

Third Annual New York State Health Care Symposium

Monday, May 4, 2026

9:00–10:00 a.m.	Breakfast
10:00–10:05 a.m.	Opening Remarks
10:05–11:05 a.m.	“Responding to Record Requests, Subpoenas, and Court Orders: Navigating Privacy and Confidentiality Laws in New York State” Presenters: Jamie Dughi Hogenkamp and Ron Oakes
11:05–11:15 a.m.	Break
11:15 a.m.–12:20 p.m.	“Navigating the 2026 Medicaid Enforcement Landscape: Trends and Tips for New York Providers” Presenters: Margaret Surowka and Michael Scott-Kristansen
12:20–1:20 p.m.	Lunch
1:20–2:25 p.m.	“Conducting Effective Internal Investigations” Moderator: Pei Pei Cheng de Castro Panelists: <ul style="list-style-type: none">› Rick Hartunian› Eric Miller <i>General Counsel, University of Vermont Health</i>
2:25–3:40 p.m.	“Medicaid and Medicare Enforcement” Moderator: Bob Hussar Panelists: <ul style="list-style-type: none">› Erin Ives <i>First Deputy, NYS Office of the Medicaid Inspector General</i>› Kate Teliska <i>Special Agent, Department of Health & Human Services Office of Inspector General</i>› Amy Held <i>Deputy Attorney General and Director, NYS Medicaid Fraud Control Unit</i>
3:40–3:45 p.m.	Closing Remarks

Responding to Record Requests, Subpoenas, and Court Orders: Navigating Privacy and Confidentiality Laws in New York State

Sample Operating Model for Release of Information Following Access and Disclosure Requests

Step 1: Centralize Intake and Triage

- Require all requests to route through a single function (HIM/medical records, compliance, or legal).
- Immediately categorize:
 - › Patient request
 - › Third-party request with authorization
 - › Subpoena
 - › Court order/motion papers
 - › Government/oversight request

Step 2: Verify Identity, Authority, and Scope

- Identity verification:
 - › Confirm requester identity and contact information independently (not solely from the request).
 - › Confirm capacity/authority (patient, personal representative, counsel of record, agency authority).
- Scope verification:
 - › What records are requested (entire chart vs. specific items)
 - › Time period
 - › Purpose stated (treatment, litigation, benefits, investigation)

Step 3: Determine the Governing Confidentiality Regime(s)

- Review with legal counsel to determine which law applies:
 - › General medical PHI (HIPAA baseline)
 - › HIV-related information (PHL Art. 27-F)
 - › SUD treatment records (42 CFR Part 2)
 - › OMH/OPWDD provider records (MHL § 33.13)
 - › Other specially protected categories referenced in New York State law/policy
- Apply the strictest applicable rule to the requested records.

Step 4: Validate the Legal Basis for Disclosure

- If relying on authorization/consent:
 - › Confirm it is properly executed, current, and sufficiently specific.
 - › Confirm it covers the requested recipient and purpose.
- If relying on legal process:
 - › Subpoena vs. a court order
 - › Confirm jurisdiction, service, and deadlines.
 - › Identify whether patient notice/opportunity to object is required by the applicable pathway.

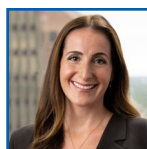
Step 5: Produce Securely and Narrowly

- Apply minimum necessary redactions where appropriate.
- Use secure transmission (encrypted portal, secure mail, or court-directed method).
- Include a production cover letter stating:
 - › What is produced and what is withheld
 - › The legal basis for production
 - › Any confidentiality/redisclosure limitations

Step 6: Document and Close Out

- Log the disclosure (what, when, to whom, why, under what authority).
- Retain a copy of the request, authorization/order, and production set (or index) per retention policy.
- Capture lessons learned for process improvement.

KEY CONTACTS



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Jamie Dughi Hogenkamp

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Education

- Albany Law School, *Summa Cum Laude* (Salutatorian); *Albany Law Review*, Senior Editor, JD
- State University of New York at Albany, School of Social Welfare, MSW
- Union College, *Cum Laude*, BS

Practices & Industries

- Health & Human Services Providers
- Health Care
- Corporate
- Pharmacy

Admitted to Practice

- New York
- Connecticut

Biography

A former law clerk to Judge Michael J. Garcia at the New York State Court of Appeals, Jamie concentrates her practice on advising health care and human services providers on matters relating to formation, corporate governance, affiliations, mergers, asset acquisitions, corporate reorganizations, and regulatory compliance and approvals. In addition to Jamie's extensive experience handling corporate transactions for not-for-profit entities, Jamie counsels for-profit and not-for-profit organizations regulated by state and federal agencies regarding regulatory and compliance matters, including advising clients on confidentiality requirements, compliance programs, administrative audits and investigations, self-disclosures, HIPAA compliance and policies and procedures, licensure and certification, and other legal matters.

Jamie's clients include behavioral health providers, substance use disorder treatment facilities, hospitals, assisted living facilities, nursing homes, developmental disability services providers, youth and family services providers, and other charitable organizations. Jamie began her career as a social worker and draws on this experience to develop innovative and effective legal strategies to advance her clients' goals and enhance their delivery of health care and human services to the communities they serve.

In addition to her legal practice, Jamie serves as one of Barclay Damon's HATCH program coordinators.

Bar Associations

- Albany County Bar Association
- Capital District Women's Bar Association
- New York State Bar Association

Selected Memberships & Affiliations

- Barclay Damon's Women's Forum

Representative Experience

- Served as transaction counsel in the corporate reorganization of two large substance use disorder treatment facilities and secured regulatory approval of the restructured entities.
- Secured Attorney General approval for various not-for-profit corporate transactions.
- Represents various behavioral health providers in response to subpoenas for confidential records.
- Served as transaction counsel to two not-for-profit entities regarding reorganization and the formation of a parent entity.
- Assisted clients in the formation of Behavioral Health Services practice.
- Represents substance abuse treatment facilities with regard to OASAS regulatory compliance and 42 CFR Part 2 confidentiality and privacy compliance.
- Handled the reorganization and asset transfer of two substance abuse treatment programs.
- Successfully secured approval from the New York State Attorney General for a not-for-profit entity's Plan and Certificate of Dissolution following the resolution of an outstanding civil lawsuit.
- Assisted in the sale of a not-for-profit adult care facility.
- Represented NYS not-for-profit corporations in complying with the New York Non-Profit Revitalization Act of 2013 and subsequent amendments.
- Successfully reduced overpayment amounts for health care clients in response to OMIG and OIG audits.
- Advised clients regarding updated HIPAA policies and procedures.
- Engaged in complex health care litigation representing former members of group self-insurance workers' compensation trusts.
- Sought emergency temporary restraining orders and preliminary injunctions for pharmacy clients excluded from their networks.

Prior Experience

- New York State Court of Appeals, Chambers of the Hon. Michael J. Garcia, Law Clerk
- Hiscock & Barclay, LLP, Law Clerk
- Hiscock & Barclay, LLP, Summer Associate
- Albany Law School Clinic and Justice Center Family Violence Litigation Clinic, Legal Intern
- NYS Supreme Court, Appellate Division, Third Department, Chambers of the Hon. Elizabeth Garry, Summer Judicial Intern
- NYS Office of Children and Family Services, Division of Child Care Services, Women and Public Policy Fellow
- Prevent Child Abuse New York, Senior Helpline Associate

Selected Community Activities

- Big Brothers, Big Sisters, Volunteer
- Global Volunteers, Volunteer

Selected Honors

- *Best Lawyers: Ones to Watch in America*®: Health Care Law, 2021–2025
- Selected to *Super Lawyers* Upstate New York Rising Stars: Health Care, 2020–2025
- Albany Law School, John B. Lurie '20 Memorial Prize, 2015
- Albany Law School, Thomson Reuters Evidence Prize, 2015
- Albany Law School, Trustees' Second Prize, 2015

Selected Media

- Healio, "What Providers Should Know About Changes to Substance Use Confidentiality Regulations"
- New York State Bar Association *Health Law Journal*, "New York State Office of Medicaid Inspector General Update"
- *United States of America v. James Alvin Castleman*, "Brief Amicus Curiae New York State Association of Chiefs of Police in Support of Petitioner"
- *Oregon Real Estate & Land Use Digest*, "The Elephant in the Seattle Court Room"

Selected Alerts & Blog Posts

- Navigating New York State's Expanded Regulatory Landscape: Implications for Health Care Transactions
- Post-Brexit Update: Is Your Medical Device Ready for Great Britain in 2022?
- Reminder: Social Adult Day Services Providers Contracting with MLTCs Must Comply with NYSOFA Regulations



Ron Oakes

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Education

- University at Buffalo School of Law, JD; *Buffalo Law Review*, Executive Publications Editor
- University at Buffalo School of Nursing, MS, Nursing Leadership in Health Care Systems
- Daemen College, BS, Nursing, *Summa Cum Laude*

Practices & Industries

- Health & Human Services Providers
- Health Care Controversies
- Health Care

Admitted to Practice

- New York

Biography

Ron's practice is informed by his background as a nurse leader, which gives him a unique perspective regarding the challenges faced by health care clients. He counsels health care and human services providers on a wide range of regulatory and compliance matters, including advising on confidentiality requirements, reimbursement issues, compliance programs, audits and investigations, not-for-profit corporate governance, contract analysis and negotiation, and HIPAA compliance and policies and procedures.

Ron has experience working with behavioral health, mental health, and substance use disorder providers; health information exchanges (HIEs); hospital systems; nursing homes; agencies serving individuals with developmental disabilities; and provider networks, including independent practice associations, among others.

Ron also regularly assists clients with health information privacy and security compliance, including negotiating privacy and security terms in health care IT contracts and responding to requests, subpoenas, and court orders for records and testimony subject to data privacy laws, such as HIPAA and 42 CFR Part 2.

Bar Associations

- Bar Association of Erie County
- New York State Bar Association, Health Law Section, E-Health and Information Systems Committee

Selected Memberships & Affiliations

- American Nurses Association of New York, Former Member
- Professional Nurses Association of Western New York, Member and Former Board of Directors President

Prior Experience

- Barclay Damon LLP, Law Clerk
- Barclay Damon LLP, Summer Associate
- US Court of Appeals for the Third Circuit, Honorable Julio M. Fuentes, Judicial Intern
- Lexis Nexis, Lexis Associate
- AYA Healthcare – NYU Langone Hospital, Critical Care Travel Nurse
- Sisters of Charity Hospital, Emergency Department, Nurse Manager
- Sisters of Charity Hospital, MSC Emergency Services and SJC Critical Care, Assistant Director of Nursing
- Sisters of Charity Hospital, St. Joseph Campus, ICU, Dialysis, and Telemetry, Nurse Manager
- Buffalo General Hospital, Surgical ICU, ICU Staff Nurse
- Holy Cross Hospital, Intermediate Care Unit, Clinical Staff Nurse II

Selected Community Activities

- University at Buffalo School of Law, Student Wellness Society, Former Treasurer
- University at Buffalo School of Law, Former Peer-to-Peer Advocate

Selected Honors

- *Best Lawyers: Ones to Watch® in America: Health Care Law, 2026*
- University at Buffalo School of Law, Jessica Ortiz '05 Federal Judicial Fellowship, 2021

Selected Media

- Healio, "What Providers Should Know About Changes to Substance Use Confidentiality Regulations"

Selected Alerts & Blog Posts

- New York's Medical Aid in Dying Act: What Patients and Health Care Providers Need to Know
- NYS Board of Regents Adopts Regulations on the Mental Health Diagnostic Privilege
- CMS Approves NYS 1115 Waiver Amendment (New York Health Equity Reform)
- OMH's New Self-Disclosure Notification Protocol: What Providers Need to Know
- OMIG's Abbreviated Self-Disclosure Process: What Providers Need to Know

Navigating the 2026 Medicaid Enforcement Landscape: Trends and Tips for New York Providers

Actionable Tactics for Successful Defense

PREPARATION IS KEY

Audit Medical Billers

- Review billing workflow and billing company contracts. Are they:
 - › Performing data match reviews?
 - › Ensuring benefits verification before billing?
 - › Submitting timely and complete appeals?
 - › Retaining complete records of each task?

