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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

Special Issue on Maternal Health


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congratulates the
NYSBA Health
Law Section on
another great
year of serving its
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GREATER NEW YORK HOSPITAL ASSOCIATION
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Persons interested in writing for this *Journal* are welcomed and encouraged to submit their articles for consideration. Your ideas and comments about the *Journal* are appreciated as are letters to the editor.

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Email: cassandra.dinova@cdphp.com

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A Message From the Section Chair

By Mary Beth Quaranta Morrissey

Summer greetings!

Permit me at the outset to share that I am so very honored to assume the role of chair of the New York State Bar Association Health Law Section this June.

I have enjoyed many wonderful and enriching years as a member of the Section and member and past chair and co-chair of the Public Health Law Committee. I reflect with joy upon my years working with Veda Collmer, Karen Gallinari, and many of our colleagues on the important work of public health. I also express my deepest gratitude to Kathleen Burke, Sal Russo, and Hermes Fernandez, as well as many other Section leaders, for their generous support, sage counsel, and mentoring during my time in the Section.

Please do join me in recognizing our Outgoing Chair Lisa Hayes for her remarkable contributions to the Section this past year. Lisa has advanced the Section's equity initiative, started by our past chair Jane Bello Burke, and also strengthened our programs and sponsorships. Very special thanks to Lisa are also in order for her lead contribution to this Health Law Journal Special Issue.

Finally, I welcome the 2024-2025 Health Law Section Officers Mark R. Ustin, chair-elect; James E. Dering, vice-chair; William P. Keefer, treasurer; and Linda Clark, secretary. I am very pleased to have the opportunity to work with a team of such talented leaders.

Turning to our Health Law Journal, it is with enthusiasm and gratitude that I introduce the June 2024 Health Law Journal Special Issue devoted to the subject of the public health crisis in maternal health. My very special thanks to Health Law Journal Editor Cassandra DiNova for the support she has provided to our contributing authors throughout the process of developing the Special Issue content. Our contributing authors will join us at this year's Fall Meeting for a special panel presenting their critically important work as we pursue our commitment to advancing equity and justice in maternal health.

Building on the Section's work in the public health law arena, on May 7, 2024, the Public Health Law Committee partnered with the Public Health Equity Law Club of Columbia University Mailman School of Public Health to hold the "Integrating Care: Addressing Social Needs Through the Transformative New York Health Equity 1115 Medicaid Waiver - Panel Discussion & Reception." Panelists engaged in dialogues concerning the recently passed New York State Health Equity Reform 1115 Medicaid Wavier, a significant step toward addressing health disparities and advancing health equity. Participants also received important updates about the legal framework of the waiver, its implications for healthcare delivery, and the integration of social determinants of health into the Medicaid program.

In follow up to the work of the New York State Bar Association Medical Aid in Dying Task Force and the adoption of the Task Force Report in January by the House of Delegates, the Public Health Law Committee also sponsored a Continuing Legal Education Program on May 22nd titled, "The End-of-Life Care Continuum: Hospice, Palliative Care, and the Medical Aid in Dying Bill." The CLE program was co-sponsored by the Committee on Disabilities Rights.

On other fronts, I am pleased to share that the OMIG Task Force, appointed by past chair Jane Bello Burke in May 2023, has issued its initial report addressing recommendations for reforms in OMIG's audit process. The Health Law Section Leadership has now approved the Task Force Report and Resolution.

The Health Law Section kicked off the summer with a scintillating networking reception generously hosted by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C,. at their Manhattan offices on Wednesday evening, June 6th. Special thanks to Andria Adigwe, co-chair of the Membership Committee, and Mintz Associates Jeannie Mancheno and Cody Keetch, for their planning efforts. The event opened with roundtable conversations, followed by a delightful repast, courtesy of the Mintz firm. Our special thanks to Mintz Health Law Section Chair Karen Lovitch for her warm welcome to our Health Law Section members, colleagues, and guests.

Fall Meeting Chair Anoush Koroghlian Scott and co-chair Heather Butts have hit the ground running with the Fall 2024 Meeting Planning. I am pleased to share that the Fall Meeting will be held on Monday, October 21st at the Gideon Putnam in Saratoga Springs. More details will follow soon regarding the Fall Meeting Program agenda and other activities in the works. But please hold the date and hope many of you will be able to join us for a fun Fall weekend at the Gideon.

We are working diligently to provide support to all our committees and committee chairs as we transition into the Fall. I am pleased to share updates regarding several of the Section's committees, including our newly formed Psychedelics Committee and committee leadership roles. Lisa Smith and Heather Butts will be co-chairing the Subcommittee on Psychedelics of the Public Health Law Committee; Alex Elegudin will be moving into the role of co-chair of the Membership Committee; and Andria Adigwe will be joining the E-Health Committee as a co-chair. Congratulations to all our new chairs.

Our Diversity Committee, now under the energetic leadership of Michael Fraser, has selected the Section's Summer Fellows. Congratulations to Danya Mekkielamin, 2L Albany Law School, who is placed at the Albany Offices of Hodgson Russ, and to Divya Sethi, 1L Brooklyn Law, placed at the Manhattan Offices of Martin Clearwater & Bell. We look forward to hearing about their experiences.

In closing, I encourage all committee chairs to engage with our communities across the Section and throughout the summer to plan your agendas for the upcoming year.

On behalf of the Section, we wish all our members pleasant summer sojourns.

Cordially,

Mary Beth Quaranta Morrissey

Introduction to Special Issue

By Mary Beth Quaranta Morrissey

Entanglements of Law, Jurisprudence, and Science and Their Contributions to Structural Racism and Disparate Treatment in Black Maternal Health

The New York State Bar Association Health Law Section is pleased to provide our members, audiences, and communities with this Health Law Journal Special Issue devoted to the public health crisis of maternal health and maternal mortality and morbidity in the United States. The articles in the Special Issue build on the work of the Health Law Section initiated in 2019 with a Fall Meeting panel addressing the complexities of the problem, and a publication in the Health Law Journal titled, “Framing the Public Health Problem of Maternal Morbidity and Mortality: A Social Justice and Moral Imperative.”[1] It is noteworthy that the current project expands further upon the Health Law Section’s interdisciplinary collaborations across the fields of law, medicine, and public health and social science research.

The central focus of this Special Issue is the subject of maternal health outcomes and maternal mortality and morbidity in the context of the entanglements of law, jurisprudence, and science, and their contributions to structural racism in U.S. health care and impacts upon Black women and communities.

Immediate Past Health Law Section Chair Lisa Hayes examines the history of the U.S. Supreme Court and the judicial system in her article, “Disparate Treatment in Health Care Under the Law: How Did We Get Here?”

In his article titled, “Patient Care Decision Tools: Protections Against Discrimination in Final Rule Revisions to Section 1557 of the Affordable Care Act,” guest contributor Lou Hart, M.D., calls attention to the discriminatory impact of the ecological fallacy in healthcare research, policy, and clinical care created by using population level data to design and make clinical decisions about individuals. In this context, Dr. Hart discusses the critical importance of protections against discrimination in final rule changes to Section 1557 of the Affordable Care Act.

In her contribution titled, “Racial Inequities in Maternal Health,” guest contributor Karen Bullock, Ph.D, maps out a historical perspective specificially addressing Black maternal health and recommendations for policy change and culturally competent workforce education.

Dorothy Shuldman and Andria Adigwe explore initiatives at the federal level in their article, “Data Mapping To Address Maternal Health, Morbidity and Mortality,” as well as policy steps taken in New York State and New York City to address the problem of maternal health.

In the closing article of the Special Issue, Cauolyn Baptiste, Cornell Law Student, is joined by Heather Butts, J.D., MPH, MA, and guest contributor Mavis Smith, MSW, Ph.D Candidate, in an examination of the impact of private equity on maternal health – a discussion of first impression in this Health Law Journal.

Endnotes

1. Burgansky et al., 2019.

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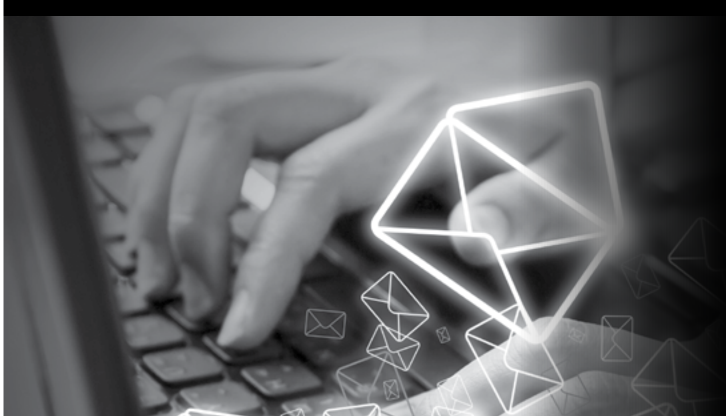

If you have written an article you would like considered for publication, or have an idea for one, contact the *Health Law Journal* Editor:

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

REQUEST FOR ARTICLES

NYSBA

In the Legislature

By Michael A. Paulsen

The New York State Legislature concluded the 2024 Legislative Session in early June, marked by another extended budget negotiation cycle, leaving legislators with a shortened timeline to advance policy in the final weeks remaining in session. The legislative session most notably resulted in an agreement on a record $237 billion budget as well as the passage of several bills of significance, including legislation to: restrict social media entities' ability to collect and share the personal data of children, enact the Climate Change Superfund Act, which will make fossil fuel polluters pay for costs associated with climate change, and expand New York's wrongful death statute (Grieving Families Act).

In health care, perhaps the most significant bill passed is the Local Input in Community Healthcare (LICH) Act (also known as the Hospital Closure bill). This bill, if signed by the governor, would significantly alter the process for an operator to close a hospital or unit of a hospital by requiring that such actions be subject to additional levels review and public input (described in more detail below). While a version of this bill had under review by the Legislature for many years, the recent proposals to close the Burdett Birth Center at Samaritan Hospital and Mount Sinai Beth Israel heavily influenced legislators to act on this bill. In particular, the Health Equity Impact Assessment (HEIA) and community input regarding the proposed closure of the Burdett Center influenced a state grant commitment for the next five years to keep the center open, resulting in a withdrawal of the proposed closure. The Hospital Closure bill includes the completion of the HEIA and community forum as mandatory components of the closure process and extends these requirements to the closure of individual units within a hospital.

While this legislative session was more budget-focused than prior years, the Legislature was able to pass 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. Those that have already been signed into law are noted by 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

Local Input in Community Healthcare (LICH) Act (S8843B Rivera/A1633B Simon): This bill amends the process for the closure of a general hospital or a unit of a general hospital, requiring that a closure be subject to review by the Public Health and Health Planning Council (PHHPC) and to public input through a public community forum.

A hospital that seeks to close entirely will be required to provide written notice to DOH and other parties no later than 270 days prior to the proposed closure date. The hospital must submit a closure application containing a health equity impact assessment at least 210 days prior to the proposed closure, which is subject to a full review by PHHPC. The hospital is prohibited from pausing, transferring, or limiting any service while the closure application is pending without prior written approval of the commissioner. This prohibition includes the moving of services to other facilities or the transfer of personnel that results in a reduction or unavailability of services.

The bill establishes a similar process, with different timelines, for a hospital that seeks to close a unit of a general hospital and includes a requirement that the commissioner hold a community public forum to obtain public input concerning the anticipated impact of the unit's closure. A "unit" is defined to include a portion of a hospital that offers licensed emergency, maternity, mental health, or substance use services, including any specialty care or any other hospital service in an operating certificate. The bill provides that the reduction of services constitutes a unit closure if it results in a reduction of more than 15% of patient capacity within one year, 25% of patient capacity within a two-year period, or 35% of patient capacity within a three-year period. The law does not apply to any proposed closures on notice to DOH as of the date of enactment.

Information Provided to Prospective Maternity Patients (A5576 Sillitti/ S3610 Webb): This bill requires hospitals and birth centers to provide additional informational material to prospective maternity patients, including information related to the conduct of safety drills, whether a facility participates in quality improvement initiatives, whether an agreement has a policy to arrange emergency transfer if care for critically ill pregnant people/infants, whether a facility has a written community needs assessment plan to reduce racial disparities and address community needs, whether an autopsy is available upon request for stillbirth, and if bereavement services are offered.

Doula Access During Cesarian Section (A7606 Solages/ S5991-A Persaud): This bill establishes the right of a pregnant person to have their designated doula in the operating room during a cesarean section when no other support person is available to them. This bill requires all maternal health facilities (hospitals and birthing centers) to post online and in patient waiting areas information stating a birthing parent is allowed to have a doula present in the operating room for the duration such person is in an operating room. This statement shall made available in English and the six most common non-English languages.

Access to Patient Designated Doulas (A6168A Solages/S5992A Persuad): This bill requires maternal health facilities, defined to include hospitals and birthing centers to allow a pregnant person a full access to their designated doula during delivery and/or inpatient care post-delivery. The facility is prohibited from denying a patient access to the patient's designated doula.

Congenital Heart Defect Information for Maternity Patients (A7516A Fall/S9283 Kavanagh): This bill requires hospitals and birth centers to provide an informational leaflet on congenital heart defects, to be developed by DOH, to all maternity patients.

Grieving Families Act (A9232B Weinstein/S8485B 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). Compared to prior versions, this bill removes "loss of love, society, protection, comfort, companionship, and consortium resulting from the decedent's death" as recoverable damages. A version of this bill was vetoed by Governor Hochul in each of the last two years (Veto #192 of 2022 and Veto #151 of 2023). The amendments to this version of the bill appear to response the concerns raised by Governor Hochul in her veto messages.

Pressure Ulcer Prevention Program (A9718B Paulin/S9067A Krueger): This bill requires hospitals and residential health care facilities to implement a pressure ulcer prevention program. The bill requires that DOH evaluate the current reimbursement policy regarding pressure ulcer prevention programs and report on the current reimbursement options that would reduce the incidence of pressure ulcers. It further directs the commissioner to create a pressure ulcer prevention center of excellence within the DOH by April 1, 2025.

Donate Life Registry Access through EHR (A7079 Gunther/S8456 Rivera): The bill amends the public health law to require every electronic health record vendor (EHR) providing services to a general hospital in New York State to implement in their EHR product for general hospitals the ability for patients to register in the Donate Life Registry as an organ donor. EHR vendors are required to provide this capability without increasing the cost to hospitals for either existing or new EHR products. The implementation requires, at a minimum, patient facing elements to allow patients to directly register in the Donate Life Registry.

Dispensing of Controlled Substances by ER Practitioners (A5984B McDonald/S7177B Fernandez): This bill authorizes practitioners in a hospital with a full-time pharmacy to dispense controlled substances (methadone and buprenorphine) to a patient in a hospital emergency room for up to three days. Currently, NYS Bureau of Narcotic Enforcement (BNE) policy and regulations allow for only 24 hours of a controlled substance to be dispensed. This modification aligns with current DEA policy that allows practitioners working in hospitals, clinics, and emergency rooms to dispense three days of buprenorphine and methadone.

Hospital Home Care Physician Collaboration Program (A9204 Paulin/S9049 Scarcella-Spanton): This bill amends the Hospital-Home Care-Physician Collaboration Program to require an application for a waiver of any regulation under the program to be subject to a public notice process. It requires notice of an application requesting a waiver to be published in the State Register and subject to a public comment period prior to being approved by the commissioner.

Access to Patient Information (A7860 Sillitti/S7846 Webb): This bill requires health care facilities and providers to honor a request by a qualified person for a physical copy of patient information, subject to statutory copying and shipping charges.

Long Term Care

Closure of Nursing Homes (A3703 Epstein/S2984 Kavanagh): This bill establishes new requirements for the closure of a nursing home by requiring that the operator submit written notice to DOH at least 90 days prior to the anticipated date of closure of the nursing home and that copies of such notice to the local legislative body or community board, if applicable. Upon the submission of a closure plan, the bill prohibits the operator from increasing fees or charges to residents, accepting new residents or transfers, or closing the nursing home until all residents have transferred to appropriate alternative settings. The bill provides DOH with express authority to impose penalties under the Public Health Law for the failure to comply with the new requirements. If signed by the governor, this law will take effect on April 1, 2025, and apply to all closures of nursing homes occurring on or after such date.

Posting of Nursing Home Ratings (A2188 Dinowitz/S3498 Sanders): This bill expands the existing requirement for nursing homes to post their overall CMS rating to include ratings for health inspections, staffing and quality measures on the home page of any website maintained by such facility and conspicuously post these ratings so that they are visible to the public and residents.

Temporary Operator Program (A6034B Paulin/S9131 Rivera): This bill expands the Temporary Operator Program to include nursing homes. The Temporary Operator program authorizes DOH to appoint temporary operators to hospitals, adult care facilities, and assisted living residences if a facility faces serious financial instability or conditions in the facility seriously endanger the life, health, or safety of residents or patients. The bill does not make any other modifications to the program.

Advanced Residential Health Care for Aging Adults Medical Fragility Demonstration Program (A10189B Gunther/S9519A Scarcella-Spanton): This bill creates a demonstration program to establish a new facility or discrete unit to provide services to adults from age 35 to end of life who have chronic debilitating conditions and require complex medical treatment to maintain their health status. Eligibility for participation in the program is limited to not-for-profit nursing homes that operates 110 adult beds or are licensed to provide diagnostic and treatment services.

Quality Improvement and Consumer Transparency in Assisted Living (A5790A Paulin/S8865 Cleare): This bill requires all Assisted Living Residences (ALRs) to report annually on quality measures no later than January 15, 2025. The department is directed to establish quality measures in consultation with industry and consumer representatives. The bill also requires ALRs to post information, including the starting monthly service rate, range for rent, approved admission agreement, and a consumer-friendly summary of all service fees through a reporting system to be developed by the department, and to post such information to the facility's website and in a public space within the facility. The bill further requires DOH to score the results of the quality reporting and provides that facilities scoring in the top quartile shall be granted advanced standing for purposes of their annual surveillance schedules.

Social Adult Day Services (A10142 Kim/S9356 Cleare): This bill establishes that the rules and regulations issued by the State Office of the Aging (SOFA) apply to all social adult day care programs, regardless of their source of funding. It further requires SOFA to inspect each social adult day care program to ensure the program has met the standards and requirements prior to operating and no less than every five years.

Public Health

Develop a Maternal Health Care and Birthing Standards Workgroup (A8207A Clark/S7702A Webb): This bill requires the Commissioner of Health to convene a maternal health care and birthing standards workgroup to make recommendations related to the development of maternal health care and birthing standards to ensure that patients receive the highest quality of care. The workgroup is to be comprised of stakeholders, including but not limited to hospitals, obstetricians, midwives, doulas, maternal health care provider organizations, mental health care provider organizations to ensure the highest quality of care.

Maternity Care Program for Veterans (A8162 Cunningham/S9259 Scarcella-Spanton): This bill requires the Women Veterans Coordinator of the Department of Veterans' Services to develop and implement a maternity care program in consultation with the Department of Veterans Affairs, DOH and OMH, to improve the capacity of maternity care providers to address the unique needs of pregnant and postpartum veterans. It directs the Commissioner of Health to make information on veterans' reproductive mental health care available to maternal health care providers, which includes information to ensure that all pregnant veteran patients are appropriately screened for depression, partner/domestic violence, military sexual trauma, PTSD, anxiety, substance abuse and postpartum depression.

Modernize Physician Assistant Practice Standards (S9038A May/A8378A Paulin): This bill modernizes practice standards for PAs by allowing a physician to supervise up to six PAs at one time (current limit is four) and allow PAs to prescribe and order a non-patient specific regimen to an RN for immunizations and testing.

Provider Network Information in Physician Profile (A7214 McDonald/S3472 Rivera): This bill provides that for purposes of the Department of Health Physician Profile, the reporting of a physician's participation in a healthcare plan is not the responsibility of the physician, but the Department of Health utilizing provider network participation information and other reliable sources of information submitted by health care plans. It also establishes that, as a condition of a physician's licensure renewal, a physician must update his or her Physician Profile within six months prior to the submission of the re-registration application.

Definition of Medical Debt (A9438 Paulin/S8373A Rivera): The bill amends the definition of "medical debt" under the General Business Law and Public Health Law to provide that "medical debt" does not include debt charged to a credit card unless the credit card is issued under an open-ended or closed-ended plan offered specifically for the payment of health care services, products, or devices.

HERDS Data Transparency (A5370 Paulin/S5732 Skoufis): The bill establishes the health emergency response data system (HERDS) in statute and provides authorization to collect information and statistical data relating to public health emergencies. It requires DOH to make HERDS information available to governmental entities, health care providers, and the public on the department's website as close to real time as practicable, but no later than seven days after it is received.

Authorization for Ambulance and Advance Life Support First Response to Store and Distribute Blood (A5789-A Woerner/S6226-A Hinchey): The bill amends the public health law to authorize ambulance services and advanced life support first response services to store and distribute blood and to initiate and administer blood transfusions. The bill expands current provisions for air transport to apply to motor vehicle-based ambulance services.

Commission a Study on People With Developmental Disabilities That Have Traumatic Brain Injuries (A7215 McDonald/S1478 Hinchey): This bill directs the Commissioner of Health and the Office for People with Developmental Disabilities to conduct a study to evaluate the availability and accessibility of quality services, emerging trends, regional disparities, and the effectiveness of the administrative process for individuals with traumatic brain injury. As part of the study, the agencies must consult with those with traumatic brain injury and their families, organizations representing such people, and providers of services to those with traumatic brain injury.

Commission a Study on Veteran Healthcare (A4201 Stern/S7501 Martinez): This bill requires the Department of Veterans' Services, in consultation with the DOH, to undertake a study regarding veteran healthcare, including increasing primary, reproductive and mental health care services for women veterans in New York State.

Health Care Proxy Information and Palliative Care Patients (A7872A Paulin/S8632A Holyman-Sigal): This bill expands the requirement for health practitioners providing information and counseling on palliative care and end-of-life options to further require that such providers counsel patients about the benefits of completing a health care proxy and appointing a health care agent. This bill also requires the practitioner to request a copy of the newly completed or existing health care proxy to be made a part of the patient's medical record.

Prohibits Label Obstruction of Over the Counter (OTC) Drugs (A1010B Weprin/S8880A Sanders): This bill prohibits any retailer to knowingly obstruct any part of a label or packaging of any OTC drug or cosmetic. These labels are required by the federal Food, Drug and Cosmetic Art, and by the Food and Drug Administration's (FDA) and are used to promote and protect the health and safety of purchasers of OTC drugs and cosmetics.

Early Intervention (EI) Program Review (A10175Paulin/S1198A Rivera): This bill requires the Commissioner of Health to conduct a comprehensive study and review of the EI program, including the models of service delivery and rates of reimbursement for services provided under the program. The commissioner is required to conduct an analysis of the costs to providers participating in the EI program and develop recommendations for maintaining or changing reimbursement methodologies and rates.

DOH Study on Cancer Clusters (A4219 Rivera/S4193 Sanders): This bill directs DOH to conduct a study on the incidences of cancer clusters in cities and towns have a population over 90,000 people. The study shall include an analysis of high-risk neighborhoods, examining disparities in income, race, housing, and the effectiveness of existing medical facilities in the immediate area.

Drug-Induced Movement Disorder Screening and Awareness Program (A6799B Paulin/S8965A Rivera): This bill requires DOH to establish a drug-induced movement disorder screening and awareness program to promote education and awareness of drug-induced movement disorders and screening of these disorders. It directs DOH to develop educational materials for health care providers regarding treatment for such disorders, in coordination with relevant health care provider groups.

Spinal Cord Injury Research Program (SCRIP) Trust Fund (A9632 Paulin/S9144 Fernandez): This bill removes the current statutory cap of $8.5 million in funds from surcharges on moving traffic violations from being devoted to SCRIP. The bill converts the cap to a minimum amount of $8.5 million to allow for additional funds from traffic surcharges to be allocated to SCRIP.

Modernizing Supervision of Radiologic Technologists (A8247C Paulin/S8470A Rivera): This bill allows nurse practitioners and physician assistants, in addition to physicians, to directly supervise the administration of intravenous contrast by licensed and certified radiologic technologists.

Expand Scope of Practice for Dental Assistants and Licensed Practical Nurses Related to Application of Topical Fluoride Varnish (A7402B Peoples-Stokes/S9308A Fernandez): This bill permits dental assistants and licensed practical nurses to perform the application of topical fluoride varnish when there is a prescription and under protocols of an authorized provider.

Medicaid, Medicaid Managed Care, and Managed Long Term Care

Medicaid Reimbursement for Ambulance Services Without Transportation or Transportation to Alternative Sites (S8486C Hinchey/A9102C Kelles): This bill authorizes Medicaid reimbursement to ambulance service providers for providing emergency medical care to Medicaid enrollees without requiring the transportation of patients from the location where the medical was administered. It also authorizes Medicaid reimbursement for providing emergency medical care when transporting enrollees to alternative destinations (i.e., locations other than a hospital), including urgent care, mental health, or rehabilitation facilities.

TBI/NHTD Waiver Program Carve Out (S2867 Rivera/A7369 McDonald): This bill establishes a permanent carve out of services provided pursuant to the TBI/NHTD Waiver programs from being provided through Medicaid Managed Care. The transition of TBI/NHTD program participants into managed care was most recently delayed until January 1, 2026.

Physician's Assistants as Primary Care Practitioners in Medicaid (S2124 Rivera/A7725 Paulin): This bill adds physician assistants (PAs) to the definition of primary care practitioner for Medicaid, allowing PAs to serve as primary care practitioners in Medicaid managed care. The bill requires managed care providers to provide the same access to and enrollment of PAs as other primary care practitioners.

Medicaid Coverage for Remote Ultrasound Scans and Fetal Non-Stress Tests (A8168 Paulin/S7690 Webb): This bill clarifies that remote ultrasound scans and remote fetal non-stress tests are fully covered as a Medicaid benefit.

Medicaid Coverage for Licensed Creative Arts Therapists (A9018 Bronson/S8715 Brouk): This bill authorizes licensed creative arts therapists to bill Medicaid directly for services provided to Medicaid enrollees.

Applications for Medicaid Coverage of New Health Technology and Services (A6022A Paulin/SS4787A Rivera): This bill amends the existing Evidence Based Benefits Review Advisory Committee (EBBRAC) process for providers of health technologies and services to provide evidence for the purpose of determining whether Medicaid should cover such service or technology. The bill provides DOH with the ability to approve or disapprove recent technologies or services without a vendor, provides clear timelines for the review of applications, and in the event of a negative determination, requires DOH to detail the insufficiency of evidence and allow the applicant to cure stated deficiencies.

