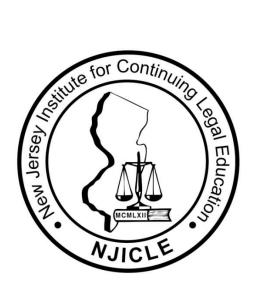
## 2023 HEALTH LAW SYMPOSIUM

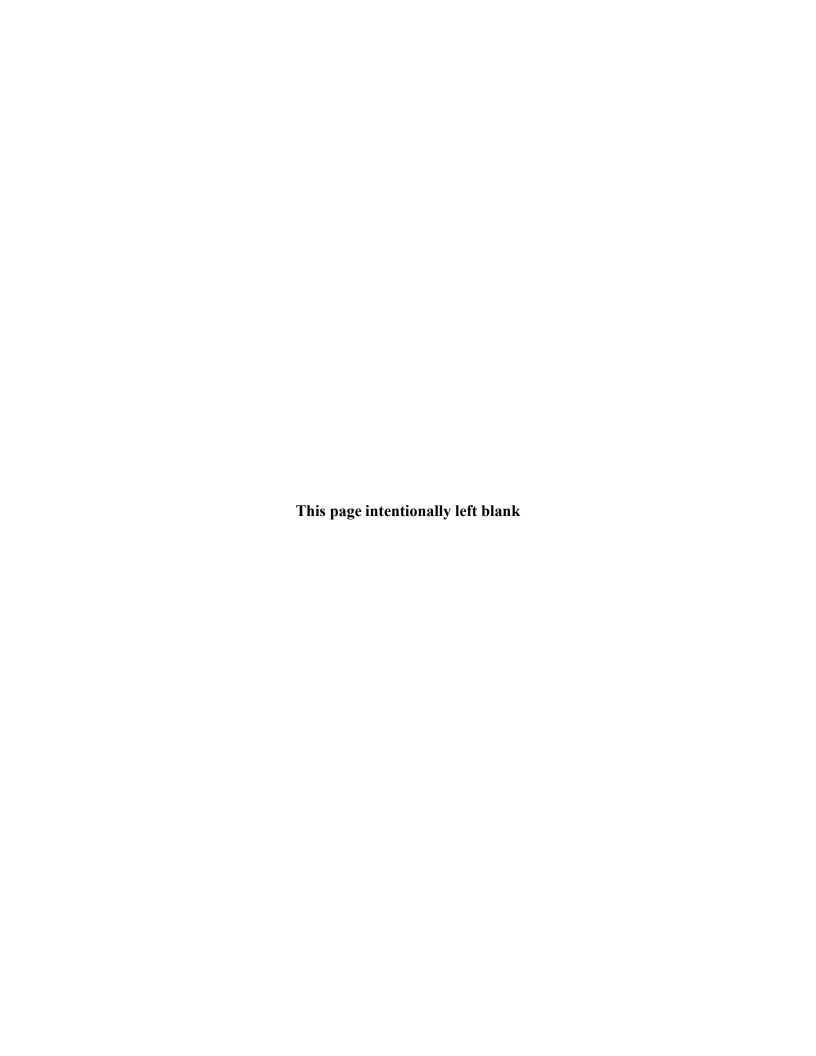
#### **2023 Seminar Material**

#### MI0091.23

New Jersey Institute for Continuing Legal Education

A Division of the State Bar Association NJICLE.com





### **2023 HEALTH LAW SYMPOSIUM**

#### **Moderators**

Michael F. Schaff, Esq. Wilentz, Goldman & Spitzer, P.A. (Woodbridge, Eatontown; New York City;

Philadelphia, PA)

Lisa D. Taylor, Esq.

Inglesino, Webster, Wyciskala & Taylor LLC (Parsippany; Boca Raton, FL)

**Speakers** 

Margaret J. Davino, Esq.

Fox Rothschild LLP

(Princeton; New York City)

Nicole DiMaria, Esq.

Chiesa Shahinian & Giantomasi P.C. (Roseland)

Joseph M. Franck, Esq.

Inglesino, Webster, Wyciskala & Taylor LLC (Parsippany)

Ashley McEnroe, Esq.

Atlantic Health System, Inc. (Morristown)

Lana Ros, Esq.

Lehigh Valley Health Network (Allentown, PA)

Michelle M. Skipper, MBA

American Arbitration Association (Charlotte, NC)

Julia Burnett Walker, Esq.

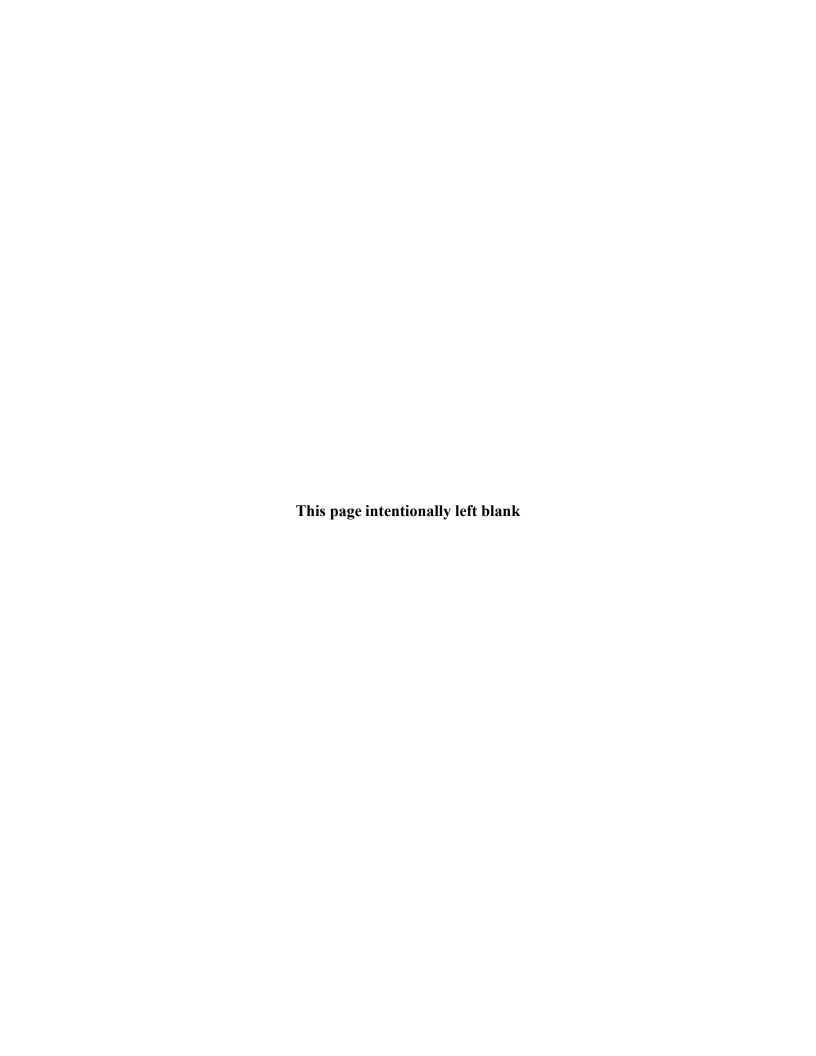
Atlantic Health System, Inc. (Morristown)





#### Table of Contents

	<u>Page</u>
Maximizing the Benefits of Arbitration PowerPoint Presentation Michelle Skipper	1
What In-House Counsel Wants You to Know PowerPoint Presentation Ashley McEnroe, Esq. Lana Ros, Esq. Julia Walker, Esq.	37
About the Panelists	59

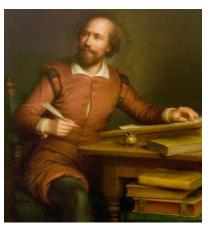




#### SESSION OVERVIEW

- Benefits for Utilizing Arbitrations
- Myths about Arbitration
- AAA Healthcare Payor Provider Arbitration rules
- Drafting ADR Clause Resources

Part 1: To Arbitrate or Not?



#### ARBITRATION V. LITIGATION

#### Factors favoring arbitration

- Greater confidentiality
- Greater privacy not public
- · Need for certain level of discovery
- Comparative cost
- · Expertise v. Judge
- · Court backlog

#### Other Considerations

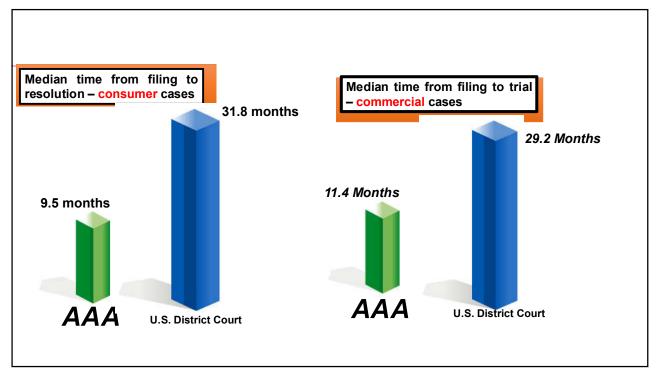
- Managing client expectations with arbitration understanding or lack thereof
- Challenges with arbitration and opportunity to manage

#### **GENERAL MYTHS ABOUT ARBITRATION**



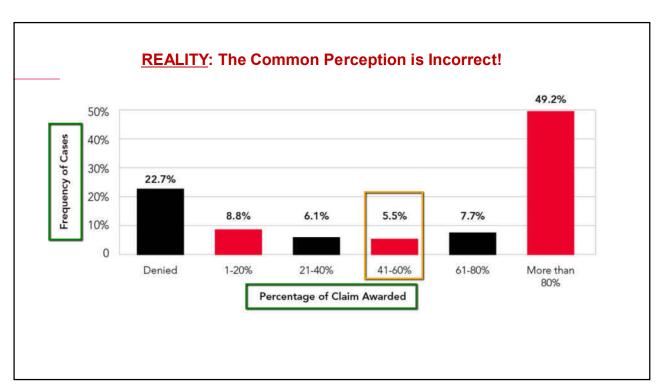


Arbitration Takes as Long as Litigation





Monetary Arbitration Awards Are Compromises



# (BIGGEST)MYTH

Arbitration is too expensive!

10

#### **REALITY**: Arbitration is only more expensive when you treat it like litigation

Arbitration does **not** mean you must have:

- Slew of dispositive motions
- Numerous depositions & endless discovery
- Rigid adherence to rules of evidence and courtroom decorum
- Lengthy final awards from arbitrator(s)





Appeals Are Not Available in Arbitration



Parties can choose to include the AAA Optional Appellate Arbitration Rules in their clause. This will provide an appellate process on an expedited schedule.

