, or review fraud, waste, and abuse cases related to its participation in the Medicaid Program. Such audits, investigations, and review must involve at least one percent or more of the aggregate of the Medicaid Program claims it pays to providers and subcontractors and must be of the MMCO's clinical and billing records.[41]

Fraud, Waste, and Abuse Prevention Plan Requirements—§ 521-2.4(i)

MMCOs must develop and submit to OMIG a fraud, waste, and abuse prevention plan within 90 calendar days of the effective date of this Subpart or of signing a new contract with the Department of Social Services to begin participation as an MMCO. MMCOs must implement a fraud, waste, and abuse prevention plan within 180 calendar days from the date the MMCO executes its contract with the Department of Social Services to participate as a MMCO and develops its plan pursuant to this section. Such fraud, waste, and abuse prevention plans must include the following:

- A description of the MMCO's program for preventing and detecting fraud, waste, and abuse.
- A description, if applicable, of the SIU's organization, including: Titles and job descriptions of the investigators, investigative supervisors, and other staff; the minimum qualifications for employment in the positions; the geographical location and assigned location of each investigator and investigative supervisor; the support staff and other physical resources available to the SIU; and the supervisory and reporting structure within the SIU and between the SIU and the management of the MMCO.
- A detailed description of the roles, responsibilities, and interaction between SIU and the MMCO's compliance officer; the MMCO's legal department; the claims, quality, member services, utilization review, compliant procedures, and underwriting functions of the MMCO; and OMIG, the Department of Social Services, and MFCU.
- The MMCO's policies and procedures as further detailed above under Compliance Program and in Subpart 521-1.4(a).
- The criteria for internal referral of a case to the SIU for evaluation. In addition, the plan must include the criteria SIU uses for reporting cases of potential fraud, waste, and abuse to the Department of Social Services and OMIG.[42]

MMCO Annual Reports—§ 521-2.4(j)

After January 31 of each calendar year, each MMCO must file an annual report (on a form to be developed by the Department of Social Services) for the preceding year that must include at least the following:

- A description of the MMCO's experience, performance, and cost effectiveness in implementing the fraud, waste, and abuse program.
- The MMCO's proposals for modifications to its fraud, waste, and abuse prevention program and plan to amend its operations to remedy deficiencies.
- A summary of the MMCO's SIU staffing.
- A summary of the MMCO's subcontractors or vendors who perform audit investigation or review functions.
- The total number of reported cases of potential fraud, waste, or abuse identified by the MMCO.
- The MMCO's SIU work plan for the next calendar year.
- The results of service verification reviews as specified in the MMCO's contract with the Department of Social Services.[43]

Subpart 521-3: Self-Disclosure Program

Subpart 521-3 would establish regulations, consistent with the provisions found in the Social Services Law,[44] for reporting, explaining, and returning overpayments to OMIG. This Subpart also provides the requirements for submissions through OMIG's Self-Disclosure program.

Scope and Definitions—§ 521-3.1 and § 521-3.2

The regulation applies to all persons who have received an overpayment from the Medicaid program. "Persons" is defined to include providers, MMCOs, and subcontractors and network providers of MMCOs, but does not include Medicaid recipients. An "overpayment" includes any amount that Medicaid did not authorize payment of, regardless of the reason, and can include payments resulting from inaccurate or improper cost reporting, improper claiming, unacceptable practice, fraud, abuse, or mistake.[45]

Reporting and Returning Overpayments—§ 521-3.3

In the event of an overpayment, a Self-Disclosure Statement must be submitted to OMIG by the later of sixty (60) days after the date of the overpayment's identification of the overpayment or, if applicable, the date that a corresponding cost report is due.[46] OMIG will toll this deadline (i) upon receiving a Self-Disclosure Statement and the deadline will remain tolled until the execution of a Self-Disclosure and Compliance Agreement (defined below), (ii) the person withdraws from the Self-Disclosure Program, (iii) the full amount of the overpayment is repaid, or (iv) OMIG terminates that person's participation in the Self-Disclosure Program.[47]

An overpayment is considered identified when a person "has or should have, through the exercise of reasonable diligence, determined that they have received an overpayment and quantified the amount of the overpayment."[48]

Self-Disclosure Program Eligibility—§ 521-3.4(b)

A person is eligible to participate in the Self-Disclosure Program if the following conditions are satisfied:

- the disclosing party is not currently under audit, investigation, or review by OMIG for the disclosed overpayment;
- OMG has not previously identified the overpayment;
- the disclosing party has complied with all overpayment reporting deadlines; and
- the disclosing party is not the subject of a criminal investigation being conducted by the New York Medicaid Fraud Control Unit or the federal government.[49]

Following a written request, OMIG, in its discretion, can allow the following to occur:

- waive the interest on an amount of an overpayment, in whole or in part;
- allow repayment to occur in installments pursuant to a Self-Disclosure and Compliance Agreement;
- consider the reporting and returning of overpayments a mitigating factor in determining whether to pursue an administrative enforcement action; and
- consider the person's reporting and returning of overpayments as a factor in determining whether the person has adopted and implemented a compliance program that is effective.