Health Insurance

Coverage Scalp Cooling Systems (A38A Rosenthal/S2063A Stavisky): This bill requires commercial insurance policies to include coverage for scalp cooling systems used in connection with cancer chemotherapy treatment. A scalp cooling system includes any device used to cool the human scalp to prevent or reduce hair loss during cancer chemotherapy treatment, provided that such device is designed and intended for repeated use and is customarily used to serve a medical purpose.

Coverage of Breast Tattooing Following a Mastectomy or Partial Mastectomy (A5729A Paulin/S6146A Cleare): This bill requires commercial health insurance policies to provide coverage for tattooing of the nipple-areolar complex, which is the final stage of the reconstruction process following a mastectomy or partial mastectomy, if the tattooing is performed by a licensed physician or other health care practitioner licensed, certified, or authorized and acting within their scope of practice.

Coverage for Human Donor Milk (A7790A Solages/S6674A Hoylman-Sigal): This bill requires commercial health insurance policies to cover outpatient use of pasteurized donor human milk (PDHM) for infants that meet certain requirements. As a result of this bill, coverage of PDHM is expanded to include use in both inpatient and outpatient settings.

Coverage of Additional Screenings for Breast Cancer (A1696C Hunter/S2465C Persaud): The bill requires commercial health insurance policies to provide coverage for additional screenings for breast cancer, including diagnostic mammograms, breast ultrasounds, or magnetic resonance imaging (MRI), when the patient's provider deems such screening is necessary under nationally recognized clinical practice guidelines for the detection of breast cancer.

Removing Enrollment Penalties for Pregnant Individuals (A2656 Walker/S201 Cleare): This bill prohibits a health insurance policy or contract offered under the New York State of Health from imposing a fee or waiting period for the enrollment of a pregnant individual during the special enrollment period for pregnant individuals.

Prevention of Non-Covered Dental Services in Insurance Contracts (A7862A Weprin/S7577A Breslin): This bill prohibits an insurer from including a provision in a contract or participating provider agreement with a dentist that a participating dentist provide services to an insured at a fee set by, or subject to the approval of, the insurer, unless the dental services are covered services under the insured's dental plan.

Prevention of Discrimination against HIV Individuals (A8834B Weprin/S8144C Breslin): This bill prohibits an insurer from refusing to insure, refusing to continue to insure or limiting the amount, extent, or kind of coverage available to an individual or charging a different rate for the same coverage solely because the insured or potential insured was prescribed pre-exposure prophylaxis (PrEP) medication for the prevention of HIV infection.

Coverage of Prenatal Vitamins (A3865A Gunther/S1965A Addabbo): The bill requires health insurance policies that provide coverage for prescription drugs to provide coverage for prenatal vitamins when prescribed by a healthcare practitioner acting within his or her scope of practice. Coverage of prenatal vitamins may be subject to deductible and coinsurance.

Prohibits Prior Authorization for Antiretroviral Drugs (S1001A Hoylman-Siegal/A1619A Rosenthal): This bill prohibits health insurance policies that provide coverage for antiretroviral drugs prescribed for the treatment or prevention of HIV or AIDS from being subject to prior authorization.

Utilization Review Rules when Establishing Step Therapy Protocols (A901A McDonald/S1267A Breslin): This bill establishes new requirements for utilization review agents when establishing a step therapy protocol. The bill provides that step therapy protocols cannot require the use of a prescription drug that has not been approved by the FDA for the medical condition that is being treatment and/or is not supported by current evidence-based guidelines for the medical condition being treated, or require an insured to try and fail on more than two drugs within one therapeutic category.

Coverage of Neuropsychological Testing for Dyslexia (A2898A Carrol/S5481A Hoylman-Sigal): This bill requires health insurance policies to provide coverage for testing for suspected dyslexia, including comprehensive neuropsychological examinations for the purpose of diagnosing dyslexia and determining the psychological, emotional, and educational wellness needs of the individual tested.

Copayments for Physical and Occupational Therapy (S1470 Breslin/A6345 Weprin): This bill prohibits health insurance policies from imposing copayments for physical therapy and occupational therapy services that is greater than the copayment amount imposed on the insured for services provided to the insured for an office visit for the service of a primary care physician or osteopath for the same or similar diagnosed condition, even if a different name is used to describe the condition for which the services are provided.

Pharmacy

Expands Drug Adulterant Testing Supplies (A8525 McDonald/S8061 Harckham): This bill adds xylazine and other substances to the scope of drug adulterant testing supplies under "Matthew's Law," which authorizes pharmacists to dispense drug adulterant testing supplies.

Expansion of "Gag Clause" Prohibition (S9040 Gounardes/A9764 Rosenthal): This bill allows pharmacies to disclose the cost of prescription drugs to the pharmacy and the pharmacy's reimbursement for that prescription drug with a patient. It prohibits pharmacy benefit managers (PBMs) from prohibiting or penalizing a pharmacy from disclosing prescription drug costs and reimbursement rates to a patient.

Mental Health

Routine Maternal Depression Screenings (A2870B Solages/S2039B Brouk): This bill requires the Commissioner of Health to develop and publish guidance and standards for incorporation of maternal depression screenings into routine perinatal and postpartum care. Such guidance and standard requirements include when and how often to conduct screenings; social needs screening; substance use disorders screening; referrals for appropriate follow up; and reimbursement methodologies to incentivize provider participation. DOH is directed to include relevant training resource and include on the department's website.

Peer Service Qualifications (A7395 Darling/S9787 Brouk): This bill authorizes the Commissioner of Mental Health to approve programs to certify and credential mental health peers. It further establishes definitions of Mental Health Peer, Family Peer Advocate, Youth Peer Advocate, New York State Certified Peer Specialist, Credentialed Family Peer Advocate and Credentialed Youth Peer Advocate.

Suicide and Crisis Lifeline and Crisis Text Line Education Campaign (A6563A Clark/S1865B Brouk):This bill requires that an education campaign about the 9-8-8 suicide and crisis lifeline and the crisis text line, be established at institutions of higher education to educate campus communities, including students, faculty, and staff, about when to use the lifeline and text line and to provide contact information for such services for through annual distribution or to include on student identification cards.

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 Nicola Coleman and Binny Seth

1/24/24:

Admission and Discharge Criteria for Psychiatric Inpatient Units of General Hospitals

Notice of Proposed Rule Making. The Office of Mental Health proposed to amend Part 580 of Title 14 N.Y.C.R.R. to standardize admissions and discharges. *See* N.Y. Register January 24, 2024.

Admission and Discharge Criteria for Comprehensive Psychiatric Emergency Programs

Notice of Proposed Rule Making. The Office of Mental Health proposed to amend Part 590 of Title 14 N.Y.C.R.R. to standardize admissions and discharges. *See* N.Y. Register January 24, 2024.

Admission and Discharge Criteria for Hospitals for Persons with Mental Illness

Notice of Proposed Rule Making. The Office of Mental Health proposed to amend Part 582 of Title 14 N.Y.C.R.R. to standardize admissions and discharges. *See* N.Y. Register January 24, 2024.

1/31/24:

Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards for Full and Fair Disclosure, *et al.*

Notice of Proposed Rule Making. The Department of Financial Services proposed to amend Parts 52 (Regulation 62) and 215 (Regulation 34) of Title 11 N.Y.C.R.R. to ensure that accident, hospital indemnity and travel insurance are not misleading and provide substantial economic value. *See* N.Y. Register January 31, 2024.

Medical Respite Program (MRP)

Notice of Adoption. The Department of Health added Part 1007 to Title 10 N.Y.C.R.R. to establish procedures for review and approval of applications from a not-for-profit corporation to be certified as an MRP operator. Filing Date: January 17, 2024. Effective Date: January 31, 2024. *See* N.Y. Register January 31, 2024.

2/7/24:

Credentialing of Addiction Professionals

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 853 of Title 14 N.Y.C.R.R. to add a new credentialing pathway for a "CASAC-Provisional" and modify outdated terminology. Filing Date: January 1, 2024. Effective Date: February 2, 2024. *See* N.Y. Register February 7, 2024.

2/14/24:

Early Intervention Program

Notice of Adoption. The Department of Health amended Subpart 69-4 of Title 10 N.Y.C.R.R. to conform existing program regulations to Federal regulations and State statute, as well as to provide additional clarification. Filing Date: January 29, 2024. Effective Date: April 14, 2024. *See* N.Y. Register February 14, 2024.

Statewide Health Information Network for New York (SHIN-NY)

Notice of Proposed Rule Making. The Department of Health proposed to amend Part 300 of Title 10 N.Y.C.R.R. to establish the State Designated Entity and Enhancing SHIN-NY Efficiency and Flexibility. *See* N.Y. Register February 14, 2024.

2/21/24:

Network Adequacy and Access Standards

Notice of Proposed Rule Making. The Department of Financial Services proposed to add Part 38 (Regulation 230) to Title 11 N.Y.C.R.R. to establish network adequacy and access standards and other protections to improve access to behavioral health services. *See* N.Y. Register February 21, 2024.

General Hospital Emergency Services Behavioral Health

Notice of Proposed Rule Making. The Department of Health proposed to amend Section 405.19 of Title 10 N.Y.C.R.R. hospital emergency departments to establish policies and procedures to identify, assess, and refer patients with behavioral health presentations. *See* N.Y. Register February 21, 2024.

2/28/24:

Trauma Centers – Resources for Optimal Care of the Injured Patient

Notice of Adoption. The Department of Health amended Section 405.45 of Title 10 N.Y.C.R.R. to update the edition of Resources for Optimal Care of the Injured Patient from 2014 to 2022. Filing Date: February 9, 2024. Effective Date: February 28, 2024. *See* N.Y. Register February 28, 2024.

Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements

Notice of Adoption. The Department of Health amended Sections 405.11 and 415.19 of Title 10 N.Y.C.R.R. to ensure that all general hospitals and nursing homes maintain a 60-day supply of PPE. Filing Date: February 9, 2024. Effective Date: February 28, 2024. *See* N.Y. Register February 28, 2024.

3/13/24:

Updated Quality Improvement Committee Requirements

Notice of Adoption. The Department of Health amended Sections 478.10 and 490.10 of Title 18 N.Y.C.R.R. to update quality improvement committee requirements of adult homes and residences for adults. Filing Date: February 23, 2024. Effective Date: March 13, 2024. *See* N.Y. Register March 13, 2024.

Relating to Residential Treatment Facilities (RTF)

Notice of Proposed Rule Making. The Office of Mental Health proposed to repeal Part 583, add Part 583 and amend Part 584 of Title 14 N.Y.C.R.R. to provide clarity and provide uniformity relating to RTF's and to implement Chapter 58 of the Laws of 2020. *See* N.Y. Register March 13, 2024.

3/20/24:

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 amended Part 52 (Regulation 62) of Title 11 N.Y.C.R.R. for the preservation of general welfare. Filing Date: March 5, 2024. Effective Date: March 5, 2024. *See* N.Y. Register March 20, 2024.

Standards for Tissue Banks and Nontransplant Anatomic Banks

Notice of Adoption. The Department of Health amended Part 52 of Title 10 N.Y.C.R.R. to remove discriminatory requirements pertaining to reproductive tissue and make technical corrections. Filing Date: March 5, 2024. Effective Date: March 20, 2024. *See* N.Y. Register March 20, 2024.

Adult Day Health Care

Notice of Adoption. The Department of Health amended Part 425 of Title 10 N.Y.C.R.R. to regulate adult day health care programs for registrants with medical needs in a non-residential health care facility. Filing Date: March 5, 2024. Effective Date: March 20, 2024. *See* N.Y. Register March 20, 2024.

Exemption of Earned Income and Public Assistance (PA) and Supplemental Nutrition Assistance Program (SNAP) Employment Program Requirements Updates

Notice of Proposed Rule Making. The Office of Temporary and Disability Assistance proposed to amend Section and Part 385 of Title 18 N.Y.C.R.R. to update State regulations pertaining to exemption of earned income and PA and SNAP employment program requirements consistent with updated Federal and State laws. *See* N.Y. Register March 20, 2024.

3/27/24:

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

Notice of Proposed Rule Making. The Department of Financial Services proposed to amend Parts 450, 452, 454 (Regulations 219, 222 and 224) and add Parts 456, 457, 458 and 459 (Regulations 226, 227, 228 and 229) to Title 11 N.Y.C.R.R. to establish definitions, licensing, contracting with pharmacies, acquisition of PBMs, consumer protections and audit regulations. *See* N.Y. Register March 27, 2024.

Notice of Expiration

The following notice has expired and cannot be reconsidered unless the Office for People with Developmental Disabilities publishes a new notice of proposed rulemaking:

The Office for People with Developmental Disabilities, General Purposes and Certification of the Facility Class Known as Individualized Residential Alternatives, I.D. No. PDD-10-23-00002-EP. Proposed on March 8, 2023. Expired on March 7, 2024. *See* N.Y. Register March 27, 2024.

4/3/24:

Enterprise Risk Management and Own Risk and Solvency Assessment; Group-Wide Supervision

Notice of Proposed Rule Making. The Department of Financial Services proposed to amend Part 82 (Regulation 203) of Title 11 N.Y.C.R.R. to implement Chapter 344 of the Laws of 2023, which imposed an annual group capital calculation (GCC) filing requirement. *See* N.Y. Register April 3, 2024.

Lead Testing in School Drinking Water

Notice of Adoption. The Department of Health amended Part 67-4 of Title 10 N.Y.C.R.R. to lower the action level for lead in school drinking water from 15 parts per billion (ppb) to 5 ppb and revise reporting requirements. Filing Date: March 14, 2024. Effective Date: April 3, 2024. *See* N.Y. Register April 3, 2024.

Long Term Care Ombudsman Program

Notice of Adoption. The Department of Health amended sections 405.28 and 411.1 of Title 10 N.Y.C.R.R. and section 485.13 of Title 18 N.Y.C.R.R. to clarify language relative to access by the long-term care ombudsmen and adding reference to section 218 of Elder Law. Filing Date: March 18, 2024. Effective Date: April 3, 2024. *See* N.Y. Register April 3, 2024.

4/10/24:

Ionizing Radiation

Notice of Proposed Rule Making. The Department of Health proposed to repeal of Part 16 and add a new Part 16 to Title 10 N.Y.C.R.R. to be compatible with federal standards and modernization to reflect current technology. *See* N.Y. Register April 10, 2024.

Prior Approval Review Process

Notice of Proposed Rule Making. The Office of Mental Health proposed to repeal Part 551 and add a new Part 511 to Title 14 N.Y.C.R.R. to update the Prior Approval Review Process. *See* N.Y. Register April 10, 2024.

4/17/24:

Newborn Hearing Screening

Notice of Adoption. The Department of Health amended Subpart 69-8 of Title 10 N.Y.C.R.R. to improve follow-up after newborn hearing screening and articulate reporting requirements. Filing Date: April 2, 2024. Effective Date: April 17, 2024. *See* N.Y. Register April 17, 2024.

Assisted Living Residences

Notice of Adoption. The Department of Health amended 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. Filing Date: March 28, 2024. Effective Date: April 17, 2024. *See* N.Y. Register April 17, 2024.

Clarify Reimbursement Methodologies

Notice of Proposed Rule Making. The Office of Mental Health proposed to amend Part 588 of Title 14 N.Y.C.R.R. to clarify reimbursement methodologies. *See* N.Y. Register April 17, 2024.

4/24/24:

Credit For Reinsurance

Notice of Proposed Rule Making. The Department of Financial Services proposed to amend Part 125 (Regulation 17, 20, 20-A) of Title 11 N.Y.C.R.R. to prescribe the collateral requirements for reinsurance reserve credit. *See* N.Y. Register April 24, 2024.

Expanded Syringe Access Programs (ESAPs)

Notice of Adoption. The Department of Health amended section 80.137 of Title 10 N.Y.C.R.R. to remove the requirement that ESAPs may only furnish a quantity of 10 or fewer syringes at a time. Filing Date: April 8, 2024. Effective Date: April 24, 2024. *See* N.Y. Register April 24, 2024.

5/1/24:

General Hospital Medical Staff Recertification

Notice of Adoption. The Department of Health amended sections 405.4 and 405.6 of Title 10 N.Y.C.R.R. to change the medical staff recredentialing timeframe from every two years to every three years. Filing Date: April 11, 2024. Effective Date: May 1, 2024. *See* N.Y. Register May 1, 2024.

Provide Programs the Flexibility in the Provisions of Both Medical and Mental Health Services

Notice of Proposed Rule Making. The Office of Mental Health proposed to amend Part 599 of Title 14 N.Y.C.R.R. to raise the limitation on the total number of annual visits for which a program licensed solely under Article 31 may provide. *See* N.Y. Register May 1, 2024.

5/8/24:

Reproductive Health Care Standards

Notice of Proposed Rule Making. The Department of Health proposed to amend Part 12 of Title 10 and section 505.2(e) of Title 18 N.Y.C.R.R. for reconciliation with article 25-a of the Public Health Law and alignment with evidence-based clinical guidelines. *See* N.Y. Register May 8, 2024.

Adult Home Admission and Reporting Requirements

Notice of Proposed Rule Making. The Department of Health proposed to amend sections 487.4 and 487.10 of Title 18 N.Y.C.R.R. to clarify the pre-admission screening process and strengthen the reporting of residents with serious mental illness diagnoses. *See* N.Y. Register May 8, 2024.

5/15/24:

In-Person Medical Evaluation Requirements and Exceptions for Controlled Substance Prescribing

Notice of Proposed Rule Making. The Department of Health proposed to amend sections 80.62, 80.63 and 80.84 of Title 10 N.Y.C.R.R. to clarify patient evaluation requirements with regards to the issuance of a controlled substance prescription. *See* N.Y. Register May 15, 2024.

Hospital Cybersecurity Requirements

Notice of Revised Rule Making. The Department of Health proposed to add section 405.46 to Title 10 N.Y.C.R.R. to create cybersecurity program requirements at all Article 28 regulated facilities. *See* N.Y. Register May 15, 2024.

Clinical Review Criteria

Notice of Adoption. The Office of Mental Health amended Part 514 of Title 14 N.Y.C.R.R. to adopt standards and processes to obtain and approve clinical review criteria. Filing Date: April 29, 2024. Effective Date: May 15, 2024. *See* N.Y. Register May 15, 2024.

5/22/24:

Notice of Expiration

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

The Department of Health, Update Standards for Adult Homes and Standards for Enriched Housing Programs, I.D. No. HLT-18-23-00013-P. Proposed on May 3, 2023. Expired on May 2, 2024. *See* N.Y. Register May 22, 2024.

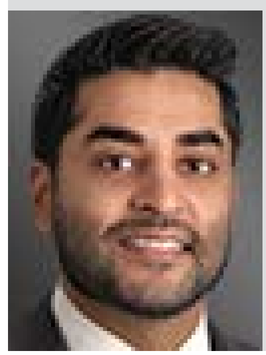
6/5/24:

Educational Requirements for Certified Emergency Medical Services Providers

Notice of Adoption. The Department of Health amended Part 800 of Title 10 N.Y.C.R.R. to improve the overall educational and certification experience that will ease barriers to recruitment of individuals. Filing Date: May 20, 2024. Effective Date: June 5, 2024. *See* N.Y. Register June 5, 2024.

Disease Outbreak Investigation and Response Clarifications

Notice of Proposed Rule Making. The Department of Health proposed to amend section 2.6 of Title 10 N.Y.C.R.R. to authorize NYSDOH to provide flexibilities to Local Health Departments (LHDs) to prioritize reportable diseases that need to be fully investigated. *See* N.Y. Register June 5, 2024.



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

New York State Fraud, Abuse and Compliance Developments

Edited by Margaret M. Surowka

New York State Department of Health Medicaid Decisions

Compiled by Ron L. Oakes

National Seating & Mobility, Inc. (Decision After Hearing, May 6, 2024, John Harris Terepka, ALJ)

Appellant is a durable medical equipment (DME) and medical/surgical supplies provider. In December of 2020, the New York State Office of the Medicaid Inspector General (OMIG) initiated an audit of the claims submitted by appellant for the calendar years 2015 through 2017. A random sample of 160 of the 1,586 claims appellant submitted during the audit period were reviewed and OMIG identified one or more errors in 113 of the claims, resulting in a disallowance of $142,645.64, which was extrapolated to $270,804. The final audit report included findings and disallowances in five categories, but only one category was in dispute at hearing: "Original signed follow order not received within 30 calendar days." This finding applied to 110 claims and resulted in disallowances in the amount of $141,130.09. In each of these cases, OMIG determined that an original signed follow-up order to a non-serialized official prescription form for a telephoned or faxed order was not received within 30 calendar days.

At hearing, appellant's three initial assertions regarding the validity of the audit were each summarily rejected by Administrative Law Judge (ALJ) Terepka. First, appellant asserted that the audit was untimely and prejudicial. This argument was rejected by the ALJ as appellant failed to present any credible evidence that it was prejudiced by any unreasonable delay. Second, appellant's assertion that the final audit report was facially deficient because it failed to discuss the electronically transmitted fiscal order policy was rejected based on ALJ Terepka's determination that the final audit report complied with OMIG's regulatory obligation to advise appellant of the basis for the audit findings. *See* 18 N.Y.C.R.R. § 517.6. Finally, appellant's third argument that OMIG could not recover restitution of payments for documentation issues was rejected by the ALJ as appellant was required to maintain and produce contemporaneous records demonstrating appellant's entitlement to payment. *See* 18 N.Y.C.R.R. §§ 504.3(a); 517.3(b); 518.1(c).

The main issue presented at hearing was whether the disallowed fiscal orders met the documentation requirements applicable to electronically transmitted fiscal orders. As relevant to the issues presented at hearing, appellant utilized a process wherein appellant generated an order template which was sent to the practitioner by fax or efax for review. The ordering practitioner would print, sign, and date the order, and add handwritten comments, corrections, or notations to the order, if needed. The hand-signed and dated paper order would then be faxed or efaxed back to appellant. Appellant did not subsequently obtain the original version of the template form that had been signed, dated, and sent back to appellant.

In response to the draft audit report, appellant argued that the fiscal orders were original signed fiscal orders, which were created on the ordering practitioners' computers and, after signing their names, were transmitted to appellant. At hearing, the ALJ determined that these assertions were neither accurate nor consistent with the evidence presented. The ALJ also noted that none of the orders were signed electronically by the provider (rather than by hand on paper) and none of the orders showed any indication that they were transmitted to appellant by any other way than fax or efax. Based on a review of appellant's fiscal order process, ALJ Terepka determined that the orders appellant produced were not original signed orders, were not created by the ordering practitioners on their computers, and were not signed electronically or via scanned signature.

Appellant also argued that the paper orders which were printed, signed, scanned, and efaxed constituted electronically transmitted fiscal orders, and that these orders "originated from the practitioner's computer" because they were scanned into the practitioner's computer before being transmitted to appellant. ALJ Terepka rejected this argument relying on testimony from an OMIG audit supervisor, who testified that only a fiscal order where the provider's signature has been affixed electronically by the Electronic Health Record (EHR) system is considered an electronically transmitted fiscal order.

Next, appellant argued that its email-to-fax system converted emails from ordering practitioners into fax transmissions, but that the orders attached to those emails were electronically transmitted fiscal orders since they were generated from the practitioner's computer and sent directly to appellant's computer or fax. According to the ALJ, regardless of whether the order was sent by fax or email, a paper order that was signed by hand and then scanned and sent as an email attachment or through fax was not an electronically transmitted fiscal order. ALJ Terepka also determined that the orders at issue were generated by appellant, not the ordering practitioners, as evidenced by the fact that appellant's header was on the orders, and that appellant offered no evidence that the ordering practitioners were using any email-to-fax system or an EHR system that was in compliance with the requirements for electronic protected health information set out in the Health Insurance Portability and Accountability Act (HIPAA), as required by the DME fiscal order process. The ALJ also rejected appellant's argument that the meaning of "originating from the ordering practitioner's computer" was unclear and found that "originate from the practitioner's computer" meant created and signed on the practitioner's computer with an electronic or facsimile signature added on the computer, for which no paper copy is necessary nor does a paper copy ever even exist to be produced for audit.

Appellant's argument that the auditors did not apply a consistent standard to the audit was also rejected by the ALJ. Specifically, the OMIG auditors did allow fiscal orders that had a header which indicated that the orders were transmitted through an EHR system and where the signature and date on the order were clearly affixed electronically by the EHR. Electronically signed orders for which OMIG could not be 100% confident that there was a paper original were also accepted. ALJ Terepka determined that this documentation was demonstrably different than the documentation that was rejected by OMIG and concluded that it reflected consistency in the audit findings. Finally, appellant's argument that later versions of the DME Policy Manual would allow appellant's practices regarding orders was also rejected by the ALJ as the appellant was not entitled to rely on a version of the Policy Manual that did not exist during the audit period.

Based on the information presented at hearing, the ALJ concluded that appellant failed to meet its burden of establishing entitlement to the payments at issue, and the disallowance in the amount of $142,645.64 was affirmed.

Beth Abraham Center for Rehabilitation & Nursing (Decision After Hearing, March 22, 2024, John Harris Terepka, ALJ)

Appellant is a residential health care facility (RHCF) located in Bronx, New York. OMIG reviewed appellant's documentation in support of its Minimum Data Set (MDS) submissions for the census period ending on January 25, 2017. The MDS submissions under review were those used to calculate appellant's Medicaid program reimbursement rate for the period of July 1, 2017 through December 31, 2017. Following the audit, OMIG determined that the Resource Utilization Group (RUG) categories assigned to six patients were not accurate, but only one was in dispute at hearing. Specifically, OMIG determined that the medical basis and specific need for occupational therapy during the week before the assessment review date (ARD) for Sample 3 were not fully and properly documented because there was no documentation of any reason why the resident was evaluated for therapy. After adjusting the RUG categories, OMIG recalculated appellant's Medicaid reimbursement rate, resulting in $77,915.06 in overpayments.

