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NYSBA

Health Law Journal

A Peer Reviewed Law Journal

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

The Direct Primary Care Model: Considerations for New York Providers, Patients and Employers

A Patchwork Framework: A Range of State Health Care Transaction Review Laws Emerges

Taking a Closer Look: Assessing Biometric Authentication in Healthcare Settings and Beyond

GNYHA congratulates the **NYSBA Health Law Section** on another great year of serving its members!

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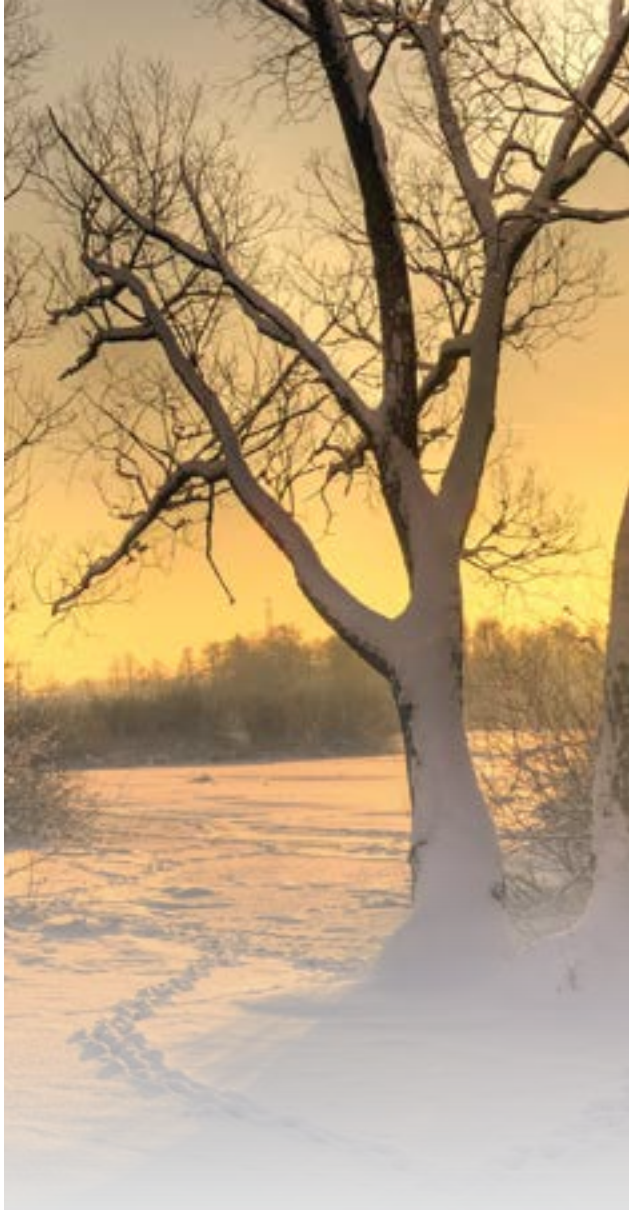

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In Each Issue

Publication and Editorial Policy

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

Publication Policy
All articles should be submitted to:

Cassandra DiNova
Email: cassandra.dinova@cdphp.com

Submitted articles must include a cover letter giving permission for publication in this *Journal.* We will assume your submission is for the exclusive use of this *Journal* unless you advise to the contrary in your letter. Authors will be notified only if articles are rejected. Authors are encouraged to include a brief biography with their submissions. Authors will be asked to sign a copyright agreement that can be found here:
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Accommodations for Persons with Disabilities
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A Message From the Section Chair

By Lisa D. Hayes

I want to extend a very Happy New Year to everyone. We are looking forward to another exciting year of sharing ideas through legal education, advocacy and networking. The health care industry is facing ongoing struggles with, for example, workforce challenges post-pandemic, as well as clinical practice expansions using innovations and artificial intelligence. The Health Law Section and the Health Law Journal continue to be resources for current news and information from industry experts and we encourage you to join us.

Health Law Journal

We welcome all the new members of the Health Law Journal Editorial Board and we thank you for lending your expertise to the Journal. Please read more about the new Editorial Board in the Editor's Column. Thank you again Cassandra DiNova, legal counsel, CDPHP, for your leadership as editor of the Health Law Journal.

Health Law Section – Annual Meeting

The Health Law Section will return to New York City for its annual meeting entitled "Emerging Issues in Health Law" on Tuesday, January 16, 2024 at the New York Hilton. Under the leadership and direction of Margie Davino, Fox Rothschild and Daniel Weinstein, Manatt, Phelps & Phillips, LLP, this year promises to be another successful legal education and networking opportunity. The Committee Continental Breakfast starts at 7:30 am and provides colleagues an opportunity to network and plan for the 2024 calendar year. The section will also host its Annual Health Law Luncheon sponsored by the Greater New York Hospital Association. Panel discussions includes a General Counsel Roundtable; "Artificial Intelligence in Healthcare;" "Physician Practice Transactions;" "CMS/CMMI Innovation Models;" and "Healthcare Antitrust Considerations: DOJ/FTC Guidelines." Lastly, we would like to thank the sponsors of the Health Law Section's Annual Meeting; platinum lunch sponsor – Greater New York Hospital Association; silver sponsor: Phillips Lytle, LLP and Proskauer; and bronze sponsor: Buchanan.

Stay Connected

Please follow us on LinkedIn at New York State Bar Association Health Law Section (#nysbahls) for information about health law issues and upcoming legal education and networking events.

Lisa D. Hayes

Editor Announcement

By Cassandra DiNova

I am very excited to announce the appointment of the Editorial Board to the NYSBA Health Law Journal (the Journal), please see below members of the Editorial Board.

Editorial Board

Mary Beth Morrissey, Yeshiva University

Christine Moundas, Partner, Ropes and Gray

Danielle Tangorre, Partner, Robinson & Cole

Robert Swidler, recently retired as general counsel to St. Peter's Health Partners and St. Joseph's Health

I appreciate everyone's support and dedication to the Journal. Thank you to our loyal Health Law Section members for reading the Journal!

In the Legislature

By Michael A. Paulsen

The new legislative session is almost underway, with early indications that the Governor and Legislature will face fiscal challenges with a projected budget deficit of almost $9 billion for State Fiscal Year 2025 (FY 25). As health care expenditures represent a significant portion of the State budget, any deficit closing measures are anticipated to impact New York's health care delivery system.

Looking ahead, we anticipate that many health care policy issues will be influenced by the projected budget deficit. The following health care policy issues are likely to be under consideration during the upcoming New York State legislative session:

Healthcare Provider Finances

The last two enacted budgets have provided significant support for health care providers and workers, with investments including the Health Care and Mental Hygiene Worker Bonus program (HWB), home health worker minimum wage increases, health care capital funding for providers, substantial increases to Medicaid reimbursement for hospitals and nursing homes, and increased funding for distressed and safety net hospitals. Despite these investments, both historically financially stable and distressed health care providers continue to face financial pressures, mainly as a result of sustained higher labor costs due to workforce shortages.

The challenging fiscal environment is expected to limit the ability of the State to support new investments in the upcoming budget and may impact the ability to sustain existing investments. Solving the fiscal needs of the health care system with limited financial resources is likely to present one of the most significant challenges to policymakers over the upcoming years.

Commission on the Future of Health Care

The Governor announced a proposal to establish a new 'Future of Health Care' Commission in her 2023 State of the State address. The Commission was tasked with developing a roadmap for transformation, guide statewide and regional planning, make recommendations on policy, regulation and reimbursement, and shape the allocation strategy of subsidies for financially distressed hospitals and health care capital funding. While the enacted budget did not contain statutory authorization or provide an appropriation to support the Commission and its process, it appears that the Commission has started work to develop recommendations.

With fiscal constraints likely arising in the upcoming budget, it is likely that recommendations developed by the Commission will be under consideration this session. While it is unclear what the Commission will ultimately recommend, initial comments regarding the Commission indicate that it may include cuts to the Medicaid program or provider consolidation.

Medical Debt

The Governor and Legislature have both expressed a clear desire to reduce the burdens and impact of medical debt on New Yorkers. There continues to be significant activity and new proposals on this issue. In 2023, the Legislature passed

the Fair Medical Debt Reporting Act, which would prohibit medical debt from being reported to credit reporting agencies or included in a consumer's credit report.[1] More recently, legislation was introduced that would prohibit state-operated hospitals from bringing litigation against a patient to collect a medical debt.[2] While the impact of this legislation would be limited to the five New York State operated hospitals, it would establish a significant precedent in New York if passed.

These recent changes would join the growing list of enacted legislation over the last few years designed to both reduce instances of medical debt arising and from causing financial harm, including:

- A prohibition on health care providers placing home liens on an individual's primary residence or garnishing wages to collect on medical debt;[3]
- A prohibition on hospitals and providers from charging a patient a "facility fee" that is not covered by their insurance unless the patient was notified prior to the service that a facility fee was charged;[4] and
- A reduction in the statute of limitations for medical debt lawsuits from six to three years.[5]

Single Payer

For the first time in almost 30 years, the New York Health Act (single-payer health coverage) was not an active bill in the Assembly in 2023. The interruption was short-lived, as significant changes were made to the bill shortly after session concluded. An amended version of the bill (S7590/A7897) was reintroduced in July, resulting in the bill being active again in both houses, with Assemblymember Amy Paulin taking over as lead sponsor in the Assembly.

The recent amendments were designed to gain the support of public-sector employees and the unions that represent them. As revised, the bill sets a cost-sharing structure for public sector union members and their employers, setting a floor for all public employers to cover at least 80% of the new tax on behalf of their employees. Public employers that pay over 80% of the cost of employees' health benefits before the New York Health Act goes into effect would be required to cover that same share of the new payroll tax with public employers. The sponsors to the bill indicated that the changes were designed to broaden support for the bill and the overall single-payer health coverage concept.

Michael A. Paulsen is of counsel in the Albany office of Manatt, Phelps & Phillips, LLP, where he focuses his practice on legal, regulatory and legislative issues for health care providers.

Endnotes

1. A.B. 6275A/S.B. 4970A (2023). This bill was signed by the governor on December 13.
2. A.B. 8170 (2023).
3. N.Y. CPLR 5201 (b) and 5231(b).
4. N.Y. Public Health Law § 2830.
5. N.Y. CPLR 213(d).

In the New York State Agencies

Compiled by Nicola Coleman and Binny Seth

6/14/23:

Voluntary Certification of Recovery Residences in New York State

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services proposed to add Part 860 to Title 14 N.Y.C.R.R. to establish requirements for recovery residences certified by the Office of Addiction Services and Supports (OASAS). *See* N.Y. Register June 14, 2023.

Gender Identity and Expression

Notice of Adoption. The Office for People with Developmental Disabilities amended § 633.4 of Title 14 N.Y.C.R.R. to ensure people are treated with dignity and respect. Filing Date: May 30, 2023. Effective Date: June 14, 2023. *See* N.Y. Register June 14, 2023.

Protection of Individuals Receiving Services

Notice of Adoption. The Office for People with Developmental Disabilities amended § 633.16 of Title 14 N.Y.C.R.R. to add clarity and consistency. Filing Date: May 26, 2023. Effective Date: June 14, 2023. *See* N.Y. Register June 14, 2023.

Eligibility Determination

Notice of Adoption. The Office for People with Developmental Disabilities amended § 629.1 and added 629.2 to Title 14 N.Y.C.R.R. to establish the eligibility criteria for individuals applying for OPWDD services. Filing Date: May 26, 2023. Effective Date: June 14, 2023. *See* N.Y. Register June 14, 2023.

6/21/23:

Humane Euthanasia of Animals

Notice of Proposed Rule Making. The Department of Health proposed to amend § 80.134 of Title 10 N.Y.C.R.R. to provide for humane euthanasia of animals. *See* N.Y. Register June 21, 2023.

6/28/23:

Registration and Operation of Central Fill Pharmacies

Notice of Proposed Rule Making. The Department of Education amended §§ 29.7, 63.6 and 63.8 of Title 8 N.Y.C.R.R. to establish parameters for the central fill pharmacy model. *See* N.Y. Register June 28, 2023.

Cybersecurity Requirements for Financial Services Companies

Notice of Revised Rule Making. The Department of Financial Services amended Part 500 of Title 23 N.Y.C.R.R. to ensure that DFS-regulated entities most effectively address new and evolving cybersecurity threats. *See* N.Y. Register June 28, 2023.

Licensure and Practice of Nursing Home Administration

Notice of Adoption. The Department of Health amended Part 96 of Title 10 N.Y.C.R.R. to clarify and update the nursing home administrator licensure program. Filing Date: June 12, 2023. Effective Date: June 28, 2023. *See* N.Y. Register June 28, 2023.

7/12/23:

Registration of Pharmacy Benefit Managers

Notice of Emergency Rule Making. The Department of Financial Services amended Part 451 (Regulation 221) of Title 11 N.Y.C.R.R. to maintain the status quo while the Department promulgates permanent regulations under Public Health Law § 280-a. Filing Date: June 23, 2023. Effective Date: June 23, 2023. *See* N.Y. Register July 12, 2023.

General Duties, Accountability, and Transparency Provisions for Pharmacy Benefit Managers; Electronic Filings

Notice of Adoption. The Department of Financial Services amended Part 6 (Regulation 195) and added Part 452 (Regulation 222) to Title 11 N.Y.C.R.R. to define and clarify the provisions of PHL 280-a(2) and to require electronic filings for PBMs. Filing Date: June 23, 2023. Effective Date: July 12, 2023. *See* N.Y. Register July 12, 2023.

Excess Line Placements Governing Standards

Notice of Adoption. The Department of Financial Services amended Part 27 of Title 11 N.Y.C.R.R. to conform to changes made by chapter 833 of the Laws of 2022 and chapter 93 of the Laws of 2023 and prior amendments. Filing Date: June 23, 2023. Effective Date: July 12, 2023. *See* N.Y. Register July 12, 2023.

Supported Employment

Notice of Proposed Rule Making. The Office for People with Developmental Disabilities amended Subparts 635-10 and 635-99 of Title 14 N.Y.C.R.R. to update requirements of supported employment. *See* N.Y. Register July 12, 2023.

7/19/23:

Investigation of Communicable Disease

Notice of Emergency Rule Making. The Department of Health amended Part 2 and § 405.3 of Title 10 N.Y.C.R.R. to control communicable disease. Filing Date: June 29, 2023. Effective Date: June 29, 2023. *See* N.Y. Register July 19, 2023.

Hospital and Nursing Home Personal Protective Equipment (PPE) 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: June 29, 2023. Effective Date: June 29, 2023. *See* N.Y. Register July 19, 2023.

Clinical Staffing in General Hospitals

Notice of Adoption. The Department of Health amended §§ 400.25, 405.5, 405.12, 405.19, 405.21, 405.22 and 405.31 of Title 10 N.Y.C.R.R. to require general hospitals to have clinical staffing committees and create clinical staffing plans. Filing Date: June 30, 2023. Effective Date: July 19, 2023. *See* N.Y. Register July 19, 2023.

Notice of Expiration

The following notice has expired and cannot be reconsidered unless the Department of Health publishes a new notice of proposed rulemaking:

The Department of Health, *Repeal of Limits on Administrative Expenses and Executive Compensation*, I.D. No. HLT-26-22-00003-P. Proposed on June 29, 2022. Expired on June 29, 2023. *See* N.Y. Register July 19, 2023.

8/2/23:

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

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 810 of Title 14 N.Y.C.R.R. to update outdated and stigmatizing language, clarify the certification process and create a provisional operating certificate. Filing Date: July 12, 2023. Effective Date: August 02, 2023. *See* N.Y. Register August 2, 2023.

Financial Statement Filings and Accounting Practices and Procedures

Notice of Proposed Rule Making. The Department of Financial Services proposed a consensus rulemaking to amend

Part 83 (Regulation 172) of Title 11 N.Y.C.R.R. to update reference to NAIC AP&P Manual as of date from March 2021 to March 2023, and other non-substantive changes. *See* N.Y. Register August 2, 2023.

Expanded Syringe Access Programs (ESAPs)

Notice of Proposed Rule Making. The Department of Health proposed to amend § 80.137 of Title 10 N.Y.C.R.R. to remove the requirement that ESAPs may only furnish a quantity of 10 or fewer syringes at a time. *See* N.Y. Register August 2, 2023.

Temporary Assistance (TA) Resource Limits and New York Achieving a Better Life Experience (NY ABLE) Program Accounts

Notice of Proposed Rule Making. The Office of Temporary and Disability Assistance amended § 352.23(b) and added § 352.23(b)(12) to Title 18 N.Y.C.R.R. to update State regulations consistent with statutory amendments to SSL § 131-n(1)(a) and (k). *See* N.Y. Register August 2, 2023.

8/16/23:

Definitions, Licensing of PBMs, Contracting with Network Pharmacies, Acquisition of PBMs, Consumer Protections and Audits

Notice of Proposed Rule Making. The Department of Financial Services proposed to amend Parts 450 (Regulation 219), 454 (Regulation 224); addition of Parts 456 (Regulation 226), 457 (Regulation 227), 458 (Regulation 228) and 459 (Regulation 229) to Title 11 N.Y.C.R.R. to establish definitions, licensing, contracting with pharmacies, acquisition of PBMs, consumer protections and audit regulations. *See* N.Y. Register August 16, 2023.

8/30/23:

Inclusion of a Health Equity Impact Assessment as Part of the Certificate of Need (CON) Process

Notice of Adoption. The Department of Health added § 400.26 and amended §§ 600.1 and 710.2 of Title 10 N.Y.C.R.R. to ensure community members and stakeholders are meaningfully engaged and considered in proposed facility projects. Filing Date: August 16, 2023. Effective Date: June 14, 2023. *See* N.Y. Register August 30, 2023.

COVID-19 Vaccination Program

Notice of Proposed Rule Making. The Office of Mental Health proposed to repeal part 557 of Title 14 N.Y.C.R.R.. *See* N.Y. Register August 30, 2023.

Clinical Review Criteria

Notice of Proposed Rule Making. The Office of Mental Health proposed to add Part 514 to Title 14 N.Y.C.R.R. to adopt standards and processes to obtain and approve clinical review criteria for the treatment of mental illness. *See* N.Y. Register August 30, 2023.

9/6/23:

Principle-Based Reserving

Notice of Proposed Rule Making. The Department of Financial Services proposed to amend Part 103 (Regulation 213) of Title 11 N.Y.C.R.R. to adopt the 2023 Valuation Manuel. *See* N.Y. Register September 6, 2023.

Use of Telehealth in Crisis Stabilization Centers

Notice of Proposed Rule Making. The Office of Mental Health and the Office of Addiction Services and Supports proposed to add Part 602 to Title 14 N.Y.C.R.R. to establish regulations regarding the use of Telehealth in Crisis Stabilization Centers. *See* N.Y. Register September 6, 2023.

9/13/23:

Utilization Review

Notice of Adoption. The Department of Health amended §§ of 505.2, 506.5 and Part 511 of Title 18 N.Y.C.R.R. to decrease the administrative burden on enrolled Medicaid fee-for-service members and providers. Filing Date: August 29, 2023. Effective Date: September 13, 2023. *See* N.Y. Register September 13, 2023.

Lead Testing in School Drinking Water

Notice of Proposed Rule Making. The Department of Health proposed to amend Subpart 67-4 of Title 10 N.Y.C.R.R. to lower action level for lead in school drinking water from 15 parts per billion (ppb) to 5 ppb and revise reporting requirements. *See* N.Y. Register September 13, 2023.

Communicable Diseases Reporting and Control — Adding Respiratory Syncytial Virus (RSV) and Varicella

Notice of Proposed Rule Making. The Department of Health proposed to amend § 2.1 of Title 10 N.Y.C.R.R. to dd Respiratory Syncytial Virus (RSV) and Varicella to the list of diseases. *See* N.Y. Register September 13, 2023.

9/27/23:

Investigation of Communicable Disease

Notice of Emergency Rule Making. The Department of Health amended Part 2 and § 405.3 of Title 10 N.Y.C.R.R. to control the spread of communicable disease. Filing Date:

September 9, 2023. Effective Date: September 9, 2023. *See* N.Y. Register September 27, 2023.

Trauma Centers — Resources for Optimal Care of the Injured Patient

Notice of Emergency/Proposed Rule Making. The Department of Health amended § 405.45 of Title 10 N.Y.C.R.R. to update the edition of Resources for Optimal Care of the Injured Patient from 2014 to 2022. Filing Date: September 12, 2023. Effective Date: September 12, 2023. *See* N.Y. Register September 27, 2023.

Standard Utility Allowances (SUAs) for the Supplemental Nutrition Assistance Program (SNAP)

Notice of Emergency/Proposed Rule Making. The Office of Temporary and Disability Assistance amended § 87.12(f)(3)(v)(a)-(c) of Title 18 N.Y.C.R.R. to set forth the federally-approved SUAs for SNAP benefit calculations effective October 1, 2023. Filing Date: September 11, 2023. Effective Date: October 1, 2023. *See* N.Y. Register September 27, 2023.

10/4/23:

Credentialing of Addiction Professionals

Notice of Emergency/Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 853 of Title 14 N.Y.C.R.R. to add a new credentialing pathway for CASAC-Provisional and modify outdated terminology. Filing Date: September 19, 2023. Effective Date: September 26, 2023. *See* N.Y. Register October 4, 2023.

Investigation of Communicable Disease

Notice of Adoption. The Department of Health amended Part 2 of § 405.3 of Title 10 N.Y.C.R.R. to control communicable disease. Filing Date: September 15, 2023. Effective Date: October 4, 2023. *See* N.Y. Register October 4, 2023.