Protect Data in Vendors' Custody

- Review vendor contracts and vendor compliance.
 - › What data did the vendor agree to maintain and for how long?
 - › Is the vendor complying? Do you know?
- Back Up Vendor Data
 - › Do not solely rely on your vendor. Conduct regular backups.
 - › Work with your IT department, CO, and legal to identify how often backups should be completed, and ensure those are done on time.
 - › Include metadata in the back up wherever possible.
- Pain Points
 - › Transitions and Terminations
 - Ensure all vendor data is saved and in your custody before any terminations or transitions to new vendors or products or systems.
 - › Emails
 - Include emails in your vendor data protection plan.
 - › Digitization of Paper Records
 - Understand where original paper records may be required (e.g., original fiscal order, etc.).
 - › Lost Data Reporting
 - Ensure you are complying with OMIG's 30-day loss reporting requirements for vendor documentation **and data**.

Self-Audit Your Compliance Work Plan

- Does it include service level, service documentation, and billing audits?
- Do your audits incorporate OMIG audit protocols?
- Do your audits incorporate any MCO contract service and billing requirements?
- Do you regularly search for and incorporate Medicaid updates, MCO policy changes, and provider manual updates?

AUDITS: UNDERSTAND PROCEDURAL RIGHTS

Process and Timing Are Critical – Start Strong

- Understand Your Rights and Consult Experienced Legal Counsel
 - › What are the deadlines and opportunities to submit new documentation or arguments?
 - › What intangibles about the audit process may affect the outcome?
- Understand Your Obligations
 - › What information and documentation are you required to provide?
- Identify the Deadlines
 - › A response that is 10 minutes late can cost you everything.
- Silence Is Consent
 - › Always identify and voice disagreements.
- Document
 - › Document every conversation. Confirm phone calls in writing.
- Document Retention
 - › Meet with IT, your CO, and legal counsel to identify what documentation needs to be preserved and what data retention and destruction policies must be put on hold.

KEY POINTS FOR INVESTIGATIONS

- Investigations are almost never routine. Engage or consult with legal counsel as early as possible.
- Identify the state, federal, or private entity and bureau that is handling the investigation.
 - › Is it criminal or civil?
 - › How did the investigation arise?
 - Was there a complaint made to the agency by a patient, client, or caregiver?
 - Was there an internal investigation or report?
 - Was there a claim and was that claim billed, paid, or refunded?
 - Was a self-disclosure involved?
 - Were data analytics used?
- Identify if the investigation pertains to fraud, waste, or abuse.
 - › Who was involved or had knowledge?
- Retain documentation related to the issue.
 - › Identify the required documentation for billing.
 - › Is there any additional contemporaneous documentation?

KEY CONTACTS



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Education

- Albany Law School, *Cum Laude*; *Albany Law Review*, Executive Editor for Production, JD
- Hamilton College, BA

Practices & Industries

- Health & Human Services Providers
- Health Care Controversies
- Labor & Employment
- Lobbying & Election Law Compliance
- Health Care
- Pharmacy

Admitted to Practice

- New York

Court Admissions

- US District Court for the Eastern District of New York
- US District Court for the Northern District of New York
- US District Court for the Southern District of New York
- US District Court for the Western District of New York
- US Supreme Court

Biography

Margaret serves as co-team leader of Barclay Damon's Health Care and Health & Human Services Providers Teams. A former general counsel at the New York State Dental Association with over 30 years of legal experience, Margaret has unique experience in health care and labor and employment. Her health care practice includes representing agencies, facilities, and individual providers in compliance matters, licensure, disciplinary, and ethics proceedings. She routinely counsels clients facing Medicaid, Medicare, and other governmental investigations and audits as well as assists with employment and contract matters. She assists clients with compliance programs and has successfully represented health care entities with significant disclosures to the federal and state government. Margaret also defends clients facing license revocation and represents them in disciplinary matters before the Office of Professional Medical Conduct and the Office of Professional Discipline. She also has defended daycare centers in proceedings brought by the New York State Office of Children and Family Services.

Margaret has decades of experience practicing labor and employment law. She counsels and represents employers on employment compliance issues and defends employers before the NYS Division of Human Rights. Margaret has conducted several internal investigations relating to sexual harassment allegations, discrimination complaints, and diversity and equity initiatives. She trains governing boards with respect to not-for-profit law and governance issues.

Bar Associations

- Capital District Women's Bar Association, Former President
- New York State Bar Association, Commercial & Federal Litigation, Health Law, and Corporate Counsel Sections
- Women's Bar Association of the State of New York, Former Legislative Committee Co-Chair

Selected Memberships & Affiliations

- Barclay Damon's Women's Forum
- National Institute of Trial Advocacy
- National Society of Dental Practitioners, Board of Directors Member

Representative Experience

- Represented numerous health care providers in OMIG audits and achieved termination and other successful audit results.
- Represented and advised clients undergoing OMIG compliance-effectiveness reviews.
- Represented health care professionals before state regulatory agencies and federal agencies with respect to licensure and Medicaid participation.
- Represented health care professionals with substance-use disorders in disciplinary, certification, and insurance matters.
- Represented and defended a restaurant owner in a NYS Department of Labor audit.
- Successfully defended a physician in a revocation proceeding and subsequent appeal by the medical board.
- Served as counsel in a trial in which the NYS Department of Health (DOH) and the NYS Office for People With Development Disabilities (OPWDD) were found responsible for funding the reasonable actual costs of administrative overhead in providing services under Medicaid.
- Conducted a sexual harassment investigation involving claims against a CEO.
- Conducted internal investigations relating to discrimination and diversity and equity.
- Trained and advised board of directors in not-for-profit law duties and obligations.
- Handled an internal sexual harassment and hostile work environment investigation for a not-for-profit agency and provided training on sexual harassment prevention.
- Conducted an internal investigation of an agency's policies and procedures in handling discrimination allegations and diversity, equity, and inclusion issues at the behest of the

CEO. An investigation and review were conducted and a summary was given to the CEO recommending new policies and procedures to improve diversity, equity, and inclusion efforts.

Prior Experience

- Hiscock & Barclay, LLP, Counsel
- New York State Dental Association, General Counsel
- McNamee, Lochner, Titus & Williams, P.C., Senior Litigation Associate
- Corbin Silverman & Sanseverino, Litigation Associate
- Chadbourne & Parke, Litigation Associate

Selected Community Activities

- St. Joseph's Addiction Treatment & Recovery Centers, Board of Directors Member
- Hubbard Hall Center for the Arts and Education, Board Chair

Selected Speaking Engagements

- Cerebral Palsy Associations of New York State Annual Conference, "Ask the Lawyer: Compliance and Quality Assurance," Co-Presenter
- 45th Annual Association for Community Living Agencies in Mental Health (ACLAIMH) Conference, "Lawsuits, Audits, Investigation, and Other Legal Threats: Be Prepared for Your Next Legal Challenge," Co-Presenter
- Barclay Damon, "Will Your Company Survive a Department of Labor Audit?" Webinar
- Greater New York Dental Meeting, "Medicaid Fraud Forum," Moderator and Presenter
- Henry Spenadel Continuing Education Program, "Dental Jurisprudence and Ethics," Course Developer and Presenter
- Nurse Practitioner Association of New York State, "Steps to Starting and Maintaining a Successful NP Private Practice"

Selected Media

- *The Capitol Pressroom*, "Understanding New York's Medicaid Exclusion List"
- *Medical Economics*, "Physician Discipline in the New Age of Telehealth"
- *Medical Liability Monitor*, "Physicians With Multiple State Licenses Face Complex Disciplinary Risks"
- *NYSBA Health Law Journal*, "Nurse Practitioner Practice in New York State"
- *Bulletin for Ninth District Dental Society*, "A Guide to Avoiding OPD"
- *New York State Dental Journal*, "Prescription for Passing Inspection"; "New York Setting the Standard for Responsible Dentistry"
- *MGMA New York New York Beat*, "COVID-19 Workplace Updates: Vaccinations and Safety Rule"

Selected Alerts & Blog Posts

- New York State Board of Pharmacy to Require Individual Pharmacist Licensure for Shared Pharmacy Services
- OMH's New Self-Disclosure Notification Protocol: What Providers Need to Know
- OMIG's Abbreviated Self-Disclosure Process: What Providers Need to Know
- The No Surprises Act: What Does It Mean for Covered Providers?
- Stay Lifted on OSHA Vaccinate-or-Test Rule: DOL to Begin Enforcement in February 2022

Selected Podcasts

- *Barclay Damon Live: Labor & Employment Podcast*—"What's Up With COVID-19 Vaccination Mandates? Part 1: CMS and NY Vaccine Rules, With Maggie Surowka"



Michael Scott-Kristansen

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Education

- University at Buffalo School of Law, *Magna Cum Laude*; *Human Rights Law Journal*, JD
- State University of New York at Brockport, *Summa Cum Laude*, BS

Practices & Industries

- Health Care Controversies
- Health & Human Services Providers
- Pharmacy

Admitted to Practice

- New York
- Illinois

Court Admissions

- US District Court for the Western District of New York

Biography

Michael focuses his practice on representing health care and human services providers in a wide range of litigation and compliance matters.

He regularly advises clients on matters involving audits and investigations, reimbursement and billing, conditions of participation, regulatory compliance and enforcement, HIPAA compliance and breach investigations, insurance and payor disputes, licensing and professional discipline, and debt collection.

Michael prosecutes and defends lawsuits on behalf of health care and human services providers and administrative hearings involving the Centers for Medicare & Medicaid Services, the Department of Health, the Office of the Medicaid Inspector General, the Office of Professional Medical Conduct, the Office of Professional Discipline, and other administrative bodies concerning reimbursement, overpayments, compliance, conditions of participation, and licensing matters.

Bar Associations

- New York State Bar Association, Health Law Section, Long-Term Care Committee and Litigation Committee, Member

Representative Experience

- Led the defense of multiple year-long investigations by the Office of the New York State Attorney General into various nursing homes' responses to the COVID-19 pandemic.
- Successfully negotiated six-figure settlements with managed care plans on behalf of long-term care and adult care facilities for wrongfully denied claims and delayed payments.

