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COFFEE TALK:
A HEALTH INDUSTRY SEMINAR SERIES

VANCOUVER CALGARY EDMONTON SASKATOON REGINA LONDON KITCHENER-WATERLOO GUELPH TORONTO VAUGHAN MARKHAM MONTRÉAL

Bill 160, *Strengthening Quality and Accountability for Patients Act, 2017* - What You Need to Know

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Overview

1. Summary of Bill 160
2. New legislation
3. Amendments to existing legislation
4. Conclusion

Strengthening Quality and Accountability for Patients Act, 2017 (Bill 160)

- Stated purpose:

  [t]o enhance transparency, accountability and the quality of care across the health care sector, including greater oversight of long-term care homes and pharmaceutical companies

- Became law on December 12, 2017

Bill 160

- Omnibus legislation that: creates 3 new Acts, repeals 5 Acts and amends 7 Acts
- Brings about significant changes to many areas of the health care system
- While some provisions came into force on the day the Act became law, most of the Act will come into force on a future date (not yet known)
- A lot of the details have been left for supporting regulation

Bill 160: New Legislation

NEW LEGISLATION	STATUS	AFFECTED LEGISLATION
Health Sector Payment Transparency Act, 2017	Not in force	None
Oversight of Health Facilities and Devices Act, 2017	Not in force	Repeals: • *Independent Health Facilities Act* • *Healing Arts Radiation Protection Act* • *Private Hospitals Act*
Medical Radiation and Imaging Technology Act, 2017	Not in force	Repeals: • *Medical Imaging and Radiation Technology Act, 1991*

Bill 160: Other Affected Legislation

Act	Schedule of Bill 160	Action
Ambulance Act	1	Amended
Excellent Care for All Act, 2010	2	Amended
Health Protection and Promotion Act	3	Amended
Long-Term Care Homes Act, 2007	5	Amended
Health Care Consent Act, 1996	5	Amended
Ontario Drug Benefit Act	7	Amended
Ontario Mental Health Foundation Act	8	Repealed
Retirement Homes Act	10	Amended

Health Sector Payment Transparency Act, 2017 (HSPTA) (not in force)

- Purpose (s. 1)

  …to require the reporting of information about financial relationships that exist within Ontario's health care system, including within health care research and education, and to enable the collection, analysis and publication of that information in order to,

  (a) strengthen transparency in order to sustain and enhance the trust that patients have in their health care providers and in the health care system;

  (b) provide patients with access to information that may assist them in making informed decisions about their health care;

  (c) provide the Minister and others with information for the purposes of health system research and evaluation, planning and policy analysis; and

  (d) provide for the collection, use and disclosure of personal information for these purposes.

HSPTA

- Mandates reporting of **transfers of value** provided by a **payor** (or intermediary/affiliate of payor) to a **recipient** in relation to **medical products**
- **Transfer of value**: a transfer of value of any kind and includes a payment, benefit, gift, advantage, perquisite or any other prescribed benefit
- **Medical Products:**
  - **Drugs** (as defined by clauses (a)-(d) of the definition of drug in the *Drug and Pharmacies Regulation Act* for human use, not including a natural health product within the meaning of the Natural Health Products Regulation under the *Food and Drugs Act* (Canada) (FADA);
  - **Medical devices** (a device, as defined in s. 2 of the FADA, that is intended for human use other than a prescribed device, and any other prescribed instrument, apparatus, contrivance or similar article intended for human use);
  - Any other prescribed product used in the health care system.

HSPTA

- Payors and recipients must maintain records regarding transfers of value
- Reports must be made by the payor to the Minister of Health and Long-Term Care
  - Affiliates and intermediaries can also be subject to reporting obligations where required by the Minister
  - Manner and frequency of reporting by payors not yet known
- The Minister of Health and Long-Term Care must publish data online

HSPTA - Who is Affected?

Payor (s. 3):

1. A manufacturer that sells a medical product under the manufacturer's own name or under a trade-mark, design, trade name or other name or mark that is owned or controlled by the manufacturer and that fabricates, produces, processes, assembles, packages or labels the product, even if those tasks are performed by someone else on the manufacturer's behalf.

2. A person who fabricates, produces, processes, assembles, packages or labels a medical product on behalf of a manufacturer described in paragraph 1.

3. A wholesaler, distributor, importer or broker that promotes or facilitates the sale of a medical product.

4. A marketing firm or person who performs activities for the purposes of marketing or promoting a medical product.

5. A person who organizes continuing education events for members of a health profession on behalf of a manufacturer described in paragraph 1.