At hearing, the issue before ALJ Terepka was whether appellant established that OMIG's determination to recover overpayments attributable to the disallowance of occupational therapy reported for Sample 3 was not correct. As relevant to the audit, the MDS is among the reports that are used to determine a RHCF's Medicaid reimbursement rate. MDS information is submitted to the Department of Health's Bureau of Long-Term Care Reimbursement (BLTCR), which uses the MDS data to classify residents into a RUG classification in order to calculate a nursing home's "case mix index" (CMI). A facility's CMI is adjusted in July and January of each year for a six-month rate period. *See* 10 N.Y.C.R.R. §§ 86-2.10(a)(5), (c); 86-2.37; 86-2.4(m)(6). A higher average case mix index for a RHCF's residents results in a higher rate of Medicaid program reimbursement during that six-month period. *See Elcor Health Servs. Inc. v. Novello*, 100 N.Y.2d 273 (2003). The MDS requires RHCFs to make a comprehensive assessment of residents' needs using the Resident Assessment Instrument (RAI) according to requirements detailed in the Centers for Medicare and Medicaid Services' (CMS) Long-Term Care Facility Resident Assessment Instrument Manual (CMSRAI Manual). *See* 42 CFR § 483.20; *see also* 10 N.Y.C.R.R. §§ 86-2.37; 415.11. Based on the coding rules set out in the CMSRAI Manual, occupational therapy is reported by the number of minutes of therapy provided during the seven-day lookback period from the ARD. A resident who receives therapy during the lookback period will be coded in a RUG category with a higher CMI number.

In his decision, ALJ Terepka noted that whether the occupational therapy that was reported for Sample 3 during the look back period was documented in compliance with requirements turned on the interpretation of "medically necessary therapies." According to the CMSRAI Manual, the responsibility for determining the need for therapy lies with the qualified therapist, in conjunction with the physician and nursing administration. At hearing, OMIG asserted that because appellant did not produce supportive nursing documentation, the occupational therapist's recommendation and physician order for six weeks of occupational therapy, by themselves, were insufficient to show why the resident was evaluated. Appellant argued that OMIG's audit staff were not qualified to second guess the recommendation and order and, as such, the recommendation and order must be accepted. ALJ Terepka rejected this argument, noting that "therapy must have some reason and must be based on some documented information about the resident to substantiate the need for it to be given during the look back period." *See* Decision at 9. The ALJ further noted that courts have upheld OMIG's interpretation and have required documentation beyond a therapist's recommendation and physician order. *See Elderwood at Cheektowaga v. Zucker*, 188 A.D.3d 1578, 136 N.Y.S.3d 581 (4th Dept. 2020); *Elderwood at Amherst v. Zucker*, 188 A.D.3d 1568, 134 N.Y.S.3d 591 (4th Dept. 2020); *Elderwood at Grand Island v. Zucker*, 188 A.D.3d 1580, 135 N.Y.S.3d 208 (4th Dept. 2020), *lv. denied*, 36 N.Y.3d 910, 142 N.Y.S.3d 477 (2021).

At hearing, the OMIG auditor conceded that evidence of a decline within the resident's record would have been sufficient to support a finding of need. In response, appellant argued that a decline is not required by regulation to justify therapy. ALJ Terepka agreed with appellant, but distinguished documentation of a decline from the requirement to document medical necessity. The ALJ concluded that OMIG correctly determined that appellant had not fully and properly documented the medical need for occupational therapy at the time it was ordered.

The ALJ noted that "reasonable and documented improvement from therapy may also be sufficient" and pointed out that OMIG did not address appellant's documentation up to and including the look back week. *See* Decision at 10. After ten treatments, the therapy progress note documenting the look back period demonstrated that the resident had significant improvements in bed mobility, self-care dressing, self-care hygiene/grooming, and transfers. ALJ Terepka then dismissed OMIG's allegation of conflicting documentation regarding the resident's cognitive status as irrelevant to the disallowance.

Based on the information presented at hearing, the ALJ held that appellant's documentation for the week under review substantiated that occupational therapy was reasonable and necessary for the treatment of the resident's condition during the look back period, and reversed OMIG's determination to correct the RUG category for Sample 3.

New York State Attorney General Press Releases

Compiled by Dena M. DeFazio, AbiDemi M. Donovan, and Amanda N. Rhodes

Attorney General James Wins Trial Against Quincy Bioscience for Deceptive and Fraudulent Advertising of "Memory Improvement" Supplemental Prevagen—May 8, 2024—A Manhattan federal judge accepted a jury's finding of liability in a suit brought by the New York State Office of the Attorney General (OAG) against Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC (collectively, Quincy), and four corporate defendants for violations of New York's consumer protection laws. The suit alleged that the defendants made fraudulent and deceptive statements about the supplemental Prevagen—which derives its active ingredient from a protein that makes jellyfish glow—including advertising the supplement as a way to reduce memory problems, improve memory, and support cognitive health. Following a two week trial, a jury concluded that Quincy failed to substantiate any of its claims about Prevagen with reliable scientific evidence, that some of its claims about the supplement were materially misleading, and that all of its claims had the tendency to deceive and constitute fraud under Section 63(12) of the Executive Law. The evidence presented by the OAG at trial included expert and other testimony on the flaws in Quincy's clinical trial for Prevagen, and documents which admitted that Prevagen is quickly digested and unlikely to reach the brain. Based on the evidence presented, the jury found Quincy liable for deceptive acts and practices, false advertising, and repeated and persistent fraud about Prevagen. With the jury verdict having been accepted, the OAG will seek a permanent injunction blocking Quincy from continuing to make deceptive statements in the sale of its product and will seek monetary relief. In addition to the OAG, the Federal Trade Commission (FTC) assisted in the trial and will have its claims determined separately by the U.S. district court for the Southern District of New York.

https://ag.ny.gov/press-release/2024/attorney-general-james-wins-trial-against-quincy-bioscience-deceptive-and

Attorney General James Sues Anti-Abortion Group and 11 New York Crisis Pregnancy Centers for Promoting Unproven Abortion Reversal Treatment—May 6, 2024—The OAG has sued Heartbeat International, Inc. (Heartbeat), an anti-abortion group, and 11 "pro-life pregnancy organizations" (also known as crisis pregnancy centers) throughout New York. The suit alleges that Heartbeat and the other 11 organizations use false and misleading statements to advertise an unproven treatment they call "Abortion Pill Reversal" (APR). APR involves the administration of repeated doses of progesterone to a pregnant person who has taken mifepristone but has not yet taken misoprostol. The groups advertise APR as a safe and effective treatment that can reverse medication abortions, but according to the OAG, there is a lack of scientific evidence to support the safety and effectiveness of APR. To this end, the only clinical trial which has been conducted to evaluate APR was stopped due to concerns regarding patient safety, it is not an accepted mainstream medical practice, and major medical associations, such as the American College of Obstetricians and Gynecologists (ACOG), have cautioned against APR due to the lack of scientific backing and the failure to meet clinical standards. Despite these health and safety concerns, the OAG has alleged that the defendant organizations advertise APR as a treatment which reverses the effects of taking medication abortion. The suit filed by the OAG alleges that the organizations are using false and misleading claims about APR to convince pregnant people to receive the treatment constitutes fraud, deceptive business practices, and false advertising under New York law—including Section 63(12) of the Executive Law and Sections 349 and 350 of the General Business Law—and seeks an order requiring all false and misleading claims about APR's safety and effectiveness to be removed from marketing materials and prohibiting further violations, as well as the payment of civil penalties for violations of applicable laws.

https://ag.ny.gov/press-release/2024/attorney-general-james-sues-anti-abortion-group-and-11-new-york-crisis-pregnancy

Attorney General James Secures Over $270 Million Multistate Settlement in Principle with Amneal Pharmaceuticals for Its Role in the Opioid Crisis—May 3, 2024—Attorney General (AG) Letitia James announced a multistate settlement in principle with Amneal Pharmaceuticals (Amneal) for its role in the nationwide opioid epidemic. Amneal is an opioid manufacturer which produces several generic opioid products and was one of the largest opioid manufacturers from 2006 to 2019, having sold nearly nine billion pills. The settlement stemmed from a suit filed by the OAG and a multistate coalition of attorneys general alleging that Amneal knowingly failed to monitor and report suspicious orders placed by customers, as required under federal law. Through the settlement in principle, which was negotiated by AG James and the attorneys general of California, Delaware, Tennessee, Utah, and Virginia, participating states and local governments will receive $92.5 million in cash over ten years and $180 million worth of naloxone nasal spray, an overdose treatment medication.

https://ag.ny.gov/press-release/2024/attorney-general-james-secures-over-270-million-multistate-settlement-principle

Attorney General James Urges UnitedHealth Group to Help Patients and Providers Harmed by Cyberattack—April 29, 2024—AG James joined a multistate, bipartisan coalition of 22 attorneys general urging UnitedHealth Group, Inc. (United) to better protect those harmed by the cyberattack on United's subsidiary, Change Healthcare. United is the United States' largest insurer and Change Healthcare, which was acquired by United in 2022, runs the country's largest electronic health care payment system. A cyberattack on Change Healthcare in February of 2024 by ALPHV/Blackcat, a cybercriminal group, crippled the company's platform and disrupted health care providers' networks, leaving providers, pharmacies, and health care facilities throughout the nation unable to verify insurance coverage, obtain prior authorizations for health care services, process claims, or obtain reimbursements for patients. The disruption has also caused harm to patients, including delays in access to care, inability to access prescription drugs, and difficulty scheduling appointments or procedures. The bipartisan coalition's letter to United urges it to act quickly to limit the harm to health care providers and patients, improve transparency about the cyberattack, quickly resolve backlogged claims, and take additional steps to protect patient data.

https://ag.ny.gov/press-release/2024/attorney-general-james-urges-unitedhealth-group-help-patients-and-providers

Attorney General James Releases Statement on St. Peter's Health Partners' Decision to Stop Plans to Close the Burdett Birth Center—April 29, 2024—St. Peter's Health Partners no longer plans to close the Burdett Birth Center at Samaritan Hospital of Troy. Due to the fact that the Burdett Birth Center is the only maternity center in Rensselaer County, the previous announcement of its planned closure caused concern within the community. St. Peter's Health Partners' decision to keep the Burdett Birth Center open came after the OAG held a public hearing to discuss the impact the potential closure would have on the Capital Region of New York. AG James released a statement in response to the decision, applauding the news but stating she would keep monitoring the situation and take action if warranted.

https://ag.ny.gov/press-release/2024/attorney-general-james-releases-statement-st-peters-health-partners-decision

Attorney General James Calls on Congress to Expand Access to IVF and Other Reproductive Health Services—April 24, 2024—AG James and 20 other attorneys general wrote a letter to Congress to request the passage of the Access to Family Building Act. The bill would guarantee the right to access assisted reproductive technology (ART) across the country. ART, which includes services like in-vitro fertilization (IVF), provides people with the opportunity to grow their families; however, ART services are costly and often not covered by insurance. The coalition of attorneys general seeks federal protections for patients' reproductive health care rights after a recent Alabama Supreme Court decision, *Le Page v. Center for Reproductive Medicine, P.C.*, where the Alabama Supreme Court ruled that frozen embryos used in IVF are considered "extrauterine children," and subjecting the destruction of such embryos to the state's Wrongful Death of a Minor Act. The decision caused IVF clinics across the state to close their doors, jeopardizing access to IVF services within Alabama, along with the right of individuals to make their own reproductive healthcare decisions.

https://ag.ny.gov/press-release/2024/attorney-general-james-calls-congress-expand-access-ivf-and-other-reproductive

Attorney General James Secures More Than $1 Million from Northwell Health for Deceptively Advertising COVID-19 Testing Sites—April 12, 2024—AG James announced that the OAG reached an agreement with Northwell Health to resolve allegations that patients were receiving bills with charges for emergency room visits, despite only taking a COVID-19 test. An investigation by the OAG found that three Northwell Health locations with emergency departments advertised themselves as COVID-19 testing locations, while billing hundreds of patients for emergency room visits. The OAG found that Northwell Health collected $81,761.46 in payments for COVID-19 tests and related services, in violation of state and federal laws prohibiting cost sharing for such services. Pursuant to the settlement agreement, Northwell Health returned $400,169.29 to patients that were wrongfully charged. The agreement also requires Northwell Health to pay the state $650,000 in penalties and notify patients seeking COVID-19 testing at an emergency department that they will be charged for an emergency room visit.

https://ag.ny.gov/press-release/2024/attorney-general-james-secures-more-1-million-northwell-health-deceptively

Attorney General James Takes Action to Protect Access to Emergency Abortion Care—March 29, 2024—AG James co-led a coalition of 24 attorneys general in filing an amicus brief in the U.S. Supreme Court. The brief, filed in *Idaho v. U.S.* and *Moyle v. U.S.*, asks the court to affirm a preliminary injunction against enforcement of Idaho's abortion ban. The preliminary injunction required Idaho hospitals to provide emergency abortion care in compliance with the Emergency Medical Treatment and Labor Act (EMTALA). EMTALA is applicable to hospitals with emergency departments that participate in the Medicare program and requires emergency rooms to provide treatment for emergency medical conditions to stabilize the patient's condition. The administration of abortion care is considered emergency care under EMTALA. Idaho's abortion ban criminalizes abortion care in most situations, including when an abortion is necessary to prevent serious harm to a pregnant patient's health. In the brief, the coalition argued that the denial of emergency abortion care endangers the lives of pregnant patients.

https://ag.ny.gov/press-release/2024/attorney-general-james-takes-action-protect-access-emergency-abortion-care

Attorney General James Secures $8.6 Million and Significant Reforms to Long Island Nursing Home after Repeated Financial Fraud and Resident Mistreatment—March 4, 2024—AG James announced that the OAG reached a settlement agreement with Fulton Commons Care Center, Inc. (Fulton Commons) related to allegations that Fulton Commons committed financial fraud and mistreated residents for years. An investigation into the nursing home by the OAG found evidence of resident neglect, abuse, and mistreatment. Due to insufficient staffing, residents lived in poor conditions and suffered unexplained bruising, cuts, and other injuries, and staff failed to administer medication or assist with basic tasks such as clothing changes and trips to the bathroom. Fulton Commons also covered up reports of sexual assault against residents, which resulted in a guilty plea and sentencing of Fulton Commons for criminal acts related to the cover ups, including a $5,000 fine. The OAG investigation also uncovered financial fraud by Fulton Commons' owners, including two financial schemes to divert money intended for patient care to themselves. The schemes involved fraudulent inflated rental payments and fraudulent salaries. The settlement agreement requires Fulton Commons to appoint an Independent Healthcare Monitor to oversee the nursing home's operations, an Independent Financial Monitor to oversee its finances, and a Chief Compliance Officer to ensure that the recommendations of the Independent Healthcare Monitor are implemented. The agreement also requires Fulton Commons to pay back $1.5 million in Medicaid and Medicare funds, pay $100,000 to the OAG to reimburse the investigation costs, and pay between $6 million and $7 million to create a Resident Care Fund, which would cover the costs of improvements recommended by the Independent Healthcare Monitor.

https://ag.ny.gov/press-release/2024/attorney-general-james-secures-86-million-and-significant-reforms-long-island

Attorney General James Calls for Urgent Action to Protect Children from Harmful Effects of Asthma and Allergy Drug Singulair—February 22, 2024—AG James issued a letter calling on the U.S. Food and Drug Administration (FDA) to urgently adopt more stringent and clearer warnings about the potential harmful side effects the asthma and allergy drug, montekulast—known by the brand name Singulair—may cause in children. Multiple studies have shown that the commonly prescribed drug is correlated with the development of severe neuropsychiatric disorders in children, including aggression, depression, and suicide. Among other measures, the letter urged the FDA to issue a new Drug Safety Communication about the drug's potential harm to children under the age of 18, further evaluate whether Singulair's risks outweigh any therapeutic benefit, and to send a Dear Health Care Provider letter to physicians, pharmacists, and other providers urging them to consider other FDA-approved medications for asthma or allergic rhinitis in pediatric patients.

https://ag.ny.gov/press-release/2024/attorney-general-james-calls-urgent-action-protect-children-harmful-effects

Attorney General James Secures Full Refunds for New Yorkers Wrongfully Charged for COVID-19 Vaccines—February 12, 2024—The OAG reached an agreement with Northwell Health-GoHealth Urgent Care (Northwell-GoHealth) and secured refunds for patients who were charged a total of nearly $15,000 in improper fees to obtain COVID-19 vaccines from the clinics. The AG's investigation revealed that Northwell-GoHealth, which operates 57 urgent care clinics in the state, improperly charged as many as 731 New Yorkers $28 per dose for COVID-19 vaccines. Under the Centers for Disease Control (CDC) Provider Agreement regarding COVID-19 vaccine distribution, healthcare providers were required to administer vaccines at no out-of-pocket cost to the patient. Under the agreement, Northwell-GoHealth has been assessed a $25,000 penalty, refunded payments to all patients or guarantors who were improperly charged, and is expected to take further action to strength their billing practices to prevent reoccurrence.

https://ag.ny.gov/press-release/2024/attorney-general-james-secures-full-refunds-new-yorkers-wrongfully-charged-covid

Attorney General James Secures $350 Million from Publicis for its Role in the Opioid Crisis—February 1, 2024—AG James co-led a coalition of every attorney general in the United States to secure a $350 million settlement from Publicis Health, LLC (Publicis) for its role in the opioid crisis. New York is expected to receive $19,176,750.60, which will be used to fund opioid abatement, treatment, and prevention. Publicis was largely responsible for the massive marketing and advertising campaign relied upon by Purdue Pharma and others to promote OxyContin as safe from the risk of abuse, despite the falsity of the claim. The company was similarly instrumental in targeting healthcare providers to increase OxyContin prescriptions, and deceptively expand opioid usage to patients for whom it was neither medically necessary nor appropriate. The settlement prohibits Publicis from accepting any future contracts or engagements related to the marketing or sale of opioids and requires the company to release internal communications detailing its work with opioid manufacturers for the purpose of public disclosure.

https://ag.ny.gov/press-release/2024/attorney-general-james-secures-350-million-publicis-its-role-opioid-crisis

Attorney General James Secures $150 Million Multistate Settlement in Principle with Hikma Pharmaceuticals to Help Combat Opioid Crisis—February 1, 2024—A $150 million multistate settlement in principle has been reached with opioid manufacturer, Hikma Pharmaceuticals (Hikma), for its role in the opioid crisis. Between 2006 and 2021, Hikma allegedly failed to monitor and report suspicious opioid orders from potentially illegal distributors. The settlement in principle further requires Hikma to provide $35 million worth of opioid addiction treatment medication to participating states and localities.

https://ag.ny.gov/press-release/2024/attorney-general-james-secures-150-million-multistate-settlement-principle-hikma

Attorney General James Takes Action to Protect Medication Abortion Access—January 31, 2024—AG James co-led a multistate coalition of 24 attorneys general seeking to protect access to medication abortion nationwide. In a recent decision in *Food and Drug Administration v. Alliance for Hippocratic Medicine and Danco Laboratories LLC v. Alliance for Hippocratic Medicine*, the Fifth Circuit reinstated certain restrictions on mifepristone, the sole medication approved by the FDA for abortion care, despite the FDA's determination that the restrictions were medically unnecessary. The coalition filed an amicus brief with the U.S. Supreme Court supporting the efforts of the FDA and Danco Laboratories LLC to reverse said restrictions. AG James and the coalition argued that if the restrictions are permitted to take effect, it would disrupt access to the most common method of abortion and in turn cause widespread disruptions to the health care system in New York and other states, ultimately depriving many individuals of reproductive health care altogether. The Supreme Court's decision is expected in June of 2024.

https://ag.ny.gov/press-release/2024/attorney-general-james-takes-action-protect-medication-abortion-access

New York State Office of the Medicaid Inspector General Update

Compiled by Dena M. DeFazio

OMIG Assists State Attorney General in Holding Long Island Nursing Home Accountable for Financial Fraud, Resident Mistreatment—March 6, 2024—https://omig.ny.gov/news/2024/omig-assists-state-attorney-general-holding-long-island-nursing-home-accountable.

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 and James Lauria

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

A Loophole in the Fourth Amendment: The Government's Unregulated Purchase of Intimate Health Data, Rhea Bhatia, 98 Wash L Rev Online 67 (2024).

Addressing Mental Health in Young Adults: A Modern Approach Compared to Previous Generations, Breeha Shah, 25 DePaul J. Health Care L. 3 (2024).

Advanced Practice Nurse Liability in an Age of Increased Independence, Jesse Klein, 57 UIC L. Rev. 891 (2024).

Ain't No Sunshine: Bringing Physician Conflicts Out of the Dark, Jacob T. Elberg, 58 U. Rich. L. Rev. 285 (2024).

Avoiding the Medical Malpractice Money Pit, James H. Dawdy, 112 Ill. B.J. 34 (2024).

Combating Online Medical Misinformation by Physicians: Expansion of Fiduciary Duty of Care, Winnie Zhong, 76 Fed. Comms. L.J. 373 (2024).

COVID-19 Tort Reform, Clayton J. Masterman, 34 Health Matrix 133 (2024).

Crisis Standards of Care and Triage: Medico-Legal Conundrums, George P. Smith, 128 Penn St. L. Rev. 751 (2024).

Don't Swab Me! Limitations of the Genetic Information Privacy Act in the Modern Genetic Testing Landscape, 54 N.M. L. Rev. 265 (2024).

Empirically Assessing Medical Device Innovation, George Horvath 25 Minn. J.L. Sci. & Tech. 73 (2024).

Feminism Without Roe, Natalia Niedmann Álvarez, 27 J. Gender Race & Just. 251 (2024).

Find a 'Rational Relation': Balancing Whistleblower Incentives and DOJ Discretion Under the False Claims Act, Denisa Zobeideh, 73 DePaul L. Rev. 1231 (2024).

From Pixels to Prescriptions: The Case for National Telehealth Licensing & AI-Enhanced Care, Fazal Khan, MD-JD, 57 Ind L Rev 581 (2024).

Gene Patents: Striking the Right Balance Between Incentive and Innovation, Josh Saul, 92 Fordham L. Rev. 2765 (2024).

Global Regulation of the Organ Trade: Implementing a Multi-Layered Approach to Decrease the Demand for Illegal Organ Transplantation, Anna Johnson, 16 U. St. Thomas J. L. & Pub. Pol'y 860 (2024).

How Bodily Autonomy Can Fail Against Vaccination Mandates; The Few vs. The Many, Jason Yadhram, 37 J.L. & Health 127 (2024).

Jail and Prison Suicides in Massachusetts, Jennifer Honig, 104 Mass. L. Rev. 101 (2024).

Medical Research Without Consent? It's like Déjà Vu All Over Again, Lois Shepherd, Donna Chen, 99 Ind. L.J. 933 (2024).

Nonfinancial Conflict of Interest in Medical Research: Is Regulation the Right Answer?, Nehad Mikhael, 37 J.L & Health 225 (2024).

'Normal,' David R. Katner, 33 S. Cal. Rev. L. & Soc. Just. 427 (2024).

Off-Label Preemption, David A. Simon, 2024 Wis L Rev 1079 (2024).

Outside the Usual Course: Prosecuting Medical Professionals for the Unlawful Prescription of Controlled Substances, Alexis Gregorian, Katherine Payerle, Jillian Willis, 72 DOJ J. Fed. L. & Prac. 33 (2024).

Personal Data & Vaccination Hesitancy: COVID-19's Lessons for Public Health Federalism, Charles D. Curran, 73 Cath. U. L. Rev. 1 (2024).

Poked, Prodded, and Privacy: Parents, Children, and Pediatric Genetic Testing, Allison M. Whelan, 109 Iowa L. Rev. 1219 (2024).

Prison Or Treatment? Gender, Racial, and Ethnic Inequities in Mental Health Care Utilization and Criminal Justice History Among Incarcerated Persons with Borderline and Antisocial Personality Disorders, Emily R. Edwards, Gabriela Epshteyn, Caroline K. Diehl, Danny Ruiz, Brettland Coolidge, Nicole H. Weiss, Lynda Stein, 48 Law & Hum. Behav. 104 (2024).

Random Drug Testing of Physicians: A Question of Safety, Jeffrey A Julian MD, I. Glenn Cohen JD, Eli Y. Adashi MD, 25 DePaul J. Health Care L. 1 (2024).

Re/Descheduling Marijuana Through Administrative Action, Scott Bloomberg, Alexandra Harriman, Shane Pennington, 76 Okla. L. Rev. 517 (2024).

Revolutionizing Healthcare: The Transformative Power of Artificial Intelligence in Medicine, Samuel D. Hodge, Jr., 70 Loy. L. Rev. 375 (2024).

Systemic Failures in Health Care Oversight, Julie. L Campbell, 58 Ga. L. Rev. 737 (2024).

Telehealth Solutions for Black Maternal Health, Katherine "Yenny" Wu, Esq., MPH, 33 Annals Health L & Life Sci 145 (2024).

The Federal Pregnant Workers Fairness Act: Statutory Requirements, Regulations, and Need (Especially in Post-Dobbs America), Deborah A. Widiss, 27 Employee Rts & Emp Pol'y J 84 (2024).

The Medical/Legal/Human Disconnect in Cure Cases: A Proposal for Reform, Thomas C. Galligan, Jr., 48 Tul. Mar. L.J. 193 (2024).

The Shortcomings of Mental Health and Substance Use Disorder Parity and Opportunities for Improved Enforcement, Madeleine Larock, 57 UIC L. Rev. 543 (2024).

Too Stubborn to Care For: The Impacts of Discrimination on Patient Noncompliance, Alice Abrokwa, 77 Vand. L. Rev. 461 (2024).

Jeff Ehrhardt is an associate in the Health Services and Commercial Litigation practice groups at Rivkin Radler LLP.