- Obtained a 95 percent reduction in the recoupment and penalty for a medical billing service targeted by the Medicaid Fraud Control Unit for allegations of fraudulent billing.
- Successfully prosecuted administrative appeals in cases of first impression concerning Medicaid documentation requirements for long-term care providers, which served as the basis for overturning over two dozen OMIG final audit reports.

Prior Experience

- Pullano & Farrow PLLC, Associate
- Hurwitz & Fine, PC, Associate

Selected Community Activities

- Mary M. Gooley Hemophilia Center, Board of Directors, Chairperson

Selected Honors

- Selected to *Super Lawyers* Upstate New York Rising Stars: Health Care, 2017–2025
- Healthcare Business Academy, Fellow, 2017
- *New York Daily Record*, Up & Coming Attorneys, 2017

Selected Speaking Engagements

- 45th Annual Association for Community Living Agencies in Mental Health (ACLAIMH) Conference, "Lawsuits, Audits, Investigation, and Other Legal Threats: Be Prepared for Your Next Legal Challenge," Co-Presenter
- LeadingAge 2022 Annual Meeting, "Getting Paid: Best Practices to Avoid Non-Payment"
- Estate Planning Council of Rochester, "Medicare, Medicaid & Health Care Cost Considerations During Retirement"
- *Rochester Business Journal*, "Business Focus First 100 Days"

Selected Media

- *Buffalo Business First*, "Meet the New Partners at Buffalo's Top 5 Law Firms"
- News 10 NBC, "Good Question: Do HIPAA Rules Apply to Vaccine Passports?"
- Defense Research Institute, "Sexual Torts: Providing a Path Through the Fire"
- Harmonie Group, "Omnibus Rule Implication for Covered Entities"; "Omnibus Rule Implications for Law Firms as Business Associates"

Selected Alerts & Blog Posts

- Beyond the Denial: A Roadmap for Recovering Out-of-Network Infusion Claims
- CDPAP Providers Get First Look at the Future of CDPAP Without FIs
- The New York FY 2025 Budget – CDPAP FIs Under Threat
- The New York Fiscal Year 2025 Executive Budget Takes Aim at Long-Term Care
- New York State Nursing Facilities: Important Deadline Looming for Eligible Rate Appeals

Conducting Effective Internal Investigations

Guidance for Compliance and Legal Leaders

Purpose of an Internal Investigation

Internal investigations help health care organizations:

- Identify and stop potential misconduct
- Assess regulatory and legal exposure
- Protect patient safety and organizational integrity
- Demonstrate good-faith compliance efforts to regulators

Decision to Investigate/Common Triggers

- Issues involving potential legal exposure; fraud, waste, and abuse; intent; or senior leadership typically warrant a formal investigation. Routine errors, control gaps, or process issues are often better suited for a compliance review or audit.
- Look at materiality:
 - › *Universal Health Services Inc. v. U.S. et al. ex rel. Escobar et al.*, 579 U.S. 176, 136 S. Ct. 1989 (2016)
 - Not every regulatory or contractual violation rises to the level of fraud under the False Claims Act. The key question is whether the issue is material to the government’s decision to pay—making this a critical threshold in deciding whether to escalate to a formal investigation.
 - *Escobar* set a high bar:
 - The issue must be important to the government’s payment decision, not just a technical violation.
 - If the government regularly pays claims despite knowing about similar violations, that cuts against materiality.
 - If the government refuses payment when it knows of the violation, that supports materiality.
 - Also important:
 - The court did NOT create a bright-line rule.
 - › So, materiality is a fact-intensive, judgment call in every case.
- Common Triggers
 - › Whistleblower complaints (hotline, employee reports)
 - › Billing or coding irregularities
 - › Adverse patient events or quality concerns
 - › Government inquiries, subpoenas, or audits
 - › Conflicts of interest or physician relationship concerns

Governance and Independence

- **Assign appropriate leadership:** Compliance, legal, or external counsel depending on severity.
- **Preserve independence:** Avoid conflicts of interest; consider outside counsel for sensitive matters.
- **Define scope early:** What questions must be answered? Which departments, timeframes, and individuals are involved?
- **Decision on hiring outside counsel**

Legal and Regulatory Considerations

- **Attorney-client privilege:** Structure investigation to preserve privilege where appropriate.
 - › Recent Case Example: *People v. Nat'l Rifle Ass'n of Am., Inc.*, 2023, 223 A.D.3d 84, (App. Div. 1st Dept.)
 - **Facts**
 - The National Rifle Association of America retained outside counsel to conduct an internal investigation into alleged financial misconduct.
 - Counsel prepared an internal report summarizing findings and recommendations.
 - After completion, the report was shared with the organization’s outside auditor.
 - The auditor used the report in connection with its independent financial audit.
 - The report was not created specifically for litigation, and disclosure occurred after the investigation was completed.
 - **Holding**
 - The court held that the attorney-client privilege was waived by disclosure of the report to an outside auditor.
 - Disclosure was not necessary to facilitate legal advice but instead served a separate business purpose.
 - The presence of a third party (auditor) defeated privilege because it was not essential to the legal communication.
- **Mandatory reporting:** Understand obligations (e.g., overpayments, patient safety events).
- **Regulatory frameworks:** Consider implications under fraud and abuse laws, privacy regulations, and payor rules.
- **Documentation:** Maintain clear, factual, and defensible records.

Data Collection and Preservation

- Promptly issue a **document hold** (emails, EHR data, billing records).
 - › Issue timely holds, review metadata or audit logs, and understand how data is stored or overwritten in EHR systems.
 - › Do not rely on screenshots or extracts instead of preserving native data.
 - › Recent Example: *VOOM HD Holdings LLC v. EchoStar Satellite L.L.C.*, 2012 93 A.D.3d 33, (App. Div. 1st Dept.)
 - Background:
 - The defendant knew a lawsuit was likely (they were threatening to terminate a contract).
 - BUT they kept automatically deleting emails every seven days.
 - They didn't properly stop this deletion, even after the lawsuit started.
 - They also relied on employees to decide what to save (instead of a real legal hold).
 - Holding/Takeaway:
 - Spoliation sanctions were awarded against the defendant.
 - Once litigation is reasonably anticipated, a party must suspend routine deletion and implement a proper litigation hold.
 - Failure to do so constitutes spoliation of evidence.
- Identify relevant systems (EHR, billing platforms, HR files).
- Ensure data integrity and chain of custody.
- Be mindful of patient privacy and minimum necessary standards.

Interviews

- Develop an interview plan and sequence.
- Use trained interviewers (legal/compliance preferred).
- Provide **Upjohn warnings** (clarify representation of the organization, not the individual).
 - › See *Upjohn Co. v. United States*, 449 U.S. 383 (1981)
 - The US Supreme Court held that communications between company employees and corporate counsel can be protected by attorney-client privilege when made for the purpose of obtaining legal advice.
 - › Example Upjohn warning: “I am conducting an internal investigation for the company. I represent the company, not you personally. This interview is confidential, but that privilege belongs to the company, not you. The company can decide to

disclose our conversation to third parties, including the government, without your consent. Do you understand and are you willing to proceed?”

- Document interviews consistently and objectively.

Patient Safety and Clinical Impact

- Prioritize immediate risks to patients.
- Coordinate with clinical leadership when care delivery is involved.
- Implement interim safeguards if needed.

Findings and Root Cause Analysis

- Distinguish between isolated errors and systemic issues.
- Evaluate contributing factors: training gaps, process failures, cultural issues.
- Quantify financial impact where applicable (e.g., overpayments).

Remediation and Corrective Action

- Update policies and procedures.
- Conduct education and training.
- Carry out disciplinary action where appropriate.
- Correct billing errors and issue refunds if required.
- Strengthen monitoring and auditing controls.

Reporting and Disclosure

- Determine whether **self-disclosure** is appropriate.
- Prepare clear, concise investigation reports for leadership/board.
- Coordinate communications (internal and external) carefully.
- OIG Self-Disclosure Protocol (<https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf>)
 - › Benefits of Self-Disclosure:
 - **Reduced penalties:** Typically lower multipliers (often ~1.5x damages) compared to government-initiated enforcement.
 - **Avoidance of exclusion:** Presumption against Corporate Integrity Agreements and exclusion when disclosure is made in good faith.
 - **Tolling of 60-day repayment rule:** Suspension of repayment obligation while the disclosure is under review.
 - **Cooperation credit:** Signals an effective compliance program and can improve credibility with regulators.
 - **More efficient resolution:** Streamlined process with OIG coordination, often faster than contested investigations.

› Key Requirements/Realities:

- Must conduct and complete an internal investigation (typically within ~90 days of submission).
- Must quantify damages (often using statistically valid sampling) and identify affected federal programs.
- Must implement corrective action before or at disclosure—not after.
- Minimum settlement expectations apply (including baseline dollar thresholds and multipliers).
- Requires full cooperation—failure to cooperate can result in removal from the SDP.

› When SDP is (and isn't) appropriate:

- Appropriate for potential fraud, kickbacks, or conduct creating CMP/FCA exposure.
- Not appropriate for pure overpayments or errors—those should go through standard refund processes.

• OMIG Self-Disclosure

- › 42 U.S.C. § 1320a-7k(d): Requires reporting and returning overpayments within 60 days of identification.
- › N.Y. Soc. Serv. Law § 363-d(6): Mandates reporting, returning, and explaining Medicaid overpayments within 60 days.
- › 18 NYCRR Part 521: Establishes New York's self-disclosure program requirements.
- › ACA § 6402: Federal statutory basis for the 60-day rule.

› **Process and Requirements:**

- Submit either a Full Self-Disclosure (for systemic, significant, or potential fraud issues) or an Abbreviated Disclosure (for routine errors).
- Provide:
 - Overpayment amount
 - Root cause analysis
 - Applicable law/regulation violated
 - Affected claims/data
 - Corrective action plan
- OMIG reviews, verifies, and issues a determination; repayment is required (generally within 15 days of notice unless otherwise arranged).

Follow-Up and Monitoring

- Track implementation of corrective actions.
- Conduct post-investigation audits.
- Reinforce a culture of compliance and speak-up environment.

Practical Tips

- Move quickly, but don't rush to conclusions.
- Keep a tight "need-to-know" circle.
- Separate fact-finding from decision-making where possible.
- Anticipate how findings would appear to regulators or in litigation.

KEY CONTACTS



Pei Pei Cheng de Castro | Partner
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Rick Hartunian | Partner
rhartunian@barclaydamon.com

Conducting Effective Internal Investigations Panel Bios



Eric Miller, Senior Vice President, General Counsel | UVM Health

Eric Miller serves as a member of the senior leadership team while overseeing the system's legal, compliance, privacy, and risk management functions. He joined UVM Health in May 2017 as Deputy General Counsel and Senior Advisor and began his current role in October 2018. Prior to joining UVM Health, Miller served as President Barack Obama's United States Attorney for Vermont and as a private practice lawyer representing health care providers.