Removal of the COVID-19 Vaccine Requirement for Personnel in Covered Entities

Notice of Adoption. The Department of Health repealed § 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 remove the COVID-19 Vaccine Requirement for Personnel in Covered Entities. Filing Date: September 18, 2023. Effective Date: October 4, 2023. *See* N.Y. Register October 4, 2023.

Notice of Expiration

The following notice has expired and cannot be reconsidered unless the Department of Health publishes a new notice of proposed rulemaking:

The Department of Health, *Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements*, I.D. No. HLT-23-22-00001-P. Proposed on May 19, 2022. Expired on September 6, 2023. *See* N.Y. Register October 4, 2023.

10/11/23:

Minimum Standards for the New York State Partnership for Long-Term Care Program

Notice of Proposed Rule Making. The Department of Financial Services proposed a consensus rulemaking to amend Part 39 (Regulation 144) of Title 11 N.Y.C.R.R. to update the current minimum daily benefit amounts for partnership long term care coverage for the period 1/1/2024-1/1/2033. *See* N.Y. Register October 11, 2023.

Early Intervention Program

Notice of Revised Rule Making. The Department of Health proposed to amend Subpart 69-4 of Title 10 N.Y.C.R.R. to conform existing program regulations for the Early Intervention Program to Federal regulations and State statute, as well as to provide additional clarification. *See* N.Y. Register October 11, 2023.

Nicola Coleman and **Binny Seth** both participate in the Health & FDA Business Group and the Insurance Regulatory & Transaction Group at Greenberg Traurig's Albany office, where they both focus on health care issues, including regulatory, contracting, transactional and compliance matters. Prior to joining the firm, Ms. Coleman served as deputy counsel for the New York State Senate and as an associate counsel for the New York State Assembly, as well as counsel for the New York Department of Health during the creation of the Health Insurance Marketplace. Mr. Seth's past experience includes serving as in-house counsel to one of the largest Medicaid Managed Care organizations in New York.

New York State Fraud, Abuse and Compliance Developments

Edited by Margaret M. Surowka, compiled by various attorneys at Barclay Damon as indicated within column

New York State Department of Health Medicaid Decisions

Compiled by Dena M. DeFazio

Warren Center for Rehabilitation and Nursing a/k/a Warren Operations Associates, LLC (Decision, September 7, 2023, Tina M. Champion, ALJ).

Appellant is a residential health care facility ("RHCF") located in Queensbury, New York. The New York State Office of the Medicaid Inspector General ("OMIG") performed a field audit to review Appellant's documentation in support of its Minimum Data Set ("MDS") submission for the census period ending on January 25, 2016, which was used to calculate Appellant's Medicaid Program reimbursement rate for the period of July 1, 2016 through December 31, 2016. Following the audit, OMIG determined that the Resource Utilization Group ("RUG") category assigned to one of the 12 patients reviewed was not supported by documentation that minimally complied with applicable State and Federal requirements. Specifically, OMIG determined to disallow three activities of daily living ("ADLs") for the patient due to insufficient supporting documentation, resulting in a finding that the one patient was assigned the incorrect RUG category and an alleged overpayment of $7,643.88.

At hearing, the issue before Administrative Law Judge ("ALJ") Champion was whether Appellant established that OMIG's determination to recover overpayments was incorrect. ALJ Champion began her decision by noting that the overpayment was based on OMIG's disallowance of three self-performance ADL codes—bed mobility, transfer, and eating—for one sample. These three disallowances were based on the fact that Appellant coded the self-performance ADLs on the MDS submission, but failed to provide documentation that minimally complied with both Federal and State regulations, as well as the requirements set out in the Centers for Medicare and Medicaid Services' ("CMS") Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual ("CMSRAI 3.0").

As relevant to the audit, RHCFs are required to make a comprehensive assessment of residents' needs using the Resident Assessment Instrument ("RAI") specified by the applicable State—the CMSRAI 3.0 in New York—and the assessment must include documentation of summary information regarding the additional assessment areas performed on the care areas triggered by completion of the MDS. *See* 42 CFR § 483.20(b); *see also* 10 N.Y.C.R.R. §§ 86-2.37, 86-2.40(m)(1). MDS data is used to classify residents into a RUG classification, which is used to determine a RHCF's Medicaid reimbursement. *See* 10 N.Y.C.R.R. §§ 86-2.37(a), 86-2.40(m). New York's MDS includes an assessment of each resident's need for assistance with ADLs, which requires each resident to be evaluated as of a specific assessment reference date ("ARD"). *See* 10 N.Y.C.R.R. 415.11(a). The RHCF chooses the ARD within the required timeframe for ADL assessments, and based on the coding rules set out in the CMSRAI 3.0, must assess each episode of a resident's ADL activity for each ADL type within a seven day lookback period from the ARD selected. Codes are then assigned on the MDS for the ADLs, including those that are self-performed and those where support is required. This information translates into the RUG classification with an associated case mix index number, with higher average case mix indexes resulting in higher rates of Medicaid reimbursement. *See* 10 N.Y.C.R.R. §§ 86-2.10, 86-2.40(m); *see also In re Elcor Health Servs. v. Novello*, 100 NY2d 273, 276–77 (2003).

In her decision, ALJ Champion noted that Appellant selected January 5, 2016 as the ARD for sample one, resulting in a seven day lookback period of December 30, 2015 through January 5, 2016. The ADL self-performance coding requirements, as set out in CMSRAI 3.0, require the use of the "rule of three," which requires ADL self-performance activities to occur at least three times within the seven day lookback period for a level of care value to be coded as one, two, three, or four, and in order to code value four, full staff performance of every occurrence of the ADL within the lookback period must have been required (*i.e.*, the resident must have been totally dependent on staff to perform the ADL). As set out in CMSRAI 3.0, documentation can only be used to apply the rule of three for MDS coding purposes when the documentation includes the type and level of support that was provided to a resident for an ADL self-performance activity during the seven day lookback period on at least three instances.

At hearing, OMIG asserted that the documentation produced by Appellant only showed two occurrences of self-performance of bed mobility, eating, and transfer. According to OMIG, since three documented occurrences were not indicated in the documentation, Appellant should have coded these ADLs as zero. While Appellant acknowledged that the documentation produced did not meet the rule of three requirements, Appellant argued that the records provided showed that the resident would likely have needed the levels of care coded by Appellant on the MDS. ALJ Champion characterized Appellant's asser-

tion as "an argument that the detailed ADL coding rules [we] re essentially optional and meaningless[,]" and rejected Appellant's position. *See* Decision at 7. Instead, the ALJ found that assumptions regarding the likely level of care based on a resident's records were insufficient, since changes to a resident's self-performance level of care are common, and as such, the information contained in a resident's record may not correlate with the actual levels of care provided.

Therefore, ALJ Champion held that Appellant failed to meet its burden to show that OMIG's determination was incorrect, and the determination to recover Medicaid Program overpayments in the amount of $7,643.88 was affirmed.

MA Surgical Supplies, Inc. (Decision, August 18, 2023, Jeanne T. Arnold, ALJ).

Appellant, a durable medical equipment provider, requested a hearing of OMIG's determination to recover Medicaid Program overpayments of durable medical equipment claims. In the decision, ALJ Arnold considered the timeliness of Appellant's request for a hearing.

The Final Audit Report ("FAR") issued by OMIG was dated April 13, 2023, and was received and signed for by Appellant on April 19, 2023. As set out in the FAR, Appellant was required to request a hearing within 60 days of the date of the FAR, or by June 12, 2023. *See* 18 N.Y.C.R.R. § 517.6(b)(4). Although Appellant's request for a hearing was dated June 8, 2023, the request was not mailed until June 13, 2023, and was not received by OMIG until June 15, 2023. According to the ALJ, based on the applicable timeframes, Appellant's request for a hearing was not timely.

Appellant presented two arguments, both of which were rejected by ALJ Arnold. First, Appellant argued that the 60 day time period to appeal does not begin to run until receipt of the FAR, and as such, the request for a hearing received by OMIG on June 15, 2023 was timely. The ALJ rejected this argument as contrary to applicable statute and regulation, which provide that the applicable period commences when OMIG's notice is mailed to the Appellant and that the 60 days runs from the date of OMIG's written determination. *See* N.Y. Soc. Serv. Law § 145-a(2); 18 N.Y.C.R.R. § 519.7(a). ALJ Arnold also found that the position was contrary to the language contained in the FAR, which stated that Appellant was required to request a hearing within 60 days of the FAR's date. The date a FAR was received is not implied as an applicable factor in any of these mandates.

In support of its position, Appellant cited to the Court of Appeals' interpretation of the applicable statute and regulation as meaning that the 60 day limitations period begins when the FAR is delivered. *See West Midtown Mgmt. Grp. v. NYS Dep't of Health*, 31 NY3d 533, 538 (2018). ALJ Arnold rejected this argument, finding that the term "delivery" is not the same as "receipt," and as such, the Court of Appeals' determination that the 60 day period began to run when the FAR was "delivered" to the provider did not necessarily mean that the applicable date was the date of "receipt." *See* Decision at 5. This position was supported by a prior administrative determination that was upheld on appeal, and which found that the request for appeal must be made within 60 days of the date of the FAR. *See In re West Midtown Med. Grp., Inc.*, Audit # 08-3717 (Nov. 19, 2010).

Second, and in the alternative, Appellant argued that since the FAR was not received until six days after it was dated, good cause existed to extend the 60 day period to appeal. In support of the position, Appellant cited to a prior administrative decision which noted that a delay in the mailing or transit of the FAR might have constituted a reason to extend the 60 day period. *See In re Grandell Rehab. & Nursing Ctr.*, Audit # 15-5357 (Dec. 19, 2018). ALJ Arnold rejected this argument since there was no delay in the present case. Appellant's argument that the timeliness of the request for appeal should run from the date the request for a hearing was mailed was also rejected, as no support for the argument was cited and Appellant had not made any attempt to contact OMIG to express the intent to appeal prior to sending the request.

As Appellant failed to establish good cause for the failure to timely appeal the FAR, Appellant's request for a hearing was denied as untimely.

New York State Attorney General Press Releases

Compiled by Jamie Dughi Hogenkamp, Ron L. Oakes, and Bridget C. Steele

Attorney General James Secures $300,000 from CareCube for Wrongfully Charging New Yorkers for COVID-19 Tests—July 27, 2023—Attorney General ("AG") James announced an agreement with CareCube that concluded the Office of the New York State Attorney General's ("OAG") investigation into consumer complaints regarding the health clinic's billing practices for COVID-19 tests. The more than 20 testing sites operated by CubeCare at the height of the COVID-19 pandemic were investigated by OAG following the receipt of dozens of consumer complaints. The investigation found that the company improperly charged for COVID-19 tests that should have been free for patients where CareCube was an in-network provider. OAG also found that CareCube charged for tests for children under 18 and provided inaccurate information about billing for asymptomatic patients. As part of the agreement, CareCube will pay $300,000 in penalties to the State of New York, and must retain an auditor to identify all patients who were wrongfully charged in order to refund the amounts paid. Any patients who paid for a covered COVID-19 test when CareCube was an in-

network provider in the patient's health plan will be refunded for the test and any related service charges, and consumers who paid a surcharge for an office visit related to COVID-19 tests for children will also be refunded.

https://ag.ny.gov/press-release/2023/attorney-general-james-secures-300000-carecube-wrongfully-charging-new-yorkers

Attorney General James Takes Action to Stop Anti-Choice Group from Blocking Access to Abortion Care—July 26, 2023—AG James filed a motion for a preliminary injunction against Red Rose Rescue and its members to stop them from blocking access to abortion care in New York. OAG's motion for a preliminary injunction seeks to prohibit the anti-abortion extremist group and its members from coming within 30 feet of any reproductive health care facility in New York State, pending trial on the lawsuit filed against the group and its members in June. According to OAG, Red Rose Rescue and its members have repeatedly trespassed at New York State abortion clinics, including physically blocking access to the reproductive health care services in an effort to prevent the clinics from operating, resulting in delays and interference with the provision of reproductive health care services at three New York State clinics. Obstructing or interfering with access to reproductive health care clinics, including abortion clinics, is illegal under Federal and New York State law.

https://ag.ny.gov/press-release/2023/attorney-general-james-takes-action-stop-anti-choice-group-blocking-access

Attorney General James Announces Indictment and Arraignment of Owner and Manager of New York City Pharmacy for Allegedly Stealing Millions from Medicaid—July 11, 2023—AG James announced the indictment, arrest, and arraignment of the owner and manager of a pharmacy located in Queens for their alleged roles in the submission of false claims to the Medicaid Program and payment of kickbacks to Medicaid recipients. The indictment alleges that an investigation by OAG's Medicaid Fraud Control Unit ("MFCU") found that the pharmacy's owner and manager allegedly paid or directed others to pay cash kickbacks to Medicaid recipients to influence their choice of pharmacy when filling their HIV prescriptions. The indictment also alleges that the pharmacy owner and manager stole more than $2.9 million by billing a Medicaid-funded managed care organization for HIV drugs that were illegally obtained or never existed. A Queens County Grand Jury indicted the owner, manager, and pharmacy for Grand Larceny in the First Degree, Health Care Fraud in the Second Degree, and for violations of the New York State Social Services Law for the payment of unlawful kickbacks to Medicaid beneficiaries. The pharmacy owner, the pharmacy, and another corporation allegedly registered to the owner were also charged with Money Laundering in the First Degree, and the owner, pharmacy, and another corporation allegedly registered to a relative of the owner were indicted for Money Laundering in the Second Degree for allegedly conducting financial transactions designed to conceal the funds. Both Grand Larceny in the First Degree and Money Laundering in the First Degree are class B felonies carrying a maximum sentence of 25 years in prison, and Health Care Fraud in the Second Degree is a class C felony carrying a maximum sentence of 15 years. MFCU has executed search warrants at two other Queens pharmacies in connection with the investigation, which remains ongoing.

https://ag.ny.gov/press-release/2023/attorney-general-james-announces-indictment-and-arraignment-owner-and-manager

Attorney General James Sues Owners and Operators of Four Nursing Homes for Financial Fraud and Resident Neglect—June 28, 2023—AG James filed a lawsuit against the owners, operators, and landlords of four nursing homes in Bronx, Erie, Queens, and Westchester counties. The lawsuit alleges that an investigation by MFCU found that the owners and operators of the nursing homes engaged in fraud and converted more than $83 million in Medicaid and Medicare funds. These funds were allegedly used to enrich the owners and operators, as well as their families and business associates, through a network of related companies and fraudulent transactions, rather than to provide sufficient staffing and resident care. The lawsuit also alleges that the facilities' residents experienced mistreatment, neglect, and humiliation, including sitting in their own urine and feces for hours, severe dehydration, malnutrition, increased risk of death, infections and sepsis from untreated bed sores and inconsistent wound care, life-changing injuries as a result of falls, and death. In addition to the owners and operators, the lawsuit names several of the owners' and operators' family members and business partners, various companies owned by the owners and operators, as well as their family members and business associates. In the lawsuit, OAG sought a preliminary injunction requiring the nursing homes to obtain and pay for a financial monitor and a healthcare monitor to oversee operations, as well as a permanent order prohibiting the admission of new residents until adequate staffing is obtained, requiring disgorgement of the more than $83 million received, and directing the corporations and individuals named in the lawsuit (excluding the nursing homes) to pay statutory costs and to reimburse the State for the cost of the investigation, among other remedies.

https://ag.ny.gov/press-release/2023/attorney-general-james-sues-owners-and-operators-four-nursing-homes-financial

Attorney General James Co-Leads Coalition of 24 Attorneys General in Supporting Stronger Federal Protections for Reproductive Health Data Privacy—June 16, 2023—AG James and California AG Rob Bonta led a coalition of 24 attorneys general in filing a comment letter in support of in-

creased Federal protections for patients' reproductive health information. In the comment letter, the coalition of attorneys general supported the Federal government's proposed amendments to the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule aimed at helping to safeguard reproductive health data from being wrongfully accessed and exploited.

https://ag.ny.gov/press-release/2023/attorney-general-james-co-leads-coalition-24-attorneys-general-supporting

Attorney General James Announces Final National Settlement Agreements for $17.3 Billion with Teva, CVS, and Walgreens—June 9, 2023—AG James announced final approval of $17.3 billion in opioid settlement agreements with drug makers Teva Pharmaceuticals ("Teva") and Allergan, as well as pharmacies CVS and Walgreens. New York State will receive over $1 billion as a result of the settlement agreements. In addition to settling ongoing lawsuits by other States, the agreements finalize settlement provisions negotiated between OAG and Teva, CVS, and Walgreens, with Teva agreeing to pay $523 million, and CVS and Walgreens agreeing to pay over $548 million. As part of the agreements, Teva will also be required to operate under a monitor, prevent all opioid marketing, and ensure systems are in place to prevent drug misuse, and CVS and Walgreens will be required to monitor, report, and share data about suspicious activity related to opioid prescriptions. New York is not part of the national agreement with Allergan due to a prior settlement.

https://ag.ny.gov/press-release/2023/attorney-general-james-announces-final-national-settlement-agreements-173

Attorney General James Sues Militant Anti-Abortion Group for Invading Clinics and Blocking Access to Reproductive Health Care—June 8, 2023—A lawsuit was filed by OAG against members of Red Rose Rescue, an anti-abortion group, for allegedly repeatedly trespassing at abortion clinics and physically blocking access to reproductive health care services in an effort to stop clinics from operating in Nassau and Westchester counties. The lawsuit alleges that Red Rose Rescue members interfered with clinic operations by lying to clinicians in order to gain access to the facilities under false pretenses, refusing to leave waiting rooms, and barricading entrances, resulting in delayed or missed patient appointments. The obstruction of, or interference with, access to reproductive health care clinics, including abortion clinics, is illegal under both the U.S. Freedom of Access to Clinic Entrances Act and the New York State Clinic Access Act. In addition to civil penalties and damages, the lawsuit filed by OAG seeks to prohibit Red Rose Rescue members from knowingly coming within 30 feet of any clinic in New York State.

https://ag.ny.gov/press-release/2023/attorney-general-james-sues-militant-anti-abortion-group-invading-clinics-and

Attorney General James' Health Care Helpline Recovers More Than $1.5 Million in Restitution and Savings for New Yorkers—June 6, 2023—AG James released a report titled "Health Care Bureau's 2022 Annual Report, Real Solutions for New Yorkers." The report details work done by OAG's Health Care Bureau Helpline, which is a free service that handles consumer complaints, including health care complaints and concerns ranging from simple payment processing errors to complex deceptive business practices. According to the report, the Health Care Bureau's Helpline handled more than 2,300 consumer complaints and recovered more than $1.5 million in restitution and savings for New Yorkers in 2022.

https://ag.ny.gov/press-release/2023/attorney-general-james-health-care-helpline-recovers-more-15-million-restitution

Attorney General James Secures $102.5 Million Multistate Agreement with Maker of Opioid Addiction Treatment Drug for Illegal Monopolistic Tactics—June 2, 2023—AG James and 41 attorneys general announced a $102.5 million settlement with Indivior, Inc. ("Indivior"), the manufacturer of an opioid addiction treatment drug. The settlement resolved a 2016 lawsuit filed by OAG and the other States against Indivior alleging anticompetitive practices. Specifically, the underlying lawsuit alleged that Indivior engaged in monopolistic practices that suppressed the market for generic versions of the drug, Suboxone, including using illegal means to switch patients from Suboxone tablets to Indivior's new, patented Suboxone film, while attempting to destroy the market for tablets in order to preserve its drug monopoly. The settlement agreement was submitted to the court in the Eastern District of Pennsylvania for approval, and will require Indivior to pay the States $102.5 million, with approximately $5.7 million of this amount to be received by New York State. The settlement agreement will also require Indivior to inform the States of all Citizen Petitions it submits to the U.S. Food and Drug Administration ("FDA"), and to provide notice of all new products and changes in corporate control.

https://ag.ny.gov/press-release/2023/attorney-general-james-secures-1025-million-multistate-agreement-maker-opioid

Attorney General James Recoups $550,000 from Erie County Medical Management Company for Failing to Protect Patients' Data—May 23, 2023—AG James announced a settlement agreement with Professional Business Systems, Inc. d/b/a Practicefirst Medical Management Solutions and PBS Medcode Corp. ("Practicefirst") pertaining to Practicefirst's failure to protect personal information, including health records. Practicefirst is a medical management company that assists health care organizations with medical billing, coding, and credentialing, among other services. As a result of Practicefirst's failure to make a timely software update that would have

patched a critical vulnerability, as well as the failure to conduct penetration tests, vulnerability scans, and other security testing, Practicefirst's networks were hacked, resulting in the unauthorized access to the unencrypted personal information of more than 1.2 million people, including more than 428,000 New Yorkers. More than 79,000 files containing dates of birth, driver's license numbers, social security numbers, diagnoses, medication information, and financial information were taken during the cyberattack. OAG found that Practicefirst failed to maintain reasonable data security practices to protect private and health information, and these data security failures were in violation of both State and Federal law, including HIPAA. As part of the agreement, Practicefirst will pay $550,000 in penalties to New York, strengthen its data security practices, offer free credit monitoring services to affected consumers, and will adopt measures to better protect personal information.

https://ag.ny.gov/press-release/2023/attorney-general-james-recoups-550000-erie-county-medical-management-company