## MYTH

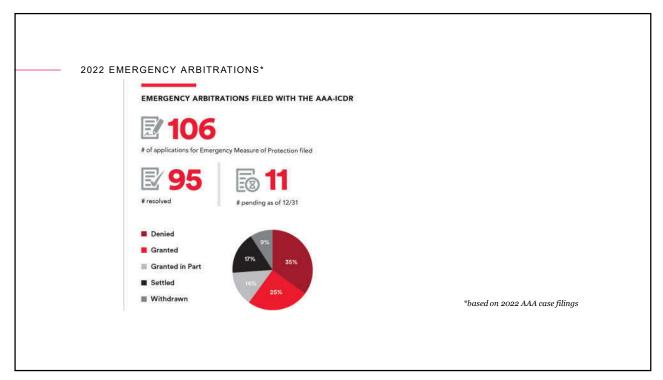
Interim (or Emergency) Relief is Not Available in Arbitration

15



Arbitration allows for emergency and interim relief and on a <u>faster</u> timeline than court intervention.

<u>Word of caution</u>: Unless your clause has a carve-out provision for seeking emergency relief in court, consider whether you are waiving arbitration by filing for emergency relief in court.



AAA'S HEALTHCARE PAYOR PROVIDER ARBITRATION RULES OVERVIEW

#### AAA HEALTHCARE PAYOR PROVIDER ARBITRATION RULES BACKGROUND

- Developed in 2011 by healthcare providers & payors
  - Including in-house counsel from major hospital systems and in house counsel from major private payors and outside counsel advocates
- Prior to 2011, healthcare payor provider arbitration cases proceed under commercial arbitration rules
- Oct. 1 2022, AAA Healthcare Payor Provider Arbitration rules revised
- 75% Healthcare Arbitrations arise between Payors & Providers

COMPARE/CONTRAST - HEALTHCARE PAYOR PROVIDER RULES, OCTOBER 1, 2022

#### Payor-Provider Rules

- Arbitration expenses
- Various tracks & amount in controversy does not determine track
- A single arbitrator is the default
- National Healthcare Roster of arbitrators
- Discovery and special initial disclosures
- Rules encourage efficient and early resolution where possible

R-1 (d) Administrative Track Designation (No language change)

Track 1- Desk/Telephonic (D-1 - D-6)

Track 2 – Regular Track (R-1 – R-62

Track 3 – Complex Track (C-1 – C-5)

**Default track is Regular Track.** 

Parties choose the track and not driven by monetary claim.

R-13 Number of Arbitrators (No language change to (a))

- (a) Unless the parties agree otherwise, the disputes will be heard and determined by one arbitrator regardless of the amount in controversy.
- (b) Clarify the terms such as "the arbitrator", an arbitrator" or the "arbitrators" in the arbitration agreement, without further specifying the number of arbitrators, shall not be deemed by the AAA to reflect an agreement as to the number of arbitrators.

#### Appointment from National Healthcare Roster Rule R-14

(former Rule R-13)

- In contrast to the Commercial Rules, this rule specifies the AAA provide arbitrator list drawn from the National Healthcare Roster
- Additionally, added language to R-14 (c) authorizing the AAA to limit the number of strikes

#### R-22 Meet and Confer, Preliminary Hearing and Scheduling Order

- This rule revision adds the requirement that the parties meet and confer on the topics outlined in R-22 (d) (j) prior to the preliminary hearing.
- Rule 22 requires party to meet and confer at least 5 days before the preliminary hearing and encourages each party with affirmative claims to share a spreadsheet of disputed claims prior to the meet and confer.
- Rule 22 includes a list of special payor-provider dispute topics to be discussed with the arbitrator at the preliminary hearing, and recent rule amendment added possible use of statistical sampling as a discussion topic.

#### R-23 Discovery (No Language Change)

#### Desk/Telephonic Track - D-4

Absent extraordinary circumstances and a finding of good cause by the arbitrator that depositions or other methods of discovery are necessary to prevent an unfair or unjust result, no additional discovery shall occur, and the dispute shall be resolved based on the documents and briefs submitted.

#### Regular Track - R-23

The parties shall each be limited to one deposition unless otherwise agreed to by the parties or ordered by the Arbitrator for good cause shown.

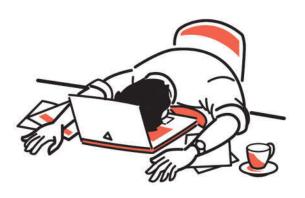
#### Complex Track - C-4

The parties shall each be limited to two depositions unless otherwise agreed to by the parties or ordered by the Arbitrator for good cause shown.

#### **New Rules and Major Rule Amendments**

- 1. Consolidation and Joinder
- 2. Appointment from National Healthcare Roster
- 3. Administrative Review Council
- 4. Discovery
- 5. Cybersecurity, Privacy and Data Protection



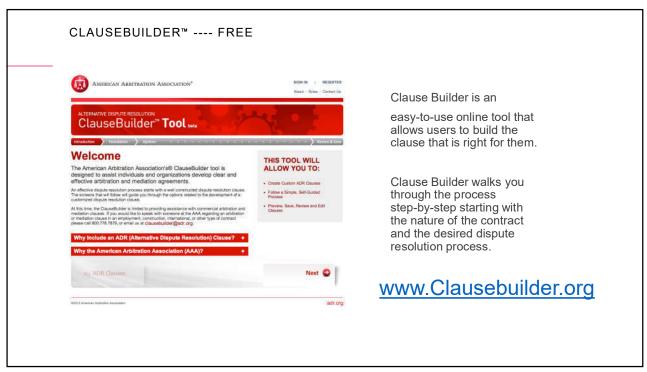


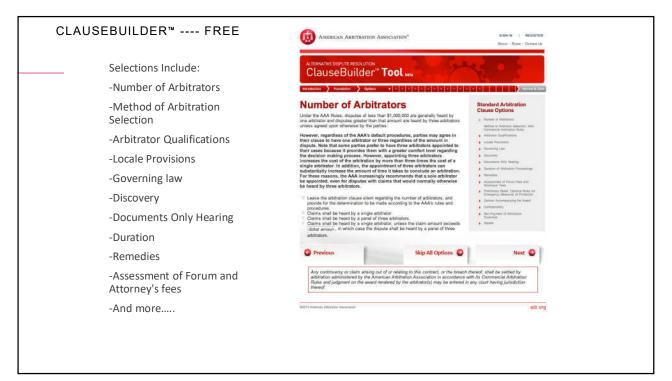
#### THE STANDARD AAA COMMERCIAL ARBITRATION CLAUSE

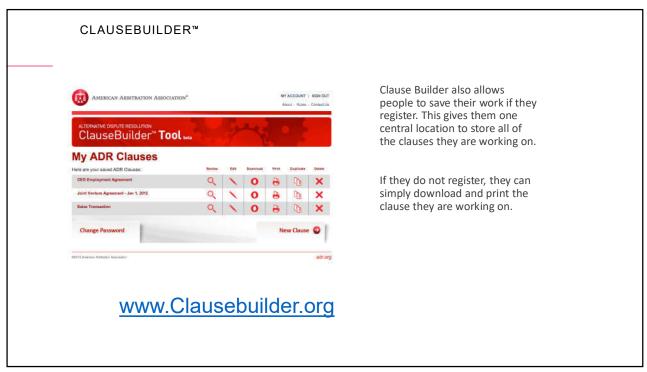
"Any controversy or claim arising out of or relating to this contract, or the breach thereof, shall be settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules and judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof."

#### Looks broad, but provides a lot:

- · Self executing by naming an administrator and specific rule set
- Neutral organization will administer the case and be there to assist if problems arise ("insurance policy")
- Provides that award will be turned into enforceable judgment







#### SAVE THE DATE

Thursday, December 7, 2023

AAA Domestic & International Life Sciences ADR Conference

Hogan Lovells Office – 390 Madison Ave., NY, NY

#### SAVE THE DATE

Thursday, October 10, 2024

AAA Healthcare Dispute Resolution Innovation & Strategy Conference

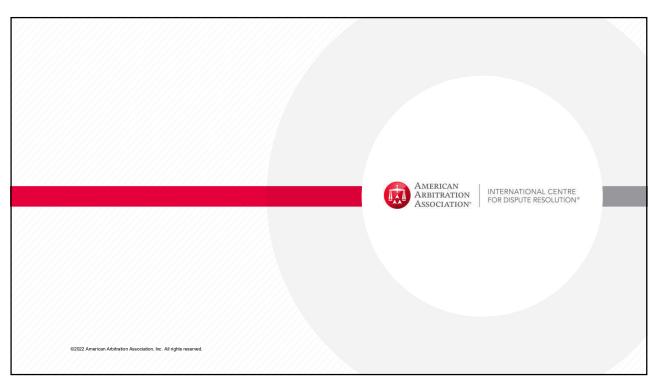
Hyatt Regency Denver at the Colorado Convention Center

### Questions?

Michelle Skipper Vice President Charlotte, NC 704-643-8605 SkipperM@adr.org Sarah Clayton Director

Charlotte, NC 704-643-8602 claytons@adr.org





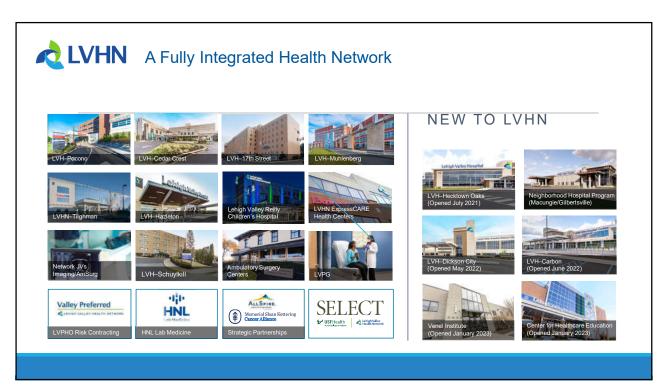
This page intentionally left blank

# What In House Counsel Wants You to Know

Ashley McEnroe, Esq., Vice President & Chief Risk Officer, Atlantic Health System Lana Ros, Esq., Vice President, Associate General Counsel, Lehigh Valley Health Network Julia Walker, Esq., Vice President, Corporate Legal Services, Atlantic Health System

### Do you KNOW your in house counsel?

- Background and experience
- Subject matter expertise
- Roles and responsibilities
- Work and time commitments
- In house counsel's clients



## Lehigh Valley Health Network

#### Who is In House Counsel?

#### CEO

#### Senior Vice President, Chief Legal Officer

- · Vice President, Associate General Counsel Labor and Employment
- Vice President, Associate General Counsel -Business and Real Estate
- Vice President, Associate General Counsel Health
   Vice President, Litigation and ERM
  - · Hospital and Ambulatory Operations
  - Licensure, Regulatory and Accreditation
  - Medical Staff