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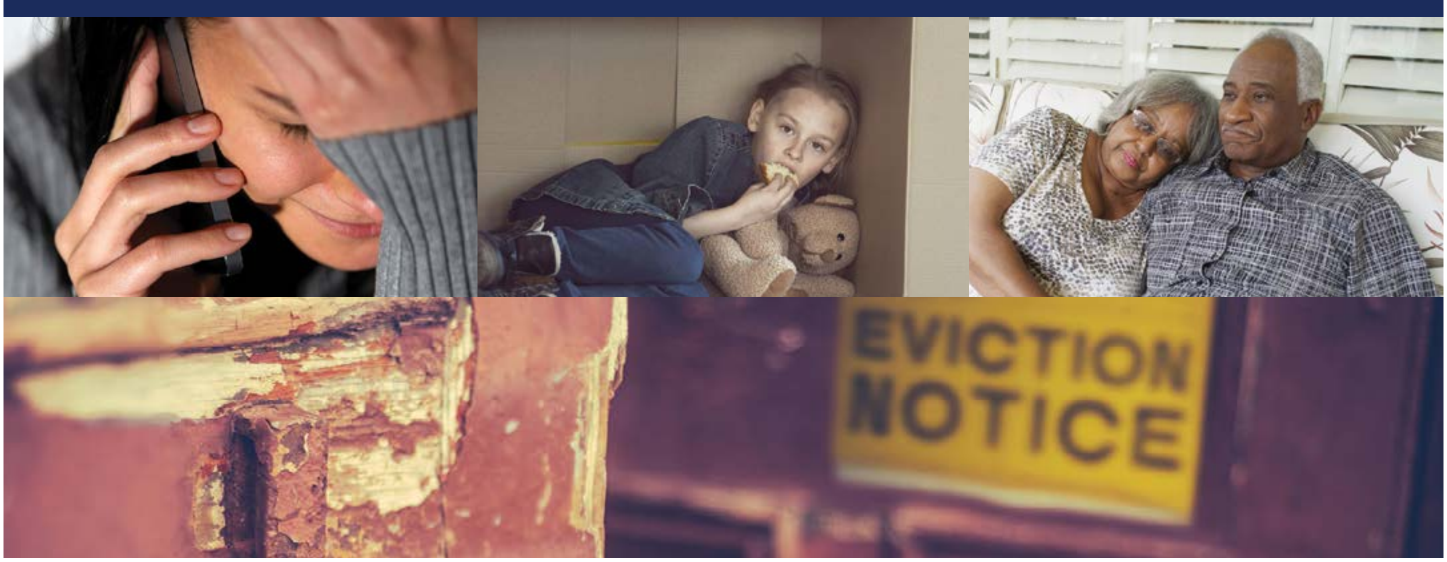


For Your Information

By Claudia O. Torrey

A few Reproductive and/or Maternal Health Legal Highlights:

On April 26, 2024, the Office for Civil Rights of the United States Department of Health and Human Services published in the Federal Register the Final Rule (Rule) regarding reproductive health privacy rights. The Rule is entitled “HIPAA Privacy Rule to Support Reproductive Health Care Privacy;[1] the effective date is June 25, 2024.[2] Under the privacy regulations promulgated under the 1996 Health Information Portability & Accountability Act (HIPAA),[3] the Rule seeks to protect access to and privacy of reproductive health care information, in particular after the United States Supreme Court case of *Dobbs v. Jackson Women's Health Organization* (Dobbs) in 2022.[4] The Dobbs decision essentially overruled the constitutional right to an abortion that was established in *Roe v. Wade*;[5] the Dobbs decision also laid the groundwork for a number of state law bans and restrictions on both abortion and other reproductive freedoms.

The Rule strengthens the HIPAA privacy protections for patients by prohibiting the use or disclosure of protected health information (PHI) by a covered entity (healthcare provider, plan, or clearinghouse) or business associate(s)/regulated entities when potentially lawfully reproductive health care is sought, obtained, or facilitated.[6] The Rule also requires an attestation to such.[7] Regulated entities have until December 23, 2024 to comply,[8] and Notice of Privacy Practices must be updated by February 16, 2026.[9]

In one of the first major cases before the United States Supreme Court since its Dobbs decision in 2022,[10] *U.S. FDA v. Alliance for Hippocratic Medicine et. al.*[11] could conceivably be decided before this column is published; the case was argued on March 26, 2024.[12] In short, this case comes to the Supreme Court from the United States Court of Appeals for the Fifth Circuit wherein Alliance et. al. (defendants in the Supreme Court case) originally challenged the FDA's (plaintiffs in the Supreme Court case) approval of the drug Mifepristone, which is often used for medical abortion procedures. Alliance et. al. alleged that the FDA did not follow its own procedures for approving Mifepristone, and thus the drug should be withdrawn from the market. In turn, the FDA alleges Alliance et. al. have no standing to sue per Article III of the United States Constitution. As stated above when this column was turned in on June 10, 2024, the Supreme Court case could be decided before this column is published; indeed, that is exactly what happened on June 13, 2024.[13] In a unanimous decision written by Chief Justice Roberts, the Supreme Court agreed with the plaintiffs holding that the defendants did not have standing – associational or otherwise.[13]

The United Nations Population Fund (UNFPA) is the sexual and reproductive health agency for the United Nations.[14] Founded in 1969 as the United Nations Fund for Population Activities, the name changed in 1987 to the United Nations Populations Fund, but the original acronym is still used.[15] Working with over 150 partners all over the world, the goal of the UNFPA is to ensure sexual (which necessarily includes maternal health) and reproductive rights and choices for all, especially women and young people, so that they can access quality health services, including maternal health care, comprehensive sexuality education, and voluntary family planning.[16] The UNFPA is not supported by the regular budget of the United Nations; the UNFPA is supported entirely by the private sector, individuals, foundations, intergovernmental organizations, and voluntary contributions by donor governments.[17] According to the group USA for UNFPA, every two minutes, somewhere in the world a woman dies of preventable pregnancy complications.[18]

A book published on June 4, 2024 entitled "The Fall of Roe: The Rise of a New America," makes the case that *Roe v. Wade* did not collapse for the first time on June 22, 2024 (when the Dobbs decision was announced from the United States Supreme Court), but was falling apart, "bit by bit," courtesy of the anti-abortion movement that gained traction because of the Roe decision, culminating in the presidency of Donald Trump (who ultimately made very conservative appointments to the United States Supreme Court). The book is authored by two New York Times journalists, Elizabeth Dias and Lisa Lerer.[19]

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

Endnotes

1. HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 89 FR 32976-33066 (2024), https://www.federalregister.gov/documents/2024/04/26/2024-08503/hipaa-privacy-rule-to-support-reproductive-health-care-privacy.
2. *Id.*
3. Pub. L. No. 104-191 (1996).
4. *Dobbs v. Jackson Women's Health Organization*, 597 U. S. 215 (2022).
5. *Roe v. Wade*, 410 U.S. 113 (1973).
6. *Supra* at note 1.
7. *Id.*
8. *Id.*
9. *Id.*
10. *Supra* at note 4.
11. *Food and Drug Administration v. Alliance for Hippocratic Medicine*, Docket No. 23-235, argued March 26, 2024 (decision and citation pending), https://www.supremecourt.gov/docket/docketfiles/html/public/23-235.html.
12. *Id.*
13. 602 U. S. 367 (2024).
14. United Nations Population Fund, www.unfpa.org.
15. *Id.*
16. *Id.*
17. *Id.*
18. USA For UNFPA, https://www.usaforunfpa.org/.
19. *See* The Fall of Roe: The Rise of a New America, Macmillian Publishers, https://us.macmillan.com/books/9781250881397/thefallofroe.

In the New York State Courts

By Dayna B. Tann and Marc A. Sittenreich

Southern District of New York Reaffirms that ERISA Does Not Completely Preempt Out-of-Network Providers' State Law Claims Against Health Plan Administrators Based on Pre-Service Promises of Payment

Jenkins v. Aetna Health Inc., No. 23 Civ. 9470, 2024 WL1795488 (S.D.N.Y. Apr. 25, 2024). Plaintiffs, including a neurosurgeon and his private practice, brought this action against Aetna, a group of related entities that insure, operate, and administer health plans in New York and, along with their affiliates, throughout the United States. To satisfy its obligations under those plans, Aetna enters into agreements with health care providers to join its "provider network" and render care to Aetna plan members at contractually discounted, "in-network" rates. Aetna's plans also provide reimbursement for health care services rendered by "out-of-network providers," who do not agree to accept discounted rates.

Plaintiffs are "out-of-network" with respect to Aetna's plans. Prior to performing surgery on an Aetna member, plaintiffs routinely reached out to Aetna by telephone to confirm what they would be paid for the proposed procedure. During those calls, Aetna representatives would frequently specify a rate, often based on the usual, customary, and reasonable charges for the proposed services (the "UCR Rate").

Plaintiffs filed suit against Aetna in the Supreme Court of the State of New York, County of New York, alleging that Aetna repeatedly failed to pay the rates it had promised in connection with its claims for reimbursement for the surgeries rendered to Aetna members. Plaintiffs asserted four causes of action, all under New York law: (1) breach of implied contract, (2) promissory estoppel, (3) negligent misrepresentation, and (4) unjust enrichment. Aetna removed the action to the United States District Court for the Southern District of New York, contending that plaintiffs' state-law claims were completely preempted by the Employee Retirement Income Security Act of 1974 (ERISA) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Act"). Plaintiffs moved to remand.

The district court began by noting that removal based on federal question jurisdiction is limited; under the well-pleaded complaint rule, the complaint itself generally must "establish[] that the case arises under federal law." The court observed that the exception and corollary to this rule is the complete preemption doctrine, where a "federal statute with 'extraordinary preemptive' power can 'convert[] an ordinary state common law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule.'"

The district court then turned to Aetna's ERISA preemption argument. Under ERISA § 502(a)(1)(B), a participant or beneficiary may bring an action "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." As Congress sought "to ensure that plans and plan sponsors would be subject to a uniform body of benefits law," courts have held that this civil enforcement scheme "completely preempts any state law cause of action that 'duplicates, supplements, or supplants' an ERISA remedy."

To determine whether a state law claim is completely preempted by ERISA, courts apply a two-prong test. The first prong is satisfied where: (1) "the plaintiff is the type of party that can bring a claim" under ERISA § 502(a)(1)(B); and (2) "the actual claim that the plaintiff asserts can be construed as a colorable claim for benefits" thereunder. The second prong is satisfied where "no other independent duty" is "implicated by the defendant's actions." Both prongs must be satisfied for the claim to be completely preempted.

Applying this test, the district court found that Aetna could not satisfy the first prong, and thus that plaintiffs' claims are not completely preempted by ERISA. While the court found sufficient evidence to conclude that two Aetna members validly assigned their plan benefits to plaintiffs, it held that the specific causes of action that plaintiffs brought "concern[ed] Aetna's promise of payment at a specified rate," and did not implicate the terms of any health plans.

The district court relied heavily on *McCulloch Orthopaedic Surgical Services, PLLC v. Aetna Inc.*, 857 F.3d 141, 145 (2d Cir. 2017), where an out-of-network physician asserted a promissory estoppel claim arising from an oral promise of payment at a specific rate by the plan administrator. The Second Circuit found that the physician did not allege "a colorable claim for benefits pursuant to Section 502(a)(1)(B)" – and that his claim was not completely preempted by ERISA – because it did "not depend on the specific terms of the relevant health care plan" or the administrator's "determination of coverage or benefits pursuant to those terms," even if the promise was based on a "mere summary of the patient's health care plan and the coverage and benefits that would apply to an 'out-of-network' provider." Although plaintiffs here brought different causes of action, the court parsed through the underlying allegations and found them to be based on similar promises of payment by Aetna.

Acknowledging that Aetna's failure to satisfy the first prong was fatal to its complete preemption argument, the district court nonetheless addressed the second prong – which considers whether there is any "other independent legal duty" underlying plaintiffs' claims – "for the sake of completeness." The court determined that Aetna satisfied this prong because plaintiffs' claim for unjust enrichment was not based upon a separate and independent duty. This is because a plaintiff alleging unjust enrichment under New York law must plead, among other things, that a benefit was conferred on the defendant. The court explained that when a health care provider renders services, the benefit that a health insurer receives is "the discharge of the obligation the insurer owes to its insured." Therefore, the court stated, plaintiffs' unjust enrichment claim "would require the Court to find that 'an ERISA plan exists.'"

Alternatively, Aetna argued that the court had federal subject matter jurisdiction based on the broad statutory preemption provision of the Medicare Act. Aetna claimed it could rely on that provision because one of the Aetna entities named in the lawsuit issued only Medicare-related policies during the relevant time period. The court rejected this argument for two reasons: First, Aetna did not identify a single claim in the action involving services rendered to a patient covered by a Medicare-related plan. Second, Medicare preemption is not a proper basis for removal under the well-pleaded complaint rule because the statute does not contain a comprehensive civil scheme that completely preempts state law claims.

Having determined that neither ERISA nor the Medicare Act completely preempted plaintiffs' claims, the court remanded the action to the Supreme Court of the State of New York for further proceedings.

[Editors' Note: Garfunkel Wild, P.C. represents plaintiffs in the *Jenkins* lawsuit.]

Federal Court Upholds Several Claims Against University for Sharing HIPAA-Protected Health Information with Facebook

Kane v. University of Rochester, No. 23 Civ. 6027, 2024 WL 1178340 (W.D.N.Y. Mar. 19, 2024). Plaintiffs brought a putative class action against the University of Rochester ("defendant" or the "university") in the United States District Court for the Western District of New York, alleging that it improperly disclosed their private health information to Facebook when they used the university's website to search for, make appointments with, and communicate with health care providers. The university moved to dismiss the complaint in its entirety. After plaintiffs withdrew four of their twelve causes of action, the court considered the remaining eight.

The dispute stems from defendant's use of "web tracking" products offered by Facebook, namely the Facebook Tracking Pixel (the "Pixel") and the Conversions Application Programming Interface (CAPI). Together, the Pixel and CAPI are designed to track user activity, including "how long they spend on a particular page, which buttons they click, which pages they view, and the text they enter into search bars, chats, or text boxes." Moreover, when a user is logged into Facebook on a device and uses that device to access a website equipped with the Pixel, the Pixel transmits additional information to Facebook's servers. This information includes the user's Facebook ID – which is linked to the user's Facebook profile and, as a result, to the user's "real world identity." Defendant's website also used the Pixel to capture search parameters and "key words" entered by users. As the court observed, "[w]hen a user . . . selects a physician, the Pixel transmits": (i) "the [user]'s unique and persistent Facebook ID"; (ii) "the fact that the patient clicked on a specific provider's profile page"; (iii) "the patient's search parameters," *i.e.,* "that they specifically searched for a female or male doctor and their specialty"; and (iv) "the [user]'s location." Then, if the user selects a physician by "click[ing] the 'Schedule an Appointment' button," the Pixel would "transmit that action to Facebook . . . along with the user's search parameters and Facebook ID." Notwithstanding its use of the Pixel and CAPI, the university's privacy policies represent that it does not transmit protected health information to any third party without authorization.

The district court first considered plaintiffs' claim under the federal Wiretap Act, which affords a civil cause of action to individuals whose communications are intercepted for the purpose of committing a crime or tort. In support of this claim, plaintiffs cited the Health Insurance Portability and Accountability Act (HIPAA) and its accompanying regulations, under which it is a crime to "'knowingly . . . disclose[] individually identifiable health information,' or IIHI, 'to another person.'" Thus, the court confronted two questions: (i) whether plaintiffs plausibly alleged the information at issue is IIHI and, if so, (ii) whether defendant intercepted plaintiffs' communications for the purpose of knowingly disclosing them to another person.

As to the first question, plaintiffs alleged that defendant disclosed several categories of sensitive information, including (a) their status as patients; (b) their communications with defendant through its website and "patient portal"; (c) their medical appointments, location of treatments, specific medical providers, and specific medical conditions and treatments; and (d) their locations, IP addresses, device IDs and individual, unique Facebook IDs. The court held that such information is indeed IIHI, because it may be used to "identify a specific individual who is seeking treatment from a specific physician." The court was particularly swayed by the fact that defendant transmitted "the user's Facebook ID, which can be linked to a specific Facebook profile. This tells Facebook that a particular individual sought medical care from one of defendant's providers in a specific specialty." As to the second question, the court held that plaintiffs plausibly alleged that defendant disclosed IIHI for financial gain – namely "to enhance its marketing efforts." Thus, the court denied defendant's motion to dismiss plaintiffs' Wiretap Act claim.

The district court then addressed plaintiffs' two causes of action for breach of express and implied contract. The university argued that plaintiffs failed to state a claim because its privacy policies merely notified patients of their privacy rights, contained no reciprocal obligations, and specified that plaintiffs' sole remedy was to "stop using [defendant's] service." The court disagreed, finding that plaintiffs plausibly pleaded a breach of express contract claim by alleging that the university "required them to enter certain information into [its] website as a condition of using [the] website and receiving healthcare services," which defendant agreed to keep "secure and confidential, and to timely and accurately notify Plaintiffs . . . if their data had been breached or compromised and stolen." The court excerpted several portions of defendant's privacy policies containing such express promises allegedly breached by defendant. The court rejected the university's reliance on an "exculpatory clause," finding that such clauses do not excuse willful or grossly negligent acts. While the court declined to dismiss plaintiffs' express contract claim, it dismissed plaintiffs' implied contract claim as duplicative of their claim for breach of confidence.

Next, the district court allowed plaintiffs' bailment claim to proceed, on a theory that "Defendant owed a duty distinct from the duty of confidentiality, arising out of Defendant's 'possession and [] control of Plaintiffs' . . . Private Information.'" The court noted the absence of any "binding precedent addressing whether a bailment may be created solely for intangible property."

Turning to plaintiffs' cause of action for breach of confidence, the district court observed that the duty of confidentiality covers only "information relating to the nature of the treatment rendered and the diagnosis made." The court held plaintiffs did not allege disclosure of information that falls within the narrow scope of this duty and thus failed to state a cause of action. However, the court granted plaintiffs' request for leave to amend, affording them an opportunity to cure this deficiency.

The district court also disposed of plaintiffs' claim for breach of fiduciary duty, finding it duplicative of breach of confidence because "the same alleged breach of the same duty underlie[d]" both claims.

As to plaintiffs' unjust enrichment claim, the court rejected plaintiffs' allegation that defendant's actions somehow diminished the value of plaintiffs' IIHI. In particular, the court found plaintiffs failed to identify some "specific loss or deprivation of opportunity." Still, the court allowed the unjust enrichment claim to proceed on an alternate theory, namely that defendant's practices denied plaintiffs the "benefit of the bargain" because they "paid Defendant for services that they would not have had they known about Defendant's disclosure of their private information."

Lastly, the district court declined to dismiss plaintiffs' claim for deceptive business practices under N.Y. General Business Law § 349. The court found that the university's privacy policies evidenced "consumer-oriented conduct" and that plaintiffs plausibly alleged that the university's "representations as to its use of analytics and personally identifiable information were 'likely to mislead a reasonable consumer acting reasonably under the circumstances.'" Further, the court found that plaintiffs adequately pleaded injury by alleging "financial losses related to payments they would not have made to Defendant had they known of Defendant's disclosures," as well as by alleging that they never would have provided their personal information had they known defendant would share it with Facebook.

Eastern District of New York Holds that Voluntary Staff Physicians Cannot Sue Hospitals for Race Discrimination under Section 1981

Hutchinson v. Northwell Health, Inc., No. 23 Civ. 2116, 2024 WL 1308691 (E.D.N.Y. Mar. 27, 2024). Plaintiff, a physician specializing in cardiology and electrophysiology, commenced a lawsuit in the United States District Court for the Eastern District of New York against Northwell Health, Inc., alleging impairment of her ability to make or enforce contracts due to her race in violation of 42 U.S.C. § 1981 and retaliation against her for asserting her rights thereunder. Plaintiff also brought discrimination and retaliation claims under the New York State Human Rights Law (the NYSHRL) and the New York City Human Rights Law (the NYCHRL).

Plaintiff alleged that she was an independent contractor with privileges to practice cardiology at defendant's member hospitals, including Southside Hospital (now known as South Shore University Hospital), where she served as chairperson of the Electrophysiology Department. In 2004, after one of her patients died during a complex procedure performed at Southside Hospital, plaintiff was allegedly disciplined by defendant, despite a peer review panel purportedly finding that the death was the result of "known potential complications or risks of the procedure." As a result, plaintiff claimed, defendant prohibited her from performing surgeries for three months and directed her to complete remedial training. Plaintiff alleged that defendant continued to impose restrictions on her ability to practice medicine by preventing her from performing procedures and by restricting or denying her request for privileges at Southside Hospital and Lenox Hill Hospital. Plaintiff further alleged that defendant retaliated against her, as the treatment worsened after she complained internally to defendant's general counsel, filed a complaint with the New York State Division of Human Rights, and sent a letter to the governor of New York.

Plaintiff, who is African American, asserted that defendant's actions were motivated by discrimination. She claimed that other electrophysiological surgeons with hospital privileges at defendant's facilities were predominantly white men. Plaintiff further claimed that her hospital privileges were revoked and/or denied in a manner that was inconsistent with hospital bylaws, which she argued were intended to form a binding relationship between the hospital and physician.

Defendant moved to dismiss the complaint, arguing, among other things, that plaintiff's Section 1981 claims were subject to dismissal because: (a) plaintiff failed to identify an impaired contractual relationship with defendant under which she has rights; and (b) a hospital's medical staff bylaws do not provide contractual rights sufficient to support a Section 1981 claim.

The district court reviewed the governing legal standards applicable to Section 1981 claims and then considered the issue of whether plaintiff adequately alleged that the purported discrimination concerned the making and enforcement of a contract under which she has rights. The court noted that plaintiff did not allege the existence of an employment relationship, nor could she have done so, since she claimed she was an independent contractor.

The district court next analyzed whether a hospital's medical staff bylaws could create an enforceable contract sufficient to support a Section 1981 claim. The court turned to *Mason v. Central Suffolk Hospital*, 3 N.Y.3d 343 (2004), a longstanding decision from the New York Court of Appeals holding that medical staff bylaws generally do not create any enforceable contractual rights unless they contain "clear language" entitling a physician to sue for damages. The court observed that "decisions applying *Mason* confirm that hospital bylaws will only rarely create contractual rights."

Following *Mason*, the court determined that nothing in the bylaws at issue suggested that they intended to create an enforceable contract. Indeed, they were analogous to the bylaws that the Court of Appeals found insufficient, in that case, to establish a right to damages.

Since plaintiff could not establish that she had any contract with defendant, the district court held that it "logically follows" that plaintiff could not sue defendant under Section 1981. Although the court asserted that this was a matter of first impression in New York, "[o]ther federal courts have consistently dismissed § 1981 claims premised on hospital bylaws after determining that those bylaws could not support a breach of contract claim under state law." Because plaintiff had no claim arising under federal law, the court declined to exercise supplemental jurisdiction over her claims under the NYSHRL and NYCHRL.

[Editors' Note: Garfunkel Wild, P.C. represented defendant in the *Hutchinson* lawsuit.]

Southern District of New York Declines to Enjoin Enforcement of New York Statute Prohibiting the Sale of Dietary Supplements for Weight Loss and Muscle Building to Minors

Council for Responsible Nutrition v. James, No. 24 Civ. 1881, 2024 WL 1700036 (S.D.N.Y. Apr. 19, 2024). In October 2023, the New York State Legislature enacted General Business Law § 391-oo (the "statute"), which prohibits the sale of dietary supplements for weight loss or muscle building to anyone under the age of 18. The statute was meant to address concerns regarding eating disorders affecting young people in light of studies showing that they are a mental health condition that may be identified and diagnosed based on the presence of unhealthy weight control behaviors. One signal for these disorders is the misuse of dietary aids to try to lose weight or build muscle. The Legislature was concerned that dietary supplements for weight loss or muscle building were readily available alongside other safer supplements, like multivitamins, even though there had been a number of reported instances of deaths and serious harms due to the use of unregulated dietary supplements.

The statute authorizes the Attorney General of the State of New York to bring special proceedings to enforce its terms. During those proceedings, courts should consider whether the supplement contains certain ingredients, and may also consider the retailer's conduct in "placing signs, categorizing, or tagging the supplement with statements" suggesting that it will impact weight, fat, appetite, metabolism, muscle, or strength, or by "grouping the supplements with other weight loss or muscle building products in a display, advertisement, webpage, or area of the store."

Council for Responsible Nutrition (CRN), a nonprofit trade organization representing various dietary supplement manufacturers and distributors, sued the attorney general in the United States District Court for the Southern District of New York, asserting various constitutional and preemption claims and seeking a declaratory judgment and injunctive relief to prevent enforcement of the statute. Right before the statute came into effect, CRN moved for a preliminary injunction, which the court denied, finding, *inter alia*, that CRN had not demonstrated a likelihood of success on the merits and that granting a preliminary injunction was not in the public interest.

The district court first addressed CRN's claim that the statute violates the First Amendment. CRN argued that the statute restricts access to products based on what retailers or manufacturers have said about the product or its ingredients in the labeling, marketing, or advertising materials. The court held that this argument was based upon a misreading of the statute, which simply imposes an age-based restriction for products that contain weight-loss or muscle-building ingredients. While courts may consider the labeling, advertising, or marketing of the products in enforcement proceedings, the court found that this is merely an "explanatory provision aiming to assist courts with enforcement of the Statute." Therefore, the statute does not regulate what sellers "may or may not say" about their products, and CRN members were free to advertise and market their products as they wish.

Because the statute regulates conduct and only incidentally burdens commercial speech, the district court held that it does not violate the First Amendment. Even if it did, the court held, CRN still failed to demonstrate a likelihood of success on its claim because the statute likely survives intermediate scrutiny, which applies to commercial speech. Intermediate scrutiny for commercial speech is subject to a four-prong test, requiring courts to determine whether "(1) the expression is protected by the First Amendment, concerns lawful conduct, and is not misleading; (2) the asserted governmental interest is substantial; (3) the regulation directly advances the asserted government interest; (4) and the regulation is no more extensive than necessary to serve that interest." Although the burden of proof falls on the "party seeking to uphold a restriction," CRN conceded the first two prongs by admitting that New York "has a substantial government interest in protecting public health and regulating misleading information," and that "eating disorders in minors are unquestionably real harms."

With regard to the third prong, CRN argued that the state failed to proffer evidence suggesting that the harms the statute sought to address were "directly mitigated by the Statute." CRN contended that the statute cited to "irrelevant materials masquerading as genuine evidence" and that the Legislature "should have demanded to see the body of research on the causal link between these types of supplements and eating disorders." The district court rejected CRN's arguments because legislation may be justified by "reference to studies and anecdotes . . . or even based solely on history, consensus, and simple common sense." Relying on the testimony of Dr. Joseph Nagata, which was submitted to the Legislature in support of the statute and which referenced the causal connection between eating disorders and the misuse of dietary supplements, the court determined that the state had sufficiently met its burden to satisfy this prong at the preliminary injunction stage.

Turning to the fourth prong, the district court determined that the statute does not institute a complete ban on "the sale of dietary supplements that are labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building." And, because the statute also leaves "open alternative avenues for vendors to convey information about products" the court held that the statute's restriction is not more extensive than necessary to serve the government's interest.

Additionally, the district court found that the statute falls within the scope of the Legislature's broad police powers to regulate health and safety. Under a rational basis review, which applies to a state's exercise of its police powers, there is a "'strong presumption of validity' such that attacks to rationality 'must discredit any conceivable basis which could be advanced to support the challenged provision, regardless of whether that basis has a foundation in the record, or actually motivated the legislature.'" The court found that the statute "easily satisfies rational basis review" since it survived "the more demanding level of intermediate scrutiny."

