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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 Repeal of New York's Do Not Resuscitate Law: A Technical Clean-up Bill – And an Occasion for Reflection

An Examination of State Trends in Facility Fee Legislation as New York's Public Health Law § 2830 Takes Effect

Intersex Infants and Unjustified Surgical Intervention

NYSBA PUBLICATIONS

Legal Manual For New York Physicians

Sixth Edition

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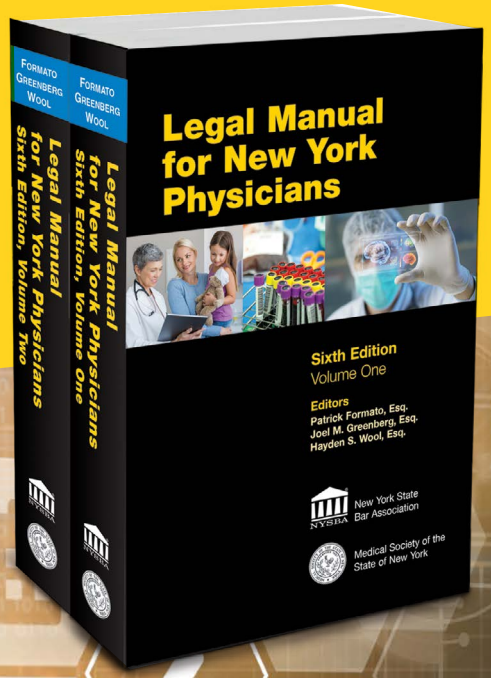

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NYSBA

Health Law Journal

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Email: cassandra.dinova@cdphp.com

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A Message From the Section Chair

I am honored to be the new section chair and I am so looking forward to the exciting year ahead for the Health Law Section. I want to first thank Frank J. Serbaroli and Karen Gallinari, both past chairs of the section, for encouraging me to join the section and appointing me as the first chairperson of the Diversity Committee. I encourage all members, if you are looking to become more active or merely network, to review the list of committees and reach out to the committee chairs for more information.

Health Law Journal

This issue of the Health Law Journal has a number of interesting articles. First, the journal profiles the 2023 Diversity Health Law Fellows. The Fellowship Program has placed nearly 20 students at legal in-house health care systems since 2011. In 2013, the section received a NYSBA Section Diversity Champion Award. We want to thank all of the in-house counsel and health systems for their generosity and commitment to diversity by hosting Fellows. Joshua Joseph, a student at the Hofstra University Maurice A. Deane School of Law, will be placed at Catholic Health Systems, and Bernard Robert, a student at the Pace University Elisabeth Haub School of Law, will be placed at Downstate Medical Center. This issue also focuses on a number of health law topics, including the status of religious vaccination exemptions for health care workers; changes to New York State Public Health Law regarding DNR orders; and an update on Senate Bill S52521C regarding facility fees. Thank you again Cassandra DiNova, legal counsel at CDPHP, for your leadership as editor of the Health Law Journal.

The Year Ahead

This year the Health Law Section will return to the New York State Bar Association Law Center for the fall meeting on October 26, 2023. Under the leadership of past chair Anoush Koroghlian-Scott, the fall meeting promises to be an exciting event. Topics will include: (1) Legal Changes to Physician Practice Ownership; (2) Regulatory Changes by the New York State Office of the Medicaid Inspector General; and (3) What New York Attorneys Should Know About Health Equity. Lastly, we also encourage you to make plans to attend the Annual Meeting of the Health Law Section Tuesday, January 16, 2024 at the New York Hilton. Under the leadership and direction of Margie Davino, Fox Rothschild, this year promises to be another successful Annual Meeting.

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

In the Legislature

By Michael A. Paulsen

The New York State Legislature concluded its 2023 legislative session in early June. The legislative session most notably resulted in an agreement on a record $229 billion budget, albeit over a month late, as well as the passage of several bills of significance, including legislation to: seal criminal records; modify campaign finance laws and move town and county elections to even-numbered years; and expand New York's wrongful death statute (Grieving Families Act, or GFA).

Unlike last year when Democrats who controlled the Legislature and Gov. Kathy Hochul, a Democrat, were running for election and there was a clear effort to cooperate, this legislative session saw notable disagreements. Governor Hochul was unable to secure her signature policy priority to reform local land use authority that has been restricting the development of much needed housing and several proposed appointments – including her initial pick to be the chief judge of the Court of Appeals and, more recently, her picks for the New York Power Authority and the State Parole Board – were rejected by the Senate. Governor Hochul did succeed, however, in securing changes to the 2019 bail reform laws in a contentious negotiation with the Legislature, which contributed to the state budget being more than a month late.

With budget negotiations playing such a significant role in this legislation session, it is important to highlight the result of some of the more significant budget actions proposed.

Approval Process for Physician Practice Transactions: The enacted budget significantly modified Executive's proposal to provide the Department of Health (DOH) with oversight of material transactions, establishing a requirement that health care entities disclose and provide prior notice to DOH of transactions that meet the materiality threshold. The enacted version further defines a "material transaction" as any transaction or series of related transactions which result in a health care entity increasing its total gross in-state revenues by more than $25 million, and exempts transactions that are already subject to review under Article 28, 30, 36, 40, 44, or 46 of the Public Health Law.

As enacted, the new law requires health care entities to provide written notice of a material transaction to DOH at least 30 days prior to the closing of a material transaction. DOH is directed to establish a form and process for the submission of the required information and to post a copy of the submission for public comment. As currently written, it appears that unless DOH raises an issue of non-compliance with the written notice requirements, material transactions would be permitted to close in compliance with these requirements after the 30-day review period expires, provided that they must notify DOH upon the closing of the transaction.

As you may recall, the governor originally proposed establishing a structure for DOH to have the authority to both review and approve material transactions and established a review process that included a review as to the financial condition of the parties, character and competence of the parties, source of funding for the transaction and whether the potential positive impacts outweigh the potential negative effects on cost, access, health equity, and health outcomes. It would have also provided DOH with the authority to require undertakings as a condition of approval, including required community investments.

This new law takes effect on August 1, 2023, and applies to any transaction that meets the definition of a material transaction closing on or after that date. It is anticipated that DOH will develop regulations and forms for the purpose of implementing this requirement in the near future. New York now joins several other states, including Washington, Nevada, Massachusetts and Oregon, that have established notice and/or approval requirements for health care transactions.

Managed Long Term Care Reforms: The enacted budget made significant modifications to the Executive's proposal to competitively bid the Managed Long-Term Care (MLTC) program but extends the MLTC moratorium until 2027 and sets new criteria for existing plan participation. Specifically, the enacted budget establishes a requirement that active MLTC plans must have an active D-SNP with either a Medicare Advantage quality rating of three stars or higher or no quality star rating from CMS as of January 1, 2024. This requirement will require several existing MLTC plans to either be acquired by another MLTC plan that meets the criteria or cease operations.

MLTC plans will also be subject to meeting new performance standards to continue to operate. These standards include a requirement that plans contract with an adequate number of Licensed Home Care Services Agencies (LHCSAs) and Fiscal Intermediaries (FIs) needed to provide necessary personal care services and consumer directed personal assistance services (CDPAS), respectively, to the greatest practicable number of enrollees. Plans will be ineligible to contract with DOH if, in the three years preceding application, they have been classified as a poor performer or similar by CMS or

had an excessive volume of penalties, statements of findings or deficiency, intermediate sanctions or enforcement actions.

While this legislative session was more budget focused than prior years, the Legislature was able to pass a total of 788 bills and include a wide range of health-related legislation. The following list reflects most of the bills passed by both houses that impact the health and human service industry, organized into somewhat arbitrary categories. As of this writing, the governor has not acted on many of these bills. As noted previously, it is unclear whether the change in relationship between the governor and Legislature may result in an increased use of the veto pen this year. Those that have already been signed into law are noted by a reference to their chapter number**.** To check on whether a bill has been enacted, you can access the status of any legislation by clicking the home tab at the Legislative Bill Drafting Commission site at: http://public.leginfo.state.ny.us/navigate.cgi?NVMUO.

Hospitals

Grieving Families Act (A6698 Weinstein/S6636 Hoylman-Sigal): This bill expands New York's wrongful death statute to extend the statute of limitations, permit recovery of damages for grief and emotional loss, and permit recovery by close family members. The bill would extend the statute of limitations to commence a wrongful death action from two years to three years (compared to three years and six months under the 2022 legislation). The bill would allow surviving close family members to recover damages in the same manner as the 2022 legislation, but expressly defines this term as being "limited to decedent's spouse or domestic partner, issue, foster children, step children, and step grandchildren, parents, grandparents, step parents, step grandparents, siblings, or any person standing in loco parentis to the decedent." It further provides that a jury determines who is entitled to damages as close family members based upon the specific circumstances relating to the person's relationship with the decedent.

A version of this bill was vetoed by Governor Hochul in late January, following a public compromise offer by the governor to narrow the focus of the bill and exempt medical malpractice claims. In re-introducing the GFA, the sponsors stated that the revised version responded to the concerns raised by Governor Hochul in her veto message.

Health Care Practitioner Licensure (A6697-B Fahy/S7492-A Stavisky): In anticipation that Executive Order #4 (E.O. #4), which permits physicians, nurse practitioners (NPs), RNs, and LPNs licensed and in good standing in any state of the United States to practice in New York, would be allowed to expire, the Legislature worked quickly to develop legislation to address the need for temporary out-of-state health care practitioners to continue to work in New York.

As enacted, this bill authorizes physicians, RNs and LPNs who are licensed and in good standing in any state or territory, and who were practicing in New York on May 22, 2023 pursuant to E.O. #4, to continue to practice in New York on a temporary basis. In order to be eligible to temporarily practice, the practitioner must have filed an application for licensure with the State Education Department (SED) and cannot practice until the application is filed. A practitioner seeking to practice under this temporary authorization, and a representative of their employing facility, must provide written notification to SED that they intend to practice. The temporary authorization to practice is limited to 180 days or 10 days after notification that the individual does not meet the qualification for licensure. Notably, this legislative response does not apply to all the health care practitioners included under E.O. #4, including practitioners such as NPs, physician assistants and midwives.

NYSHIP Hospital Pricing Report (A5817A Solages/S4097B Gounardes): This bill requires the Department of Civil Service to annually publish a hospital pricing report for hospital claims under NYSHIP that includes a comparative analysis of hospital prices based on inpatient hospital, outpatient hospital, and emergency room services. The bill requires the collection of health care claims data from health insurers and HMOs on hospital in-network negotiated rates and out-of-network allowed amounts at each hospital.

Physician Continuing Medical Education in Nutrition (A5985A Rosenthal L/S4401A Webb): This bill amends public health law related to physician coursework or training in nutrition. The bill requires the Department of Health develop, maintain, and distribute to licensed physicians a resource library related to continuing medical education courses and training opportunities in nutrition. The bill directs that resource library must be developed in consultation with organizations with expertise in nutrition and diet-related illness.

Collaborative Program to Address Health Disparities (A782 Peoples-Stokes/S1451 Sanders): This bill expands the Hospital-Home Care-Physician Collaborative Program to include person-centered programs to address disparities in health care access or treatment, including conditions of higher prevalence in certain populations. Collaborative models may include reimbursement for uncovered services and bundled or other payment methods to support the necessary coordination of services.

Certificate of Need Health Equity Impact Assessment (A03113A Clark/S3609B Webb): This bill expands the requirements for Health Equity Impact Assessments (HEIA) submitted in connection with Certificate of Need (CON) applications to require that applicants demonstrate how their projects will impact the availability and provision of repro-

ductive health services and maternal health care in the applicant's service area. The HEIA requirement was effective June 22, 2023, requiring HEIAs to be filed with certain CON applications for the establishment, ownership, construction, renovation, and change in service of health care facilities.

Southeast Queens Hospital Study (A5970 Aubrey/S5712 Comrie): The bill authorizes DOH to make recommendations regarding the opening of a public hospital in southeast Queens. The study must include analysis of possible locations, associated costs, demographics of those who may be served, socio-economic conditions of the area, proximity to public transportation and other health care facilities, and the timeline and process for opening.

Hospital Protocols for Fetal Demise (A1297B Bichotte-Hermelyn/S4981-B Brouk): This bill requires hospitals to develop and implement standard protocols for the management of fetal demise. It requires hospitals to adopt protocols for determining whether a pregnant person is experiencing an emergency medical condition in relation to fetal demise and admit them for treatment until it is deemed medically safe for discharge or transfer.

Maternal-Infant Care Centers (A5448A Gunther/S266-A Rivera): This bill requires DOH, in consultation with OASAS, to establish at least 4 maternal infant centers for infants suffering from drug withdrawal as a result of in utero exposure in areas of need.

Long-Term Care

Demonstration Program To Reduce Use of Temporary Staffing Agencies in Residential Health Care Facilities (A7328 Paulin/S6897 Rivera): This bill creates incentives for nursing homes to reduce the use of temporary staffing by allowing for the reduction in penalties assessed for the failure to meet minimum spending requirements on resident care and staffing required under current law, which requires nursing homes to spend at least 70% of revenue on resident-facing care and 40% on direct care staff. It would allow for a 50% reduction in penalties if a facility has 50% or less staffing agency usage and has reduced staffing agency use by 30% or more during the year.

LGBTQ Long-Term Care Bill of Rights (S1783A Hoylman-Sigal/A372-A Bronson): This bill creates the "Lesbian, Gay, Bisexual, and Transgender, Long-Term Care Facility Residents' Bill of Rights" to establish certain unlawful actions taken on the basis of a person's actual or perceived sexual orientation, gender identity or expression, or HIV status. Unlawful actions include denying admission, discharging or evicting a resident, denying a request by residents to share a room, refusing to assign a room to a transgender resident other than in accordance with the resident's gender identity, or willfully failing to use a resident's preferred name or pronouns.

Long-Term Care Ombudsman Reporting (S7211 Cleare/A7218 Kim): This bill requires DOH to provide a status report no later than 60 days upon receipt to the ombudsman staff or volunteer who reported an issue to the department. Following the initial report, the department must provide additional reports to such staff or volunteer no less than every 60 days thereafter until the issue is resolved. Upon a resolution, the department must provide a timely report to such staff or volunteer and the ombudsman indicating the resolution.

DOH Report on Home Care Services (A1926A Gonzalez-Rojas/S1683A Hinchey): This bill requires DOH to prepare and annually publish a report on home care services usage in New York, including the number of individuals receiving home care services by managed care plans. It also requires the report to include the number of individuals who have had a permanent transfer from home care services to a nursing home or assisted living facility.

Office of Hospice and Palliative Care Access and Quality (A5587 Wallace/S4858 Hinchey): This bill would establish an office of hospice and palliative care access and quality within the Department of Health. The office would be granted several responsibilities, including the opportunity to provide expertise and input on hospice and palliative care policy development and regulation.

Special Needs Assisted Living Program for Residents with Neurodegenerative Diseases (A7035A Fahy/S2161A Rivera): This bill establishes a neurodegenerative with behaviors enhanced special needs assisted living residence program to serve persons with neurodegenerative diseases (such as Alzheimer's dementia, Lewy body dementia, frontotemporal dementia, and Parkinson's disease). Assisted living operators would be required to obtain certification as both enhanced assisted living residence and special needs assisted living residence and meet certain staffing requirements to operate this program.

Health Department Core Public Health Services (A7365 Paulin/S6641A Rivera): This bill authorizes local health departments to provide certain core public health services in the home, without being subject to licensure requirements under Article 36 of the Public Health Law, provided that the home visits are limited to core public health services and are not intended to serve as nursing services. To the extent core public health services are eligible for reimbursement under Medicaid, a local health department may seek reimbursement for such services.

Public Health

Sickle Cell Disease Report (A2609A Hyndman/S1839A Sanders): This bill requires the Minority Health Council, under the DOH Office of Health Equity, make recommendations to the commissioner of health on the promotion of sickle cell disease screening and detection. The bill also requires the council to consider the feasibility of establishing a statewide public education and outreach campaign related to sickle cell screening and detection, the provision of grants to approved organizations, and a health care professional education program on sickle cell screening and detection.

Latina Suicide Prevention Task Force (A6960 Davila/S5082 Fernandez): This bill establishes a temporary task force to examine, evaluate, and determine how to improve mental health and suicide prevention amongst Latina New York residents. Members of the task force will have expertise related to mental health and suicide prevention and knowledge of the Latina community; members will be appointed by the governor, ranking members in the Assembly and Senate, and the commissioner of mental health.

Access to Death Certificates (A6180A Braunstein/S6815 Rivera): This bill expands the list of people authorized to request and receive either a certified copy or certified transcript of a New York State death certificate. The bill extends authorization to domestic partners, grandparents, aunts, uncles, cousins, nieces, nephews, and agents of the deceased.

Health Care Proxy Remote Witnessing (A2190 Dinowitz/S5100 Cleare): This bill would authorize remote witnessing for completing a health care proxy via audio-video technology. Currently, witnessing a health care proxy is required to be performed in person. This bill will permit witnessing of health care proxies to be done remotely, provided that the principal, if not personally known to a remote witness, must provide photographic identification to the remote witness, the technology allows for direct interaction between the principal and remote witness, and the remote witness receives a copy of the health care proxy within 24 hours of the proxy being signed by the principal.

Medicaid, Medicaid Managed Care, and Managed Long-Term Care

Medicaid Coverage for Violence Prevention Programs (S580A Hoylman-Sigal/A2893-A Gonzalez-Rojas): This bill would direct DOH to seek approval from CMS to include community violence prevention services available to Medicaid beneficiaries and allow for Medicaid reimbursement for services provided to qualifying beneficiaries.

Medicaid Managed Care Rate Transparency (A5381 Paulin/6075 Skoufis): This bill is designed to increase the transparency and timeliness in the annual Medicaid managed care plan rate development process. It requires DOH's independent actuary disclose in the actuarial memorandum any additional materials submitted to the Centers for Medicare and Medicaid Services (CMS), any correspondence between the state and CMS related to rates, and any other information and methodologies DOH considered but did not use in the development of the proposed rates. Further, DOH would be required to notify managed care plans of reimbursement rates prior to the effective date of such rates.

This bill also authorizes managed care plans to request DOH and its independent actuary conduct additional review of the actuarial soundness of the rate setting process and/or methodologies and requires DOH to respond to any requests from managed care plans for additional review of the actuarial soundness of the rate setting process or methodology prior to submission of rates to CMS for approval.

Community Doula Directory for Doulas Serving Medicaid Enrollees (A5435A Solages/S1867A Rivera): This bill requires DOH to establish and maintain a community doula directory for doulas for purposes of Medicaid reimbursement and promoting doula services to Medicaid recipients. The bill requires every doula seeking Medicaid reimbursement to be registered in the directory and to submit a copy of the doula's certification to the department, in addition to other information.

DME, Orthotics, Prosthetics, and Supplies Rate Study (A5113 Gunther/S2230 Cleare): This bill requires the Department of Health (DOH) to conduct a study of the Medicaid reimbursement rates for durable medical equipment (DME), orthotics, prosthetics and supplies for rate adequacy and patient access. It directs DOH to review all orthotic and prosthetic codes on both the Medicaid and Medicare fee schedule, including those not included on the New York fee schedule.

Medicaid Managed Care and MLTC Quality Incentive Program Authority (A6021A Paulin/S3146 Mannion): This bill requires that the Department of Health establish a quality incentive program for both Medicaid managed care and managed long term care plans. The bill would require that quality objectives be set prospectively and that quality incentive funds are distributed such that the greatest level of funding is provided to the plans receiving the highest quality scores.

Health Insurance

Biomarker Testing Coverage (A1673A Hunter/S1196A Persaud): This bill requires health insurers and Medicaid, including Medicaid managed care plans, to cover biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test provides clinical utility to the patient.

Notice of Adverse Determination for Step Therapy Override (A463 McDonald/S2677 Breslin): This bill requires health plans to have a written procedure for notices of an adverse determination to a step therapy protocol override request. The notice is required to include the reason for the adverse determination, including any clinical rationale, instructions on how to initiate appeals, and information on the clinical review criteria relied upon to make the determination and any applicable alternative covered medication.

Direct Payment to Out-of-Network Ambulance Providers (S1466A Breslin/A250 Magnarelli): This bill requires health insurers to make payments to non-participating or non-preferred providers of ambulance services directly to the provider, provided that an executed assignment of benefits was given to the provider by the patient. In the absence of a negotiated rate between the insurer and ambulance provider, insurers are required to pay for ambulance services at the usual and customary charge for the services provided.

Veterans Health Coverage on New York State of Health (A1399A Bichotte-Hermelyn/S2323A Bailey): This bill requires the New York State of Health, New York's health plan marketplace, to ascertain if a marketplace applicant is eligible for health care through the Department of Veterans Affairs (VA) and, if eligible for such health care, provide the applicant with resources to contact a local intake coordinator with the VA to obtain VA health care coverage. The bill is designed to reduce the number of veterans in New York using Medicaid when they are eligible for VA health care.

Pharmacy

Prevents Price Gauging During Drug Shortage (A5653B Reyes/S608C Salazar): This bill prohibits manufacturers, suppliers, wholesalers, distributors or retail sellers of any drug subject to a shortage to sell a drug at an unconscionably excessive price during that shortage. The bill defines "drug shortage" to mean the issuance of a notice by the U.S. Food and Drug Administration (FDA) declaring a drug shortage.

Provides Access to Medication Abortion Drugs at SUNY and CUNY Campus (A1395C Epstein/S1213B Cleare): This bill requires that every State University of New York (SUNY) and City University of New York (CUNY) campus, including community college campuses, to provide access to abortion medication to their student body either by employing or contracting with authorized individuals who may prescribe abortion prescription drugs, or by providing students with information and referrals to providers authorized to prescribe abortion medication.

Increases Access to Self-Administered Hormonal Contraceptives (A1060A Paulin/S1043A Stavisky): This bill authorizes pharmacists to dispense hormonal contraception (birth control) over-the-counter pursuant to a non-patient specific standing order from a physician or nurse practitioner. Pharmacists will be able to dispense birth control provided they provide the patient with a self-screening risk assessment and a fact sheet.

Mental Health

Repeals Separate DNR Law for Residents of Mental Hygiene Facilities (A4332 Gunther/S2930 Rivera): This bill repeals Public Health Law Article 29-B, Orders Not to Resuscitate (DNR) for Patients in Mental Hygiene Facilities, as there is no longer a need for a separate DNR law for residents of such facilities. Article 29-B, the successor to New York's former DNR Law, governs DNR orders only for patients in psychiatric hospitals and units. The bill amends provisions of the Family Health Care Decisions Act (FHCDA) to clarify that DNR decisions for patients in psychiatric hospitals and units of general hospitals are governed by the FHCD, and that DNR decisions for all persons with developmental disabilities are governed by SPCA 1750-b. The bill is designed to eliminate the confusion by having different DNR laws apply to different hospital patients.

Mental Health Housing Evaluation Task Force for Aging in Place (A5119 Gunther/S5178 Brouk): This bill establishes a temporary task force within the Office of Mental Health (OMH) to evaluate and provide recommendations to ensure residents of community-based mental health housing programs can successfully age in place while receiving adequate care. The task force will also identify opportunities to remove barriers to residents of mental health housing programs to receive both mental health and medical care.

Post-Traumatic Stress Disorder Training Program (A793 Hunter/S7274 Parker): The bill requires OMH, in cooperation with any other state agency or relevant stakeholders, to develop a training program for mental health providers and mental health clinicians on the diagnosis and treatment of post-traumatic stress disorder for military veterans. The training program must include a component on military cultural competency.

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.

In the New York State Agencies

By Binny Seth

2/15/23

Charges for Professional Health Services

Notice of Adoption. The Department of Financial Services amended Part 68 (Regulation 83) and Appendix 17-C to Title 11 N.Y.C.R.R. regarding the charges for Professional Health Services to establish schedules of maximum permissible charges for professional health services payable as no-fault insurance benefits. The regulation states in part that the charges for services specified in Insurance Law Section 5102(a)(1) and any further health service charges that are incurred as a result of the injury and that are in excess of basic economic loss, shall not exceed the charges permissible under the schedules prepared and established by the chair of the Workers' Compensation Board for industrial accidents that are in effect for purposes of no-fault at the time the charges are incurred. Filing Date: January 26, 2023. Effective Date: February 15, 2023. *See* N.Y. Register February 15, 2023.

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

Notice of Proposed Rule Making. The Department of Financial Services proposed to add Part 452 (Regulation 222) and amend Part 6 (Regulation 195) to Title 11 N.Y.C.R.R. in order to define and clarify the provisions of PHL 280-a(2) and to require electronic filings for PBMs. The regulation is intended in part to clarify, define and limit the duties, obligations, requirements, and other provisions relating to pharmacy benefit managers under Public Health Law Section 280-a(2), and which provides a safe harbor provision for compliance with the regulation. *See* N.Y. Register February 15, 2023.

Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements

Notice of Emergency Rulemaking. The Department of Health amended §§ 405.11 and 415.19 of Title 10 N.Y.C.R.R. to ensure hospital and nursing home staff, as well as the patients and residents for whom they provide care, are adequately protected during the 2019 COVID-19 or another communicable disease outbreak. The regulations are specifically meant to address the lessons learned from the COVID-19 pandemic. The regulations generally require that all general hospitals and nursing homes maintain a 60-day supply of PPE to ensure that sufficient PPE is available to in the event of a resurgence of the COVID-19 outbreak or another communicable disease outbreak. Filing Date: January 26, 2023. Effective Date: January 26, 2023. *See* N.Y. Register February 15, 2023.

Repeal of Collection of Source Plasma

Notice of Adoption. The Department of Health repealed § 58-2.14 to Title 10 N.Y.C.R.R. regarding the Collection of Source Plasma. Filing Date: January 31, 2023. Effective Date: February 15, 2023. *See* N.Y. Register February 15, 2023.

Source Plasma Donation Centers

Notice of Adoption. The Department of Health added subpart 58-4 to Title 10 N.Y.C.R.R. to distinguish source plasma donation centers as a separate regulatory entity from blood banks. Filing Date: January 31, 2023. Effective Date: February 15, 2023. *See* N.Y. Register February 15, 2023.