If OMIG determines that a person is ineligible for the Self-Disclosure Program, OMIG will provide notice in writing.[50]

Self-Disclosure Statement—§ 521-3.4(c) and § 521-3.4(d)

A Self-Disclosure Statement must contain the following information:

- **Estimation of Overpayment:** The Self-Disclosure Statement must contain both the estimated overpayment and the methodology used to arrive at the estimation.
- **Explanation of Overpayment:** The explanation of the overpayment shall include (i) a description and explanation of the circumstances leading to the overpayment; (ii) how the circumstances were discovered; (iii) the dates that the overpayment was received and identified; (iv) the method for calculating the overpayment; and (v) the actions taken to correct the overpayment.[51]

The Self-Disclosure Statement must also include the person's contact information as well as all relevant data files and indicate any requests for repayment through installment plans or the waiver of any applicable interest.[52] In addition, the Self-Disclosure Statement must include an agreement to return the full amount of the overpayment and interest, if applicable.[53] OMIG must acknowledge receipt and conduct a preliminary review within twenty (20) days of receiving the submission. Following the preliminary review, OMIG will either provide a notification that the submission is complete or return the submission as incomplete.[54] If the submission is determined to be incomplete, OMIG will identify the information that is needed to render the submission complete. Once OMIG determines that a submission is complete and accepts it, OMIG will verify the overpayment amount and issue notification of that amount, as well as the instructions for repayment. An overpayment must be remitted to OMIG within fifteen (15) days of this notification.[55]

Self-Disclosure and Compliance Agreement and Termination—§ 521-3.4(e)-(f)

A Self-Disclosure and Compliance Agreement is an agreement between OMIG and a person who agrees to repay an overpayment and related interest through installment payments and/or agrees to implement corrective action to prevent such overpayment from reoccurring.[56] A Self-Disclosure and Compliance Agreement must include the following terms and conditions:

- an agreement to repay the amount of the overpayment and, if applicable, interest;
- a repayment schedule, if the Self-Disclosure and Compliance Agreement allows for repayment in installments; and
- identification and agreement to implement any corrective actions to address what caused the overpayment to occur.[57]

The Self-Disclosure and Compliance Agreement must be executed and returned within fifteen (15) days of receiving it from OMIG and the failure to do so can result in terminate of participation in the Self-Disclosure Program.[58] OMIG also can terminate a person's participation in the Self-Disclosure Program immediately for attempting to defeat or evade an overpayment or for omitting material information, or providing false material information in the Self-Disclosure Statement or in other communications.[59] OMIG will give notice within five (5) business days if it terminates participation.

Conclusion

The public comment rules for the proposed Part 521 expired on Sept. 12, 2022. Though it is still to be determined if the Department of Social Services will adopt these regulations, each Subpart provides excellent food for thought and considerations for how Medicaid providers and MMCOs should approach fraud, waste, and abuse prevention within their organizations. Whether through implementation of new policies, considering the appointment of additional compliance personnel, or undertaking an overhaul of existing compliance policies and protocols, the proposed Part 521 can certainly provide guidance to providers and attorneys alike on the elements of effective Medicaid fraud, waste, and abuse prevention programs.

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Endnotes

1. 44 N.Y. Reg. 14 (July 13, 2022).
2. *Id.*
3. 9 N.Y.C.R.R. 8.5.
4. *About the Medicaid Redesign Team*, N.Y. Dep't of Health, at https://health.ny.gov/health_care/medicaid/redesign/aboutmrt.htm (revised March 2022).
5. 9 N.Y.C.R.R. 8.5.
6. *About the Medicaid Redesign Team*, *supra* note 4.
7. *Medicaid Redesign Team (MRT) II*, N.Y. Dep't of Health, at https://health.ny.gov/health_care/medicaid/redesign/mrt2/ (revised February 2022).
8. *Medicaid Redesign Team (MRT) II*, N.Y. Dep't of Health, at https://health.ny.gov/health_care/medicaid/redesign/mrt2/ (revised February 2022).
9. *Id.*
10. N.Y. Soc. Serv. Law § 363-D
11. *Id.*
12. 44 N.Y. Reg. 15 (July 13, 2022)
13. *Id.*
14. *18 N.Y.C.R.R. Part 521 – Fraud, Waste and Abuse Prevention*, N.Y. Dep't of Soc. Services, https://omig.ny.gov/media/77671/download?attachment (last accessed October 19, 2022).
15. 18 N.Y.C.R.R. 521-1.1 (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 8–11.
16. 18 N.Y.C.R.R. 521.1; 18 N.Y.C.R.R. 521.2(a).
17. 18 N.Y.C.R.R. 521-1.2(b)(3) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 9–10.
18. 18 N.Y.C.R.R. 521-1.3(c)(2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 12.
19. 18 N.Y.C.R.R. 521-1.2(b)(1) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 9–10.
20. 18 N.Y.C.R.R. 521-1.3(d) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 12.
21. 18 N.Y.C.R.R. 521-1.2(b)(9) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 9–10.
22. 18 N.Y.C.R.R. 521-1.3(d) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 13.
23. 18 N.Y.C.R.R. 521-1.3(f) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 13.
24. 18 N.Y.C.R.R. 521-1.4(a) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 14.
25. 18 N.Y.C.R.R. 521-1.4(b) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 16–17.
26. 18 N.Y.C.R.R. 521-1.4(c) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 16–17.
27. 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 20.
28. 18 N.Y.C.R.R. 521-1.5 (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 25–27.
29. 18 N.Y.C.R.R. 521-1.5 (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 25–27.