Likewise, the district court determined that CRN failed to demonstrate a likelihood of success on its claim that the statute is expressly preempted by 21 U.S.C. § 343-1(a), which prohibits states from imposing any nutritional level or health benefit labeling requirement that is inconsistent with 21 U.S.C. § 343(r). The court found that the statute "merely institutes an age restriction" and "does not does not mandate any alterations to the labeling of dietary products."

The district court also rejected CRN's claim that the statute is unconstitutionally vague, as its "plain language . . . is uncompromisingly clear such that people of ordinary intelligence would have a reasonable opportunity to understand what conduct it prohibits." The court also noted that the statute is "not vague in all of its applications," as at least one of CRN's members had identified a number of "impacted products" and intended to either revise product labeling and marketing or to age-restrict those products.

Next, the district court determined that CRN failed to prove irreparable harm. Among other things, the court noted a "substantial and inexcusable delay" by CRN in moving for preliminary relief five months after the statute was enacted.

Finally, the district court held that the public interest and a balancing of the equities did not support injunctive relief in CRN's favor. The court noted that the statute "unquestionably" addressed "real harms," by CRN's own admission and as supported by multiple studies. Therefore, the court found that enjoining the statute would "deprive New York residents of the protections of the law."

Second Circuit Holds that Students Did Not Have a Fundamental Right to a Medical Exemption from the State Mask Mandate

Doe v. Franklin Square Union Free Sch. Dist., 100 F.4th 86 (2d Cir. 2024). In the fall of 2020, the Commissioner of the New York State Department of Health (the DOH) issued a series of interim guidance governing in-person instruction at schools during the COVID-19 pandemic. The first interim guidance, issued on August 26, 2020, required all "students, faculty, staff, and other individuals" at schools to wear "at least, an acceptable face covering," and permitted "exemptions of alternatives for those medically unable to wear masks." On April 9, 2021, the DOH issued updated interim guidance that permitted exemptions from the school mask mandate for "[s]tudents who are unable to medically tolerate a mask, including students where such mask would impair their physical health or mental health."

Plaintiff's daughter suffers from asthma, which allegedly prevented her from medically tolerating a face mask. Plaintiff made multiple requests to the Franklin Square Union Free School District (the "school district") for a full or partial medical exemption to the mask requirement for her daughter. All of those requests were denied, except that plaintiff's daughter was permitted to request "mask breaks." In responding to plaintiff, the superintendent noted that the school district had adopted an official policy not to give any child a mask exemption. The school district's consultant also conferred with plaintiff's daughter's physician and concluded that the mask was "not creating difficulty with [her] asthma."

On September 7, 2021, plaintiff sued the school district in the United States District Court for the Eastern District of New York, alleging violations of her and her daughter's constitutional and statutory rights. Initially, the parties came to a settlement where the school district agreed to allow plaintiff's daughter to wear a mesh mask at school. However, plaintiff subsequently filed an amended complaint, seeking a full exemption from the mask mandate on the ground that her daughter still had trouble breathing and that the mesh mask caused other health problems. In her amended complaint, plaintiff sought declaratory and injunctive relief and damages under various constitutional, statutory, and common law theories, including a substantive due process claim under the Fourteenth Amendment.

The school district moved to dismiss the amended complaint. The district court granted the motion, finding that plaintiff's constitutional claim was moot given that the mask mandate had since been lifted, and that the mask mandate did not infringe any fundamental right. The district court also held that plaintiff's damages on her statutory claims under the Americans with Disabilities Act (the ADA) and Section 504 of the Rehabilitation Act ("Section 504") would be limited to the time period before the school district offered to permit plaintiff's daughter to use a mesh mask as a reasonable accommodation, and, in any event, that those claims were subject to dismissal for failure to exhaust administrative remedies under the Individuals with Disabilities Education Act (the IDEA). Finally, the district court dismissed plaintiff's claim under the New York State Human Rights Law (the NYSHRL) because she failed to satisfy the notice of claim requirement under the New York Education Law. Plaintiff appealed.

The United States Court of Appeals for the Second Circuit first addressed plaintiff's substantive due process claim. Plaintiff asserted that the school district's enforcement of the mask mandate infringed three fundamental rights: (1) "the right to a medical exemption deriving from the right to self-preservation," (2) "the right to refuse medical treatment," and (3) "the parental right to make medical decisions for one's own children."

The Second Circuit recognized that it had "not previously considered whether a student has a fundamental right to a medical exemption from a mask mandate imposed during the COVID-19 pandemic based solely on a treating physician's recommendation." Citing prior holdings that no such fundamental right exists in the context of school vaccination requirements, the court ruled that it is "not unreasonable for a school policy to require that requests for a medical exemption be reviewed by the school's physician." Moreover, the court held that it is "reasonable for the government to condition the application of a medical exemption to a public health mask mandate on a determination that the individual seeking the exemption would, in fact, be harmed by wearing a mask."

Next, the Second Circuit held that the mask mandate did not implicate the right to refuse medical treatment because wearing a mask does not constitute "medical treatment." Even if it were medical treatment, the court ruled that the school district did not infringe any fundamental right because “an individual’s desire to refuse to wear a face covering is outweighed by New York’s interest in safeguarding public health and preventing the spread of COVID-19.”

Lastly, the Second Circuit held that plaintiff’s fundamental right to make decisions about the care, custody, and control of her child had not been violated. The court noted that it was not aware of “any cases standing for the proposition that school masking requirements violate the right of parents to raise their children.”

Since there was no fundamental constitutional right at stake, the Second Circuit applied rational basis review, under which the school district’s action was afforded a strong presumption of validity, and affirmed the district court’s dismissal of plaintiff’s substantive due process claim. The court ruled that enforcement of the mask mandate was reasonably related to the state’s legitimate interest in protecting public health, and that the school district could have rationally determined that granting plaintiff’s daughter a medical exemption would have endangered her classmates and school staff. Further, the court found that the school district could have rationally decided that plaintiff’s daughter could medically tolerate a mask based on the conclusion of its consultant after conferring with the daughter’s physician.

However, the Second Circuit reversed the district court’s judgment as to plaintiff’s claims under the ADA and Section 504. The court held that plaintiff’s damages could not be cut off at the pleading stage because she plausibly alleged that the mesh mask accommodation was not effective. The court also determined that plaintiff’s remaining claims were solely for damages and thus were not subject to the IDEA’s exhaustion requirement. Although the IDEA presented certain exhaustion requirements for plaintiff’s equitable claims, the court found that those claims were rendered moot when the mask mandate was lifted.

Finally, the Second Circuit affirmed the dismissal of plaintiff’s NYSHRL claim. While plaintiff argued that she adequately pleaded that she met the notice of claim requirement by referring to two letters her counsel sent to the school district in the summer of 2021, she did not raise that argument before the district court, and the Second Circuit declined to exercise its discretion to consider it for the first time on appeal.

Southern District of New York Holds that In-Network Hospital Cannot Sue for Reimbursement for Newborn Care that ERISA-Governed Employee Health Plans Are Required by Law to Cover

NYU Langone Hosps. v. 1199SEI Nat. Benefit Fund for Health & Human Serv. Emps., No. 22 Civ. 10637, 2024 WL 989700 (Mar. 7, 2024). Defendants are two multi-employer trust funds established in accordance with Section 186(c) of the Labor Management Relations Act. Funded by employer contributions made pursuant to collective bargaining agreements, defendants provide covered health care services to eligible employees and their family members, in accordance with the terms set forth in written plan documents. Defendants’ plans constitute “employee welfare benefit plans” subject to the Employee Retirement Income Security Act of 1974 (ERISA).

Plaintiff is a not-for-profit corporation that operates health care facilities in New York County. At all times relevant, plaintiff contracted with defendants to provide covered health care services to the members of defendants’ plans at negotiated rates.

Plaintiff filed suit against defendants for breach of contract in the Supreme Court of the State of New York, County of New York. Plaintiff alleged that it provided childbirth-related services to three plan-enrolled mothers and their newborns. While plaintiff billed for services rendered both to the mothers and the newborns, defendants failed to provide any reimbursement for the newborns’ care. Importantly, plaintiff did not identify any specific term in its contracts that required defendants to cover the newborns’ hospital stays. Instead, plaintiff contended the stays were a covered maternity benefit under the Newborns’ and Mothers’ Health Protection Act of 1996 (the NMHPA), and thus defendants breached the parties’ contracts by failing to provide covered services.

Defendants removed the action to the United States District Court for the Southern District of New York and moved to dismiss. The district court granted the motion, finding plaintiff’s breach of contract claims were expressly preempted by ERISA and holding that plaintiff lacked standing to bring ERISA claims.

The district court observed that “the NMPHA and its requirements,” on which plaintiff relied, “were incorporated into ERISA.” ERISA, in turn, “contains a broad preemption provision” under which it “shall supersede any and all state laws insofar as they may now or hereafter relate to any [ERISA] plan.” The court stated that this express preemption applies wherever the plaintiffs “seek to rectify a wrongful denial benefits promised under ERISA-regulated plans, and do not attempt to remedy any violation of a legal duty independent of ERISA.”

Here, the district court found, “plaintiffs’ argument boil[ed] down to the contention that by failing to cover the newborns’ hospital stays,” defendants “violated the NMPHA, a part of the ERISA statute.” Thus, plaintiff’s claims were predicated entirely on ERISA and not any independent legal duty. Therefore, the court concluded, even if plaintiff’s interpretation of the NMPHA were correct, its challenge could be brought only through ERISA's civil enforcement scheme, and not through a common-law breach of contract claim.

Lastly, the district court declined to grant plaintiff leave to amend its complaint. It held that such request was futile because plaintiff had already amended its complaint once to address the legal deficiencies identified by defendants. The court also found that plaintiff had no standing to bring ERISA claims; while the plan members at issue had assigned their maternity benefits to plaintiff, the underlying plans "explicitly and unambiguously" prohibited such assignments.

Court Rejects COVID-19 Vaccine Claims Couched as Religious and Race Discrimination

Hughes-Greene v. Westchester Med. Ctr., Index No. 63095/2023, 2024 WL 2143053 (Sup. Ct. Westchester County Feb. 6, 2024). This case involves 10 N.Y.C.R.R. § 2.61 (the "state mandate"), which required all hospitals in the state of New York, including defendant Westchester Medical Center (WMC or the "hospital"), to ensure that their patient- and staff-facing personnel were fully vaccinated against COVID-19, with no religious exemptions. Plaintiff Wanda Hughes-Greene served as an administrative assistant in WMC's anesthesiology department, and plaintiff Cheryl Gillen was a labor and delivery nurse at the hospital, until they were both terminated for refusing the COVID-19 vaccine. Both plaintiffs alleged that they sought, and were denied, a religious exemption from the state mandate's vaccination requirement.

Plaintiffs filed suit against WMC in the Supreme Court, Westchester County, alleging religious discrimination and retaliation in violation of the New York State Human Rights Law (the NYSHRL). Hughes-Greene also alleged that she suffered race-based discrimination arising from statements related to the state mandate and the COVID-19 vaccine. Defendants moved to dismiss the complaint in its entirety.

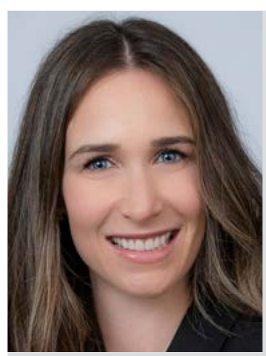
The Supreme Court initially noted that there was no dispute that the hospital was a covered entity subject to the state mandate's requirements. Turning to plaintiffs' religious discrimination claim, the court observed that the NYSHRL – which is "analytically identical" to Title VII in this context – requires employers to reasonably accommodate their employees' sincerely held religious beliefs and practices unless it would impose an undue hardship on the employer. The court explained that undue hardship exists where the burden is "substantial in the overall context of an employer's business," such that the costs "rise to an excessive or unjustifiable level." Following several "recent cases" addressing this very issue, the court found that WMC met its burden to show undue hardship, as granting plaintiffs' requests for religious exemptions would have caused the hospital to violate the state mandate.

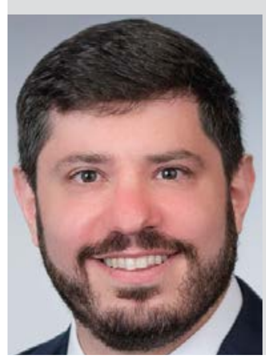
While plaintiffs contended that the state mandate was "held back from implementation due to a stay," the court asserted that the preliminary injunction issued by the United States District Court for the Northern District of New York in 2021 was quickly reversed by the United States Court of Appeals for the Second Circuit. The court also rejected plaintiffs' argument that WMC should have placed them on "unpaid leave with employment status" until the state mandate was "sorted out in Court," because indefinite leave is not considered a reasonable accommodation under the NYSHRL.

The supreme court then addressed Hughes-Greene's separate race claim. Hughes-Greene, who is Black, alleged that comments about "anti-vaxxers" were made within her "earshot," and that a supervisor and the chair of WMC's Anesthesiology Department discussed vaccine hesitancy by African Americans and asked her whether she had been vaccinated against COVID-19. The court found that these statements could not have given rise to race discrimination or a race-based hostile work environment because they "relate more to vaccination status than Hughes-Greene's race or color" and "could have been directed at any unvaccinated employee." Even if there were a racially derogatory connotation, the court held, it amounted to no more than a "petty slight or trivial inconvenience."

Accordingly, the supreme court dismissed plaintiffs' NYSHRL discrimination claims. As plaintiffs did not oppose dismissal of their retaliation claim, the court dismissed the complaint in its entirety.

[Editors' Note: Garfunkel Wild, P.C. represented defendants in the *Hughes-Greene* lawsuit.]





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Disparate Treatment in Health Care Under the Law: How Did We Get Here?

By Lisa D. Hayes

"Of all forms of inequality, injustice in health care is the most shocking and inhuman"

Dr. Martin Luther King, Jr. at the National Convention of the Medical Committee on Human Rights, Chicago 1966

In its 2020 Call to Action, the American Heart Association declared that structural racism has been and remains a fundamental cause of persistent health disparities in the United States.[1] Structural racism refers to "the normalization and legitimization of an array of dynamics – historical, cultural, institutional and interpersonal – that routinely advantages white people while producing cumulative and chronic adverse outcomes for people of color.[2] The historic legal context of structural racism in health care is important to appreciate just how fundamental racism has been in the development of our current health care system. The purpose of this article is to highlight the role of the Supreme Court and the judicial system in forming a legal framework for disparate treatment contributing to structural racism in the health care industry.

The Separate-but-Equal Doctrine and the Institutionalization of Racial Discrimination in Health Care

Between 1619 and 1865, millions of men, women and children were legally enslaved in the United States. In 1857, the principles of slavery were institutionalized and legalized by the Supreme Court in the Dred Scott decision, which upheld state laws that recognized slaves as property and therefore were protected by the Fifth Amendment.[3] Under the Dredd Scott decision, the Supreme Court held that formers slaves did not have standing in federal court because they lacked citizenship.[4]

Dred Scott was nullified in 1865, when the Thirteenth Amendment abolished slavery and involuntary servitude.[5] Despite the Civil War and the end of slavery, however, state laws (often referred to as Black Code or Jim Crow laws) were passed to severely curtail the rights of Black citizens gained during the post-Civil War and Reconstruction period. Jim Crow laws provided for widespread racial discrimination in education, public facilities, travel and health care. Racial discrimination and the disparate treatment of U.S. citizens based solely on race became the cultural and societal norm.

In 1896, the Supreme Court, in *Plessy v. Ferguson*, sanctioned state racial discrimination laws and practice by upholding state segregation laws for public facilities.[6] The Supreme Court in Plessey held that under the Fourteenth Amendment,[7] state segregation laws were constitutional, if the facilities were "separate but equal."[8] The impact of the *Plessy v. Ferguson* decision had a far-reaching and devastating impact on American culture and identity. Institutionalized racism under the doctrine of separate-but-equal resulted in white-only hospitals, nursing homes, medical schools, nursing schools and universities. These white-only facilities refused admission of Black patients, refuse to train Black students and refused admitting privileges to Black medical professionals. Such disparate treatment severely limited access to health care treatment and medical training for Black citizens.

Structural racism was not only supported by law, but by racist norms and ideology. For example, by the late 19th century, there were as many as 14 black medical schools.[9] Howard University, the first college of medicine to train Black doctors, was established in 1867 and Meharry Medical School was established 1868.[10]

These achievements, however, were undermined by the influence of the Flexner Report,[11] commissioned by the Carnegie Foundation to study medical education in the United States and Canada. According to the Flexner Report, "(O)f the seven Black medical schools for negroes in the United States, five are at this moment in no position to make any contributions of value." Despite acknowledging that "the practice of the negro doctor will be limited to his own race,"[12] Flexner recommended that only Howard and Meharry were worth developing. Tragically, in the years following the Flexner Report the five referenced Black medical schools[13] did indeed close their doors and "the number of Black physicians decreased while the number of White physicians increased."[14]

Dismantling Institutionalized Racism – the Hill-Burton Act and the Landmark Decision – *Simkins v. Moses H. Cone Memorial Hospital*

Some of the earliest strategies to dismantle health care apartheid involved attacking the inherent inequities caused by federal funding of programs supporting institutionalized and structural racism. It would be difficult to overstate the role of the NAACP Legal Defense Fund in the elimination of overt discrimination in hospitals and professional organizations.[15]

The 1946 Hospital Survey and Construction Act,[16] often referred to as the Hill-Burton Act, was a national effort to increase the number of hospital beds. Federal grant funds were provided to state agencies to assess the need for hospital beds and allocate construction funds. The Hill-Burton Act originally required assurance from all applicants that the facility would be available to all people residing in the area without discrimination based on race, creed or color. "However, the law permitted an exception to this requirement in localities where separate health facilities were planned for separate population groups if the facilities and services were of like quality for each group,"[17] effectively applying the separate-but-equal doctrine to hospital construction. The result was an expansion of hospital beds and hospital construction under a segregated hospital system. Despite providing assurances of nondiscrimination, of the hospitals receiving Hill-Burton assistance "most denied Black physicians and dentists admitting privileges and segregated Black and White patients in separate wards."[18]

In 1956, Howard University, in collaboration with the National Urban League, conducted a survey of hospital integration in 60 cities where Urban League Chapters were located, 45 in the North and 15 in the South.[19] The survey found that "83% of hospitals in the North reported some degree of integrated services versus only 6% in the South."[20] In the South "31% of hospitals did not admit Blacks under any condition, even emergency; 47% had segregated wards for Blacks and Whites."[21] Regarding Black staffing, in the North only 13% of hospitals accepted Black interns, while those with Black courtesy and active staff members was 22.9% and 25% respectively. Staffing patterns were not much better in the South, with 9.3% accepting interns, while those with Black courtesy and active staff was 11.5% and 25.1% respectively. It should be noted that although white physicians could care for patients in any bed, Black physicians were restricted to treating only Black patients.

The NAACP Legal Defense Fund (LDF), staffed by Howard University graduates Thurgood Marshall and Conrad Odell Pearson and supported by Howard University School of Law faculty member Charles Hamilton Houston, were the legal architects of the legal battle to end discrimination in public facilities, education and health care. Conrad Odell Pearson, general counsel of the North Carolina NAACP, bought an action on behalf of George Simkins, DDS, a Black dentist in Greensboro, N.C., and other physicians and patients against Moses H. Cone Memorial Hospital and Wesley Long Community Hospital. The action alleged that the plaintiffs had been discriminated against because of their race, in violation of the Fifth and Fourteenth Amendment to the U.S. Constitution. The plaintiffs sought injunctive relief from defendants to deny the admitting privileges to physicians and dentists and the admission of patients to hospital facilities based on race.[22] More importantly, the plaintiffs alleged that the Hill-Burton Act was unconstitutional and void as violative of the Fifth and Fourteenth Amendments. Both defendant hospitals had received funds under the Hill-Burton Act and at the time of the filing of the case, Cone hospital had been appropriated $1,269,950 and Wesley $1,948,800.[23] The NAACP argued that this allocation of Hill-Burton funds constituted state action in the operation of private hospitals which would allow the plaintiffs to seek protection against discrimination under the Fifth and Fourteenth Amendments.

The case was dismissed by the district court and the NAACP appealed to the Fourth Circuit Court. Fortunately, the U.S. Assistant Attorney General submitted a brief in support of the plaintiffs, recommending that courts overthrow the separate-but-equal provision of Hill-Burton and ". . . agreed that the use of federal funds in a discriminatory manner was unconstitutional and that these professionals and patients should be granted the privileges and services they sought."[24] It should be noted that the NAACP did not argue on the basis of equality, i.e., the doctrine of separate-but-equal, but argued that "the degree of participation by the national and state government in the geographical proration of hospital facilities throughout the state constituted 'state action' for purposes of federal law."[25] In November 1963, the Fourth Circuit ruled in favor of the defendants, effectively ending years of discrimination in hospitals. The defendants appealed the decision, but the Supreme Court denied issuance of a writ of certiori, which effectively upheld the Fourth Circuit decision. Although the decision originally had limited impact as only hospitals seeking Hill-Burton funds in the Fourth Circuit[26] were bound by the decision, its impact on cases in other jurisdictions was far-reaching. Between 1963 and 2001, there were over 260 references to *Simkins* in other cases involving hospital racial discrimination.[27]

A court decision, however, is only half of the battle, real change must happen on the ground backed by regulation and compliance. "Between July 2,1960 and March 1, 1966, the NAACP Legal Defense Fund maintained about 35 cases against southern medical facilities. The Fund worked hard with state attorneys to identify noncompliant hospitals that could be submitted as cases to the courts, and that could be used to pressure the Department of Health, Education, and Welfare (HEW) to develop a rigorous compliance program, first under the Hill-Burton program and then under Title VI of the 1964 Civil Rights Act[28] Accordingly, following the decision in *Simkins*, on March 9, 1964, the Surgeon General published new regulations which provided in part:

> Before a construction application is recommended by the State agency for approval, the State agency shall obtain assurances from the applicant that all portion and services for the entire facility for the construction of which

> . . . aid under the Federal Act is sought, will be made available without discrimination on account of race, creed, or color; and that no professionally qualified person will be discriminated against on account of race, creed or color with respect to the privilege of professional practice in the facility.[29]

1964 Civil Rights Act

The 1964 Civil Rights Act and its regulatory compliance requirements was the determinative factor in ending racial discrimination in federally assisted programs, making separate-but-equal illegal in public accommodations, including hospitals. Title VI of the Civil Rights Act provides that:

> No person in the United States shall, on the ground of race, color or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

In support of the legislation, Anthony Celebrezze, secretary of HEW "testified that he had ample evidence that there were hospitals, nursing homes and outpatient clinics around the country that received federal funds while engaging in racial discrimination.[30] Discriminatory practices by Hill-Burton aided facilities based on race, color or national origin were now forbidden by Title VI regulations.[31] As a result of Title VI, facilities participating in the Hill-Burton program were subject to the following regulations: 1) Separate but equal facilities were no longer approved for federal financial assistance; 2) Patients must be admitted to facilities without regard to their race, creed, color or national origin; 3) Professionally qualified persons may not be denied the privilege of practice in the facility on account of race, creed, color, or national origin; and 4) Residents, interns, nurses and medical technicians may not be denied training opportunities in the facility on account of their race, creed, color or national origin.[32] The passage of Medicaid and Medicare Legislations required that hospitals receiving funds had to be in compliance with Title VI of the Civil Rights Act, effectively requiring all hospitals to desegregate, not just those receiving Hill-Burton funds.[33]

Challenges Persist – Structural Racism and De Facto Segregation

It has been a mere 60 years since the legal desegregation of healthcare institutions under the Civil Rights Act of 1964. As we move forward to address structural racism and the lasting impact of hospital segregation as a means of reducing health disparities, challenges persist with how to address de facto discrimination, i.e. discrimination that exists not in law, but in fact. In a recent Call for Health Care Desegregation, Drs. Marquez and Lever observed that, "(w)hile sanctioned racial segregation in hospital ended with the Civil Rights Act of 1964 and subsequent implementation of Medicare in 1966, health care organizations continue to practice de facto racial discrimination today."[34] In our commitment to health equity, the legal community must use its resources to challenge de facto discrimination as it did with de jure discrimination.[35] For example, in 2008 the New York Lawyers for the Public Interest (NYPL) filed a civil rights complaint with the New York State Office Attorney General, alleging that three medical systems, New York-Presbyterian, Mount Sinai, and Montefiore maintained separate and unequal systems of outpatient clinics, sorting patient based on payer source and resulting in disparate treatment of patients based on race and national origin.[36]

In "Structural Racism and Supporting Black Lives – the Role of Health Professionals,"[37] the authors outlined three ways in which health professionals can combat structural racism in health care. First, we must research and better understand how race has shaped our scientific research and clinical practice and how segregation of care based on race is deeply rooted in the U.S. health care system. Second, we must research and understand how racism has shaped our narrative about disparities, including, for example, the impact of implicit biases on health care practice. Lastly, we must develop "consistent definitions an accurate vocabulary for measuring, studying, and discussing race and racism and their relationship to health."[38]

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Special thank you to **Bernard Robert**, J.D. candidate 2026, Seton Hall University School of Law.

Endnotes

1. American Heart Association "Call to Action: Structural Racism as a Fundamental Driver of Health Disparities," 142 Circulation 454 (2020).