- Vice President, Chief Compliance Officer
- Vice President, Internal Audit

#### Atlantic Health System

#### Who is In House Counsel?

Executive Vice President, Legal Affairs & General Counsel

- Vice President, Corporate Legal Services
- Vice President & Chief Risk Officer
- Vice President, Chief Compliance, Privacy & Internal Audit Officer
  - Clinical Risk Management, Insurance & Claims
    - 5 hospital-based risk management departments;
    - Physician practice/ambulatory services risk management department
    - RN, MD and LCSW risk managers on site
    - 5 litigation counsel
    - Insurance personnel

- Corporate/Regulatory Affairs Department
  - 5 corporate counsel
  - 1 contract manager lawyer
  - 1 contract specialist paralegal

## Atlantic Health System Legal Department

#### Risk Management, Insurance & Claims

- Clinical Risk Management
- Insurance Program
- Litigation & Claims Management
- Cyber Security
- Medical Staff Matters
- Human Resources

#### Atlantic Health System Legal Department

#### What do Corporate/Regulatory lawyers work on?

#### Physician Contracts -

- Employment And 1099
- Professional Services Agreements
- Leased Arrangements

#### Vendor Contracts -

- Purchasing
- Saas/Paas/Software Licensing
- Delegated Credentialing
- Timeshares/Leases
- Clinical Affiliation Agreements
- Transfer Agreements
- Event Contracts
- Consulting Agreements
- Transport and Ambulance Agreements

Investigations/Due Diligence

#### Transactions -

- Mergers/acquisitions
- Affiliations
- Joint ventures

#### Represent the following in-house clients -

- Ambulance
- Real Estate
- At Home Medical
- Home Care and Hospice

#### Areas of Law referenced most often -

- Stark/AKS/CMP/fraud and abuse
- Medicare and Medicaid compliance
- HIPAA
- Restrictive covenants

#### Medical Staff

- Unified Medical Staff
- Counsel Representation
- Know your client's philosophy
- Day-to-day operations
- Meetings
- Bylaws
- Disciplinary Actions

### DATA – PHI and PII – SaaS Agreements

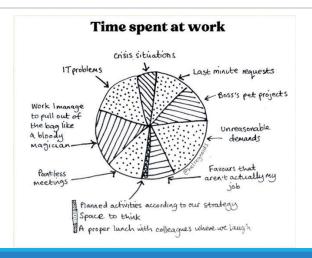
- Understanding the data flow is everything
- Cybersecurity and AI must be considered
- Risk Mitigation Tools
- Issue spotting around the following areas is part of contract review:
  - Information blocking
  - Gathering patient consent around vendor contact with patients
  - Pixels and Tags OCR Bulletin December 2022

## Litigation & Claims Management

- Understand your client's insurance structure
- Understand your client's business
- Know your client's philosophy on claims management
- Believe in your client's objective, while establishing realistic expectations

## Top Ten Things In House Counsel Wants You to Know

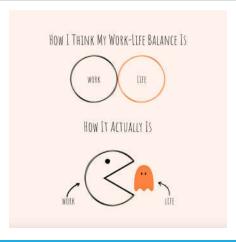
## 10. No one cares about my time sheets!



## 9. I never actually knew what I was talking about until I came in house!



## 8. I thought I was going to find work life balance!



## 7. Hospitals have budgets too!



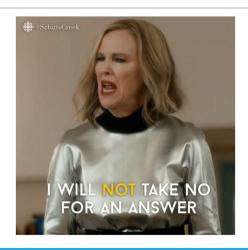
## 6. I've already read your white paper!



## 5. I am drinking from a fire hose!



### 4. "No" is not the answer!



3. They all think I am part of the operations team!



2. Who says not-for-profits don't need to make money?





## 1. You can't make this stuff up!



This page intentionally left blank

#### About the Panelists...

**Margaret J. Davino** is a Partner in Fox Rothschild LLP with offices in Princeton, New Jersey, and New York City. For more than 20 years she has handled a broad spectrum of healthcare matters, including transactional, compliance, contractual, corporate, regulatory, governance, managed care/payer and risk management issues. Her clients include hospitals, physicians and physician groups, start-up companies, FQHCs, home care agencies, ACOs, pharmacies, laboratories, agencies for the developmentally-disabled, care management companies, billing companies, nonprofit companies, healthcare IT vendors and other providers and entities in the healthcare field.

Admitted to practice in New Jersey, New York and Connecticut, Ms. Davino has been Chair of the Providers and In-House Counsel Committee of the New York State Bar Association Health Law Section, is Past Chair of the New Jersey State Bar Association Health and Hospital Law Section and has been a member of the American Health Lawyers Association (AHLA). She has sat on the boards of a number of organizations, including Women in Health Management and Lifespire, and is a former member of the Board of Directors of the New Jersey Hospice & Palliative Care Organization.

Ms. Davino has lectured on multiple healthcare legal topics and has written articles and a book chapter in *Managed Care – Survival Strategies* on the legal issues associated with managed care. Also a registered nurse, she wrote a column on HIPAA issues for two years for the publication *Medical Economics*.

Ms. Davino received her B.S.N., with honors, from the University of Michigan, her J.D. from Vanderbilt University School of Law and her M.B.A. in Finance, *magna cum laude*, from Seton Hall University.

**Nicole DiMaria** is a Member of Chiesa Shahinian & Giantomasi P.C. in Roseland, New Jersey. She represents a wide range of health care entities including health care professionals, physician groups, ambulatory care facilities, health care and hospital systems, long-term care facilities, medical device and pharmaceutical manufacturers, and companies/vendors that provide services to the healthcare industry. She assists clients in navigating complex health care corporate and regulatory issues, advising on matters including Federal Stark and Anti-Kickback Law compliance, HIPAA/HITECH Covered Entity and Business Associate compliance, Medicare/Medicaid reimbursement and enrollment, CHAPA and state health care/professional regulatory compliance.

Admitted to practice in New Jersey, Ms. DiMaria is Chair-Elect of the New Jersey State Bar Association's Health Law Section and Co-Chair of the Section's Legislative Coordination Committee, which is responsible for assessing proposed healthcare legislation in New Jersey. In 2009, she was selected for the AHLA's inaugural Leadership Development Program and later served as Vice-Chair of the Association's Hospitals and Health Systems Practice Group and as Co-Chair of its Health Law Curriculum Task Force. She is a frequent author and speaker for organizations including ICLE, the American Health Law Association (AHLA) and the Health Care Compliance Association.

Ms. DiMaria received her B.A. from Rutgers University and her J.D., with a concentration in Health Law, from Seton Hall University School of Law, where she was Managing Editor of the Seton Hall Constitutional Law Journal and served as its acting Editor-in-Chief. While at Seton Hall, she served as research assistant to the founder of Seton Hall Law's health care program, Dean Kathleen Boozang, and received the 1999 Gibbons Health Law Fellowship, the 2001 Seton Hall Constitutional Law Journal Distinguished Service Award and won the 2001 Brach Eichler Health Law Writing Competition.

**Joseph M. Franck** is a Partner in Inglesino, Webster, Wyciskala & Taylor, LLC in Parsippany, New Jersey, where he concentrates his practice in health care law, employment law, municipal law and a wide range of litigation matters including complex business litigation; partnership, shareholder and contract disputes; insurance litigation; land use litigation personal injury litigation and criminal matters.

Mr. Franck is admitted to practice in New Jersey and New York, and before the United States District Court for the District of New Jersey. He is Chair of the New Jersey State Bar Association's Health Law Section and serves on the District XB Ethics Committee. Prior to joining Inglesino, Webster, Wyciskala & Taylor he was as associate in a mid-sized Essex County law firm.

Mr. Franck received his B.A. from Pennsylvania State University and his J.D. from Hofstra University School of Law, where he was Articles Editor for the *Journal of International Business and Law*. He interned with the Honorable Vito L. Bianco, New Jersey Tax Court, and the Honorable Charles Apotheker, Rockland County Supreme Court. He was a judicial clerk for the Honorable Maryann L. Nergaard, J.S.C., Superior Court of New Jersey, Morris County.

**Ashley McEnroe** is Vice President and Chief Risk Officer at Atlantic Health System, Inc. in Morristown, New Jersey.

Ms. McEnroe received her B.S. from Rutgers University and her J.D. from Seton Hall University School of Law.

**Lana Ros** is Vice President, Associate General Counsel, Health Services, at Lehigh Valley Health Network in Allentown, Pennsylvania.

Ms. Ros is admitted to practice in New Jersey, New York and Pennsylvania. She is a member of the New Jersey State Bar Association.

Ms. Ros received her B.S. from Rutgers University and her J.D. from Seton Hall University School of Law.

**Michael F. Schaff** is a Shareholder in Wilentz, Goldman & Spitzer P.A., with offices in Woodbridge and Eatontown, New Jersey; New York City; and Philadelphia, PA. Co-Chair of the Corporate and Healthcare Departments and the Cannabis Practice Group, and a member of the firm's Management Committee, he handles the structuring of professional practices for many healthcare professionals including physicians, dentists, chiropractors and other professionals.

He also handles the structuring of business entities and assists entities interested in buying, selling or merging businesses.

Admitted to practice in New Jersey and New York, and before the United States District Court for the District of New Jersey and the District of Maryland, and the United States Tax Court, Mr. Schaff is a Fellow of the American Health Lawyers Association (AHLA), having served on the Board of Directors, Executive Committee, and in several other capacities for the organization. He is a Trustee of the New Jersey State Bar Association, Co-Chair of the NJSBA Cannabis Law Committee, a past Chair of the NJSBA Health Law Section, serves on the Section's *Emeritus* Board and is a past Chair of the NJSBA Internet and Computer Law Committee.

Mr. Schaff is an Adjunct Associate Professor at Robert Wood Johnson Medical School (formerly UMDNJ) and St. John's University, serves on the Advisory Board of Seton Hall Law School's Center for Health & Pharmaceutical Law & Policy, and frequently lectures to healthcare, accounting, computer and insurance professionals, attorneys and business owners. In December 2016, he received ICLE's 2016 Distinguished Service Award and in 2006 was the recipient of the NJSBA Health Law Section's first Distinguished Service Award. He is also the 2008 recipient of the Middlesex County Bar Association's Transactional Attorney of the Year Award.

Having served as Chair of the Editorial Board of the *New Jersey Lawyer Magazine* and as special editor of several issues of the periodical, including issues on Health Care, Business Law, Internet and the October 2018 issue on *Cannabis Law*, Mr. Schaff is the author of numerous articles which have appeared in the *New Jersey Law Journal* and other publications, and the coauthor of a monthly column in the *New Jersey Law Journal* on the impact of legal cannabis on New Jersey businesses. He is author and editor of several editions of the *Representing Physicians Handbook* and has contributed to *AHLA Fundamentals of Health Law, Representing Hospitals Handbook* and *The ACO Handbook: A Guide to Accountable Care Organizations*. Mr. Schaff is also a member of the Editorial Advisory Board of *Bloomberg Law Health Law and Business* and serves on several other editorial and advisory boards. He has been listed in *Who's Who in American Law, Who's Who in the World* and *Who's Who in the East*, and is the recipient of the AHLA *Pro Bono* Champion Award, the 2018 AHLA David J. Greenburg Service Award and several other honors.