30. 18 N.Y.C.R.R. 521-2.2(b)(1) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 28–29.
31. 18 N.Y.C.R.R. 521-2.2(b)(2) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 28–29.
32. 18 N.Y.C.R.R. 521-2.3(a)-(c) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 29–30.
33. 18 N.Y.C.R.R. 521-2.4(a) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 30–31.
34. 18 N.Y.C.R.R. 521-2.4(b) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 31.
35. *Id.*
36. *Id.*
37. 18 N.Y.C.R.R. 521-2.4(a)(1)(i) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 31–33.
38. 18 N.Y.C.R.R. 521-2.4(a)(2) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 33.
39. 18 N.Y.C.R.R. 521-2.4(a)(3) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 33.
40. 18 N.Y.C.R.R. 521-2.4(a)(4) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 33.
41. 18 N.Y.C.R.R. 521-2.4(c) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 34.
42. 18 N.Y.C.R.R. 521-2.4(i) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 37–39
43. 18 N.Y.C.R.R. 521-2.4(j) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 39.
44. *See* N.Y. Soc. Serv. Law § 363-d(6)–(7).
45. 18 N.Y.C.R.R. 521-3.2(b)(3)–(4) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 42.
46. 18 N.Y.C.R.R. 521-3.3(b)(1) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 43.
47. 18 N.Y.C.R.R. 521-3.3(b)(1) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 43–44.
48. 18 N.Y.C.R.R. 521-3.3(b)(2)-(3) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 43.
49. 18 N.Y.C.R.R. 521-3.4(b)(1) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 44.
50. 18 N.Y.C.R.R. 521-3.4(b)(2); 18 N.Y.C.R.R. 521-3.4(b)(4) (2022); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 43.
51. 18 N.Y.C.R.R. 521-3.4(c)(2)(i)–(ii).
52. *Id.*
53. *Id.*
54. 18 N.Y.C.R.R. 521-3.4(d)(1); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 47–48.
55. *Id.*
56. 18 N.Y.C.R.R. 521-3.4(e)(1); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 49.
57. 18 N.Y.C.R.R. 521-3.4(e)(2); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 49.
58. 18 N.Y.C.R.R. 521-3.4(e)(3); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 49.
59. 18 N.Y.C.R.R. 521-3.4(f); *see also* 18 N.Y.C.R.R. Part 521 – *Fraud, Waste and Abuse Prevention*, *supra* note 14, at 50.

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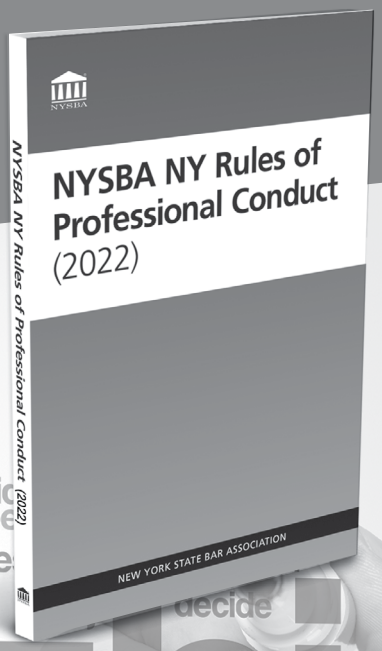

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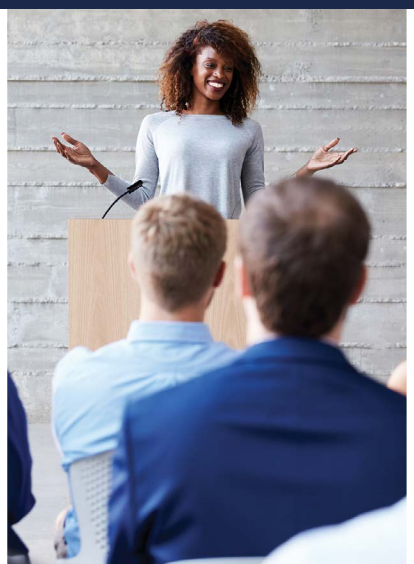

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