Pei Pei Cheng de Castro

Partner

New York

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Education

- New York Law School, JD
- University of California at Berkeley, BA

Practices & Industries

- Commercial Litigation & Complex Trials
- White Collar & Government Investigations
- Regulatory
- Lobbying & Election Law Compliance
- Labor & Employment
- Higher Education
- Pharmacy

Admitted to Practice

- New York

Court Admissions

- US Supreme Court
- US District Court for the Eastern District of New York
- US District Court for the Southern District of New York

Biography

Pei Pei has more than 20 years of experience in private practice and at the highest level of New York State government. She has represented clients across a range of industries in complex commercial litigation, and she has assisted clients with complex regulatory and compliance issues, government and internal investigations, criminal defense in federal and state courts, and ethics and lobbying matters. Pei Pei is uniquely qualified, given her experience both in and out of government, to advise business and individual clients with respect to government procurement, ethics, lobbying, regulatory issues, and congressional inquiries. Her experience is also invaluable when providing representation with respect to governmental inquiries and interactions in New York City, New York State, and at the federal level.

In her role as deputy counsel to the governor of New York, Pei Pei managed high-profile disputes and controversies for all executive agencies, handled special projects for the governor, oversaw executive state litigation, and was liaison to the Office of the Attorney General and to the State Comptroller. She further had responsibility for matters involving ethics, risk management, compliance, and procurement across New York State's executive agencies. While in her role as deputy counsel to the governor, Pei Pei also served as counsel to the Executive Chamber, which works to advance the governor's policy initiatives and agenda by overseeing government operations and coordinating with state agencies, federal and local governments, and community stakeholders.

In Pei Pei's prior role as executive deputy inspector general at the Metropolitan Transportation Authority, she oversaw investigations into capital projects and services contracts with the MTA. She also spent five years as the director of investigations at the New York State Joint Commission on Public Ethics, where she conducted investigations focused on potential lobbying and ethics laws violations.

Pei Pei served as a part-time adjunct professor of law at Fordham Law School and New York Law School.

Bar Associations

- Asian American Bar Association of New York, Former Vice President of Programs and Operations

Selected Memberships & Affiliations

- New York State Interest on Lawyer Account Fund, Chair and Trustee

Prior Experience

- New York State Office of the Governor, Executive Chamber, Deputy Counsel to the Governor
- Office of the Metropolitan Transportation Authority Inspector General, Executive Deputy Inspector General Legal
- New York State Joint Commission on Public Ethics, Deputy General Counsel and Director of Investigations
- Peluso & Touger, LLP, Partner

Selected Community Activities

- Museum of Chinese in America, Advisory Board Member
- Center for New York State and City Law, Senior Fellow
- Friends of Central Queens Academy, Inc., Board of Trustees, Chairperson
- Tricarico Institute for Business Law and In-House Counsel, Board Member
- Central Queens Academy Charter School, Former Founding Board of Trustees Member and Former Board of Trustees Chairperson
- New York Law School Charter School for Law & Justice, Former Project Advisory Member
- Fordham Law School, Former Adjunct Professor
- New York Law School, Former Adjunct Professor

Selected Honors

- *Crain's New York Business*, Notable Women in Law, 2026
- *New York Law Journal*, Rising Star, 2016
- Selected to *Super Lawyers* New York Metro: General Litigation, 2013

Selected Media

- *New York Law Journal*, "Sorting Out the Law on Homicide Prosecutions Against Corporations"; "Barclay Damon's Newest Partner Served 2 Years as NY Gov's Deputy Counsel"; "FCPA: How Much Have Things Really Changed?"
- *Bloomberg Law*, "Counsel Have Toolbox to Fight Geofence Warrants as Split Widens"
- Law360, "The Growing Role of Wearable Health Tech in Criminal Probes"
- CityLand, "Must Defendants Unlock Their Cellphones? What the Law Says," "New York May Finally Have an Ethics Commission That's Here for Good and to Do Good"
- Law360 Pulse, "Former Deputy Counsel to NY Governor Joins Barclay Damon"
- New York State Joint Commission on Public Ethics, *Ethics & Lobbying in New York State: A Comprehensive Guide*, 2019 and 2017 Editions, Managing Editor and Contributing Writer

Selected Alerts & Blog Posts

- College Sports Commission Issues Notice Regarding Violations Arising From Third-Party NIL Deals



Rick Hartunian

Partner

Albany, New York

P: 518.429.4243

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Education

- Albany Law School, JD
- Georgetown University, BA, *Cum Laude*

Practices & Industries

- White Collar & Government Investigations
- Commercial Litigation & Complex Trials
- Canada-US Cross-Border
- Higher Education

Admitted to Practice

- New York

Court Admissions

- US District Court for the Eastern District of New York
- US District Court for the Northern District of New York
- US District Court for the Southern District of New York
- US District Court for the Western District of New York
- US District Court for the Southern District of Texas

Biography

A veteran of the Department of Justice, Rick has two decades of experience as lead government counsel in high-profile, high-stakes criminal and civil disputes. He defends clients against allegations of white-collar crime, health care fraud, BSA/AML violations, and environmental and defense procurement fraud and advises on cross-border security and trade issues. Rick also helps clients manage crises that result from litigation and government enforcement efforts, particularly when investigations involve multiple agencies and jurisdictions.

During his tenure as United States Attorney for the Northern District of New York, Rick served in national leadership positions as a member, vice chair, and chair of the Attorney General's Advisory Committee of US Attorneys, providing advice and guidance to the department's leaders on the full range of criminal and civil issues affecting DOJ and United States Attorneys' Offices nationally. Within the Northern District of New York, Rick headed several key initiatives and prosecutions and strengthened his office's Civil Division by emphasizing affirmative civil enforcement to combat health care, procurement, and environmental fraud. Rick also worked closely with the FBI and US Department of Homeland Security on initiatives to tackle illegal immigration and cybercrime, including trade secret and customer data theft.

Prior to his appointment as US Attorney, Rick served as an Assistant United States Attorney (AUSA), where he investigated and prosecuted immigration, narcotics, and violent crime offenses as well as white collar cases, including tax and bankruptcy fraud matters. He also served as narcotics chief and coordinator of the Organized Crime Drug Enforcement Task Force. As an AUSA, he gained vast experience working with all federal investigative agencies and their task forces, in addition to many state and local law enforcement agencies. Rick was recognized with several awards and case-related commendations for the numerous cases he prosecuted.

Rick has substantial knowledge of and good working relationships with US and Canadian border security agencies, enabling him to assist US and Canadian businesses that have pressing border-related concerns. Rick also has experience with Native American tribal affairs and gaming matters.

In addition, Rick represents higher education institutions in sensitive internal matters and high-stakes litigation.

Frequently interviewed by the legal press, Rick is also regularly invited to address both public and private organizations and bar associations.

Bar Associations

- NDNY Federal Court Bar Association
- New York State Bar Association
- Albany County Bar Association
- Armenian Bar Association

Selected Memberships & Affiliations

- National Association of Former United States Attorneys, Board of Directors
- Federal Bar Council

Representative Experience

- Secured a win for ICON Foundation, a not-for-profit organization that founded and supports the ICON Network, a decentralized system on which the cryptocurrency “ICX” is transacted. US District Judge William Orrick awarded ICON \$3.5 million in attorney’s fees and costs it incurred in litigation with ICON user Mark Shin relating to approximately 14 million ICX tokens he received after exploiting a bug in the network software.
- Represented a leading global supplier of vision safety solutions to the bus and truck marketplace in the favorable settlement of its patent infringement lawsuit against its supplier. The action involved the client’s patents covering its multiple camera systems and rearview mirror monitor technology.
- Represented a federally recognized tribal nation in establishing its cannabis regulatory system.
- Represented employees of private, publicly traded, and foreign corporations in connection with investigations conducted by the DOJ, SEC, and other federal agencies.
- Assisted in securing presidential clemency for an incarcerated client who received a 30-year sentence for a first-time, non-violent drug offense.

- Assisted in successfully representing a Marine veteran in his request to upgrade his service discharge from Under Other Than Honorable Conditions in a hearing before the Naval Discharge Review Board. After a formal hearing before the NDRB, the board granted the requested relief—upgrading his discharge from Under Other Than Honorable Conditions to Under Honorable Conditions (General). This change in discharge status entitled the client to a whole series of VA benefits that he was not previously entitled to and removed a significant blemish from his record.

Prior Experience

- Manatt, Phelps & Phillips, LLP, Partner
- US District Court for the Northern District of New York, United States Attorney
- US District Court for the Northern District of New York, Assistant United States Attorney
- Albany County District Attorney, Assistant District Attorney

Selected Honors

- Albany Law School, Alumni in Government Award, 2017
- Armenian Bar Association, Public Service Recognition Award, 2017
- Numerous Organized Crime Drug Enforcement Task Force awards and case-related commendations for significant investigations and prosecutions as an assistant United States Attorney, 1999–2008

Selected Speaking Engagements

- HCCA New York Regional Healthcare Compliance Conference, "Navigating Healthcare Fraud Investigations: Current Trends, Developments and Solutions"

Selected Media

- *Anti-Corruption Report*, "Zaglin Conviction Offers Insights on Individual Prosecutions in Trump 2.0"; Balt Settlement: New DOJ Policies in Action"
- *New York Law Journal*, "FCPA: How Much Have Things Really Changed?"
- Law.com, "How Prepared Are You for Trump 2.0's Worksite Enforcement Regime?"
- *California Litigation*, "Attorney Proffers Post-Menendez: How to Make the Risk Worth the Reward"

Medicaid and Medicare Enforcement Panel Key Takeaways

KEY CONTACT

Erin Ives, First Deputy | NYS Office of the Medicaid Inspector General

Self-Disclosure: Medicaid Entities/Providers who received and identified Medicaid overpayments are required to report, return and explain those overpayments via OMIG's Self-Disclosure process.

Effective Compliance Program: NYS Social Services Law (SOS) § 363-d and Title 18 of the New York Codes, Rules and Regulations (18 NYCRR) SubPart 521-1 defines the factors that require providers to have a compliance program. Compliance | Office of the Medicaid Inspector General

Reporting: Providers and the public should report suspected Medicaid fraud, waste and abuse by calling OMIG's Fraud Hotline at 1-877-87 FRAUD (1-877-873-7283) or file a claim electronically.

Audit Protocols: OMIG has developed a series of audit protocols to assist the Medicaid provider community in developing programs to evaluate compliance with Medicaid requirements under federal and state statutory and regulatory law. The protocols are applied to a specific fee-for-service provider or category of service in the course of an audit and involve OMIG's application of articulated Medicaid agency policy and the exercise of agency discretion. These audit protocols are intended to serve solely as guidance and do not alter any statutory or regulatory requirement. Audit Protocols | Office of the Medicaid Inspector General

KEY CONTACT

Kate Teliska, Special Agent | Department of Health & Human Services Office of Inspector General

Report suspected fraud, waste, or abuse directly to HHS-OIG.

Use the OIG fraud hotline at 1-800-HHS-TIPS (1-800-447-8477) or submit a report online at <https://oig.hhs.gov/fraud/report-fraud/>. Tips can be submitted anonymously and are a critical source of investigative leads.

HHS-OIG Self-Disclosure Protocol (SDP) for potential fraud.

Providers and entities may voluntarily disclose conduct that potentially violates federal health care program requirements. The SDP is designed to facilitate resolution of matters involving potential civil monetary penalties and often results in reduced penalties compared to exclusion or litigation.

CMS Self-Referral Disclosure Protocol (SRDP) for Stark Law issues.