2. *Id.* at 455 (quoting: Lawrence K, Kelcher T "Chronic disparity: strong and pervasive evidence of racial inequities." Paper presented at Race and Public Policy Conference, Berkely CA; November 11, 2004).
3. *Dred Scott v. Sandford,* 60 U.S. 393 (1857).
4. *Id.*
5. U.S. Const. amend. XIII.
6. *Plessy v. Ferguson,* 163 U.S. 537 (1896). *Plessy v. Ferguson* challenged Louisiana's Separate Car Act of 1890, which required railway companies in the state to provide "equal but separate accommodations for the white and colored races."
7. U.S. Const. amend. XIV All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.
8. *Ferguson* 163 U.S. at 563.
9. Harley, Earl H., "The Forgotten History of Defunct Black Medical Schools in the 19th and 20th Centuries and the Impact of the Flexner Report," Journal of the National Medical Association, Vol 98 No. 9 (September 2006).
10. *Id.*
11. Flexner Report, Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching, New York, NY 1910.
12. *Id*. at 180.
13. The five schools were: Flint at New Orleans, Leonard at Raleigh, the Knoxville at Memphis and Louisville. *Id*. at 181.
14. Harley at 1425.
15. Reynolds, Preston P., "Professional and Hospital Discrimination and the US Court of Appeals Fourth Circuit 1956-1967," American Journal of Public Health, Vol 94. No. 5 (May 2004)710-720.
16. The Hospital Survey and Construction Act, Pub. L. No. 79-725, 60 Stat. 1040 (1946) (current version at 42 U.S.C. §§291-297 (1976 and supp. 11 1978)).
17. U.S. Commission on Civil Rights, "Equal Opportunity in Hospitals and Health Facilities: Civil Rights Policies Under the Hill-Burton Program," CCR Publication – Number 2. March 1965.
18. Reynolds, Preston P., "Professional and Hospital Discrimination and the US Court of Appeals Fourth Circuit 1956-1967," American Journal of Public Health, Vol 94. No. 5 (May 2004)710-720 at 713.
19. Cornely, Paul B., "Trend in Racial Integration in Hospital in the United States," Journal of the National Medical Association, Vol 49. No. 1 (January 1957).
20. Reynolds at 711.
21. *Id.*
22. *Simkins v. Moses H. Cone Memorial Hospital,* 211 F. Supp, 628 (M.D.C.C 1962).
23. *Simkins* at 633.
24. *Supra* note 18.
25. *G.C. Simkins, Jr. et al v. Moss H. Cone Memorial Hospital et al*, 323 F2d 959 (4th Cir., November 1, 1963, cert den. 376US938 (March 2, 1964)).
26. States subject to the Simkins decision included Maryland, Virginia, West Virginia, North Carolina and South Carolina.
27. Professional and Hospital Discrimination at 714.
28. *Id.* at 715.
29. Reynolds, Preston P., "Hospitals and Civil Rights, 1945-1963: The Case of *Simkins v. Moses H. Cone Memorial Hospital*," Annals of Internal Medicine, Vol. 126, No. 11 (June 1997) 898-906, 903.
30. Reynolds, Preston P., "The Federal Government's Use of Title VI and Medicare to Racially Integrate Hospitals in the United States, 1963 Through 1967," American Journal of Public Health. Vol. 87, No. 11 (1850 to 1858) (November 1997) at 1851.
31. Department of Health, Education and Welfare: Title VI regulations: 45 C.F.R. 80.1, December 1964.
32. U.S. Commission on Civil Rights, "Equal Opportunity in Hospitals and Health Facilities: Civil Rights Policies Under the Hill-Burton Program," CCR Publication – Number 2. March 1965. At page 3.
33. *Cypress G.C. et al. v. Newport News General and Non-Sectarian Hospital Association et al.*, 375 F2d 648. Reaffirmed the federal government's application of Medicare certification guidelines to force hospitals to open patient admissions, education programs and staff privileges to all citizens and physicians.
34. Marquez, Denisse Rojas, Lever, Hazel, A., Call for Health Care Desegregation, AMA Journal of Ethics, Vol. 25, Number 1: E3-6. (January 2023) at p.3.
35. Thomas N. Shorter et al., "We Have Met the Enemy and He Is Us," Why the Legal Profession Must Commit Itself to Health Equity, 16 J, Health and Life Sci. L. 16 (2022).
36. Agarwal, Nisha, Using Civil Rights Law to Undermine Profitability of Ongoing Racial Segregation in Health Care, AMA Journal of Ethics, AMA Journal of Ethics, Vol. 25, Number 1: E48-54. (January 2023).
37. Rachel R. Hardeman et al., "Structural Racism and Supporting Black Lives – The Role of Health Professionals," N Engl J Med 375;22 (December 1, 2006) 2113-2115.
38. *Id*. at 2114.

Patient Care Decision Tools: Protections Against Discrimination in Final Rule Revisions to Section 1557 of the Affordable Care Act

By Lou Hart

Introduction

This commentary highlights a major vulnerability facing medicine and the health care industry. Community clinics, hospitals, large health systems, health plans, professional medical societies, medical schools, and individual medical professionals must begin to confront published patient-care decision support (CDS) tools and practice guidelines that recommend separate and unequal care based on a patient's race. Well over 50 CDS tools have been identified that utilize race, color, or national origin as an input variable. In May 2024, the Department of Health and Human Services (HHS) issued final rule revisions to Section 1557 of the Affordable Care Act (ACA). These revisions strengthened protections against discrimination on basis of race, color, national origin, age, sex, or disability (i.e., protected status) in health care programs or activities that are federally funded. Made explicit in these revisions is 45 CFR 92.210, which states, "The final rule requires those covered to make reasonable efforts to identify patient care decision support tools that use input variables or factors that measure race, color, national origin, sex, age, or disability, and to make reasonable efforts to mitigate the risk of discrimination that may result from the use of such tools."[1] This commentary will explore the current health care landscape and the necessary actions that HHS-covered entities must take to become compliant within the 300-day deadline starting July 5th, 2024.

Background

Despite race being a socio-political system of human categorization without any universal biological basis, race historically and currently continues to play a prominent role in shaping medical diagnosis, treatment, and follow up decisions.[2] The misuse of race to inform clinical care reifies flawed notions that race is genetic and can act as a good enough proxy for "personalizing" treatment of disease based on a patient's skin color.[3] Separate and unequal health care contributes to a lower standard of care for all patients by corrupting knowledge production (i.e., by not recognizing social and political inequities as drivers of illness).[4] It also directs resources away from racially minoritized, often higher risk patients, and normalizes societal injustices and their health consequences as immutable and biologically innate.[5] However, this is not to say that race is not an extremely important variable for health care organizations and biomedical researchers to use to measure for population disparity and to ask critical questions evaluating the roots of persistent racial, social and political health inequities seen in their patient population or study participants.

From diagnosing kidney and lung disease, to interpreting prenatal test results for Down's syndrome, to recommending C-sections for repeat births, or earlier follow up for jaundice in newborns, a litany of clinical guidelines and tools have been in place to encourage separate and unequal care based solely on a patient's race.[6] Up until 2020, most of these practices went publicly unquestioned, mainly being critiqued by medical students, medical residents, and more junior academic faculty. Following the murder of George Floyd and the societal inequities made visible throughout the COVID-19 pandemic, many historical medical practices have been called into question for their misuse of race as biological or innate and their potential propagation of racial bias and race-based clinical discrimination. A more recent eye-opening example of such racially biased practices may be seen in the ubiquitous patient-care decision support tool deployed within pulmonary function testing (i.e., PFTs) used to predict lung health.

Prior to March 2023, the American Thoracic Society (ATS) recommended utilizing a standardized equation when predicting lung function after undergoing spirometry. Spirometry measures how much air one can breathe in and out of their lungs, as well as how easy it is to blow air out of one's lungs. With these measurements, professional medical societies recommended that clinicians utilize the Global Lung Function Initiative (GLI) calculator to predict underlying lung health after spirometry. Other variables in the GLI calculation included age, height, sex, and "ethnicity." The "ethnicity" option was utilized to normalize differences seen in lung function across "ethnic" populations who had been studied. The limited "ethnicity" choices were Caucasian, African American, Northeast Asian, Southeast Asian, and Other/

Mixed. Each "ethnicity" had a different predicted reference range of normal. For example, what was interpreted as sickness for one "ethnicity," may be interpreted as healthy for another "ethnicity."

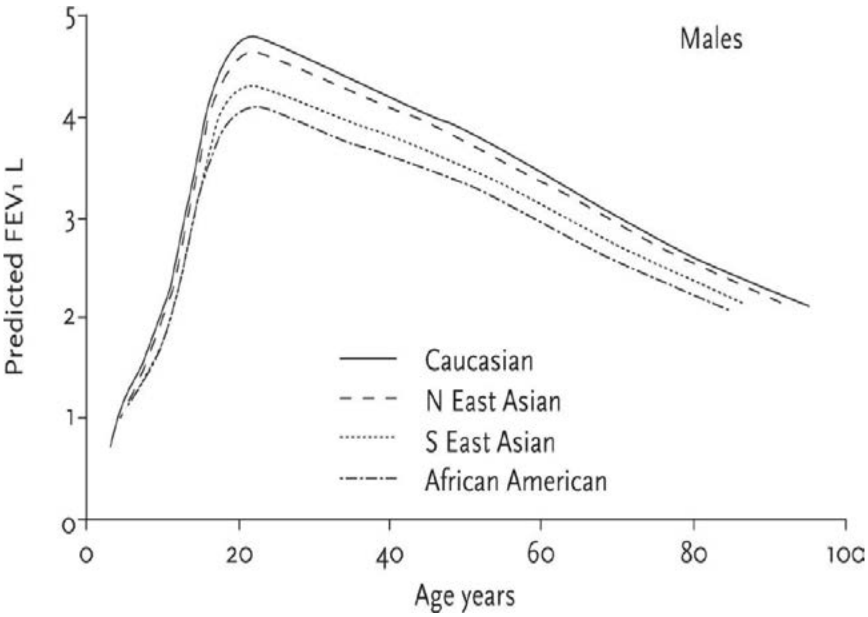


Figure 1.[7]

These medical standards effectively normalized disparity and were quickly programmed into the computers and software that were attached to the spirometers and then auto-generated into reports reviewed by physicians. What would be considered sick for a White patient, and deserving of additional treatment or referral, might be considered normal for all non-White patients. This created disparities in diagnosis, treatment, and health outcomes, solely based on patient race, and institutionalized separate and unequal care. This practice of race-norming sickness had devastating consequences for countless individuals, including mothers, fathers, grandparents, children, and their loved ones. As opposed to interrogating these disparities in outcomes and in the absence of robust research evidence, researchers concluded that these variations represented fundamental differences between broad "ethnicity" groups were likely due to universal physiological differences.

From government funded biomedical researchers, to tax-exempt professional medical societies, to commercial and government health insurance payers like CMS (i.e., Medicaid and Medicare), to large health systems, small community clinics and individual health care professionals, this system embedded lower standards of normal for Black, Asian, and other racially minoritized patients' lungs. All these actors were complicit in the patient care decision support tool's creation, promulgation, payment and end delivery. They all share in the responsibility for the disparate impact, whether intentional or unintentional, of using race, color, or national origin (i.e., protected status) as a variable to discriminate through a patient clinical decision support tool when paying for or providing health care with public dollars.

In March 2023, a joint recommendation from the American Thoracic Society (ATS) argued against the continued use of race or ethnicity in interpreting lung function testing.[8] The ATS made this decision given the potential for global structural racism and bias in prior standard equations to inappropriately influence the diagnosis and management of lung disease in diverse populations.[9] Researchers working on this ATS taskforce stated, "reviews of clinical algorithms throughout medicine in the past decade have spawned concerns about bias and harm when race is used as a variable and has led to revisions of these algorithms."[10] As the health care community begins the costly and time-consuming transition of its computers, software, spirometry machines and electronic health records to the new GLI race-neutral standard, further insights are emerging as to the consequences of moving away from a racially discriminatory approach to a race-neutral approach in pulmonary care.

Recently published in The New England Journal of Medicine in May 2024, independent researchers confirmed that both race-based and race-neutral PFT equations calculate similarly accurate predictions of lung health outcomes for patients.[11] They, however, found that the race-neutral equation will likely create reclassifications of lung function and disease in over 25 million eligible American patients alone. In this study, by using the race-neutral equation, the largest reclassification changes occurred for Black and White patients. The study calculated that classification severity of non-obstructive airway diseases may increase by 141% for Black patients and may decrease 69% for White patients. They also estimated yearly disability payments may increase by $1 billion for Black veterans and may decrease by $0.5 billion for White veterans.

Discussion

On May 6th, 2024, the Department of Health and Human Services (HHS) issued a final rule regarding Section 1557 of the Affordable Care Act (ACA). It requires nondiscrimination in the use of patient care decision support tools (e.g., clinical algorithms). The rule went into effect July 5th, 2024, and covered entities will have 300 days to comply. The rule is codified under:

45 CFR 92.210. Nondiscrimination in the use of patient care decision support tools.[12]

(a) *General prohibition*. A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs or activities through the use of patient care decision support tools.

(b) *Identification of risk*. A covered entity has an ongoing duty to make reasonable efforts to identify uses of patient care decision support tools in its health programs or activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability.

(c) *Mitigation of risk*. For each patient care decision support tool identified in paragraph (b) of this section, a covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the tool's use in its health programs or activities.

Clearly there will be large and grave consequences by the spring of 2025 if updated provisions in Section 1557 of the ACA are enforced by HHS. Not only will this impact patients clearly, as seen above with the recent example of changes made to PFTs. However, if change comes slow to covered entities, they may face extensive liability for being in violation of a federally enforceable law through their continued use of CDS tools that utilize protected status to discriminate in clinical decision making. This now begs the bigger question of whether a model (e.g., AI) or a CDS tool can ever consider these protected statuses as predictive variables to improve accuracy? What if a model that predicts cancer risk is more accurate when race or ethnicity is included?[13] What if that same model is less accurate for racially and ethnically minoritized patients when race, color, or national origin variables are removed? Which competing interest do we prioritize, antidiscrimination or accuracy? This is a real concern given the potential for investigators to perceive liability for racial discrimination under the law. Undoubtedly, a contentious time within the medical and legal community is ahead of us. Clear guiding principles are needed to lead the development and utilization of CDS tools, and more generally AI models, used to provide health care.

A seminal piece published in NEJM in 2020 recommends three principles for evaluating CDS tools that use race:[14]

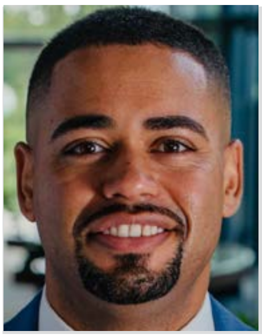
- Is the need for race correction based on robust evidence and statistical analyses (e.g., with consideration of internal and external validity, potential confounders, and bias)?
- Is there a plausible causal mechanism for the racial difference that justifies the race correction?
- And would implementing this race correction relieve or exacerbate health inequities?

Another option to consider when evaluating the potential for discrimination in CDS tools is to evaluate the relative population group fairness. What if a screening model is 95% sensitive for White patients, but only 70% sensitive for Black patients? Is it fair to use? What if the model was tweaked and improved by including race, and now becomes 90% sensitive for both White and Black patients? Is this new version fairer and more equitable to use, despite being less sensitive for White patients than the original version? By measuring population group fairness, perhaps this is a compelling way to analyze for potential for algorithmic discrimination. Pioneering researchers out of the University of Pittsburgh have begun to analyze race based CDS tools, to measure their population group fairness across multiple types of statistical analysis.[15] If fairness metrics were published by AI model or CDS tool authors, and reviewed by regulatory agencies (i.e., FDA), perhaps there would be more transparency on the identification and mitigation of potential for population group (e.g., protected status) based algorithmic discrimination.

While these scientific and technical solutions offer a great place to start our critical evaluation, they may be incomplete. Even if utilizing protected status can make the model or CDS tool more accurate across numerous statistical domains, using them to drive clinical care decisions may commit a statistical inference error known as the ecological fallacy. This formal fallacy is when conclusions about an individual are drawn from inferences about a population group that the individual is assigned to. Race-based models that may be more accurate at a population level are likely far less accurate at the individual level. To a statistically more lay reader, this can be thought of as a stereotype or generalization about an individual based on their assigned population group (e.g., race, color, or national origin) not always being right. Clearly, we need to build models and CDS tools that are personalized to the patient in front of us, not built on population level inferences that represent some statistical population group average. By investing in more transparency in model development and openly sharing datasets, we might begin to measure and improve upon individual level fairness metrics.[16] This will likely be at the crux of future litigation. Not whether the model was accurate at the population level, but whether the model was individually unfair because it was trained on historical population group averages that have been generalized to the individual. Our current use of population group models to drive racially discriminatory care at the individual level does not seem congruent with our universal aim of delivering precision health care to all.

Conclusion

Over the past decade, recent criticisms of race-based patient care decision support (CDS) tools have flourished within the medical community. Well over 50 CDS tools have been identified that utilize race, color, or national origin as an input variable. Combined with an extensive literature base of contemporary research showing the real clinical and human implications of ending these racially biased practices, it has inevitably caught the eye of elected officials and federal regulatory agencies. By May 1st, 2025, HHS' covered entities must be in compliance with new nondiscrimination rules in their utilization of CDS tools when providing patient care. As health care professionals we must remember our commitment of first doing no harm. As we begin to critically re-evaluate the litany of CDS tools that utilize race[17] and other protected statuses, we must remain steadfast in our guiding principle of maximizing individual level fairness in patient care decision support tools (i.e., AI and CDS). If covered entities do not achieve meaningful compliance through careful identification and mitigation of the potential for AI or CDS tools to racially discriminate in health care services, there will undoubtedly be real legal consequences that follow.



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Endnotes

1. *Strengthening Nondiscrimination Protections and Advancing Civil Rights in Health Care through Section 1557 of the Affordable Care Act: Fact Sheet*, Dept. of Health and Hum. Servs., https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557-fact-sheet/index.html (last visited June 1, 2024).
2. Sharon Ostfeld-Johns et al., *Removing Race from Hyperbilirubinemia Guidelines Is Not Enough*, J. Am. Med. Ass'n. Pediatrics (2024).
3. *Use of Race in Clinical Diagnosis and Decision Making: Overview and Implications*, Kaiser Family Foundation, https://www.kff.org/racial-equity-and-health-policy/issue-brief/use-of-race-in-clinical-diagnosis-and-decision-making-overview-and-implications/ (last visited June 1, 2024).
4. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, Inst. Of Med. (US) Comm. On Understanding and Eliminating Racial and Ethnic Disparities in Health Care, https://pubmed.ncbi.nlm.nih.gov/25032386/ (last visited June 1, 2024).
5. Ruqaiijah Yearby, Race Based Medicine, *Colorblind Disease: How Racism in Medicine Harms Us All*, Am. J. of Bioethics (2020).
6. Darshali A. Vyas et al., *Hidden in Plain Sight – Reconsidering the Use of Race Correction in Clinical Algorithms,* New Eng. J. Med. (2020).
7. Sanja Stanojevic et al., *The Global Lung Function Initiative: dispelling some myths of lung function test interpretation*, Breathe (2013).
8. Sanja Stanojevic et al., *Race and Ethnicity in Pulmonary Function Test Interpretation: An Official American Thoracic Society Statement,* Am. J. Respiratory Critical Care Med. (2023).
9. ATS Publishes Official Statement on Race, Ethnicity and Pulmonary Function Test Interpretation, Am. Thoracic Soc'y., https://site.thoracic.org/about-us/news/ats-publishes-official-statement-on-race-ethnicity-and-pulmonary-function-test-interpretation (last visited June 1, 2024).
10. *Id.*
11. J.A. Diao et al., *Implications of Race Adjustment in Lung-Function Equations*, New Eng. J. Med. (2024).
12. Nondiscrimination in Health Programs and Activities, Dep't of Health and Hum. Servs., https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities#sectno-reference-92.210 (last visited June 1, 2024).
13. Sara Khor et al., *Racial and Ethnic Bias in Risk Prediction Models for Colorectal Cancer Recurrence When Race and Ethnicity Are Omitted as Predictors*, J. Am. Med. Ass'n. Network Open (2023).
14. *Supra* note 6.
15. Shyam Visweswaran was appointed to a National Academies of Sciences, Engineering, and Medicine committee, Univ. of Pittsburgh Pittwire, https://www.pitt.edu/pittwire/accolades-honors/visweswaran-race-ethnicity-biomedical-research (last visited June 1, 2023).
16. Joshua W. Anderson and Shyam Visweswaran, *Algorithmic Individual Fairness and Healthcare: A Scoping Review*, medRxiv (2024).
17. Risk calculators, laboratory tests, and therapy recommendations with race-based guidelines, Clinical Algorithms with Race, https://clinical-algorithms-with-race.org/risk-calculators-laboratory-tests-therapy-recommendations (last visited June 1, 2024).

Racial Inequities in Maternal Health

By Karen Bullock

"Maternal death rates are highest among Black and American Indian and Alaska Native (AIAN) people, as both populations were hit hard by the COVID-19 pandemic, especially AIAN women."

- Sara R. Collins, 2024 State Scorecard on Women's Health and Reproductive Care (July 2024), Commonwealth Fund

Introduction

Black women in the United States experience disproportionately high rates of maternal morbidity and mortality in comparison to other groups, with white women being almost three times less likely to experience pregnancy-related deaths than Black women.[1, 2] More than a decade of research has consistently documented racial disparities in maternal mortality and morbidity rates across groups. Between the years of 2011 and 2013, the estimated maternal mortality rate was 17.0 deaths per 100,000 live births, with African American/Black women having a 3.4 times higher mortality rate than Anglo-white women.[3] The estimated maternal mortality ratio in 2019 was 20.1 per 100,000 live births and 23.8 per 100,000 live births in 2020, with Black women's rate at 55.3 per 100,000 live births, which was the highest for all racial groups.[4]

An exhaustive review of the literature confirms that racial gaps in maternal mortality and morbidity persist, and reports show Black women have a more significant number of adverse pregnancy experiences than their white counterparts.[5, 6, 7, 8, 9] For almost two decades, it has been documented that health and well-being prior to pregnancy account for a significant proportion of complications and maternal deaths.[10] Moreover, maternal health specialists argue that while other factors such as income and education may contribute to maternal health outcomes, such risks can be addressed, and more than 80% of the deaths are preventable.[11] However, it is worth noting that in the absence of such predisposing and underlying health conditions, significant racial disparities continue to exist between Black and white women's maternal health outcomes.[12]

Background

Globally, the United States has the highest number of women dying of pregnancy-related complications during or within 12 months of the end of pregnancy.[13] Maternal morbidity studies show the current rates of deaths and pregnancy adversity are higher now than they were 25 years ago. Furthermore, Black women are dying at significantly higher rates than other racial/ethnic groups across various risk factors. For example, the Centers for Medicare and Medicaid provide medical coverage for more than 65% of births to Black mothers. Many of these women find it impossible to afford health insurance at preconception, but when they become pregnant, they become eligible for Medicaid.[14] Pregnancy may be the first time that some of these women are receiving care from a medical provider and, for the first time, are having pre-existing health conditions diagnosed. Furthermore, educational attainment, which is often positively correlated with good health outcomes, does not so translate for pregnant Black women. Research shows that a college-educated Black woman has a 60% greater risk for maternal death than a white or Latina woman with less than a high school education[15] These surprising data are quite misunderstood. Notwithstanding, attention to reducing the increasing rates of deaths and severe complications for Black women during pregnancy is long overdue.

Examining maternal mortality and morbidity through the lens of social determinants alone does not yield a complete picture of the depth or complexity of the problem, illuminating the importance of engaging individuals, families, and policymakers in the public health policy discourse. Moreover, in light of the harsh racial inequities and structural and systemic racism that have been revealed by the COVID-19 pandemic, a call for attention to policy change remains a moral imperative.[16, 17] In 2021, the maternal mortality rate for Black women was 69.9 deaths per 100,000 live births, while the rate for white women was 26.6. This heightened risk applies across all income and education levels.

Moreover, racial disparities in the utilization and access to the standard of care during pregnancy and childbirth actually contribute to the high prevalence of maternal mortality among Black women.[18, 19, 20, 21] Researchers have quantified the prevalence by gathering data confirming the incidence rate of deaths among Black women in the United States, during or after childbirth, and report that Black women's reproductive health outcomes are at crisis levels. Examining the association between racism and maternal mortality outcomes is promising because it strengthens the case for advancing health equity and closing the gaps in equitable service delivery.

Nearly a decade ago, the CDC reported that Black women in the U.S. experienced a maternal mortality rate of 44 deaths per 100,000 live births, while for white women, the mortality rate is 13 deaths per 100,000 live births.[22] A nonprofit organization examined this phenomenon of health disparities more closely, aiming to understand some of the factors that influence such outcomes.[23] What they found from self-reports in a mixed methods exploration conducted with community-dwelling women is that the problem may be systemic, and the root cause is likely social inequities that are endemic in the lives of Black people, specifically racial minority groups, generally. Furthermore, the experience of racism from childhood through adulthood (including, but not limited to, personal lived experiences, vicarious trauma, and institutionalized structural racism) is believed to contribute to infant mortality in the U.S.[24] This led the researchers to conclude that when inherent inequities are combined with conscious and unconscious biases in health care systems, public health crises that are difficult to curtail, such as maternal morbidity and mortality for Black women, require more targeted interventions and prevention strategies.

Because of its importance and magnitude as a public problem, the Biden Administration allocated funds to improving maternal health, and The Centers for Medicare & Medicaid Services (CMS) invested a significant portion of its resources in targeting the root causes of the perpetual racial inequities in maternal health outcomes in the U.S.[25] To this end, CMS Office of Minority Health developed new initiatives to eliminate disparities in health care, with the goals of ensuring equitable access to the highest quality health care for all CMS enrollees. The strategies are aimed at (a) supporting states through the Enhancing Reviews and Surveillance to Eliminate Maternal Mortality (ERASE MM) Program; (b) supporting state perinatal quality collaboratives (PQCs) to improve the quality of care for mothers and their babies; (c) helping states standardize their assessments of levels of maternal and newborn care for their delivery hospitals by offering the CDC Levels of Care Assessment; and (d) promoting the Hear Her campaign, which messages the public about urgent maternal warning signs and resources for pregnant and postpartum women to improve communication between the patient and the health care clinician. CMS hopes to move beyond simply identifying the problem of maternal morbidity and mortality to prevention by implementing these strategies universally. However, a precaution worth considering comes from the recent work of research scientists in HIV prevention.[26]

Researchers have argued that the implementation of CDC guidelines for Black women affected disproportionately by high risk of HIV was inconsistent and ineffective in initiating preexposure prophylaxis (PrEP) counseling as a prevention measure.[27] Notably, Black women respond well to interventions when the clinician has cultural awareness and knowledge and is nonjudgmental in the engagement and delivery of care. They recommend moving toward a more inclusive and status-neutral model of care, creating the space for Black women to sit at the tables where discussions about reproductive health care can extend beyond the conventional rhetoric about social determinants of health is essential.[28, 29] Furthermore, obstetrics and gynecology literature has made the point clear that to reduce racial disparities in maternal morbidity and mortality for Black women and create health equity, it is time to reframe the discussion about race-based medicine and acknowledge that the treatable and preventable pregnancy complications experienced by Black women, differentially, should not be relegated to the misnomer of [Black race] being the culprit.[30, 31, 32, 33] Clare insists that differences are not related to genetics or biology but rather to historical human experience, ancestry, and racism.[34] Thus, building equity into the care experience and addressing structural and systemic barriers that currently exist require strategies that call into question the perpetuation of race as a biological construct in obstetrics and gynecology.[35]

In a policy brief about closing the gap, the report from the Center on Budget and Policy Priorities espouses the notion that exposure to adverse experiences, such as structural racism, can create toxic stress that influences the development of disease and health complications. These medical conditions are linked to a greater risk of maternal and infant death. Furthermore, Solomon suggests that structural racism is a social determinant of maternal mortality and morbidity, low birthweight and infant mortality, and lower life expectancy.