Mr. Schaff received his B.A. from Rutgers College, his M.B.A. from Bernard M. Baruch College, C.U.N.Y., his J.D. from New York Law School and his LL.M. in Taxation from Boston University.

**Michelle M. Skipper, M.B.A.** is Vice President of the Commercial Division of the American Arbitration Association (AAA) in Charlotte, North Carolina, where she is responsible for the case management of large, complex commercial arbitrations for the mid-Atlantic regions. She also identifies and recruits arbitrators and mediators to join the AAA roster of neutrals, and provides training to clients and attorneys on the appropriate and effective use of dispute resolution processes.

Ms. Skipper is the AAA's National Healthcare lead, where she is responsible for all AAA healthcare initiatives and chairs the AAA Healthcare Dispute Resolution Advisory Council. She is Vice Chair of the American Bar Association Health Law – Litigation and Risk Management Group and the ABA Business Law, Health and Life Sciences Section.

Ms. Skipper received her undergraduate degree from the University of Texas, San Antonio, and her M.B.A. from the McColl School of Business, Queens University.

**Lisa D. Taylor,** Board Certified as an Expert in Health Law by the Florida Bar, is a founding Partner of Inglesino, Webster, Wyciskala & Taylor, LLC in Parsippany, New Jersey, and Boca Raton, Florida, and concentrates her practice in health care law. She also handles business and employment transactions, employment and immigration issues, regulatory matters and litigation, and represents professionals in disciplinary matters. She serves as a neutral arbitrator and mediator, and as an expert witness in health care disputes and professional proceedings.

Admitted to practice in New Jersey, New York, Pennsylvania, Tennessee and the District of Columbia, and before numerous federal courts, Ms. Taylor is a two non-consecutive term Past Chair of the New Jersey State Bar Association Health Law Section and a member of the Section's *Emeritus* Board, after serving for 20 years on its Board of Directors. She is a Fellow of the American Health Law Association, has held numerous leadership positions with the Association, and serves as Vice Chair of the American Bar Association's Health Law Section and Chair of the Health Care Certification Committee of The Florida Bar. A Life Fellow of the American Bar Foundation, she is also a member of the Million Dollar Advocates Forum, which recognizes lawyers who have achieved a trial verdict, award or settlement of \$1,000,000 or more.

Ms. Taylor is the recipient of the New Jersey State Bar Association Health & Hospital Law Section's 2007 Distinguished Service Award for service to the health bar and health industry as well as ICLE's Distinguished Service Award for Excellence in Continuing Legal Education in 2014. In 2016 she received the Ira Geller Award from Community Access Unlimited for zealous advocacy of the disabled and in 2004 was one of ten attorneys nationally recognized as Outstanding Physician Practice Lawyers by Nightingale's Healthcare News. She is listed in Who's Who in America, Who's Who in American Law and Who's Who in the World, and is the recipient of several other honors.

Ms. Taylor received her undergraduate degree, *cum laude*, from Barnard College, Columbia University, her M.A. in Philosophy from Duke University and her law degree from Duke University. She also studied finance and accounting at Columbia Business School and attended Executive and Continuing Professional Education at Harvard University's T.H. Chan School of Public Health.

**Julia Burnett Walker** is Assistant General Counsel at Atlantic Health System, Inc. in Morristown, New Jersey.

Ms. Walker received her B.A. from Vanderbilt University and her J.D. from University of Kentucky College of Law.



## NEW JERSEY HEALTH LAW UPDATE

Margaret Davino Fox Rothschild LLP

Princeton Pike Corporate Center 997 Lenox Drive, Building 3 Lawrenceville, NJ 08648-2311 (646) 601-7615 - direct mdavino@foxrothschild.com

© 2016 Fox Rothschild

# 1) Bullet from patient's surgery subject to search warrant

State of NJ v Ross, Appellate Division, Docket #A-0244-22, January 4, 2023

Background: Patient shot during gunfire with Camden police, admitted to Cooper, and four years later had elective surgery to remove a bullet lodged in his abdomen. Bullet turned over to security, who notified police. Prosecutor applied for a search warrant directing Cooper to turn over the bullet.

Appellate division: Bullet was subject to search warrant

- State did not make patient's decision to remove bullet
- Prosecutor merely reacted to info from a third party
- Tangible evidence at a known location is subject to a search warrant

Margaret Davino



# 2) Case proceeds vs doctor who didn't report child abuse

MM v AHS et al, Appellate Div., Docket # A-2218-22, August 30, 2023

Facts: Parents alleged pediatric GI began to treat patient at 9 years old, and sexually assaulted her at 18 yo (in 2016) during an exam and on other occasions.

Parents alleged that another patient's mom in 2017 had told **that** patient's pediatrician (the defendant) that the peds GI had looked down her child's pants w/o a female present

\* the pediatrician called the GI, who explained he was short-staffed, and then called the child's mom to address her concerns

Margaret Davino



# Case proceeds vs doctor who didn't report child abuse

Sole question: Could case proceed against pediatrician without an affidavit from a qualified medical expert?

In a medical malpractice case, a qualified medical expert must opine as to the standard of care applicable to the defendant doctor regarding any claim of negligence

**Margaret Davino** 



# Case proceeds vs doctor who didn't report child abuse

Court: No affidavit of merit is needed in this case

- \* No doctor-patient relationship existed between patient and pediatrician
- \* NJSA 9:6-8.10: Any person having reasonable cause to believe that a child has been subjected to child abuse shall report the same immediately to the State
- \* The standard under the reporting statute applies to everyone, not just physicians, so no expert affidavit required in this case
- \* But no finding beyond just the affidavit of merit



## 3) Lower medication prices may be anti-competitive

Indivior v Alvogen Pine Brook, U.S. District Court NJ, Civ. 18-5285, 7/10/23

Facts: Indivior sued Alvogen for patent infringement on a drug. Alvogen countersued for antitrust, alleging Indivior blocked generic versions of Alvogen's suboxone film from gaining share with PBMs and payers, and that action was equal to a rebate wall.

Rebate wall: a drug company offers rebates, or increased rebates, in exchange for preferred or exclusive positions on a PBM or payor's formulary (list of prescription meds covered).

\* if a manufacturer removes a rebate if a competing drug is added to the formulary, it may foreclose competition from lower cost options



# Lower medication prices may be anti-competitive

Facts: Indivior structured its rebates so that if payers put generic film on their formularies, Indivior's price for the branded suboxone film would increase substantially

Court: Indivior's rebate contracts raised a question for a jury trial as to whether it was anti-competitive

- \* Indivior had substantial market share
- \* Looked at whether Alvogen gained less market share than it would have absent Indivior's challenged conduct
- \* Internal documents pointed to Indivior's rebate wall strategy to block internal competition
- \* need not show higher prices, but what prices and output would be absent the exclusionary conduct



## 4) Contractual obligations w/membership change

Deborah Heart & Lung Center vs Our Lady of Lourdes Health System, Superior Ct Burlington Cty, May 22, 2023

Facts: In 2009, Deborah and Lourdes entered into a contract for Lourdes to operate a satellite emergency department at Deborah. The contract prevented the parties from entering into any "arrangement, partnership or affiliation" re cardiology services in Burlington Co.

- 2019, Virtua replaced Lourdes' sole member Trinity
- Deborah had previously used Virtua alleging an antitrust conspiracy in cardiology
- Deborah sought to block the transaction
- Court declined injunctive relief, and case transferred to Law Div'n and amended to allege tortious interference and unfair competition against Virtua



# Be clear w/contractual obligations re membership

Court holding: The language of whether an "arrangement, partnership or affiliation" includes a membership change is unclear

- neither party had evidence supporting their position
- case law does not define membership change in context of "arrangement, partnership or affiliation"
- AG CHAPA approval is irrelevant, as it looked only at whether charitable assets and objectives were safeguarded during the acquisition
- parties must go to trial to determine whether either party breached the contract



## 5) Medicaid can't use process with no notice

Melmark v NJ Dept of Human Services, DMAHS, Appel Div, A-2446-20, Jan 27, 2023

Facts: Provider is an intermediate care facility in PA that provides long-term care for individuals with intellectual disabilities. It receives monthly reimbursement from DMAHS for Medicaid residents. It didn't receive payment for 30 submitted claims, and when it resubmitted, DMAS denied saying the resubmissions were untimely. DMAHS admitted that it did not send denials, but stated that Provider should have followed up itself. All claims were required to be on paper.

Court: Provider filed claims timely, and received no notice of any errors. Provider was under no duty to "follow up" with DMAHS as to nonpayment. Provider is entitled to be paid since it submitted claims timely and received no notice of problems.



## 6) Arbitration clause in provider website upheld

Santana v. SmileDirectClub, Appellate Division, A-2433-21, April 3, 2023

Facts: SmileDirectClub is a telemedicine platform that enables affiliated dentists and orthodontists to provide clear-aligner treatment as an alternative to traditional braces. To receive treatment and aligners via the internet a user must register online and affirmatively check to agree to SDC's Informed Consent and Conditions. Each hyperlink takes the user to a new webpage revealing the full terms of the documents. The Informed Consent document contains a mandatory arbitration agreement.

Plaintiff purchased aligners and registered an account. He later filed a products liability action against SDC alleging he had suffered personal injuries from his aligners. SDC moved to dismiss, arguing mandatory arbitration.



# Arbitration clause in provider website upheld

Trial judge: "the arbitration clause was not clearly or conspicuously presented to plaintiff and is thus not enforceable." Plaintiff could click on "I agree" without ever viewing the hyperlinked documents.

#### Appellate Division:

NJ policy favors arbitration as a means of dispute resolution.

But an arbitration provision is not enforceable unless the consumer has reasonable notice of its existence

NJ recognizes the validity of consumer web-based contracts

- but with a browsewrap agreement where the online hosts assents merely by using the site, the terms or a hyperlink must be reasonably conspicuous on the webpage to provide notice



# Clickwrap arbitration clauses may be enforceable

### Appellate Division:

But a contract that requires that a user consent by clicking on a dialog box to proceed with the transaction (a "clickwrap agreement") is uniformly enforced by the court

The offeree will be bound by the agreement if a reasonably prudent user would be on inquiry notice of the terms, i.e., there is a manifestation of assent

Although none of SDC's hyperlinks included the word "arbitration" or "waiver of right to sue" in their titles, the context in which "I Agree" appeared is significant, i.e., "CLICK HERE to acknowledge." Also, the arbitration link was the first document in the screen entitled "Informed Consent", was capitalized, was the only capitalized text, and included explanation of benefits and risks, and consent to treatment. Therefore, the arbitration was valid.