Family Care Homes

Notice of Adoption. The Office for People with Developmental Disabilities amended Part 687 to Title 14 N.Y.C.R.R. to clarify terminology and limit the number of individuals residing in family care homes. Filing Date: January 25, 2023. Effective Date: February 15, 2023. *See* N.Y. Register February 15, 2023.

2/22/23

Part 113 – Medical Cannabis

Notice of Adoption. The Office of Cannabis Management added Part 113 to Title 9 N.Y.C.R.R. to establish the framework for medical use of cannabis for the cannabis medical use program in New York. The rules are intended to regulate medical cannabis in New York State, including but not limited to, establishing practitioner requirements and board determination of practitioner eligibility to certify patients for medical cannabis. Filing Date: February 8, 2023. Effective Date: February 22, 2023. *See* N.Y. Register February 22, 2023.

Original Issuance of License or Change of Control of a Licensee

Notice of Proposed Rule Making. The Department of Financial Services proposed to amend § 400.1 to Title 3 N.Y.C.R.R. to eliminate existing language in the regulation that requires every licensed check cashing location to have a minimum dimension. The proposed amendment eliminates a sentence in the current version of the regulation that requires every licensed check cashing location to have a dimension of at least 480 square feet. No additional costs will be imposed on licensed check cashers as a result of the proposed

amendment, rather the proposed regulation aims to make it possible for licensed check cashers to reduce their overhead costs by limiting the amount of space required to operate a licensed check cashing location. *See* N.Y. Register February 22, 2023.

Updated Retention Standards for Adult Care Facilities

Notice of Adoption. The Department of Health amended §§ 487.4, 488.4 and 490.4 to Title 18 N.Y.C.R.R. to ensure admission and retention standards for adult care facilities are consistent with the Americans with Disabilities Act. The regulation states in part that

> An operator shall not exclude an individual on the [sole] basis [that such individual is a person who primarily uses a wheelchair for mobility,] *of an individual's mobility impairment*, and shall make reasonable accommodations to the extent necessary to admit such individuals, consistent with [the Americans with Disabilities Act of 1990, 42 U.S.C. 12101 et seq. and with the provisions of this section] *federal, state, and local laws*.

Filing Date: February 7, 2023. Effective Date: February 22, 2023. *See* N.Y. Register February 22, 2023.

3/1/23

Principle-Based Reserving

Notice of Adoption. The Department of Financial Services amended Part 103 (Regulation 213) to Title 11 N.Y.C.R.R. to adopt the 2022 Valuation Manual and amend the scope of § 103.4 to include certain group term life insurance. Filing Date: February 10, 2023. Effective Date: March 1, 2023. *See* N.Y. Register March 1, 2023.

Mpox to the List of Sexually Transmitted Diseases (STDs)

Notice of Adoption. The Department of Health amended § 23.1 to Title 10 N.Y.C.R.R. to add Mpox to the list of sexually transmitted diseases (STDs). The amendment states in part that facilities referred to in § 23.2 must provide diagnosis and treatment, including prevention services, as provided in § 23.2(d) of this part for the following STDs: Human Papilloma Virus (HPV), Genital Herpes Simplex, Human Immunodeficiency Virus (HIV) and Mpox. Filing Date: February 10, 2023. Effective Date: March 1, 2023. *See* N.Y. Register March 1, 2023.

Clinical Staffing in General Hospitals

Notice of Proposed Rule Making. The Department Health amended §§ 400.25, 405.5, 405.12, 405.19, 405.21, 405.22 and 405.31 to Title 10 N.Y.C.R.R. to require general hospitals to have clinical staffing committees and create clinical staffing plans. The objective of Chapter 155 of the Laws of 2021 is to establish clinical staffing committees and staffing plans for nursing and unlicensed direct care staff in hospitals to help ensure that these facilities operate in a manner that guarantees the public safety and the delivery of quality health care services. *See* N.Y. Register March 1, 2023.

3/8/23

Notice(s) of Expiration

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

1. The Department of Health, *Clinical Staffing in General Hospitals*, I.D. No. HLT-07-22-00010-P. Proposed on February 16, 2022. Expired on February 16, 2023. *See* N.Y. Register March 8, 2023.

2. The Office for People with Developmental Disabilities, *Certification of the Facility Class Known as Individualized Residential Alternative*, I.D. No. PDD-07-22-00004-EP. Proposed on February 16, 2022. Expired on February 16, 2023. *See* N.Y. Register March 8, 2023.

3. The Office for People with Developmental Disabilities, *General Purpose*, I.D. No. PDD-07-22-00005-EP. Proposed on February 16, 2022. Expired on February 16, 2023. *See* N.Y. Register March 8, 2023.

General Purposes and Certification of the Facility Class Known as Individualized Residential Alternatives

Notice of Proposed Emergency Rule Making. The Office for People with Developmental Disabilities amended §§ 686.3 and 686.16 to Title 14 N.Y.C.R.R. to increase IRA capacity in cases of emergent circumstances. The emergency amendment of §§ 14 N.Y.C.R.R. 686.3 and 686.16 that authorizes the commissioner to increase capacity of individualized residential alternatives (IRAs) in cases of exigent circumstances, is necessary to protect the health, safety, and welfare of individuals who receive these services. In addition, the regulation must be issued by emergency regulation to allow OPWDD the ability to quickly move individuals into facilities with enough staff to take care of them appropriately. Filing Date: February 17, 2023. Effective Date: February 17, 2023. *See* N.Y. Register March 8, 2023.

Eligibility Determinations

Notice of Proposed Rule Making. The Office for People with Developmental Disabilities (OPWDD) amended § 629.1 and added § 629.2 to Title 14 N.Y.C.R.R. to estab-

lish the eligibility criteria for individuals applying for OPWDD services. The proposed regulations further legislative objectives embodied in MHL §§ 13.07, 13.09(b), and 16.00, which include providing and encouraging the provision of appropriate programs, supports, and services in the areas of care, treatment, habilitation, rehabilitation, and other education and training of persons with intellectual and developmental disabilities. This ties into the rule because without an eligibility determination, people cannot access OPWDD services (such as the programs, supports, services identified here). *See* N.Y. Register March 8, 2023.

3/15/23

State Aid for Public Health Services; Counties and Cities

Notice of Adoption. The Department of Health amended Part 40 to Title 10 N.Y.C.R.R. to increase Article 6 base funding to local health departments. Filing Date: February 24, 2023. Effective Date: March 15, 2023. *See* N.Y. Register March 15, 2023.

3/22/23

Adult-Use Packaging, Labeling, Marketing and Advertising of Cannabis Products

Notice of Adoption. The Office of Cannabis Management added parts 128 and 129 to Title 9 N.Y.C.R.R. to protect the health and safety of consumers and help prevent targeting cannabis products to youth by establishing parameters around the packaging, labeling, marketing, and advertising of adult-use cannabis products. The regulations discuss in part the minimum standards for retail packaging for adult-use cannabis products, including but not limited to, the requirements that products be packaged in a manner that is child resistant, tamper-evident, resealable if it contains more than one serving, fully enclosed to minimize oxygen exposure and prevent the contamination or degradation of the cannabis product, and is non-toxic. Filing Date: March 7, 2023. Effective Date: March 22, 2023. *See* N.Y. Register March 22, 2023.

Cannabis Laboratories

Notice of Adoption. The Office of Cannabis Management added Part 130 to Title 9 N.Y.C.R.R. to protect public health and safety through regulating and permitting laboratories to ensure accurate and reliable results are released by such laboratories and aiding in the determination that final cannabis products accurately reflect potency and meet regulatory limits for contaminants. The regulation discuss among other things a process under the Office of Cannabis Management for a cannabis laboratory to apply for a permit which includes the minimum requirements necessary to fill out an application to be authorized as a cannabis laboratory, including but not limited to requirements regarding required information submissions, analyte approvals, performance on proficiency test and proficiency test sample, quality documentation, facility requirements and withdrawal of an application. In addition, the regulations regarding such permit applications were amended to authorize laboratories certified by the Department of Health as provisional permitees. Filing Date: March 7, 2023. Effective Date: March 22, 2023. *See* N.Y. Register March 22, 2023.

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

Notice of Emergency Rule Making. The Department of Financial Services added § 52.16(p) to Title 11 N.Y.C.R.R. to waive cost-sharing for in-network visits and laboratory tests necessary to diagnose the novel coronavirus (COVID-19). This rule affects health maintenance organizations and authorized insurers (collectively, "health care plans") and health care providers (providers). This amendment prohibits health care plans from imposing copayments, coinsurance, or annual deductibles for covered in-network laboratory tests to diagnose COVID-19 and for visits to diagnose COVID-19 at an in-network provider's office, an in-network urgent care center, any other in-network outpatient provider setting able to diagnose COVID-19, or an emergency department of a hospital, and includes telehealth visits. Copayments, coinsurance, or annual deductibles may be imposed in accordance with the applicable policy or contract for any follow-up care or treatment for COVID-19, including an inpatient hospital admission, as otherwise permitted by law. The amendment also requires every health care plan to provide written notification of the requirements of the amendment to its in-network providers in order to ensure that the providers do not require any insured to pay a copayment, coinsurance, or annual deductible that is prohibited from being imposed under the amend-

ment. Filing Date: March 6, 2023. Effective Date: March 6, 2023. *See* N.Y. Register March 22, 2023.

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

Notice of Emergency Rule Making. The Department of Financial Services added § 52.76(b) to Title 11 N.Y.C.R.R. to require immediate coverage, without cost-sharing, for COVID-19 immunizations and the administration thereof. This emergency measure requires authorized insurers and health maintenance organizations that issue a policy or contract that provides hospital, surgical, or medical care coverage, excluding grandfathered health plans, to provide coverage, with no cost-sharing, of COVID-19 immunizations and the administration thereof immediately upon the earliest of the date on which: (1) the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices issues a recommendation for the COVID-19 immunization; (2) the United States Preventive Services Taskforce issues a recommendation with an "A" or "B" rating for the COVID-19 immunization; or (3) the Superintendent of Financial Services (Superintendent) determines, in consultation with the Commissioner of Health, that a policy or contract must cover the COVID-19 immunization. This emergency measure also applies to immunizations and the administration thereof by non-participating providers until the expiration of the federally declared public health emergency. Filing Date: March 6, 2023. Effective Date: March 6, 2023. *See* N.Y. Register March 22, 2023.

Reporting of Acute HIV Infection

Notice of Adoption. The Department of Health amended §§ 63.2 and 63.4 to Title 10 N.Y.C.R.R. to require clinicians to report any case of acute HIV within 24 hours of diagnoses. These regulations apply to physicians and other persons authorized by law to order laboratory tests or to make medical diagnoses, laboratories, blood banks, tissue banks and organ procurement organizations, to persons who receive confidential HIV-related information in the course of providing any health or social service and to persons who receive confidential HIV-related information pursuant to a release. Filing Date: March 2, 2023. Effective Date: March 22, 2023. *See* N.Y. Register March 22, 2023.

Newborn Hearing Screening

Notice of Proposed Rule Making. The Department of Health amended Subpart 69-8 to Title 10 N.Y.C.R.R. to improve follow-up after newborn hearing screening and articulate reporting requirements. The proposed regulations satisfy the objective of PHL § 2500-g to establish a statewide program for screening newborns for hearing problems and detecting hearing problems as early as possible in an infant's life. Particularly, this statute directs the commissioner to incorporate medical guidelines and protocols that reflect the most cost-effective methods for early detection of newborn hearing problems. Consistent with this objective, the regulations will align with National Joint Committee on Infant Hearing (JCIH) evidence-based practices for newborn hearing screening to ensure early detection and referral for infants identified as having hearing difficulties, while also reducing the number of infants requiring follow-up hearing screening following discharge from neonatal care, which can result in cost savings. *See* N.Y. Register March 22, 2023.

Contingent Reserve Requirements for Managed Care Organizations (MCOs)

Notice of Proposed Rule Making. The Department of Health amended § 98-1.11(e) to Title 10 N.Y.C.R.R. to maintain the contingent reserve requirement at 7.25% through 2023 applied to the Medicaid Managed Care, HIV SNP and HARP programs. *See* N.Y. Register March 22, 2023.

3/29/23

Certified Residential Opportunities

Notice of Adoption. The Office for People with Developmental Disabilities added Subpart 636-3 to Title 14 N.Y.C.R.R. to provide equity in opportunities for certified residential housing. The proposed regulation adds Title 14 N.Y.C.R.R. Subpart 636-3 in order to provide equity in the process for obtaining certified housing based on an individual's level of need. Filing Date: March 10, 2023. Effective Date: June 14, 2023. *See* N.Y. Register March 29, 2023.

Notice(s) of Expiration

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

1. The Office for People with Developmental Disabilities, *Training Flexibilities*, I.D. No. PDD-10-22-00010-EP. Proposed on March 9, 2022. Expired on March 9, 2023. *See* N.Y. Register March 8, 2023.

4/5/23

Cannabis Research License

Notice of Proposed Rulemaking. The Office of Cannabis Management is proposing to add Part 132 of Title 9 N.Y.C.R.R. to establish an application process, requirements and prohibitions associated with the Cannabis Research License. The proposed regulations will establish a license that will authorize the licensee to produce, process, purchase and/or possess cannabis for cannabis research within New York

State while ensuring that the cannabis research is safe and limited in scope. *See* N.Y. Register April 5, 2023.

Repeal of Zika Action Plan; Performance Standards

Notice of Adoption. The Department of Health has taken action to repeal § 40-2.24 of Title 10 N.Y.C.R.R. given the provisions are no longer applicable. Filing Date: March 20, 2023. Effective Date: April 5, 2023. *See* N.Y. Register April 4, 2023.

Assisted Living Residences

Notice of Proposed Rulemaking. The Department of Health is proposing to amend Part 1001 of Title 10 N.Y.C.R.R. to update admission, operator authority, personnel, environmental standards and resident protections for assisted living residences. The purpose of the rulemaking is to promote the life, health, safety and comfort of adults residing in adult care facilities and ensure that adult care facilities keep and maintain accurate records concerning the veteran status of their residents and notify veterans that they may be eligible for the benefits. The proposed regulations will allow strong safety measures in the event of an emergency evacuation and deletes portions of the regulations the department is no lot legally able to enforce to reflect the outcome of 2008 litigation brought by the Empire State Association of Assisted Living and the NY Coalition of Quality Assisted Living. *See* N.Y. Register April 5, 2023.

4/19/23

Utilization Reviews

Notice of Proposed Rulemaking. The Department of Health is proposing to amend §§ 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. The regulations changes are being made to conform to statutory changes in the social services laws, which eliminated utilization thresholds as service limits while continuing to meet federal regulatory requirements of continued utilization monitoring in a post-payment review process with referral to OMIG for suspected fraud, waste or abuse are identified in the unnecessary or inappropriate use of care, services or supplies. The modified regulations would remove the requirement for provider-submitted increase requests for overrides of service limits and move to a retrospective review. *See* N.Y. Register April 19, 2023.

4/26/23

Violations, Hearings and Enforcement

Emergency Rulemaking. The Office of Cannabis Management added Part 133 of Title 9 N.Y.C.R.R. to preserve the public health, public safety and general welfare by taking punitive action against any person issued a license, registration or permit that is in violation of the Cannabis Law. The regulations establish the parameters around violations, hearings and enforcement which accords with the Cannabis Law and creates requirements that are intended to further protect public health, safety, and welfare by preventing the unlawful cannabis or unsafe practices from permeating the marketplace. Filing Date: April 6, 2023. Effective Date: April 6, 2023. *See* N.Y. Register April 26, 2023.

5/3/23

Update Standards for Adult Homes and Standards for Enriched Housing Programs

Notice of Proposed Rulemaking. The Department of Health proposes to amend Part 485, 486, 487, 488 and 490 of Title 18 N.Y.C.R.R. to address changes required to achieve and sustain compliance with the Federal Home and Community Based Setting final rule. The proposed regulations set forth additional resident rights and articulate specific instances that must be reported to both the department and The Justice Center for the Protection of People with Special Needs. The regulations intend to protect adult care residents and ensure their safety and well-being is improved by, for example, permitting many residents to have greater access to their community. The regulations also intend to provide clarity and direction for the operation of facilities and conform to state statutory changes. *See* N.Y. Register May 3, 2023.

Standards for Tissue Banks and Nontransplant Anatomic Banks

Notice of Proposed Rulemaking. The Department of Health proposes to amend Part 52 of Title 10 N.Y.C.R.R. to remove discriminatory requirements pertaining to repro-

ductive tissue and make technical corrections. The proposed regulation removes discriminatory language that treats same-sex couples differently than heterosexual couples, consistent with the legislative intent, without increasing public health risks. *See* N.Y. Register May 3, 2023.

5/10/23

Investigation of Communicable Disease

Notice of Emergency Rulemaking. The Department of Health is amended Part 2, § 403.5 and add § 58-1.14 of Title 10 N.Y.C.R.R. for the purpose of providing the department with the authority to take specific actions to monitor the spread of disease, including actions related to the investigation and response to a disease outbreak. Specifically, the regulation repeals and replaces current § 2.6 related to investigations, sets forth the actions the department must take to investigate a case, suspected case, outbreak or unusual disease, and requires entities to cooperate with the department and local health departments. Filing Date: April 24, 2023. Effective Date: April 24, 2023. *See* N.Y. Register April 19, 2023.

5/17/23

Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements

Notice of Emergency Rulemaking. The Department of Health amended §§ 405.11 and 415.19 of Title 10 N.Y.C.R.R. to ensure hospital and nursing home staff, as well as the patients and residents for whom they provide care, are adequately protected during the 2019 COVID-19 or another communicable disease outbreak. The regulations are specifically meant to address the lessons learned from the COVID-19 pandemic. The regulations generally require that all general hospitals and nursing homes maintain a 60-day supply of PPE to ensure that sufficient PPE is available to in the event of a resurgence of the COVID-19 outbreak or another communicable disease outbreak. Filing Date: April 26,2023. Effective Date: April 26, 2023. *See* N.Y. Register May 17, 2023.

5/24/23

Pharmacy Benefits Bureau, Pharmacy Benefit Manager Assessments, Filings and Other Requirements for Issuance

Notice of Proposed Rulemaking. The Department of Financial Services proposes to amend Part 450 (Regulation 219), add Parts 453 (Regulation 223), 454 (Regulation 224) and 455 (Regulation 225) to Title 11 N.Y.C.R.R. for the purposes of establishing rules for PBMs regarding assessments, license requirements, reporting and record keeping, and to clarify definitions. The proposed regulations establish licensing and reporting standards for a PBM to perform pharmacy benefit managements services in New York. *See* N.Y. Register May 24, 2023.

Clinical Laboratories and Blood Banks

Notice of Adoptions. The Department of Health amended Subpart 58-1 of Title 10 N.Y.C.R.R. to allow for the remote supervision and updates to align with NYSED law for qualifications of technical personnel. Filing Date: May 11, 2023. Effective Date: May 24, 2023. *See* N.Y. Register May 24, 2023.

Waiver Eligibility

Notice of Proposed Rulemaking. The Office of People with Developmental Disabilities proposes to amend § 635.10.3 of Title 14 N.Y.C.R.R. to use gender neutral language and align with the Social Services Law Section 366. The proposed regulation mirrors the statutory language for individuals seeking to qualify for waiver services. *See* N.Y. Register May 24, 2023.

6/1/23

Perinatal Services, Perinatal Regionalization, Birthing Centers and Maternity Birthing Centers

Notice of Proposed Rulemaking. The Department of Health proposes to amend §§ 12.2, 405.21, Parts 721, 754 and 795 of Title 10 N.Y.C.R.R. to update the regulatory requirements of birthing hospitals and centers meet current standards of clinical care. The amendments fulfill the recommendations of the department's perinatal regionalization expert panel and address the role of Regional Perinatal Centers (RPCs), hospitals and free-standing birth centers, including midwifery-led centers. *See* N.Y. Register May 31, 2023.

Binny Seth participates in the Health and FDA Business Group and the Insurance Regulatory and Transaction Group at Greenberg Traurig's Albany office, where he focuses on health care issues, including regulatory, contracting, transactional, and compliance matters. 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 and Ron L. Oakes

Whittier Rehabilitation and Skilled Nursing Center (Decision After Hearing, May 11, 2023, John Harris Terepka, ALJ).

Appellant is a residential health care facility (RHCF) located in Ghent, New York. The New York State Office of the Medicaid Inspector General (OMIG) audited appellant's reimbursement from the Medicaid program for the rate period of January 1, 2013 through December 31, 2017. As set out in OMIG's final audit report dated September 24, 2020, OMIG identified overpayments in the amount of $2,233,595. These overpayments were attributable to OMIG's audit determination to eliminate utilization review and inhalation therapy as noncomparable costs in appellant's 2013 through 2017 rates.

The base year for appellant's 2013 through 2017 Medicaid operating rates was 2007, and at that time, appellant operated a 20-bed long term ventilator unit and a 100-bed nursing home, which received separate Medicaid per diem reimbursement rates. Appellant's 2007 RHCF-4 cost report included costs for inhalation therapy and for utilization review, and these allowed costs were subsequently used to calculate appellant's nursing home Medicaid reimbursement rate for the 2013 through 2017 rate years. In 2008, appellant closed its 20 bed ventilator unit and the New York State Department of Health (DOH) approved a conversion of the 20 ventilator unit beds to nursing home beds. Pursuant to applicable regulation, appellant was required to report changes in services offered at the RHCF—including inhalation therapy and utilization review—to DOH. *See* 10 N.Y.C.R.R. § 86-2.27. Appellant's cost reports for 2013 through 2017 did not include any reported costs for inhalation therapy, and its cost reports for 2015 through 2017 did not include any costs for utilization review. On audit, OMIG eliminated noncomparable costs attributable to inhalation therapy and utilization review for the applicable rate years, and the recalculation of appellant's Medicaid program reimbursement for those years resulted in the alleged overpayment.

At hearing, Administrative Law Judge (ALJ) Terepka considered whether appellant established that OMIG's audit determinations to recover Medicaid reimbursement attributable to noncomparable costs for inhalation therapy and utilization review were not correct. At the outset, appellant objected to the lack of an audit closing (exit) conference prior to OMIG issuing its draft audit report. This argument was rejected by the ALJ, as the audit at issue was a desk audit which does not require an exit conference before a draft audit report can be issued. *See* 18 N.Y.C.R.R. § 517.5(a).

ALJ Terepka also summarily rejected appellant's argument that the audit "disallow[ed] or adjust[ed] appellant's reported 2007 costs[,]" instead finding that the audit disallowed reimbursement for appellant in the applicable rate years. *See* Decision at 8. According to the ALJ, the audit at issue reviewed the reimbursement paid to appellant for the 2013 through 2017 rate years, was not an audit of appellant's 2007 base year cost report, and the overpayment findings were based only on the audit's findings that during the 2013 -2017 rate years, relevant services had been deleted within the meaning of applicable regulation. *See* 10 N.Y.C.R.R. § 86-2.27.

According to hearing testimony from OMIG's audit manager, the desk audit at issue was one of a number of nursing home audits where OMIG reviewed cost reports to identify noncomparable costs that were not reported in the rate year. In instances where a RHCF did not report costs in a rate year for a noncomparable cost allowed in its base year, OMIG would eliminate the cost from the rate for that year based on a determination that the service had been deleted or dropped. Upon review of appellant's 2007 base year cost report and the 2013 through 2017 rate years, OMIG concluded that appellant had deleted the inhalation therapy and utilization review services without notifying DOH as required by applicable regulation. *See* 10 N.Y.C.R.R. § 86-2.27. As such, the previously allowed noncomparable costs were disallowed, and appellant's reimbursement rate for the rate years were recalculated, resulting in a reduction in appellant's per diem noncomparable reimbursement and overall nursing home reimbursement rate.

ALJ Terepka noted that OMIG's audit determinations were based entirely on the grounds that appellant had deleted or terminated utilization review and inhalation therapy services, as OMIG is barred from adjusting a rate in instances where a rate year cost was reduced, but where the service was still provided. As such, a change in the cost reported in a rate year would only lead to an audit adjustment if there was no corresponding cost

reported (*i.e.*, the cost went down to zero). Since OMIG did not verify whether appellant actually provided any utilization review or inhalation therapy services during the rate years—the determination that services were deleted was based entirely on the absence of reported costs in the rate year cost reports—ALJ Terepka found that the underlying issue to be considered at hearing was whether OMIG correctly determined that there was a deletion of the services in 2013 through 2017 within the meaning of 10 N.Y.C.R.R. § 86-2.27.

Appellant's argument that utilization review and inhalation therapy services were mandated services which it could not delete was rejected by the ALJ, as the rregulations regarding required services do not reference or include utilization review or inhalation therapy services. *See* 10 N.Y.C.R.R. §§ 415.11, 415.23(k). Moreover, the regulations applicable to cost centers describe specific services, rather than minimum operating standards, and as such, appellant's argument that the information reported in the cost center is irrelevant to the issue of service deletion was rejected. *See* 10 N.Y.C.R.R. §§ 455.20, 455.27. Instead, according to ALJ Terepka, DOH's conclusion that the provision of a service requires a cost to be incurred was rational for purposes of reimbursement under 10 N.Y.C.R.R. Part 86-2, a view which is supported by relevant case law. *See N. Metro. Residential Healthcare Facility v. Novello*, 777 N.Y.S.2d 277 (Sup. Ct., Albany Cty., 2004); *see also Wells Nursing Home, Inc. v. Novello*, 866 N.Y.S.2d 806 (3d Dep't 2008). Appellant's attempt to distinguish these cases by asserting that the reasoning in *Northern Metropolitan* and *Wells* was inapplicable to services that were not billed directly by third parties was also rejected as not reflective of the language found in both the decisions and regulation.