The SRDP is the appropriate mechanism to disclose actual or potential violations of the physician self-referral law. It is administered by CMS and allows providers to resolve Stark Law liability arising from prohibited financial relationships.

Other compliance and resolution pathways remain available.

Depending on the issue, overpayments may be returned through contractor processes, compliance programs may resolve systemic issues internally, and in certain cases whistleblowers may bring actions under the False Claims Act through the Department of Justice. Each mechanism serves a distinct role in mitigating risk and ensuring program integrity.

KEY CONTACT

Amy Held, Deputy Attorney General and Director | NYS Medicaid Fraud Control Unit

Medicaid provider fraud is not a victimless crime. Medicaid provider fraud harms patients, the many honest providers who comply with the law, the Medicaid program, and the public's trust.

Medicaid provider fraud results not only in financial loss to New York State's Medicaid program, but also often results in harm, risk of injury and humiliation or vulnerable patients, and/or exploitation of vulnerable Medicaid beneficiaries.

Patient injury, risk of harm, and humiliation can result from providers and others engaging in fraud schemes that result in many ways, including:

- Patients suffering from not receiving care and services they need;
- Patients being subjected to unnecessary and invasive medical tests;
- Patients being exploited by being induced to forego needed medical and/or substance abuse treatment through payment of kickbacks to enable providers to bill Medicaid for services not provided;
- Patients receiving poor quality and/or worthless care from provider employees who are unlicensed, unqualified, untrained, unsupervised, acting beyond the scope of license, and/or over-assigned to more care duties than can be performed in a given shift;
- Patients deprived of current and future quality of care, which is dependent on accurate treatment information in medical records, which is denied by false records of inaccurate treatment and diagnoses; and/or
- Patients not being able to obtain needed care or services because their fraudulent medical records falsely reflect their receipt of care or services not provided.

Medicaid provider fraud can result in serious criminal, civil, and/or administrative liability and exclusion for the provider and, individually, for owners and high managerial agents of the provider.

Providers claiming they are "too important to fail" fail to account for fact that officers and boards can be replaced without the Institution being put out of operation.

Providers claiming "Medicaid does not pay enough" does not excuse fraud, waste, and abuse—those are unrelated concepts.

A provider having an effective compliance program that is supported by owners and management can prevent Medicaid fraud and patient harm and exploitation.

Medicaid and Medicare Enforcement Panel Bios



Erin Ives, First Deputy | NYS Office of the Medicaid Inspector General

Erin Ives joined OMIG in January of 2007 and was instrumental in the development of the agency's internal control program and instituting agency reporting standards and processes, including the creation of a Reporting Standards Workgroup and Cost Savings Workgroup. She also served as the state liaison to the Centers for Medicare and Medicaid Services for the purposes of the Medicaid Program Integrity Reviews conducted of New York State. At OMIG, she guides the agency's program integrity initiatives in the Medicaid program. She served as the Director of the Bureau of Quality Control and Enterprise Projects, overseeing and directing the agency's enterprise and information technology portfolios, producing the agency's Annual Report and supervising OMIG's first Project Management Office. Prior to this position with OMIG, Ms. Ives served as the Director of Racing Programs as part of the Office of the Secretary to the Governor within the New York State Executive Chamber. In this capacity, she created and implemented policy initiatives for various state agencies including the New York State Racing and Wagering Board, New York State Division of the Lottery, the Non-Profit Racing Association Oversight Board, and the Ad Hoc Committee on the Future of Racing. Additionally, she developed regulations for video lottery gaming with emphasis on distribution of authorized marketing allowance, drafted and approved press releases and media statements for various state agencies, and researched and generated briefing material on racing and gaming industry issues for the Governor and Executive Staff. Ms. Ives is a graduate of Siena College, with a Bachelor's Degree in Marketing and Management.



Kate Teliska, Special Agent | Department of Health & Human Services Office of Inspector General

Special Agent Kate Teliska began her federal government career in 2006 as a Special Agent with the United States Secret Service where she was assigned to the elite Electronic Crimes Task Force. In 2010, she joined the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG) and has served as the lead case agent on numerous healthcare fraud matters related to Health Care Fraud and Abuse Control (HCFAC) Program. She has led several long-term criminal and civil investigations into violations of state and federal law related to false claims, kickbacks, bribery, medical identity theft, and facility misconduct. Special Agent Teliska has also led investigations into federal employee misconduct and drug diversion. Special Agent Teliska's investigations have identified systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and her work has resulted in recommendations to prevent their recurrence. She has served on the Medicare Strike Force in the District of New Jersey and is a member of the Northern District of New York's Health Care Task Force.

Special Agent Teliska was the lead case agent on the \$7.1 million settlement and closing of the Saratoga Center for Rehabilitation and Skilled Nursing Care and the \$21.3 million settlement of The Grand Health Care System involving false claims against the government. Special Agent Teliska was the lead case agent in the federal criminal case against Dr. Alexander Baldonado, who was recently sentenced to seven years in prison for causing the submission of over \$24 million in fraudulent claims to Medicare for medically unnecessary laboratory tests and orthotic braces.

Special Agent Teliska is a graduate of the United States Military Academy at West Point and served 8 years as an officer in the United States Army. She has a master's degree in Education Leadership from NOVA Southeastern University and a master's degree in Health Care Administration from Champlain College.



Amy Held, Deputy Attorney General and Director | NYS Medicaid Fraud Control Unit

Amy Held is the Deputy Attorney General and Director of the Medicaid Fraud Control Unit, serving in this role since 2013. Previously, she served as MFCU's Chief of Civil Enforcement, and she investigated, negotiated and litigated False Claims Act cases as a MFCU AAG. Before that, she worked as an AAG in the Litigation Bureau of the State Counsel Division, representing NYS healthcare agencies and other state entities in complex litigation in federal and state court. Before joining the Attorney General's Office, Amy was in private practice at Proskauer Rose and Cooley LLP in New York City, and the law firm of McCarter & English in New Jersey, where she litigated complex cases in federal and state court and in arbitrations. She received her B.A. from Swarthmore College, and her J.D. with honors from Rutgers Law School, where she was a member of the Law Review.



Bob Hussar

He | Him | His
Of Counsel

Albany

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Education

- Western New England College School of Law, JD
- Union College, MS
- Union College, BA

Practices & Industries

- Health & Human Services Providers
- Health Care Controversies
- Health Care

Admitted to Practice

- New York

Biography

The former first deputy for the NYS Office of the Medicaid Inspector General, Bob has over 25 years of experience providing public and private clients with strategic advice and guidance on Medicare, Medicaid, and other payor regulatory, compliance, licensure, and reimbursement issues.

Bob is widely recognized for his extensive experience counseling providers, payors, boards of directors, and other health care industry stakeholders with regard to the development, assessment, and implementation of compliance programs; the performance of compliance due diligence and effectiveness reviews; the provision of interim compliance services; internal investigations; and the full range of regulatory matters, including self-disclosures, audit defense, settlement negotiations, and Justice Center matters. Bob is certified in health care compliance through, and is a past board member of, the Health Care Compliance Association.

In addition to his practice, Bob is the founder and managing partner of Healthcare Compliance Connections, a boutique executive search firm that assists providers in identifying and recruiting qualified health care compliance professionals.

Bar Associations

- New York State Bar Association Health Law Section, Former Chair
- New York State Bar Association Reimbursement, Enforcement and Compliance Committee, Former Chair

Selected Memberships & Affiliations

- Health Lawyers Association
- Health Care Compliance Association, Former Board Member
- Health Care Compliance Association, Chair, New York Regional Annual Meeting
- NYS Department of Health Value-Based Payment Program Integrity Work Group, Co-Chair

Representative Experience

- Defended various types of providers against Medicaid, Medicare, and commercial-plan billing audits.
- Advised providers and negotiated terms of Medicaid and Medicare self-disclosures and repayment agreements.
- Conducts compliance-effectiveness reviews for hospitals, managed-care plans, home-care providers, transportation companies, and health care and human services organizations.
- Served as interim chief compliance and privacy officer for a variety of health care organizations, ranging from a large academic medical center to a small health care and human services organization.
- Represented numerous employees and provider agencies related to OPWDD and NYS Justice Center investigations and appeals.
- Represented OPWDD providers at administrative hearings related to patient-discharge issues.
- Represented physicians and pharmacists before Office of Professional Medical Conduct (OPMC) and NYS State Education Department (SED) investigations.
- Represented multiple providers related to OMIG compliance-effectiveness reviews.
- Provided training to association members on conducting effective abuse and neglect investigations.
- Drafted legislation to limit and clarify the authority of the NYS Justice Center.
- Advised a specialty lab related to OIG Corporate Integrity Agreement (CIA) readiness.
- Guided a home-care agency through a HIPAA privacy-breach disclosure related to an incident involving more than 500 individuals.
- Counsels DSRIP Performing Provider Systems (PPS), ACOs, and FIDA plans on program-integrity obligations and strategies.
- Serves as a facilitator for a hospital association's compliance work group.

Prior Experience

- Rivkin Radler LLP, Partner
- Barclay Damon LLP, Partner
- Manatt, Phelps & Phelps, LLP, Counsel
- Deloitte, Senior Manager
- NYS Office of the Medicaid Inspector General, First Deputy
- Northeast Health, Compliance Officer
- NYS Governor's Office of Regulatory Reform, Assistant Counsel

Selected Community Activities

- Bethlehem Youth Hockey, Volunteer Coach
- Bethlehem Youth Soccer, Volunteer Coach
- Tri-Village Little League, Volunteer Coach
- First United Methodist Church and RPM Youth Group, Sunday School Teacher and Youth Service Trip Chaperone

Selected Honors

- *The Best Lawyers in America*®: Health Care Law, 2026

Selected Media

- *The Capitol Pressroom*, "Understanding New York's Medicaid Exclusion List"
- *Report on Medicare Compliance*, "New NYS Compliance-Program Requirements May Be Useful Everywhere as a 'Fresh Look'"
- *Health Law Daily Wrap Up*, "Strategic Perspectives: Pandemic Response, Fraud, and Abuse Top Biden's Enforcement Priorities"
- *CCH Health Care Compliance Professional's Manual*, Co-Author

Selected Alerts & Blog Posts

- Attention Providers! OMIG Audit Update: New Settlement Flexibility at Lower Confidence Payment Restored and DME Protocol Released
- DOH Sepsis Reminder Opens Doors for Provider Recoveries
- Justice Center Prosecutorial Authority Restricted
- Compliance Program Effectiveness: What To Measure and How To Measure It?

- Justice Center Lacks Jurisdiction to Assert "Concurrent" Finding of Neglect by Provider



Melissa Zambri

She | Her | Hers

Partner

Albany

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Education

- Albany Law School, *Cum Laude*; *Albany Law Journal of Science & Technology*, Executive Editor, JD
- Union College, MBA
- Siena College, *Summa Cum Laude*, BS

Practices & Industries

- Health & Human Services Providers
- Higher Education
- Health Care

Admitted to Practice

- New York

Biography

Melissa serves as co-leader of Barclay Damon's Health Care Practice Group and is co-team leader of the Health Care and Health & Human Services Providers Teams.