# 7) Increasing patient copay for meds to get drug help

Johnson & Johnson Health Care Systems v Save On SPC, LLC, US District Ct NJ 1/25/2023

Background: J&J has a payment assistance program for patients using certain of its costly, specialty meds.

SaveOnSP is a company that works with PBM Express Scripts to administer a program to determine patients/plan participants' cost-sharing obligations. SavOn reviewed several J&J drugs, and classified them as non-essential (versus essential) benefits, thereby increasing the patient's copay for the drug to a very high amount.

\* J&J: the very high copay forces patients into J&J's drug assistance program and depletes J&J's program.



# Increasing patient copay for meds to get drug help

J&J sued, claiming: 1) tortious interference with a patient's J&J drug assistance contract, and 2) the patient-targeting aspects is a deceptive trade practice under the GBL

SaveOnSP arguments: 1) J&J complaint preempted by ERISA's objectives to facilitate standard procedures

2) SaveOnSp did not deceive participants or mislead patients

Court findings: SaveOnSP causes patients to breach their contract with J&J every time they use J&J funds while enrolled in the SaveOn Program

\* the J&J program is not meant for payers, but for patients



## 8) NJ LAD's definition of discrimination is not limitless

Guzman v Teixeira Int'l, Appellate Division, Docket # A-0841-21, June 7, 2023

Plaintiff was machine operator who reported to working feeling ill on 7/23/2020. CEO after work told him he must have a Covid test before returning.

Plaintiff had test next day, and while waiting for results, told CEO he was feeling better and offered to return to work. However, on 7/29, before test results returned, CEO terminated him, stating he had Covid symptoms and could not provide negative result.



## NJ LAD's definition of discrimination is not limitless

Plaintiff sued under LAD, contending he was fired because he was perceived as having Covid.

Trial court: while Covid is a disease, it Is not a disability under LAD.

Appellate Division: Not every illness is a disability under LAD

Illness was transitory, did not require medical treatment, and he was fired only after telling CEO he was feeling better

Holding: plaintiff failed to show he had a disability or was perceived as having a disability



## NJ LAD's definition of discrimination is not limitless

Note: EEOC guidance: person with Covid or long Covid is not necessarily someone with a disability

Disability: physical disability, infirmity, malformation for disfigurement caused by bodily injury, birth defect or illness (LAD)

Minor symptoms may not manifest a serious medical condition, which is the intent of protection of the disability discrimination laws



# 9) No private right of action under CREAMMA for employees

Zanetich v Walmart, US District Ct NJ, May 25, 2023

Facts: Plaintiff was given a conditional offer of a job in Walmart's Asset Protection Dept. His offer was revoked after drug test was positive for marijuana. Plaintiff brought a class action with others alleging that Walmart and its subsidiary Sam's Club violated CREAMMA.

CREAMMA (the NJ Cannabis Regulatory, Enforcement, Assistance and Marketplace Modernization Act) states that an employer cannot take adverse employment action against an employee based solely upon a drug test returning a positive cannabis result. NJSA 224:61-52a(1), and the employment protections became effective February 2021.



## No private right of action under CREAMMA for employees

Walmart removed to federal court and filed a motion to dismiss, arguing at CREAMMA does not contain an explicit private right of action for civil lawsuits, and the statute provides for the Cannabis Regulatory Commission to enforce.

District Court: CREAMMA contains neither an express nor implied private right of action for enforcement by way of individual lawsuits. It characterized CREAMMA as "incomplete legislation" and could not "re-write" CREAMMA to "create remedies" where the legislature did not.



# No private right of action under CREAMMA for employees

Lawsuit also alleged companies violated NJ Common law for "failure to hire/wrongful discharge." But Court stated plaintiff only received a condition offer of employment which was later rescinded, and therefore, because he was never actually employed, he could only have a failure to hire claim, not wrongful discharge.

- NJ courts have not recognized failure to hire Pierce v Ortho Pharmaceutical, 84 NJ 58, 1980), which established a common law claim for wrongful termination

Case appealed to 3<sup>rd</sup> Circuit. NJ Supreme Court accepts certified questions of state law from 3<sup>rd</sup> Circuit.

# 10) Medical staff bylaws as protection against privileges

Comprehensive Neurosurgical PC/dba NJ Brain & Spine v Valley, Appellate Div, Docket A-2866-19, Aug 8, 2022

Facts: 11 neurosurgeons and their practice, NJ Brain & Spine Ctr, had privileges at several hospitals, including Valley. For over 10 years, they provided on-call coverage in the ED at Valley and assisted Valley to obtain specialized equipment, including a gamma knife.

In 2015, Valley entered into an exclusive agreement with Columbia, granting exclusive rights to ED coverage and use of the gamma knife.

NJ Brain sued, alleging breach of contract, breach of implied covenant of good faith and fair dealing, and tortious interference with prospective economic advantage. Claimed that reason involved Valley's rivalry with Hackensack, where neurosurgeons also had privileges.



# Medical staff bylaws as protection against privileges revocation

## Jury:

- 1. No breach of contract. A contract existed but no breach occurred.
- 2. Valley violated its implied covenant of good faith and fair dealing, and awarded \$24.3 as a result of Valley's wrongful conduct.

Appellate Division affirmed.



# Medical staff bylaws as protection against privileges revocation

NJ Supreme Court has accepted the case.

Physician group had no contract with Valley, but claim the hospital's medical staff bylaws gave protections akin to those provided by a contract

NJHA submitted a brief supportive of hospital



# 11) Cashing a PIP check not waiver of an appealed claim

Hackensack Meridian v Citizens United Reciprocal Exchange, Appel Div, # A-1486-21, 6/29/2023

Facts: Hackensack treated CURE's insured after a car accident, and billed \$360,000 pursuant to personal injury protection (PIP) benefits under patient's insurance. After no response for 6 months, Hackensack sent a letter to CURE, asking all checks and correspondence be sent directly to Hackensack.

CURE wrote a letter disputing the billed amount, and sent an EOB and check for \$67,000. The top of the check stub stated "depositing of the attached check constitutes acknowledge of notice of dispute and acceptance of check as complete settlement of claim." The letter provided an address to return check if offered not accepted.



# Cashing a PIP check not waiver of an appealed claim

Hackensack commenced an integral appeal with CURE, seeking the \$360,000. It also deposited the check.

### Court:

PIP benefits are mandated by law to go to arbitration. CURE cannot avoid such, and the case does not satisfy the high standard for appellate review of arbitration.



# 12) Hospital must allow med records metadata inspection

Lawsiw v. Hackensack, Appellate Division, April 19, 2023

Facts: Plaintiff in malpractice suit sought prosecution of an audit trail of the patient's EMR for a year following the patient's discharge.

Plaintiff sought to have her expert review EMR onsite, to identify metadata she wants copied.

Court: access to metadata granted under HUMC's supervision and control, and HUMC could object to prosecution of any metadata based on an asserted privileged, as not burdensome.



## 13)Pharma co not defamed by article critical of its med

Pacira Biosciences v. American Society of Anesthesiologists, US Court Appeal 3rd Circuit, # 22-1411, 3/24/2023 Facts: ASA journal published an article critiquing painkiller Exparel as being "not superior" to other local anesthetics. Pacira sued the ASA, the Editor in chief and 12 authors for defamation. It claimed that sales from Exparel represented all its revenue in 2020.

3<sup>rd</sup> Circuit: Statements in article expressly claimed they are tentative scientific conclusions. E.g., before concluding Exparel is not superior to standard analgesics, article enumerates five "notable limitations" of study, including variabilities, publication bias in selecting studies, and statistical limitations due to scarcity of data. Pacira did not allege that the data in the articles was false.

Context of the statements mattered: the articles were in a peer-reviewed medical journal and directed to an audience of specialists who would interpret the data themselves.



# 14) Injury plaintiffs need not justify exam observers

DiFiore v Pezic, Supreme Court NJ, case # 087091, 6/15/2023

Facts: 3 personal injury actions brought: one against a cab company after a taxi accident, one against a hospital, and one against a property owner after fall. Plaintiff in one case did not speak English. In each case, the defendants required plaintiffs to submit to a DME. A judge blocked third parties from attending the exam; in one case only audio recording was allowed and in another the plaintiff was ordered to attend alone.

Court: NJ Court Rule 4:19 changed what conditions defendants could set for a DME. A plaintiff may have third party observation or recording of an DME.



## 15) U.S. Supreme Court won't review 3rd Circuit order mooting challenge to vaccine mandate for health care workers

Katie Sczesny et al. v. Philip Murphy et al, US Supreme Court, case number 23-265, November 13, 2023

• Facts: Governor Murphy issued Executive Order 283 on April 18, 2022, requiring healthcare employees to be "up to date with their Covid 19 vaccinations." Four nurses filed for a preliminary injunction in US district court, which in June 22 upheld the executive order. They had argued that their choice to refrain from further vaccination was a matter of personal liberty.

The Third Circuit heard <u>oral arguments</u> on the appeal in March 2023, after which Murphy rescinded the mandate in June. The panel dismissed the nurses' appeal as moot later that month, finding that it "no longer presents a live issue" and expressed no opinion on whether the case itself was moot. The court remanded the case for further proceedings.

The nurses petitioned to the US Supreme Court, arguing that the appellate court ruled their appeal moot without requiring the state to show that the vaccine mandate, or an equivalent, will not be reinstated.

The US Supreme Court rejected the petition without comment.