Next, appellant argued that even if the lack of cost for a service constitutes deletion for reimbursement purposes, the services at issue were not deleted because appellant incurred costs for the services that were reported elsewhere. Relying on applicable regulations, ALJ Terepka noted that if appellant did have utilization review or inhalation therapy costs in the rate years, appellant was required to report them accurately and properly in the appropriate functional cost centers. *See* 10 N.Y.C.R.R. § 454.2(b)(4). Appellant's argument that it was not given the opportunity to correct the rate year cost reports or produce records to show that costs were incurred and reported elsewhere was rejected. Despite the fact that no onsite audit and exit conference occurred, appellant had an opportunity to correct any errors in response to the draft audit report and at hearing. Appellant also failed to identify why or where any alleged errors in cost reporting were made, and was unable to trace and substantiate the alleged costs, as required by regulation. *See* 10 N.Y.C.R.R. § 454.2; 18 N.Y.C.R.R. § 504.3(a).

Appellant's next argument at hearing related to the provision of services. Specifically, appellant argued that the reporting of zero costs was not dispositive of the hearing issues, so long as appellant was able to show that it provided the services at issue. As to the inhalation therapy services, ALJ Terepka concluded that appellant's documentation failed to demonstrate that the services were delivered, as the general respiratory care services that appellant provided were not sufficient to meet the regulatory requirements applicable to the provision of inhalation therapy services. *See* 10 N.Y.C.R.R. §§ 415.12(k), 455.27. Inhalation therapy services are specifically defined in applicable regulation, and are differentiated from the provision of respiratory care required under the nursing home minimum operating standards. *See* 10 N.Y.C.R.R. § 415.1(a)(3). As such, appellant failed to meet its burden of proving that inhalation therapy services were provided in the relevant rate years.

As to the utilization review services, appellant produced Minimum Data Set (MDS) forms and argued that the basic data for individual case review was created through the completion of the MDS forms. ALJ Terepka rejected this argument, finding that the use of MDS assessments when performing utilization review does not demonstrate that the assessments' preparation was utilization review as defined in regulation. *See* 10 N.Y.C.R.R. § 455.20. Moreover, the standard unit of measure for utilization review is the total number of patient cases reviewed by the RHCF's Utilization Review Committee, but appellant was unable to identify a Utilization Review Committee or produce documentation of any case reviews. *See* 10 N.Y.C.R.R. §§ 454.(a), 455.20(a) – (b). According to the ALJ, although MDS and utilization review may be interrelated, they are not interchangeable for cost reporting purposes. *See Odd Fellow & Rebekah Rehab. & Health Care Ctr., Inc. v. Comm. of Health*, 966 N.Y.S.2d 587 (3d Dep't 2013). Finally, since RHCFs are not always entitled to utilization review reimbursement in the noncomparable component of their rates, appellant's argument that it must have performed utilization review because it had an obligation to do so was rejected. *See id.*; *see also* Atlantis Rehab. & Residential Health Care Facility, LLC, DOH Decision After Hearing # 14-4064 (Sep. 24, 2021); Nesconset Ctr. for Nursing & Rehab., DOH Decision After Hearing # 15-4992 (Dec. 1, 2021).

Appellant's final argument at hearing was that the 2007 closure of its vent unit, addition of 20 beds to the nursing home, and sale in 2017 resulted in rate determinations by DOH that preclude OMIG's audit adjustments. ALJ Terepka found that the 2016 documents from DOH's Public Health and Health Planning Council (PHHPC), which appellant relied upon, neither mentioned nor suggested any determination or concern related to ensuring that any components of appellant's allowable costs or reimbursement rate were continued. Appellant also argued, but failed to provide any evidence of, a DOH determination regarding rate methodology to remedy any disparities in appellant's nursing home rate as compared

with other RHCFs in Columbia County. Finally, appellant's arguments that DOH determined to create a blended rate or any rate setting judgment to improve appellant's reimbursement were similarly rejected due to a lack of evidence to support the claims.

Therefore, ALJ Terepka found that it was reasonable for OMIG to conclude that the costs for inhalation therapy and utilization review were not reimbursable in the noncomparable component of appellant's rate and that appellant failed to meet its burden of proving that OMIG's determination that the services were deleted in the rate years was incorrect. As such, OMIG's determination to disallow reimbursement for the inhalation therapy and utilization review costs was affirmed.

Elmhurst Hospital Center, Kings County Hospital Center (Decision, April 3, 2023, Natalie J. Bordeaux, ALJ).

Appellants are two hospitals located in Queens and Brooklyn, New York. Appellants sought hearings to appeal determinations by OMIG to recover Medicaid program overpayments stemming from audits of partial hospitalization Medicaid claims paid from January 1, 2011 through December 31, 2015. In its final audit reports dated April 6, 2017 and April 13, 2017, OMIG sought to recoup overpayments in the amount of $33,544.97 from Elmhurst Hospital Center and $26,693.07 from Kings County Hospital Center for partial hospitalization claims that exceeded six calendar weeks and were inappropriately billed to, and paid by, the Medicaid program.

As a procedural matter, after requesting hearings to contest the overpayment determinations, appellants requested a decision without a hearing for both audits. In the request, appellants only disputed OMIG's application of the regulatory provision, 14 N.Y.C.R.R. § 588.9(a)(2), which formed the basis for the overpayment findings, and argued that the regulation does not limit partial hospitalization services to 42 days, or six calendar weeks. Although OMIG alleged that there were facts in dispute that required a hearing, ALJ Bordeaux found that appellants had conceded the accuracy of the facts set out in the audit reports, and as such, there were no material facts in dispute. Based on this determination, appellants' request for a decision without a hearing was granted. *See* 18 N.Y.C.R.R. § 519.23(a).

As to the overpayment determinations, ALJ Bordeaux noted that OMIG disallowed claims for services provided after the six week service period that OMIG determined applied. Although OMIG did correct the end date of certain service periods to extend them to longer than six weeks after the first service date, OMIG did not disallow any services for dates that were less than six weeks from the first date of service. At hearing, appellants argued that OMIG incorrectly applied the reimbursement standards found in applicable regulation, asserting that the six week course of treatment limitation on reimbursement did not require consecutive weeks. *See* 14 N.Y.C.R.R. § 588.9(a)(2). The ALJ rejected this argument, finding that "the regulation implicitly considers treatment as necessitating consecutive weeks[,]" a position which was also supported by guidance from the New York State Office of Mental Health (OMH). *See* Decision at 6.

Appellants' argument that a calendar week means a week beginning with Sunday and ending with Saturday was also rejected by the ALJ, as no such definition is set out in applicable law and the case law cited by appellants did not provide a clear and applicable definition of calendar week. Appellants also did not provide an explanation as to how case law regarding different legal topics would supersede OMIG's method of determining a calendar week, which was based on OMH guidance indicating that the first calendar week begins on the first treatment date. Appellants' argument that a patient who is admitted to the program on a Wednesday should not be considered to have started treatment for reimbursement limitation purposes until the following Sunday was also rejected by the ALJ. ALJ Bordeaux also similarly rejected appellants' arguments related to OMIG's Audit Protocol for OMH Partial Hospitalization, finding that the protocols are intended as guidance only and do not supplant applicable law and regulation.

Relying on regulatory authority authorizing more than six weeks of treatment when a patient is discharged and then readmitted, appellants also asserted that the six week course of treatment limitation was arbitrary. ALJ Bordeaux rejected this argument, finding that the regulatory provision recognizes that more than one course of treatment in a single year is possible, and contemplates discharge and readmission being required in order for there to be a new course of treatment. *See* 14 N.Y.C.R.R. § 588.9(a)(2) – (3). Appellants' argument that the readmission requirements are arbitrary and capricious was also rejected, as OMIG's audit determinations were consistent with, and reflected adherence to, the applicable regulatory requirements. Finally, the ALJ rejected appellants' argument that the 180 or 360 hours limitation for a course of treatment was the only relevant timeframe as inconsistent with the applicable regulations. *See* 14 N.Y.C.R.R. § 588.9(a)(2) – (3).

As appellants failed to establish that OMIG's determinations to disallow payments made for partial hospitalization treatment exceeding six calendar weeks was not correct, OMIG's determinations to recover $33,544.97 in overpayments from

Elmhurst Hospital Center and to recover $26,693.07 in overpayments from Kings County Hospital Center were affirmed.

Rachel Liyun Sun, DMD (Decision After Hearing, March 2, 2023, John Harris Terepka, ALJ).

Appellant was a dentist enrolled as a Medicaid program provider and practicing at various locations in New York City between 2006 and 2012. By Notice of Agency Action (NOAA) dated July 30, 2015, OMIG determined to exclude appellant from the Medicaid program for a period of three years and to seek restitution of $24,945 in Medicaid program overpayments, plus interest.

The first issue considered at hearing was whether appellant engaged in unacceptable practices in the Medicaid program. OMIG determined to exclude appellant from the Medicaid program based on appellant's failure to comply with repeated directives to produce records to support claims submitted under appellant's Medicaid provider number. Specifically, by way of two notices dated November 13, 2012 and March 29, 2013, OMIG requested complete patient records for 22 patients treated by appellant, as well as the office appointment schedule for 49 dates in the years 2008 through 2010. Appellant failed to produce any records or documentation to support the relevant claims. At hearing, ALJ Terepka found that OMIG has the authority to determine where and the manner in which an audit will be conducted, and that OMIG's exercise of authority in this case was not unreasonable. *See* 18 N.Y.C.R.R. § 517.3(f). Moreover, appellant's failure to comply with OMIG's directives to produce records was an unacceptable practice under applicable regulation, and appellant's failure to produce records to justify the relevant claims was also unacceptable record keeping (an unacceptable practice) under applicable regulation. *See* 18 N.Y.C.R.R. § 515.2(a)(1), (b)(6).

ALJ Terepka next considered whether OMIG was entitled to recover Medicaid program overpayments from appellant. According to the ALJ, the 389 claims at issue were not authorized to be paid under the Medicaid program because appellant failed to maintain and produce documentation demonstrating compliance with applicable payment requirements. Appellant had the burden of proving her entitlement to Medicaid program payments for the claims, and failed to meet that burden by admitting that she was unable to produce any records to substantiate the claims submitted for the services. *See* 18 N.Y.C.R.R. § 519.18(d). As such, OMIG was entitled to recover the overpayments from appellant. *See* 18 N.Y.C.R.R. § 518.3(a).

The final issue at hearing was whether OMIG properly determined to exclude appellant from the Medicaid program. Pursuant to applicable regulation, OMIG may impose sanctions, including exclusion, upon a determination that a person has engaged in an unacceptable practice. *See* 18 N.Y.C.R.R. §§ 515.3(a), 515.4(a). According to ALJ Terepka, the fact that nearly $25,000 in Medicaid program payments was unaccounted for as a result of appellant's failure to provide patient records substantiating the claims weighed in favor of exclusion. Moreover, Medicaid payment records reviewed by OMIG showed that at least one patient was hospitalized on the days that appellant allegedly provided services, which suggested that services may have been billed that were not actually provided. The office location at issue was also the location for other claims that were questioned by OMIG's investigators, including, for example, instances where claims were submitted for one patient on three consecutive days. Based on this "data mining," OMIG visited the office in an attempt to conduct a "credential verification review," but instead found that the office no longer existed. *See* Decision at 9. Importantly, appellant's failure to produce patient records prevented OMIG from assessing any violations that may have occurred at the location and any impact on Medicaid recipients.

ALJ Terepka also found that appellant failed to meet her burden of proving any mitigating factors affecting the severity of the sanction imposed. *See* 18 N.Y.C.R.R. § 519.18(d)(2). Appellant's arguments that the records were the property of the practices she worked for and that she made attempts to obtain the records were found to be insufficient to establish mitigating circumstances, particularly given the fact that appellant was unable to identify any other person who practiced at or owned the dental office in question. Moreover, appellant's claim that she only received a percentage of the Medicaid program payments at issue was found to "enhance the nature and seriousness of the violations[,]" rather than establish mitigating circumstances. *See* Decision at 10.

Therefore, since appellant failed to produce documentation demonstrating her entitlement to Medicaid program payments, OMIG's determination to exclude appellant from the Medicaid program for three years and to seek restitution of the payments that appellant failed to produce documentation to substantiate was within its discretion. As such, OMIG's determination to exclude appellant and to recover overpayments in the amount of $24,945 was affirmed.

Schenectady ARC (Decision After Hearing, February 16, 2023, Matthew C. Hall, ALJ).

Appellant is a private, not-for-profit organization enrolled as a Medicaid program provider, and operating under the New York State Office for People With Developmental Disabilities (OPWDD) in Schenectady, New York. OMIG audited appellant's Medicaid reimbursement of Article 16 clinic claims between January 1, 2012 through December 31, 2014, with the goal of determining whether appellant's records reflected compliance with Medicaid program requirements. The audit universe consisted of 44,089 claims totaling $4,312,085.25

in Medicaid program payments, and OMIG reviewed a random sample of 100 claims with Medicaid payments totaling $8,737.31. By final audit report dated September 11, 2018, OMIG notified appellant of its determination to recover $1,020,319 in overpayments based on six categories of audit findings.

The issue at hearing before ALJ Hall was whether OMIG was entitled to recover Medicaid program overpayments from appellant. Notably, appellant did not challenge all of OMIG's alleged disallowances at hearing, and instead, only challenged the following findings: (1) No Explanation of Benefits (EOB) / Documentation for Medicare Covered Service; (2) No EOB for Third Party Health Insurance (TPHI) (Excluding Medicare); and (3) Failure to Meet Minimum Duration Requirements.

In response to OMIG's draft audit report, appellant raised two general objections which were addressed in ALJ Hall's decision. First, appellant objected to any reliance on OMIG's OPWDD Article 16 Clinic Services audit protocol, and argued that the protocol was illegal and retroactive rulemaking that was not adopted in accordance with the requirements of the State Administrative Procedure Act. However, appellant was unable to identify any provision of the protocol or its application that were inconsistent with applicable regulations, and as such, ALJ Hall rejected the argument. Second, appellant argued that the disallowances imposed by OMIG were unreasonable and improperly imposed sanctions. This argument was rejected as the overpayment finding was not a penalty or a sanction, and instead, was directly related to the claims appellant submitted which failed to comply with the Medicaid billing requirements.

Next, appellant challenged the methods used by OMIG to determine the extrapolated overpayment finding. Specifically, appellant asserted that flaws in the sampling and extrapolation methodology entitled it to a missing witness inference. However, the statistical sampling methodology OMIG employed in the audit allowed for the extrapolation of the sample findings to the claims universe, and appellant was provided with all of the records needed to verify the extrapolation methodology OMIG used prior to hearing, including the universe of claims, the audit frame, the sample, and the computer programs used. At hearing, OMIG presented the required certification showing the extrapolation as valid, and as such, the extrapolation was presumed to be accurate unless appellant submitted expert testimony challenging the extrapolation or an actual accounting of all claims paid. *See* 18 N.Y.C.R.R. § 519.18(g). Appellant's argument that OMIG's method must be testified to by an expert witness at hearing was rejected as not required by applicable regulation. *See id.* Moreover, although appellant offered an expert report opining that the statistical study and extrapolation were both invalid and fatally flawed, appellant failed to offer evidence at the hearing—specifically, either expert testimony or an accounting of the claims—to rebut the presumption, and as such, OMIG's methodology and overpayment calculation were presumed to be valid.

Next, ALJ Hall moved to appellant's challenges to the specific audit findings. According to the final audit report, OMIG identified 30 instances wherein no EOB was found for a Medicare eligible recipient who received services covered by Medicare, and four instances wherein no EOB was found for a Medicaid recipient who received services covered by a TPHI. As to these findings, appellant admitted the lack of Medicare and/or TPHI EOBs for the samples identified, and instead argued that there was no requirement that obligated the clinicians providing the services at issue to enroll in the Medicare program, and since Medicare could not be billed, appellant could not bill any TPHI. ALJ Hall rejected these arguments. Since Medicaid is the payor of last resort, providers are required to investigate and bill available third-party resources before billing Medicaid, and must maintain appropriate records supporting the same. *See* 18 N.Y.C.R.R. §§ 360-7.2, 540.6(e)(2). These obligations require providers to take all necessary actions to meet these requirements, including enrolling in the Medicare program when necessary. According to the ALJ, the lack of a regulation requiring Article 16 clinics to enroll in Medicare was not a defense, and providers bear the burden of following all Medicaid program rules, regulations, and policies, including billing Medicare and TPHIs before billing Medicaid. *See* 18 N.Y.C.R.R. § 504.3(i), 540.6(2). According to the testimony of the OMIG Auditor in Charge, no disallowance would have been taken if there was documentation to prove that appellant attempted to bill Medicare and the services were not covered. The audit findings related to occupational and physical therapy assistants were, in fact, removed from the audit as these providers are not eligible to bill Medicare. Based on the exhibits and testimony provided at hearing, ALJ Hall concluded that appellant was required to, but did not seek, reimbursement from third parties before submitting claims to the Medicaid program, and that this requirement applied regardless of appellant's belief that the services would not be covered.

The audit's third finding, Failure to Meet Minimum Duration Requirements, was based on four instances related to four Medicaid recipients where the clinical documentation of the services' duration was less than the required minimum set out in the descriptive terms and guidelines of the Current Protocol Terminology/Healthcare Common Procedure Coding System (CPT/HCPCS). Specifically, the findings related to vocational rehabilitation services, which were disallowed because the services began at the same time that another service ended, and based on an assumption that there was some travel time involved in getting to the other service location, OMIG determined that the full 15 minute per unit could not have oc-

curred. At hearing, appellant challenged three of the four samples in this findings category, and presented witness testimony confirming the times the counselor met with the applicable Medicaid recipients and the location of the meetings, which occurred either on the work floor or in the counselor's office, which was "seconds away" from the work floor. *See* Decision at 13. Based on witness testimony and the attendance logs, ALJ Hall determined that appellant had provided convincing evidence to refute the three findings in this category.

Therefore, OMIG's determination to recover Medicaid program overpayments for the first and second categories of findings were affirmed, as the disallowed claims were not authorized to be paid by the Medicaid program due to the lack of evidence demonstrating appellant's entitlement to payment. The overpayment findings for three of the four samples in the third category of findings, however, were reversed.

Dutchess Center for Rehabilitation and Health Care (Decision, January 13, 2023, Kimberly A. O'Brien, ALJ).

Appellant operates a RHCF in Pawling, New York. OMIG initiated an audit of appellant's Medicaid reimbursement for specific fee-for-service claims submitted for services provided to Medicaid recipients residing in the nursing home during the period of October 1, 2009 through October 31, 2011. As set out in its final audit report dated August 20, 2015, OMIG sought to recoup $37,409.04, inclusive of interest, in overpayments stemming from claims submitted to the Medicaid program for payment that were not reduced by each resident's Net Available Monthly Income (NAMI).

At hearing, ALJ O'Brien considered whether OMIG's determination to recover overpayments and calculation of interest on the overpayments were correct. In regards to OMIG's determination to recover Medicaid program overpayments related to NAMI, appellant argued that it should be entitled to Medicaid program payment of a resident's NAMI if the RHCF has been unable to collect it. The ALJ rejected this argument, finding that appellant was attempting to conflate cost report and rate setting issues with fee-for-service claims issues. Moreover, although appellant provided a list of outstanding NAMI amounts during the audit period, appellant failed to provide any contemporaneous records to substantiate any of the amounts it alleged were outstanding. Appellant's reliance on *Eden Park v. Axelrod*, 494 N.Y.S.2d (3d Dep't 1985) was rejected by ALJ O'Brien, in favor of an October 26, 2001 "Dear Administrator Letter" issued by DOH directing RHCFs to deduct NAMIs from Medicaid claims even when the NAMI cannot be collected, which the ALJ found to be consistent with applicable case law. *See Florence Nightingale Nursing Home v. Perales*, 782 F.2d 26 (2d Cir. 1986).

Appellant's argument that OMIG incorrectly imposed interest from the date of payment, instead of the date the audit report was issued, was also rejected by the ALJ as another attempt to conflate rate setting issues with fee-for-service claims issues. *See* 18 N.Y.C.R.R. § 518.4(b) – (c), (e). Since the audit at issue was a fee-for-service claims audit, rather than a cost audit, the regulations applicable to the imposition of interest on cost audits were not applicable. *See* 18 N.Y.C.R.R. § 518.4(e). Appellant also attempted to raise issues that were not directly related to OMIG's audit findings, and these issues were not considered by ALJ O'Brien. *See* 18 N.Y.C.R.R. § 519.18(a). Appellant's final argument, that interest may have been imposed for periods before the overpayments were received, was rejected by the ALJ, as the interest at issue was calculated from the date of each overpayment as recorded in Medicaid payment records. *See* 18 N.Y.C.R.R. § 518.4(b) – (c). These records are entitled to a presumption of accuracy, and appellant failed to present any evidence demonstrating that the dates of payment were inaccurate or that OMIG's calculations were incorrect. *See* 18 N.Y.C.R.R. § 519.18(f).

Therefore, as appellant did not reduce its Medicaid claims by each resident's NAMI and interest on the overpayments, which accrued from the date of each payment, was properly charged, OMIG's determination to recover overpayments and its calculations of interest on the overpayments were affirmed.

Chittenango Center for Rehabilitation and Health Care (Decision, January 5, 2023, Kimberly A. O'Brien, ALJ).

Appellant operates a RHCF in Chittenango, New York. OMIG initiated an audit of appellant's Medicaid reimbursement for specific fee-for-service claims submitted for services provided to Medicaid recipients residing in the nursing home during the period of February 1, 2010 through April 30, 2012. As set out in its final audit report dated August 12, 2015, OMIG sought to recoup $26,433.77, inclusive of interest, in overpayments stemming from claims submitted to the Medicaid program for payment that were not reduced by partial or full NAMI.

At hearing, ALJ O'Brien considered whether OMIG's determination to recover overpayments and calculation of interest on the overpayments were correct. In regards to OMIG's determination to recover Medicaid program overpayments related to NAMI, appellant argued that it should be entitled to Medicaid program payment of a resident's NAMI if the RHCF has been unable to collect it. The ALJ rejected this argument, finding that appellant was attempting to conflate cost report and rate setting issues with fee-for-service claims issues. Moreover, although appellant provided a list of outstanding NAMI amounts during the audit period, appellant failed to provide any contemporaneous records to substantiate any of the amounts it alleged were outstanding. Appellant's reliance on *Eden Park v. Axelrod*, 494 N.Y.S.2d (3d Dep't 1985) was rejected by ALJ O'Brien, in favor of an October 26, 2001 "Dear Administrator Letter" issued by DOH directing RHCFs to deduct NAMIs from Medicaid claims even when the NAMI cannot be collected, which the ALJ found to be consistent with applicable case law. *See Florence Nightingale Nursing Home v. Perales*, 782 F.2d 26 (2d Cir. 1986).

Appellant's argument that OMIG incorrectly imposed interest from the date of payment, instead of the date the audit report was issued, was also rejected by the ALJ as another attempt to conflate rate setting issues with fee-for-service claims issues. *See* 18 N.Y.C.R.R. § 518.4(b) – (c), (e). Since the audit at issue was a fee-for-service claims audit, rather than a cost audit, the regulations applicable to the imposition of interest on cost audits were not applicable. *See* 18 N.Y.C.R.R. § 518.4(e). Appellant also attempted to raise issues that were not directly related to OMIG's audit findings, and these issues were not considered by ALJ O'Brien. *See* 18 N.Y.C.R.R. § 519.18(a). Appellant's final argument, that interest may have been imposed for periods before the overpayments were received, was rejected by the ALJ, as the interest at issue was calculated from the date of each overpayment as recorded in Medicaid payment records. *See* 18 N.Y.C.R.R. § 518.4(b) – (c). These records are entitled to a presumption of accuracy, and appellant failed to present any evidence demonstrating that the dates of payment were inaccurate or that OMIG's calculations were incorrect. *See* 18 N.Y.C.R.R. § 519.18(f).

Therefore, as appellant did not reduce its Medicaid claims by each resident's NAMI and interest on the overpayments, which accrued from the date of each payment, was properly charged, OMIG's determination to recover overpayments and its calculations of interest on the overpayments were affirmed.

Cortland Park Rehabilitation and Nursing Center (Decision, December 22, 2022, John Harris Terepka, ALJ).

Appellant operates a RHCF located in Cortland, New York. OMIG completed a MDS audit of appellant for the census period ending January 25, 2012. The issue before ALJ Terepka was whether appellant's request for a hearing was timely made.

Under applicable regulation, a request for a hearing must be made within 60 days of the date of OMIG's final audit report. *See* 18 N.Y.C.R.R. § 519.7. Despite the relevant final audit report having been dated July 21, 2016, appellant did not suggest that it sought to seek a hearing on the audit until October 27, 2016. Although appellant did timely request a hearing for a different audit report (with a different audit number and date of issuance), the request for a hearing on the audit at issue was not timely made. Therefore, appellant's request for an administrative hearing was denied as not timely made.

New York State Attorney General Press Releases

Compiled by Jamie Dughi Hogenkamp, James L. Ko, Rex M. McKeon, and Bridget C. Steele

CONSUMER ALERT: Attorney General James Cautions Against Price Gouging of Children's Medication—December 26, 2022—The Office of Attorney General (OAG) issued a consumer alert following reports of children's medication being sold online for up to three times the medications' retail values. Facing this year's "tripledemic" of COVID-19, RSV, and the flu, Attorney General (AG) James urged New Yorkers to be on alert for potential price gouging of children's painkillers and fever reducers, and to report dramatic price increases to the OAG.

https://ag.ny.gov/press-release/2022/consumer-alert-attorney-general-james-cautions-against-price-gouging-childrens

Attorney General James Releases Statement on Decision to Restrict Access to Medication Abortion—April 7, 2023—In a statement after the U.S. District Court for the Northern District of Texas ordered the U.S. Food and Drug Administration (FDA) to stay its decades-old approval of mifepristone for use in medication abortion, AG James described the decision as "blatantly disregard[ing] decades of medical research for politically motivated reasons that will jeopardize the health of millions of people nationwide." She further recognized that "abortion continues to be legal in New York and New York will remain a safe haven for anyone seeking abortion care."

https://ag.ny.gov/press-release/2023/attorney-general-james-releases-statement-decision-restrict-access-medication

Attorney General James Announces Indictment and Arraignment of Westchester Caseworker for Stealing More Than $300,000 from an Elderly Client—March 24, 2023—AG James announced the indictment of an Danbury, Connecticut caseworker on charges of grand larceny in the second and third degree, identity theft in the first degree, and

official misconduct for stealing over $300,000 from a 95-year old woman with dementia. The OAG alleges that while employed by Westchester County Adult Protective Services, the caseworker depleted the elderly woman's bank and retirement accounts in a matter of months.