In her practice, Melissa focuses on enterprise development and regulatory guidance for the health care industry. She provides counsel to individual practitioners, owners, administrators, executives, and employees of health care practices and health care-related facilities, including physicians, licensed medical personnel, providers of services to the developmentally disabled, hospitals, clinics, home-health agencies, senior residences and assisted-living facilities, laboratories, health care trade associations, durable-medical-equipment providers, alcohol- and substance-use-disorder treatment facilities, physician practice-management companies, mental-health programs, and medical-transportation companies.

Melissa assists health care clients with certificate-of-need applications, compliance programs, audits, investigations and self-disclosures, HIPAA compliance, and licensure issues. She also helps clients obtain approvals to operate health care facilities and to complete significant transactions. She counsels providers on federal anti-kickback and self-referral requirements, regulations governing federal- and state-funded health care programs, including Medicare and Medicaid, and other regulatory requirements applicable to health care providers.

In addition to her practice, Melissa is an adjunct professor for Albany Law School's Online Graduate Programs, where she teaches Health Care Compliance and HIPAA Compliance. She is also an adjunct professor at Clarkson University, where she teaches Legal Aspects of Health Care.

Melissa is a member of Barclay Damon's Management Committee and managing director of the Albany office.

Bar Associations

- American Bar Association, Health Law Section
- New York State Bar Association, Health Law Section, Former Chair, and Committee on Fraud, Abuse, and Compliance

Selected Memberships & Affiliations

- Barclay Damon's Women's Forum
- American Health Lawyers Association

Representative Experience

- Provided regulatory guidance to a NYS performing provider system.
- Assisted in the purchase of an OASAS-licensed facility, which included negotiation, licensing work, and due diligence regulatory review.
- Prepared a comprehensive HIPAA-compliance manual for clients serving the developmentally disabled.
- Served as general counsel to a 200-bed community hospital, which involved coordinating all of the hospital's legal work and counseling its administration and board during the hospital's acquisition by a larger hospital system.
- Served as general counsel to a New York-based not-for-profit assisted-living provider, which involved licensing all four of its client residences and helping obtain ALR, enhanced, and special-needs licensure and certification. Melissa also drafted a winning HEAL grant application, which resulted in the client receiving \$3.8 million from the NYS Department of Health to build a new assisted-living facility with enhanced capabilities.
- Assisted in the combination of a not-for-profit Article 28 diagnostic and treatment center and a hospital system.
- Served as health care regulatory counsel to a not-for-profit provider serving the developmentally disabled. In this role, she provided advice on compliance issues, gave board training on compliance, and provided counsel regarding a \$3 million audit by the Office of the Medicaid Inspector General.
- Serves as health care compliance counsel to a significant provider serving the developmentally disabled. In this role, she performs monthly audits of programs and provides compliance training to staff, board members, and management as well as assistance on all health care compliance matters.
- Drafted an assisted-living program (ALP) application for which the client was given conditional approval to construct a new assisted-living residence with ALP and special-needs beds.

- Provides clients with compliance advice and annual board and management training on a regular basis.
- Successfully defended HIPAA complaints to the US Department of Health and Human Services Office of Civil Rights.
- Represented a provider challenging a certificate-of-need application of a competitor hospital.
- Assisted with inspection and licensing issues with the NYS Office for Persons With Developmental Disabilities.
- Assisted numerous providers with self-disclosure to the NYS Office of the Medicaid Inspector General.
- Provided counsel to a large pharmacy chain regarding a pharmacy audit by the NYS Medicaid Inspector General.
- Assisted clients in the purchase of a pediatric medical practice.

Prior Experience

- Hiscock & Barclay, LLP, Partner

Selected Community Activities

- Albany Law School, National Alumni Association, Board Member
- Proctors Theatre, Board of Directors, Chair
- Clifton Park Soccer, Former Travel Coach, Board Member, and Secretary
- Miss Shen Softball, Former Board of Directors Member and Former Coach

Selected Honors

- *The Best Lawyers in America*®: Albany "Lawyer of the Year": Health Care Law, 2026
- *The Best Lawyers in America*®: Health Care Law, 2013–2026
- State of New York Supreme Court, Appellate Division, Third Judicial Department, Mark R. Sonders Award, 2025
- *Albany Business Review*, Power 50 Duos List, 2025
- Albany Law School, Distinguished Teaching Award, 2023

Selected Speaking Engagements

- Barclay Damon LLP, New York Health Care Compliance Symposium, "Hot Topics in Privacy," Co-Presenter
- Cerebral Palsy Associations of New York State and The Arc New York, Compliance & Quality Connections Conference, "A Year of Change: On the Compliance Carousel," Panelist
- Cerebral Palsy Associations of New York State Annual Conference, "Ask the Lawyer: Compliance and Quality Assurance," Co-Presenter
- Cerebral Palsy Associations of New York State, Human Resources Professionals Conference, "Navigating Complaints and Investigations for Human Resources Staff," Co-Presenter
- Association for Community Living, Inc. Management Symposium, "OMIG's Amended Compliance Program Regulation: What Providers Need to Know," Co-Presenter; "HIPAA Privacy Rule Changes: A Preview of What's Expected," Presenter

Selected Media

- *New York Law Journal*, "Attorney Retires as Lawmaker, but Is Remaining Plugged in at Barclay Damon"
- *Albany Business Review*, "The Business of Law Is Changing"
- *New York State Bar Association Health Law Journal*, "New York State Fraud, Abuse and Compliance Developments"
- Thomson Reuters/Aspatore's *Inside the Minds: Health Care Law Enforcement and Compliance*, "Blowing the Whistle on Yourself: Requirements to Disclose Mistakes Made Continue to Increase," Chapter Author

Selected Alerts & Blog Posts

- Attention Providers! OMIG Adopts 12-Month Review Period for Newly Initiated Compliance Program Reviews Beginning July 1, 2025
- OMH's New Self-Disclosure Notification Protocol: What Providers Need to Know
- NYS Submits 1115 Waiver Amendment (Health Equity Reform) to CMS
- The No Surprises Act: What Does It Mean for Covered Providers?
- NYS DOH Hosts Webinar on the Availability of Funds for Residential Health Care and Other Providers

Health & Human Services Providers

Our Clients

Our attorneys have extensive experience handling corporate, regulatory, and compliance issues for a wide spectrum of health and human services providers. Our wide-ranging list of clients includes:

- Adult daycare providers
- Ambulatory surgery centers
- Assisted living residences (ALRs)
- Behavioral health providers
- Behavioral health care collaboratives (BHCCs)
- Care coordination organizations (CCOs)
- Clinical laboratories
- Continuing care retirement communities (CCRCs)
- Developmental disability providers
- Health homes
- Health information exchanges (HIEs)
- Home care agencies
- Hospice
- Hospitals and health systems
- Independent practice associations (IPAs)
- Medical transportation companies
- Mental health providers
- Performing provider systems (PPSs)
- Pharmacies
- Physicians, dentists and group practices
- Senior independent living facilities
- Skilled nursing facilities (SNFs)
- Substance use disorder (SUD) providers

Our Services

We deliver value to our health care and human service clients by providing counsel in the following service areas:

- Acquisitions, sales, mergers, affiliations, and joint ventures
- Board, management, and staff trainings
- Certificate of need (CON) applications
- Corporate compliance, internal investigations, and self-disclosures
- Corporate formation and reorganization
- Corporate governance
- Contract review and negotiation, including software and third-party vendor contracts
- Cybersecurity and data privacy
- Data breach response and reporting

- Employment and independent contractor agreements and medical staff issues
- EMTALA and anti-dumping provisions
- Financing and restructuring
- Fraud and abuse issues, including Stark, Anti-Kickback, Civil Monetary Penalties, Fee-Splitting
- Government surveys and enforcement
- Group practice establishment and disputes
- HIPAA and health information privacy
- Independent practice association formation and operation
- Justice Center matters and incident reporting
- Managed care contracting and value-based payment
- Medicare and Medicaid certification and compliance
- Governmental and private payor audits and investigations (OMIG, MFCU, OSC, OPWDD, SED, OIG, HHS-OCR, Attorney General)
- Payor contract review, negotiation, non-renewal, and termination
- Professional licensure and discipline before the Office of Professional Medical Conduct (OPMC) and Office of Professional Discipline (OPD)
- Reimbursement issues and rate challenges
- Risk management, patient care, and familial disputes
- Subpoena responses and production of medical records
- Surrogate decision-making
- Tax exemption and tax planning
- Telehealth

Representative Experience

- Served as counsel to a direct support professional of a developmental disabilities provider that, after an investigation by the NYS Justice Center for the Protection of People With Special Needs, was the subject of a substantiated finding of Category 2 physical abuse. After the client's request for an amendment of the substantiated finding was denied, we requested a hearing before an Administrative Law Judge. Two days before the matter was to go to hearing, the Justice Center's Administrative Appeals Unit amended the finding to unsubstantiated.
- Served as counsel to a direct support professional of a developmental disabilities provider that, after an investigation by the NYS Justice Center for the Protection of People With Special Needs, was the subject of a substantiated finding of Category 1 serious physical abuse and Category 2 neglect. Filed a request for an amendment of the substantiated findings, resulting in the Category 1 claim being dropped and the Category 2 neglect being reduced to Category 3 neglect. After requesting a hearing before an administrative law judge, a few days before the matter was to go to hearing, the Justice Center's Administrative Appeals Unit amended both of the findings to unsubstantiated.
- Represented a not-for-profit outpatient mental health facility in its petition to the attorney general to transfer substantially all of its assets to another not-for-profit corporation.
- Represented a psychiatry practice in its formation and organization of a NYS professional service limited liability company.
- Represented an optometry practice during its transition to a successor and preparation of the related practice transfer agreement and record transfer agreement.
- Represented a dentist in the sale of his dental practice, associated assets, and office real property.

- Acted as outside counsel to a not-for-profit development disability health care provider in its transfer of assets to another provider.
- Represented a hospital group in the sale of its large urology and radiation oncology medical practice and related real estate.
- Obtained a no probable cause determination for a behavioral health provider in a race and criminal conviction discrimination and retaliation case.
- Obtained a no probable cause determination for an addiction treatment center in a gender discrimination and retaliation case.
- Obtained a no probable cause determination for an addiction treatment center in a gender, conviction record, and parolee status discrimination case before the NYS Division of Human Rights.
- Served as counsel to a NYS Office of Alcoholism and Substance Abuse Services (OASAS) chemical-dependency treatment program in a case of first impression, creating precedent from a NYS appellate court that chemical-dependency-treatment clients who participate in licensed chemical-dependency residential treatment programs are not entitled to an eviction proceeding or substantive due process prior to discharge.
- Handled a HIPAA privacy breach for a provider involving disclosures to and settlements with the US Department of Health & Human Services Office for Civil Rights (HHS-OCR) and the NYS Attorney General.
- Represented behavioral health care providers in their formation of a Medicaid health home.
- Represented behavioral health care providers in their formation of a Medicaid health home.
- Served as counsel in a trial in which the NYS Department of Health (DOH) and the NYS Office for People With Development Disabilities (OPWDD) were found responsible for funding the reasonable actual costs of administrative overhead in providing services under Medicaid.
- Represents an administrative data exchange in organizational planning, governance, regulatory compliance, contract negotiations, and building and implementing business-sustainability strategies.
- Represented a regional health information organization (RHIO) in developing the Statewide Health Information Network of New York (SHIN-NY), including research on cutting-edge privacy, security, and consent issues for governmental, public, and private collaborations. Continues representing the RHIO in organizational planning, governance, regulatory compliance, contract negotiations, and building and implementing business-sustainability strategies.
- Represented a consortium of numerous not-for-profit behavioral health care providers in designing and developing a behavioral health care network intended to engage in value-based contracting under a statewide Medicaid reform initiative, including assisting with corporate governance, contract negotiations, value-based payment agreements, and data privacy issues.
- Represented a consortium of numerous local governments and not-for-profit behavioral health care providers in designing and developing a behavioral health care network intended to engage in value-based contracting under a statewide Medicaid reform initiative.
- Served as general counsel to a NY-based not-for-profit assisted living provider, including licensing all four of its client residences and helping obtain ALR, enhanced, and special-needs licensure and certification. This included drafting a winning HEAL grant application, resulting in the client receiving \$3.8 million from the NYS Department of Health (DOH) to build a new assisted-living facility with enhanced capabilities.
- Assisted a NYS care coordination organization (CCO) with health care compliance matters during its initial formation and once operational, including assisting with vendor contracting, reviewing data-use agreements and security attestations, corporate matters, HIPAA compliance and policies, and preparing a corporate compliance plan and related policies.
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- Served as outside counsel to a residential health care facility operator in the \$7.5 million sale of a facility and related real property.