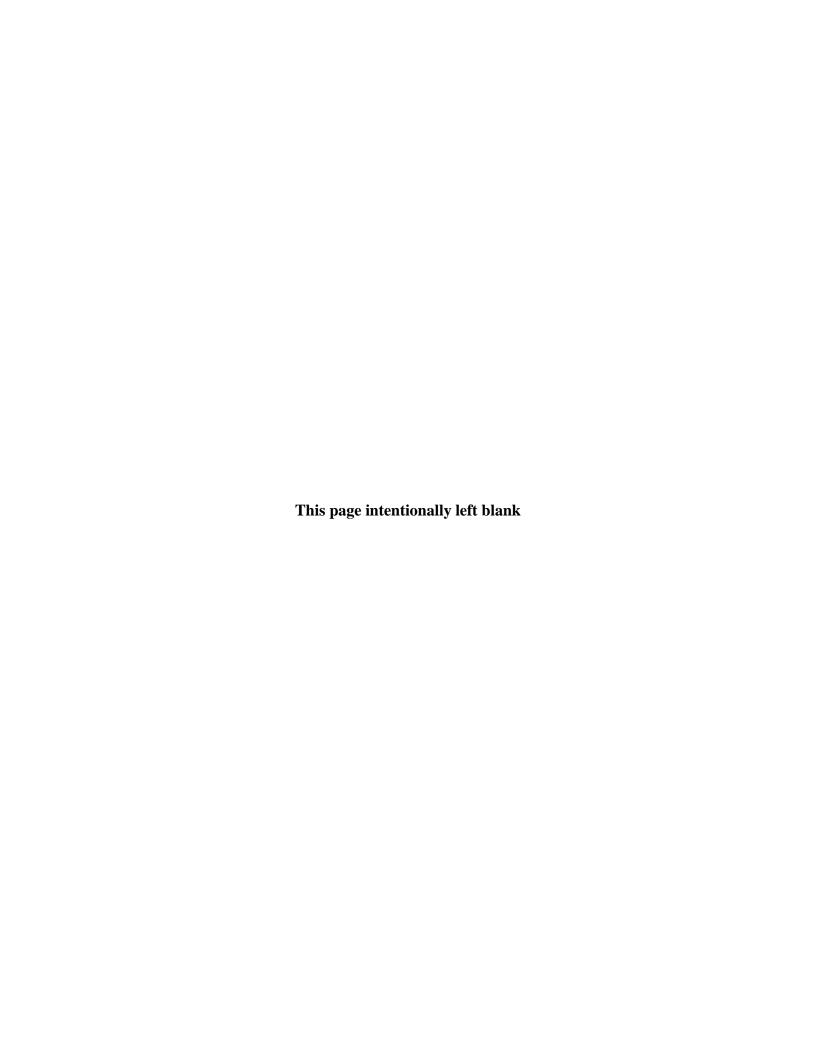


## **Questions?**

Margaret Davino
Fox Rothschild
mdavino@foxrothschild.com

(646) 601-7615







# Adopted Regulations Since 11/1/2022\*

 ${}^*\mathsf{This}$  is a selection and does not represent all healthcare regulations adopted within timeframe.

## Department of Health

## N.J.A.C. 8:39-43.10 - Approval of a Nurse Aide in Long-Term Care Facilities Training Program - Nurse Aide Training Program Instructor/Evaluator

- 55 N.J.R. 2258(b)
- Effective: November 06, 2023
- NJ Department of Health Standards for Licensure of Long-Term Care Facilities
- Result of a Petition for Rulemaking received March 29, 2021
- Changes New Jersey's nurse aide instructor requirements to be more in line with less stringent Centers for Medicare and Medicaid Services (CMS) requirements (e.g., reduces length of time required for nursing experience)

### N.J.A.C. 8:67 - Expedited Partner Therapy

- 55 N.J.R. 108(a)
- Effective: January 17, 2023
- Department of Health New Rule, Chapter 67
- Implements P.L. 2019, c. 336, which authorizes health care professionals to provide "expedited partner therapy" (EPT), a harm reduction practice by which a health care professional, who diagnoses a patient as having a sexually transmitted infection (STI), provides treatment for the patient's recent sexual partners without first conducting an examination of the partners.
- Regulations, in part:
  - Define STIs that warrant EPT, referring to Centers for Disease Control's "Sexually Transmitted Infections Treatment Guidelines, 2021"
  - Require health care professionals to adhere to the STI Treatment Guidelines in administering EPT

## N.J.A.C. 8:43B - Standards for Licensure of Adult Family Care Caregivers and Sponsor Agencies

- 55 N.J.R. 377(a)
- Effective: March 06, 2023
- Department of Health Certificate of Need and Healthcare Facility Licensure
- Rules to implement P.L. 2001, c. 304, the New Jersey Adult Family Care Act
- Establishes requirements for adult family care (AFC) caregiver and AFC sponsor agency licensure applicants and licensees
- "AFC offers individuals with different disabilities and frailties, who are no longer able to live alone, the opportunity to move in and share the home of an AFC caregiver who is capable of providing needed assistance and supervision. AFC provides a home-like environment and encourages participation in the family and community. For many individuals, an AFC caregiver, and his or her family, may become a client's surrogate family."

#### N.J.A.C. 8:63 - Harm Reduction Services

• 55 N.J.R. 1478(a)

• Effective: June 12, 2023

• Department of Health

- Special Rule implementing changes to Bloodborne Disease Harm Reduction Act, as amended by P.L. 2021, c. 396 (harm reduction services), which broadens the concept of harm reduction services in the State to encompass services in addition to access to sterile syringes:
  - includes, but shall not be limited to: syringe access, syringe disposal, referrals to health and social services, harm reduction counseling and supplies including, but not limited to, fentanyl test strips, and HIV and hepatitis C testing
- Repeal of existing N.J.A.C. 8:63, Sterile Syringe Access Program Demonstration Project Rules, and adopts, and concurrently proposes to readopt, special new rules at N.J.A.C. 8:63, Harm Reduction Centers.
- Includes rules establishing registration and operational requirements for entities seeking to register as harm reduction centers and the criteria for registration approval

N.J.A.C. 8:36, 8:37, 8:39, 8:43 - Standards for Licensure of Assisted Living Residences, Comprehensive Personal Care Homes, and Assisted Living Programs; Licensing Standards for Dementia Care Homes; Standards for Licensure of Long-Term Care Facilities

- 55 N.J.R. 2258(a)
- Effective: November 06, 2023
- Department of Health
- Emergency Rule to implement new statutory requirements set forth at N.J.S.A. 26:2H-12.97 et seq., pursuant to which DOH is directed to adopt emergency rules to establish standards for the prevention of social isolation of residents of long-term care facilities
- Rules and standards intended to ensure that nursing homes, assisted living facilities, comprehensive personal care homes, residential health care facilities, and dementia care homes take steps to prevent the social isolation of residents at all times
- Social Isolation = a state of isolation, wherein a resident of a long-term care facility is unable to
  engage in social interactions and religious and recreational activities with other facility residents
  or with family members, friends, and external support systems
- Requires provision of technology to residents for the purpose of maintaining contact with individuals outside of the facility

# Law and Public Safety, Division of Consumer Affairs

## N.J.A.C. 13:35-6.20A - Radiologist assistant performing procedures

- 55 N.J.R. 67(a)
- Effective: January 03,2023
- State Board of Medical Examiners General Rules of Practice
- Proposed new rule to effectuate statutory requirements at P.L. 2017, c. 281
- Permits radiologist assistants to perform delegated fluoroscopic procedures under the supervision of licensed radiologists provided certain requirements are met
- Sets forth the procedures that are appropriate for licensed radiologist assistants to perform and the level of supervision licensed radiologists must provide when radiologist assistants are performing these procedures and other related tasks

## N.J.A.C. 13:34-2.2 - Associate marriage and family therapist: requirements for licensure; licensure procedure

- 54 N.J.R. 2396(a)
- Effective: December 19, 2022
- State Board of Marriage and Family Therapy Examiners Requirements for Licensure
- Adopted as a result of petition for rulemaking received on April 28, 2021
- Removes requirement to submit a written plan of supervision as a precondition for licensure as an associate marriage and family therapist; adds provision that the written plan for supervision of the licensed associate marriage and family therapist must be approved by the Board prior to the performance of counseling by the licensed associate marriage and family therapist in accordance with requirements at N.J.S.A. 45:8B-18.2.

## N.J.A.C. 13:35-7.6 Limitations on prescribing, administering, or dispensing of controlled dangerous substances; special requirements for management of acute and chronic pain

- 55 N.J.R. 110(b)
- Effective: January 17, 2023
- State Board of Medical Examiners Prescription, administration and dispensing of drugs
- Places increased requirements on practitioners to identify, in advance, psychological comorbidities that affect prescribing and overall treatment decisions and assess whether continued opioid therapy is working to address the patient's treatment needs (e.g., requires practitioners to make a reasonable effort to obtain and review the patient's medical record and heightens documentation requirements)
- Implements P.L. 2021, c. 54, by requiring a health care practitioner who issues a prescription for an opioid drug to also issue a prescription for an opioid antidote when certain conditions are met

### N.J.A.C. 13:42-4.1 - State Board of Psychological Examiners - Supervised Practical Experience for Doctoral Degree

- 54 N.J.R. 2091(a)
- Effective: November 07, 2022
- State Board of Psychological Examiners Supervision of Candidates for Licensure
- Amends N.J.A.C. 13:42-4.1 to effectuate the provisions at P.L. 2020, c. 134.
- Removes a provision that required at least one year of professional experience be completed subsequent to the applicant receiving a doctoral degree; amendments recognize that applicants may complete required two years of professional experience prior to receiving a doctoral degree and permit pending applicants to satisfy the professional experience requirement through experience completed prior to receiving a doctoral degree.

## N.J.A.C. 13:39-4A - Remote Processing of Prescriptions by Pharmacy

- 55 N.J.R. 954(b)
- Effective: May 01, 2023
- State Board of Pharmacy— New Rule, Remote Processing of Prescriptions
- Based upon Board's experience with pilot programs
- Allow pharmacy to have licensed pharmacists and registered pharmacy technicians perform limited pharmaceutical functions at a location other than on the premises of a pharmacy (e.g., data entry of prescription medication information and refill authorizations)

## N.J.A.C. 13:35 - Board of Medical Examiners - License by Reciprocity; License Renewal

- 55 N.J.R. 2136(a)
- Effective: October 02, 2023
- State Board of Medical Examiners
- Amendments, repeals, and new rules to effectuate the provisions at N.J.S.A. 45:1-7.1, 7.4, and 7.5 for licensed physicians and podiatrists.
- Allows the Board to issue a license to an applicant licensed in another state with licensure standards substantially equivalent to the Board's standards, as long as the applicant has been practicing for at least two years within the five years prior to applying for a license.
- Revises reactivation requirements for inactive licensees and reinstatement requirements for licensees who have a suspended license for failure to renew.

## N.J.A.C. 13:34 - Marriage and Family Therapy Supervision Through Technology-Assisted Media (Telesupervision)

- 55 N.J.R. 2014(a)
- Effective: September 18, 2023
- Division of Consumer Affairs State Board of Marriage and Family Therapy Examiners
- Amendments and new rule concerning the provision of marriage and family therapy supervision through technology-assisted media (telesupervision)
- Rules define telesupervision, mandate that supervisors who seek to provide telesupervision be appropriately trained, and establish certain telesupervision standards.

## Department of Human Services

### N.J.A.C. Title 10, Human Services

- **★** □ Chapter 44A. Standards for Community Residences for Individuals with Developmental Disabilities
- 🛨 🗀 Chapter 44B. Manual of Standards for Community Care Residences
- **★** Chapter 44C. Standards for Community Residences for Persons with Head Injuries

### N.J.A.C. 10:44A - Community Residences for Individuals with Developmental Disabilities

- 55 N.J.R. 171(a)
- Effective: February 06, 2023
- Department of Human Services, Office of Program Integrity and Accountability
- Applies to "community residences," also known as group homes, supervised apartments, or supported living, which are licensed by the Department to serve individuals with developmental disabilities
- Rules set minimum requirements in the areas of general provisions and licensing procedures, organization and administration, advocacy and rights, service delivery/habitation, health and safety, and fire safety and physical environment
- Amendments, repeals, and new rules to comply with the Department's Fee-for-Service initiative, the Centers for Medicare and Medicaid Services' guidelines for funding, Danielle's Law, P.L. 2003, c. 191 (N.J.S.A. 30:6D-5.1 5.6), and Stephen Komninos' Law, P.L. 2017, c. 238 (N.J.S.A. 30:6D-9.1 et seq., 30:6D-5.4, and 30:6D-74 et seq.)