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

Attorney General James Secures More Than $860,000 from Medical Transportation Company for Medicaid Provider Fraud—March 20, 2023—AG James announced a settlement with Ismat Farhan and his company, USA Medical Transport, resolving the OAG's findings that the provider submitted over 2,500 false claims and billed the Medicaid program for approximately $400,000 for transportation services that did not occur as described, lacked the required documentation, or never took place at all in violation of the New York State False Claims Act. Specifically, the OAG found that between June 2015 and February 2020, Farhan, through USA Medical Transport, submitted fraudulent claims to the Medicaid program, including claims for rides that were not provided, mileage amounts significantly greater than the actual ride, single rides that should have been bundled as a group ride, rides provided by drivers with suspended licensed (including Farhan, himself), rides that lacked supporting documentation, and reimbursement for tolls that were not actually incurred by USA Medical Transport. As a result of the settlement, Farhan will pay $862,500 to the New York State Medicaid program.

https://ag.ny.gov/press-release/2023/attorney-general-james-secures-more-860000-capital-region-medical-transportation

Attorney General James and Governor Hochul Demand Answers From Major Pharmacy Chains on Medication Abortion Access—March 9, 2023—AG James and Governor Kathy Hochul sent a letter to the Chief Executive Officers (CEOs) of Walgreens (owner of Duane Reade), Rite Aid, and CVS calling on the three major pharmacy chains to provide information about their plans to make the abortion medication, mifepristone, available. The letter asked that the chains commit to dispensing mifepristone in New York, both in pharmacy locations and through mail orders, and reminded the CEOs that abortion is legal and protected as a fundamental right under New York State law, and that there are no legal barriers to dispensing mifepristone in pharmacies in the State. The letter asks the pharmacies to respond within 10 business days confirming whether they will commit to distributing mifepristone, or explaining a legal rationale if they refuse to do so.

https://ag.ny.gov/press-release/2023/attorney-general-james-and-governor-hochul-demand-answers-major-pharmacy-chains

Attorney General James Leads Coalition To Support New Mexico's Actions to Support Abortion Access—March 3, 2023—AG James and a coalition of eight attorneys general released a joint statement in support of New Mexico's effort to protect access to abortion care in all localities within its borders. Abortion is legal in New Mexico; yet, several localities have tried to independently ban or restrict access to abortion care by issuing ordinances. Subsequently, New Mexico filed a lawsuit against four localities asking the New Mexico Supereme Court to nullify these ordinances and rule that abortion is protected under the State's constitution.

https://ag.ny.gov/press-release/2023/attorney-general-james-leads-coalition-support-new-mexicos-actions-support

Attorney General James Leads Multistate Coalition To Defend and Protect Access to Medication Abortion—February 10, 2023—AG James and a coalition of 22 attorneys general filed an amicus brief in *Alliance of Hippocratic Medicine v. U.S. Food and Drug Administration*, a case which is pending in the U.S. District Court for the Northern District of Texas. The brief asks the court to reject a challenge brought by anti-abortion groups seeking to revoke the FDA's approval of the abortion medication, mifepristone. The brief warns that withdrawing federal approval for mifepristone would drastically reduce access to safe abortion care and miscarriage management for millions of people across the country, including in New York.

https://ag.ny.gov/press-release/2023/attorney-general-james-leads-multistate-coalition-defend-and-protect-access

Attorney General James and Multistate Coalition Support CVS and Walgreens for Offering Medication Abortion—February 16, 2023—AG James and 22 other attorneys general sent a letter to CVS and Walgreens in support of the pharmacies' decision to offer mifepristone and misoprostol, also known as medication abortion. The letter emphasizes that making these medications available at pharmacies and by mail is safe and legal.

https://ag.ny.gov/press-release/2023/attorney-general-james-and-multistate-coalition-support-cvs-and-walgreens

Attorney General James Stops Home Care Company from Deceiving Patients and Caregivers—February 24, 2023—Affordable Senior Care of New York LLC ("Affordable"), a Brooklyn-based fiscal intermediary, and Laszlo Friedman must pay the State a combined penalty of $400,000 and cooperate with ongoing investigation into the home care industry. An investigation by the OAG found that Friedman, acting on behalf of Affordable, entered into an unlawful agreement with another fiscal intermediary, Marks Homecare, to not take each other's existing patients. This agreement prevented patients and their chosen caregivers from moving to the

company of their choice. As part of the settlement agreement with the OAG, Friedman and Affordable are also barred from entering into any anti-competitive agreements in the future.

https://ag.ny.gov/press-release/2023/attorney-general-james-stops-home-care-company-deceiving-patients-and-caregivers

Attorney General James Secures Over $7.1 Million from Former Saratoga County Nursing Home for Years of Fraud and Neglect—February 27, 2023—AG James and the United States Attorney for the Northern District of New York have secured more than $7.1 million from a New York State RHCF and related parties, including the landlord and an unlicensed operator. Following a financial dispute in 2017, the RHCF failed to report a change in operator to DOH. Under the settlement, the owners, landlord, and unlicensed operator were ordered to pay more $7.1 million to Medicaid, with $4.3 million flowing directly to New York State.

https://ag.ny.gov/press-release/2023/attorney-general-james-secures-over-71-million-former-saratoga-county-nursing

Attorney General James Addresses Mental Health Crisis in Western New York in Public Hearing—January 19, 2023— In a statement regarding the second public hearing on mental health care, AG James thanked "those who shared their personal and often painful experiences." Challenges accessing and providing mental health care shared through testimony included underfunding for community health groups and health care facilities, gaps in coordinated care, understaffing, and stigma around mental health care. The statement acknowledged that the views of impacted individuals, health care providers, elected officials, and community members were reflected through the oral testimony of 21 individuals and the written testimony of nearly 100 individuals.

https://ag.ny.gov/press-release/2023/attorney-general-james-addresses-mental-health-crisis-western-new-york-public

Attorney General James To Hold Public Hearing on Mental Health Access in Western New York—January 6, 2023—AG James announced the OAG's second in-person public hearing on the provision of mental health care for people with serious mental illness in the Western New York region. The intent of the hearings is to gain insight from the public regarding the problems people suffering mental health crisis or chronic severe mental illness experience in accessing mental health services, and to use that information for legislative and enforcement solutions. Members of the public, advocacy groups, and health care providers were encouraged to testify at the hearing.

https://ag.ny.gov/press-release/2023/attorney-general-james-hold-public-hearing-mental-health-access-western-new-york

Attorney General James Announces Sentencing of Former Nursing Home Employee for Raping a Resident—January 6, 2023—AG James announced the sentencing of Khadka Pradhan for the rape and sexual assault of an 81-year-old nursing home resident. Following Pradhan's November 2022 conviction, the 52-year-old was sentenced to 25 years' imprisonment and 20 years' post-release supervision.

https://ag.ny.gov/press-release/2023/attorney-general-james-announces-sentencing-former-nursing-home-employee-raping

New York State Office of the Medicaid Inspector General Update

Compiled by Dena M. DeFazio

OMIG ANNOUNCES SCHEDULE OF STATEWIDE HEALTHCARE PROVIDER ENGAGEMENT FORUMS—March 31, 2023— https://omig.ny.gov/news/2023/omig-announces-schedule-statewide-healthcare-provider-engagement-forums

OMIG POSTS COMPLIANCE RESOURCES AND INFORMATION—March 8, 2023— https://omig.ny.gov/news/2023/omig-posts-compliance-resources-and-information

OMIG POSTS COMPREHENSIVE GUIDANCE ON COMPLIANCE PROGRAMS, SELF-DISCLOSURE, AND MEDICAID MANAGED CARE FRAUD, WASTE AND ABUSE PREVENTION PROGRAMS REGULATIONS—January 31, 2023— https://omig.ny.gov/news/2023/omig-posts-comprehensive-guidance-compliance-programs-self-disclosure-and-medicaid

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

A Framework for Assessing Whether Civil Penalties Under the False Claims Act Violate the Excessive Fines Clause of the Eighth Amendment, Joel D. Hesch, 91 U. Cin. L. Rev. 1012 (2023).

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For Your Information

By Claudia O. Torrey

On June 8, 2023, the United States Supreme Court affirmed the Seventh Circuit in a 7-2 decision that upheld the right of public nursing home residents and safety-net program recipients to enforce their rights in court; the opinion was written by Justice Jackson.

In *Health and Hospital Corporation of Marion County v. Talevski*,[1] defendant (through his wife) brought a lawsuit using 42 U.S.C. § 1983 against a county-owned nursing home in Indiana alleging HHH's treatment violated his rights under the federal Nursing Home Reform Act (NHRA).[2] Defendant alleged that the NHRA gives him the right to be free from unnecessary chemical restraints,[3] and the right not to be transferred under certain preconditions.[4] The NHRA via § 1983 "unambiguously confers" individually enforceable rights on nursing home residents. The case also potentially impacts the rights of people: on Medicaid, receiving housing assistance and/or food stamps should they seek redress for violated rights. Section 1983 basically allows for one to sue any person acting under the color of state law that deprives one of any rights, privileges, or immunities secured by the Constitution and the laws of the United States.

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

Endnotes

1. "HHH;" Slip Opinion #21-806, pp. 1-74, June 8, 2023.
2. 42 U.S.C. § 1396r(c).
3. Section 1396r(c)(1)(A)(ii).
4. Section 1396r(c)(2)(A).

In the New York State Courts

By Dayna B. Tann and Marc A. Sittenreich

Second Department Holds That Residency Contract Disputes Are Subject to the Two-Step Grievance Process of Public Health Law § 2801-b

***Khass v. New York Presbyt. Brooklyn Methodist Hosp.*, 213 A.D.3d 824 (2d Dep't 2023)**

Plaintiff was a medical student at the Saint George's University School of Medicine (the university). Prior to graduating, plaintiff applied to, and was accepted by, the pediatric residency program at New York Presbyterian Brooklyn Methodist Hospital (the hospital) via the National Resident Matching Program (the NRMP). In accordance with a match participation agreement (the agreement), plaintiff and the hospital agreed to be bound to the NRMP match, and only the NRMP may waive the match commitment.

In April 2019, the hospital requested that the NRMP waive the agreement after it learned that plaintiff made social media posts that were anti-Semitic and had been placed on a three-month suspension from the university. The NRMP denied the hospital's waiver request. Despite not receiving a waiver from the NRMP, the hospital refused to admit plaintiff into its pediatric residency program.

Thereafter, plaintiff commenced an action in the Supreme Court of the State of New York, County of Kings, against the hospital and the university, among other parties, seeking specific performance of the agreement. Before issue was joined, plaintiff moved for a preliminary injunction barring the hospital from denying him admission into its pediatric residency program. The hospital opposed the motion, arguing, *inter alia*, that the Supreme Court lacked subject matter jurisdiction over the causes of action asserted against it because plaintiff failed to exhaust his administrative remedies under Article 28 of the New York Public Health Law.

By order dated February 13, 2020, the Supreme Court rejected the hospital's argument and converted the action, pursuant to CPLR 103(c), into a CPLR Article 78 proceeding for mandamus relief compelling the hospital to admit plaintiff into its pediatric residency program. The Supreme Court then granted this relief by order and judgment dated June 23, 2020. The hospital appealed both orders.

As a preliminary matter, the Second Department held the Supreme Court erroneously invoked CPLR 103(c) to convert plaintiff's motion and the subject action into a CPLR Article 78 proceeding. While CPLR 103(c) empowers courts to convert a civil proceeding brought in the improper form to the proper form, the court asserted that a proceeding pursuant to CPLR Article 78 is not the proper vehicle to resolve contractual rights. Since plaintiff asserted violations of his rights under a contract, the court found that "the appropriate remedy is an action alleging breach of contract."

Then, the Second Department held the Supreme Court incorrectly rejected the hospital's argument that plaintiff's request for a preliminary injunction should be denied because he failed to exhaust his administrative remedies under Public Health Law § 2801-b. That provision "makes it an 'improper practice' for a hospital to deny, withhold, or terminate professional privileges for a reason unrelated to 'patient care, patient welfare, the objectives of the institution or the character or competency of the applicant.'" The statute contains a two-step grievance process by which a physician may obtain injunctive relief: First, the physician must submit a complaint to the Public Health and Health Planning Council (the PHHPC). Following the PHHPC's review of the complaint, the physician may commence an action under Public Health Law § 2801-c to enjoin a hospital from improperly denying or terminating staff privileges.

Although plaintiff argued that Public Health Law § 2801-b was inapplicable because "he was a resident who had not yet begun his employment with the hospital," the Second Department clarified that a medical resident is "undoubtedly a physician," and thus the proper recourse for challenging his termination from a hospital residency program is the two-step grievance process set forth in the statute. Because plaintiff sought reinstatement of his professional privileges (i.e. his admission to the pediatric residency program), he was "required to file an administrative complaint with the PHHPC, and await the administrative disposition of that complaint before seeking redress in the courts." Accordingly, the Second Department held that the Supreme Court should have denied plaintiff's request for a preliminary injunction barring the hospital from denying him admission into its pediatric residency program.

Second Circuit Holds That Parties Cannot Remove Ordinary Malpractice and Negligence Claims to Federal Court Based on PREP Act Immunity

***Solomon v. St. Joseph Hospital*, 62 F.4th 54 (2d Cir. 2023)**

Plaintiff, who was admitted to St. Joseph Hospital (the hospital) for COVID-19 symptoms and developed severe

pressure sores during his admission, brought an action against the hospital and its operator, Catholic Health System of Long Island Inc. (collectively, defendants) in New York state court, alleging medical malpractice, negligence, and gross negligence. Defendants removed the case to the United States District Court for the Eastern District of New York and then moved to dismiss the complaint. Defendants argued that plaintiff's claims were barred by the PREP Act, a federal statute that limits liability for injuries caused by certain "covered countermeasures" during a public health emergency, and the Emergency or Disaster Treatment Protection Act (EDTPA), a New York state law that immunized health-care facilities from liability from claims resulting from health-care decisions made "in response to or as a result of" COVID-19.

The district court denied defendants' motion to dismiss. The court found that plaintiff's claims did not fall within the immunity provision of the PREP Act, as his claims stemmed from a "common type of hospital-acquired injury that results from not being rotated while stationary." Likewise, the court determined that defendants were not entitled to EDTPA immunity because they failed to show that plaintiff's alleged injuries directly resulted "from decisions or activities in response to or as a result of the COVID-19 outbreak." Lastly, the court found that plaintiff sufficiently pleaded a claim for gross negligence, which is exempt from EDTPA immunity. Defendants filed an interlocutory appeal, alleging that the collateral-order doctrine entitled them to immediate review of the district court's denial of immunity from plaintiff's claims.

Although plaintiff had not challenged the removal to federal court, the United States Court of Appeals for the Second Circuit's ruling focused on whether the district court had subject-matter jurisdiction over plaintiff's claims. The court first rejected defendants' contention that the PREP Act completely preempts plaintiff's state-law claims. The PREP Act, which principally provides for an immunity scheme, permits a claimant to assert only one federal cause of action, for willful misconduct, defined as "a standard for liability that is more stringent than a standard of negligence *in any form*." The court determined that plaintiff's claims for medical malpractice, negligence, and gross negligence did not rise to this standard. The court also found that permitting plaintiff "to proceed in state court simply by declining to allege willfulness" would not frustrate the purpose of the Prep Act. While the PREP Act demonstrates Congress's intent to "eliminate *all other causes of action*" for immunized claims, the court found nothing in the statute suggesting that Congress intended to eliminate state law causes of action for non-immunized claims. Moreover, the court asserted that the PREP Act would still be available as a defense to defendants, regardless of whether the action proceeds in state or federal court.

Next, the Second Circuit rejected defendants' argument that removal was appropriate under the federal-officer removal statute. The court found that "[d]efendants do not 'act under' a federal officer simply because they operate in a heavily regulated industry." The court also found that "[d]efendants' role during the COVID-19 pandemic has nothing to do with whether they were 'acting under' a federal officer."

Lastly, the court rejected defendants' argument that plaintiff's claims "arise under federal law." Federal courts have subject-matter jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." Subject-matter jurisdiction may also exit where claims that find their "origins in state law:" (1) necessarily raise a federal issue; (2) are actually disputed; (3) are substantial; and (4) are capable of resolution in federal court "without disrupting the federal-state balance approved by Congress." The fact that a defense may be founded under a federal statute is insufficient to confer federal subject-matter jurisdiction. Applying these factors, the court determined that removal to federal court was improper because plaintiff's complaint did not, on its face, necessarily raise a federal issue.

Third Department Upholds Revocation of Medical License Held by Physician Who Branded Women During Cult Ritual

Matter of Roberts v. New York State Bd. for Prof'l Med. Conduct, 215 A.D.3d 1093 (N.Y. App. Div. 2023)

After receiving her medical license in 2009, Danielle Roberts joined a "personal development organization" known as NXIVM. Roberts was later invited to join a secret society operating within NXIVM known as Dominus Obsequious Soroium (DOS). Among other requirements, DOS members were required to undergo a ritualistic initiation ceremony during which they were branded in the pelvic region with the initials of NXIVM's founder. Roberts personally performed 17 of these video-recorded brandings for DOS using an electrocautery device.

In 2020, following an investigation into a complaint made by a former DOS member who had been branded by Roberts, the Bureau of Professional Medical Conduct (the bureau) charged Roberts with committing 47 specifications of professional misconduct. The charges stemmed not only from Roberts' participation in the 17 branding ceremonies, but also from her failure to report an infectious disease outbreak at an NXIVM corporate retreat she attended.

Roberts narrowly challenged the bureau's charges on jurisdictional grounds, claiming that: (1) "she was not engaged in the practice of medicine while performing the branding"; and (2) that "her duty to report a disease outbreak did not extend to her attendance at a corporate retreat." A Bureau Hearing

Committee sustained all of the charges against Roberts. Roberts did not seek review by the bureau's Administrative Review Board, but commenced a CPLR Article 78 proceeding before the Appellate Division, Third Department, seeking to annul the Hearing Committee's determination.

The Third Department's review was limited to whether the Hearing Committee's decision was supported by substantial evidence. Although Roberts claimed that the branding was performed for non-medical reasons, the court observed that Roberts "used her medical knowledge and training" to create the permanent scar on the 17 DOS members. The court also noted that several witnesses testified that following the ritualistic branding, Roberts provided wound care to the DOS members, and that Roberts was the only physician with whom DOS members were permitted to consult regarding their wounds. Based on these findings, the court declined to disturb the Hearing Committee's determination that Roberts was engaged in the practice of medicine during the ritualistic branding ceremonies.

The court also found that substantial evidence supported the Hearing Committee's determination to sustain the professional misconduct charges against Roberts for her failure to report an infectious disease outbreak at a NXIVM corporate retreat. Roberts failed to refute the bureau's infectious disease expert, who testified that a physician has a duty to report a disease outbreak to public health officials even while on vacation. The bureau's expert further testified that there was "no question" that the illness that spread at that retreat – which "mirrored norovirus and spread rapidly to attendees" – constituted an infectious disease outbreak that triggered Roberts' duty to report.

Lastly, the court rejected Roberts' challenges to certain "evidentiary rulings" made by the bureau's Administrative Law Judge at her hearing. The court noted that the rules of evidence are not strictly applied in administrative proceedings. "In order to warrant annulment of the Committee's determination," the court held, an "erroneous evidentiary ruling must infect the entire proceeding with unfairness." The court found that Roberts failed to make such a showing.

Northern District of New York Holds That the U.S. Supreme Court's Decision Overturning *Roe v. Wade* Is Insufficient to Revive Constitutional Challenge to the New York Reproductive Health Act

Smith v. Hochul, No. 21 Civ. 35, 2023 WL 2598841 (N.D.N.Y. Mar. 22, 2023)

Plaintiffs, proceeding pseudonymously, brought this action against Governor Kathy Hochul and several other State officials challenging certain provisions of the New York Reproductive Health Act (RHA). Plaintiffs raised seven counts in their complaint, including First and Fourteenth Amendment challenges to the RHA's amendments to Penal Law § 125.05 – which defines a "person," for the purposes of homicide and related charges, as "a human being who has been born" – on behalf of a class of women, "Viable Unborn Children," and "Abortion Survivors." Among other things, plaintiffs alleged that the changes to the Penal Law violated women's "right to freedom from state-created threats of violence" and their "right to legal redress." Plaintiffs also brought a claim on behalf of a class of physicians, alleging that two provisions of New York's Public Health Law, as amended by the RHA, are void for undue vagueness. Defendants moved to dismiss, which the court granted, finding that plaintiffs had failed to state a claim in regard to their first two counts (brought on behalf of a putative class of women) and lacked standing to bring their remaining five counts.

After the court entered judgment in defendants' favor, the Supreme Court issued its decision in *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022) overturning *Roe v. Wade*, 410 U.S. 113 (1973) and *Planned Parenthood v. Casey*, 505 U.S. 833 (1992). Plaintiffs filed multiple post-judgment motions, alleging that the *Dobbs* ruling affected their case in "significant ways" that justified vacating the judgment and allowing them to amend their pleadings. By Decision and Order dated March 22, 2023, the Northern District of New York denied plaintiffs' motions in their entirety.

The court first addressed plaintiffs' motion to vacate the judgment dismissing the claims brought on behalf of "Viable Unborn Children" for lack of standing. Plaintiffs argued that standing arises not from their status as "next friends" of the "Viable Unborn Children," but because plaintiffs' counsel is capable of directly representing the minors comprising the class. Noting that it had previously considered and rejected this exact same argument, the court denied plaintiffs' motion on the basis that it sought "only to relitigate issues already decided."

The court then rejected plaintiffs' contention that the *Dobbs* decision was a "change in decisional law" and an "extraordinary circumstance" that justified reopening or vacating its judgment. Plaintiffs claimed that the *Dobbs* decision "eliminated what had previously been regarded as a fundamental right, destroyed the foundation for the New York's RHA," which sought to protect the rights identified in *Roe*, "and otherwise reshaped the constitutional contours around which plaintiffs have shaped their suit." The court disagreed, holding that *Dobbs* does not "[r]epresent a change of controlling law that would have warranted a different outcome in the Judgment." Although the *Dobbs* court found that there was no constitutional right to an abortion, it "did not impose any affirmative obligation on state governments to prohibit

abortion" and thus had no effect on the RHA. The court also rejected plaintiffs' argument that *Dobbs* conferred standing on unborn children, stating that "[n]owhere in *Dobbs* does the majority hold—or even suggest in dicta—that prenatal life qualifies as 'persons' under the Fourteenth Amendment."

Lastly, the court addressed plaintiffs' motions to file a post-*Dobbs* amended complaint. Although the court acknowledged that "a successful motion to vacate the Judgment is a pre-requisite to plaintiffs' motion for leave to file" an amended complaint, it nevertheless found that vacating a judgment to allow an amended pleading was permitted to "prevent a manifest injustice" when "the plaintiff was never given an opportunity to replead in the first place." The court noted, however, that it may deny such relief if the "proposed amendments would be futile."

The court then examined plaintiffs' proposed amended complaint and determined that vacating the judgment and granting leave to amend would be futile. The court found that plaintiffs' new allegations regarding the purported deleterious effects that the RHA had on the proposed class of women did not remedy the fact that plaintiffs "failed to demonstrate that defendants condoned violence against pregnant women," so as to invoke the state-created danger exception to the Fourteenth Amendment, nor did they remediate plaintiffs' claim for violation of their "right to legal redress" since "[i]t remains the case that a private citizen does not have a constitutional right to bring a criminal complaint against another individual."

The court then determined that the proposed amendments to the remaining counts were insufficient to confer standing. The court found that the newly proposed representatives for the class of "Viable Unborn Children" lacked a "significant relationship" to the class members necessary for next friend appointment, and that plaintiffs did not allege that "Baby Nicholas," named in the proposed amended complaint, suffered or stood to suffer any harm because of defendants' conduct. Likewise, the court held that the proposed amended complaint was devoid of any allegation that medical professionals faced a "credible threat of prosecution" were they to violate the challenged provisions of the New York Public Health Law.

Southern District of New York Dismisses Nurse's Constitutional and Statutory Challenge to COVID-19 Vaccine Mandate

Riley v. New York City Health & Hosps. Corp., No. 22 Civ. 2736, 2023 WL 2118073 (S.D.N.Y. Feb. 17, 2023)

Plaintiff is a nurse who worked at North Central Bronx Hospital (the hospital), which is managed by the New York City Health + Hospitals Corporation (HHC). In August 2021, New York State enacted an emergency rule requiring HHC's facilities, including the hospital, to ensure that certain employees become vaccinated against COVID-19 (the state mandate). The state mandate permitted medical exemptions, but not religious exemptions, to the vaccination requirement. Plaintiff alleged that HHC then issued its own mandate requiring all employees "to be vaccinated against COVID-19 or face termination." Plaintiff sought a religious exemption or another reasonable accommodation from HHC's mandate based on her Christian beliefs. After granting her a two-month unpaid leave of absence, HHC determined that granting any additional leave would pose an undue burden and ultimately terminated her employment.

Plaintiff commenced an action in the United States District Court for the Southern District of New York, alleging that the HHC violated her rights under the Free Exercise Clause of the First Amendment and the Equal Protection Clause of the Fourteenth Amendment by denying her a reasonable religious accommodation from HHC's vaccine mandate. Plaintiff also alleged that HHC violated Title VII and the New York State and City Human Rights Laws. HHC moved to dismiss for failure to state a claim.