- Served as outside general counsel to a regional pharmacy, pharmaceutical products, and long-term and assisted living consulting company in a \$14 million sale of assets.
- Assisted with the restructuring of all secured and unsecured debt related to the \$25 million merger of two hospitals, including redeeming and reissuing civic facility bonds, coordinating consents from the PA and NY Departments of Health, and handling all real estate and title insurance work related to financing.
- Performed all legal responsibilities related to the \$225 million development, construction, and financing of a children's hospital, including negotiating and preparing all development, design, and construction contracts and preparing all loan and real property documentation related to HUD-insured mortgage financing and EB-5 financing.
- Prepared a HIPAA business associate manual for a Fortune 100 company's electronic medical record vendor and provided training.
- Designed corporate structures for an intellectual and developmental disabilities (IDD) agency to facilitate the telehealth delivery of health care services.
- Successfully challenged improper Medicaid rates for an intellectual/developmental disability (I/DD) agency that was acquired by a larger agency.
- Represented a client in an \$85 million transaction involving the sale of a large medical practice specializing in urology and radiation oncology to a captive medical practice controlled by a large regional hospital system together with all related real estate owned by entities affiliated with the practice. The real estate was purchased by a local developer and leased back to the captive practice pursuant to a master lease.
- Successfully defeated a \$1.6 million liability arising from an Office of Medicaid Inspector General (OMIG) finding that an intellectual/developmental disability (I/DD) agency documentation was insufficient to support reimbursement it received for services provided.
- Served as outside general counsel to a performing provider system (PPS) in the acquisition of a Rochester-area regional health home network.
- Served as outside general counsel to a WNY behavioral health provider in its merger with a regional child and adolescent behavioral health provider and in obtaining related regulatory approvals.
- Served as outside general counsel for nursing home facilities and related sellers in a \$45 million multiyear, progressive equity sale of nursing home entities and in the NYS Department of Health (DOH) regulatory approval process.
- Represented a person-centered not-for-profit organization supporting individuals with developmental disabilities in claims of sexual harassment, sex discrimination, and retaliation in violation of federal and state law. The New York State Division of Human Rights found no probable cause and dismissed the claims.
- Representing a not-for-profit rural health care enterprise in restructuring and corporate governance matters.
- Successfully obtained dismissal of the complaint and denial of a motion for leave amend in a matter against a health services provider and individual administrator concerning an alleged delay of medical treatment where the complaint asserted claims under 42 USC 1983, Article 26 of the Massachusetts Declaration of Right, and the Massachusetts Tort Claim Act.
- Represented a provider in a disability discrimination claim brought by a former patient before the New York State Division of Human Rights. The complainant claimed the provider refused to accommodate her medical condition by making her wear a face mask due to COVID-19. After the investigation, the New York State Division of Human Rights found no probable cause to believe the patient's rights were violated.
- Represented a health care provider in an audit of patient records by an insurance company that alleged approximately \$400,000 in overpayments. The insurance company rescinded its determination regarding the overpayment, and the client was not required to repay any of the alleged overpayments.

- Conducted an internal investigation of an agency's policies and procedures in handling discrimination allegations and diversity, equity, and inclusion issues at the behest of the CEO. An investigation and review were conducted and a summary was given to the CEO recommending new policies and procedures to improve diversity, equity, and inclusion efforts.
- Handled an internal sexual harassment and hostile work environment investigation for a not-for-profit agency and provided training on sexual harassment prevention.
- Represented an autism services provider being charged for allegedly violating Section 8(a)(1) of the National Labor Relations Act (NLRA) by terminating an employee in retaliation of the employee's protected concerted activities. After investigation, the National Labor Relations Board (NLRB) found no evidence of concerted activities nor animus toward individual concerns the complainant expressed about staffing and other workplace issues. The NLRB found that our client discharged the complainant because she refused to sign a performance improvement plan.

Health Care Controversies

Our Health Care Controversies Team provides clients with access to a team of experienced attorneys with the skills necessary to resolve complex disputes that arise in the health care and pharmacy industries.

Health care controversies represent the crossroads between adversarial proceedings, including litigation and administrative proceedings, and the highly regulated health care industry. A health care controversy can include major litigation involving health care providers, credentialing proceedings before licensing bodies, or disciplinary proceedings before the many state agencies with jurisdiction over providers. They include administrative and arbitration hearings and, if necessary, state or federal court appearances.

Regulators' increasing focus on the use of recovery-driven adversarial proceedings to enforce developing standards of compliance and fraud waste and abuse detection makes this a growing area of concern for clients in the health care industry. Now more than ever, health providers are likely to find themselves affected by investigations or enforcement proceedings that carry the risk of substantial, and even exponential, civil or criminal liability.

Our clients in the pharmacy industry face ever more complicated investigations, audits, and enforcement actions, including those by the Office of Inspector General (OIG), the Drug Enforcement Administration (DEA), and other regulatory bodies. While helping clients avoid risk is always our goal, we also represent them in dispute resolution and aggressively in litigation when needed.

Our team of attorneys has years of experience representing clients in government investigations and regulatory proceedings, including Medicare and Medicaid, and in the litigated or adversarial proceedings they can spawn. They have the required aggressive litigation skills and thorough knowledge of substantive health care laws and laws affecting the pharmacy industry.

Representative Experience

- Served as counsel to a direct support professional of a developmental disabilities provider that, after an investigation by the NYS Justice Center for the Protection of People With Special Needs, was the subject of a substantiated finding of Category 2 physical abuse. After the client's request for an amendment of the substantiated finding was denied, we requested a hearing before an Administrative Law Judge. Two days before the matter was to go to hearing, the Justice Center's Administrative Appeals Unit amended the finding to unsubstantiated.
- Served as counsel to a direct support professional of a developmental disabilities provider that, after an investigation by the NYS Justice Center for the Protection of People With Special Needs, was the subject of a substantiated finding of Category 1 serious physical abuse and Category 2 neglect. Filed a request for an amendment of the substantiated findings, resulting in the Category 1 claim being dropped and the Category 2 neglect being reduced to Category 3 neglect. After requesting a hearing before an administrative law judge, a few days before the matter was to go to hearing, the Justice Center's Administrative Appeals Unit amended both of the findings to unsubstantiated.
- Conducted a sexual harassment investigation involving claims against a CEO.
- Successfully obtained a reversal of the termination of five pharmacy locations.
- Successfully appealed a PBM's audit findings related to "advisory" prescriptions on behalf of a NY pharmacy.
- Successfully obtained an injunction to delay the termination of a pharmacy contract after the client was terminated from the network for fraud.

- Successfully secured a preliminary injunction barring the NYS Department of Health from implementing dramatic cuts in Medicaid reimbursement for incontinence supplies. Through an Article 78 proceeding, plaintiffs alleged the severity of the cuts would eliminate local home-delivery-service networks, leaving a de facto mail-order system in its place. The Kings County Supreme Court issued a preliminary injunction in the plaintiffs' favor, barring the NYS Department of Health (DOH) from implementing the reduced rates through the pendency of the litigation, representing a big win for the DME and pharmacy provider communities.
- Served as counsel to a home health care agency and provided representation in multiple audits by the Office of Medicaid Inspector General (OMIG), resulting in significant reductions in overpayment amounts. Also negotiated settlement agreements with OMIG, resulting in agreements for even lower overpayment amounts.
- Representing a physician in a landmark lawsuit against insurers for failing to protect the physician's confidential information from fraud and abuse by third parties.
- Successfully advocated for a physician's enrollment in Medicaid following a wrongful exclusion and successfully negotiated the physician's return into numerous health care provider networks.
- Brought an Article 78 proceeding against the Office of Mental Health to eliminate COPS payment recoupments and negotiated a settlement where the client paid less than what was demanded.
- Represented a state employee in federal civil-rights actions involving constitutional due-process issues and allegations of the denial of the First Amendment, due process, and Equal Protection rights, including allegations of rights violations by individuals under the auspice of the NYS Office of People With Developmental Disabilities (OPWDD) following investigations by the NYS Justice Center and the Department of Health (DOH).
- Represented multiple health care industry employers who were former members of health care group self-insurance workers' compensation trusts, defending multimillion-dollar claims brought by the NYS Workers Compensation Board and helping to recover substantial proceeds in multiparty lawsuits against the third parties responsible for the \$188 million trust deficit.
- Served as counsel in a trial in which the NYS Department of Health (DOH) and the NYS Office for People With Development Disabilities (OPWDD) were found responsible for funding the reasonable actual costs of administrative overhead in providing services under Medicaid.
- Successfully defeated a \$1.6 million liability arising from an Office of Medicaid Inspector General (OMIG) finding that an intellectual/developmental disability (I/DD) agency documentation was insufficient to support reimbursement it received for services provided.
- A former employee of a Central New York hospital system filed a charge of discrimination with the United States Equal Employment Opportunity Commission claiming sex and disability discrimination. After the investigation, the EEOC dismissed the charge of discrimination.
- Successfully obtained dismissal on summary judgment of a claim for a \$2 million "finder's fee" arising from the sale of a pharmacy business.
- Successfully represented several NYS fiscal intermediaries before OPWDD, resulting in the cessation of withholding 20 percent of non-Medicaid local assistance payments.
- Successfully obtained injunctive relief during the COVID-19 shutdown on behalf of an OPWDD provider enjoining the determination of DOH and OPWDD not to recalculate the provider's recently issued group day habilitation Medicaid reimbursement rate. The matter was ultimately remanded for a recalculation of the rate.
- Represented a health care provider in an audit of patient records by an insurance company that alleged approximately \$400,000 in overpayments. The insurance company rescinded its determination regarding the overpayment, and the client was not required to repay any of the alleged overpayments.

Pharmacy

From independent pharmacies to wholesalers, manufacturers, health innovators, and investors, the pharmacy industry is navigating an era of intense regulation, consolidation, and transformation. To thrive, you need more than legal compliance—you need a partner who understands your business, anticipates risks, and drives results.