Attorney General James Co-Leads Bipartisan Coalition of 39 AGs to Protect Communities from Dangers of Illicit Xylazine—May 18, 2023—AG James co-led a bipartisan coalition of 39 attorneys general who urged Congressional leadership to pass the Combating Illicit Xylazine Act. In response to increased overdose deaths around the nation related to xylazine, the Act would provide measures to combat the drug's illicit use and trafficking, as well as to prevent xylazine-related deaths. Xylazine is a veterinary medication that is easily obtainable on the internet, and is only approved by the FDA as a veterinary medicine used to sedate and relieve pain in large animals. When used by humans, the drug is known to depress breathing and heart rate, lower blood pressure, and cause unconsciousness, necrosis, and death. Xylazine is known to often be mixed with opioids, and according to the U.S. Drug Enforcement Administration ("DEA"), there has been a substantial increase in xylazine-related overdose deaths throughout the United States. The drug has also been linked to hundreds of deaths throughout New York State. The letter from the coalition of attorneys general highlights the measures outlined in the Combating Illicit Xylazine Act, including classifying the illicit use of the drug as a Schedule III drug under the Federal Controlled Substances Act, allowing the DEA to track manufacturing and sales of the drug, requiring the submission of a report to Congress on regulating the drug's illicit use, and ensuring that all forms of xylazine are covered when restricting its illicit use.

https://ag.ny.gov/press-release/2023/attorney-general-james-co-leads-bipartisan-coalition-39-ags-protect-communities

CONSUMER ALERT: Attorney General James and Acting Department of Health Commissioner Dr. McDonald Issue Alert to Protect New Yorkers from Health Insurance Renewal Scams—May 12, 2023—AG James and Acting Department of Health Commissioner, Dr. James McDonald, warned New Yorkers about a scam targeting individuals enrolled in public health insurance programs. The scam involves individuals who need to renew their enrollment in Medicaid, Child Health Plus, and the Essential Plan, and involves enrollees being told that their Medicaid coverage is at risk of cancellation or has been cancelled unless money is paid to reinstate or continue the benefits. New York agencies that administer Medicaid benefits will never charge customers or ask for money in order to enroll or re-enroll, and New Yorkers who suspect they have been a victim of this scam are encouraged to make a report to OAG online or by telephone at 1-800-771-7755.

https://ag.ny.gov/press-release/2023/consumer-alert-attorney-general-james-and-acting-department-health-commissioner

Attorney General James Leads Coalition to Protect Patients' Access to Emergency Abortion Care—May 9, 2023—AG James co-led a multistate coalition of 23 attorneys general in an effort to protect access to abortion care during life-threatening medical emergencies. The coalition filed an amicus brief in support of Emergency Medical Treatment and Labor Act ("EMTALA") guidance issued by the U.S. Department of Health and Human Services ("HHS"), which requires hospitals to provide emergency abortion care when needed to stabilize a patient experiencing an emergency medical condition. The amicus brief was filed in *Texas v. Becerra*, a lawsuit filed by Texas challenging the EMTALA guidance. The U.S. District Court for the Northern District of Texas enjoined the guidance from being enforced in the State, and the Federal government filed an appeal asking the U.S. Court of Appeals for the Fifth Circuit to reverse the ruling. As set out in their brief, the attorneys general argue that allowing the district court's ruling to stand would endanger patients in Texas and would have significant repercussions on other States' health systems. Specifically, if hospitals and providers in Texas do not provide the emergency abortion care required by EMTALA, patients would be forced to turn to providers outside of the State, which would add strain to other States' already overburdened emergency departments, and would result in additional delays and threats to the health and safety of all patients requiring emergency care.

https://ag.ny.gov/press-release/2023/attorney-general-james-leads-coalition-protect-patients-access-emergency

Attorney General James Fights to Protect Medication Abortion Access and Family Planning Privacy Rights—May 2, 2023—As the leader of two separate multistate coalitions, AG James filed amicus briefs in the U.S. Court of Appeals for the Fifth Circuit seeking reversal of two decisions issued by the

U.S. District Court for the Northern District of Texas. The first amicus brief was filed by a coalition of 25 attorneys general in *Alliance for Hippocratic Medicine v. FDA*. The brief argues that the medical consensus and 20 years of use of mifepristone, the medication abortion drug, supports the FDA's determination that the drug is safe and effective, and that the FDA's other decisions regarding the drug—including authorizing the generic version, permitting qualified non-physician clinicians to authorize use, and enabling distribution of the drug by mail—are supported by evidence. The coalition urged the Fifth Circuit to reverse a lower court ruling regarding the drug, and argues that if the ruling were allowed to stand, millions of Americans would be harmed, with historically underserved groups experiencing the most substantial negative impacts. The second amicus brief was filed by a coalition of 25 attorneys general in *Deanda v. Becerra*, and argues that eliminating the confidentiality protections found in Title X for adolescents in Texas would have significant negative consequences for teenage patients seeking family planning services. Since 1970, Title X has provided publicly funded family planning and reproductive medical services to Americans on a confidential basis, including adolescents. Specifically, the coalition's amicus brief argues that the confidentiality protections afforded to adolescents in Title X are essential to the safe delivery of necessary healthcare to minors, and that if the lower court's ruling requiring minors to receive parental consent for family planning and reproductive services in Texas were to stand, minors' ability to seek services would be threatened and could lead adolescents to not seek medical care.

https://ag.ny.gov/press-release/2023/attorney-general-james-fights-protect-medication-abortion-access-and-family

Attorney General James Secures Agreement with Insulin Manufacturers to Cap Insulin Prices for Uninsured New Yorkers—May 2, 2023—AG James announced agreements with the nation's largest insulin manufacturers, Eli Lilli and Company ("Lilli") and Sanofi-Aventis U.S. LLC ("Sanofi"), to cap the price of insulin at $35 per monthly prescription for uninsured New Yorkers for a period of five years. The agreements stem from an investigation by OAG which found that the list prices insulin manufacturers set for patients resulted in substantial out-of-pocket costs for some insulin users, which caused patients to ration or not use insulin as prescribed. The list prices for insulin have also increased drastically over the past 20 years, and these increased costs are not attributable to insulin manufacturing costs. Under the agreements, uninsured New Yorkers who use Lilli or Sanofi insulin products will not be charged more than $35 for a month's supply of insulin for the next five years. Lilli and Sanofi have committed to offering affordable programs to ensure that patients have access to insulin, and will implement a streamlined process which allows pharmacies to automatically advise cash-paying customers of their ability to have their monthly prescription filled for $35. Lilli will also offer free insulin products through national relief agencies to eligible non-profit clinics in high-need geographical locations in New York State, and Sanofi will offer free insulin to consumers who meet certain income thresholds.

https://ag.ny.gov/press-release/2023/attorney-general-james-secures-agreement-insulin-manufacturers-cap-insulin

Attorney General James Releases Statement on Supreme Court's Order on Medication Abortion—April 21, 2023—AG James released a statement following the U.S. Supreme Court's granting of a stay pending appeal in *Alliance for Hippocratic Medicine v. FDA*. Under the stay, the lower court's orders restricting access to the abortion medication, mifepristone, will not take effect while the appeals process continues.

https://ag.ny.gov/press-release/2023/attorney-general-james-releases-statement-supreme-courts-order-medication

Attorney General James Co-Leads Multistate Coalition Calling for Increased Transparency of Nursing Home Ownership—April 18, 2023—In a letter to the HHS and CMS, AG James co-led a coalition of 18 attorneys general in support of a CMS proposed rule that would require nursing facilities and their owners to disclose the true decision makers exercising control over nursing home operations. The letter points to often inferior quality of care at for-profit nursing facilities as compared to non-profit. The attorneys general contend that disclosure of the true decision makers would improve their ability to hold bad actors accountable for providing substandard care.

https://ag.ny.gov/press-release/2023/attorney-general-james-co-leads-multistate-coalition-calling-increased

Attorney General James Leads Multistate Coalition to Urge U.S. Supreme Court to Maintain Medication Abortion Access—April 14, 2023—AG James led a coalition of 24 attorneys general in filing an amicus brief with the U.S. Supreme Court in *Alliance of Hippocratic Medicine v. FDA* challenging the decision by the U.S. Court of Appeals for the Fifth Circuit that upholds a Texas district court's order that would restrict access to the medication abortion drug mifepristone nationwide. If allowed to take effect, the lower court's ruling would halt the FDA's approval of a generic version of mifepristone, and would ban access to the drug by mail, as well as block the non-doctors from being able to prescribe and dispense the medication. In the brief, the attorneys general warn that the Fifth Circuit's order would drastically reduce access to safe abortion care and miscarriage management for millions of Americans. The brief urges the Court to stay the Fifth Circuit decision, pending its appeal.

https://ag.ny.gov/press-release/2023/attorney-general-james-leads-multistate-coalition-urge-us-supreme-court-maintain

Attorney General James Releases Statement on Supreme Court Order to Temporarily Block Lower Court Rulings Restricting Medication Abortion Access—April 14, 2023—AG James released a statement following U.S. Supreme Court Justice Samuel Alito's decision to issue an administrative stay of the Fifth Circuit's decision in *Alliance of Hippocratic Medicine v. FDA*. The stay temporarily blocked a Fifth Circuit ruling that would have restricted access to the medication abortion drug, mifepristone.

https://ag.ny.gov/press-release/2023/attorney-general-james-releases-statement-supreme-court-order-temporarily-block

Attorney General James Secures $462 Million from JUUL for Its Role in the Youth Vaping Epidemic—April 12, 2023—AG James and California AG Rob Bonta co-led a multistate agreement with JUUL Labs Inc. ("JUUL") and its former directors and executives for their alleged role in contributing to the youth vaping epidemic which led to a nationwide rise in underage e-cigarette use. Through the agreement, JUUL will pay $462 million to six states and the District of Columbia. New York will receive $112.7 million as part of the agreement, with the funds to be used to support underage vaping abatement programs across the state. The agreement also places stringent restrictions on JUUL's marketing, sales, and distribution practices, and requires JUUL to secure its products behind retail store counters and to verify the age of consumers directly selling or promoting its products online. The agreement resolves a November 2019 lawsuit by OAG which alleged that JUUL engaged in deceptive and misleading marketing practices, and violated New York's General Business Laws, Common Law Public Nuisance, and Executive Law.

https://ag.ny.gov/press-release/2023/attorney-general-james-secures-462-million-juul-its-role-youth-vaping-epidemic

Attorney General James Leads Multistate Coalition to Fight Back Against Decision to Block Medication Abortion Access—April 10, 2023—AG James led a coalition of 24 attorneys general in filing an amicus brief in *Alliance for Hippocratic Medicine v. FDA*. In the brief, the attorneys general asked the Fifth Circuit Court of Appeals to stay an order by the U.S. District Court for the Northern District halting the FDA's prior approval of the medication abortion drug, mifepristone, pending appeal of the ruling. According to the attorneys general, revoking Federal approval for mifepristone would reduce access to safe abortion care and miscarriage management for millions of people in the United States, and would impact states' authority to protect and promote abortion access. The amicus brief also argues that the lower court's decision is unprecedented and legally erroneous due to the many years of clinical research and studies demonstrating that mifepristone is safe and plays a critical role in reproductive health care, particularly for low income, underserved, and rural communities.

https://ag.ny.gov/press-release/2023/attorney-general-james-leads-multistate-coalition-fight-back-against-decision

New York State Office of the Medicaid Inspector General Update

Compiled by Dena M. DeFazio

Acting Medicaid Inspector General Frank Walsh Takes State's Pledge for Accountability Against Gender-Based Violence—September 13, 2023— https://omig.ny.gov/news/2023/acting-medicaid-inspector-general-frank-walsh-takes-states-pledge-accountability-against.

OMIG Announces Updates to the Self-Disclosure Program—August 21, 2023— https://omig.ny.gov/news/2023/omig-announces-updates-self-disclosure-program.

OMIG Assists in Investigation that Leads to Indictment of Owners and Manager of New York City Pharmacy in Alleged $2.9 Million Medicaid Fraud Scheme—July 13, 2023— https://omig.ny.gov/news/2023/omig-assists-investigation-leads-indictment-owner-and-manager-new-york-city-pharmacy.

OMIG POSTS COMPLIANCE PROGRAM SELF-ASSESSMENT FORM—June 22, 2023—https://omig.ny.gov/news/2023/omig-posts-compliance-program-self-assessment-form.

UPDATE: OMIG Healthcare Provider Engagement Forum Presentation Now Posted—June 2, 2023— https://omig.ny.gov/news/2023/update-omig-healthcare-provider-engagement-forum-presentation-now-posted.

Margaret M. Surowka is a former general counsel at the New York State Dental Association with over 30 years of legal experience. She routinely counsels clients facing Medicaid, Medicare, and other governmental investigations and audits as well as assists with employment and contract matters. She trains governing boards with respect to the not-for-profit law and governance issues and is a long-serving member of the Board of the National Society of Dental Practitioners. Margaret is also chair of the Hubbard Hall Center for the Arts and Education in Cambridge, N.Y.

In the Law Journals

Compiled by Jeff Ehrhardt

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

An Epidemic in Enforceability: A Growing Need for Individual Autonomy in Health Care Data-Privacy Protection in an Era of Digital Tracking, Madeline Knight, 25 Vand. J. Ent. & Tech. L. 749 (2023).

An Overlooked Argument for A Single-Payer Healthcare System: Eliminating Misalignment Among Payment Models, Jessica Mantel, 32 Annals Health L. & Life Sci. 101, 101 (2023).

Anything but Prideful: Free Speech and Conversion Therapy Bans, State-Federal Action Plans, and Rooting Out Medical Fraud, Jordan Hutt, 92 Fordham L. Rev. 255 (2023).

Clicking Away Consent: Establishing Accountability and Liability Apportionment in Direct-to-Consumer Healthcare Artificial Intelligence, Stephanie L. Lee, 88 Brook. L. Rev. 1355 (2023).

Constitutional Contagion: Covid, the Courts, and Public Health, Wendy E. Parmet, Marshall Kapp, Fla. B.J., at 37 (2023).

Data for Sale: Navigating the Role of Data Brokers and Reproductive Health Information in A Post-Dobbs World, Heather Chong, 26 SMU Sci. & Tech. L. Rev. 99 (2023).

Exacerbating Ambiguity: Why the Final 340b Administrative Dispute Resolution Rule Is A Distraction from Needed Reform, Caryn Levite Marshall, 53 Seton Hall L. Rev. 1743 (2023).

Health Monitoring from Home: Legal Considerations of Wearable Technology in Telemedicine, Polina DeClue, 26 SMU Sci. & Tech. L. Rev. 111 (2023).

HIPAA Interviews Revisited, and Whose Body Is It?, David Paul Horowitz & Katryna L. Kristoferson, N.Y. St. B.J., at 56 (2023).

How Blockchain in Healthcare May Revolutionize the Digital Health Data Marketplace by Putting the Patient in Control, Ashfin Islam, ABA SciTech Law., at 14 (2023).

Inadequate Privacy: The Necessity of HIPAA Reform in A Post-Dobbs World, Katherine Robertson, 47 Seattle U. L. Rev. 301 (2023).

Increasing Equity in the Transnational Allocation of Vaccines Against Emerging Pathogens: A Multi-Modal Approach, Ana Santos Rutschman, 51 J.L. Med. & Ethics 247 (2023).

Inflated Health Care Costs: Why Hospital Billing Practices Are Problematic and How Federal Procurement Can Help, Sophie Marsh, 52 Pub. Cont. L.J. 681 (2023).

Is Secretive Peer Review Good or Bad for Patients and Doctors?, Clifford A. Rieders, 94 Pa. B.A. Q. 123 (2023).

Is There A Fundamental Right to Privacy When an Educational Institution Requires A Student to Disclose Proof of His or Her Vaccination Status?, Mary D. Fatscher, 38 Touro L. Rev. 1453 (2023).

Legal and Health Risks of Abortion Criminalization: State Policy Responses in the Immediate Aftermath of Dobbs, Adrienne R. Ghorashi, JD, DeAnna Baumle, JD, MSW, 37 J.L. & Health 1 (2023).

Limiting Overall Hospital Costs by Capping Out-of-Network Rates, David Orentlicher *et. al.*, 32 Annals Health L. & Life Sci. 131, 131 (2023).

"Out Like A Lion:" Terminating the Covid-19 National Public Health Emergency, James G. Hodge, Jr. (FNa2), 51 J.L. Med. & Ethics 443 (2023).

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For Your Information

By Claudia O. Torrey

As I sat down to pen my thoughts for this column on the concept of healthcare during the current Israelis/Hamas "unprovoked" war, news of the bombed hospital in Gaza was making all the headlines! I took this as an "ironic sign" that I was on the right track to give the healthcare of the situation some thought, especially since I am dealing with my own unexpected illness. This is not to exclude in thought, by any means, the atrocities in Ukraine or the earthquake devastation in Afghanistan.

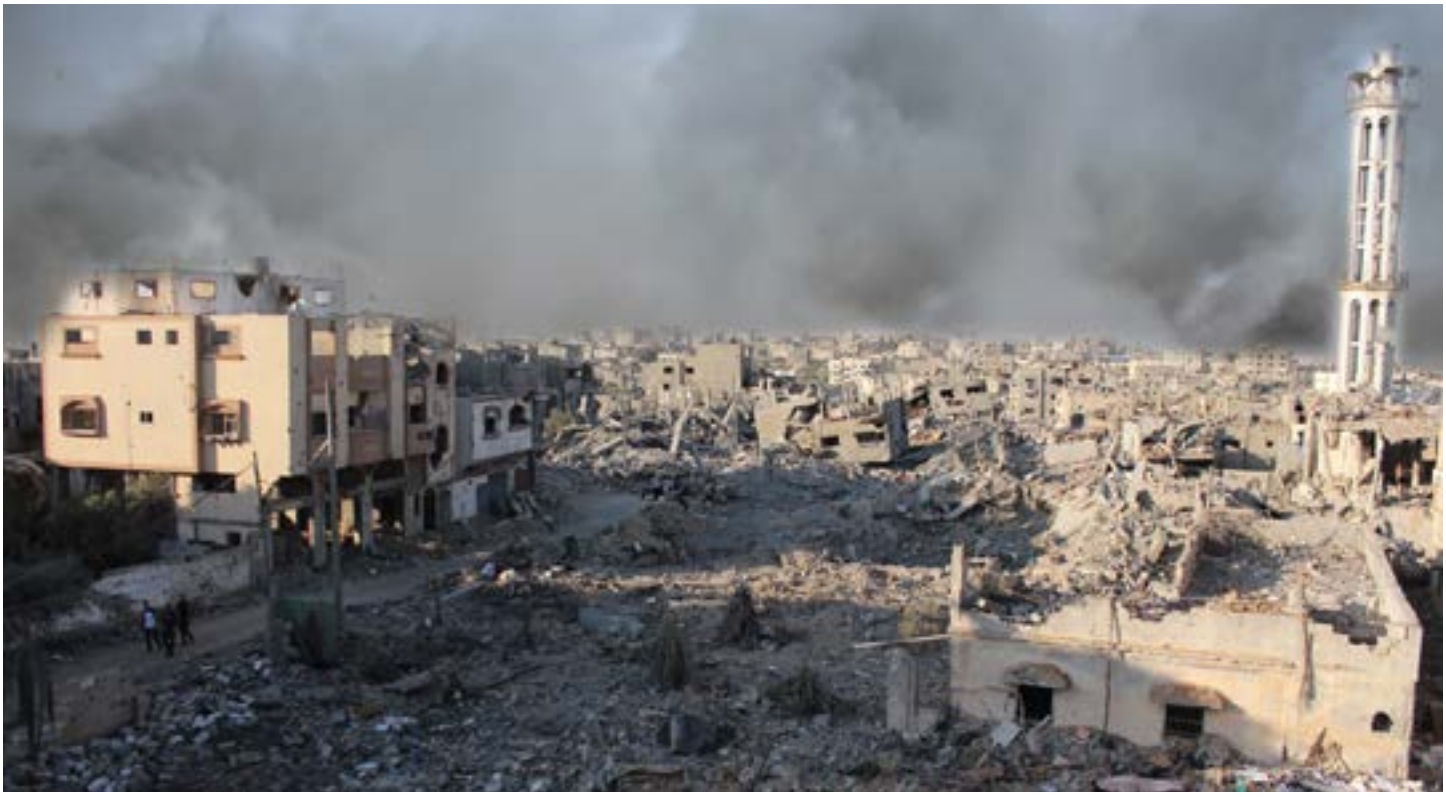
The Charter of the United Nations is the foundational document of the United Nations, which was signed, post-World War Two, on June 26, 1945 in San Francisco, California; the Charter took effect October 24, 1945.[1] Currently, there are 193 Member States/Countries of the United Nations; the original creators/signatories of the Charter consisted of five Member/States: The United States, China (AKA The Peoples' Republic of China), the Soviet Union, France, and the United Kingdom.[2] These five are permanent members of the Security Council and have veto power; ten non-permanent members are elected for a two-term by the General Assembly of the United Nations, without veto power,[3] but approved by the Security Council. Currently the 193 Member States/Countries each have one seat in the General Assembly.[4]

The basic tenets of the Charter are: peace & security, development, and human rights,[5] while the work of the United Nations covers five main areas: (a) maintain International Peace & Security, (b) protect human rights, (c) deliver humanitarian aid, support sustainable development & climate, (d) and uphold international law; the above mentioned items are to take place without distinction regarding race, gender, language, or religion.[6] There are two Countries/States as of 2019 that have permanent Non-Member Observer Status with the General Assembly: Palestine and the Holy See (Vatican City);[7] these two States/Countries can make comments, but cannot vote.[8]

The rules of armed conflict concerns international laws, including the Geneva Conventions forbidding the intentional targeting of civilians, torture, hostage taking and other inhumane treatment(s).[9] The Rules of War in the Geneva Conventions requires armed soldiers/military people to be treated humanely when in enemy hands[10] and prohibits torture, murder, the taking of hostages, and wounded, sick, and shipwrecked should be cared for; Geneva Convention IV applies the same thing to civilians. The four Conventions of the Geneva Convention have been ratified by all 193 Members of the United Nations, including the two permanent non-member Observers, and the Cook Islands.[11]

The United Nations Charter has an international Court of Justice located in The Hague, Netherlands, known as the international City of Justice and Peace, in an attempt to foster justice via peace and not conflict.[12] A good argument can be made that the current Hamas/Israeli War is violating all kinds of international concerns; not all Palestinians condone Hamas/Hezbollah behavior, and not all Israelis hate Palestinians.