The court first addressed plaintiff's Title VII claim. It observed that the statute requires an employer to reasonably accommodate an employee's religious observance or practice unless the accommodation sought by the employee would cause undue hardship. Although plaintiff had alleged a prima facie claim, the court held that the specific religious accommodation that she sought – "to continue working as a patient-facing nurse while unvaccinated" – would have caused undue hardship because it would have required HHC to violate the state mandate.

The court then turned to plaintiff's First Amendment claim. The court observed that when government actors enforce rules that are "neutral and of general applicability," they "need only demonstrate a rational basis" for doing so. While plaintiff claimed that HHC's mandate was non-neutral, the court found that she pleaded "no facts suggesting that" it "explicitly single[d] out a religious practice" or "target[ed] religious conduct for distinctive treatment." The court also found that to the extent plaintiff "allege[d] that the mandate's lack of a religious exception alone makes it non-neutral," her argument was foreclosed by *We The Patriots USA, Inc. v. Hochul*, 17 F.4th 266 (2d Cir. 2021), a Second Circuit decision finding that the state mandate was likely valid under the Free Exercise Clause.

The court did not address the merits of plaintiff's remaining causes of action. It noted that plaintiff had abandoned her Equal Protection Clause claim by failing to respond to HHC's argument in support of its dismissal. And, having dismissed

all of plaintiff's federal claims, the court declined to exercise supplemental jurisdiction over plaintiff's state-law claims.

Western District of New York Upholds USDA's Refusal To Ban Slaughter of Non-Ambulatory Pigs

Farm Sanctuary v. U.S. Dep't of Agric., No. 20 Civ. 6081, 2023 WL 2673141 (W.D.N.Y. Mar. 28, 2023)

The origin of this case dates back to Congress' 2002 amendment of the Humane Methods of Slaughter Act of 1978 (the HMSA). The amendment required the U.S. Department of Agriculture (the USDA) to investigate and submit a report to Congress on "non-ambulatory" livestock. In the wake of the report, the Food Safety and Inspection Service (the FSIS), a subdivision of the USDA, promulgated a rule prohibiting the slaughter of non-ambulatory cattle for food, based on a finding that such animals have a higher incidence of bovine spongiform encephalopathy – colloquially referred to as "mad cow disease" – than ambulatory cattle.

Plaintiffs in this case, a group of animal welfare advocacy organizations, filed a 2014 petition requesting that the USDA expand this prohibition on slaughter to include non-ambulatory pigs. The USDA denied the petition by letter dated September 16, 2019, prompting a challenge by plaintiffs in the United States District Court for the Western District of New York under the HMSA and the Administrative Procedure Act (the APA). Plaintiffs pleaded three causes of action: (i) failure to investigate and report to Congress on non-ambulatory pigs, in violation of the HMSA and the APA; (ii) failure to "regulate the humane treatment, handling, and disposition" of non-ambulatory pigs, in violation of the HMSA and the APA; and (iii) arbitrary and capricious denial of plaintiffs' petition for regulatory action, in violation of the APA. In a decision issued March 28, 2023, the court rejected plaintiffs' challenges and granted defendants' motion for summary judgment.

The court began its decision by addressing the issue of standing and examined the two potential avenues for plaintiffs to assert "organizational standing." First, the court noted that an organization may sue on behalf of its members by demonstrating that "some particular member . . . would have had standing to bring the suit individually." This is commonly referred to as "associational standing." Alternatively, an organization "may have standing in its own right to seek judicial relief from injury to itself." Under this theory, the organization must satisfy the same three-part test applicable to individuals: (i) an injury-in-fact; (ii) causation; and (iii) redressability.

The court held that plaintiffs lacked associational standing to pursue their first and second causes of action, for failure to investigate and take regulatory action. Because the HMSA did not compel disclosure of any particular information to plaintiffs (or to the public at large), the court found that the USDA's mere failure to furnish Congress with a report on non-ambulatory pigs was insufficient to establish an "injury" for standing purposes. Notably, the court rejected plaintiffs' reliance on the Freedom of Information Act (FOIA), finding that "the potential availability of a to-be-produced report via FOIA is too attenuated to satisfy [the] requirement of a concrete informational injury."

Turning to the alternative grounds for organization standing, the court cited the Second Circuit's decision in *Connecticut Parents Union v. Russell-Tucker*, 8 F.4th 167 (2021), which "rejected an expansive concept of organizational injury for standing purposes." Specifically, an organization lacks standing to challenge a law or regulation unless it imposes an "involuntary material burden [and] a cost (e.g., in time, money or danger)" that adversely affects the organization. Despite observing that plaintiffs expended significant resources educating the public about defendants' failure to protect non-ambulatory pigs, the court found "that did not constitute an *involuntary* material burden . . . because plaintiffs were not required to do so in order to alleviate an obligation placed on them by [d]efendants." In other words, plaintiffs' unilateral "decision to embark on new [educational and advocacy] activities in response to [agency] action (or in this case, inaction)," was insufficient to confer standing.

The court made similar findings with respect to plaintiffs' third cause of action, which challenged the USDA's denial of plaintiffs' petition for regulatory action. The court found, once again, that plaintiffs' devotion of substantial resources to "combat the effects of defendants' failure to prohibit the slaughter of non-ambulatory pigs" was not an involuntary material burden. The court observed that plaintiffs' claims were devoid of "any evidence that defendants' denial of the petition caused pigs to become [non-ambulatory] and in need of rescue, versus merely maintaining the *status quo*." The court then rejected plaintiffs' associational standing for this claim, which relied on multiple affidavits from plaintiffs' members explaining that they "consume pork products and are concerned . . . about the potentially fatal health risks that they face from their potential exposure to meat from [non-ambulatory] pigs contaminated with pathogens." Upon review, the court found that such declarations "do not contain any statistical evidence about the likelihood of these individuals actually encountering pathogens, nor any evidence of actual exposure," and failed to account for "the role of FSIS inspections in the production process—inspections that are designed to catch and weed out any pork that would be harmful for humans to consume." Given these deficiencies, the court found that plaintiffs' alleged injuries were speculative and contingent, and thus "simply . . . not concrete enough to satisfy the requirements of Article III."

Despite its conclusion that plaintiffs lacked standing on all three causes of action, the court proceeded to consider the merits of plaintiffs' claims. The court rejected plaintiffs' first cause of action, which challenged the USDA's failure to investigate and report to Congress on non-ambulatory pigs. The court first noted that the HMSA did not require defendants to report "on non-ambulatory livestock *generally*," nor did it compel defendants to "investigate *each and every species* of livestock." The court then found ample evidence in the administrative record of the USDA's compliance with the statutory mandate, including its submission of reports to Congress in 2004 and 2006 concerning non-ambulatory livestock. As a result, the court found that plaintiffs could not substantiate "[d]efendants' [alleged failure] to take a discrete agency action that they were required to take."

The court similarly rejected plaintiffs' second cause of action – alleging failure to regulate – based on long-settled precedent dictating that "the APA explicitly excludes from judicial review those agency actions that are committed to agency discretion by law." Here, the operative statutory language directed the USDA to take regulatory action to ensure humane treatment of non-ambulatory livestock – but *only* where the "Secretary [of Agriculture] determines it necessary." This discretionary language rendered the USDA's inaction essentially unreviewable.

Last, the court rejected plaintiffs' third cause of action, which challenged, as arbitrary and capricious, defendants' denial of plaintiffs' petition for regulatory action banning the slaughter of non-ambulatory pigs. The court first noted the "highly deferential" standard of review under the APA, which "presumes the agency's action to be valid." On review of the administrative record, the court emphasized FSIS' finding that "existing regulations and inspection procedures are sufficient and effective in ensuring that [non-ambulatory] pigs are handled humanely at slaughter and in preventing diseased animals from entering the human food supply." Moreover, the administrative record sufficiently demonstrated that "measures already in place – including rigorous ante-mortem and post-mortem inspections – effectively control the safety and public health risks presented by the slaughter of [non-ambulatory] pigs." The court then squarely addressed plaintiffs' overlying premise, namely "the fact that FSIS treats [non-ambulatory] pigs distinctly from [non-ambulatory] cattle." The court rejected this premise outright, finding substantial evidence in the record explaining and justifying such differences in treatment, including FSIS' determination that "market [pigs] are not subject to [the] same practices [as cattle] prior to slaughter and thus do not arrive at slaughter under conditions that increase the risk that they will become non-ambulatory or be inhumanely handled."

Given both the deferential standard of review and the sufficiency of the administrative record, the court was satisfied that defendants "considered the pertinent evidence, examined the relevant factors, and articulated a satisfactory explanation for [their] action." As a result, the court concluded that the denial of plaintiffs' petition was not arbitrary and capricious.

Third Department Affirms Dismissal of Hospitals' Challenge to Medicaid Reimbursement Rates for Chemical Dependency Rehabilitation Units

Arnot Ogden Med. Ctr. v. New York State Dep't of Health, 214 A.D.3d 1195 (3d Dep't 2023)

Petitioners, who operate general hospitals that include distinct chemical dependency rehabilitation units, commenced a CPLR Article 78 proceeding to annul the commissioner of health's 2020 Medicaid reimbursement rates for their chemical dependency units and to compel recalculation of the rates. Specifically, petitioners alleged that: (1) the commissioner had improperly certified that these reimbursement rates were "reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities"; and, (2) the commissioner's continued use of 2005 as the base year to calculate the operating cost component of the rates was irrational. Following joinder of issue, the trial court dismissed the petition. Petitioners appealed.

The Appellate Division, Third Department noted that rate setting determinations are "quasi-legislative in nature" and will not be annulled absent a compelling showing that the methodology used to calculate the rates is "unreasonable and unsupported by any evidence." Applying this standard, the court rejected the petitioners' argument that the reimbursement rates lacked a rational basis for certification by the commissioner. The court reasoned that even though petitioners submitted proof that the set rates did not cover the actual costs of their chemical dependency units, they fatally neglected to provide evidence that their chemical dependency units were efficiently and economically operated. Given this lack of evidence, the court held that the petitioners failed to "satisfy their burden of showing that the commissioner improperly certified the rates as compliant with Public Health Law § 2807."

The court also held that the commissioner's refusal to update the base year used to calculate the operating cost was not irrational. The court credited an affidavit from the director of the Department of Health's bureau of Hospital and Clinic Rate Setting explaining that changing the base year could lead to Medicare expenditures exceeding a "global cap" imposed in 2011. While the commissioner had the authority to update the base year, the court observed that the Public Health Law directs that such authority be used only when "neces-

sary to achieve no aggregate, net growth in overall Medicaid expenditures related to such rates" from the prior year. Thus, the court concluded that the commissioner advanced "'ample explanation for setting rates' consistent with [the Department of Health's] historical practice" and that petitioners did not meet their burden to show that the rates were irrational.

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

Meet the 2023 Summer NYSBA Diversity Health Law Fellows

Bernard Robert

My name is Bernard Robert and I'm from Long Island, New York. I'm first generation Haitian-American and currently live in Queens, New York. Health care has always been an interest of mine. I studied health information technology at Stony Brook University and volunteered as an emergency medical technician (EMT) at my local fire department. I then received my master's in public health at Hofstra University. While in graduate school, I conducted a month-long research study in Nairobi, Kenya where I worked with the Kenyan Ministry of Health. That is where my interest in health law and policy began.

I currently attend Seton Hall Univeristy School of Law. I am a second-year part time student and intend to specialize in health care law. I am also interested in litigation and competed in the national Black Law Student Association mock trial competition as a first-year student in Washington, D.C. I'm interested in learning about all aspects of health law. In particular, I'm interested in health technology, health policy, hospitals systems, compliance, regulation, health insurance and medical malpractice. Outside of school, my hobbies include traveling, golfing, and spending time with family.

This summer, I have been placed at SUNY Downstate Medical Center.

Joshua Joseph

My name is Joshua Joseph, and I am a first-generation Indian-American from Long Island, New York. My parents and grandparents immigrated to the United States from Kerala, India. Most of my family works in health care, so I wanted to follow their path while making my own imprint, particularly in health law. I would not have had the opportunity to pursue a law school education without my parents and grandparents' sacrifices and the values they instilled in me. One of these values that I have always held onto is to wholly pursue and earn everything I desire regarding my education and professional career.

For my undergraduate education, I attended CUNY Baruch College from 2019 to 2021 and graduated cum laude with a Bachelor of Arts in political science and philosophy. During this time, I held various legal internships, including a position in New York City's Department of Social Services and a judicial internship under the honorable Claire R. Kelly of the United States Court of International Trade. These opportunities allowed me to see the scope of legal work that I could pursue in my career, ranging from administrative, litigation, and transactional practices. My specific focus on health law began when I volunteered with Hofstra's Medical-Legal Partnership (MLP) with Northwell Health. While volunteering with the MLP, I gained a first-hand account of the diverse matters within health law and how people

critically rely on healthcare for enhanced well-being to pursue important life goals. For my long-term legal career, I would like to work as an in-house hospital or health care system attorney.

Regarding my legal education, I recently concluded an enriching 1L year at Maurice A. Deane School of Law at Hofstra University. I am heavily involved in the school's Health Law Society and served as a first-year representative for the club. For my upcoming 2L year, I look forward to taking many health law-oriented classes, declaring a concentration within health law, and even pursuing a certificate in bioethics offered through the law school. Outside the classroom, I enjoy playing basketball, hiking, and trying new restaurants.This summer, I have been placed at the Office of the General Counsel at Catholic Health.

About the Fellowship

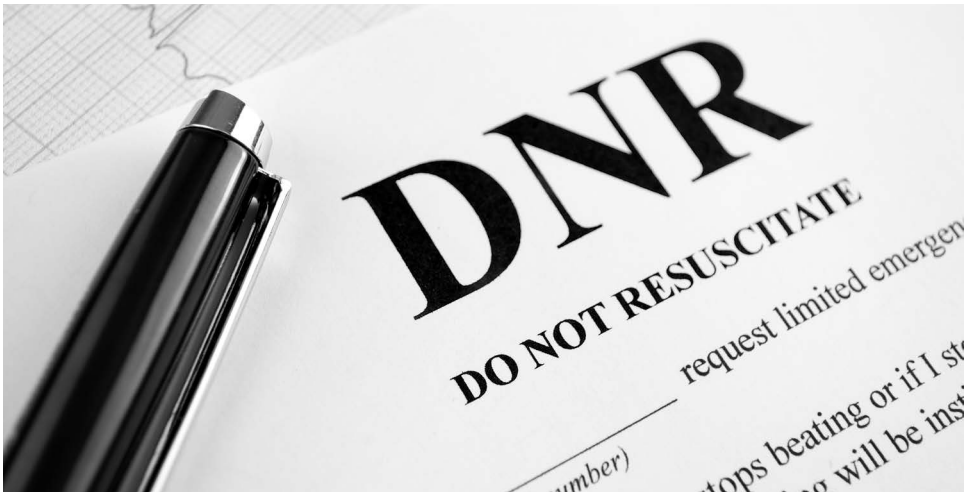
The Diversity Summer Fellowship in Health Law was developed in 2011 by the Health Law Section as part of the New York State Bar Association's Diversity Challenge to develop and execute initiatives to increase the diversity of its membership, leadership and programs and to evaluate the results. The primary goal of the Diversity Summer Fellowship in Health Law is to increase representation of lawyers and students from a diverse range of backgrounds in health law.

The Fellowship will provide students from a diverse range of backgrounds an opportunity to experience health law practice. The ultimate goal of the diversity effort of the Health Law Section is to create a network and forge relationships which will foster greater diversity among health law attorneys throughout the state.

Since 2012, the Health Law Fellowship Program has placed law students at NYU Langone Medical Center, Montefiore Medical Center, Mount Sinai Health System, and Catholic Health Services of Long Island. NYU Langone Medical Center has been a special partner of this program sponsoring the very first Fellow in 2013 and continuing to sponsor students year after year. The Diversity Committee has also sponsored panel discussions to promote interest in health law. In 2014, the first panel discussion was held at Proskauer and in 2016, the second panel discussion was held at Brooklyn Law School. The Fellowship is operated in partnership with and administered by the New York State Bar Foundation. Under the direction of Lisa D. Hayes, the Diversity Committee of the Health Law Section was awarded a Section Diversity Champion Award in 2013 for its efforts. Special thanks to Diversity Committee members Kathleen Lyons, Beverly Jones, Dionne Schuler (2013 Fellow), and Edwina Martin, member, Bar Foundation.

The Repeal of New York's Do Not Resuscitate Law: A Technical Clean-up Bill – And an Occasion for Reflection

By Robert Swidler



In the 2023 session, the New York State Legislature passed a bill to repeal New York's landmark 1987 Do-Not-Resuscitate (DNR) Law.[1] As of this writing, the bill is awaiting signature by the governor.

This is a noncontroversial and helpful technical clean-up bill and should promptly be signed into law. The 1987 DNR Law originally applied to DNR orders for any patients in any inpatient setting,[2] but its scope of applicability has all-but disappeared. Since 2011, DNR orders in most inpatient settings have been governed by the Family Health Care Decisions Act (FHCDA),[3] not the old DNR Law. Moreover, DNR orders for persons who receive services for developmental or intellectual disabilities are governed by a separate law, the Health Care Decisions Act (HCDA).[4] As a result, the old DNR Law, by default, now applies only in Office of Mental Health (OMH) operated or licensed psychiatric hospitals or hospital psychiatric units – where there are few DNR orders. This 2023 repealer provides that the FHCDA will now apply to DNR orders in such units.[5] The DNR principles in the 1987 DNR law and the 2010 FHCDA are so similar that psychiatric hospitals and units may not even notice the change.

So again, this is a technical clean-up bill. But the bill includes some details that health care providers and health lawyers should know about. Moreover, the repeal affords an occasion for a quick history of the DNR Law, and a mention of some unresolved DNR issues.

New York's 1987 DNR Law

A do-not-resuscitate order, or DNR order, is a medical order instructing clinical staff, in the event a patient's heartbeat and breathing stop, not to attempt to start them again by cardiopulmonary resuscitation (CPR) measures. Typically, a DNR order is considered appropriate when patient is dying and would prefer comfort care without extraordinary measures at the moment of death or when, due to the patient's diagnosis and prognosis, CPR is not likely to restore heartbeat or restore it for very long.

Until the mid-1980s the legality of DNR orders was uncertain.[6] Consequently, it was the practice of physicians at some New York City hospitals to write DNR orders secretly, without patient or family knowledge or consent. In some instances, the order was recorded in chalk on a blackboard, or by removable sticky colored dots on the patient's chart. These practices were widely reported in the media and became the subject of a Queens County grand jury investigation. In 1984 governor Mario M. Cuomo formed a multidisciplinary "Task Force on Life and the Law" to study policy issues relating to medical ethics, and he directed the Task Force to study DNR orders and make recommendations.[7] In 1986, the Task Force issued a report that advised that DNR orders are ethical, and should be recognized as lawful, under three circumstances:

1. If the patient has capacity, and consents to the DNR order.

2. If the patient lacks capacity, meets medical criteria,[8] and an appropriate surrogate decisionmaker consents to the order based on the patient's wishes if reasonably known or else the patient's best interests.

3. If the patient lacks capacity, there is no surrogate, and the attending physician and a concurring physician find that resuscitation would be medically futile – that is, will not be successful in starting the heart or that resuscitation would be needed repeatedly.

The Task Force proposal was unique in several respects, first and foremost for recognizing the legality of DNR orders

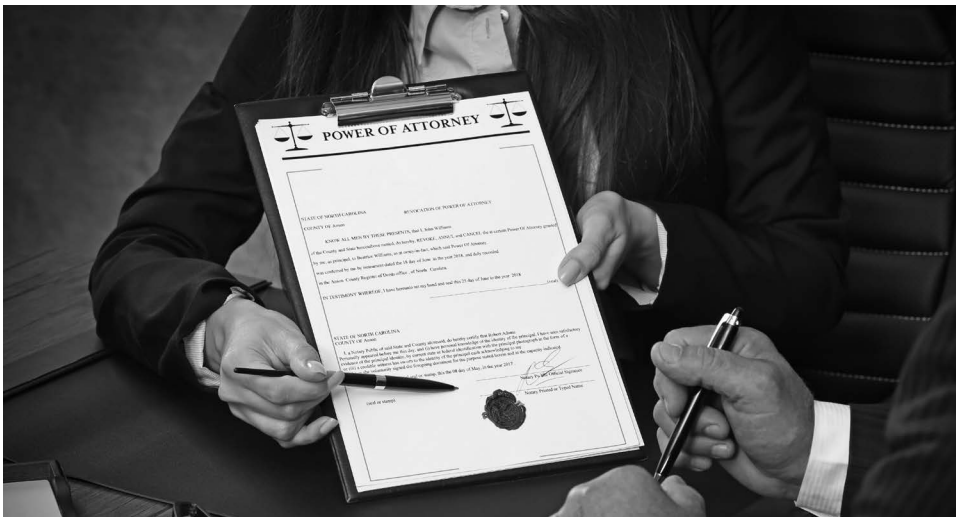
when issued in accordance with the principles above. But it was also unique for (i) crafting a bedside process to determine incapacity; (ii) listing a clear hierarchy of surrogate decisionmakers; and (iii) articulating a surrogate decision making standard based on bioethical principles.

The New York State Legislature, wary about DNR orders, added several additional constraints and requirements, but passed the proposal in in 1987.[9] It became Public Health Law (PHL) Article 29-B – Orders Not to Resuscitate.

The 1987 DNR Law was quite controversial, with criticisms from opposite perspectives: A widespread view in both the public and Legislature was that physicians should never be allowed to "give up" on a patient by writing a DNR order, even if asked to do so or consented to by the patient or family. Meanwhile, physician groups and others criticized the law from a different standpoint by arguing that a physician should have the authority to write a DNR when the physician determines, as a medical matter, that resuscitation would not be medically indicated.[10] Over time, it is fair to say that the public and the medical profession have come to accept the core principle of the DNR Law – that a DNR order can be acceptable but generally should be based on patient or surrogate consent. Thus, the 1987 DNR Law brought an end to the era of legal uncertainty and to secret DNR orders.

The 2010 Family Health Care Decisions Act

The DNR Law was a treatment-specific law: it authorized surrogate decision-making only for DNR decisions. It did not authorize an incapable patient's closest family member or friend to make other life-sustaining treatment decisions such as whether to withhold or withdraw a ventilator, tube feeding, dialysis, antibiotics, chemotherapy, or surgery. In fact, in most cases family members did not even have clear authority under New York law to consent to beneficial treatment, like surgery, for an incapable patient, although that was common practice.[11] Accordingly, in 1991, the Task Force issued a proposal for general surrogate decision making.[12] It was promptly introduced in the Legislature and became known as "The Family Health Care Decisions Act."[13]



The FHCDA addressed decisions for incapable patients and offered an approach to end of life decisions that was structurally similar to the DNR law. That is, it allowed the withdrawal or withholding of any life-sustaining treatment, including resuscitation:

1. If the incapable patient meets medical criteria similar to but more general than that in the DNR Law, and an appropriate surrogate decisionmaker consents to the order based on the patient's wishes if reasonably known or else the patient's best interests; or

2. If there is no surrogate, the attending physician and a concurring physician find that the treatment would – in effect – be medically futile.

Notably, the FHCDA was designed to apply to any type of life-sustaining treatment decision for an incapable patient, including but not limited to the DNR decision. The Task Force and drafters therefore recognized that the basic policies of the DNR Law should be merged with the FHCDA.[14]

The FHCDA was introduced and tabled repeatedly for 17 years.[15] But by 2009, the two houses appeared ready to update, finalize and pass the bill. One of the final outstanding issues was whether the FHCDA should apply to persons in or from facilities for persons with developmental disabilities and patients in or from OMH licensed hospitals or hospital units.

With respect to persons with developmental disabilities, the Office of Mental Retardation and Developmental Disabilities or OMRDD (later renamed the Office for People with Developmental Disabilities or OPWDD) and some allied advocacy groups contended that this population was better served by the principles in the HCDA and by OMRDD regulations governing treatment decisions. Accordingly, the drafters "carved out" this population from the bill to the extent the HCDA or OMRDD regulations already addressed the treatment issue.[16] Accordingly, going forward the HCDA governed DNR orders for this population.

Meanwhile, OMH contended that it needed to consider further the implications of extending the FHCDA to patients in OMH licensed or operated hospitals and hospital units. So the drafters

similarly "carved out" that population from the FHCDA to the extent OMH regulations governed the treatment issue.[17] More specifically, the bill renamed PHL Article 29-B from "Orders Not to Resuscitate" to "Orders Not to Resuscitate for Residents of Mental Hygiene Facilities."[18]

At the same time, the FHCDA bill directed the Task Force to study both the OPWDD and OMH carve-outs and make recommendations as to whether the FHCDA should be extended to those patients.[19]

The FHCDA was enacted in 2010 and became effective in 2011.[20] As of the FHCDA effective date, the 1987 DNR Law was reduced to applying only to patients in or from psychiatric hospitals and general hospital psychiatric units.

The 1987 DNR Law Since 2011

As explained above, since 2011 the 1987 DNR Law has applied only to patients in or from psychiatric hospitals or hospital psychiatric units. Over time, it has become increasingly clear that: (1) the principles in the FHCDA regarding DNR orders are substantially similar to those in the old DNR Law; (2) that the minor differences in the DNR Law cannot be considered special safeguards for psychiatric patients but are vestigial historical features; (3) that those differences simply cause confusion and noncompliance; and finally (4) that there is no rationale for preserving the DNR Law in such settings.

In 2016 the Task Force issued the report that the Legislature had called for on whether the FHCDA should be extended to previously "carved out" populations.[21] Most of the report focused on the extending the FHCDA to end of life decisions for persons with developmental or intellectual disabilities. But it also spoke about extending the FHCDA to cover DNR orders for persons in psychiatric hospitals or units. It wrote:

> [I]t has become apparent that there is no need for a separate law for DNR orders in psychiatric hospitals and units, and its existence is a source of complexity and confusion. Bills to repeal this vestige of the original DNR law and apply the FHCDA to DNR orders in those settings have been introduced in the state Legislature.[22]

For over a decade, bills have been introduced to "repeal this vestige of the original DNR law." Year after year they died in one committee or another – probably because there was no great grassroots advocacy for a technical clean-up bill. Finally in the 2023, the Legislature took this action.