At Barclay Damon, our national Pharmacy Team offers comprehensive legal support tailored to the entire pharmacy ecosystem. The team brings together attorneys from a range of practice areas who are cross-trained in pharmacy law and have deep knowledge of the pharmacy industry. This structure allows team members to leverage their individual practice—whether focused on health care compliance, corporate, litigation, or government investigations—while collaborating seamlessly to provide multidisciplinary, comprehensive counsel tailored to our clients' evolving needs. We combine litigation and regulatory fluency, transaction experience, and industry insight to help protect your business, solve complex problems, and pursue bold opportunities.

Full-Service Legal Counsel for the Pharmacy Industry—Nationwide

Barclay Damon's Pharmacy Team works with clients at every point in the pharmacy supply chain and provide strategic, multidisciplinary legal services that draw on years of industry experience of the members.

Pharmacies rely on us for support with enrollments, audits, terminations, licensing, daily compliance, and long-term planning—whether they're a single location or multistate, multistore operators. Community, specialty, compounding, infusion, long-term care, and 340B pharmacies trust us to help them meet strict regulatory and contractual requirements while scaling services and expanding opportunities.

Wholesalers and manufacturers face ongoing operational and supply chain challenges. We help them navigate FDA oversight, distribution agreements, and drug pedigree compliance, ensuring continuity and strategic growth.

Private equity firms and investors benefit from our combined regulatory and transactional experience as we help them assess risk, structure deals, and manage compliance from pre-closing to exit.

We also advise startups and tech companies transforming how pharmacies operate. From software licensing, artificial intelligence, data security and protection, and HIPAA compliance to entity formation and venture funding, we help founders launch and scale responsibly.

Comprehensive Services for a Complex Industry

Barclay Damon brings together attorneys from across the firm to deliver a seamless, full-service experience. Our legal support covers the entire spectrum of what pharmacy-related businesses need to operate, grow, and defend their interests.

Regulatory and Compliance Guidance

Barclay Damon helps clients stay ahead and navigate contractual and regulatory challenges by developing proactive strategies and ensuring full compliance. Whether it's responding to a government or pharmacy benefit manager (PBM) investigation or audit or a desire to work with a new vendor, we guide you with clarity and speed.

We also support clients with HIPAA and cybersecurity issues, privacy protocols, and fraud and abuse risk mitigation.

Corporate Transactions and Investment

From single location sales to complex multi-entity acquisitions, we represent buyers, sellers, and investors across the pharmacy space. Our team handles due diligence, licensing, structuring, and integration with a deep understanding of the regulatory and PBM landscape that defines pharmacy deals.

We advise on business formation, corporate governance, structure, licensing, joint ventures, strategic alliances, and partnership agreements, supporting everything from strategic investments to multistate platform rollups.

Risk Mitigation, Litigation, and Investigations

We work to help clients prevent problems before they happen, but when disputes or investigations arise, we're ready to respond. Our team defends pharmacies and industry participants in PBM and government investigations, audits, enforcement actions, and litigation.

From PBM terminations to reimbursement disputes to federal investigations, including those by the Department of Justice, attorneys general, Office of Inspector General (OIG), Drug Enforcement Administration (DEA), Office of Professional Discipline, and other regulatory bodies, we bring experienced litigators and regulatory counsel to the table to protect your business and reputation.

Intellectual Property, Branding, and Technology

Your innovation and identity are assets worth protecting. We help clients secure and enforce trademarks, patents, and trade secrets. For tech companies and digital health platforms, we draft and negotiate licensing agreements, navigate HIPAA and data-sharing rules, and advise on compliance for platform-enabled pharmacy services.

Workforce, Tax, and Real Estate

As businesses expand, so do their operational needs. Our team advises on employment matters ranging from pharmacist contracts and HR compliance to non-compete enforcement and dispute resolution. We support tax strategy and structuring of entities of all sizes and in certain circumstances handle leasing, acquisition, and real estate development for pharmacy sites and offices.

Bankruptcy & Restructuring

Pharmacy businesses are not immune to financial distress—whether due to tightening margins, regulatory shifts, or broader market forces. Barclay Damon's Pharmacy Team also includes attorneys from the firm's nationally recognized Restructuring, Bankruptcy & Creditors' Rights Practice Area who have supported clients along the pharmacy supply chain facing financial challenges. We provide strategic counsel on out-of-court workouts, Chapter 11 and Chapter 7 reorganizations and liquidations, distressed acquisitions, Article 9 sales, and enforcement actions, always with a deep understanding of the unique regulatory and operational issues at play in the pharmacy industry.

Our multidisciplinary approach allows us to protect clients' interests in every phase of the restructuring process. We advise on DIP financing, 363 sales, creditor claims, PACA and 503(b)(9) issues, and preference or fraudulent transfer litigation. Whether helping a pharmacy operator restructure operations, guiding an investor through a distressed transaction, or defending a creditor's rights in bankruptcy court, we deliver practical, cost-effective solutions designed to preserve value, ensure compliance, and support long-term recovery.

Why Industry Leaders Choose Barclay Damon

We bring more than legal knowledge; we bring industry fluency. Our attorneys are deeply involved in organizations like the National Community Pharmacy Association and National Association of Specialty Pharmacy, giving us insight into emerging trends, enforcement priorities, and operational challenges before they hit your inbox.

Clients choose us because we're responsive, practical, and committed to helping them succeed. Whether serving as outside general counsel, helping a startup to market, or guiding a buyer through a transaction, we bring the same focus, actionable advice, strategic execution, and long-term value.

No matter where you sit in the pharmacy industry, Barclay Damon is ready to support your mission with legal counsel that goes beyond checklists and red tape.

Representative Experience

- Collaborated in the clearing, filing, and prosecution of trademark applications for the global rebranding of a pharmaceutical company.
- Successfully obtained a reversal of the termination of five pharmacy locations.
- Successfully appealed a PBM's audit findings related to "advisory" prescriptions on behalf of a NY pharmacy.
- Successfully obtained an injunction to delay the termination of a pharmacy contract after the client was terminated from the network for fraud.
- Successfully secured a preliminary injunction barring the NYS Department of Health from implementing dramatic cuts in Medicaid reimbursement for incontinence supplies. Through an Article 78 proceeding, plaintiffs alleged the severity of the cuts would eliminate local home-delivery-service networks, leaving a de facto mail-order system in its place. The Kings County Supreme Court issued a preliminary injunction in the plaintiffs' favor, barring the NYS Department of Health (DOH) from implementing the reduced rates through the pendency of the litigation, representing a big win for the DME and pharmacy provider communities.
- Served as outside general counsel to a regional pharmacy, pharmaceutical products, and long-term and assisted living consulting company in a \$14 million sale of assets.
- Represented the seller of a New York City–based specialty pharmacy in the sale of its assets to a strategic buyer in a transaction valued at \$10 million.
- Represent buyers and sellers of independent pharmacies in asset and equity transactions involving community-based retail pharmacies, specialty pharmacies, and compounding pharmacies.
- Successfully obtained dismissal on summary judgment of a claim for a \$2 million "finder's fee" arising from the sale of a pharmacy business.
- Represented a publicly traded pharmaceutical manufacturer in the drafting and negotiation of international product development agreements as well as patent and know-how license agreements.
- Mediated a claim against a multinational consumer goods company brought by a pharmaceutical company in the American Arbitration Association.

White Collar & Government Investigations

Chaired by a former US attorney, the White Collar & Government Investigations Practice Area consists of experienced attorneys who have collectively handled over 100 criminal trials as well as complex investigations. Our team assists clients who find themselves affected by state, federal, and international government investigations and enforcement proceedings that carry the risk of significant enforcement penalties. We represent businesses and individual clients in matters involving health care fraud, environmental crimes, the Foreign Corrupt Practices Act, the False Claims Act, money laundering, RICO, tax, securities, and other white collar issues.

Our attorneys represent clients in all aspects of criminal defense matters, from the execution of search warrants and grand jury proceedings through trial and appeal. We also defend clients in parallel civil or administrative litigation that is frequently associated with criminal investigations. In these matters, our White Collar & Government Investigations Practice Area attorneys routinely interact with the full range state and federal enforcement and regulatory agencies.

Our attorneys conduct internal investigations to detect and prevent problems, allowing us to advise clients on the implementation of effective compliance programs. Preventing enforcement actions and criminal investigations through compliance programs and internal safeguards is a critical aspect of the White Collar & Government Investigations Practice Area.

Our team additionally collaborates with other firm practice areas to provide industry-specific knowledge and experience that is critical to effectively representing clients and delivering the most comprehensive legal services possible.

Representative Experience

- Successfully negotiated a civil resolution of a federal investigation into the submission of false claims for payment to the United States in connection with the Environmental Protection Agency's Disadvantaged Business Enterprise (DBE) program. The investigation arose out of the client's improper use of a contractor who was not performing a commercially useful function and, thus, was not an authorized DBE contractor. Also successfully defended the client in a related investigation by the EPA's suspension and debarment division, which ultimately took no adverse debarment action against the client.
- Successfully negotiated a civil resolution for a manufacturing client subject to a federal False Claims Act investigation that arose out of the client supplying a China-sourced component part to a US defense munitions contractor without the proper ITAR license.
- Represented a manufacturing company in connection with providing a voluntary disclosure to the Directorate of Defense Trade Controls – US Department of State (DDTC) concerning a potential violation of the International Traffic in Arms Regulations (ITAR) related to the outsourcing of a munitions component part from China without proper ITAR licenses. The DDTC ultimately closed the case without taking any adverse action or penalty against the client.
- Represented an individual charged with 30 counts of health care fraud and conspiracy to make false statements in connection with health care billing. The case was tried before a federal jury in Utica, New York.
- Represented an individual in connection with a federal tax investigation. Successfully negotiated a plea agreement that included an agreed-upon sentence and barred the government from bringing any further criminal charges in exchange for a guilty plea to subscribing and filing a false tax return. The client received no jail time.

- Represented an individual in connection with a federal immigration investigation concerning allegations of harboring illegal immigrants. Successfully negotiated a plea agreement that barred the government from bringing any further criminal charges in exchange for a guilty plea to one count. The client received no jail time.
- Represented an individual in connection with a federal tax investigation. Successfully negotiated a plea agreement that included an agreed-upon sentence and barred the government from bringing any further criminal charges in exchange for a guilty plea to two counts.
- Represented a physician accused of health care fraud, including fraudulent billing and falsifying records. Successfully negotiated a civil resolution with no criminal charges imposed. Assisted in instituting a practice-wide compliance program.
- Represented a law firm partner accused of fraud by the US Department of Justice (DOJ) and US Department of Labor (USDOL). No charges or civil penalties were imposed.
- Represented a business owner charged with 21 felony counts of criminal sales-tax fraud involving amounts approaching \$750,000. Successfully reduced the counts to one misdemeanor charge of failure to maintain adequate records and successfully negotiated the abatement of civil-fraud penalties.
- Represented a business under criminal investigation by the NY Attorney General's Antitrust Bureau for numerous violations of antitrust laws under threatened penalties of millions, incarceration for top executives, and forced closure of the business. Negotiated a civil resolution favorably with no criminal charges imposed.