6. A prescribed person or entity.

HSPTA - Who is Affected?

- **Recipient**: A prescribed person or entity that receives a transfer of value from a payor
  - Prescribed = prescribed by regulation
  - May include all regulated health care professionals, health care organizations, their executives and others
- **Intermediary**: A person or entity who provides or facilitates a transfer of value to a recipient on behalf of a payor
- **Affiliate**: As set out in the Ontario *Business Corporations Act*

HSPTA – Information to be Reported

- Names of the parties to the transaction (legal and operating)
  - If a party is an individual, the individual's name, profession or title and any other prescribed identifying information must be provided
- Source of the transfer of value (if the reporting party is an intermediary or affiliate from whom the Minister requests a report)
- Parties' respective business addresses
- Date of the transfer of value
- Transfer of value's dollar value/approximate dollar value
- Description for the transfer of value & reasons for it
- Any other prescribed information

HSPTA – Oversight and Enforcement

- Minister may appoint inspectors, who may enter a premises, demand production of documents, question any person on relevant matters, or audit accounts and financial transactions
- Obligation of directors and officers of a corporation to ensure compliance
  - Good faith carve-outs

HSPTA - Penalties

- Significant financial penalties for contravention of the Act:
  - Individual:
    - up to $10,000 **per day** (first offence)
    - up to $25,000 **per day** (subsequent offences)
  - Corporation:
    - up to $50,000 **per day** (first offence)
    - up to $100,000 **per day** (subsequent offences)
- No imprisonment/probation

Oversight of Health Facilities and Devices Act, 2017 (OHFDA) (not in force)

- Establishes a regulatory system for licensing and operation of:
  - community health facilities (CHFs)
  - energy applying and detecting medical devices (EADMDs).

OHFDA - CHFs

- Community health facility
  - A place/collection of places where one or more services prescribed in regulations are provided (including part of such a place); or
  - A place/collection of places prescribed in regulations
- "Places" that will be captured not yet clear as no regulations to-date
  - Will include private hospitals currently licensed under *Private Hospitals Act*, Independent Health Facilities licensed under *Independent Health Facilities Act*
  - May include other types of facilities (e.g. out-of-hospital premises)

OHFDA - CHFs

- Comprehensive regime
  - Licensing and funding
  - Corporate licenses
  - Requirements and standards
  - Inspection and compliance
  - Includes transitional provisions for facilities currently in operation

OHFDA – CHF Licensing

- All CHFs must meet certain requirements in order to obtain and maintain licensure
- CHFs intending to provide/providing insured or funded services, are subject to additional considerations for licensing, including:
  - nature of services to be provided
  - extent to which services are currently available in Ontario and current and future need for the services
  - public cost of establishing and operating CHF and availability of public funding
  - concentration of ownership, control or management of CHFs;
  - any other matter deemed relevant (s. 5(3))

OHFDA - EADMDs

- EADMDs are **prescribed** devices that are manufactured, sold, or represented for use in diagnosing or treating individuals or for restoration of body structures or functions, as well as devices used to apply or detect acoustic, electromagnetic, or particle radiation
- Specific EADMDs that require licensing will be set out in regulation

OHFDA – EADMD Licensing

- No person shall operate an EADMD except under the authority of a license issued with respect to the device – licenses are non-transferrable
- Applicants and devices must meet all prescribed requirements and pass any requested inspection
- In the absence of regulations, we do not know what devices may be captured

OHFDA – EADMD Licensing

Following factors will be considered in determining whether to issue a license:

- Proposed use of the device
- Extent to which it is already available in Ontario
- Current and future need for the proposed use of the device in Ontario
- Any other matter relevant to the management of the health care system

OHFDA – Offences and Liability

- Part V: Prohibitions
  - CHFs: Holding out as a CHF, payments, non-discrimination, funding, etc.
  - EADMDs: Operating without a license, improper use
- Vicarious liability of licensees for any person working in connection with anything regulated by the Act

OHFDA – Enforcement

- Act provides for creation of inspecting bodies
  - Broad powers re: quality and safety
  - Submission of reports which may be publicly available
  - Appoint inspectors
- Inspectors are granted broad inspection authorities regarding CHFs and EADMDs