Certainly, the health issues of the war (hospitals with no water, injured and bleeding people, no fuel, and very limited supplies) are not good. The rules of war concerning healthcare were intimated above, the goal of international humanitarian law is to limit harm to civilians (non-combatants), protect health & humanitarian workers, as well as sick and wounded soldiers and prisoners of war.[13] The humanitarian law includes a duty not to obstruct healthcare (such as blocking the passage of ambulances).[14] At this writing about 20 medical aid trucks are trying to get to Gaza, but much more aid is needed; both sides have attacked hospitals.



It can be said that during a war, healthcare entities and services have a strategic significance since they may be targeted to prevent soldiers from receiving treatment that could return them back to the ongoing war or targeting healthcare entities could potentially destroy morale.[15] The Director of The World Health Organization has stated that attacks on healthcare entities, services, or medical personnel are a violation of international humanitarian law.[16] One can only hope that this war may compel a renewed global consciousness and collective good action.[17]

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

Endnotes

1. Charter of the United Nations, Preamble Charter I-XIX including Amendments to Articles 23, 27, 61, and 109, *available at* www.un.org.
2. *Id.*
3. *Id.*
4. *Id.*
5. *Id.*
6. *Id.*
7. *Id.*
8. *Id.*
9. https://www.britannica.com/event/Geneva-Conventions.
10. *Id.*
11. *Id.*
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13. Len Rubenstein, *The Rules of War and Human Rights in the Israel-Hamas War*, John Hopkins Bloomberg School of Public Health, Oct. 27, 2023, https://publichealth.jhu.edu/2023/the-rules-of-war-and-human-rights-in-the-israel-hamas-war.
14. *Id.*
15. Jonathan Kaplan, *Targeting healthcare in war: a tragically tried and tested strategy that humanity must disown*, BMJ, 2022 Apr 12:377:o884 (2022), *available at* https://pubmed.ncbi.nlm.nih.gov/35414531/.
16. *Id.*
17. *Id.*

In the New York State Courts

By Dayna B. Tann and Marc A. Sittenreich

Second Circuit Upholds Connecticut Law Repealing Religious Exemptions for Mandatory School Vaccinations

We the Patriots USA, Inc. v. Connecticut Office of Early Childhood Dev., 76 F.4th 130 (2d Cir. 2023)

On April 30, 2021, Governor Ned Lamont signed into law Public Act 21-6 (the "Act"), which repealed Connecticut's religious exemption to mandatory vaccinations for school enrollment. The Act was passed in response to declining vaccination rates among Connecticut schoolchildren, which left the public vulnerable to the spread of preventable diseases. With the Act, Connecticut joined four other states – California, New York, Maine and Mississippi – that have similarly ended religious exemptions to their school vaccination requirements (along with West Virginia, which has never provided for such exemptions).

Connecticut's school vaccine mandate dates back to 1882, the same year that the State began requiring school attendance for all children ages eight to fourteen. Before the Act was passed, both a medical exemption and a religious exemption to the vaccine mandate were available. A student could obtain a religious exemption if his or her parent or guardian submitted a statement that "such vaccination would be contrary to the religious beliefs of such child." The Act repealed this provision, but contained a "legacy" provision allowing certain students who had previously obtained a religious exemption to remain exempt from the vaccination requirement. The Act did not repeal the medical exemption provision; to the contrary, it broadened the grounds on which a student could be medically exempted.

Plaintiffs include two not-for-profit organizations advocating for religious freedom, as well as three individuals who have at least one child who must be vaccinated in order to attend Connecticut schools and who object to vaccination on religious grounds. Two days after the Act was signed, Plaintiffs filed suit in the U.S. District Court for the District of Connecticut against three State agencies and three local school boards, seeking declaratory and injunctive relief. Plaintiffs claimed that the Act violated: (1) the Free Exercise Clause of the First Amendment; (2) the implied constitutional right to privacy and medical freedom; (3) the Equal Protection Clause of the Fourteenth Amendment; (4) the Fourteenth Amendment Due Process liberty interest in childrearing; and (5) the Individuals with Disabilities Education Act (the "IDEA"). Defendants moved to dismiss Plaintiffs' Complaint in its entirety, which the district court granted. Plaintiffs appealed.

The Second Circuit first addressed Plaintiffs' Free Exercise Clause claim. The court began its analysis with the long-settled precedent that a neutral law of general applicability is subject to rational basis review, and will typically be found constitutional, even if it incidentally burdens religious exercise. The court stated that a law is not neutral if it "explicitly singles out a religious practice" or "targets religious conduct for distinctive treatment," and that a law is not generally applicable if it provides a "mechanism for individualized exemptions" or "prohibits religious conduct" while permitting comparable secular conduct that undermines the law's stated purpose. The court noted that a series of Supreme Court decisions concerning COVID-19 restrictions on religious congregation have made clear that a law that treats any comparable secular activity more favorably than religious activity is neither neutral nor generally applicable and is thus subject to strict scrutiny. The court observed, however, that under Supreme Court precedent and in its own "[r]ecent cases," vaccine mandates have most often survived constitutional challenge.

In applying these principles, the Second Circuit determined that the Act is neutral. The court found nothing in the Act's legislative history that would suggest any hostility toward religious believers. Rather, the Act's proponents acknowledged the impact it would have on children and families with religious objections, but sought to accommodate them in various ways, including by enacting the legacy provision. While Plaintiffs contended that the Act is hostile to religion *per se* because it repealed religious exemptions that had previously been available, the court found this argument unpersuasive because, among other things, there was no evidence of anti-religious animus in the legislative record, the constitution does not require that vaccine mandates contain religious exemptions, and such a holding would disincentivize states from accommodating religious practices in the first place.

Likewise, the Second Circuit found that the Act is generally applicable. The court noted that the Act does not create a system of individualized exemptions because the medical exemption is both mandatory and framed in objective terms (*i.e.* it requires a certification from a medical professional) and thus does not give discretion to government officials to decide whether the "reasons for requesting exemption are meritorious." The court also determined that the Act is not "substantially underinclusive" because medical exemptions and religious exemptions are not comparable to one another in relation to the State's interest in promoting health and safety. The Court asserted that repealing religious exemptions promotes health and safety by decreasing the risk that unvaccinated students (including those with medical exemptions) will acquire a vaccine-preventable disease by lowering the overall number of unvaccinated students. Similarly, medical exemptions promote health and safety by permitting the "small proportion of students who cannot be vaccinated for

medical reasons to avoid the harms that taking a particular vaccine would inflict on them."

Given the Second Circuit's conclusion that the Act is a neutral law of general applicability, the court applied rational basis review. As Plaintiffs conceded that "protecting public health is a compelling government interest," the court affirmed the dismissal of Plaintiffs' Free Exercise claim.

Next, the Second Circuit considered, and rejected, Plaintiffs' other constitutional claims. The court found Plaintiffs' "privacy and medical freedom" claim "foreclosed by binding precedent" holding that the constitution implies no fundamental rights to freedom from unwanted vaccination or to an education. The court also held that Plaintiffs' Equal Protection challenge – alleging that the legacy provision created an impermissible age-based classification that burdened the free exercise of their religious practices – was subject to dismissal because "age is not a suspect classification" and because the court already concluded that the Act does not violate the Free Exercise Clause. The court then held that Plaintiffs' "childrearing" claim was properly dismissed because there is no parental right, absent a violation of the Religious Clauses of the First Amendment, to direct how a public school provides education.

Finally, the Second Circuit turned to the IDEA claim, asserted by one of the individual plaintiffs against her child's local school board. The IDEA requires states receiving federal funding to provide children with disabilities a "free appropriate public education that emphasizes special education and related services." The district court dismissed the claim on standing grounds, holding that the student at issue did not qualify as a "child with a disability" under the statute because he receives "special services" and not "special education." The Second Circuit found that the distinction drawn by the district court was "overly strict" and remanded to the district court to consider the school board's challenge to the substantive merits of the IDEA claim.

Second Circuit Upholds FDA's Denial of E-Cigarette Manufacturer's Application to Market Flavored Pods

Magellan Tech., Inc. v. U.S. Food & Drug Admin., 70 F.4th 622 (2d Cir. 2023)

Petitioner is a manufacturer of electronic nicotine delivery systems ("ENDS"), commonly known as e-cigarettes, which deliver an aerosolized liquid derived from tobacco when the user inhales. Petitioner's ENDS products include reusable containers, known as "pods," that come in various fruit and dessert flavors ("Flavored Products"), in addition to tobacco and menthol flavors. A relatively new tobacco product, ENDS have become popular among young people, who overwhelmingly favor Flavored Products.

The U.S. Food and Drug Administration (the "FDA") regulates ENDS products under the Family Smoking Prevention and Tobacco Control Act (the "TCA"), enacted in 2009. The TCA requires manufacturers to submit a premarket tobacco application ("PMTA"), and to receive approval from the FDA, before placing any "new tobacco product[]" into interstate commerce. To obtain such approval, the manufacturer must demonstrate that the product would be "appropriate for the public health." To determine whether the applicant meets that criterion, the FDA considers both: (1) whether the new product will cause users of existing tobacco products to stop using those products; and (2) the likelihood that individuals who do not presently use tobacco products will start using the new product. The FDA must base this determination on "'well-controlled investigations' or other 'exist[ing] valid scientific evidence . . . which is sufficient to evaluate the tobacco product.'" For the purposes of the TCA, the FDA distinguishes between Flavored Products and tobacco or menthol ENDS products.

Because ENDS products became subject to the TCA after the statute was passed, the FDA set a deadline of September 9, 2020 for manufacturers to submit their PMTAs. In anticipation of that deadline, the FDA issued multiple guidance documents, including a June 2019 guidance to applicants outlining the evidence needed to demonstrate that an ENDS product is appropriate for the public health. Although the document recognized that there was "limited data" on ENDS products and, as a result, indicated that the FDA would consider scientifically valid studies beyond randomized control trials ("RCTs") and longitudinal cohort studies, it cautioned that "[n]onclinical studies alone" would "generally" be insufficient. In July 2021, the FDA issued an internal guidance document indicating that PMTAs for Flavored Products would be summarily rejected if they did not include either an RCT or a longitudinal control study. In August 2021, the FDA released a superseding internal guidance document stating that it would consider other types of studies if they "could reliably and robustly assess behavior change . . . comparing users of flavored products compared with those of tobacco-flavored products."

Petitioner submitted a PMTA for various ENDS products, including Flavored Products, on September 8, 202. In support of its application, Petitioner offered four non-clinical studies, only one of which of involved more than two dozen participants, and none which "robustly 'evaluat[ed] the effects of the ENDS on users," as recommended by the June 2019 guidance. Petitioner also submitted a marketing plan regarding its "strategy to restrict youth access to its products and to limit youth exposure to its marketing."

On September 8, 2021, the FDA denied Petitioner's PMTA with respect to Flavored Products, finding insufficient evidence that it would "provide a benefit to adult users that would be adequate to outweigh the risks to youth." Because of this finding, the

FDA expressly did not review "other aspects" or the PMTA, including Petitioner's marketing plan. Petitioner sought review by the Second Circuit on three grounds, all of which were denied.

First, Petitioner argued that the FDA changed the standard of review without properly notifying it or considering its "reliance interests." Petitioner stated that the FDA's July 2021 internal guidance "heightened" the standard set forth in the June 2019 guidance to ENDS applicants. The Second Circuit rejected this argument, finding that the FDA consistently held the same position: that it would consider evidence other than long-term studies only if that evidence has "sufficient scientific underpinnings." The court found no evidence in the record that Petitioner's application was summarily rejected based on the July 2021 internal guidance, which had been superseded. Instead, the court asserted, the FDA considered the evidence in Petitioner's PMTA but found it insufficient. As the FDA did not change the evidentiary standard, the court found there was no need to provide notice to Petitioner or consider its reliance interests.

Second, Petitioner contended that the FDA's decision was arbitrary and capricious because the agency failed to consider its marketing plan. The Second Circuit found that this had no impact on the outcome of Petitioner's PMTA, and thus was no more than harmless error, because of the other defects in its application. Among other things, the court observed that the FDA had found similar age verification strategies insufficient to "address youth use of [ENDS] products."

Third, Petitioner challenged the FDA's statutory authority to "impose on applicants a comparative efficacy requirement" between Flavored Products and tobacco or menthol ENDS products. Contrary to Petitioner's argument, the Second Circuit found that a "comparative analysis among tobacco products" was expressly contemplated by the TCA, and thus that the FDA acted "well within its authority."

Southern District of New York Rules that Oxford Is Not an ERISA Plan Administrator and Holds That External Appeal Agent Is Immune from Suit under the New York Insurance Law

Kwasnik v. Oxford Health Insurance, Inc., No. 22 Civ. 4767, 2023 WL 5050952 (S.D.N.Y. Aug. 8, 2023)

Plaintiff Fiana Kwasnik is the beneficiary of an employer-sponsored large group health insurance policy written by Defendant Oxford Health Insurance, Inc. ("Oxford"). This dispute dates back to September 2021, when Plaintiff's physician recommended in vitro fertilization ("IVF") treatment. The recommended course of treatment involved retrieving and fertilizing new eggs, thawing and fertilizing previously-retrieved eggs that Plaintiff had cryopreserved in 2017, and conducting genetic testing. Because infertility treatment is covered by Plaintiff's benefit plan, Plaintiff sought pre-authorization from Oxford.

Oxford denied coverage in September 2021, deeming the procedure not medically necessary. Specifically, Oxford determined Plaintiff had to use the cryopreserved 2017 eggs before Oxford would approve another round of egg retrieval. Plaintiff submitted a "first-level appeal" to Oxford, referencing New York's so-called "IVF Mandate," which requires large group insurance policies to provide coverage for up to three rounds of IVF (N.Y. Ins. Law §§ 3221(k)(6)(c)(vii) & 4303(s)(3)(G)). While the first-level appeal was pending, Plaintiff underwent an egg retrieval at her own expense. On November 2, 2021, Oxford upheld its decision, prompting a "second-level appeal." On December 5, 2021, Oxford approved only limited coverage for thawing of the cryopreserved 2017 eggs, but upheld its denial of coverage for the October 2021 egg retrieval and related genetic tests. Plaintiff then sought external review under the New York Insurance Law, and the matter was assigned to Defendant Island Peer Review Organization ("IPRO"). By letters dated January 27 and February 11, 2022, IPRO upheld Oxford's determination that "a fresh round of IVF was not medically necessary."

Plaintiff then commenced this action in New York State court, before Defendants jointly removed the case to federal court on ERISA preemption grounds. Plaintiff asserted four causes of action. Plaintiff's first cause of action was two-pronged, alleging (i) a violation of ERISA § 502(c), on the ground that Oxford failed to provide Plaintiff with certain documents related to its denial of coverage; and (ii) wrongful denial of benefits under ERISA § 502(a)(1)(B). Plaintiff's second cause of action sought a declaratory judgment that Oxford could not use Plaintiff's cryopreserved 2017 eggs as a basis for its medical necessity determination. Plaintiff's third and fourth causes of action, respectively, challenged IPRO's decision to uphold Oxford's denial of benefits (under CPLR Article 78), and Oxford's claim of statutory immunity under the New York Insurance Law. In December 2022, IPRO moved to dismiss the case in its entirety, while Oxford moved to dismiss Plaintiff's second cause of action and the first prong of Plaintiff's first cause of action. Oxford did not move to dismiss the portion of Plaintiff's first cause of action seeking money damages for its alleged violation of ERISA § 502(a)(1)(B).

ERISA § 502(c) requires a "plan administrator" to provide, upon request by a participant, copies of certain documents "under which the plan is established or operated," and provides financial penalties for failure to comply. Plaintiff alleged that Oxford violated this statutory duty by failing to provide information relevant to her appeal, including any internal rules or guidelines relied upon by Oxford, and an explanation of the clinical or scientific basis for its decision. But the court rejected Plaintiff's claim, finding that this duty applies only to "plan administrators," defined as "the person specifically designated [as such] by the terms of the instrument under which the plan is operated." Here, because Plaintiff's plan expressly stated that Oxford "is not

the ERISA plan administrator," Oxford cannot be liable for failure to furnish documents. Likewise, the court found that Oxford did not "act as the plan administrator" merely by communicating its coverage determinations and notifying Plaintiff of her right to access certain documents. On these grounds, the court dismissed the first prong of Plaintiff's first cause of action.

Although couched as a request for declaratory judgment, the court found that Plaintiff's second cause of action was duplicative of her claim for money damages. Here, Plaintiff sought "a declaration that Oxford violated Plaintiff's rights under the terms of the [plan] by failing to pay Plaintiff's medical benefits [and a judgment] ordering Oxford to pay Plaintiff all applicable medical benefits to which she is entitled plus interest." But the court observed as follows: "a declaratory judgment stating that Oxford was wrong to deny such coverage is, in essence, identical to and thus impermissibly duplicative of [Plaintiff's] claim for benefits." In addition, because a declaratory judgment claim "is not appropriate where it is merely duplicative of a claim for benefits . . . and can be adequately redressed with money damages," the court dismissed Plaintiff's second cause of action, thereby granting all relief sought by Oxford.

The court then turned to Plaintiff's claims against IPRO, assessing the third and fourth causes of action in reverse order. The court first addressed the governing statutes and regulations, noting that Article 49 of the New York Insurance Law establishes "an insured's right to external appeal of a final adverse determination by a health plan" and allows the Department of Financial Services ("DFS") to adopt rules for the random assignment of external appeal agents. Moreover, Insurance Law § 4914(c) grants limited statutory immunity, providing that "no external appeal agent or clinical peer reviewer shall be liable in damages to any person for any opinions rendered . . . upon completion of an external appeal conducted pursuant to this section, unless such opinion was rendered in bad faith or involved gross negligence." Similarly, DFS Rule 410.11(e)(1) states that an insured who requests an external appeal "shall agree not to commence *any legal proceeding* against an external appeal agent [except for actions] for damages for bad faith or gross negligence." The court found that this "statutory and regulatory framework operates to shield IPRO from any suit unless it was grossly negligent or acted in bad faith."

Notwithstanding Rule 410.11(e)(1), Plaintiff's fourth cause of action sought a ruling that IPRO was not immune from a suit seeking only declaratory relief, not damages. In support of this position, Plaintiff "raise[d] a novel argument that no New York court has squarely considered: whether [Rule 410.11(e)(1)] constitutes an abuse of DFS's authority by prohibiting an insured from bringing *any lawsuit* of any kind against an external review agency . . . when the statutory text [in Article 49] only precludes suits for damages." But the court sidestepped this issue, finding that the ultimate relief sought by plaintiff – "a declaration that the regulation is null and void" – would only be available in a lawsuit against DFS (as "the regulatory body that promulgated the purportedly unconstitutional regulation"). Because DFS was not a party, the court dismissed Plaintiff's fourth cause of action. As a corollary – and "[b]ecause the question of whether Rule 410.10(e) is a valid exercise of DFS's authority [was] *not* properly before it" – the court was compelled to dismiss Plaintiff's third cause of action on the ground that IPRO is immune from suit, and to dismiss IPRO as a party. Here, the court observed that Plaintiff failed to allege bad faith or gross negligence and that, by seeking an external review, Plaintiff "waived her right to bring a legal action against the external review agent." The court also cited a 2020 decision by the New York Supreme Court, County of Albany, in which IPRO was held to be immune from an Article 78 challenge (*Meyer v. N.Y.S. Off. Fin. Servs.*, Index No. 5946-19).

As the court dismissed all other claims, the case will proceed only on the second prong of Plaintiff's first cause of action, which seeks money damages based on Oxford's alleged wrongful denial of benefits under ERISA § 502(a)(1)(B).

Third Department Rejects Argument that Department of Health's Medicaid Risk Freeze Was an Unlawful Unpromulgated Rule

Evercare Choice, Inc. v. Zucker, 218 A.D.3d 882 (3d Dep't 2023)

Petitioner, a managed long-term-care ("MLTC") plan that provides health and long-term care services to chronically ill or disabled Medicaid recipients, brought a combined plenary action, action for declaratory judgment, and proceeding pursuant to CPLR Article 78 to challenge determinations made by the Department of Health ("DOH") in calculating Petitioner's nursing home transition rates for the 2017-2018 fiscal year.

Pursuant to a contract with DOH, MLTC plans are funded on a set monthly rate for each Medicaid recipient enrolled in the plan that month, *i.e.* the monthly capitation rate. To compute the monthly capitation rate paid to each plan, DOH calculates a plan's "risk score" from the average risk of the population of members enrolled with each plan during the relevant time period. In 2018, DOH circulated draft documents showing, among other things, Petitioner's revised risk scores for the 2017-2018 fiscal year. However, after a plan representative contacted DOH expressing concerns about the score assigned to a particular MLTC plan, DOH decided to impose a state-wide freeze on risk scores and reverted to its previously-calculated risk scores (which, for Petitioner, was lower than what was in the draft documents). DOH eventually reworked its risk-setting methodology and assigned Petitioner a new, higher risk score.