By definition, structural racism can be understood as a "system in which public policies, institutional practices, and cultural representations work to perpetuate racial inequity."[36] This commentary focuses on the legalized structural racism known as the Jim Crow laws in the U.S., and how this system of state and local policies, institutional practices and laws enforced racial segregation for almost a century, from the post-Civil War era until the late 1960s, and influences health inequities today. The laws were named after a (fictitious) minstrel show character, specifically as an attempt to dehumanize and marginalize Black Americans by denying them basic rights and opportunities including access to health care.[37] Notwithstanding, the impact of Jim Crow was profound, deleterious, and long-lasting. U.S. hospitals and clinics denied Black people access to basic care, including Black pregnant women. The health systems were legally and racially segregated until 1965, and many hospitals did not comply with the desegregation laws until the 1970s.[38, 39, 40] Arguably, the legacies of legalized structural racism have not been adequately addressed in the public health literature nor in medicine or among other health disciplines. The experiences of patients, families, and communities of historically marginalized populations are revealed in the narratives that they share in safe and trusted spaces.[41] Yet, more clinicians need to prepare to have such necessary conversations with their patients. Furthermore, very little outreach is being done in communities to build capacity for engaging individuals and families prior to their medical encounter in the hospital setting.[42] Understanding maternal mortality and morbidity through a conceptual lens of structural racism may add a perspective that begins to make visible what was invisible to many prior to the COVID-19 pandemic, which was the interplay between policies and practices of racial equity in health care.[43]

Health Inequities Lessons Learned From the COVID-19 Pandemic

COVID-19 exacerbated the Black women's maternal health crisis to disastrous proportions.[44] They were more likely to be infected with SARS-CoV-2 and to be hospitalized or die than women in other racial groups.[45] Moreover, the pandemic provided a somber reminder that the lack of effort to close the racial gaps, to date, left Black women exposed to COVID with disproportionately adverse health outcomes.[46] Most strikingly, in the last two years of the pandemic, maternal deaths among Black women continued to rise significantly higher than white women.[47] The persistence has led to increased public health concerns about new and innovative approaches to understanding and addressing health equity for pregnant women across racial lines.[48] Thus, this article focuses on the proliferation of research on structural and systemic racism, aimed at identifying barriers, and expands recommendations to promote equitable access to care by engaging individuals, communities, health systems and clinicians to address the historical marginalization that has long existed between Black communities and U.S. health care systems.[49]

According to researchers, in contemporary times the legacy of slavery, which predates Jim Crow, should be examined through a framework of structural racism that has resulted in disproportionate maternal and infant death among Black/African American women.[50, 51] The deep roots of these patterns that intersect race and gender lie with the historical commodification of enslaved Black women's childbearing and physicians' perpetuation of self-serving the interests of white supremacy. The suggestions that obstetrics and gynecology owe a debt to enslaved women who were experimental subjects in the development of the fields of clinical practice open the dialog to a window of understanding about mistrust of the medical profession and in particular, the framing of racialized maternal morbidity and mortality as a public health problem that requires a social justice intervention.[52, 53] Public health endeavors to close racial gaps in maternal health could benefit from the acknowledgment of such historical legacies and attending to the systemic racism that is scaffolded by implicit bias in medicine and other health care fields of practice. Increasing one's cultural awareness about Black people's experiences of historical atrocities that occurred under the auspices of medicine and health, which impacted Black women, families and communities in ways that no other racial group has experienced in the U.S. is essential. This step requires the deconstruction of antiquated theoretical models and an understanding of health and well-being that centers on white patients' experiences as the standard by best practices are established and measured. For example, in a research study that examined residential segregation and disparities in severe maternal morbidity before and during the COVID-19 pandemic, researchers argued that residents living in predominantly Black, segregated communities had worse maternal morbidity outcomes than other racial groups.[54, 55] However, a timely shift in the explanation of these findings was their argument that the disparate outcomes may have been the totality of historical and structural racism rather than individual deficits.

Increasingly, racial differences in maternal health outcomes are articulated through the epistemology of morbidity and mortality for Black women and infants.[56, 57, 58, 59] Arguably, a person's self-identified race can have political implications for access to political processes or not. As a socio/political construct, race serves a purpose that could result in advantaging some groups while systematically disadvantaging other groups. Most commonly, this is reflected in the assertion of the biological inferiority of dark-skinned populations and, historically, the biological superiority of white skin. Beliefs about the biological differences between Black and white patients in health outcomes have continued among medical students, residents, and educators, leaving unchartered territory and gaps that have not been closed since the origins of obstetrics and gynecology as fields of medical practice.[60, 61]

The tragedy of continuing to focus on race as a biological construct that explains health outcomes in obstetrics and gynecology, rather than structural racism as a social determinant of health and service delivery, is that while focused on the wrong direction Black women and their infants continue to die from preventable conditions.[62, 63] Cumulative and mutually reinforcing discrimination of one's basic human need for housing, employment and other economic opportunities is related to attainment of education and health care access, and such structural barriers take a long-term toll on Black women's health.[64]

Reconsidering the standards of practice in which race would be understood as a social construct, which racism intercedes by adding stress when Black women systematically receive poorer quality of care than white women, are denied adequate pain management. The health system provides care without dignity, value, and respect for the health of racialized populations that are presumed to be the authors of their fate as it relates to income and, wealth, educational attainment, all of which influence access to health insurance, housing, food, transportation, clean air, and water, a shift to reframe accountability and understanding is warranted.[65, 66] If clinicians and health care systems, in general, understood the historical roots of reproductive oppression for Black women and the implications of racism when infused throughout the structures of society, including public policies, institutional practices, and cultural representations that reinforce racial inequality in maternal health, the field of global public health could be a leading force in educating and preparing the next generation of culturally competent practitioners to address maternal mortality, morbidity and work toward dismantling the legacy of structural racism that is a major contributing factor.[67, 68]

A Historical Perspective on Black Maternal Health

Notably, it has been argued that defenders of segregation often clung to any evidence from biology to assert fundamental differences between races.[69] There is evidence of researchers, clinicians and educators maintaining a stance about unmet need in health disparities being the responsibility of the patient. There is a need to disrupt these perpetual ideologies.[70] Segregation that denied Black American access to health care, legally, had extensive implications for patients, health professions, and health disparities. The structures of separate and unequal hospitals erected barriers that were impossible for Black Americans to overcome. The socialization toward having to take care of your own health and well-being without having professional medical or health care became a cultural norm in Black communities, in the absence of legal recourse to seek professional care when there were no hospitals or physicians in their (Black/segregated) communities. Marginalization was legal, but it was lethal.[71, 72] The barriers were sanctioned and supported by the American Medical Association and state medical societies. These organizations were for "whites only." Similar racial barriers shaped other health professions, and similar barriers to the professions have racial or cultural implications for other groups, most notably women and Jewish people. In 2008, the AMA publicly apologized for past racial discrimination of Black physicians.[73] Arguably this was an attempt to remove a barrier and to present an antiracist approach for moving forward in creating a more equitable U.S. health care system for all patients. Other evidence for taking such steps have been disseminated in the medical literature.[74]

Discussion

An exploration of the factors that contribute to racial disparities in maternal morbidity and mortality among Black women in the U.S. points to historical exposure to racial trauma, racial bias, legalized discrimination, and marginalization. Structural barriers such as legalized racial segregation has a lasting impact on the psychosocial and emotional wellbeing of Black women and their families. The implicit and explicit racism imposed within the health care system, the unaffordability of health insurance, limited access to reproductive health care services, and a plethora of socioeconomic factors contribute to pregnancy complications for Black women.

The legacy of racism within health care must be acknowledged and understood in order to address the structural barriers that exist today in health care systems and to create policies that appropriate resources for addressing the historical atrocities that were mandated by laws to prevent all Black people from accessing equitable health care. Black women are very much a part of and connected to individuals in their family systems that endured firsthand. Actions must be taken to ensure that all health care educators, clinicians, administrators, and policymakers are aware of the history of racism within U.S. health care. An understanding of how these factors influence the disproportionately high rates of maternal and infant mortality among Black women in the United States must be integrated into the teaching and learning of medical professionals and policymakers.

Recommendations

Cultural competence education is a recommended beginning point that should be ongoing. Acquiring awareness, knowledge, and transferrable skills when providing care for diverse populations has been known to positively influence patient satisfaction.[75] As an intervention strategy, cultural competency training has been shown to increase clinicians' self-efficacy and improve health care professionals' knowledge and skills in caring for diverse patient populations.[76] Studies across disciplines have proposed it as a strategy for eliminating racial/ethnic health care inequalities. The conceptual definition proposed in this article is expansive and intended to aid in the design and implementation of actionable, observable, and measurable constructs that can guide health equity research and practice strategies with not only Black women but also other historically marginalized cultural groups.[77, 78, 79] It has dual emphases on culture and competence, presupposing that clinicians, educators, and researchers will have a baseline level of awareness, skills, and knowledge that inform their practice behaviors in engaging with Black women. Such a heightened focus implicates the intersectional roles of racism, historical trauma, and other social determinants of health in influencing disease and mortality risk. These types of barriers can be addressed by targeting the underlying social factors discussed in this article that sustain the rates of Black maternal morbidity and mortality, and by enlisting the powerful force of policy revision and educational modifications to the health care system and industries that provide care to pregnant women and their infants.

Conclusion

Achieving cultural competence is an ongoing process that holds the promise of improving the quality of care for all people. Shared values, traditions, norms, customs, lived experiences, ways of life, and the role of institutions of a group of people influence how they engage or not engage with health care systems. Each person enters into the care encounter with her cultural beliefs and attitudes that influence interpersonal interactions with clinicians. As we recognize the influence of our cultural backgrounds, personal experiences as health care professionals, and the values and beliefs that we hold, we know that these factors inform our practice behaviors. We may need to be the first line of defense in reducing maternal morbidity and mortality by becoming more open to understanding the historical experiences of Black women in the U.S. and how their lived experiences influence their reproductive health and pregnancy outcomes.

Realizing that 60% of Black women receive their care through CMS-covered plans because of preconception coverage gaps, it is reasonable to expect that there is more that we can be doing as public health researchers, scholars, and public policy experts to redefine points of entry in developing community engagement initiatives for implementing CDC guidelines to intervene in the crisis-level maternal mortality among Black women and their infants. Excluding Black women from the conversations about their own health and the health of other women like themselves perpetuates health inequities.[80] Health care professionals have a critical role in addressing maternal health disparities. Many Black women have no relationship with a primary care physician or reproductive health specialist prior to pregnancy. Yet, health care professionals with lived experiences and/or cultural competence evidenced by cultural awareness, skills, and cultural knowledge can engage Black women in person-centered, culturally concordant care through which they may have the opportunity to experience empowerment and improved health equity.[81]

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Endnotes

1. Centers for Disease Control and Prevention [CDC] (2022), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2022/maternal-mortality-rates-2022.htm.
2. Anuli Njoku et al., *Listen to the whispers before they become screams: Addressing black maternal morbidity and mortality in the United States Multidisciplinary Digital Publishing Institute* (2023), https://www.mdpi.com/2227-9032/11/3/438.
3. Andrea Creanga et al., *Pregnancy-related mortality in the United States, 2011–2013 Obstetrics & Gynecology* (2017), https://journals.lww.com/greenjournal/abstract/2017/08000/pregnancy_related_mortality_in_the_united_states,.15.aspx.
4. Njoku et al*., supra.*
5. Juanita Chin et al., *Maternal mortality in the United States: research gaps, opportunities, and priorities American Journal of Obstetrics & Gynecology* (2020), https://www.ajog.org/article/S0002-9378(20)30742-0/abstract.
6. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice, McHugh, K., Martinez, R. M., & Alper, J. (Eds.). (2021), *Advancing Maternal Health Equity and Reducing Maternal Morbidity and Mortality: Proceedings of a Workshop*, National Academies Press (U.S.).
7. Denise Carty et al., *Addressing racial disparities in pregnancy-related deaths: An analysis of maternal mortality-related federal legislation, 2017–2021* (2022), Journal of Women's Health, *31*(9), 1222-1231.
8. Kathleen Simpson et al., *Effect of the COVID-19 Pandemic on Maternal Health in the United States* (2023) MCN. *The American Journal of Maternal Child Nursing, 48*(2), 61, https://doi.org/10.1097/NMC.0000000000000895.
9. Ryan Huang et al., *Racial disparities in national maternal mortality trends in the United States from 2000 to 2019: A population-based study on 80 million live births* (2024), Archives of Gynecology and Obstetrics, 309(4), 1315-1322.
10. Cynthia J. Berg et al., *Pregnancy-related mortality in the United States, 1998 to 2005 LWW Obstetrics & Gynecology* (2010), https://journals.lww.com/greenjournal/abstract/2010/12000/pregnancy_related_mortality_in_the_united_states,.11.aspx.
11. Centers for Disease Control and Prevention [CDC] (2024), Health Equity, *Working together to reduce Black maternal mortality*, Retrieved

on May 1, 2024, from https://www.cdc.gov/healthequity/features/maternal-mortality/index.html.

12. Njoku et al., *supra.*

13. Roosa Tikkanen et al. (2020), *Maternal mortality and maternity care in the United States compared to 10 other developed countries,* The Commonwealth Fund.

14. Centers for Medicare & Medicaid Services (2022), Health Equity, https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.

15. Judith Solomon, *Closing the coverage gap would improve Black maternal health.*

16. Kathleen Simpson, *Effect of the COVID-19 Pandemic on Maternal Health in the United States* (2023), MCN, The American Journal of Maternal Child Nursing, 48(2), 61, https://doi.org/10.1097/NMC.0000000000000895.

17. Anna Burgansky et al., *Framing the Public Health Problem of Maternal Morbidity and Mortality: A Social Justice and Moral Imperative* (2019), New York State Bar Health Law Journal, 24(1), 27-33.

18. Center for Disease Control (2016), *CDC Foundation partnership to help reduce maternal mortality in the United States,* Retrieved on January 5, 2019 at https://www.cdcfoundation.org/pr/2016/cdc-foundation-partnership-help-reduce-maternal-mortality-united-states.

19. Centers for Disease Control and Prevention [CDC] (2021), Retrieved on May 1, 2024 from https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm#:~:text=In%202021%2C%20the%20maternal%20mortality,for%20White%20and%20Hispanic%20women.

20. Centers for Disease Control and Prevention [CDC] (2022), Retrieved on May 1, 2024 from https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2022/maternal-mortality-rates-2022.htm.

21. Centers for Medicare & Medicaid Services (2022), Health Equity, Retrieved on May 1, 2024 from https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.

22. Center for Disease Control (2016), *supra.*

23. Martin, N. (2017), *Nothing protests Black women from dying in pregnancy and childbirth*, Retrieved on January 2, 2019 at https://www.propublica.org/article/nothing-protects-black-women-from-dying-in-pregnancy-and-childbirth.

24. Grimm, M., and Cornish, D.L., *Infant mortality and racism in the United States* (2019), International Journal of Undergraduate Research and Creative Activities, 10, 1-7. DOI: https://doi.org/10.7710/2168-0620.10977.

25. Centers for Medicare & Medicaid Services, *supra.*

26. Whitney C. Irie et al., *Social and Structural factors associated with interest in HIV pre-exposure prophylaxis among Black women in the United States* (2024), Psychological and Sociomedical Aspects of AIDS/HIV, 36, 672-681.

27. *Id.*

28. Solomon, *supra.*

29. Grimm, *supra.*

30. Allison Bryant et al., *Racial/ethnic disparities in obstetric outcomes and care: Prevalence and determinants (*2010), American Journal of Obstetrics and Gynecology, 202(4), 335-343.

31. Juanita Chinn et al., *Maternal mortality in the United States: Research gaps, opportunities, and priorities* (2020), American Journal of Obstetrics and Gynecology, 223(4), 486-492.

32. Camille Clare et al., *Race as a social construct should not be cited as a risk factor for postpartum preeclampsia* (2022), American Journal of Obstetrics & Gynecology, 227(2), 357-358.

33. Nkechi Conteh et al., *Medical mistrust in perinatal mental health* (2022), Harvard Review of Psychiatry, 30(4), 238-247.

34. Clare, *supra.*

35. *Id.*

36. Jamilla Taylor, *Structural racism and maternal health among Black women* (2020); The Journal of Law, *Medicine & Ethics: A Journal of the American Society of Law*, Medicine & Ethics, 48(3), 506–517, https://doi.org/10.1177/1073110520958875.

37. Harriet A. Washington, *Medical apartheid: the dark history of medical experimentation on Black Americans from colonial times to the present* (2006), New York, Doubleday.

38. Timothy Smith, *Health Equity: How legacy of medical racism shapes U.S. health care today* (2022), American Medical Association, Retrieved on 5/15/2024 from https://www.ama-assn.org/delivering-care/health-equity/how-legacy-medical-racism-shapes-us-health-care-today.

39. Rice, M.F., *Hospital/health facilities and the Hill-Burton obligations: A secret from the Black community* (1985), Urban League Review, 9(2):39-46.

40. Saul A., *How Social Security helped desegregate America's Hospitals* (2021), retrieved from https://blog.ssa.gov/how-social-security-helped-desegregate-americas-hospitals/ on May 15, 2024.

41. Bullock, K., and Bullock-Johnson, R., *Cultural humility: Necessary but insufficient for equitable access to care.* In Doka, K.J., Jennings, B., Kirk, T.W., and Tucci, A.S. (Eds.), *End-of-Life Ethics in a Changing World* (pp. 73-85), Washington, DC: Hospice Foundation of America Press.

42. Bullock, K., and McGraw, S.A. (2006), *A community capacity-enhancement approach to breast and cancer screening among older women of color*, Health & Social Work, 31(1), 16-25.

43. Laurencin, C. T., and Walker, J. M. (2020), *A Pandemic on a Pandemic: Racism and COVID-19 in Blacks*, Cell systems, 11(1), 9–10. https://doi.org/10.1016/j.cels.2020.07.002.

44. Simpson, *supra.*

45. Hung P. et al. (2022), *Analysis of residential segregation and racial and ethnic disparities in severe maternal morbidity before and during the COVID-19 pandemic*, AMA Netw Open, 5(10), 1-14.

46. *Id.*

47. United States Government Accountability Office (2022, October 19), *Maternal health outcomes worsened and disparities persisted during the pandemic* (Report to Congressional Addressees), https://www.gao.gov/products/gao-23-105871.

48. Centers for Disease Control and Prevention [CDC] (2024), Health Equity, *Working together to reduce Black maternal mortality*, Retrieved on May 1, 2024 from https://www.cdc.gov/healthequity/features/maternal-mortality/index.html.

49. Geronimus A. T. (1992), *The weathering hypothesis and the health of African-American women and infants: evidence and speculations*, Ethnicity & Disease, 2(3), 207–221.

50. Owens, D. C., and Fett, S. M., *Black Maternal and Infant Health: Historical Legacies of Slavery* (2019), American Journal of

Public Health, 109(10), 1342–1345, https://doi.org/10.2105/AJPH.2019.305243.

51. Solomon, *supra.*

52. Wailoo K., *Historical aspects of race and medicine: The case of J. Marion Sims* (2018), JAMA, 320(15):1529–1530. doi:10.1001/jama.2018.11944.

53. Burgansky, A. et al. (2019), *Framing the Public Health Problem of Maternal Morbidity and Mortality: A Social Justice and Moral Imperative*, New York State Bar Health Law Journal, 24(1), 27-33.

54. Solomon, *supra.*

55. Hung et al., s*upra.*

56. Carty, D. C., Mpofu, J. J., Kress, A. C., Robinson, D., and Miller, S. A. (2022), *Addressing racial disparities in pregnancy-related deaths: An analysis of maternal mortality-related federal legislation*, *2017–2021*, Journal of Women's Health, 31(9), 1222-1231.

57. Elliot, J.P. (2012), *The medical and legal aspects of maternal mortality*, Seminars in Perinatology, 36(1), 73-78, https://doi.org/10.1053/j.semperi.2011.09.014.

58. Owens, D. C., and Fett, S. M. (2019), *Black Maternal and Infant Health: Historical Legacies of Slavery*, American Journal of Public Health, 109(10), 1342–1345, https://doi.org/10.2105/AJPH.2019.305243.

59. Taylor J. K. (2020), *Structural racism and maternal health among Black women*, The Journal of Law, Medicine & Ethics: A Journal of the American Society of Law, Medicine & Ethics, 48(3), 506–517. https://doi.org/10.1177/1073110520958875.

60. Hoffman, K.M., Trawalter, S., Axt, J.R., Oliver, M.N. (2016), *Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites*, Psychological and Cognitive Sciences, 113(16), 4296-4301, https://doi.org/10.1073/pnas.1516047113.

61. Futterman, J., Bi, C., Crow, B., Kureshi, S., and Okah, E. (2024), *Medical educators' perceptions of race in clinical practice*, BMC Medical Education, 24 (230), 1-9.

62. Grimm and Cornish, *supra.*

63. Taylor, *supra.*

64. Solomon, *supra.*

65. Hoffman, *supra.*

66. Clare 2022, *supra.*

67. Taylor, *supra.*

68. Solomon, *supra.*

69. Wailoo, *supra.*

70. Barrett, N.J., Bullock, K., and Johnson, K.S. (2022), *Unmet Needs in Health Disparities Research—It's Not Just About Patients*, JAMA Internal Medicine, 182(9), 995–996. doi:10.1001/jamainternmed.2022.2877.

71. Washington, H. A. (2006), *Medical apartheid: the dark history of medical experimentation on Black Americans from colonial times to the present*, New York, Doubleday.

72. Owens and Fett, *supra.*

73. Wailoo, *supra.*

74. Carla Boutin-Foster et al., *Promoting Anti-Racism in Clinical Practice: Lessons Learned in the Process of Removing the Race Coefficient from the Estimated Glomerular Filtration Rate Algorithm Health Equity* (2023), https://www.liebertpub.com/doi/10.1089/heq.2023.0095.

75. Bullock and Bullock-Johnson, *supra.*

76. Nathan A. Boucher and Kimberly S. Johnson, *Cultivating Cultural Competence: How are hospice staff being educated to engage racially and ethically diverse patients?,* American Journal of Hospice and Palliative Medicine (2021), https://journals.sagepub.com/doi/10.1177/1049909120946729.

77. Diane Bridges et al., *Interprofessional Collaboration: Three best practice models of interprofessional education Journal of Medical Education Online* (2011), https://www.tandfonline.com/doi/full/10.3402/meo.v16i0.6035.

78. Bullock and Bullock, Johnson, *supra.*

79. Li, S., Miles, K., George, R. E., Ertubey, C., Pype, P., and Liu, J. (2023), *A critical review of cultural competence frameworks and models in medical and health professional education: A meta-ethnographic synthesis: BEME Guide No. 79*, Medical Teacher, 45(10), 1085–1107, https://doi.org/10.1080/0142159X.2023.2174419.

80. Irie et al., *supra.*

81. *Id.*

Data Mapping To Address Maternal Health, Morbidity and Mortality

By Dorothy Shuldman and Andria Adigwe

Introduction

Despite great advancements in modern medicine, including obstetrics and gynecology, in the United States, the maternal mortality rates remain surprisingly high. The World Health Organization defines a pregnancy-related death as: "the death of a woman while pregnant or within 42 days [(about 1.5 months)] of termination of pregnancy, irrespective of the cause of death (obstetric and non-obstetric)" including unintentional/accidental and incidental causes.[1] The United States Centers for Disease Control and Prevention (CDC) establishes mortality rates by calculating maternal deaths per 100,000 live births of children. According to the most recent CDC report, the maternal mortality is still problematic.[2] In addition, Black non-Hispanic women are 2.5 times more likely to suffer a pregnancy related death.[3] Women in rural areas are subject to poor maternal health outcomes as well. It is estimated that women in rural areas, who lack access to necessary health care providers, are 60% more likely to die compared to those living in non-rural areas.[4] This is because over half of U.S. rural counties do not have access to a hospital with a maternity department[5] and "[a]reas with low or no access to maternal care affect over 5.6 million women and nearly 350,000 births across the U.S."[6] These numbers are significant, and activists in New York and across the country have been calling for attention to this problem for years.

On the federal level, there have been recent developments since the Biden administration published the White House Blueprint for Addressing the Maternal Health Crisis.[7] In this internet-driven world, it is interesting to see efforts to address these disparities by data-mapping the presence of broadband internet: the Data Mapping to Save Moms' Lives Act. This article discusses the Act's background, its implementation and effectiveness in New York, and considers the future of the Act.

"Data Mapping to Save Moms' Lives Act"

In June 2022, the Biden administration published the *White House Blueprint for Addressing the Maternal Health Crisis* which outlines five goals to address the maternal health crisis. These goals include: (i) increase access to and insurance coverage of comprehensive high-quality maternal health care; (ii) ensure that those giving birth and facing this maternal health crisis are able to voice their issues and that they are also active decision makers in their own care; (iii) strengthen data collection, standardization, harmonization, transparency, and research; (iv) grow and diversify the perinatal workforce; and (v) enhance the economic and social supports for women and families throughout all stages of pregnancy, including the preconception and postpartum periods.[8] The Blueprint recognizes that data collection on the maternal health crisis is "fragmented, unstandardized, nontransparent, and irregular" and "[a]s a result, health care systems, communities, and government entities do not have a fully informed grasp of the problem and what solutions should be deployed."[9] Therefore, it follows that soon after the Blueprint's release, a law was enacted to address this problem.