DNR Law v. the FHCDA

The provisions in the DNR law differ in some respects from those in the FHCDA. First, the DNR Law includes several provisions that uniquely relate to DNR orders. For example:

- The DNR law includes a presumption that patient consents to CPR unless there is a DNR order.[23] The FHCDA, which addresses a broad range of emergency and non-emergency treatments, has no similar presumption.
- The DNR law includes a definition of medical futility that relates specifically to CPR. When an incapable patient does not have a surrogate, the attending practitioner may write a DNR order when he or she finds that:

  > cardiopulmonary resuscitation will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs.[24]

  The FHCDA does not use the term "medical futility" but includes the same concept. It provides that the attending practitioner does not need to provide a treatment (including CPR) in cases where the incapable patient does not have a surrogate, and the practitioner finds that:

  > life-sustaining treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and (ii) the provision of life-sustaining treatment would violate accepted medical standards.[25]

- The DNR Law specifies periods for the review of a DNR order;[26] the FHCDA leaves the review of DNR and other treatment orders up to hospital policies.[27]
- The DNR law also addresses DNR decisions for capable patients;[28] the FHCDA does not because it governs only decisions for patients who lack capacity.
- The DNR Law is missing several provisions that appear in the later FHCDA. For example:
  - The FHCDA allows a broader range of providers to make the concurring determination of incapacity.[29]
  - The FHCDA surrogate decision making standard offered more detailed guidance. [30]

- The FCHDA definition of terminal illness is narrower than the DNR definition: the patient must be expected to die within 6 months not one year.[31]
- The FHCDA authorizes the attending practitioner to enter a DNR order for a patient without a surrogate not only on the basis of futility but also as part of a hospice admission and plan of care.[32]
- The FHCDA addresses provider conscience objections.[33]

Again, none of these differences were crafted to meet needs of patients in psychiatric hospitals or units; they are just holdovers from the 1987 law. In practice, these differences cause confusion and noncompliance.

The Repealer Bill

Section 1 of the Repealer Bill repeals the old DNR Law, PHL Article 29-B. Bill §§ 2 – 4 take care of related housekeeping:

- Section 2 amends the FHCDA to make it apply to DNR decisions for persons in a psychiatric hospital or unit (that is, to eliminate the former carve-out).
- Section 3 amends the PHL article that governs non-hospital orders not to resuscitation to provide that consent by patient or surrogate for a patient in a psychiatric hospital or unit to a nonhospital DNR order is governed by the FHCDA, while consent to such order for a person who is intellectually or developmentally disabled is governed by the HCDA.
- Section 3 amends the FHCDA to provide that the FHCDA section on interinstitutional transfers applies to a patient with a non-hospital DNR order who is admitted to a hospital, as well as to a patient with a hospital DNR who is transferred to another hospital.

Unsettled Issues

This repealer is a helpful clean-up bill. But it also draws attention to longstanding unresolved legal, professional, ethical and policy issues regarding DNR orders. Here are two issues that stand out:

1. **Futility or No Benefit DNR Orders.** Surprisingly, neither the DNR Law nor the FHCDA clearly resolve a fundamental question – Does a practitioner need patient or surrogate consent for a DNR order if the practitioner determines that, in the event of cardiac arrest, CPR would not provide any medical benefit? To be sure the DNR Law and FHCDA both provide that a DNR is lawful if written with patient or surrogate consent. And both laws provide that a practitioner may write a DNR for in capable patient based on medical futility (or its equivalent) if there is no surrogate. Both laws confer immunity on the provider who writes a DNR in compliance with these principles. But it does not necessarily follow from those principles that it is unlawful to write a DNR order without consent when CPR would be medically futile. Indeed, there may be no other example in medicine where consent is required to ***not*** provide a futile, useless, medically unnecessary treatment. At various times, the Department of Health and or health commissioner expressed support for the view that consent is not required for a DNR order based on medical futility.[34]

The key policy counterargument is that the physician may never be completely certain that CPR would be useless. A second counterargument is that futility DNR orders, if permitted, would become the rule rather than the exception and undermine efforts to urge providers to seek consent from, or even tell, the patient or surrogate. There is also a concern that unconsented futility DNR orders will disproportionately be written for poor or minority patients.

There are legitimate weighty legal, policy, ethical, professional arguments on both sides of this question, and a great deal of literature on the question.[35] It remains the greatest unsettled DNR issue.

2. **Extending the FHCDA to Persons With Intellectual Disabilities.** After this repealer becomes law, the FHCDA will govern end of life decisions for everyone except persons with Intellectual/Developmental Disabilities. Decisions for this population are governed by the HCDA. This disparate treatment is problematic for many reasons, described at length in the Task Force's 2016 report. The Task Force recommended extending the FHCDA to include this population, with some additional safeguards derived from the HCDA.[36] That is a second great unsettled DNR issue.

Robert Swidler recently retired as general counsel to St. Peter's Health Partners and St. Joseph's Health, not-for-profit health care systems in New York's capital region and central region. He plans to remain active in the NYSBA Health Law Section and the Empire State Bioethics Consortium, and to continue to teach in the Alden March Bioethics Center at Albany Medical College.

Endnotes

1. A.4332 (Gunther) (passed by Assembly March 27, 2023) / S.2930 (Rivera)(passed by Senate June 1, 2023). The bill repeals NY Public Health Law Article 29-B (Orders Not to Resuscitate for Residents of Mental Hygiene Facilities).
2. A separate statute, PHL Article 29-CC, governs non-hospital DNR orders.
3. NY Public Health Law Article 29-DD.
4. NYS Surrogate Court Act § 1750-B "Health Care Decisions for Persons who are Intellectually Disabled."
5. A.4332 § 2.
6. *See* NYS Task Force on Life and the Law, DNR Orders: Report and Recommendations.
7. *See* Governor Mario M. Cuomo, Executive Order No. 56, Dec. 21, 1984, https://www.governor.ny.gov/sites/default/files/2022-02/13__new_york_regulations_section_456_executive_order_n.pdf. *See also*, https://www.health.ny.gov/regulations/task_force/about.htm.
8. The medical criteria set forth in the DNR Law as a predicate for a surrogate decision are: (i) the patient has a terminal condition; or (ii) the patient is permanently unconscious; or (iii) resuscitation would be medically futile; or (iv) resuscitation would impose an extraordinary burden on the patient in light of the patient's medical condition and the expected outcome of resuscitation for the patient. PHL § 2995.3(c).
9. NY Laws of 1987, Chapter 818, creating NY PHL Article 29-B Orders Not to Resuscitate.
10. *See, e.g.,* R. Baker, The Legitimation and Regulation of DNR Orders, in R. Baker & M.A. Strosberg (eds.), Legislating Medical Ethics: A Study of the New York Do-Nat-Resuscitate Law, 33-101.
11. NY Task Force on Life and the Law, *When Others Must Choose: Deciding for Patients Without Capacity* (March 1992), pp 75, 93.
12. *When Others Must Choose, supra*. https://www.health.ny.gov/regulations/task_force/reports_publications/docs/when_others_must_choose.pdf.
13. *See* R. Swidler, *New York's Family Health Care Decisions Act – The Legal and Political Background, Key Provisions and Emerging Issues, NYSBA Journal,* June 2010, p.18.
14. *When Others Must Choose,* p. 269.
15. *See* R. Swidler, *supra* note 13.
16. PHL § 2994-b.3.
17. PHL § 2994-b.3.
18. NY Laws of 2010, Chapter 8 § 4.
19. *Id.* § 28.
20. Chapter 8, Laws of 2010.
21. NYS Task Force on Life and the Law, *Recommendations for Amending the Family Health Care Decisions Act to Include Health Care Decisions for Persons with Developmental Disabilities and Patients in or Transferred from Mental Health Facilities*, June 21, 2016, https://www.health.ny.gov/regulations/task_force/reports_publications/docs/2016-06_recommendations_for_amending_fhcda.pdf.
22. *Id.*, p. 26.
23. PHL § 2962. This provision has sometimes been misread to impose a duty to commence CPR unless there is a DNR order. It does not say that or mean that. It simply reflects the longstanding caselaw principle that in an emergency, consent is presumed. *See, e.g.*, PHL § 2805-d.2, and 4(c). So when a patient has a cardiac arrest, CPR can be provided without the patient's consent, unless there is a DNR order. The presumption of consent does not address a duty to provide CPR.
24. PHL § 2961.12.
25. PHL § 2994-g.5.
26. PHL § 2970.
27. PHL § 2994-k.
28. PHL § 2964.
29. *Compare* PHL § 2963 *with* PHL § 2994-c.
30. *Compare* PHL § 2965 *with* PHL § 2994-d.4. and d.5.
31. *Compare* PHL § 2961 *with* PHL §2994-a.
32. PHL § 2994-g.5-a.
33. PHL § 2994-n.
34. *See, e.g.*, NYS Health Facilities Memorandum Series 88-24, March 18, 1988; NYS Task Force on Life and the Law, *When Others Must Choose*, p. 274.
35. *E.g.,* M. Cantor, C. Braddock, A. Derse, *Do-Not-Resuscitate Orders and Medical Futility*, Arch Internal Medicine 2003; 163(22); L. Vivas, T Carpenter, *Meaningful Futility: requests for resuscitation against medical recommendation*, J Med Ethics 2021;47:654–656 (2020); Bailey S., The concept of futility in health care decision making, Nurs. Ethics 2004;11(1):77–83; Youngner SJ, *Who defines futility?,* JAMA 1988; 260(14):2094–5; Pellegrino E., *Decisions at the end of life – an abuse of the concept of futility*, Practical Bioethics 2015;1(3):4–6; Schneiderman LJ., *Defining medical futility and improving medical care*, J Bioeth Inq. 2011;8(2):123.
36. *See* note 17, *supra.*

Religious Vaccine Exemptions for Health Care Workers – Autonomy or Maleficence?

By Will Matthews

I. Introduction

The COVID-19 pandemic pushed the American medical system to its limits.[1] Although the pandemic continues to affect the lives of many Americans, a new tool to prevent infection and spread exists today: the COVID-19 vaccine.[2] Though the effectiveness of the vaccine is well documented,[3] there remains significant resistance to vaccination among several groups of Americans.[4] One of these groups is Americans who object to vaccines on religious grounds.[5] One subset of this group, Health Care Workers (HCWs), who object to vaccines on religious grounds, has been subjected to vaccine mandates that require them to be vaccinated based on their field of work.[6] While most COVID-19 vaccine mandates have exemptions available for HCWs with sincerely held religious beliefs against vaccination,[7] New York and Maine are two states that do not specify any such exemption.[8] Thus far, legal challenges to the New York and Maine HCW vaccination mandates have been unsuccessful in obtaining a final injunction.[9] Still, there are several justices on the Supreme Court who appear interested in overturning New York's and Maine's HCW vaccine mandates.[10]

The fact that religious exemptions for vaccines are so prevalent, and may become required in the future, leads to an obvious question: is it ethical for HCWs with sincerely held religious beliefs to eschew vaccination? To answer this question, this article will first discuss the bioethical issues of autonomy and nonmaleficence that stem from an HCW refusing vaccination. Next, this article will evaluate the present and future legality of state vaccine mandates for HCWs that do not include religious exemptions. Finally, this article will offer a philosophical justification, grounded in bioethics, as to why vaccine mandates should supersede the religious beliefs of HCWs.

II. HCWs Refusing Vaccination Creates a Conflict Between Autonomy and Nonmaleficence

The bioethical principle of autonomy holds unique importance in American medicine.[11] This importance has been echoed in law as early as 1914, when Judge Cardozo enthusiastically supported the principle of autonomy by requiring that a physician obtain a patient's consent prior to operating.[12] The principle of autonomy is often invoked to support a patient's choice to decline a treatment recommended by the patient's physician.[13] Autonomy, as a value, applies to all persons, even HCWs.[14] Though HCWs are an integral component of the treatment of patients in health care facilities, they are also patients in the context of their own medical care. This means that an HCW should be given the same degree of autonomy granted to all patients when deciding whether to receive a medical intervention, including vaccines. The interest in autonomy is especially strong in those who have religious objections to vaccines, as their sincere spiritual beliefs compel them to abstain from vaccination.[15] Indeed, some groups even claim that vaccination will result in permanent separation from their God, a fate that would give any believer pause.[16]

Despite the importance of autonomy, it is not absolute.[17] Autonomy must be balanced against the other principles of bioethics.[18] One such principle is nonmaleficence. Nonmaleficence requires that HCWs do not harm their patients.[19] This principle traces its roots to Hippocrates and the very origins of Western medicine.[20] While the "do no harm" commandment of nonmaleficence logically precludes actions that would directly harm the patient without significant medical benefit,[21] there are also less obvious applications of the principle.[22] One such application, offered by Beauchamp and Childress, is harm caused by the absence of due care.[23] When an HCW increases the risk of harm to patients by knowingly failing to perform a reasonable act expected in the course of due care, the principle of nonmaleficence is violated.[24] This concept can be applied to vaccination, where an extremely low incidence of significant side effects[25] makes vaccination a reasonable act because it is accompanied by a demonstrable reduction in infection risk to patients.[26] This has led some commentators to suggest that not encouraging patients to get vaccinated could violate the principle of nonmaleficence.[27] The same logic used to label failure to encourage patients to vaccinate as a violation of nonmaleficence can be applied to HCWs who refuse to vaccinate themselves. Indeed, an HCW's choice not to vaccinate is a knowing failure to perform a reasonable act that results in an increased risk of harm, in this case exposing patients to disease.[28] Similar to a surgeon not washing their hands or wearing gloves, a failure to vaccinate would constitute a violation of the principle of nonmaleficence.[29] Thus, when an HCW refuses vaccination, it places the HCW's own autonomy interest in direct conflict with their ethical obligation of nonmaleficence.[30]

For one of the competing interests of autonomy or non-maleficence to prevail, a bioethical argument must be made showing why one interest should supersede the other.[31] As bioethics is ultimately "dominated by a troika of medicine, law, and philosophy,"[32] a proper conclusion must not only consider the medical science and philosophical principles of bioethics, but also the legal history and potential future of both vaccine mandates and an American's right to free exercise of religion.

III. Vaccine Mandates and the Free Exercise Clause: Past, Present and Future

The United States Supreme Court has directly ruled on the legality of vaccine mandates only twice.[33] The first time was in *Jacobson v. Massachusetts*,[34] a case concerning a Massachusetts statute used by the city of Cambridge to require all adults to be vaccinated or revaccinated against smallpox.[35] Jacobson invoked his Fourteenth Amendment right to substantive due process, claiming that his liberty was violated by forced vaccination.[36] The Supreme Court was unconvinced, holding that individuals could be forced to "submit to reasonable regulations established by the constituted authorities, under the sanction of the State, for the purpose of protecting the public collectively against [the dangers of disease]."[37] The court held that the statute, and accompanying mandatory vaccinations, were constitutional,[38] largely relying on the police powers held by the states as justification for its decision.[39]

The second time the Supreme Court considered mandatory vaccination was only seventeen years later in *Zucht v. King*.[40] This time, a city ordinance requiring vaccination for admittance into public schools was at issue.[41] In a short opinion by Justice Brandeis, the court reiterated that imposing mandatory vaccinations was within the police powers of a state.[42] Because the ordinances addressed issues of public health, the court found them valid and constitutional.[43]

Despite the relative lack of authority on the subject, the application to present day HCW vaccine mandates appears to be clear: they are perfectly constitutional. Indeed, *Jacobson* even addressed aspects of the bioethical debate, responding to Jacobson's argument that "every freeman [has a right] to care for his own body and health in such way as to him seems best"[44] by holding that "[t]here are manifold restraints to which every person is necessarily subject for the common good."[45] The *Jacobson* court also considered religious opposition to measures designed to protect the public, holding that "even [a citizen's] religious or political convictions" could be subject to the greater good.[46] However, several weaknesses limit the usefulness of *Jacobson* (and, by extension, *Zucht*) in determining the constitutionality of vaccine mandates without religious exemptions today.[47]

The primary reason why *Jacobson* has questionable relevance to today's vaccine mandates without religious exemptions is because the First Amendment did not apply to state actions when *Jacobson* was decided.[48] Therefore, a challenge to the constitutionality of vaccine mandates without religious exemptions is no longer restricted to the protections directly written into the Fourteenth Amendment; a plaintiff can instead invoke the Free Exercise Clause[49] of the First Amendment.[50] This distinction potentially transforms a court's analysis from rational-basis review—which heavily favors the government—to difficult-to-surmount strict scrutiny.[51] However, under current Supreme Court precedent, a plaintiff's claim that their right to religious free exercise has been violated does not automatically subject the contested state action to strict scrutiny review.[52]

The current standard for assessing religious free exercise violations by state actors, created in *Employment Div. v. Smith*, is that "the right of free exercise does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability."[53] If the contested law meets this standard, there is no Free Exercise violation, and the law is constitutional.[54] A law fails to be neutral "if the object of [the] law is to infringe upon or restrict practices because of their religious motivation."[55] For its part, a law fails to be generally applicable "if it 'invite[s]' the government to consider the particular reasons for a person's conduct by providing 'a mechanism for individualized exemptions,'"[56] or "if it prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way."[57] If the contested law is either not neutral or not generally applicable, it is instead subjected to strict scrutiny review.[58]

Under strict scrutiny, the state must establish a specific compelling interest justifying denial of religious exemptions, and must also prove that its interest could not be achieved without denying religious exemptions.[59] Finally, due to Congress passing the Religious Freedom Restoration Act[60] (RFRA) and the Religious Land Use and Institutionalized Persons Act[61] (RLUIPA), any action taken by the federal government, any state action impacting institutionalized persons, and any state land use regulations all bypass *Smith* and are instead automatically subjected to strict scrutiny.[62]

Despite *Smith* itself citing vaccine mandates as one of many examples of laws conceivably permitted under its standard,[63] there is reason to question whether vaccine mandates without religious exemptions satisfy *Smith's* two-prong test.[64] Such mandates could be susceptible to *Smith's* second prong of general applicability, due to the existence of medical exemptions to vaccine mandates.[65]

When considering *Smith's* requirement of general applicability, the argument has been made that a vaccine mandate permitting medical exemptions but not religious exemptions

"permit[s] secular conduct that undermines the government's asserted interests in a similar way."[66] However, medical exemptions do not undermine the government's asserted interests at all.[67] Medical exemptions allow those who would be physically endangered by vaccination to be protected from harm.[68] This aligns perfectly with a government's interests in imposing mandatory vaccinations—promoting the health and safety of workers, ensuring the most staff possible are available to perform their duties during a crisis, limiting the spread of a dangerous disease, minimizing fatalities caused by the disease, and protecting those most vulnerable to the disease.[69] Even if a court viewed medical exemptions as undermining the government's asserted interests, medical exemptions still do not do so in a "similar way" to religious exemptions, as medical exemptions exist to save lives that would be endangered by vaccination, unlike religious exemptions.[70] Similarly, an argument that vaccine mandates with medical exemptions impermissibly permit individualized exemptions[71] lacks merit, as medical exemptions are strictly defined and are only granted to a specific group of people who meet clear, objective criteria.[72] Finally, vaccine mandates without religious exemptions should not fail *Smith's* other prong of neutrality, as they have been designed and implemented without impermissibly targeting religion.[73]

Despite strong arguments supporting the constitutionality of HCW vaccine mandates without religious exemptions under *Smith*, considering how such mandates would fare under a strict scrutiny analysis is necessary for several reasons. First, it is not guaranteed that courts will hold that vaccine mandates without religious exemptions satisfy *Smith*.[74] The Supreme Court has described Americans as "a religious people" on multiple occasions, showing a willingness to grant value to faith and spirituality in decisions.[75] Spirituality, by its nature as an unmeasurable and subjective aspect of human life, is difficult to compare to measurable categories such as infections and deaths. An argument that medical exemptions are permissible because they promote physical health and safety could be viewed as ignoring spiritual health and wellbeing. Some Americans have sincerely held religious beliefs that being vaccinated will severely damage or even sever their connection to their faith.[76] Though inadvisable, as doing so would equate the unknowable world of spirituality with our tangible medical understanding of physical life and death, a court could view a risk to spiritual health as undermining a state's interest in promoting health and safety, allowing it to hold that vaccine mandates without religious exemptions "permit[] secular conduct that undermines the government's asserted interests," thus violating *Smith*.[77] Second, any vaccine mandates without religious exemptions within the boundaries of RFRA or RLUIPA are automatically subject to strict scrutiny if challenged, bypassing *Smith* entirely.[78] Finally, it is possible, if not likely, that *Smith* will be overruled in the near future, subjecting all vaccine mandates without religious exemptions to strict scrutiny.[79]

Applying strict scrutiny to vaccine mandates without religious exemptions, it appears that the first prong of a compelling governmental interest justifying the denial of a religious exemption is met.[80] A government has an overwhelming interest in the health and safety of its workers and their patients,[81] making preventing the spread of a dangerous illness a sufficiently compelling state interest.[82] The second prong of employing the least restrictive means to achieve the government's goal is less definite. In *Spivack*, the Eastern District of Pennsylvania held that all alternatives to mandatory vaccination were insufficient to achieve the government's goals.[83] However, any states setting goals for achieving their asserted health and safety interest must be mindful of the *Fulton* court's decree that "so long as the government can achieve its interests in a manner that does not burden religion, it must do so."[84] This would likely require the state to prove that the number of religious objectors to vaccination would compromise its asserted interests, a difficult showing if the state sets its goal as a percentage HCW vaccination,[85] as studies suggest religious objection to vaccines is in the low single digits of percent.[86] However, states could counteract this by asserting a health and safety interest that is only satisfied by preventing every serious illness and death possible, an especially reasonable interest in a health care setting where HCWs interact with many citizens who may be particularly susceptible to infection, or may be unvaccinated themselves due to medical reasons.[87] By setting the goal as vaccinating every person without a medical excuse, the relative rarity of religious vaccine exemptions is no longer a factor. Ultimately, it should be possible for prudent state legislatures and agencies to implement HCW vaccine mandates without religious exemptions that satisfy strict scrutiny.

IV. The Principles of Bioethics Suggest That Mandatory Vaccination is Necessary and Ethical

If the study of bioethics is truly "dominated by a troika of medicine, law, and philosophy,"[88] then all three perspectives are necessary to determine whether vaccine mandates without religious exemptions are ethical. The perspective of the field of medicine is clear, and it guides the assessment of the maleficence posed by religious exemptions to vaccination.[89] Medical institutions, and any governments overseeing them, should evaluate the best available medical science to determine whether a disease poses enough of a threat to patients and staff that mandatory vaccination of HCWs is a necessary measure.[90] Any vaccine mandates originating from such an evaluation are scientifically supported. Therefore, avoiding such a vaccination mandate, even for a sincerely held religious belief, increases the risk of disease for other staff and patients in the facility,[91] creating a clear violation of nonmaleficence by the HCW.[92] The HCW's autonomy interest is enfeebled

by this medical lens, as the field of medicine has long placed patient safety and wellbeing ahead of the self-interest of those working in the medical field.[93] Given the duty of care expectations of workers in the field of medicine, vaccine mandates without religious exemptions are reasonable and ethical from a medicine-focused perspective.

Having already established the past, present, and possible future of mandatory vaccine laws without religious exemptions in the United States,[94] the ethical weight of autonomy and nonmaleficence in the legal context is difficult to ascertain. While it is true that protecting the health and safety of citizens has met the high standard of a "compelling justification" for state and federal action,[95] thus suggesting that nonmaleficence is of great importance, the value of autonomy is potentially in flux. Currently, *Smith* has hamstrung any free exercise religious objections to most laws,[96] making an HCW's autonomy interest in following their religious beliefs appear subservient to their obligation to nonmaleficence. However, *Smith* could be overturned in the near future,[97] returning a citizen's right to practice their religion to the highest level of constitutional protection. Despite this, since a compelling state interest can survive strict scrutiny when there are no less-restrictive alternatives, courts recognize that compelling state interests are more important than our most highly protected rights when there are no alternatives that preserve both.[98] While it would be a much closer comparison should *Smith* be overturned, under current law, an HCW's autonomy interest in following their sincerely held religious beliefs is beneath their nonmaleficence obligation to promote the health and safety of their patients when viewed from a legal perspective.

The final scale to weigh autonomy and nonmaleficence is the highly subjective scale of philosophy. While the ethical philosophy underpinning bioethics has often been critiqued as overcentralizing patient autonomy,[99] the same cannot be said of physician autonomy.[100] While HCWs are certainly entitled to autonomy when acting as individuals in their private lives, vaccine mandates targeting them are not designed to reach this private aspect of their existence. Instead, vaccine mandates are aimed at their professional conduct as members of the medical community. HCWs have willingly chosen to accept work in a highly regulated field with detailed and unique ethical expectations, including a duty of care[101] and a guiding principle of nonmaleficence.[102] By accepting employment in this field, HCWs have tacitly accepted the heightened expectations that come with working in medicine. Because of this, it is absolutely reasonable to expect them to place patient safety and wellbeing ahead of their own sincerely held religious beliefs, or, at a minimum, expect them to leave the field of medicine if those sincerely held beliefs would place patient safety at risk.

After assessing the perspectives of the fields of medicine, law, and philosophy, HCW vaccine mandates without religious exemptions should be considered ethical and justified under a reasonable, multidisciplinary bioethical analysis.

V. Conclusion

HCWs, by virtue of having chosen to work in the medical field, can be subjected to vaccine mandates without exceptions for their sincerely held religious beliefs without violating bioethical or legal principles. The law has supported recent vaccine mandates without religious exemptions implemented in response to the COVID-19 pandemic. While the law may, in the future, challenge this conclusion, the field of medicine and the philosophical underpinnings of bioethics support this finding. While religious exemptions to vaccine mandates outside the field of medicine may be reasonable, HCWs are subject to unique ethical obligations. The religious beliefs of HCWs should not be disrespected or ignored, but the safety and well-being of patients in their care should always be the top priority of any health care facility, and the use of available means to maximize that safety and well-being should be respected and followed.

