



Lydia Wakulowsky

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[Health Care Integration & Transformation](#)

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She frequently develops and negotiates complex contracts, participates in briefings with various stakeholders, and assists in the development and review of policy for health sector clients.

She is regularly called upon to provide advice on the Canadian landscape for health regulatory matters; health product and establishment licensing, funding programs, marketing and advertising, interactions with health professionals, freedom of information, privacy and data protection.

Her clients include:

- hospitals
- long-term care facilities
- retirement homes
- healthcare agencies
- health-related charities
- other public healthcare organizations
- drug and medical device manufacturers and distributors
- laboratories
- pharmacies
- medical supplies and service providers

Lydia is the Co-Chair of the firm's Health Sector Services Group.

Experience

- Acting on mergers and acquisitions.
- Advising on market-access issues, including product and establishment licensing and obtaining registered vendor status with provincially-funded assistive device programs.
- Advising on matters concerning the manufacturing, distribution, packaging and labeling of drugs, medical devices, natural health products and consumer health products.
- Advising on research ethics matters, clinical trial agreements (including associated agreements for monitors and investigators, conflict of interest, consent and privacy guidelines) and research ethics board terms of reference and policies.
- Advising on the development of global policies and Canadian corporate compliance policies on interactions with health professionals, reflecting the requirements of federal and provincial laws, regulations and industry codes of conduct (including the Innovative Medicines Canada Code of Ethical Practices, MedTech, Code of Conduct on Interactions with Health Professionals), provincial health profession laws and regulations, advertising laws and government requirements arising from registered vendor agreements.
- Reviewing advertising material (television, online and print) before dissemination.
- Advising on proposed sponsorship arrangements.
- Advising on regulatory matters related to Health Canada inspections and enforcement actions, crisis management and recalls, adverse events and public advisories.
- Acted for the Ministry of Health and Long-Term Care (MOHLTC), several Local Health Integration Networks (LHINs), the Ontario Hospital Association (OHA), the Ontario Medical Association (OMA), the Ontario Association of Community Care Access Centres, and numerous public hospitals and other healthcare providers (and their associations) to provide advice on corporate governance issues in the health care sector.
- Developed comprehensive governance policy frameworks following the amalgamation of several Ontario hospital corporations and participated in comprehensive governance policy framework renewal processes for Ontario public hospitals that have voluntarily undertaken this initiative or as a result of the appointment of a hospital supervisor.
- Developing or revising corporate and professional staff bylaws, (common) credentialing and mid-term revocation policies, clinical inter-professional policies and professional staff rules and regulations to ensure they are clear, concise and aligned with legal and regulatory requirements and leading practices.
- Served as lead legal counsel for the voluntary merger of two hospitals on two separate files (one by way of asset transfer and the other by way of amalgamation), both involving governance renewal and education.
- Developing complex agreements for the health sector, including various memoranda of understanding, management services, affiliation, funding and accountability, physician and healthcare provider services, alternate payment plan, drug and medical equipment supply, shared services, cost sharing, laboratory, rehabilitation and other service agreements.
- Developing submissions in response to federal and provincial access to information and freedom of information requests.
- Developed privacy-compliance checklists, policies, codes and notices, outsourcing and privacy agreements with third parties, data-sharing agreements with hospitals and researchers, employee pledges, consent forms, access-request forms, and a job description for a privacy officer and terms of reference for a privacy team.

Insights & Events

- Health Canada's modernized clinical trial framework: Implications for stakeholders
- Product advertising and marketing in the time of COVID-19
- 3D printing during COVID-19
- Spotlight on medical devices in the age of COVID-19
- Ontario Health Teams Series
- [Co-Author, "3D Printed Medical Devices and Organs: *The Canadian Legal Framework*" Rx for The Defense, Defence Research Institute, Fall 2019](#)
- All Eyes On Hospitals: Mandatory Drug And Medical Device Adverse Event Reporting
- Privacy Tips for Medi-Spas and Other Wellness Providers
- Governance Options: Getting Started and Evolving Towards Maturity
- Top Five Legal Tips for the Health and Wellness Industry
- Ontario Government's Healthcare Reform Legislation, Bill 74, The People's Health Care Act, 2019
- The New Ontario Autism Program – What's Law Got to Do with It?
- Conflict of Interest Revisited
- Co-author, "Ministry Focuses on Transparency in the Ontario Health Care Sector," BLG's Health Law Bulletin, December 2017
- Update – Ontario Passes the Patients First Act to Implement Health Sector Reform
- Co-author, "Ontario Reintroduces Patients First Act, 2016 with Important Changes," BLG Publication, October 2016.
- Co-author, "Guidance for Health Care Organizations on the New Cannabis Regulations," BLG's Health Law Bulletin, August 2016
- Speaker, "Consent in Clinical Trials," Osgoode Certificate in Health Law, 2016.
- Speaker, "Practical Tips for Reviewing Affiliation Agreements with Educational Institutions," HIROC, 2015.
- Speaker, "Primer on the Law of Contracts," Ontario Hospital Association, 2015.
- Speaker, "Accountability in Healthcare: The Legal Framework," Osgoode Certificate in Health Law, 2010-2017.
- Principal author, LHIN/Health Service Provider Governance Resource and Toolkit for Voluntary Integration Initiatives
- Principal author, OHA/OMA/IPC Hospital Privacy Toolkit

Beyond Our Walls

Professional Involvement

- Member, Ontario Bar Association
- Member, Canadian Bar Association
- Member, American Bar Association
- Member, biologics and regulatory affairs group of BIOTECanada
- Member, Life Sciences Ontario

Awards & Recognitions

- Recognized in the 2022 edition of *The Canadian Legal Expert Directory* (Life Sciences & Health).

- Recognized in the 2022 edition of *Lexpert Special Edition: Technology & Health Sciences*
- Selected by peers for inclusion in the 2022 edition (and since 2018) of *The Best Lawyers in Canada*® (Health Care Law) and in the 2022 edition (Privacy and Data Security Law)
- Martindale-Hubbell® peer review AV® Preeminent™ rating, 4.9/5.0 in 2020 and 2019
- Certified by the Law Society of Ontario as a specialist in Health Law

Bar Admission & Education

- Ontario, 1995
- LLB, University of Ottawa, 1993
- BA, University of Toronto, 1990

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