In addition to capitation rates, DOH also pays MLTC plans an add-on rate for its member population that were permanent nursing home residents. This rate is calculated using multi-year

nursing home transition data submitted by the plans. For the 2017-2018 fiscal year, Petitioner submitted erroneous data and asked for an opportunity to correct the data to have its add-on rate adjusted. DOH reviewed the data, but determined it would not update Petitioner's add-on rate.

Petitioner thereafter sued seeking a declaratory judgment that the risk score freeze was an unpromulgated rule in violation of: (i) the State Administrative Procedure Act ("SAPA") and (ii) the New York Constitution, and that the risk score freeze, DOH's reversion to a prior risk score during the freeze, and DOH's refusal to correct Petitioner's add-on rate for the 2017–2018 fiscal year were (iii) arbitrary and capricious; (iv) an impermissible refusal to perform a duty enjoined upon DOH by law; and (v) a breach of contract. On Respondents' motion for partial summary judgment, the trial court dismissed the petition, finding that DOH did not violate SAPA or the New York Constitution, that DOH's actions were not arbitrary and capricious, and that the court lacked subject matter jurisdiction over the breach of contract claim.

On appeal, the Appellate Division, Third Department affirmed in part and reversed in part. The court affirmed the dismissal of Petitioner's claim under SAPA and the New York Constitution, finding the risk score freeze was not a "rule." As the court explained, a "rule is 'a fixed general principle to be applied by an administrative agency without regard to other facts and circumstances'" and the score freeze did not meet that criteria. Rather, the freeze was a temporary response to concerns about DOH's methodology, and during that process, DOH was required to review the data submitted by the MLTC plans to ensure that the risk scores used were actuarially sound and that "the capitation rates were adequate to provide quality of care to the plans' members." Since DOH's process during the freeze involved considering fixed and variable factors unique to a particular industrial activity on a case-by-case basis, it was not a rule that required promulgation under SAPA or the New York Constitution.

The court further affirmed the dismissal of the portion of Petitioner's arbitrary and capricious claim that pertained to DOH's refusal to correct Petitioner's add-on rate. The court held that DOH had submitted evidence, through affidavits, that it refused to correct Petitioner's add-on rate because making the correction would have also required DOH to recalculate the capitation rates for other plans. The court held that even though Petitioner's expert had offered alternative processes that could have been taken to retroactively correct Petitioner's add-on rate, DOH's explanation was rational and did not need to be annulled based on the mere existence of alternative proposals.

However, the court reversed the dismissal of that portion of Petitioner's arbitrary and capricious claim that pertained to DOH's imposition of the risk score freeze, its reversion to the prior risk score for the duration of the freeze, and its refusal to retroactively correct such score. The court held that there were material issues of fact on this issue that required a hearing because the record was devoid of necessary evidence, such as the certification of the risk scores and the rates used during the freeze.

The court then affirmed the dismissal of Petitioner's claim for mandamus to compel, finding such relief was not available because DOH's decisions involved the exercise of reasonable judgment, rather than the exercise of ministerial tasks.

Finally, the court disagreed with the trial court's decision to dismiss the breach of contract claim for lack of subject matter jurisdiction. As the court explained, while the Court of Claims is the proper forum for claims that only seek money damages against the state, a petitioner in a CPLR Article 78 proceeding may obtain monetary damages where such damages are incidental to the primary relief sought. Here, the court determined that Petitioner's claim focused on the allegedly arbitrary and capricious determinations by DOH, and the award of any monetary damages from a breach of contract claim would be incidental to such claim. The court therefore allowed Petitioner to proceed on the breach of contract claim to the extent that the claim related to the portion of the arbitrary and capricious claim that survived the motion for summary judgment.

Southern District of New York Limits Deaf Plaintiff's Recovery Under the Rehabilitation Act and Affordable Care Act to Nominal Damages

Nieves v. Plaza Rehab. & Nursing Ctr., No. 20 Civ. 1191, 2023 WL 4763945, (S.D.N.Y. July 26, 2023)

Plaintiff, who is deaf and contends American Sign Language ("ASL") is his primary and preferred method of communication,

was a resident at the Plaza Rehabilitation and Nursing Center (the "Plaza") for approximately six weeks following a heart surgery in 2018. Prior to his admission, staff were made aware that Plaintiff was deaf and needed sign language interpretation services. While he was at the Plaza, he was evaluated by a speech language pathologist whom he advised that "ASL was his primary and preferred language and that he did not want to use speech to communicate." During his admission, a Video Remote Interpreting ("VRI") device was located at the nursing station and his chart indicated that staff should use the device to communicate with Plaintiff. Despite this, the speech language pathologist "determined that he was high functioning and could comfortably make his needs known without an assistive device."

Approximately one year after the Plaza discharged him, Plaintiff commenced a lawsuit against the Plaza and Citadel Care Center, an entity that provides management and oversight to the Plaza. He claimed that Defendants discriminated against him based on his disability by failing to provide him with ASL interpreters in violation of the Americans with Disabilities Act ("ADA"), Rehabilitation Act ("RA"), Affordable Care Act ("ACA"), New York State Human Rights Law ("NYSHRL"), New York City Human Rights Law ("NYCHRL"), and New York Public Health Law. He sought injunctive relief, compensatory damages for emotional distress, and punitive damages. Both Plaintiff and Defendants moved for summary judgment.

As a threshold matter, the court granted summary judgment dismissal of Plaintiff's ADA claim because the ADA only allows for injunctive relief and Plaintiff withdrew his claim for injunctive relief.

Turning to Plaintiff's RA claim, the court rejected both parties' arguments that there was no dispute of fact as to whether Defendants discriminated against Plaintiff based on his disability and whether Plaintiff is entitled to monetary damages. The court held that to show discrimination, Plaintiff was required to establish that Defendants did not provide a means of effective communication and denied him meaningful access to services. The court held there was a dispute as to the subject matter, scope, and length of Plaintiff's interactions with staff, and whether he could effectively communicate without an interpreter.

As for the recovery of monetary damages, the court held that Plaintiff was required to demonstrate that Defendants intentionally violated the RA, which may be inferred "when a qualifying official, or policymaker, acted with at least deliberate indifference to the strong likelihood that a violation of federally protected rights will result." On this issue, the court held there were material facts in dispute warranting the denial of summary judgment since the Plaza had a policy to provide interpreters, there was an order in Plaintiff's chart to use VRI, and Plaintiff testified that Defendants refused to provide such services when he requested them. However, the court limited Plaintiff's potential damages at trial solely to nominal damages because: (i) emotional distress damages and compensatory damages for dignitary harm are not recoverable under the RA; and (ii) Plaintiff's conclusory claim for expectation damages fails to satisfy the requisite standard to determine such damages with "reasonable certainty." As the court explained, the United States Supreme Court's decision in *Cummings v. Premier Rehab Keller P.L.L.C*, 142 S. Ct. 1562 (2022) concluded that tort damages are not available under statutes enacted by Congress pursuant to the Spending Clause, which permits damages that are "traditionally available in suits for breach of contract." Pursuant to this standard, the court held that while Plaintiff could recover nominal damages under the RA or ACA since such damages are available in suits for breach of contract, Plaintiff could not recover emotional distress damages and compensatory damages for dignitary harm since those damages are types of tort damages. As for expectation damages, the court held that such damages could be recovered under the RA or ACA pursuant to *Cummings*, but a plaintiff's recovery is limited to an amount that the "evidence permits to be established with reasonable certainty." Here, Plaintiff could not recover expectation damages because Plaintiff did not provide any evidence that could permit the factfinder to conclude, with reasonable certainty, that he was entitled to expectation damages.

As for liability under the ACA, the court similarly rejected the parties' arguments that there was no dispute of fact. The court held that, under the ACA, Defendants must honor Plaintiff's primary consideration for communication unless they can demonstrate "that another equally effective means of communication is available or that the aid or service requested would fundamentally alter the nature of the program, service, or activity or would result in undue financial and administrative burdens." Here, there were disputed facts as to whether Defendants honored Plaintiff's primary consideration, and whether he was able to use equally effective communication with staff.

As to the NYSHRL and NYCHRL claims, the court determined that summary judgment on liability would be inappropriate for the same reasons as the RA claim, and further declined to grant summary judgment on damages. As the court explained, a plaintiff can recover compensatory damages for humiliation for these claims, and may also recover punitive damages under the NYCHRL where the defendant acts with conscious disregard of the rights of others. Here, there was a dispute as to whether Plaintiff suffered emotional distress based on his claim that he could not understand his medications and treatment during his stay, and whether he was refused interpreting services with "conscious disregard" for his rights.

Finally, the court held summary judgment was inappropriate on the Public Health Law claim. The court found that, under the Public Health Law, any healthcare facility that deprives a patient of any right or benefit will be liable to that patient for the patient's injuries. The court further held that "a right or benefit" under the statute includes rights created by federal or state stat-

utes, and, since Plaintiff's claims under several other federal or state statutes were proceeding to trial, the claim under the New York Public Health Law could also proceed to trial.

Court Denies Mental Hygiene Legal Services' Application to Mandate In-Person Mental Hygiene Law Article 9 Hearings

Matter of St. Joseph's Hosp. Health Ctr. v. B.V., 80 Misc. 3d 1011 (Sup. Ct., Onondaga County 2023)

In connection with an application by St. Joseph's Hospital Health Center (the "Hospital") to retain a patient and provide treatment pursuant to Mental Hygiene Law § 9.33, Mental Hygiene Legal Services ("MHLS") moved the Supreme Court, Onondaga County for an order directing that the proceedings be held in-person. Because MHLS made several identical motions in other mental hygiene proceedings, the court directed that all the motions be adjourned and heard together.

In support of the motion, MHLS argued that case precedent establishes that the court may require virtual proceedings only where there are "exceptional circumstances" or upon consent of the parties, and that no exceptional circumstances apply here because the COVID-19 era administrative orders mandating virtual appearances had been rescinded.

In opposition, the Hospital argued that the cases relied upon by MHLS predate the COVID-19 pandemic, during which the New York State Courts made great strides in video/virtual proceedings. The Hospital further argued that missing from MHLS's application are any affidavits or evidence indicating the patient's preference for an in-person appearance, and the patient therefore waived his or her right to appear. Finally, the Hospital argued that virtual proceedings were more cost-effective.

Weighing the positions of both parties, the Supreme Court, Onondaga County, denied MHLS's motion. In reaching its decision, the court first distinguished the cases cited by MHLS. Agreeing with the Hospital, the court held that technology had evolved since the early days in which applications like Zoom, Facetime and Skype were first introduced. Reinforcing that point, the court noted that it had conducted numerous virtual proceedings without significant issue.

The court further concluded that the patients' due process rights are not infringed by a virtual proceeding. While the court appreciated that treatment-over-objection was a significant private interest that could be impacted, the court quickly dispensed with the possibility that an erroneous deprivation of the patient's interest would occur if the proceedings were conducted through virtual means. The court also found that there were significant fiscal and administrative benefits to holding a virtual hearing, including reduced cost, increased safety, and time efficiency. One example the court relied upon is that an in-person proceeding could require as much as four hours for a doctor to leave the facility, appear in court, testify, and return to work with patients. Virtual appearances, on the other hand, would only take about 20 minutes. This "additional three-plus hours robs other patients of meaningful treatment [from the testifying doctor]." Another factor militating towards virtual hearings is MHLS's "shocking" admission that "they have not sought their purported client's opinion on whether to appear in-person or virtually." Holding that "[t]he Respondents are the parties in these matters, not MHLS," the court found MHLS's motions "procedurally defective for the lack of a respondent's affidavit."

Finally, the court addressed MHLS's argument that *State v. Robert F.*, 25 N.Y.3d 448 (2015), limited the application of remote hearings to only where "exceptional circumstances" require it. The court reasoned that by the very nature of MHL § 9.27 proceedings, the respondents are in a delicate mental state and thus present an "exceptional circumstance," which in this context does not necessarily mean "rare." Specifically, the court highlighted that the additional safety guards required of in-person appearances — including the transportation of the patient, many times in restraints, along with additional hospital staff and security to ensure the safety of the respondent and others — weighed in favor of finding that these cases were "inherently 'exceptional circumstances.'" Accordingly, the Court denied MHLS's request for in-person Mental Hygiene Law Article 9 hearings rather than virtual proceedings conducted via Microsoft Teams.

Third Department Upholds New York State Mandate Restricting the Number of Individuals with a Serious Mental Illness Allowed to Reside at a Transitional Adult Home

Oceanview Home for Adults, Inc. v. Zucker, 215 A.D.3d 140 (3d Dep't 2023)

In 1999, the United States Supreme Court issued a landmark decision (*Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581 (1999)) construing the states' obligations under Title II of the Americans with Disabilities Act (the "ADA") to ensure that mentally disabled individuals are afforded services in the most integrated setting suitable to their needs. In an effort to comply with *Olmstead*, the New York State Department of Health (the "DOH") implemented regulations mandating that the number of persons with a serious mental illness residing at a transitional adult home shall not exceed 25% of the facility's resident population (the "DOH Regulations").

Petitioner-Respondent Oceanview Home for Adults, Inc. ("Oceanview") is a private owner and operator of a transitional adult home that brought a hybrid CPLR Article 78 proceeding and action for declaratory judgment against Respondent-Appellant Howard Zucker, the New York State Commissioner of Health ("Zucker"), after the DOH upheld a citation finding Oceanview in violation of the 25% admissions cap pertaining to persons with a serious mental illness. Oceanview challenged

the DOH Regulations under several legal theories, including that they violate the Fair Housing Act (the "FHA") by discriminating against individuals with a serious mental illness.

The New York State Supreme Court granted judgment in favor of Oceanview and permanently enjoined enforcement of the DOH Regulations. In doing so, the Supreme Court rejected Zucker's argument that the 25% admissions cap did not violate the FHA because it furthers the integration mandate of *Olmstead* by "diverting such persons away from institutions and into alternative settings that are more integrated in the community." Conversely, the Supreme Court held that transitional adult homes are not "institutions" as defined by Title II of the ADA or as addressed in *Olmstead* insofar as they "are not owned, established, or operated by the State." Additionally, the Supreme Court held the DOH Regulations are not necessary for compliance with *Olmstead*, nor are they narrowly tailored to suit an individual's particular needs, and that the applicable "least restrictive alternative" standard requires the use of less discriminatory alternatives to promote the goal of integration. In response, Zucker filed an appeal with the Appellate Division, Third Department.

On appeal, the Third Department generally agreed with the Supreme Court that the DOH Regulations are discriminatory on their face insofar as the 25% admissions cap applies solely to individuals with a serious mental illness. Significantly, however, the Third Department disagreed with the Supreme Court's utilization of the "least restrictive alternative" standard to gauge the propriety of the DOH Regulations under the FHA in light of the facial discrimination. Further, the Third Department did not agree with the Supreme Court's holding that Title II of the ADA does not apply to privately owned and operated transitional adult homes. The Third Department also rejected the Supreme Court's determination that transitional adult homes cannot be equated to the type of institutions at issue in *Olmstead*.

First, instead of utilizing the "least restrictive alternative" standard, the Third Department chose to adopt the standard used by the Sixth, Ninth, and Tenth Circuits, which states housing restrictions that facially discriminate against people with disabilities will comply with the FHA upon a showing that: (1) the restriction benefits the protected class; or (2) the restriction is in response to legitimate safety concerns raised by the individuals affected. In the view of the Third Department, the standard employed by these Circuits, as compared to the "least restrictive alternative" standard, best achieves a balance to implement the ADA and FHA mandates. The Third Department also explained that the U.S. Department of Justice — the governmental entity tasked with enforcing the FHA — recommends utilizing this approach while managing the interplay between the discrimination protections of the FHA and the integration mandate of Title II of the ADA.

Second, the Third Department held the Supreme Court erred in concluding that because transitional adult homes are privately owned and operated, Title II of the ADA is inapplicable and cannot serve as a valid justification for the admissions cap. Instead, the Third Department explained that Oceanview challenged the DOH Regulations in accordance with its plan to administer mental health services in accordance with the ADA, and that the State's administration of mental health services, including in transitional adult homes, is subject to the ADA's integration mandate regardless of whether the transitional adult homes at issue are privately owned and operated.

Lastly, the Third Department noted that the Supreme Court's reading of the *Olmstead* decision was too narrow, and claimed the trial court ignored pertinent evidence equating transitional adult homes to institutionalized settings encompassed by the provisions of the ADA. Accordingly, the Third Department held that transitional adult homes do fall within the categories of facilities discussed in *Olmstead*, and that Title II of the ADA is applicable to Oceanview.

Based on the foregoing, the Third Department concluded that under the standard applied by the Sixth, Ninth, and Tenth Circuits, the DOH Regulations do not violate the FHA. The Third department explained that, after considering the justification proffered by Zucker in support of the DOH Regulations (*i.e.*, to benefit individuals with a serious mental illness by implementing the integration mandate from *Olmstead*), the circumstances under which they were promulgated cannot be overlooked, and that it is clear the 25% admissions cap was implemented to benefit, rather than to discriminate against, persons with a serious mental illness. In addition, the Third Department determined that the DOH Regulations were narrowly tailored to implement the integration mandate of Title II of the ADA because the 25% cap only applies to people with a "serious" mental illness.

In closing, the Third Department stressed the importance of leaving room for flexible solutions to address the complex problem of discrimination and to realize the goals established by Congress in the FHA. The Third Department noted that although the DOH Regulations "may not be a perfect solution to the problem articulated in *Olmstead*, they reflect a sound public health policy judgment undertaken in conjunction with the State's mental health experts to implement reasonable modifications to the State's provision of services in furtherance of the 'national mandate for the elimination of discrimination against individuals with disabilities.'"

Second Circuit Finds that Theaters Failed to Raise Plausible Free Speech and Equal Protection Challenges to The Key to NYC Program

Clementine Co. v. Adams, 74 F.4th 77 (2d Cir. 2023)

The Key to NYC program, announced by the Mayor of New York in August 2021, required that patrons and staff at various indoor venues, including theaters, be vaccinated against COV-

ID-19. Entities subject to the program were required to check their patrons' vaccination status and refuse entry to those who could not provide proof of vaccination. They faced escalating fines and criminal prosecution for failing to do so.

The Key to NYC program was enacted amid the rise of the highly transmissible Delta variant to COVID-19, and its purpose was to "incentiviz[e] as many of the City's residents to get vaccinated as possible." The emergency executive order establishing the program covered "indoor entertainment and recreational settings, indoor food services, and indoor gyms and fitness centers," focusing on "establishments frequented by groups of unassociated people interacting for a substantial period of time." It did not include "residential buildings, stores, or churches or other religious institutions."

Plaintiffs-Appellants, the operators of two small theaters in New York City, filed suit against the Mayor of New York in the U.S. District Court for the Southern District of New York under 42 U.S.C. § 1983, alleging that the Key to NYC program violated their freedom of speech rights under the First and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment. Plaintiffs-Appellants complained, *inter alia*, that many of their patrons "struggle[d]" to provide proof of vaccination, which required them to process numerous refunds and deal with "angry outbursts" from people denied access to their venues, and that they needed to hire additional staff to check ID and vaccination cards and confirm that each patron was eligible to enter their premises. Plaintiffs sought a declaratory judgment, an injunction prohibiting the enforcement of the Key to NYC's vaccine mandate against them, and an award of nominal damages and attorneys' fees.

The district court dismissed the complaint, finding that Plaintiffs-Appellants lacked standing because the alleged injury was suffered not by them, but by their patrons. The district court also held that Plaintiffs-Appellants' claims were moot because the Key to NYC program expired in March 2022. Plaintiffs-Appellants appealed.

The Second Circuit began by addressing the district court's grounds for dismissal of the complaint and determined that they were both erroneous. The Second Circuit held that Plaintiffs-Appellants' nominal damages claim was "plainly not moot" because it was "based on a completed violation of a legal right." Likewise, the Second Circuit held that Plaintiffs-Appellants alleged an injury-in-fact, and thus had standing to bring their claims, because "'even a small fractional loss' suffices."

Nevertheless, the Second Circuit affirmed the dismissal of Plaintiffs-Appellants' complaint on the alternative ground that it failed to state plausible claims for relief under the First or Fourteenth Amendments. The court held that the Key to NYC program did not implicate Plaintiffs-Appellants' right to free speech, as it neither limited what they said nor required them to say anything. While Plaintiffs-Appellants were obligated to check their patrons' vaccination status, they were free to express any views they chose through their theatrical productions. Thus, the court held, "Key to NYC regulated conduct, not speech." The court also noted that the program did not apply to Plaintiffs-Appellants because of the "content of their speech," and that most covered entities – such as "casinos, bowling alleys, billiard halls, restaurants, and gyms" – would be "hard pressed to argue there is any speech involved in their services."

The Second Circuit then noted that even if the Key to NYC program had incidentally implicated Plaintiffs-Appellants' speech, it would have been subject to intermediate scrutiny as a content-neutral regulation. The court found that the program would have survived such review as it advanced a "compelling" government interest in promoting vaccination in order to "combat the spread of COVID-19," which would not have been achieved as effectively through other means.

Lastly, the Second Circuit ruled that Plaintiffs-Appellants did not state a plausible Equal Protection claim, but merely "repackaged" their deficient free speech claim. Plaintiffs-Appellants alleged that the Key to NYC program impermissibly treated theaters differently from other similarly situated venues, such as houses of worship and schools that staged theatrical performances. The court rejected this claim because Plaintiffs-Appellants failed to identify any suspect class that it targeted or any fundamental right that it implicated. As the court found ample rational basis for the Key to NYC vaccination requirement, it held that Plaintiffs-Appellants' claim could not survive.