### N.J.A.C. 10:44B - Manual of Standards for Community Care Residences

- 55 N.J.R. 52(b)
- Effective: January 03, 2023
- Department of Human Services, Office of Program Integrity and Accountability
- Amends rules to establish minimum requirements for the provision of residential services to individuals with developmental disabilities residing in "community care residences," living arrangements in which a Family Care or Skill Development program is provided in a private home or apartment
- Amendments update the rules to be consistent with best practices and to include provisions for the Fee-for-Service Initiative; the Centers for Medicare and Medicaid Services' guidelines for funding; the Central Registry of Offenders against Individuals with Developmental Disabilities (N.J.S.A. 30:4D-77); P.L. 2017, c. 328 (an act concerning background checks and licensing of certain entities); Stephen Komninos' Law (P.L. 2017, c. 238); and updated organizational changes.

## N.J.A.C. 10:44C - Community Residences for Persons with Head Injuries

- 55 N.J.R. 58(a)
- Effective: January 03, 2023
- Department of Human Services, Office of Program Integrity and Accountability
- Applies to "community residences," also known as group homes, supervised apartments, or supported living, which are licensed by the Department to serve individuals for persons with head injuries (traumatic brain injuries) that are licensed by the Department
- Amends rules for individualized delivery of services to persons served, the establishment and maintenance of a safe environment, the support and encouragement to undertake dignified risk, and the delineation of personal rights
- Amendments to comply with the Department's Fee-for-Service initiative, the Centers for Medicare and Medicaid Services' guidelines for funding Home and Community Based Services (42 CFR 441.300 et seq.), and Stephen Komninos' Law, P.L. 2017 c. 238.

## N.J.A.C. 10:53 - Home- and Community-Based Services Provided in Assisted Living Residences, Comprehensive Personal Care Homes, and Assisted Living Programs

- 54 N.J.R. 2389(a)
- Effective: December 19, 2022
- Department of Human Services Division of Medical Assistance and Health Services
- New rules is to implement the Medicaid/NJ FamilyCare waiver for HCBS for Medicaid/NJ FamilyCare Managed Long-Term Services and Supports beneficiaries in assisted living residences, comprehensive personal care homes, and assisted living programs licensed by the Department of Health pursuant to N.J.A.C. 8:36
- Sets standards for, among other things, person-centered service plans and beneficiary community integration

### N.J.A.C. 10:76 - Programs of Assertive Community Treatment

- 55 N.J.R. 1333(b)
- Effective: July 03, 2023
- Department of Human Services Division of Medical Assistance and Health Services
- PACT services are patient-centered and outreach and recovery-oriented, to provide comprehensive clinical treatment and related support services in community settings to adults with serious and persistent mental illness with or without a co-occurring substance abuse diagnosis.
- Regulations readopted with certain amendments, including a requirement for PACT provider to have a valid National Provider Identifier (NPI) number, valid taxonomy code, and complete a provider revalidation when requested

### N.J.A.C. 10:77 - Rehabilitative Services for Children

- 55 N.J.R. 1292(a)
- Effective: June 19, 2023
- Department of Human Services Division of Medical Assistance and Health Services
- Readopts Rehabilitative Services for Children chapter with amendments
- Requires providers to obtain a Federally required National Provider Identifier (NPI) and valid taxonomy code for their provider type.

## N.J.A.C. 10:48A - Division of Developmental Disabilities Background Checks

- 55 N.J.R. 1830(a)
- Effective: August 21, 2023
- Department of Human Services Division of Developmental Disabilities
- Readopts with amendments rules for obtaining criminal history background checks for employees of agencies under contract with the Division of Developmental Disabilities.
- Amendments which, in part, add categories of persons required to obtain background checks: community care residence applicants, alternates, and household members, as required pursuant to P.L. 2017, c. 328

## N.J.A.C. 10:36/8:135 - Patient Supervision at State Psychiatric Hospitals; Transfers of Involuntarily Committed Patients Between State Psychiatric Facilities

- 55 N.J.R. 2271(a)
- Effective: November 06, 2023
- Department of Health (transfer from Department of Human Services)
- Readoption with Amendments and Recodification: N.J.A.C. 10:36 as 8:135
- Adopted New Rule: N.J.A.C. 8:135-2.5, Treatment team procedures: specifies procedure by which treatment teams evaluate the risk of violence in special status patients by requiring teams to use of evidence-based risk assessment tools.
- Substantive and non-substantive amendments throughout the chapter to delete references to the DHS and its divisions and add in place thereof, references to DOH, use gender-neutral language, reorganize sections, improve readability, improve grammar, eliminate the passive voice, remove unnecessary capitalization, and update terminology that tends to stigmatize or objectify patients who have psychiatric illnesses.

# Proposed Regulations Since 11/1/2022\*

 ${}^*\mathsf{This}$  is a selection and does not represent all healthcare regulations proposed within timeframe.

### N.J.A.C. 8:96 - Hospital Financial Transparency

- 54 N.J.R. 2054(a)
- Proposed: November 07, 2022
- · Department of Health, Office of Health Care Financing
- Implements P.L. 2019, c. 513 and proposes regulations in response to other concerns raised in Mary O'Dowd's July 17, 2014, report to the Governor, Hospital Financial Transparency: Department of Health Recommendation on Hospital Financial Transparency, available at <a href="http://www.nj.gov/health/healthcare\_transparency.shtml">http://www.nj.gov/health/healthcare\_transparency.shtml</a>.
- Proposes to amend existing N.J.A.C. 8:96-1 to increase the financial transparency of hospitals and assist in the prevention
  of hospitals becoming financially distressed due to undisclosed management contracts, payments to, or on behalf of,
  owners or related organizations, and business transactions with interested persons by requiring hospitals to:
  - disclose business transactions with interested persons to the Department and on a hospital's website;
  - annually report to the Department the names of owners of five percent or more of a hospital;
  - notify the Department before it enters into a sale-leaseback agreement; and
  - disclose the fact that it entered into a sale-leaseback agreement at its next annual public meeting.
- Also establishes additional enforcement remedies, including expansion of the instances in which the Department can
  appoint a financial monitor if a hospital is in danger of becoming, or becomes, financially distressed, aiming to prevent
  sudden hospital closures due to financial difficulties.

## N.J.A.C. 8:39 - Standards for Licensure of Long-Term Care Facilities; General Licensure Procedures and Enforcement of Licensure Regulations

- 55 N.J.R. 1249(a)
- Proposed: June 19, 2023
- Department of Health, Division of Certificate of Need and Licensing
- Proposal to implement P.L. 2020, c. 112, codified at N.J.S.A. 30:13-18, establishing minimum staffing requirements for nursing homes.
- Includes mandatory direct care staff-to-resident ratios and minimum direct care staffing standards for nursing homes to follow on day, evening, and night shifts, and the minimum number of certified nurse aides (CNAs) on each such shift.

### **NJAC 8:32 - Drug Donation Programs**

- 55 N.J.R. 1608(a)
- Proposed: August 07, 2023
- · Department of Health, Division of Certificate of Need and Licensing
- Proposal to implement P.L. 2017, c. 254, which required the DOH, the State Board of Pharmacy, and the Department of the Treasury to take administrative action to authorize one or more private entities to establish and maintain a drug donation program that would permit donors to donate over-the-counter drugs, prescription drugs, and administration supplies, which would otherwise be destroyed; and the redistribution of such unused drugs and administration supplies to those persons who are most in need.
- Sets forth standards for applicants and requirements for operations.
- Donors would be allowed a credit against tax otherwise due pursuant to the New Jersey Gross Income Tax Act, N.J.S.A. 54A:1-1 et seq., or the New Jersey Corporation Business Tax, N.J.S.A. 54:10A-1 et seq.

### N.J.A.C. 13:42B - Board of Applied Behavior Analyst Examiners

- 55 N.J.R. 989(a)
- Proposed: May 15, 2023
- Law and Public Safety, Division of Consumer Affairs, Board of Applied Behavior Analyst Examiners
- Implements P.L. 2019, c. 337, which created Board of Applied Behavior Analyst Examiners and allows for the licensure and regulation of licensed applied behavior analysts and licensed assistant applied behavior analysts.

### N.J.A.C. 13:42B - Board of Applied Behavior Analyst Examiners

"Applied behavior analysis" means the practice of designing, implementing, and evaluating instructional and environmental modifications to produce socially significant improvements in human behavior, including the empirical identification of functional relations between behavior and environmental factors, known as functional assessment and analysis. Applied behavior analysis interventions are based on scientific research and direct and indirect observation and measurement of behavior and environment. Applied behavior analysts utilize contextual factors, motivating operations, antecedent stimuli, positive reinforcement, and other procedures to help individuals develop new behaviors, increase or decrease existing behaviors, and emit behaviors pursuant to specific environmental conditions. The practice of behavior analysis does not include psychological testing, diagnosis of mental, physical, or speech language, hearing, and other communication and swallowing disorders, neuropsychology, psychotherapy, cognitive therapy, sex therapy, psychoanalysis, hypnotherapy, and counseling as treatment modalities.

### N.J.A.C. 13:44G-3.1 - Licensed Clinical Social Worker Scope of Practice

- 55 N.J.R. 1001(a)
- Proposed: May 15, 2023
- Law and Public Safety, Division of Consumer Affairs, State Board of Social Work Examiners
- Proposes to amend N.J.A.C. 13:44G-3.1 to recognize that determining whether a terminally ill patient has the capacity to make health care decisions and communicate them to a health care provider and is within the scope of practice for licensed clinical social workers.
- In support of P.L. 2019, c. 59, Medical Aid in Dying for the Terminally III Act, which permits an attending physician to write a prescription for medication that would enable a qualified, terminally ill patient to end his or her life.
- If attending or consulting physician determines that patient may not have the capacity to make this decision, physician must refer patient to psychiatrist, psychologist, or licensed clinical social worker to determine whether patient is capable.