OHFDA - Penalties

- Non-compliance
  - Compliance or cessation orders
  - Administrative penalties (amounts to be prescribed)
  - Suspension, revocation or refusal to renew license
- Prescribed offences
  - Individual:
    - Fines and/or imprisonment
  - Corporation:
    - up to $100,000 (first offence)
    - up to $250,000 (subsequent offences)

Medical Radiation and Imaging Technology Act, 2017 (not in force)

- Replaces the *Medical Radiation Technology Act, 1991*
- College of Medical Radiation Technologists → College of Medical Radiation and Imaging Technologists
  - Reflective of full membership (as of January 1, 2018, diagnostic medical sonographers are the 5th specialty regulated by the College)
- Scope of practice statement amended to include application of soundwaves

Ambulance Act - Amendments (not in force)

- Minister granted new authority to issue operational or policy directives with respect to land ambulance services - where in public interest
- May include (but not limited to) directives regarding:
  - Transportation to destination other than hospital (e.g. CHF or mental health facility)
  - Provision of on-scene treatment for lower acuity conditions (treat and release/treat and refer)
- Inspectors' and investigators' powers also broadened

Ambulance Act - Implications

- Directives could significantly expand role and responsibilities of paramedics, including decisions that may require clinical diagnoses, but there is a lack of clarity as to how they may be implemented
- Considerations re: knowledge and competencies of paramedics, informed consent requirements

Amendments re: Patient Restraint / Confinement

- *Long-Term Care Homes Act, 2007* (LTCHA)
- *Retirement Homes Act, 2010* (RHA)
- *Health Care Consent Act* (HCCA)

Restraint and Confinement: Current Regime

- Currently a patchwork regime for restraint/ confinement of patients/residents that depends on circumstances and setting
- RHA provides for:
  - use of confinement in a **secure unit** of a retirement home where part of a resident's plan of care (s. 70), however:
    - Section 70 has never been proclaimed in force
    - No regulations to provide for the designation of secure units
  - use of locks, barriers or other devices/controls:
    - At entrances/exits if they do not prevent resident from leaving
    - At stairways, as a safety measure

Current Regime

- LTCHA provides for transfer to secure units but also not in force
- HCCA, Part III dealing with admission from community to secure unit also not in force
- In most cases only authority to confine in LTC home or retirement home is pursuant to common law
- Common law authority is very limited:
  - Emergency situations where immediate action is necessary to prevent serious bodily harm to the person or others
  - Only so long as the emergency continues

Bill 160 Amendments

- Sets out circumstances where it is permissible for a resident to be restrained or confined in a LTC home or retirement home
- Consent-based system

Bill 160 Amendments - HCCA

- New Part III.1: Confining in a Care Facility
  - Care facility = long-term care homes, and any prescribed facilities (not yet any)
  - Principles for giving/refusing consent
  - Information to be communicated to incapable persons
  - Applications to the Consent and Capacity Board (CCB)

Bill 160 Amendments - LTCHA

- Amended to address both restraint and confinement
  - Inclusion in plan of care
    - Must be significant risk, consideration of alternatives and the least restrictive method and degree
    - Recommended by a physician, RN or other prescribed person
    - Consent required from resident or SDM
  - Requirements if resident is confined
    - Condition must be reassessed in accordance with requirements to be provided for in regulation
    - Resident may only be confined for as long as necessary to address the risk
    - Confinement must cease if there is an alternative to confinement or a less restrictive manner of confining the patient

Bill 160 Amendments - LTCHA

- Notification of confinement
  - Must been in writing
  - Must allow the opportunity to meet with a rights advisor
- Elements of consent for confining
  - Must relate to the confinement
  - Be informed
  - Given voluntarily
  - Must not be obtained through misrepresentation or fraud
- Right of review by CCB under HCCA

Bill 160 Amendments – RHA

- Amended to address confinement in retirement home
  - Permitted if included in resident's plan of care
  - Elements of consent/informed consent
  - Right of review (as per regulation)
- Removes reference to "secure units"

Final Thoughts

- Bill 160 changes are wide-sweeping – need to be aware of them and the potential implications for your organization
- Many of the amendments will not become law until details are fleshed out by regulation
  - May include public consultation – opportunity for affected stakeholders to provide input
  - Potential to influence scope/application of legislation

Final Thoughts

- Analysis of how changes may affect your organization directly and/or indirectly will be important
- Implementation and compliance – be proactive
- Miller Thomson's Health Industry Group will continue to monitor and provide updates as necessary

Questions?

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