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A Patchwork Framework: A Range of State Health Care Transaction Review Laws Emerges

By Cody Keetch and Pamela Polevoy

Introduction

Effective August 1, 2023, New York joined at least twelve other states in enacting legislation increasing oversight of health care transactions.[1] Over the last decade, beginning in Massachusetts, states have passed legislation that increases reporting, notice, and approval requirements for health care transactions. Of significance, these laws and regulations involve health care transactions and health care entities that have not historically been reviewed. This article provides an overview of state health care transaction review laws and how the laws present new challenges for health care transactions.

While state health care transaction review laws have added new hurdles for health care transactions, overall, the laws have noble intentions. In large part, the legislation is meant to monitor the impact of health care transactions on cost, quality, access, equity, and competition with the goal of informing actions to improve affordability, access and quality of health care.[2] A number of the laws specify that the legislation is intended to increase transparency on mergers, acquisitions and other transactions involving health care entities that may impact competition and costs. Still other laws note that they are intended to better inform the public of who profits from their healthcare. For example: California's law was motivated in part by for-profit hospital transactions and New York's law was driven at regulating investor-backed entities and unlicensed entities involved in the provision of health care.

A Law of First Impression

With the passage of Chapter 224 of the Acts of 2012 the "Health Care Cost Containment Law,"[3] Massachusetts became one of the first states to require review of certain health care provider changes, focusing on how consolidations and alignments impact the health care market. The Massachusetts law created the Massachusetts Health Policy Commission (the HPC), an independent state agency tasked with reviewing certain health care transactions and arrangements and providing policy recommendations regarding health care delivery and payment system reform.[4]

Massachusetts requires that health care providers and health care provider organizations provide at least 60 days' written notice to the HPC before implementing any "Material Change" to their operations or governance structure.[5] The Office of the Massachusetts Attorney General, and the Massachusetts Center for Health Information and Analysis, must receive copies of the "Notice of Material Change." As a threshold matter, only providers and provider organizations with $25 million or more in "net patient service revenue" in the preceding fiscal year are subject to the material change notice requirements.[6] A "Material Change" includes: a merger, affiliation or acquisition involving a carrier (including accident or health insurers, nonprofit medical service corporations, and nonprofit hospital service corporations), hospital or hospital system; any other acquisition, merger or affiliation (including a corporate affiliation or employment of health care professionals) that would result in an increase of $10 million or more in annual net patient service revenue of the provider or provider organization, or in the provider or provider organization having a near-majority of market share in a given service category or region; and any clinical affiliation between two or more providers or provider organizations that each had $25 million or more in net patient service revenue in the preceding fiscal year (excluding affiliations solely for collaboration on clinical trials or graduate medical education programs).[7]

Following receipt of the Notice of Material Change, the HPC has 30 days to inform the filing parties whether additional information is required before the HPC will consider the notice complete. Within 30 days of receipt of a complete notice, the HPC then has 30 days to conduct a preliminary review of the proposed transaction and decide whether to initiate a cost and market impact review (CMIR), which the HPC must complete within 185 days from the date it received a complete notice.[8] If the HPC determines not to initiate a CMIR, the parties may proceed with the transaction. If the HPC initiates a CMIR, the transaction may not proceed until 30 days after the HPC issues its final report on its CMIR review.[9] The HPC is may in its discretion refer any final report to the Office of the Attorney General.

The Range of Health Care Transaction Review Laws

Massachusetts established a framework through which other states seemingly have been able to develop their own health care transaction review laws (Review Laws). Today, we see states regulating health care transactions in a variety of ways. These Review Laws range from least burdensome to the most burdensome. The least burdensome include advance notice of the transaction with a relatively moderate amount of information while the most burdensome mirror those requirements of Massachusetts, requiring both prior written notice and prior approval for a transaction to proceed.

New York

New York falls on the less burdensome side of the range as it requires only notice. Article 45-A of the New York Public Health Law titled "Disclosure of Material Transactions" went into effect on August 1, 2023.[10] The law requires that "heath care entities"

provide notice to the New York State Department of Health (NY DOH) at least 30 days prior to the closing of a proposed "material transaction."[11] If a transaction involves two health care entities, although not explicitly stated in the statute, both entities may need to submit notice. During the 30-day notice period, the NY DOH will publish information regarding the proposed transaction on its website as well as submit electronic copies of the notice materials to the New York State Attorney General's Antitrust, Health Care and Charities Bureaus.[12] In addition to the 30-day pre-closing notice, health care entities must notify the NY DOH following the closing of the transaction, although at this time, no deadline for this post-closing notification has been announced.[13] The statute defines "health care entities" as physician practices and groups, management services organizations, provider-sponsored organizations and health insurance plans (subject to exemptions), and any other kind of health care facility, organization or plan providing health care services in the state.[14] In addition, the statute defines "material transaction" as any of the following: a single transaction or a series of related transactions that take place within a rolling 12 month period, that meet or exceed certain thresholds (including but not limited to revenues): (1) mergers with a health care entity; (2) acquisitions of one or more health care entities, including, transfer of control; (3) affiliations or contracts formed between a health care entity and another person; or (4) partnerships, joint ventures, accountable care organizations, parent organizations, or management service organizations formed for the purpose of administering contracts with health plans, third-party administrators, pharmacy benefit managers, or health care providers.[15] Clinical affiliations of health care entities that are formed for clinical trial collaboration, graduate medical education programs, transactions subject to the Certificate of Need or the insurance entity approval processes and "de minimis" transactions do not require notice. A "de minimis transaction" is a transaction or a series of related transactions that result in a health care entity increasing its total gross in-state revenues by less than $25 million. Insurers authorized to do business in the state and pharmacy benefit managers registered or licensed in the state are also exempt.

Washington

Similar to New York, Washington falls on the less burdensome side of the range as it requires only notice. Effective July 28, 2019, hospitals, hospital systems, and provider organizations are required to provide 60 days' prior written notice to the Washington Attorney General of a transaction resulting in a "material change."[16] The law requires that each party to such a proposed transaction submit such written notice but does not specify whether the parties should provide such notice individually or jointly.[17] A "material change" means a merger, acquisition, or contracting affiliation between a hospital, hospital system, or provider organization.[18] If one of the parties to the transaction is an out of state entity, then notice of a material change is required only if that entity generates $10 million or more in health care services revenue from patients residing in Washington.[19] Where both parties are in-state entities, there is no revenue threshold.[20]

Nevada

Like New York and Washington, Nevada falls on the less burdensome side of the range as it requires only notice but requires both a pre-closing and post-closing notice. Effective October 1, 2023, Nevada requires parties to a "reportable healthcare transaction" to submit notice to the Nevada Attorney General at least 30 days prior to the effective date of a transaction.[21] The law requires that each party to such a proposed transaction submit such written notice but does not specify whether the parties should provide such notice individually or jointly.[22] Notice is required for transactions that result in (1) a material change to the business or corporate structure of a group practice or "health carrier" such as a merger, consolidation, affiliation, acquisition, and employment of all or substantially all of the practitioners in a group practice or health carrier,[23] or (2) that would cause a group practice or health carrier to provide 50% or more of any health care service within a geographic market.[24] If a group practice or health carrier are under common ownership or have a contracting relationship that was established on or before October 1, 2021, they are exempt from this reporting requirement.[25] A "health carrier" is an entity subject to the state insurance laws and regulations or that contracts to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including, without limitation, a sickness and accident health insurance company, a health maintenance organization, a nonprofit hospital and health service corporation or any other entity providing a plan of health insurance, health benefits or health care services.[26]

In addition, Nevada requires hospitals to submit notice to the Nevada Department of Health and Human Services within 60 days following the effective date of a merger, acquisition or joint venture with any entity, including, without limitation, a physician group practice, or the execution of a contract for management of the hospital.[27] In addition, physician group practices or persons owning all or substantially all of a physician group practice must also submit a post-closing notice if (1) the physician groups party to the particular transaction or management contract represent at least 20% of the physicians who practice any specialty in a particular geographic area and (2) the physician group practice represents the largest number of physicians of any physician group practice that is a party to or owned by a party to the transaction or management contract.[28]

Delaware

Delaware falls on the less burdensome side of the range as it requires only notice, however, due the length of notice required Delaware is more burdensome than New York, Washington, and Nevada. Delaware's Review Law applies only to non-profit health care entities engaging in a "conversion transaction" with a for-profit entity.[29] The law requires a non-profit health care entity to

provide prior written notice to the Delaware Attorney General at least 180 days prior to the closing date of the proposed transaction.[30] "Conversion transactions" include, but are not limited to, the (1) sale, transfer, lease, exchange, optioning, conveyance, affiliation, merger, joint venture, or other disposition of a material amount of the assets or operations of a not-for-profit healthcare entity to a for-profit entity; (2) transfer of control or governance of a material amount of the assets or operations of a not-for-profit healthcare entity to a for-profit entity; (3) a substantial change or amendment to a certificate of incorporation which materially affects a not-for-profit healthcare entity's charitable or public benefit intent, or the disposition of reserves or control of a not-for-profit healthcare entity to a for-profit entity; or (4) a change in the composition of a not-for-profit's board of directors that results in a majority of a not-for-profit's board being affiliated with a for-profit entity.[31]

New Jersey

New Jersey's Review Law is unique, as it does not involve a government agency. Effective November 16, 2022, the law requires New Jersey "health care entities" to provide employees with at least 30 days' prior written notice of any proposed change in control of the health care entity.[32] The law places distinct and significant burdens on health care entities by requiring the successor health care entity to provide employment to the employees for a transition period of four months following the effective date of the change of control and includes a number of rules governing how the successor employer may reduce the number of employees both during and after the transition period.[33] "Health care entities" include, but are not limited to, hospitals, healthcare and treatment centers, rehabilitation centers, nursing homes, outpatient clinics, residential healthcare facilities, staffing registries and home healthcare services agencies.[34]

Connecticut

Connecticut falls closer to the middle of the range as it only requires notice, however, its notice requirements apply to any "covered transaction" regardless of annual revenue or transaction size. Effective May 14, 2018, Connecticut requires covered entities (group practices, hospitals, and hospital systems) to submit pre-closing notice to the Connecticut Attorney General at least 30 days prior to the effective date of a covered transaction as well as post-closing notice to the Connecticut Office of Health Strategy within 30 days following the effective date of a covered transaction.[35] A "covered transaction" is defined as a merger, consolidation, affiliation, acquisition of all or substantially all of a group practice's assets or equity, employment of all or substantially all of the physicians in a group practice, and acquisition of one or more insolvent group practices that, in each instance, results in a "material change" to the business or corporate structure of a group practice. A "material change" to the business or corporate structure of a group practice means the transaction is (i) with another group practice that results in a group practice comprised of eight or more physicians, or (ii) a hospital, hospital system, captive professional entity, medical foundation or other entity organized or controlled by a hospital or hospital system.[36] In addition, notice is required for "affiliations" between a hospital or hospital system and another hospital or hospital system.[37] The law defines "affiliation" as the formation of a relationship between two or more entities that permits entities to negotiate jointly with third parties over rates for professional medical services.[38]

Illinois

Illinois falls closer to the middle of the range as well as it requires notice only 30 days prior to the effective date of the transaction, however, the Illinois Attorney General may request additional information resulting in a longer review period. Effective January 1, 2024, "health care facilities" must submit notice to the Illinois Attorney General for mergers, acquisitions or contracting affiliations between two or more health care facilities or provider organizations when the entities were not previously under common ownership or contracting affiliation regardless of annual revenue or transaction size.[39] In addition, for transactions involving an Illinois health care entity and an out-of-state health care entity, notice is required when the out-of-state entity generates $10 million or more in annual revenue from patients residing in Illinois.[40] "Health care facilities" include, but are not limited to, ambulatory surgery centers, hospitals and other locations or operations licensed under the Illinois Hospital Licensing Act, outpatient surgery centers, kidney disease treatment centers, and any other institution, place, building or room used for provision of a health care category of service defined under the Illinois Health Facilities Planning Act.[41] Following receipt of pre-closing notice, the Illinois Attorney General may request additional information.[42] In such event, the transaction may not proceed until 30 days after the parties have substantially complied with the request.[43] In total, the Illinois Review Law process can last for up to 60 days.

Minnesota

While Minnesota's Review Law is similar to those in Oregon, California, and Massachusetts, Minnesota's requirements only apply to "health care entities" generating greater than $10 million in annual revenue.[44] For this reason, Minnesota falls towards the more burdensome side of the range but not as far as Oregon, California, and Massachusetts. Minnesota has different notice requirements for "health care entities" depending on the amount of revenue they generate. Effective May 27, 2023, health care entities generating $80 million of revenue of more must submit a pre-closing notice to the Minnesota Attorney General and the Minnesota Commissioner of Health (MCH) at least 60 days prior to the proposed completion date of the transaction.[45] Effective January 1, 2024, health care entities generating between $10 and $80 million of revenue must submit a pre-closing notice to the MCH at least 30 days prior to closing date or 10 business days prior to the date the parties first reasonably anticipate entering

into the transaction (if shorter).[46] "Heath care entities" includes hospitals, hospital systems, captive professional entities, medical foundations, health care provider group practices, entities that are organized by or exert control over any of the foregoing entities.[47]

Oregon

Effective January 1, 2023, Oregon requires pre-closing notice of a proposed health care transaction, approval to proceed with the transaction, and if approved, notice of the closure of the transaction.[48] For this reason, Oregon falls on the more burdensome end of the range along with California and Massachusetts. A "health care entity" must submit notice of a "material change transaction" to the Oregon Health Authority (OHA) at least 180 days in advance of the anticipated closing date.[49] In addition, health care entities that are non-profits must also submit notice to the Charitable Activities Section of the Oregon Department of Justice.[50] Following receipt of written notice of material change, OHA will conduct a preliminary review of the transaction to determine whether the transaction constitutes a material change transaction within 30 days.[51] OHA may either approve, approve with conditions, or decide to conduct a comprehensive review of the proposed transaction if it decides not to approve the transaction at the conclusion of its preliminary review.[52] "Health care entities" include individual health care providers, hospitals and hospital systems, carriers that offer health benefit plans within the state, Medicare Advantage plans, coordinated care or prepared management care health services organizations, and persons or business entities that are parent organizations of, have control over, are controlled by, or are under common control with, an entity that has a primary function of the provision of health care items or services.[53] Ultimately, a comprehensive review can take 180 days or more for OHA to deny or approve a proposed transaction.[54]

California

As a result of the California Health Care Quality and Affordability Act, California established the Office of Health Care Affordability (OHCA) to, among other things, review certain proposed health care transactions in California.[55] The act authorized OHCA to promulgate regulations to carry out its duty to oversee proposed health care transactions.[56] As a result, OHCA issued emergency regulations that went into effect January 1, 2024 and starting April 1, 2024 will require "health care entities" to submit pre-closing notice to the OHCA at least 90 days prior to the effective date of a proposed change (i.e., closing date).[57] Following receipt of notice, OHCA will notify the submitter within 45 days if OHCA determines a CMIR is not necessary, however, if OHCA determines a CMIR is necessary, it will notify the submitter within 60 days.[58] If OHCA determines a CMIR is necessary then it has 90 days (with an optional 30 day extension) to complete the review.[59] Following completion of a CMIR, OHCA will issue a preliminary report, which report will be made available for comment by the parties to the transaction and the public for a period of 10 days following its issuance.).[60] OHCA will issue a final report within 15 days of the comment period closing unless extended by OHCA for "good cause shown," which includes requiring additional time to review and evaluate written comments regarding the preliminary report.[61]

In addition to a lengthy review process, the types of entities and transactions captured in the proposed regulations are far reaching. "Health care entities" (HCE) include health care service plans, health insurers, hospitals, hospital systems, fully integrated delivery systems, pharmacy benefit managers, physician organizations (with greater than 25 physicians, subject to high-cost outlier exception), other providers (e.g., ambulatory surgery centers, certain clinics, clinical labs, imaging facilities, and other health facilities), and payers. HCEs also include "any parents, affiliates, or subsidiaries that act in California on behalf of a payer" and (i) control, govern, or are financially responsible for the HCE or are subject to the control, governance, or financial control of the HCE; or (ii) in the case of a subsidiary, a subsidiary acting on behalf of another subsidiary. HCEs do not include dentists, pharmacies, drug manufacturers, durable medical equipment suppliers, home health agencies, or emergency medical transportation.[62] The types of HCEs that are subject to these regulations are those HCEs that meet one of the following thresholds: (1) has an annual revenue of at least $25 million or that owns or controls California assets of at least $25 million; (2) has an annual revenue of at least $10 million or that owns or controls California assets of at least $10 million and is a party to a transaction with any HCE satisfying the foregoing subsection (1); or (3) is located in a designated primary care health professional shortage area in California as defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations.[63] The types of transactions and arrangements subject to these proposed regulations include, but are not limited to, those that (1) involve "health care services" and have a fair market value of at least $25 million; (2) involve the formation of a new HCE, affiliation, partnership, joint venture, or parent corporation for the provision of health services in California that is projected to have at least $25 million in annual revenue; (3) involve the sale, transfer, lease, exchange, option, encumbrance, or other disposition of 25% or more of the total California assets of any health care entity in the transaction; (4) are part of a series of related transactions for the same or related health care services occurring over the past 10 years involving the same HCE or entities affiliated with HCE (which will be analyzed as a single transaction) or (5) involve acquisition of a HCE by another HCE, where the acquirer has consummated similar transactions within the past 10 years, with a HCE that provides the same or related health care services (which will be analyzed as a single transaction).[64] Given the above requirements, California falls on the far side of the range with Massachusetts with some of the most burdensome requirements.

The Reach of Health Care Transaction Review Laws

Not all Review Laws are limited to notice, review and/or approval requirements. Several states have included reporting requirements for health care entities that extend beyond any one transaction. In addition, certain laws require that the regulatory authority prepare its own reports that analyze the impact of health care transactions on particular markets.

In Connecticut, physician groups of 30 or more, and hospitals, are required to submit annual forms to the Attorney General by January 15 for the prior year.[65] The form is comprise of the names and specialties of physicians in a group practice, the names of the business entities involved, the addresses and a description of the services provided at each location; and the primary service area served.[66] In New York, during the 30-day pre-closing period, the NY DOH will publish information on its website related to the proposed transaction.[67] Similarly, in Nevada, the Nevada Department of Health and Human Services will post the information contained in the notices. Additionally, the Nevada Department of Health and Human Services will prepare a report annually regarding market transactions and concentration in health care based on the information in the notices and post the report on an Internet website. Minnesota's law provides that for large transactions (entities generating over $80 million), the Attorney General or Commissioner of Health may hold public sessions to obtain input on the transaction from providers or the community.[68] In Oregon, following approval of a proposed transaction, OHA will conduct follow-up analyses for all approved transactions one, two and five years following the transaction's completion, at which time OHA will assess the transactional impact and compliance with approval conditions.[69] In Massachusetts, the HPC is continuously monitoring health care transactions and developing policy recommendations that are posted on is website and presented at its board meetings. Of significance, in its recent 2023 health care cost trends report and at its December 13, 2023 board meeting, the HPC recommended updating its transaction notice requirements to ensure information would be submitted about private equity investments. The report's policy recommendations included:

> C. Enhance the HPC's Market Oversight Authority of For-Profit Investment. The requirement that providers and provider organizations file notices of material change before engaging in certain transactions should be updated to reflect the increasing role of private equity and for-profit investment in health care. All new and significant for-profit investments in a provider or provider organization, including private equity investment, should require a material change notice filing.

Many state laws note that notwithstanding the law itself, there is no limitation on when the Attorney General may pursue state or federal antitrust law investigation or enforcement at a later date.

Looking Forward

When considering a potential health care transaction in a state with a Review Law, parties should determine whether the transaction is subject to a Review Law as part of their initial discussions. The parties need to ask and answer: (1) whether they are subject to the Review Law; (2) if the transaction is covered by the Review Law; and (3) whether an exclusion applies to the entity or transaction that takes them out the Review Law. Once parties know that a Review Law applies, they should build it into the transaction timeline. This will not only set the parties' expectations as to the timing of signing and closing, but also inform the parties as they prepare due diligence questions. When assessing a transaction, health care entities should be considering the impact of their proposed transaction on cost, access, and availability of health care services. These areas are going to be highly reviewed. For example, buyers might conduct analysis on the impact of transactions on reimbursement rates and access to services early on in their due diligence process. Parties should also bear in mind that the information about their transactions, agreements and related documentation will likely become visible to the public.

Parties to health care transactions covered by a Review Law should plan for lengthier and uncertain transaction timelines and understand that simultaneous signings and closings may no longer be an option for health care transactions. Business development, operations and transaction teams should be educated about these laws and the lengthier transaction timelines. Importantly, health care entities and transactions not previously subject to a regulatory review process should be prepared to be subject to regulatory oversight.

In addition, entities that are not directly impacted by the notice and approval requirements detailed in this article but otherwise transact with health care entities that are impacted, should take notice of these requirements. For example, management services agreements and arrangements may be subject to notice in certain states if an arrangement is comprehensive and transfers administrative or significant operational control to the management services entity such that it meets a state's thresholds. Given this, and the fact that most of the states with Review Laws also prohibit the corporate practice of medicine, arrangements between physician practices and management companies should be reassessed to confirm that the manager's responsibilities are in compliance with state laws and to ensure that ultimate control of the operations and administration of physician practices remains with physician shareholders.