### N.J.A.C. 17:30A - Medical Cannabis Rules; Clinical Registrant Permits

- 55 N.J.R. 1670(a)
- Proposed: August 07, 2023
- Treasury General, New Jersey Cannabis Regulatory Commission
- Proposes amendments at N.J.A.C. 17:30A and new rules relating to "clinical registrant permits," pursuant to P.L. 2019, c. 153 (N.J.S.A. 24:61-7.3)
- "Clinical registrant" means an entity that has a written contractual relationship with an academic medical
  center in the region in which it has its principal place of business, which includes provisions whereby the
  parties will engage in clinical research related to the use of medical cannabis and the academic medical
  center or its affiliate will provide advice to the entity regarding patient health and safety, medical
  applications, and dispensing and managing controlled dangerous substances, among other areas.
- Under proposed rule, an entity holding a clinical registrant permit shall be authorized to engage in all
  conduct involving the cultivation, manufacturing, and dispensing of medical cannabis as is authorized for
  an entity holding medical cannabis cultivator, medical cannabis manufacturer, and medical cannabis
  dispensary permits pursuant to P.L. 2009, c. 307, including dispensing medical cannabis and medical
  cannabis products to qualifying patients and designated and institutional caregivers.

## Other Updates

### N.J.S.A. 26:2H-7.25-27 - Transfer of Ownership of Nursing Home

- Effective: November 8, 2021
- DOH began implementing over the course of 2022
- Application process more rigorous
- New process for public comment and a public hearing for certain types of applications
- 120 days for DOH to review and approve applications, but DOH may not consider this period to begin until application deemed "complete"; if not "complete", DOH will issue "not accepted for processing" (NAP) notices.
- Applications posted at <a href="https://www.nj.gov/health/healthfacilities/certificate-need/ltc-transfer-ownership/">https://www.nj.gov/health/healthfacilities/certificate-need/ltc-transfer-ownership/</a>

N.J.S.A. 34:11-4.15 - Change in control of health care entity; employee retention agreement; effect of collective bargaining agreement; violations of section; penalties; definitions; severability

- Effective: November 16, 2022
- Requires that any change in control of a health care entity be made by agreement which provides certain protections for employees regarding their wages, benefits, and employment in connection with the change in control.
- Requires that all eligible employees be offered employment during a six-month transitional period; that none of them be discharged except in a reduction of the work force, and then only on the basis of seniority and only if the laid off workers are offered employment if the positions are restored; and that employees be given written evaluations of their work during the transitional period and retained if their work is satisfactory
- Defines "health care entity" as a health care facility licensed pursuant to P.L.1971, c. 136 (C.26:2H-1 et seq.), a staffing registry, or a home care services agency as defined in section 1 of P.L.1947, c. 262 (C.45:11-23).

### 26:2H-5.1g - Integrated Facility Licensure

- DOH being pressured to establish regulatory framework for integrated facility license that permits provision of physical and behavioral health care services in the same setting by the licensee
- Currently, behavioral health requires separate license by separate DOH unit
- 26:2H-5.1g (effective February 1, 2019) requires DOH to adopt regulations necessary to develop
  an integrated licensing system in which facilities may provide primary care, mental health care, or
  substance use disorder treatment services, or a combination of such services, under a single
  license.
- November 8, 2023 New Jersey Quality Institute letter urges DOH action:
  - "overwhelming demand for mental health and addiction treatment services"
  - "marked disparity in diagnosis, treatment, and outcomes for physical health and behavioral health conditions...due, in part to the current system of the lack of coordination between behavioral and physical conditions"
- https://www.njhcqi.org/wp-content/uploads/2023/10/Integrated-Licensure-Letter-to-DOH.pdf

## Change in DOH Facility Licensure Application Intake and Procedures

- DOH now recommends:
  - Electronic filing via <a href="mailto:CNLApps@doh.nj.gov">CNLApps@doh.nj.gov</a>
  - Payment of application fees via http://www.nj.gov/health/healthfacilities/epayments.shtml

### **DOH Websites and Email Addresses**

License Renewal General

Mailbox cnandlicensingrequests@doh.nj.gov

#### **PAYMENT & APPLICATION FORMS**

Pay Application Fees Online: http://www.nj.gov/health/healthfacilities/epayments.shtml Applications Forms at: https://healthapps.state.nj.us/forms

### **HEALTH FACILITY LICENSE RENEWALS**

License Renewal General

Mailbox cnandlicensingrequests@doh.nj.gov

SIGN UP FOR ONLINE RENEWAL
License Renewal Portal: https://dohlicensing.nj.gov/
Create Portal Account: https://dohlicensing.nj.gov/Createnewaccountinstructions/

#### WAIVERS

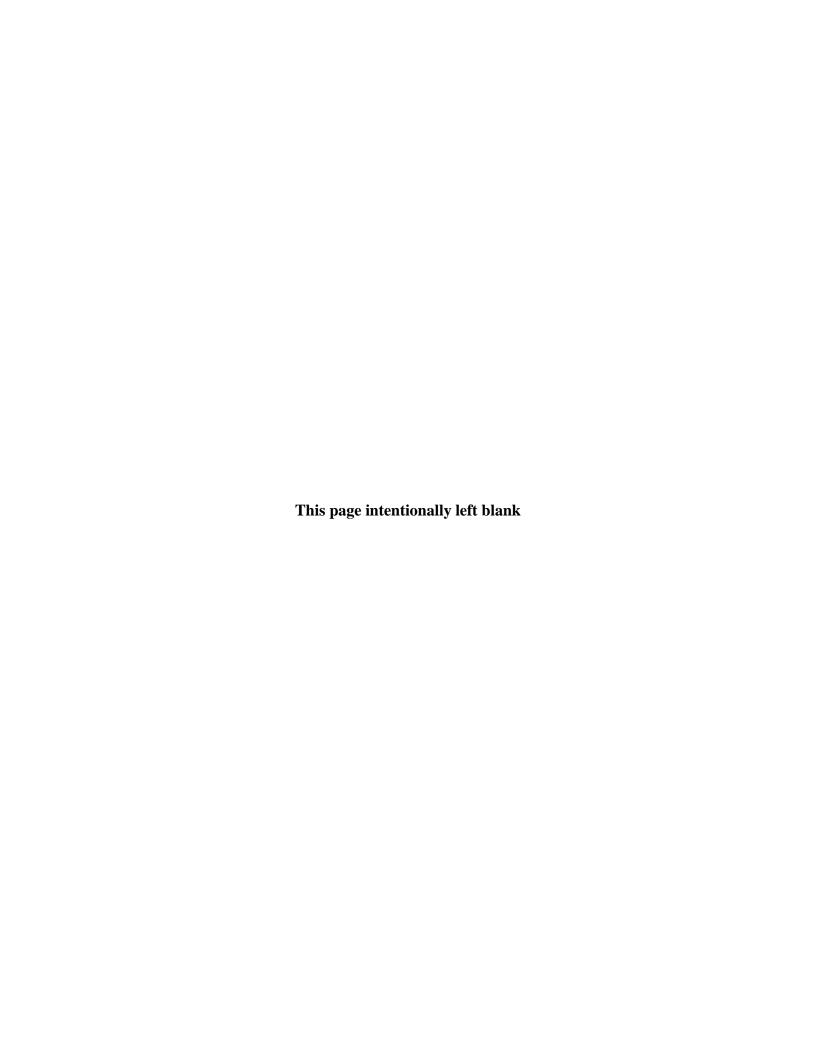
Email Waivers (CN-28 Form): <a href="mailto:cNLapps@doh.nj.gov">cNLapps@doh.nj.gov</a> No Fee Required.

### ADMINISTRATOR UPDATE

LTC, ALR Administrator: <a href="mailto:nhalbrequests@doh.nj.gov">nhalbrequests@doh.nj.gov</a> Acute Administrator: <a href="mailto:cnandlicensingrequests@doh.nj.gov">cnandlicensingrequests@doh.nj.gov</a>

Renewals: cnandlicensingrequests@doh.nj.gov
Waiver Applications: CNLapps@doh.nj.gov
Questions about an application in progress, please contact your
assigned licensing analyst.







EQUITY PARTNERS:
JOHN P. INGLESINO\*
JOHN P. WYCISKALA\*
LISA D. TAYLOR\*
DENIS F. DRISCOLL
NICHOLAS A. GRIECO
\*FOUNDING PARTNER

New Jersey: 600 Parsippany Road, Suite 204 Parsippany, New Jersey 07054 t (973) 947-7111 fax: (973) 887-2700

<u>Florida</u>: 2255 Glades Road, Suite 324A Boca Raton, Florida 33431 t (561) 235-3995

REPLY TO NEW JERSEY OFFICE

LISA D. TAYLOR
BOARD CERTIFIED IN HEALTH LAW
BY THE FLORIDA BAR
ALSO ADMITTED IN NJ, NY, PA, TN, DC
Direct: (973) 947-7135
Itaylor@itfirm.law

Lisa D. Taylor is a founding partner with Inglesino Taylor in Boca Raton, Florida and Parsippany, New Jersey and concentrates in health care law. She also handles business transactions, employment, and regulatory matters and litigation and represents professionals in disciplinary matters. Additionally, she serves as a neutral arbitrator and mediator and as an expert witness in health care disputes and professional proceedings.

Ms. Taylor served two non-consecutive terms as the Chair of the New Jersey State Bar Association Health Law Section and was a member of the Section's Board of Directors for twenty years before transitioning to the Section's Emeritus Board in 2019. Having held numerous leadership positions with the American Health Law Association of which she was elected a Fellow in 2021, she presently serves as Vice Chair of the American Bar Association Health Law Section and Chair of the Health Care Certification Committee of The Florida Bar.

Ms. Taylor is listed in Best Lawyers In America, Who's Who in the World, Who's Who in America, Who's Who in American Law, is rated "AV" by Martindale-Hubbell Law Directory and has been repeatedly named one of the Top 50 Female New Jersey Super Lawyers and Top 100 New Jersey Super Lawyers. She is also a member of the Million Dollar Advocates Forum which gives recognition to lawyers throughout the United States who have achieved a trial verdict, award or settlement in the amount of One Million Dollars (\$1,000,000) or more and is a Life Fellow of the American Bar Foundation. In November 2016, she received the Ira Geller Award from Community Access Unlimited for zealous advocacy of the disabled and in December 2014, she received the Distinguished Service Award for Excellence in Continuing Legal Education from the New Jersey Institute for Continuing Legal Education. She received the Distinguished Service Award from the New Jersey State Bar Association Health and Hospital Law Section for service to the health bar and health industry in 2007 and in 2004, she was named as one of ten attorneys nationally recognized as Outstanding Physician Practice Lawyers by *Nightingale's Healthcare News*. In August 2005, she was named to the *New Jersey Law Journal's* list of leading women and minority attorneys.

A *cum laude* graduate of Columbia University, Ms. Taylor received her law degree and a Master of Arts degree in Philosophy from Duke University. Ms. Taylor also studied finance and accounting at Columbia Business School and attended Executive and Continuing Professional Education at Harvard University T.H. Chan School of Public Health. She is Board Certified in Health Law by The Florida Bar and is also licensed to practice law in New Jersey, New York, Pennsylvania, Tennessee and the District of Columbia and is admitted to appear before numerous Federal Courts.