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Endnotes

1. *See COVID Data Tracker*, Centers for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/ (last visited Mar. 15, 2023) (showing several high peaks of weekly hospital admissions throughout the duration of the pandemic).
2. *See* Anoop Shah et al., *Effect of Vaccination on Transmission of SARS-CoV-2*, 385 N. Engl. J. Med. 1718, 1718 (2021) [hereinafter Shah et al.] (detailing how vaccination decreased the rate of viral spread within studied households).
3. *Id.*
4. *See* Frank Newport, *Vaccine Hesitancy and U.S. Public Opinion*, Gallup, https://news.gallup.com/opinion/polling-matters/352976/vaccine-hesitancy-public-opinion.aspx (last visited Mar. 15, 2023) (discussing reasons given for avoiding the COVID-19 vaccine); Peter A. Kahn, *Bioethics, Religion, and Public Policy: Intersections, Interactions, and Solutions*, 55 J. Relig. Health 1546, 1547 (2016) [hereinafter Kahn] (discussing reasons given for avoiding vaccination generally).
5. *See* Elizabeth Dwoskin, *On Social Media, Vaccine Misinformation Mixes With Extreme Faith*, Wash. Post (Feb. 16, 2021), https://

www.washingtonpost.com/technology/2021/02/16/covid-vaccine-misinformation-evangelical-mark-beast/ (last visited Apr. 12, 2023) [hereinafter Dwoskin] (discussing how some Christians view the COVID-19 vaccine as the "Mark of the Beast" that would deny them salvation if acquired); Kahn, *supra* note 4, at 1547-48 (discussing religious objection to vaccines generally); Eric Wombwell et al., *Religious Barriers to Measles Vaccination*, 40 J. Community Health 597, 599-602 (2015) [hereinafter Wombwell et al.] (detailing what objections to measles vaccination several major religions may have).

6. *See* Memorandum from the Directors of the Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG) to State Survey Agency Directors (Oct 26, 2022) (on file with Dept. of Health & Hum. Servs.) [hereinafter CMS Memo] (discussing the CMS vaccine mandate requiring that staff in Medicare- and Medicaid-certified facilities be vaccinated); Dee Pekruhn and Eram Abbasi, *Vaccine Mandates by State: Who is, Who isn't, and How?*, LeadingAge (Jan. 19, 2022), https://leadingage.org/workforce-vaccine-mandates-state-who-who-isnt-and-how/ (discussing what states have vaccine mandates, updated through Feb. 9, 2022).
7. *See* CMS Memo, *supra* note 6 (allowing for "a religious exemption in accordance with Title VII").
8. N.Y. Dept. of Health, Frequently Asked Questions (FAQs) Regarding the Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation (2022); Maine Center for Disease Control & Prevention, Maine Vaccine Exemption Law Change 2021 (2021), https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/maine-vaccine-exemption-law-changes.shtml (removing religious exemptions from existing vaccine law). Notably, New York's Department of Health endorses offering "reasonable accommodations" to personnel with religious objections to vaccination. *See* Letter from Jennifer L. Treacy, deputy director, Office of Primary Care and Health Systems Management, to Chief Executive Officers, Nursing Home Operators and Administrators, Adult Care Facility Administrators, and Home Care and Hospice Administrators (Nov. 15, 2021) (on file with the New York Department of Health).
9. *See Dr. A. v. Hochul,* 142 S. Ct. 552, 552 (2021) (denying injunctive relief in plaintiffs' challenge to New York's HCW vaccine mandate); *Doe v. Mills*, 142 S. Ct. 17, 17 (2021) (denying injunctive relief in plaintiffs' challenge to Maine's HCW vaccine mandate); in May of 2023, the Health dep't began repealing the vaccination mandate.
10. *See Dr. A.*, 142 S. Ct. at 552 (Gorsuch, J., dissenting from denial of injunctive relief) (the opinion also noting that Alito, J., joins in the dissent, and that Thomas, J., would have granted the injunctive relief); *Mills*, 142 S. Ct. at 17 (Gorsuch, J., dissenting from denial of injunctive relief) (the opinion also noting that Alito, J., and Thomas, J., join in the dissent).
11. Roger B. Dworkin, *Medical Law and Ethics in the Post-Autonomy Age*, 68 Ind. L. J.727, 727 (1993).
12. *See Schloendorff v. Soc'y of N.Y. Hospital*, 105 N.E. 92, 93 (N.Y. 1914).
13. Basil Varkey, *Principles of Clinical Ethics and Their Application to Practice*, 30 Med. Princ. Pract. 17, 19 (2021) [hereinafter Varkey]
14. *Id.*
15. *See* Wombwell *et al., supra* note 5.
16. https://www.washingtonpost.com/technology/2021/02/16/covid-vaccine-misinformation-evangelical-mark-beast/ (can't read full article yet).
17. *See* Varkey, *supra* note 13. Autonomy also has limits in the legal context, as state and federal courts have held that compelling state interests may overcome an individual's autonomy interest. *See In re Storar*, 420 N.E.2d 64, 71 (N.Y. 1981); *Jacobson v. Massachusetts*, 197 U.S. 11, 30-31 (1905).
18. *See* Varkey, *supra* note 13.
19. *Id.*
20. *See* Rachel Hajar, *The Physician's Oath: Historical Perspectives*, 18 Heart Views 154, 154 (2017) (interestingly, Hajar suggests it is unlikely that Hippocrates ever actually said "do no harm").
21. *Id.*
22. *See* Tom L. Beauchamp and James F. Childress, Principles of Biomedical Ethics 153 (Oxford University Press 7th ed. 2013) [hereinafter Beauchamp & Childress] (defining "harm" not merely as some form of injury but as "a thwarting, defeating, or setting back of some party's interests").
23. *See id.* at 155.
24. *Id.* (In their example, Beauchamp and Childress consider a hypothetical nurse who knowingly fails to change a patient's bandages, thus exposing the patient to a heightened risk of infection. Though not completely analogous, one can see how a willful failure to be vaccinated against a highly transmissible disease similarly exposes the patient to heightened risk).
25. *See* Sarah Geoghegan *et al.*, *Vaccine Safety: Myths and Misinformation*, 11 Front. Microbiol. 1, 5 (2020) (discussing how vaccines generally have very low rates of serious side effects); Ana K. Gonçalves et al, *Safety, tolerability and side effects of human papillomavirus vaccines: a systematic quantitative review*, 18 Braz. J. Infect. Dis. 651, 651 (2014) (discussing low incidence rate of serious side effects in the HPV vaccine specifically); Ibrahim M. Dighriri et al., *Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) Side Effects: A Systematic Review*, 14 Cureus 1, 1 (2022) (noting that, while side effects from the Pfizer COVID vaccine were common, they were almost always mild).
26. *See* Shah et al., *supra* note 2; Yoel Angel *et al.*, *Association Between Vaccination With BNT162b2 and Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infections Among Health Care Workers*, 325 JAMA 2457, 2457 (2021) [hereinafter Angel et al.] (concluding that vaccinated HCWs contracted COVID-19 at a lower rate than unvaccinated HCWs in Tel Aviv); TingTing Li et al., *A Systematic Review and Meta-Analysis of Seasonal Influenza Vaccination of Health Workers*, 9 Vaccines 1104, 1104 (2021) [hereinafter Li et al.] (producing a meta-analysis of several studies from multiple countries that all associated higher influenza vaccination rates among HCWs with decreased incidence of influenza within medical facilities). *But see* Paul A. Christensen et al., *Signals of Significantly Increased Vaccine Breakthrough, Decreased Hospitalization Rates, and Less Severe Disease in Patients with Coronavirus Disease 2019 Caused by the Omicron Variant of Severe Acute Respiratory Syndrome Coronavirus 2 in Houston, Texas*, 192 Am. J. Pathol. 642, 642 (2022) (discussing how, in the context of the COVID-19 pandemic, vaccinations are losing effectiveness in reducing COVID transmission due to the emergence of the Omicron variant. Of the 4,468 Omicron cases assessed in the study, 55.9% were classified as vaccine breakthrough cases).
27. C. Mary Healy *et al.*, *Medical ethics principles underscore advocating for human papillomavirus vaccine*, 18 Human Vaccines & Immunotherapeutics 1, 2 (2022) (arguing insufficient advocacy towards patients to receive the HPV vaccine may constitute maleficence); Michael O. Afolabi, *Vaccination*, *in* Encyclopedia of

Global Bioethics 2911, 2913 (Henk Have ed., 2016) (contending that failing to vaccinate populations in need could constitute harm).

28. *See* Shah *et al.*, *supra* note 2; Angel *et al., supra* note 26; Li *et al., supra* note 26.

29. *See* Richard K. Zimmerman, *Ethical analyses of institutional measures to increase health care worker influenza vaccination rates*, 31 Vaccine 6172, 6172 (2013); E. Galanakis et al., *Ethics of mandatory vaccination for healthcare workers*, 18 Euro Surveill. 1, 5 (2013) [hereinafter Galanakis et al.]. *Cf.* Vittoria Colamesta, *Cost-consequence analysis of influenza vaccination among the staff of a large teaching hospital in Rome, Italy: A pilot study*, 14 PLoS ONE 1, 1 (2019) (determining that the average unvaccinated worker missed more shifts due to influenza than the average vaccinated worker, resulting in a significant loss of productivity. This has interesting implications here, as one may be able to argue that missing shifts due to an illness that may have been prevented by vaccination could amount to maleficence even if no patients are infected, as a short-staffed hospital may struggle to deliver the same level of care to patients that it otherwise could have).

30. *See* Galanakis *et al.*, *supra* note 29; Della Maneze *et al.*, *Mandatory COVID-19 vaccination for healthcare workers: A discussion paper*, 138 Int'l J. of Nursing Stud. 1, 10-11 (2023) (evaluating bioethical arguments for and against mandatory vaccination, especially nonmaleficence and autonomy).

31. *Id.*

32. Daniel Callahan, *The Social Sciences and the Task of Bioethics*, 128 Bioethics and Beyond 275, 279 (1999) [hereinafter Callahan].

33. Marie Killmond, *Why Is Vaccination Different: A Comparative Analysis of Religious Exemptions*, 117 Colum. L. Rev. 913, 925 (2017).

34. 197 U.S. 11 (1905).

35. *Commonwealth v. Pear*, 66 N.E. 719, 719 (Mass. 1903).

36. *Jacobson*, 197 U.S. at 29-30.

37. *Id.*

38. *See id.* at 39.

39. *See id.* at 24-25.

40. 260 U.S. 174 (1922).

41. *See id.* at 175.

42. *See id.* at 176 (citing *Jacobson*, 197 U.S. at 11).

43. *See id.* at 176-77.

44. *Jacobson*, 197 U.S. at 26 (essentially invoking the bioethical principle of autonomy, *see* Varkey, *supra* note 13, though Jacobson did not present it as such).

45. *Jacobson*, 197 U.S. at 26 (effectively arguing that the autonomy interest here is necessarily defeated by the risk to public safety posed by being unvaccinated).

46. *See id.* at 29-30 (while the example used by the court was forced conscription in the armed forces, it appears that the court is likening the forced vaccinations to this example, permitting a similar conclusion. It should be noted that, although there is a long history in America of conscientious objector status to avoid conscription, there is no requirement by the court that such an option be available by default).

47. *See Agudath Isr. v. Cuomo*, 983 F.3d 620, 635 (2nd Cir. 2020).

48. *Phillips v. City of New York*, 775 F.3d 538, 543 (2nd Cir. 2015) (citing *Cantwell v. Connecticut*, 310 U.S. 296, 303 (1940) (applying First Amendment protections against state actions)).

49. U.S. Const. amend. I ("Congress shall make no law respecting an establishment of religion, **or prohibiting the free exercise thereof**" emphasis added).

50. *See* Phillips, 775 F.3d at 543.

51. *See Roman Catholic Diocese v. Cuomo*, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring) (also reiterating that strict scrutiny requires the state to employ "the most narrowly tailored means available to satisfy a compelling state interest"). *But see Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944) (saying in dicta that "[t] he right to practice religion freely does not include liberty to expose the community or the child to communicable disease").

52. *See Employment Div. v. Smith*, 494 U.S. 872, 879 (1990) (quoting United States v. Lee, 455 U.S. 252, 263, n. 3 (1982) (Stevens, J., concurring in judgment)).

53. *Id.* (quotations omitted).

54. *See id.* at 890.

55. *Church of Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 533 (1993) (citing *Smith* 494 U.S. at 878-79).

56. *Fulton v. City of Philadelphia*, 141 S. Ct. 1868, 1877 (2021) (quoting *Smith* 494 U.S. at 884).

57. *Fulton*, 141 S. Ct. at 1877 (citing *Lukumi*, 508 U.S. at 542-46).

58. *See Fulton*, 141 S. Ct. at 1881.

59. *Id.*

60. Pub. L. No. 103-141, 107 Stat. 1488 (codified at 42 U.S.C. 2000bb (1994)).

61. Pub. L. No. 106-274, 114 Stat. 803 (codified as amended at 42 U.S.C. 2000cc (2013)).

62. *See Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 691-92 (2014) (applying RFRA); *Cutter v. Wilkinson*, 544 U.S. 709, 724-25 (2005) (applying RLUIPA).

63. *Smith*, 494 U.S. at 889 (citing *Cude v. State*, 377 S. W. 2d 816 (1964)).

64. *See Mills*, 142 S. Ct. at 19 (Gorsuch, J., dissenting from denial of injunctive relief); *Dr. A.*, 142 S. Ct. at 555 (Gorsuch, J., dissenting from denial of injunctive relief).

65. *See Fulton*, 141 S. Ct. at 1877 (citations omitted).

66. *Id. See Mills*, 142 S. Ct. at 19-20 (Gorsuch, J., dissenting from denial of injunctive relief) (arguing that Maine's HCW vaccine mandate permits secular medical exemptions that undermine Maine's asserted interests, while impermissibly denying religious exemptions).

67. *See We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 285-86 (2nd Cir. 2021) (arguing that the government's interest in mandatory COVID vaccinations is in promoting the health and safety of workers, and administering vaccines to individuals who would be put at risk of death by vaccination would defeat that purpose); *Spivack v. City of Philadelphia,* 2023 U.S. Dist. LEXIS 1272 at *22-*24 (E.D. Penn. Jan. 4, 2023) (arguing the same).

68. *Id.*

69. *Id.*

70. *See Fulton*, 141 S. Ct. at 1877 (citations omitted).

71. *Id.*

72. *See We the Patriots*, 17 F.4th at 288-89; *Spivack*, 2023 U.S. Dist. LEXIS 1272 at *25-*26. *But see Mills*, 142 S. Ct. at 19-20 (Gorsuch, J., dissenting from denial of injunctive relief) (arguing that

Maine's medical vaccine exemptions do qualify as "individualized exemptions").

73. *See Lukumi*, 508 U.S. at 533 (citations omitted). *But see Dr. A*, 142 S. Ct. at 556 (Gorsuch, J., dissenting from denial of injunctive relief) (arguing that New York's HCW vaccine mandate fails to be neutral due to Governor Hochul declaring that organized religions are fine with her removal of a religious exemption to mandatory vaccination and that failing to vaccinate is rejecting God's will).

74. *See Mills*, 142 S. Ct. at 19 (Gorsuch, J., dissenting from denial of injunctive relief); *Dr. A.*, 142 S. Ct. at 555 (Gorsuch, J., dissenting from denial of injunctive relief).

75. *Marsh v. Chambers*, 463 U.S. 783, 792 (1983) (quoting *Zorach v. Clauson*, 343 U.S. 306, 313 (1952)) (permitting a religious invocation at legislative sessions partially due to the spirituality of Americans as a people).

76. *See* Dwoskin, *supra* note 5; Kahn, *supra* note 4, at 1547-48; Wombwell *et al.*, *supra* note 5.

77. *See Fulton*, 141 S. Ct. at 1877.

78. *See Hobby Lobby*, 573 U.S. at 691-92 (applying RFRA); *Cutter*, 544 U.S. at 724-25 (applying RLUIPA).

79. *See Fulton*, 141 S. Ct. at 1926 (Alito, J., concurring in the judgment) (joined by Thomas, J., and Gorsuch, J., Justice Alito concludes that *Smith* should be overruled. This conclusion is reached after a lengthy analysis of the history of Free Exercise and the issues caused by *Smith*. *See id.* at 1883-1926); *Id.* at 1883 (Barrett, J., concurring) (joined by Kavanaugh, J., Justice Barrett questions the wisdom of *Smith*, although she stops short of endorsing imposing strict scrutiny on all Free Exercise claims); *Id.* at 1876-77 (majority opinion) (in his majority opinion, Chief Justice Roberts takes notice of the interest in overturning *Smith*, but holds that deciding whether or not to do so is not necessary to decide the case, so the issue is not addressed. *Fulton* was decided in 2021, making these opinions a recent snapshot of the court's stance on the issue).

80. *See Spivack*, 2023 U.S. Dist. LEXIS 1272 at *27-*29.

81. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) (quoting *Goldfarb v. Virginia State Bar,* 421 U.S. 773, 792 (1975)) (recognizing that states have a compelling interest in protecting health and safety, including imposing requirements on professions).

82. *See Mills*, 142 S. Ct. at 20-21 (Gorsuch, J., dissenting from denial of injunctive relief) (quoting *Cuomo*, 141 S. Ct. at 67) (agreeing that preventing the spread of COVID qualifies as a compelling state interest). *But see Mills*, 142 S. Ct. at 21 (Gorsuch, J., dissenting from denial of injunctive relief) (implying that preventing the spread of a disease eventually ceases to be a compelling state interest as the deadliness and rate of the disease's spread decrease); *Smith* 494 U.S. at 888-89 (implying that mandatory vaccinations may not be supported by a compelling interest capable of surmounting strict scrutiny).

83. *Spivack*, 2023 U.S. Dist. LEXIS 1272 at *29-*32.

84. *Fulton*, 141 S. Ct. at 1881.

85. *See Mills*, 142 S. Ct. at 21-22 (Gorsuch, J., dissenting from denial of injunctive relief) (arguing that Maine's HCW vaccine mandate without religious exemptions fails strict scrutiny because Maine would still meet its HCW vaccination rate goal of 90% even if religious exemptions were given).

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95. *See Gade*, 505 U.S. at 108 (quotations omitted).

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101. *See* Beauchamp & Childress, *supra* note 22 (applying a duty of care standard when assessing activity violating nonmaleficence); Clark, *supra* note 93; Solnica *et al.*, *supra* note 93.

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An Examination of State Trends in Facility Fee Legislation as New York's Public Health Law § 2830 Takes Effect

By Sophia Temis and Jean Mancheno

Introduction

Reducing the cost of health care in the United States continues to be a priority for state and federal lawmakers. Since the passage of the Patient Protection and Affordable Care Act in 2010, many pieces of legislation have been, and continue to be, proposed and enacted with the goal of furthering access to affordable, reliable, and transparent health care.[1]

To increase transparency in the billing of health care services, Congress enacted the No Surprises Act (NSA) in December 2020. The NSA was passed with the goal of reducing the practices of "balance billing" and "surprise medical billing." Balance billing occurs when a provider bills the patient the difference between the provider's charge and the amount allowed by the patient's insurance.[2] A "surprise medical bill," to contrast, occurs when a provider bills a patient for services that the patient was not aware were out-of-network.[3] This can often occur when an out-of-network provider treats a patient at an in-network facility.[4]

Effective January 1, 2022, the NSA set a foundation of patient protections that require providers to make certain disclosures about billing practices. It also prohibits insurers from (i) surprise billing for most emergency services, (ii) charging more than the in-network cost-sharing requirement for most out-of-network emergency services and some non-emergency services, and (iii) balance billing for certain services furnished by out-of-network providers as part of a visit to an in-network facility.[5] In the wake of the NSA, states have enacted additional protections to address the rising costs of health care.[6] An example of this is seen in the momentum of state legislative activity surrounding the billing of facility fees, which are typically charged to cover the overhead costs of running a healthcare facility, rather than a charge for the actual health care service.[7] Providers contend that these fees are necessary to cover the costs of operating their facility, such as to pay staff, maintain facilities, and cover administrative costs.[8] Patients, however, are often unaware of these fees and fail to budget for the unexpected facility fee charge that appears on their medical bill.[9] Insurance providers seldom cover facility fee charges, and those that do, often only cover a portion of such charges, leaving patients with the obligation to foot the rest of the bill.[10]

New York is among the first states to pass legislation explicitly addressing when facility fees can be billed to patients.[11] On December 23, 2022, Governor Hochul signed Senate Bill S2521C/Assembly Bill A3470C into law, uniquely making New York the first state to place an outright ban on facility fees related to preventative care.[12] In this passed legislation, New York also adopts patient notice requirements, which other states have similarly undertaken. Recently, more states have introduced and even enacted legislation with the specific goal of controlling facility fees. However, the approaches to doing so have varied.

In this article, we discuss New York Public Health Law § 2830 and the new requirements it imposes on hospitals, health systems, and health care providers. We also delve into the three legislative trends we have observed in both proposed and enacted facility fee laws which (i) require health care providers to provide notice of facility fee charges, (ii) ban the billing of facility fees based on locations of care, and (iii) ban facility fee charges based on the type of health care services provided. From our review, it appears legislative decision making is influenced by the impacts facility fee regulation can have on the provider and patient stakeholders.

Notice Requirements

In New York, effective June 21, 2023, no "hospital,"[13] "health system," or "provider" can bill or seek payment from a patient for a "facility fee" that is not covered by the patient's health insurance without prior notification. A "provider" is defined as "an individual or entity, whether for profit or non-profit, whose primary purpose is to provide professional health care services."[14] A "health system" is defined as "a group of one or more hospitals and providers affiliated through ownership, governance, membership or other means."[15] "Facility fee" is defined to encompass any fee charged or billed by a hospital or by a health care professional that is intended to compensate the hospital or health care professional for the operational expenses regardless of the modality through which the health care services are provided.[16] The fee must also be distinct from a provider's professional fee.[17]

The patient must be notified of the facility fee prior to the patient's date of service with the hospital, health system or health care provider.[18] If the health care provider enters into a business relationship with a hospital or health system that would result in patients becoming subject to facility fees, the provider must provide written notice to the patients at least seven (7) days in advance.[19] The notice must be written in plain language, in conspicuous twelve-point bold face type font, and be available in the top six languages spoken in the hospital's service area. The notice must indicate the amount of the facility fee, the purpose of the fee, whether the patient's insurance plan will cover the fee and, in the case of patients without insurance, how the patient can apply for financial assistance.[20] In instances where seven (7) days advance notice is not feasible because the appointment was made less than seven days (7) beforehand, the written notice must be provided on the date the service is rendered.[21]

Other states have similarly instituted notice requirements affecting the billing of facility fees.

Connecticut

On July 1, 2016, Connecticut's own No Surprises Act, which included certain notice requirements related to the billing of facility fees, took effect.[22] "Facility fee" is defined under Connecticut law to mean any fee charged or billed by a hospital or health system for outpatient services provided in a hospital-based facility that is intended to compensate the hospital or health system for the operational expenses of the hospital or health system, and which is billed separate and distinct from a professional fee.[23] Similar to the New York regulation, Connecticut requires hospitals or health systems that charge facility fees separate from provider fees to provide patients with advance written notice of such fees.

Maryland

On July 1, 2021, Maryland established a requirement for hospitals to notify patients regarding an outpatient facility fee charge, which includes charges for hospital outpatient clinic services, supplies, or equipment.[24] The Maryland law includes a prescriptive form of written notice that hospitals are to provide to its patients.[25]

Colorado

Effective July 1, 2024, Colorado will implement a robust notice requirement. § 6-20-102 will require all providers affiliated with or owned by a hospital or health system that charge a facility fee to provide notice to their patients.[26] In addition to providing direct notice to patients about the potential of being charged a facility fee, the provider must also post a sign in their facility that indicates that a patient may be charged a facility fee in addition to the cost of the health-care service.[27]

Massachusetts

Effective January 1, 2025, Massachusetts will institute a broad range of notice requirements that will require health care providers, which includes but is not limited to doctors, dentists, nurses, social workers, pharmacists, hospitals, clinics, and nursing homes, to provide advance notice about the charges and payments for a patient's anticipated non-emergency medical services.[28] The Massachusetts law explicitly calls out the requirement for healthcare providers to provide patients with notice of facility fee amounts to be charged for prospective services.[29] This law also authorizes the Massachusetts Department of Health to penalize health care providers for failing to comply with the notice requirements.[30]

Although each of the above states implemented notice requirements, the approaches have varied. While New York, Massachusetts, Colorado, and Connecticut have implemented a broader range of notice requirements that impact various health care providers, to contrast, Maryland's facility fee disclosure law, the Facility Fee-Right-To-Know Act, only requires hospitals to provide notice of potential outpatient facility fees.[31] However, one thing that each of the above states have in common is that the notice requirement serves as a middle ground in regulating facility fees while taking into consideration the interests of both patients and providers. The notice

requirement allows patients to stay abreast of potential fees associated with receiving certain health care services, while allowing facilities to continue to cover their operational expenses through the collection of facility fees from agreeable consumers.