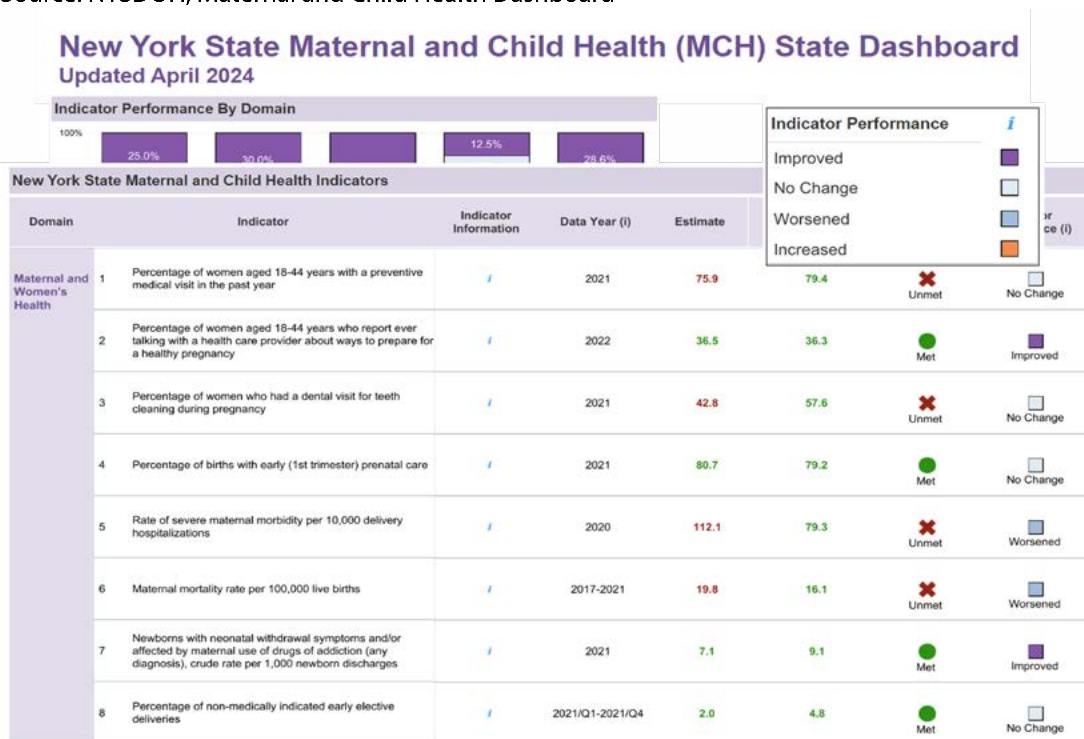
On December 20, 2022, President Biden signed the *Data Mapping to Save Moms' Lives Act* (47 U.S.C.§ 642) into law, requiring the Federal Communications Commission's (FCC), in consultation with the CDC, to include publicly available data on maternal mortality and severe maternal morbidity into the Mapping Broadband Health in America platform. Further, such data are to include at least one-year postpartum data.

The Mapping Broadband Health in America platform is a mapping tool established by the FCC's Connect2Health Task Force that allows for the analysis of the intersection in broadband access and health data.[10] The tool's purpose is to demonstrate the value of broadband as it relates to improving health outcomes, so that policy makers and stakeholders may use this platform to develop solutions. The 2023 release of the Mapping Broadband Health in America includes data on opioid use, chronic diseases, and maternal health. The tool is an "Open Integration" model by design and is available to both public and private stakeholders. Therefore, all users – whether an individual user, non-profit organization, local community, law maker, or other entity – can integrate their own datasets to allow for data customization. FCC Chairwoman Jessica Rosenworcel proffers that solutions to the U.S.'s maternal health crisis exist which include access to technology.[11] By mapping broadband access and the intersection of maternal health outcomes, we can identify the locations where poor maternal health outcomes are high and where such technological solutions could support those communities, for example, access to telehealth services.

Data Mapping in New York

New York State has a long and strong history of using data mapping to identify localities that need special attention in the area of maternal mortality and morbidity. For instance, the New York State Department of Health (NYSDOH) created a Statewide Maternal and Child Health Dashboard display state-wide data and county-specific data.[12] The numbers are based on various information sources, including but not limited to, national and state-wide vital statistics records and New York State Pregnancy Risk Assessment Monitoring System which is a mail/telephone survey of mothers who have recently given birth to a live born infant. In addition, New York City (NYC) had a neighborhood and NYC county specific dashboard displaying maternal mortality and morbidity numbers.[13] This NYC Dashboard was maintained by the NYC Office of Technology and Innovation and the Department of Health and Mental Hygiene. However, although the website states that it was last updated May 19, 2023, at the time of this writing, the data do not seem to go beyond 2020.[14] The NYC Dashboard allows the user to visualize data by borough, number of deaths, race/ethnicity, underlying cause.

Source: NYSDOH, Maternal and Child Health Dashboard[15]



Domain		Indicator	Indicator Information	Data Year (i)	Estimate			ce (i)
Maternal and Women's Health	1	Percentage of women aged 18-44 years with a preventive medical visit in the past year	i	2021	75.9	79.4	Unmet	No Change
	2	Percentage of women aged 18-44 years who report ever talking with a health care provider about ways to prepare for a healthy pregnancy	i	2022	36.5	36.3	Met	Improved
	3	Percentage of women who had a dental visit for teeth cleaning during pregnancy	i	2021	42.8	57.6	Unmet	No Change
	4	Percentage of births with early (1st trimester) prenatal care	i	2021	80.7	79.2	Met	No Change
	5	Rate of severe maternal morbidity per 10,000 delivery hospitalizations	i	2020	112.1	79.3	Unmet	Worsened
	6	Maternal mortality rate per 100,000 live births	i	2017-2021	19.8	16.1	Unmet	Worsened
	7	Newborns with neonatal withdrawal symptoms and/or affected by maternal use of drugs of addiction (any diagnosis), crude rate per 1,000 newborn discharges	i	2021	7.1	9.1	Met	Improved
	8	Percentage of non-medically indicated early elective deliveries	i	2021/Q1-2021/Q4	2.0	4.8	Met	No Change

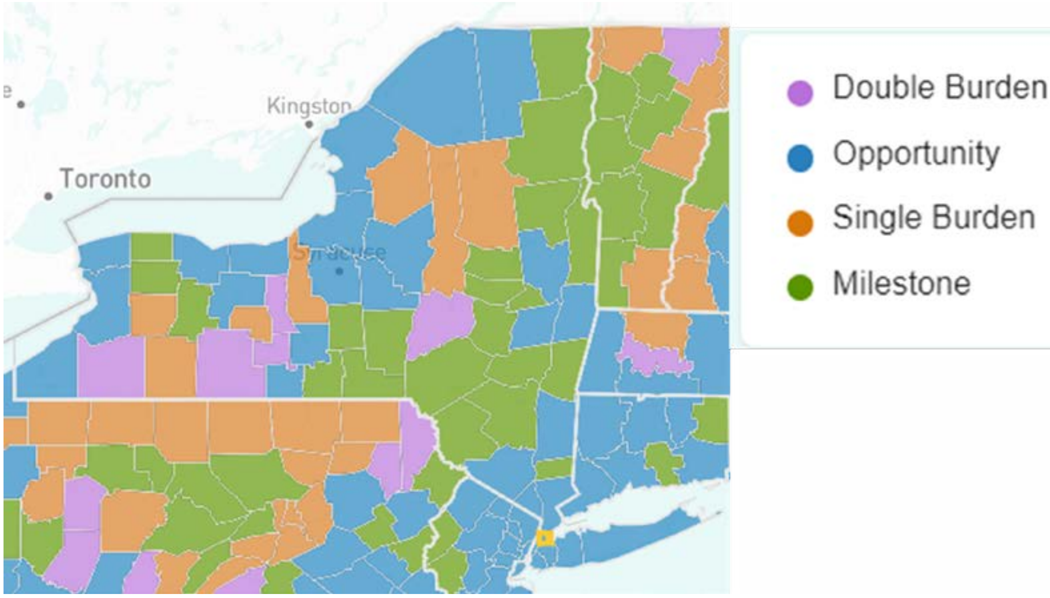
Knowledge is not always power, it seems. Despite New York's efforts bring to focus where the pain points lie, the March 14, 2024 NYSDOH reports indicate a steady increase in mortality rates among racial and ethnic minorities.[16]

On the FCC's Focus on Maternal Health platform, users can dive into maternal health and morbidity in New York and compare those with broadband access. Users can display the interconnectivity between what we could consider "broadband"[17] and "maternal health." Users can visualize the impact of internet access by changing different variables and see the effect the change has on the broadband-health space.

The platform has the capability to analyze data multiple maternal health outcomes and statistics based on data available to the CDC, including (i) maternal deaths reported between 2018 – 2021; (ii) the maternal mortality rate (number of maternal deaths up to 42 days postpartum per 100,000 live births, 2018-2021); (iii) the late maternal death rate (number of Maternal deaths up to 1 year postpartum per 100,000 live births, from 2018 to 2021); (iv) severe maternal morbidity rate (Number of women experiencing unexpected outcomes of labor and delivery across 21 indicators) per 10,000 in-hospital deliveries in 2019); (v) maternity care deserts (2020 data on access to obstetric care in a given county from none (desert) to full, and maternity care deserts are counties without a hospital, birth center, or provider offering obstetric care); and (vi) mental health provider shortage (the population-weighted average score of Mental Health Professional Shortage Areas in a county from 2020 to 2023).[18]

After selecting determining the broadband and maternal health outcome to analyze, the FCC's platform will classify states or counties[19] by the availability of broadband and whether there is a high or low health need. The four designations are as follows: (i) areas that are marked as "double burden" identify those counties that have both low broadband connectivity status and high health needs as compared to the national average; (ii) areas with the designation "opportunity" are those areas where technological solutions may have a real impact as the state as whole has a higher-than-average broadband connectivity relative to the national average and a higher health need; (iii) the areas marked as "single burden" display areas with lower connectivity status, but a lower health need; and (iv) "milestone" areas have higher connectivity status and lower health need.[20] These classifications make apparent where there is a greater need for technological solutions to be deployed to ameliorate poor health outcomes.

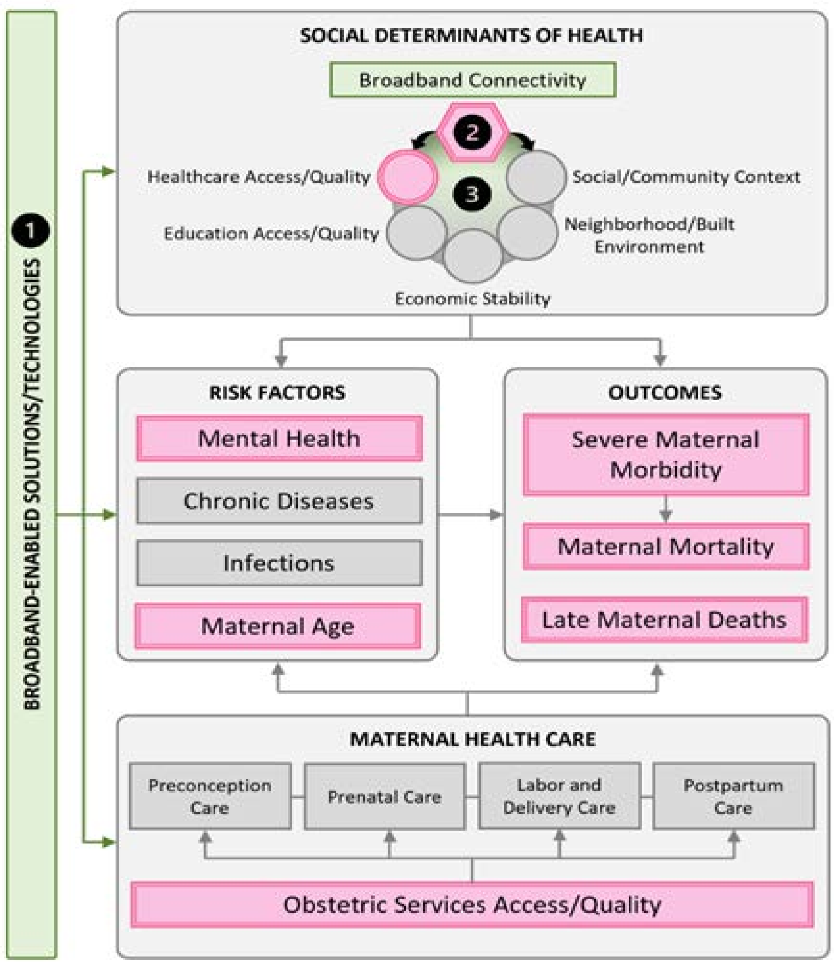
When using the platform to analyze broadband access[21] and maternal death data, most New York State counties are classified as either opportunity or milestone, and a minority are either single or double burden.[22] Further, according to the map's data on broadband connectivity and severe maternal morbidity, which only includes data level at the state level currently, New York is classified as "opportunity" overall.[23] As it relates to broadband access and maternity care deserts, New York County data per the map shows that solutions should be prioritized for Herkimer, Hamilton, Seneca, Schuyler, and Yates counties, which are each classified as double burden.[24]



The above screenshot from the FCC's "Focus on Maternal Health" platform shows the intersection of broadband access and maternal deaths in New York State.

The FCC's platform makes clear that access to the internet, where people can gain information and resources, can be a distinct social determinant of health, and as such could improve health equity and close the digital divide. Internet access can be a tool to learn about ways to improve or maintain one's health or a tool to connect individuals directly with their health care provider. Telehealth has experienced rapid growth since the beginning of the COVID-19 pandemic; however, "[m]ore work needs to be done to enable equitable access to video telehealth by addressing disparities that are further exacerbated by lack of broadband access or limitations in high-speed access impacting those residing in rural areas the most."[25] Services like telehealth can fill gaps where there are provider shortages, and the FCC's "Focus on Maternal Health" platform can identify which areas are the most vulnerable for the purposes of improved infrastructure and access to health services.

The platform is a user-friendly and easily accessible tool that can support public health stakeholders, like legislators, departments of health, health systems and other community health providers, develop targeted proposals and solutions for the areas where an urgent need exists. Importantly, as demonstrated in the workplan below, the map in place now is only phase 1 within the FCC's plan for the platform, and future goals include "incorporat[ing] additional maternal health variables and functionalities into the mapping platform, conduct important research and data analytics on the intersection of broadband connectivity and maternal health, and pursue additional activities to advance the role of broadband connectivity in improving maternal health."[26] With the introduction of additional datasets, proposed public health solutions can adopt a more focused and efficient approach.



Above was developed by the FCC'S Connect2HealthFCC Task Force as an initial conceptual framework to guide their multi-plan approach for their obligations under the Data Mapping to Save Moms' Lives Act – the items in pink show phase 1.[27]

Implementation Opportunities

There appears to be a substantial opportunity for collaboration between state efforts, such as New York data mapping endeavors and the FCC's platform. The current New York state efforts on maternal health and morbidity do not factor in broadband data access. The FCC's open integration model would allow users, such as the New York Department of Health, to import data from specific counties, for a particular demographic population to gain a better understanding of where problems may lie. This feature extends the use of the platform beyond the pre-set health conditions and demographic measures displayed on the platform to allow user customization.

As the New York State government is collecting various data, broadband data could be one of the data elements in informing and creating legislation that tackles the problem from a holistic point of view. The customized maps could help tailor investment and "right-size" public-private partnerships. These maps could help stakeholders, such as educators, activists, politicians, etc., identify the types of collaborations that may be needed to improve connectivity and health. It provides a tool for entrepreneurs to develop innovative solutions for enabling consumer health through broadband. Local communities may find the maps helpful as they allocate resources and focus efforts on leveraging broadband connectivity for health. Further, such solutions could be a source of job growth or provide for an improved workforce, as health care providers, academic institutions and local governments may need to invest in training and workforce development so that maternal health professionals can effectively leverage and utilize such technological advancements within their practice. Finally, over time and with periodic data updates and collaborations with stakeholders, the maps could be used to assess continued progress in the connected health space.

Conclusion

Over the years, we have seen panel discussions, white papers, new policies, some even discussed in this special Journal Issue, all addressing this issue with varying successes. New York State has made several efforts to combat this reality; for instance:

- NYSDOH established the New York State Maternal Mortality Review Board and the New York State Maternal Mortality & Morbidity Advisory Council. Both groups help to identify common factors contributing to death and develop the recommendations needed to improve the health and safety of pregnant New Yorkers.

- New York also participates in the National Network of Perinatal Quality Collaboratives led by the NYSDOH Division of Family Health. It aims to provide the best, safest and most equitable care.

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- New York City Council passed a package of legislation addressing significant disparities in maternal health, mortality, and morbidity in 2022.[28]

Yet, we will continue to see an increase in maternal mortality rates unless we approach this issue from a holistic point of view. Health care is a complex landscape in general; tackling certain issues within it requires access to detailed analytics, collaboration and comprehensive solutions tailored to its multifaceted challenges. There is an opportunity for New York to implement and incorporate the FCC's data mapping technology and to increase coordination with teams from hospitals and centers, perinatal care providers, professional organizations, patient advocates and other stakeholders. The initiatives New York has in place in conjunction with the FCC's Focus on Maternal Health platform can help harness technological innovations to enhance access to care, both in the maternal health care setting and beyond.

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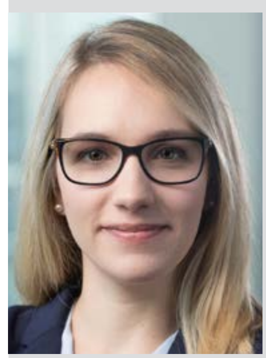

Dorothy Shuldman is an attorney in Phillips Lytle LLP's Corporate Practice Group and vice chair of the Public Health Committee of NYSBA's Health Law Section. Dorothy supports business and not-for-profit clients throughout all stages of the business life cycle, and assists on data privacy and cybersecurity matters. After earning a Master of Public Health degree and working in health care for many years before becoming an attorney, Dorothy provides a unique perspective that benefits the firm's health care clients, including on regulatory matters. She is also a member of the firm's Intellectual Property Practice Team, focusing on trademark and copyright law, and the Artificial Intelligence (AI) Practice Team.

Endnotes

1. *Maternal Deaths*, The Global Health Observatory, https://www.who.int/data/gho/indicator-metadata-registry/imr-details/4622#:~:text=A%20death%20occurring%20during%20pregnancy,this%20definition%20includes%20unintentional%2Faccidental (last visited May 29, 2024).
2. Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2022*, Nat'l Center for Health Stat. (May 2024), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2022/maternal-mortality-rates-2022.pdf.
3. *Id.*
4. *Focus on Maternal Health*, Federal Commc'ns Comm'n, https://www.fcc.gov/reports-research/maps/connect2health/focus-on-maternal-health.html (last visited May 29, 2024).
5. *Rural Maternal Health*, Rural Health Info. Hub (May 20, 2024), https://www.ruralhealthinfo.org/topics/maternal-health#:~:text=Dual%20Barriers%3A%20Examining%20Digital%20Access,higher%20poverty%20and%20uninsurance%20rates.
6. *Where You Live Matters: Maternity Care Deserts and Crises of Access and Equity*, March of Dimes, https://www.marchofdimes.org/where-you-live-matters-maternity-care-deserts-and-crisis-access-and-equity (last visited May 29, 2024).
7. *White House Blueprint for Addressing the Maternal Health Crisis*, The White House (Jun. 24, 2022), https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.
8. *Id.* at 4-6.
9. *Id.*
10. The platform can be accessed here: *Mapping Broadband Health in America: Maternal Health,* Federal Commc'ns Comm'n, https://www.fcc.gov/reports-research/maps/connect2health/maternal-health-map.html?bbSel=Broadband+Access&mhSel=Maternal+Deaths&bbThresh=90.25&mhThresh=1&md=2 (last visited May 29, 2024).
11. *Focus on Maternal Health*, *supra* note 4.
12. *New York State Maternal and Child Health (MCH) Dashboard: Reports,* Dep't of Health (Apr. 2024), https://apps.health.ny.gov/public/tabvis/PHIG_Public/mch/reports/#state.
13. *Pregnancy Associated Mortality,* Dep't of Health and Mental Hygiene, https://data.cityofnewyork.us/Health/Pregnancy-Associated-Mortality/27x4-cbi6/about_data (last visited May 30, 2024).
14. *Id.*
15. *New York State Maternal and Child Health (MCH) Dashboard: Reports*, *supra* note 12.
16. *New York State Report on Pregnancy-Associated Deaths 2018-2020,* Dep't of Health, https://www.health.ny.gov/community/adults/women/maternal_mortality/docs/maternal_mortality_review_2018-2020.pdf (last visited May 29, 2024); *New York State Maternal Mortality and Morbidity Advisory Council Report 2023*, Dep't of Health, https://www.health.ny.gov/community/adults/women/maternal_mortality/docs/2023_mmm_council_report.pdf (last visited May 29, 2024).
17. The FCC "Focus on Maternal Health" platform allows users to analyze broadband access in general, download and upload speed as it relates to broadband access, internet adoption, and rural access as it relates to fixed broadband services.
18. *Mapping Broadband Health in America: Maternal Health*, *supra* note 10.
19. Not all maternal health databases have data at the county level, and some are by state only.
20. *Mapping Broadband Health in America: Maternal Health*, *supra* note 10.
21. Here, this is the percent of population with access to fixed broadband services at 25/3 mbps or higher advertised speeds in 2019.
22. *Mapping Broadband Health in America: Maternal Health*, *supra* note 10.
23. *Id.*
24. *Id.*
25. *Updated National Survey Trends in Telehealth Utilization and Modality (2021-2022),* Assistant Sec'y for Plan. And Evaluation Off. Of Health Pol'y (Apr. 19, 2023), https://aspe.hhs.gov/sites/default/files/documents/7d6b4989431f4c70144f209622975116/household-pulse-survey-telehealth-covid-ib.pdf.
26. *Focus on Maternal Health*, *supra* note 4.
27. *Id.*
28. *Council Passes Historic Maternal Health Package to Help Address Racial Disparities, Most Severally Affecting Black Women and Birthing People,* New York City Council (Aug. 11, 2022), https://council.nyc.gov/press/2022/08/11/2240/.

Private Equity Ownership: A Pressing Concern for Maternal Health Outcomes

By Cauolyn Baptiste, Heather Butts, and Mavis Smith

Private equity ownership has infiltrated almost every sector of the health care industry and is associated with a harmful impact on patient costs as well quality of care.[1, 2] These for-profit entities prioritize profit maximization and usually have a short three to five-year turnover period to resell and to satisfy high-interest payments and debts associated with private equity investments and buyouts.[3, 4] The target market for the resale is parties with a more permanent involvement in the health care industry, such as hospitals and insurance companies. This business model holds itself out as furnishing services to benefit patients and ought to be aligning with the goals of building and maintaining a sustainable health care system with high-quality patient care.[5]

Research on Obstetrics and Gynecology

There needs to be more federal or state regulation in the relatively new area of private equity investment in health care.[6] The regulatory gap means that over 80% of private equity investments go unreviewed, often because the firms are falling below the mandatory reporting threshold.[7] Compounding this issue is the lack of transparency in private equity transactions, making it difficult to monitor their activities.[8] There is an observed trend of investors consolidating doctors' offices and medical practices into a unified system after these takeover investments and buyouts. Small acquisitions often escape reporting and can significantly impact competition in urban and rural markets through antitrust strategy.[9]

Consolidation affects patients' quality of care and the choice of where they receive care, potentially leading to gaps in care and changes in patient utilization. Therefore, private equity ownership raises the possibility that firms may take advantage of patient consumers through market power, individual vulnerabilities, and inside or unequal information.[10]

Despite the innocuous nature of small medical practice acquisitions, private equity ownership has inflicted harm on patients, in reality, due to a lack of thorough patient-centered decision-making and neglect of public health needs, with less profitable health care services being the first to be discontinued following a private equity takeover.

Additionally, private equity acquisitions increase charges. Consolidation reduces competitors in the market, allowing firms to negotiate prices with insurance companies, leading to higher patient cost-sharing. Private equity firms and insurance providers negotiate prices of privately insured patients, but Medicare and Medicaid reimbursements are set administratively using a formula developed by the Centers for Medicare and Medicaid Services based on several factors.[11] The Medicare physician fee schedule is not proportionate with physician practice expenses. Medicaid insurance reimbursements are notoriously low, influencing physicians to sell their practices to private equity firms that subsequently consolidate to gain bargaining power to negotiate more attractive rates to the financial detriment of patients.

Social determinants play a significant role in maternal health; it is equally essential to establish systems of accountability for these outcomes. Individual patients often have little control over determinants of health, which influence governmental decisions, policies, and societal norms.[12] Therefore, it is imperative to advocate for a health care system that ensures high-quality patient care and access to health care services in both the public and private sectors.

Private equity ownership was associated with a 16.6% increase in OB/GYN physician price increases between 2012 and 2021.[13] Given the potential of private equity firms to negatively affect the quality and cost of maternal health care and influence adverse maternal health outcomes, especially in marginalized populations where resources are already inadequate, policies and legislation should appropriately regulate the quality of care and the cost to patients.

Cauolyn Baptiste is a J.D. student at Cornell Law School and is expected to complete her law degree in 2025. Cauolyn aims to contribute to the dynamic field of health law, advocating for equitable health care and informed decision-making. Cauolyn served on the New York State Bar Association Medical Aid in Dying Task Force appointed by immediate past New York State Bar Association President Richard Lewis.

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Endnotes

1. https://www.ineteconomics.org/perspectives/blog/private-equity-and-surprise-medical-billing.
2. Alexander Aorsa et al., *Evaluating Trends in Private Equity Ownership and Impacts of Health Outcomes, Costs, and Quality*, Systematic Review, https://www.bmj.com/content/382/bmj-2023-075244.
3. *Id.*
4. *Id.*
5. https://www.ineteconomics.org/uploads/papers/WP_118-Appelbaum-and-Batt-2-rb-Clean.pdf.
6. Richard M. Scheffler et al., *Monetizing Medicine: Practice Equity and Competition In Physician Practice Markets* (2023), https://www.antitrustinstitute.org/wp-content/uploads/2023/07/AAI-UCB-EG_Private-Equity-I-Physician-Practice-Report_FINAL.pdf.
7. *Id.*
8. *Id.*
9. Scheffler (2023).
10. Nobel laureate economist Joseph Stiglitz: It's time for Congress to do something about the economic mess that private-equity giants have created, Business Insider, https://www.businessinsider.com/joseph-stiglitz-private-equity-impact-us-economy-jobs-wages-2019-12.
11. https://www.intelycare.com/facilities/resources/medicare-reimbursement-rates-examples-and-faq/#:~:text=The%20CMS%20developed%20a%20reimbursement,account%20to%20provide%20equitable%20compensation.
12. Crear-Perry, J., Johnson, T. L., McLemore, M. R., Neilson, E., and Wallace, M. (2021), *Social and Structural Determinants of Health Inequities in Maternal Health*, Journal of Women's Health, 30(2), 230-235, https://doi.org/10.1089/jwh.2020.8882.
13. https://revcycleintelligence.com/news/private-equity-acquisitions-led-to-higher-prices-at-physician-practices.

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