In conclusion, parties should understand that many aspects of the Review Law process will fall outside of their control. It is important that parties manage what they can and align on expectations. Careful planning, thorough and complete notices and

applications, and thoughtful communications with regulators can facilitate a smooth and easy review process.

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Endnotes

1. N.Y. Pub. Health Law § 4550.
2. Minn. Stat. Ann. § 145D.01(5)(a); Mass. Gen. Laws Ann. ch. 6D, § 5.
3. 958 CMR 7.13.
4. Chapter 224 of the Acts of 2012, "An Act Improving the Quality of Health Care and Reducing Costs Through Increased Transparency, Efficiency and Innovation."
5. Mass. Gen. Laws Ann. ch. 6D, § 13(a); 958 CMR 7.03.
6. 958 CMR 7.03.
7. Mass. Gen. Laws Ann. ch. 6D, § 13(a); 958 CMR 7.01.
8. Mass. Gen. Laws Ann. ch. 6D, § 13(f); 958 CMR 7.12.
9. *Id.*
10. N.Y. Pub. Health Law § 4550.
11. N.Y. Pub. Health Law § 4552(1).
12. N.Y. Pub. Health Law § 4552(2)(b).
13. N.Y. Pub. Health Law § 4552(3).
14. N.Y. Pub. Health Law § 4550(2).
15. N.Y. Pub. Health Law § 4550(4).
16. Wash. Rev. Code Ann. § 19.390.030(1).
17. *Id.*
18. *Id.* at (2).
19. *Id.* at (3).
20. *Id.*
21. Nev. Rev. Stat. Ann. § 598A.390.
22. *Id.*
23. Nev. Rev. Stat. Ann. § 598A.370(3)(a)-(d).
24. *Id.* at (1)(a)-(b).
25. *Id.* at (2)(a)-(b).
26. Nev. Rev. Stat. Ann. § 695G.024.
27. Nev. Rev. Stat. Ann. § 439A.126(1).
28. *Id.* at (2)(a)-(b).
29. Del. Code Ann. tit. 29, § 2531(1).
30. Del. Code Ann. tit. 29, § 2532.
31. Del. Code Ann. tit. 29, § 2531(1).
32. N.J. Stat. Ann. § 34:11-4.15(a).
33. *Id.* at (b)-(c).
34. N.J. Stat. Ann. § 34:11-4.15(f).
35. Conn. Gen. Stat. Ann. § 19a-486i(c); Conn. Gen. Stat. Ann. § 19a-486i(d)(2).
36. Conn. Gen. Stat. Ann. § 19a-486i(c).
37. *Id.* at (e).
38. *Id.* at (a)(1).
39. 740 Ill. Comp. Stat. Ann. 10/7.2a(b).
40. 740 Ill. Comp. Stat. Ann. 10/7.2a(b).
41. *Id.* at (a).
42. *Id.* at (d).
43. *Id.*
44. Minn. Stat. Ann. § 145D.01(1).
45. *Id.* at (2)(a)(2)(b).
46. Minn. Stat. Ann. § 145D.02(a).
47. Minn. Stat. Ann. § 145D.01(1)(e).
48. Or. Admin. R. 409-070-0030(2); Or. Admin. R. 409-070-0055(2).
49. Or. Admin. R. 409-070-0030(2).
50. Or. Admin. R. 409-070-0040(1).
51. Or. Admin. R. 409-070-0055(1).
52. *Id.* at (2).
53. Or. Admin. R. 409-070-0005.
54. Or. Admin. R. 409-070-0060(1).
55. Cal. Health & Safety Code § 127507(a).
56. Cal. Health & Safety Code § 127501(c)(16).
57. 22 CCR 97435(a).
58. 22 CCR 974440(a)(2).
59. 22 CCR 974440(e)(1).
60. 22 CCR 974442(c)(2).
61. *Id.* at (d).
62. 22 CCR 97431(g).
63. 22 CCR 97435(b)(1)-(3).
64. 22 CCR 97431(h); 97435(b)-(c).
65. Conn. Gen. Stat. Ann. § 19a-486i(h).
66. *Id.*
67. N.Y. Pub. Health Law § 4552(2)(b).
68. Minn. Stat. Ann. § 145D.01(2)(d)(12)(g).
69. Or. Admin. R. 409-070-0080(1).

Article 45-A of the New York State Public Health Law

Disclosure of Material Transactions

SECTION 4550

Definitions

Public Health (PBH) CHAPTER 45, ARTICLE 45-A § 4550. Definitions. For the purposes of this article, the following terms shall have the following meanings:

1. "Control" means the possession, direct or indirect, of the power to direct or cause the direction of the management, administrative functions, and policies of a health care entity, whether through the ownership of voting securities or rights, control, either directly or indirectly, by contract (except a commercial contract for goods or non-management services) or otherwise; but no person shall be deemed to control another person solely by reason of being an officer or director of a health care entity. "Control" shall be presumed to exist if any person directly or indirectly owns, controls, or holds with the power to vote ten percent or more of the voting securities of a health care entity.

2. "Health care entity" shall include but not be limited to a physician practice, group, or management services organization or similar entity providing all or substantially all of the administrative or management services under contract with one or more physician practices, provider-sponsored organization, health insurance plan, or any other kind of health care facility, organization or plan providing health care services in this state; provided, however, that a "health care entity" shall not include an insurer authorized to do business in this state, or a pharmacy benefit manager registered or licensed in this state. An "insurer" shall not include non-insurance subsidiaries and affiliated entities of insurance companies regulated under the insurance law or this chapter.

3. "Health equity" shall mean achieving the highest level of health for all people and shall entail focused efforts to address avoidable inequalities by equalizing those conditions for health for those that have experienced injustices, socioeconomic disadvantages, and systemic disadvantages.

4. "Material transaction" shall mean:

(a) any of the following, occurring during a single transaction or in a series of related transactions that take place within a rolling twelve month time period, and meet or exceed thresholds, for factors including but not limited to changes in revenue:

(i) a merger with a health care entity;

(ii) an acquisition of one or more health care entities, including but not limited to the assignment, sale, or other conveyance of assets, voting securities, membership, or partnership interest or the transfer of control;

(iii) an affiliation agreement or contract formed between a health care entity and another person; or

(iv) the formation of a partnership, joint venture, accountable care organization, parent organization, or management services organization for the purpose of administering contracts with health plans, third-party administrators, pharmacy benefit managers, or health care providers as prescribed by the commissioner by regulation.

(b) "Material transaction" shall not include a clinical affiliation of health care entities formed for the purpose of collaborating on clinical trials or graduate medical education programs and shall not include any transaction that is already subject to review under article twenty-eight, thirty, thirty-six, forty, forty-four, forty-six, forty-six-A, or forty-six-B of this chapter. "Material transaction" shall not include a de minimis transaction, which shall mean for purposes of this article a transaction or a series of related transactions which result in a health care entity increasing its total gross in-state revenues by less than twenty-five million dollars.

SECTION 4551

Disclosure of material transactions

Public Health (PBH) CHAPTER 45, ARTICLE 45-A § 4551. Disclosure of material transactions. Pursuant to this article, the department shall adopt a process for the disclosure and notice of material transactions. The items disclosed shall include the factors listed in this article. Nothing in this article shall limit or restrict the authority of the superintendent of financial services under article fifteen, sixteen, seventeen, forty-two, forty-three, seventy-one, or seventy-three of the insurance law, or regulations promulgated thereunder.

SECTION 4552

Notice of material transactions; requirements

Public Health (PBH) CHAPTER 45, ARTICLE 45-A § 4552. Notice of material transactions; requirements:

1. A health care entity shall submit to the department written notice, with supporting documentation as described below and further defined in regulation developed by the department, which the department shall be in receipt of at least thirty days before the closing date of the transaction, in the form and manner prescribed by the department. Immediately upon the submission to the department, the department shall submit electronic copies of such notice with supporting documentation to the antitrust, health care and charities bureaus of the office of the New York attorney general. Such written notice shall include, but not be limited to:

(a) The names of the parties to the material transaction and their current addresses;

(b) Copies of any definitive agreements governing the terms of the material transaction, including pre- and post-closing conditions;

(c) Identification of all locations where health care services are currently provided by each party and the revenue generated in the state from such locations;

(d) Any plans to reduce or eliminate services and/or participation in specific plan networks;

(e) The closing date of the proposed material transaction;

(f) A brief description of the nature and purpose of the proposed material transaction including:

(i) the anticipated impact of the material transaction on cost, quality, access, health equity, and competition in the impacted markets, which may be supported by data and a formal market impact analysis; and

(ii) any commitments by the health care entity to address anticipated impacts.

2. (a) Except as provided in paragraph (b) of this subdivision, supporting documentation as described in subdivision one of this section shall not be subject to disclosure under article six of the public officers law.

(b) During such thirty-day period prior to the closing date, the department shall post on its website:

(i) a summary of the proposed transaction;

(ii) an explanation of the groups or individuals likely to be impacted by the transaction;

(iii) information about services currently provided by the health care entity, commitments by the health care entity to continue such services and any services that will be reduced or eliminated; and

(iv) details about how to submit comments, in a format that is easy to find and easy to read.

3. A health care entity that is a party to a material transaction shall notify the department upon closing of the transaction in the form and manner prescribed by the department.

4. Failure to notify the department of a material transaction under this section shall be subject to civil penalties under section twelve of this chapter. Each day in which the violation continues shall constitute a separate violation.

This statute was originally published and is available on The New York State Senate website at https://www.nysenate.gov/legislation/laws/PBH/A45-A.

The Direct Primary Care Model: Considerations for New York Providers, Patients and Employers

By Louis Q. Reynolds

As of July 2023, there were more than 2,100 direct primary care practices operating in the United States, spread out over 48 states.[1] As the direct primary care concept continues to grow and become an attractive model for patients, physicians and self-funded employers, it will be important to monitor the changing legal and regulatory landscape to see how current federal and state barriers to this model are addressed.

Utilizing components of traditional retainer medicine and capitated payment models, the direct primary care model offers a primary care-based alternative to traditional fee-for-service medicine for private-pay patients. While New York has yet to specifically regulate direct primary care models, more than 30 states have enacted legislation or are in the process of passing legislation that addresses such models.[2] This article describes the DPC model and its growth across the United States, the main legal themes applicable to such models and some important considerations for providers and employers who may be exploring such models, especially within New York State.

Background

The direct primary care model is a type of retainer practice arrangement. Retainer practice arrangements generally feature a direct contract between a physician (or physician group) and a patient where the patient pays a periodic fee in exchange for access to a defined range of ongoing primary care services.[3] Direct primary care model practices charge this periodic fee, but the following two factors distinguish such arrangements from general retainer practice arrangements:

1. Direct primary care arrangements do not bill any third parties on a fee-for-service basis.

2. Any per-visit charge must be less than the monthly equivalent of the periodic fee.[4]

Direct primary care practices typically contract directly with patients or with employers administering a self-funded group health plan.[5] Monthly membership fees typically range from $65 to $85 for adult patients.[6] While the range of services covered under a direct primary care arrangement will vary by arrangement, services typically covered include preventive care, basic illness treatment for both acute and chronic conditions and care coordination.[7] Some direct primary care practices may also provide coverage for a defined panel of laboratory tests and imaging services.[8]

As alternatives to the traditional fee-for-service payment structure, direct primary care arrangements center on the importance of the relationship between patients and their primary care providers. A primary care provider generally serves as a patient's on-ramp to the health care system and plays a pivotal role in coordinating a patient's care at all levels of the health care system.[9]

Benefits

Multiple benefits flow from the direct primary care model, for both physicians and patients. For patients, this model promotes better access to a patient's primary care provider. On average, practice patient panel sizes range from 200 to 600 patients.[10] The average patient panel size for traditional primary care practices is 2,500 patients.[11] The smaller patient panel sizes in direct primary care practices limit delays for patients in scheduling appointments, result in shorter wait times for patients while at the physician's office and allow for patients to spend more time directly with their physician.[12] Overall, a strong foundation of primary care may produce better health outcomes overall, greater equity in health care access and outcomes and lower per capita health costs.[13]

For direct primary care providers, the absence of third-party reimbursement in direct primary care practices has the potential to significantly reduce administrative costs for the direct primary care practice.[14] Similarly, the absence of third-party reimbursement significantly reduces the practice's time spent on insurance paperwork and quality reporting responsibilities related to government and private payers.[15] In turn, this may reduce physician burnout, especially in smaller physician practices.[16]

For employers, because increased access to primary care may contribute to improved health outcomes and thereby reduce health care costs and utilization, employers that administer self-funded health plans may consider implementing a direct primary care option within their health plans to control and reduce costs among their employee populations.

Disadvantages and Policy Concerns

The multifaceted benefits of the direct primary care model are appealing, but there are some disadvantages that may make it a less attractive option for some patients. As noted, it is limited in scope to primary care services. As a result, an individual's membership usually must be supplemented by insurance coverage that covers specialty and hospital care. The purchase of a direct primary care membership offered through a health

insurance exchange would not meet the minimum essential coverage requirements.[17] For individuals who are not covered under an employer's group health plan and who must obtain individual health coverage, this would be an additional cost and could be cost-prohibitive for patients with lower incomes.

In addition, while the direct primary care model increases patients' access to primary care providers, patients must be members of a practice within this model in order to take advantage of this increased access. Where access increases for direct primary care members, it may decrease for the non-member population. There are two aspects to this issue.

First, if the direct primary care model grows, there may be fewer primary care physicians available to the overall patient population. Non-members may be forced to join direct primary care practices if there are no other available options in their geographic area.[18]

Second, direct primary care providers typically opt out of Medicare to avoid the regulatory risk of charging a membership fee that covers services already covered by Medicare. When providers participating in Medicare request any other payment for covered services from Medicare patients, they are subject to substantial penalties and exclusion from Medicare and other federal health care programs.[19]

Each provider that opts out of Medicare is one less provider available to provide a full scope of primary care services to Medicare patients, who already face challenges in finding primary care providers. Family practitioners accounted for one of the highest percentages of providers who opted out of Medicare in 2023.[20]

From the provider perspective, opting out of Medicare reduces the cost of regulatory compliance and the risk of penalties, but may limit providers' access to treating patients in other health care settings, including hospitals and skilled nursing facilities.[21]

As a result, from a financial perspective, providers considering whether to establish practices within this model and opt out of Medicare should be sure that they will serve enough non-Medicare patients to justify opting out of Medicare.[22]

Legal Implications and Regulatory Landscape: State Considerations

A major threshold question in determining the scope of regulation applicable to direct primary care arrangements is not a health care question, but an insurance question. The question asks whether the agreement between a practice following this model and the patient or consumer is a contract for insurance and, overall, whether the practice is engaging in an insurance business. If the practice is engaging in an insurance business, it generally must hold an insurance license and is therefore subject to a multitude of other state insurance laws.[23]

Direct primary care arrangements do resemble the basic insurance relationship, where an insured pays a set premium to an insurer in exchange for an insurer's reimbursement for an insurable event. Recognizing this, states that permit direct primary care arrangements typically do so under their insurance, health or professional code using an express carve-out that says such arrangements are not conducting an insurance business.

While statutes addressing direct primary care arrangements vary from state to state, those states that clearly permit direct primary care arrangements take a simple approach. First, the state statutes comprehensively define direct primary care, direct primary care arrangement and direct primary care contract. Next, the statutes create an exemption for these arrangements from state insurance certification and licensure.

Mississippi's Direct Primary Care Act within Mississippi's Insurance Code provides for such an exemption from state insurance certification and licensure for direct primary care practices.[24]

The Mississippi Direct Primary Care Act defines "direct primary care agreement" as "a contract between a primary care provider and an individual patient or his or her legal representative or between a primary care provider and an employer on behalf of its employees in which the primary care provider agrees to provide primary care services to the individual patient for an agreed-upon fee and period of time."[25]

It defines a "direct primary care service" as "a service that is provided by charging a periodic fee-for-services; not billing any third parties on a fee-for-service basis for the individual covered by the direct primary care agreement; and allowing for a per visit fee to be charged to the patient at the time of service."[26]

In addition, to limit the perverse incentive for direct primary care practices to only accept healthier, low-utilization patients for membership (often called "cherry picking"), the Mississippi Direct Primary Care Act prohibits practices from declining to accept new patients or discontinuing care to existing patients solely based on the patient's health status.[27]

Tennessee, under its Health Care Empowerment Act, defines a "direct medical care agreement" as a written contractual agreement between a direct medical care provider and an individual patient, or the patient's legal representative, in which:

- The direct medical care provider agrees to provide medical care services to the individual patient for an agreed fee over an agreed period of time.
- The direct medical care provider will not bill third parties on a fee-for-service basis.

- Any per visit charges under the agreement will be less than the monthly equivalent of the periodic fee.
- The agreement describes the scope of the medical care service that is covered by the periodic fee.
- The agreement contains the disclosures set forth in Tennessee Code Section 63-1-502(1)(E)(i)-(vi).[28]

As defined under The Health Care Empowerment Act, "'Direct medical care provider':

- Means an individual or legal entity that is licensed, registered or otherwise authorized to provide medical care services in [Tennessee] under this title and who chooses to enter into a direct medical care agreement; and
- Includes an individual medical care provider or other legal entity, alone or with other professionals associated with the provider or other legal entity."[29]

The Health Care Empowerment Act expressly states that "[a] direct medical care agreement is not insurance and is not subject to regulation by the department of commerce and insurance." It further states that "[e]ntering into a direct medical care agreement is not the business of insurance."[30]

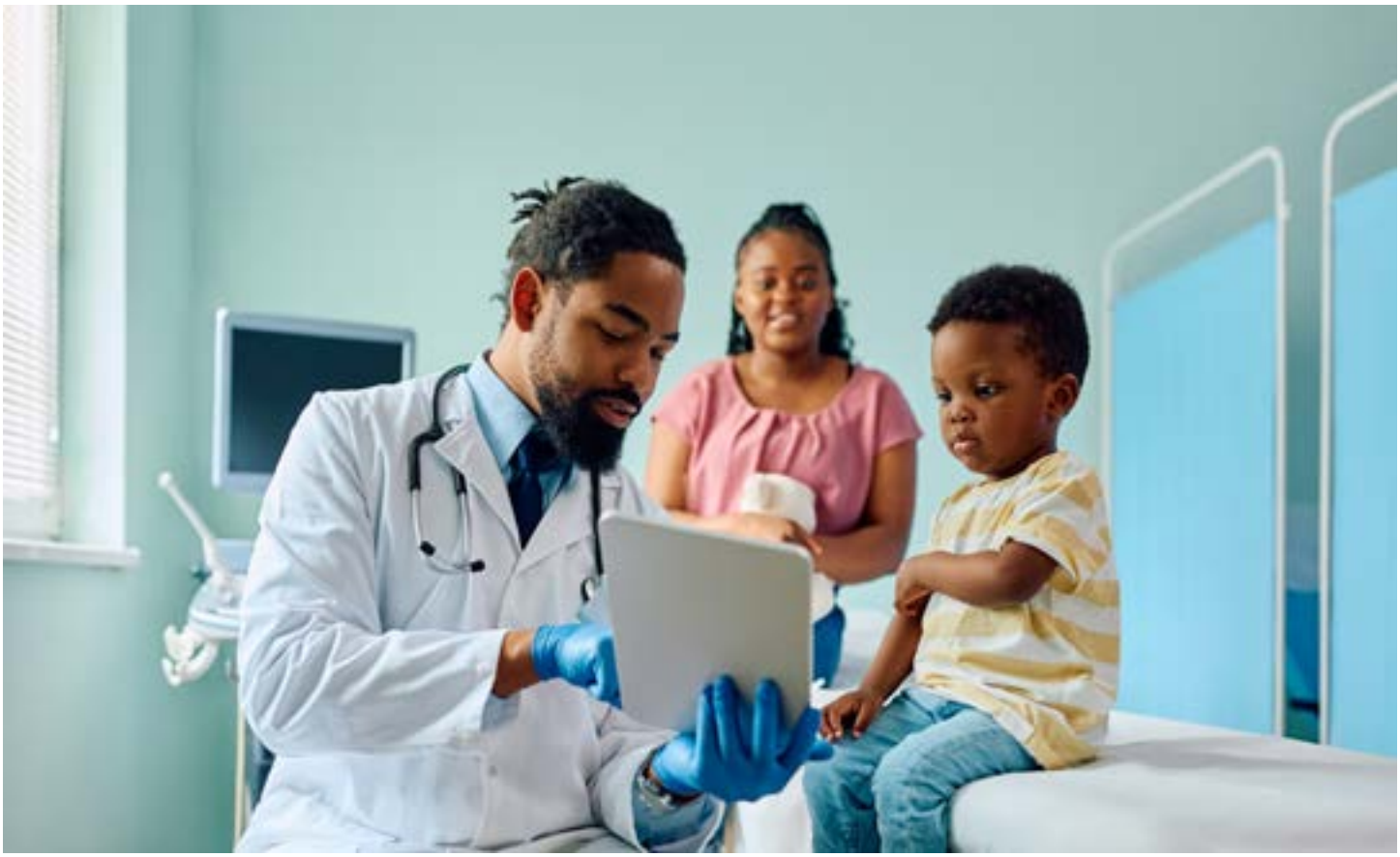
New York does not specifically regulate direct primary care arrangements at this time, and there are no proposals to do so in the legislative pipeline. New York, however, hinted how it would treat direct primary care arrangements in a 2009 Department of Financial Services advisory opinion.