Facility Fee Bans Based on Location of Health Care Services

While notice requirements allow patients to make informed decisions, it does not per se eliminate the possibility of the patient receiving a facility fee charge in their bill. Some states have sought to combat such charges by introducing and enacting legislation that would eliminate a facility fee charge altogether. Other states have introduced initiatives that ban facility fees based on the location where the patient is receiving care. For example, facility fees have come under patient scrutiny when charged for visits that do not take place within a medical facility, but instead, through a virtual telehealth visit, as patients report feeling surprised by the charge when "they haven't stepped foot in a hospital or provider's office."[32]

Connecticut

As of now, only Connecticut has restricted the charging of facility fees for telehealth services.[33] Under Conn. Gen. Stat. 19a-906(h), no telehealth provider or hospital is permitted to charge a facility fee for the provision of telehealth services.[34] The prohibition also extends to hospital telehealth services regardless of whether those services are provided on campus.[35] The law defines "telehealth provider" to include a broad scope of professions, ranging from physicians, to nurse practitioners, to respiratory care practitioners, and pharmacists.[36]

On June 27, 2023, Governor Lamont signed Public Act 23-171, An Act Protecting Patients and Prohibiting Unnecessary Health Care Costs, into law.[37] As enacted, the amendment revises Connecticut's current facility fee regulations to, among other things, prohibit hospitals and health systems from collecting facility fees for outpatient health care services provided on a hospital campus and that use a evaluation and management (CPT E/M) or an assessment and management (CPT A/M) code. This law will not apply where services are provided in a hospital campus emergency department or where the CPT E/M code or CPT A/M code are billed for "observation"[38] stays on a hospital's campus for wound care, orthopedics, anticoagulation, oncology, obstetrics, or solid organ transplant services. This is a more aggressive approach to regulating facility fees, and prior to its enactment, stakeholders in Connecticut expressed concerns that the effort to increase transparency and lower out-of-pocket costs would be overshadowed by the bill's negative impact on patient care and the potential increase in revenue retained by health insurers.

Texas

The potential quality of care consequences that could result from the certain facility fee regulation has not halted states from attempting to ban facility fees outright. In Texas, the legislature has introduced a sweeping prohibition on the charging of facility fees, including for outpatient health care services, banning them except for instances where the services are provided on a hospital campus or in a freestanding emergency medical care facility.[39]

The laws that regulate facility fee charges on the basis of the location of the provision of services also intended to strike a balance between patient and provider concerns. For patients, these restrictions serve to reduce patient confusion and expense for charges of hospital facility fees where a patient is not seen on a hospital campus and, in certain cases, not even seen in a provider setting. On the other hand, these laws allow for hospitals to continue to charge and collect facility fees in an effort to mitigate the cost of hospital resources used in patient care.

Facility Fee Bans Based on Health Care Services Provided

Finally, state legislative trends have also sought to regulate the kinds of services for which facility fees can be charged. New York has become one of the first states to restrict the charging of any facility fee for preventative health care services. As enacted, the law specifically contemplates those preventive services as defined by the United States Preventive Services Task Force, which can include screenings, counseling services, and preventive medications.[40] The scope of this law is broad in that it covers all modalities of care, unlike other states, whose laws and proposed legislation are specific to care via telehealth.

Increasingly, states are enacting or attempting to enact prohibitions for charging facility fees for certain health care services.

Colorado

On May 30, 2023, Colorado followed New York's lead in signing House Bill 23-1215 into law.[41] The bill, which adds Colorado Revised Statute 6-20-102, prohibits the charging, billing, or collection of a facility fee directly from a patient for a preventative health service that is not covered by the patient's insurance.[42] As enacted, this bill allows providers and health systems to continue to charge, bill and collect facility fees from a patient's insurance company in accordance with an underlying agreement between such provider or health system and the insurer. Unlike New York, this restriction is only applicable in outpatient settings, and the law explicitly carves out facility fees for preventative services provided in a critical access hospital, sole community hospital in a rural or frontier area, or in a community clinic affiliated with such community hospital.[43]

The Colorado law discussed above, as initially proposed, would have also restricted the provider's ability to charge a facility for certain outpatient, diagnostic, or imaging services identified by the Colorado medical services board as services that can be provided safely, reliably, and effectively in nonhospital settings.[44] However, the Legislature substantially scaled back the bill following criticism from providers, such as the Colorado Hospital Association, who contend that removing this fee would have negative consequences for providers and patients alike.[45]

Maine

On April 25, 2023, Maine lawmakers introduced a bill attempting to limit the applicability of facility fees to a small set of services. The proposed legislation also explicitly sought to prevent a healthcare provider from charging, billing, or collecting a facility fee for outpatient evaluation or management services, as well as identified outpatient, diagnostic, or imaging services, regardless of where the provider is located.[46]

However, when the legislation was signed into law on July 10, 2023, these provisions were not included. Instead, Maine opted to enact a law that supports state efforts to understand the impact of facility fees on patients. Under this law, Maine will create a task force charged with, among other responsibilities, reviewing industry practices for charging facility fees, how the funds derived from facility fees are used, and how minimization of facility fees can impact health care costs.[47]

Connecticut

The enacted Connecticut legislation discussed above, in prior draft versions, included a provision which sought to limit health care providers from charging facility fees for outpatient diagnostic or imagine services identified by the Connecticut Office of Health Strategy as services that may reliably be provided safely and effectively in a setting other than a hospital. The Connecticut Office of Health Services would have identified such services on an annual basis. Notably, however, these provisions were removed prior to enactment.[48]

Conclusion

As discussed above, New York has taken a moderately aggressive approach to its facility fee regulation. Through Public Health Law Section 2803, it appears the legislature seeks to accommodate both patients and providers alike, taking into consideration the ramifications of regulating facility fees and the impact on quality of care. In comparison, certain states chose to narrow facility fee regulations to telehealth services, while others have proposed an outright ban on billing facility fees. Concerns over who benefits from facility fee regulations, and who is most negatively affected, factor into the legislative decisions made to date with respect to each state's regulatory approach. As more states propose and enact regulations targeting the transparency and affordability of health care services, we expect to see interested stakeholders proposing alternatives to mitigate the effects of strict facility fee regulations while continuing to further the underlying agenda of the NSA.

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Intersex Infants and Unjustified Surgical Intervention

By Emily E. Dazzo

I. Introduction

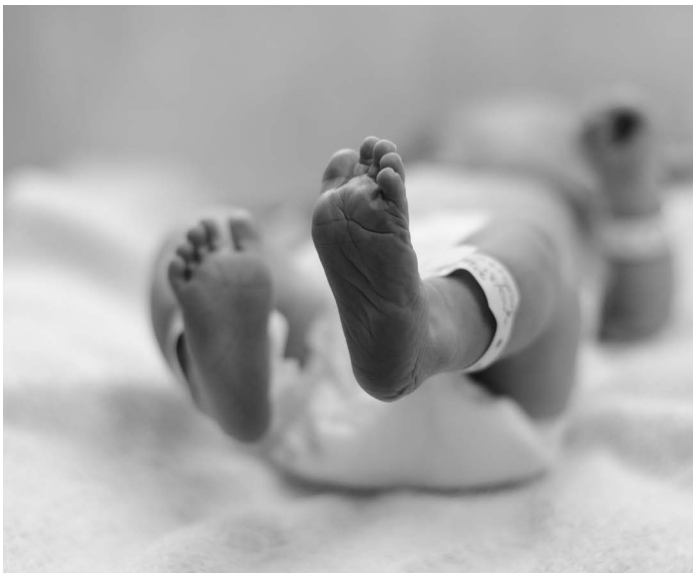
Providing sex-altering surgery to infants who are born with ambiguous genitalia has been fiercely debated.[1] Infants born with ambiguous genitalia have external organs that resemble neither the male nor female sex.[2] There are surgical techniques that make it possible to alter the physical appearance of these infants to create a "normal" looking appearance.[3] At the time of the procedure, parents have the legal authority to decide whether their infant receives surgical intervention.[4] However, the surgery is generally irreversible and this "sex-altering" surgery can result in serious physical, emotional, and psychological distress for intersex people later in life because it can lead to confusion about their sexual identity and gender.[5]

The law in the United States has not addressed the harm done to an infant who undergoes this procedure or whether allowing parents to consent to this surgery is in the child's best interests.[6] This article discusses whether surgical management for infants born with ambiguous genitalia is an act of beneficence or denial of their future right to autonomy and whether parents should be allowed to provide informed consent for their infant's elective sex assignment surgery.

II. Background

Ambiguous genitalia is typically caused by a genetic variant that results in intersexual deformities.[7] Of the three to four million children born annually in the United States, 1.7% of people are born with at least one intersex trait and the rate of ambiguous genitalia is said to affect approximately one in 2,000.[8] Infants who are born "intersex" are diagnosed through a combination of physical examinations and lab evaluations.[9] The physicians assess the location of the gonads, the prominence of the phallus, and whether a vaginal opening is present.[10] Additionally, a rectal exam is administered to determine whether the child has a uterus or prostate gland.[11] A laboratory will then analyze the genotype makeup of the infant and conduct a blood test to detect the pathophysiologic cause.[12] Once the lab tests and examinations are completed, the treating physician will make a recommendation regarding surgical reconstruction of the genitalia.[13]

When deciding the sex the infant will be assigned, a male classification is chosen for those born with hypospadias of the urethra, which is a defect in the opening of the penis, and undescended testicles.[14] However, a female assignment is often chosen for intersex infants because physicians can more effectively reconstruct a clitoris and create a vagina if there is a smaller phallus rather than form the male genitalia.[15] For instance, if an infant was born with XY chromosomes, making them genetically male at birth, the choice to have him remain male would only be made if the length of the phallus could be stretched to greater than 2.5 centimeters.[16]



Newborns with XY chromosomes born with more prominent female parts such as an enlarged clitoris, will have their masculine genitalia shortened to create a normalized appearance.[17] However, the Intersex Society of North America (ISNA) contends that in most cases there is no medically based reason to shorten the length of the labia and clitoris.[18] Aside from a small percentage of cases where the surgery is necessary to ensure the child can urinate properly, this surgery is cosmetic, vastly reducing the infant's genital matter, which results in scarring of tissue and the inability to reconstruct the genitalia a second time.[19] This may leave the child with a loss of erotic capacity.[20] Once the surgery is performed, some of the effects on the infant are irreversible later in life.[21] The surgery can result in sterilization, desensitization of the genitals, scarring, and often emotional trauma.[22]

Surgical intervention for infants born with ambiguous genitalia is often justified by the potential social and psychological risks that being born intersex poses to the child.[23] Physicians have argued that the benefits of surgery on intersex children outweigh the negatives.[24] Physicians note that there

are intersex children who undergo surgical treatment and end up with external genitalia that matches their gender identity, providing them with a better social life because of their normalized sexual body image.[25] Indeed, ambiguous genitalia was often described in medical journals as "embarrassing" and "unsightly," which lends support to performing surgery to benefit the mental well-being of the child.[26] Physicians continue to reason that normalizing surgery is the best way to offset the psychological damage that ambiguous genitalia can cause to children.[27] Yet, there is little data that shows surgical intervention is actually in the children's best interest.[28]

In the past, it was thought that ambiguous genitalia required surgery in infancy based on the theory that humans learn their sexual identity.[29] Physicians believed that reassignment performed at birth would allow the child to be raised in congruence with their gender identity and avoid confusion – regardless of chromosomal or hormonal makeup.[30] Physicians also believed that if surgery were delayed and the child's external genitalia did not reflect the way they were raised, they could have psychosocial harm throughout adulthood.[31] However, the error in this logic became apparent when further research revealed that a child generally develops a gender identity that matches their genetic sex at birth.[32] Ultimately, the re-assignment of the infant's sexual organs can strip them of the ability to self-actualize because the surgery can create permanent emotional and physical harm.[33]

For many years, surgery has been the norm when dealing with infants who have ambiguous genitalia.[34] During the early 1800s, the medical community did not generally discuss ambiguous genitalia and there was no formal treatment available.[35] An increase in the reporting of cases of ambiguous genitalia did not happen until the 1950s.[36] During that time, sex was often defined solely by the appearance of the external genitalia.[37] Physicians who performed the sex assignment surgeries generally advised the parents to proceed with the surgery and thereafter raise their child as male or female based on their surgically altered genitalia.

A. The John/Joan Case

The most notorious case of genital normalization surgery was made public in the 1970s by John Money.[38] This case involved a patient who was an identical twin and lost his phallus at the age of eight months old due to a botched circumcision repair.[39] Money was one of the first psychologists to study intersex children and child-rearing together.[40] He hypothesized that intersex children could successfully be assigned a gender at birth so long as they became acquainted with social signs of their assigned gender such as through interactions with children of that gender, toys, and clothing.[41] In applying his research, Money suggested that the parents could normalize the patient's genital appearance by consenting to sex-reassignment surgery which would remove his scrotum and create a vulva.[42] The parents followed this advice and began to raise their son, John, as a girl named Joan (J/J).[43] Post-surgery, the parents reported that the child was standing to urinate and was acting in a tomboyish fashion.[44] The child's doctor gave J/J estrogen to begin the stages of female puberty growth.[45] J/J often received counseling to cope with increasing psychological and mental health issues, but soon refused to attend these sessions.[46]

Later, Money noted that J/J had begun to contemplate suicide and he advised the parents that this distress would worsen if J/J did not return to the male sex.[47] J/J underwent mastectomies to remove the breast growth and requested a phalloplasty to fix his physical appearance, but the social problems did not end.[48] J/J got married and adopted children, however, he was unable to be erotically stimulated through intercourse.[49] Sadly, he committed suicide at 38 years old.[50] His identity was later revealed to be David Reimer.[51] J/J left his mark on the medical community by demonstrating that gender identity cannot necessarily be changed by social factors and that the psychological effects of sex reassignment surgery may be more drastic than was formerly believed.[52]

The case of John/Joan uncovers the reality of surgical management that is performed on intersex infants. With surgery, a child's gender identity is ripped away from them at a young age because their genital appearance does not look "normal." Dr. Money soon realized that infants such as David Reimer, who undergo genital normalization surgery, may be left with confusion because their inclinations do not match their external body, leaving them at risk for suicidal ideations.[53] Without this surgery, the child may have, or they could have the choice to select a surgery that matches their gender identity. With the surgery, however, the child will now be at high risk for gender dysphoria and psychological pain.[54]

III. Intersex and the Law

The doctrine of informed consent requires that the patient be competent, meaning that they understand the risks and benefits of, and alternatives to, a surgical procedure and can make informed decisions to consent to, or refuse, treatment based on the information provided.[55] In the eyes of the law, children are not capable of making their own informed decisions.[56] As early as 1923, the United States Supreme Court decided that parents have a fundamental right to make decisions regarding the medical care of their children so long as those decisions are in the child's best interests.[57] Yet, the law has not adequately addressed whether a serious procedure to normalize genitalia at infancy is in the child's best interests.[58]

In many countries, the current standard of care for infants born with ambiguous genitalia remains an interdisciplinary team approach informed by parents' wishes.[59] In the United States, some states have attempted to change the standard of

care for intersex infants. For instance, in January of 2022, InterACT proposed a bill in the State of California mandating that elective surgeries on intersex children be postponed until the child is at least six years of age and can participate in the decision.[60] Still, this bill had not been passed as of April 27, 2023.[61] Similarly, in New York, there is still no blanket law prohibiting intersex surgeries on infants. However, New York City Hospitals, one of the largest public health care systems in the United States, has instituted a policy deferring all medically unnecessary surgeries on intersex children until the child reaches the age of consent.[62] In India, one state has successfully enacted a ban on genital normalizing surgery for infants, removing it as the standard treatment except in life-threatening situations.[63] In Colombia, there is a law making it illegal for a doctor or parent to perform genital normalizing surgery on an intersex infant before the age of 18, without the child's consent.[64] Notably, Malta, was the first country to ban genital normalizing surgeries outright and provide a gender-neutral category "X" on official documentation including passports.[65]

However, the American Medical Association (AMA) has come out against the practice, issuing a statement urging doctors to defer intersex surgery on infants and young children except in the event that there are life-threatening circumstances which require emergency intervention.[66] Additionally, the American Academy of Family Physicians (AAFP) which is one of the largest medical organizations, has taken a stand against medically unnecessary surgeries on intersex children, centering their policies on the importance of bodily autonomy.[67] On a global level, the United Nations has strongly condemned the practice of surgery on intersex infants stating that it is a human rights violation and abuse to the child.[68] More than 34 states have backed the statement urging that "unnecessary surgeries performed without children's consent may lead to psychological damage later in life."[69] Nonetheless, many states and countries still continuously fail to regulate the practice despite other organizations' actions to the contrary.

In the U.S., child abuse can be defined as "an act or failure to act on the part of a parent or caretaker, which results in serious physical or emotional harm to the child."[70] However, many states use varying definitions within their own statutes. For example, in the State of New York, the Family Court Act states, parental abuse can occur when one "creates or allows to be created a substantial risk of physical injury to such child . . . which would be likely to cause death or protracted disfigurement, or protracted impairment of physical or emotional health or protracted loss or impairment of the function of any bodily organ."[71] Under the N.Y. Family Court Act's definition of parental abuse, normalization surgery could qualify because it can result in sterilization of the infant, loss of erotic capacity, and psychological distress, which can lead to serious impairment of the child's physical and emotional health.[72]

A prohibition on infant genital normalization surgery is particularly required today because society's views of sex and gender have gradually changed over time. Genetically, children can be born with female or male designated chromosomes however, they may choose to identify differently than their sex assigned at birth. The classification of what sexual and gender identity is considered "normal" has expanded. Currently, the standard of care for many physicians treating intersex infants remains surgical and if performed does not constitute parental abuse. However, if the standard of care adapts to the new attitudes towards gender identity, there would be a stronger case for parental abuse if the surgery is sought out in this country or elsewhere for infants because of the possible injury to the future child's physical and emotional well-being.[73] Further, if new protective laws were passed, it would be malpractice for a physician to perform this surgery on an infant.

The current treatment for intersex infants is one that seriously damages the child's physical and emotional well-being.[74] This is somewhat like genital mutilation in the sense that it deprives the individual of sexual sensation.[75] Genital mutilation is a cultural practice performed in many African and some Asian countries on females.[76] With genital mutilation, a girl's clitoris is removed, resulting in a loss of erotic capacity and sometimes death.[77] The U.S. has enacted laws criminalizing those who "perform[], attempt[] to perform or conspire[] to perform, female genital mutilation on another person who has not obtained the age of 18 years."[78] Parents and guardians who provide consent or facilitate surgical genital mutilation are also subject to criminal liability.[79]

In 2013, the federal law outlawing genital mutilation was amended to make it illegal to knowingly transport a female under 18 years old outside of the U.S. for the purpose of genital mutilation.[80] This federal law unquestionably recognizes the harm caused to a child who is forced to undergo genital mutilation surgery. A similar law should be passed to protect intersex infants from surgery that can result in sterilization, potential gender dysphoria, and a high risk of suicide and depression.[81] Currently, there are no federal laws in the U.S. that specifically aim to protect intersex infants from genital normalization surgery.[82]

Recently, some states, such as Georgia, have enacted law banning gender-affirming care for transgender minors until they reach the age of 18.[83] This year alone, more than two-thirds of the bills introduced aim to ban gender-affirming care for transgender youth allowing for only specific exemptions.[84] The exemption applies to intersex children, allowing doctors to perform surgery intended to assign a binary sex and makes it clear that this type of care will not be an option for transgender minors.[85] These bills selectively choose which group of minors are "too young" to undergo surgical intervention

while disregarding that intersex surgeries are often performed in infancy without their consent.[86] If transgender youth are unable to make decisions about their body until age 18, it is difficult to contend that intersex infants may still undergo surgical intervention. However, surgical intervention performed on intersex infants remains permissible in many states. Bills opposing gender-affirming care for trans-youth not only reinforces strict gender ideals, but disregards the risks associated with allowing surgery to be continued on intersex infants.

A. An Archaic Standard of Care

If federal legislation were passed prohibiting this surgery on infants until the age of 12, the child would have time to decide which gender fits them best. The child would then have the opportunity to determine if hormone blockers may be helpful as they begin puberty. Hormone blockers suppress the body's release of hormones such as testosterone and estrogen, which helps reduce distress from gender dysphoria.[87] Puberty blocker drugs are generally safe with supervision and can delay the child's development until they are ready to decide if surgery is necessary.[88] Though it varies by state, providers can often treat precocious puberty for breast growth as early as age nine and testes growth by age eight using puberty blockers.[89] Recently, some states have acted to ban the use of puberty blockers for minors; however, they are still an option for minors in other states such as New York, California, and New Jersey.[90] When a child is born with ambiguous genitalia, they are at risk of developing gender dysphoria.[91] This may be successfully treated through puberty blocking.[92] If, an intersex child reaches nine years old and is enduring feelings of gender dysphoria, they may be able to receive puberty blockers that will give them time to determine if further gender transition is needed.[93] Then if, by age 12, the child believes that the hormones don't provide enough support, a more permanent solution such as surgery may be discussed between parent-child and physician.[94] If a law such as this were passed, it would provide intersex children the time to decide for themselves whether surgical intervention is what they want.

Another case that would support enactment of federal legislation for intersex infants is a 2013 South Carolina lawsuit brought in federal court against the Medical University of South Carolina and the South Carolina Department of Social Services.[95] In this case, the plaintiff claimed that their adopted child was subjected to sex-reassignment surgery for ambiguous genitalia at 16 months old.[96] The parents argued that doctors should not have performed the surgery when they could not predict how the child would develop with respect to gender identity.[97] The couple further argued that permanently altering their child's genitalia and reproductive ability with no medical basis is an "abhorrent practice and cannot be continued."[98] The parents consulted their pediatrician and the child began to transition and identify as a boy, though the long-term effects of the surgery were irreversible.[99] In 2017, after a four-year legal battle, the adoptive parents received a large settlement of $444,000.[100] The court merely denied defendant's motion to dismiss, based on the assessment that this surgery, performed while the child was in foster care, may have violated the child's right to procreation.[101] Yet, this 2017 decision, though impactful, did not change or enact legislation to protect intersex infants.

IV. A Threat to Individual Autonomy

Autonomy is defined as one's right to self-determination as a free moral agent.[102] Patient autonomy is a foundational principle in bioethics – requiring respect for an individual's choice over what shall be done to their body.[103] Beneficence is promoting well-being and preventing harm to the patient, whereas the principle of non-maleficence proscribes actively harming a patient.[104] Performing gender normalizing surgery is often considered an act of beneficence because without surgical intervention the child may be worse off psychologically.[105] Moreover, well-intentioned parents often consent to such surgery as they believe this surgery will help their child to fit in socially.[106] However, the infant may face worse psychological trauma from having the surgery and will often also face sterilization.[107] This may be considered maleficence by parents and physicians who choose such a course of treatment.[108] Today, more of an emphasis is placed on individual choice.[109]

There has been a transformation in how society views gender and sexuality. Historically, sex was viewed as synonymous with gender, though they are completely different.[110] Gender differs from sex in that it is based on social customs and labels, whereas sex is based on the sexual anatomy of the child at birth.[111] For a long time, people believed that if a person's sex at birth and bodily characteristics were female then their gender identity must also be female, and vice versa.[112] Applying that concept, children who were born female would be raised as female and given dolls to play with, whereas children born male would be given trucks.[113] However, this method

of defining gender created a negative social stigma for those who do not adhere to the traditional characteristics of male or female.[114] Unsurprisingly, not all people fit into predetermined norms and creating a strict construct as to how a person should behave and identify has often caused unimaginable psychological pain and in some cases suicide.[115]

In recent years, many individuals have begun to openly identify as non-binary or gender non-conforming, which includes any gender that is not exclusively male or female.[116] For example, Jamie Shupe has fearlessly taken steps to ensure equality for non-binary individuals and is a prime example of what has propelled change and acceptance.[117] Shupe, who was assigned male at birth and was a United States Army sergeant, identified as female.[118] Shupe brought a proceeding against the military to amend her discharge papers to state that she was female, but the army opposed her.[119] At one point, Shupe no longer identified as either male nor female and began to struggle with gender.[120] In court, counsel presented two letters from physicians stating that Shupe identifies as neither male or female.[121] Judge Hehn, of Multnomah County Circuit Court, ruled in favor of Shupe based on the documentation provided and uncertainty in the current statute regarding gender classification.[122] Shupe's battle represented a new beginning for non-binary individuals who longed for acknowledgment of their gender identity by the government.

Because society has begun creating an environment that allows for gender exploration and expression for those who do not conform to typical gender classifications, it should be less important and stigmatizing for children with ambiguous genitalia to gain acceptance. Instead of the typical he/him and she/her designations, the use of they/them pronouns has given individuals who do not identify as strictly male or female the opportunity to be appropriately addressed.[123] Moreover, rather than using the traditional Mr./Mrs./Ms., Mx is currently used as a gender-neutral honorific for those who do not wish to use gendered titles.[124]

As gender has become more fluid, intersex individuals may find more support in embracing their intersex bodies rather than having to decide their sex at birth.[125] This new culture should allow intersex children to have an opportunity to explore their identities and pronouns making it possible for them to choose the gender identity that they feel fits them best.[126] Further, by not making a rash decision on how to "fix" an infant's genitalia, waiting until they are older and providing counseling from psychiatrists and involvement with support groups such as InterConnect and the Intersex Justice Project, for example, the child can create a healthy and positive relationship with their body.[127] Although society has begun to adapt to different gender norms, discrimination is still present globally.[128] However, progress is being made. In 2020, the U.S. Supreme Court decided *Bostock v. Clayton,* which held that Title VII extends to intersex people and protects them from discrimination.[129] With encouragement from physicians, parents can help their intersex children to reach their full potential by creating a gender-neutral environment so they can discover what identity fits them best.

V. The Road to a New Standard of Care

The justice system can take steps to protect intersex infants from premature surgical intervention, by enacting a federal law banning this course of treatment for infants, and the standard of care for intersex infants must be viewed in a different light. Apart from medically necessary situations, the standard of care should prohibit immediate surgical intervention on infants born intersex, and performing the surgery in infancy should be considered parental abuse. With the growing inclusivity of individuals who identify differently from stereotypical gender norms, intersex children can now receive support as they decide if they want to pursue gender reassignment in the future. Ultimately, it should be the autonomous decision of the child to decide their sexual and gender identity, and they should not be left to struggle with the irreversible consequences of unnecessary surgery. As Sean Safia Wall once said, "Intersex bodies are beautiful, people should have the right to choose, to bodily autonomy, to reproductive integrity. But the immediate work to be done is to educate people on what it means to be intersex. That's where we're starting."[130]

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Endnotes

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42. *Id.*
43. *Id.* [John/Joan hereinafter referred to as J/J].
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