The opinion assessed whether a New York professional services corporation that, in exchange for a monthly fee of $79 per month, provided "unlimited visits" for "comprehensive medical services" was doing an insurance business in violation of New York Insurance Law Section 1101.[31]

The practice's membership agreement provided: "All Members in good standing shall be entitled to regular preventive checkups for adults and/or well-baby checkups (including all vaccinations up to the age of ten except the Gardasil vaccine)."

The agreement provided additional coverage for unlimited sick visits charged at $10 per visit. It excluded coverage for hospital stays, emergency room visits, specialist services, imaging for specialist services and all lab tests not expressly provided for in an appendix to the agreement.

The Department of Financial Services analyzed the practice within the scope of Insurance Law Sections 1101 and 1102. New York Law defines "insurance contract" as "[a]ny agreement or other transaction whereby one party, the 'insurer,' is obligated to confer a benefit of pecuniary value upon another party, the 'insured' or 'beneficiary,' dependent upon the happening of a fortuitous event in which the insured or beneficiary has, or is expected to have at the time of such happening,



a material interest which will be adversely affected by the happening of such event."[32]

Fortuitous event "means any occurrence or failure to occur which is, or is assumed by the parties to be, to a substantial extent beyond the control of either party."[33]

Making, or proposing to make, as insurer, any insurance contract constitutes "doing an insurance business" in New York State.[34] No person, firm, association, corporation or joint-stock company may do an insurance business in New York State unless authorized by a license or exempted from such licensure.[35]

The Department of Financial Services concluded that a health care provider that offers health care at a discount to patients who pay a membership fee to join the plan constitutes the doing of an insurance business because the benefits that the plan provides are dependent on the happening of a fortuitous event – the need for health care – which is beyond the control of either party.[36] As a result, the provider needed an insurance license because the provider bore the risk of incurring a loss if the cost of the services provided exceeded the monthly fees paid by the patient.

The opinion did not categorically prohibit all such membership agreements in the state. It noted one feature of a membership agreement that would not constitute the doing of an insurance business.

> However, a service plan where there is a prepaid membership fee, and certain services occasioned by the happening of a fortuitous event are offered for an additional fee per service which is discounted from the usual fee, does not constitute the doing of an insurance business, and does not require an insurance license by the Department, provided that the fees cover the cost of rendering the service, including reasonable overhead.[37]

Therefore, to avoid the "doing the business of insurance" label, a practice operating in New York must limit the services covered by a patient's periodic fee to services for non-fortuitous events. A routine annual physical is a non-fortuitous event, for example. The practice may charge an additional fee to provide services for fortuitous events, provided that the fees charged cover the cost of rendering the service, including reasonable overhead.[38]

Legal Implications and Regulatory Landscape: Federal Considerations

Federal treatment of direct primary care arrangements, like the states, relates to the impact of these arrangements on individual and group health insurance coverage. Direct primary care arrangements have been directly addressed under the Affordable Care Act and by the Internal Revenue Service in regulatory preambles.

The ACA requires that employers offer minimum essential coverage to at least 95% of their full-time employees (and their dependents).[39] A key issue, then, is whether an employer can meet this requirement, in part, by offering primary care through a direct primary care arrangement.

The ACA treats these arrangements differently depending on whether the arrangement is offered as part of a qualified health plan or as a standalone arrangement, not paired with a supplementary qualified health plan.

The ACA allows a qualified health plan to provide coverage of certain services through a "direct primary care medical home plan," provided the qualified health plan meets all requirements that are otherwise applicable and the services covered by the medical home plan are coordinated with the entity offering the qualified health plan.[40] The U.S. Department of Health and Human Services considers a "direct primary care medical home plan" to mean "an arrangement where a fee is paid by an individual, or on behalf of an individual, directly to a medical home for primary care services, consistent with the program established in Washington [(state)]."[41]

A "patient-centered medical home" is a model of care that includes personal physicians or other primary care providers; whole person orientation; coordinated and integrated care; safe and high-quality care through evidence-informed medicine, appropriate use of health information technology and continuous quality improvements; expanded access to care; and payment that recognizes added value from additional components of patient-centered care.[42]

The Department of Health and Human Services considers "primary care services" to mean "routine health care services, including screening, assessment, diagnosis, and treatment for the purpose of promotion of health, and detection and management of disease or injury."[43]

On the other hand, a standalone agreement to receive primary care services through a direct primary care arrangement is not subject to the federal consumer protections that otherwise apply to individual health coverage. Enrollment in this type of arrangement does not qualify as "minimum essential coverage" for purposes of the ACA's individual mandate.[44, 45]

While the Department of Health and Human Services did consider allowing an individual to purchase a direct primary care medical home and separately acquire wrap-around coverage, it noted that allowing a separate offering would require consumers to make two payments for full medical coverage, "adding complexity to the process of acquiring health insurance, ensuring enrollee[s] have access to the full complement

of the essential health benefits to which they are entitled, and complicating the allocation of advance payments of the premium tax credit."[46]

The IRS issued a proposed rule in 2020 that, in part, sought to establish a definition for direct primary care arrangements and explain whether these arrangements qualify as "medical care" under Internal Revenue Code Section 213(d)(1)(A) and as "medical insurance" under IRC Section 213(d)(1)(D).[47] The determination of whether a direct primary care arrangement is medical care or medical insurance has a significant impact on (1) an individual's ability to have their membership fee reimbursed by their employer-funded health reimbursement arrangement or health savings account; and (2) an individual's overall eligibility for a health savings account.

First, the IRS permits a deduction for expenses paid during the tax year (if not compensated by insurance or otherwise) for medical care for an individual.[48]

For deduction purposes, medical care primarily includes amounts paid for the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect any structure or function of the body ("Section 213(d) medical care expenses").[49]

Health reimbursement arrangements are employer self-insured medical reimbursement plans funded solely by employer contributions, not through salary reductions. These arrangements reimburse some or all of Section 213(d) medical care expenses.

If a direct primary care membership fee is considered a Section 213(d) medical care expense, then an employee's tax-advantaged health reimbursement arrangement balance can be used to cover the costs of the membership fee.

Health savings accounts are tax-exempt trusts and custodial accounts established by eligible individuals or employees to pay qualified medical expenses in conjunction with a high-deductible health plan.[50] Both employees and employers may contribute to a health savings account if provided in conjunction with a group health plan. To be eligible, an individual generally (1) must be covered under a high-deductible health plan; and (2) must not be covered under any other health plan that is not a high-deductible health plan that provides coverage for any benefit that is covered under the high-deductible health plan.[51] In addition, the rules prohibit the purchasing of health insurance with health savings account funds.[52]

Therefore, direct primary care arrangements create two limitations with respect to health savings account eligibility and the use of health savings account funds.

First, because direct primary care arrangements provide for a broad range of primary care services, like physical examinations, vaccinations and lab testing, for example, they may be considered "other coverage" that covers the same types of services already covered under a high-deductible plan. As a result, if the arrangement is considered "other coverage," an individual who participates would be ineligible to contribute to a health savings account under current rules.

Second, if a direct primary care arrangement is considered "medical insurance," this would prohibit the use of a health savings account balance to pay for direct primary care membership fees.

In its 2020 proposed rule, the IRS noted that an individual participating in a direct primary care arrangement may maintain eligibility for a health savings account in limited circumstances.[53] If the individual is covered in an arrangement that does not provide coverage as part of a health plan or insurance or solely provides coverage for preventive care (solely provides for a routine annual physical examination, for example), the individual is not precluded from contributing to a health savings account.[54]

The proposed rule was not finalized, and there is still no definition within the Internal Revenue Code for direct primary care. New legislation addressing the same issue has been introduced, however, under the Primary Care Enhancement Act.[55] The Primary Care Enhancement Act amends the Internal Revenue Code to provide, in part, that direct primary care service arrangements are to be treated as medical care under Section 213(d) and that such arrangements do not disqualify deductible health savings contributions. It specifically provides that direct primary care service arrangements:

(1) "[S]hall not be treated as a health plan" for purposes of the health savings account eligibility rules, meaning that a direct primary care arrangement would not be considered

other coverage that would make a participant ineligible to contribute to an HSA account.

(2) "[S]hall not be treated as insurance" for purposes of rules covering the use of health savings account funds, meaning direct primary care participants with a health savings account may use the balance to pay for their membership fees.[56]

The bill was referred to the U.S. Senate Committee on Finance, and no further action has occurred at this time.[57]

Key Takeaways

New York State Providers

Without any legislation covering direct primary care arrangements, New York has yet to exclude such arrangements from regulation as "doing an insurance business."

For New York providers, this means that there is no clear protection for direct primary care practices against scrutiny from the New York State Department of Financial Services. Providers considering the model, then, to avoid conducting an unlawful insurance business in New York should adhere to the following concepts established in OGC Op. No. 09-02-02:

- Ensure that the regular, periodic fee to be charged to patients only includes coverage for non-fortuitous events like an annual physical or required vaccines.
- For services that address fortuitous events – sick visits, for example – charge a separate fee and ensure that the fee to be charged exceeds the practice's cost to render the service, including overhead costs.

Patients

Direct primary care arrangements foster increased access to a patient's primary care physician. As noted, studies indicate that increased access to a patient's primary care physician may result in improved health outcomes.

Patients should be aware, however, that this model of care alone, not paired with any other health insurance coverage, generally does not satisfy the ACA's minimum essential coverage requirement. Therefore, individual patients participating in a standalone arrangement must also enroll in other coverage, necessitating two separate payments for coverage. As a result, standalone arrangements may be cost-restrictive for lower-income patients. In addition, the growth of this model of care could reduce primary care access and limit provider choice for non-direct primary care members, especially for patients with Medicare coverage.

Self-Funded Employers

From the payor side, the direct primary care model may provide an attractive alternative benefit option for self-funded employers looking to reduce overall claim costs and utilization.

Employers exploring partnering with a practice using this model to provide primary care services to their employees must be aware of the impact of such partnership on other benefit offerings within the employer's health plan. This is especially the case if the employer offers a high-deductible health plan paired with a health savings account.

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3. *See* Philip Eskew, *Direct Primary Care Membership Medicine*, 110 W. Va. Med. J. 8 (2014).
4. *See* Philip M. Eskew & Kathleen Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, 28 J. Am. Bd. Fam. Med. 793 (2015). Direct primary care practices must typically charge per visit fees that are less than the monthly membership fee to avoid scrutiny as an insurance business under state insurance codes (as is the case with New York, as discussed later). Concierge arrangements tend to bill insurers in addition to charging retainer fees and typically cater to wealthier clientele. *See* Maanasa Kona, Kevin Lucia & Sabrina Corlette, *Direct Primary Care Arrangements Raise Questions for State Insurance Regulators*, Commonwealth Fund, Oct. 22, 2018, https://www.commonwealthfund.org/blog/2018/direct-primary-care-arrangements-state-insurance.
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14. Without third-party reimbursement for direct primary care arrangements, costs related to contracting and submitting claims are reduced. *See generally* Busch *et al.*, *supra* note 5, at 12.
15. While exemption from quality reporting lessens a burden on providers, it could negatively impact quality overall. At the very least, it will decrease the data available for the quality programs of government and commercial payors.
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18. Since membership is not a full solution for health coverage, it requires members to carry some other level of insurance to cover services that the direct primary care practice does not provide. This could be cost-prohibitive for some patients.
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22. *See* Philip Eskew, *Opting Out of Medicare*, DPC Frontier, https://www.dpcfrontier.com/opting-out-of-medicare.
23. *See, e.g.*, N.Y. Ins. Law § 1102.
24. *See* Miss. Code. Ann. § 83-81-7.
25. *Id.* § 83-81-3(b).
26. *Id.* § 83-81-3(c).
27. *See id.* § 83-81-11.
28. Tenn. Code Ann. § 63-1-502(1)(A)-(E). These disclosures include statements that the agreement does not constitute health insurance under the laws of the state, that an uninsured patient that enters into a direct medical care agreement may be subject to tax penalties under the ACA, that payments made by a patient for services rendered under a direct medical care agreement may not count towards the patient's health insurance deductibles and maximum out-of-pocket expenses, that the patient is encouraged to consult with the patient's health insurance plan before entering into the agreement and receiving care, and that a direct medical care provider who breaches the agreement may be liable for damages and subject to discipline by the appropriate licensing board.
29. *Id.* § 63-1-502(2)(A)-(B).
30. *Id.* § 63-1-504(a)-(b).
31. N.Y. Ins. Law § 1101. *See* Doing an Insurance Business, OGC Op. No. 09-02-02 (Off. of Gen. Couns., N.Y. State Dep't of Fin. Servs. 2009).
32. N.Y. Ins. Law § 1101(a)(1).
33. N.Y. Ins. Law § 1101(a)(2).
34. N.Y. Ins. Law § 1101(b)(1)-(1)(A).
35. N.Y. Ins. Law § 1102(a).
36. The DFS used the need for a tetanus vaccine after an injury as an example of a fortuitous event that the arrangement at issue would cover.
37. *See* OGC Op. No. 09-02-02.
38. *Id.* Note also that a direct primary care practice does not assume financial responsibility for medical services by other providers, which is a key feature of some capitation arrangements.
39. *See Employer Shared Responsibility Provisions*, IRS, https://www.irs.gov/affordable-care-act/employers/employer-shared-responsibility-provisions (last updated Oct. 23, 2023).
40. Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, 76 Fed. Reg. 41866, 41900 (July 15, 2011).
41. *Id.*
42. 42 U.S.C. § 256a-1(c)(2)(A)-(F).
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47. *See* Certain Medical Care Arrangements, 85 Fed. Reg. 35398 (June 10, 2020).
48. *See* I.R.C. § 213(a).
49. *Id.* § 213(d)(1)(A).
50. *See* I.R.C. § 223.
51. *See id.* § 223(c)(1)(A).
52. *Id.* § 223(d)(2)(B).
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54. *Id.*
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Taking A Closer Look: Assessing Biometric Authentication in Healthcare Settings and Beyond

By Michael O. Fraser

Background

Crises such as the Coronavirus pandemic (COVID-19) required shifts away from standard hospital protocols to ensure that lives were saved.[1] These shifts required consideration of how patient privacy rights may be superseded by measures to preserve public health.[2] To address the demands of the COVID-19 pandemic safeguards were curtailed or eliminated to optimize patient care and access.

In healthcare settings, biometric authentication is now utilized to streamline the patient registration process by minimizing paperwork and expediting patient intake to ensure secure and precise healthcare service delivery.[3] Notably Elmhurst Hospital, The Mount Sinai Health System, NYU Langone Health, and other hospitals have integrated biometric authentication technologies into their operational protocols. These technologies include fingerprint recognition for patient identification during check-in, facial recognition for mobile apps utilizing Face or Touch ID, and retina scans for body temperature through scanning sensors.[4, 5]

This article will assess privacy and technology issues, particularly in the context of biometric authentication within New York hospitals, arguing that a more transparent notice and informed consent procedure could eliminate the need for federal or state legislation. Scholars have written on the general need for enhanced healthcare privacy safeguards, the protection of consumer privacy rights, and measures against government and corporate surveillance.[6] However, this article will propose a new approach to biometric authentication in New York.

I. CHALLENGES IN PATIENT DATA PRIVACY

While biometric technology has many advantages, challenges related to patient distrust remain a primary concern. Structural inequalities such as racial and ethnic bias, gender bias, and issues of informed consent contribute to patient skepticism.[7] Legal scholars and policymakers have also raised concerns regarding the use, storage, and ethical permissibility of biometric technology use within healthcare settings.[8]

A. STRUCTURAL INEQUALITIES

Although biometric technology offers convenience and security, it also has the potential to create racial and ethnic bias through algorithmic prioritization. Gender bias may emerge due to design limitations and insensitivities for non-binary individuals who do not conform to traditional gender norms. Moreover, issues of informed consent can exacerbate these concerns, particularly when individuals from marginalized communities are incorrectly and disproportionately identified. To address biometric challenges, it is essential to prioritize diverse datasets and eliminate algorithmic biases, beginning with mindful and ethical considerations when implementing biometric systems.

B. POLICY CONCERNS

Tiffany Li, a biometric health law researcher and Associate Professor of Law at the University of San Francisco School of Law, suggests that "rather than blindly giving up our privacy for unknown benefits to public health, we should seek the privacy-preserving methods of achieving our public health goals."[9] Brenda Leong, an artificial intelligence lawyer in Washington, DC, bolsters Li's argument by suggesting that facial recognition and biometric authentication should never be the default. Leong argues biometric data should not be part of the standard terms of service or privacy policy because of the error rates in recognition and the public's lack of trust in the systems or the people running them.[10]

II. CONGRESSIONAL INITIATIVES FOR BIOMETRIC PRIVACY REGULATION

Before the pandemic, Congress introduced the Commercial Facial Recognition Privacy Act of 2019, or CFRPA, requiring consent before using biometric tracking on individuals. At the time of this writing, this bill has yet to be enacted. Another bill introduced by Congress, The Facial Recognition and Biometric Technology Moratorium Act of 2021**,** imposes limits on the use of biometric surveillance by federal, state, and local governments.[11] This bill did not receive a vote and thus did not make it through the legislative process. In addition, Congress introduced The Ethical Use of Facial Recognition Act to establish a congressional commission which recommends rules governing the use and limitations of biometrics on both government and commercial use of such technology.[12]

While these bills have been introduced, they have not been enacted. Instead, the U.S. Department of Health and Human Services, Office of the Inspector General (OIG), and the National Institute of Standards and Technology (NIST) have provided comprehensive guidelines on various aspects of biometric technology, cybersecurity, and privacy that hospitals can look to for guidance.

III. A COMPARATIVE ANALYSIS OF BIOMETRIC USE IN THE EU, U.S., AND NY

A. BIOMETRIC USE IN THE EUROPEAN UNION

It is worth considering valuable insights embraced by the European Union's General Data Protection Regulation (GDPR).[13] The GDPR not only unifies data privacy rules across all 27 E.U. member countries, it also extends its jurisdiction to non-EU entities conducting business within the E.U., thereby ensuring the strict applicability of the GDPR.[14] Embracing a similar approach in the U.S. could serve as a robust model for universally applicable biometric data protection framework. Such a framework would prioritize individuals' rights and privacy, regardless of their location or the entities involved in data processing, thus fostering trust and enhancing data security.

B. A NATIONAL USE CASE

The Health Insurance Portability and Accountability Act (HIPAA) is a comprehensive framework for safeguarding the privacy and security of health information within the United States. However, its applicability to biometric data is subject to debate. While crucial for healthcare data privacy, HIPAA's scope is primarily directed at protected health information (PHI) held by covered entities, which may not fully encompass the unique challenges associated with biometric data.[15] Biometric information, introduces distinctive complexities, including difficulties in effective de-identification, heightened risks of data breaches, and a lack of specific consent requirements. Unlike traditional health data, biometric information may not always be directly linked to an individual's health condition, posing potential privacy gaps.[16] Consequently, there is a need for a more tailored regulatory framework to address the distinct characteristics and risks posed by this type of sensitive information.[17] Illinois, Texas, Washington, and other states have enacted their individual privacy laws where private entities must notify individuals that their biometric information is being collected and destroy the data within a specific timeframe.[18, 19]

The best way to see how such regulation might work in practice is to look at Illinois's Biometric Information Privacy Act, ("BIPA").[20] BIPA is the only state law requiring both notice and signed consent from the person whose biometrics will be collected. Additionally, BIPA outlines the specific purpose and length of term for collecting, storing, and using the data.[21] Under BIPA, if a private entity fails to comply with one of the statutory requirements, it is considered an infringement on the rights of the individuals whose biometric information is involved.[22] Those aggrieved by such violations have a right of action in a State Court or as a supplemental claim in federal district court against the entity responsible.

C. NEW YORK'S APPROACH TO BIOMETRIC AUTHENTICATION

In 2021, the New York City Council enacted provisions in the City's Administrative Code to address inquiries about the use of biometric technology in local businesses.[23] For businesses operating in the City, New York City's biometric law requires that commercial establishments post a "clear and conspicuous" sign near the customer entrances prior to collecting biometric information, prohibits the sale of this data without the customer's consent, and is enforced through a private right of action, with statutory damages of $500 for each negligent violation, and $5,000 for each intentional violation.[24]

On one end, the local law protects citizens by making it unlawful to profit from biometric data. It creates a private right of action for aggrieved individuals to sue for violations. On the contrary, The New York City biometric law applies explicitly to "commercial establishments" encompassing only retail stores, places of entertainment, and restaurants.

IV. A NEW APPROACH TO BIOMETRIC AUTHENTICATION IN NEW YORK

Under The New York Privacy Act, enacted in 2023, companies are now required to disclose their methods of de-identifying personal information, place special safeguards around data sharing, and allow consumers to obtain the names of all entities with whom their information is shared.[25] The New York Privacy Act allows New Yorkers to have more control over their data and digital privacy.

Furthermore, it explicitly addresses what is permissible for covered entities like hospitals. One legal issue that New York lawmakers may not have redressed is the notice and signed consent needed from the person whose biometrics will be collected. Suppose patients are provided with information regarding the collection and storage of their data and the ability to opt-out. In that case, these procedures could potentially equip patients with the tools to make well-informed decisions concerning their health and the handling of their biometric data.

V. CONCLUSION

For HIPAA-regulated entities in New York contemplating the adoption of facial recognition technology, compliance with privacy, security, and breach notification rule requirements should be a top compliance priority and included in all risk assessments. In shaping future biometric legislation, healthcare facilities should shift to a framework centered around notice and the ability to optout because it empowers consumers and patients alike to manage the retention, storage, and sharing of their biometric data. As noted, this approach may even obviate the need for additional federal or state legislation.

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