Risk Management in Canadian Health Care

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• OVERVIEW OF SOME LEGAL ISSUES FACING THE FUTURE OF PERSONALIZED MEDICINE •

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• In This Issue •

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In the last decade, the expansion of research in genetics, genomics and other personalized health care approaches has allowed physicians to customize medical treatment according to patients' genetical, anatomical and physiological characteristics, their environment and their interactions with such environment. While the evolution of "personalized medicine" will continue to be influenced by developments in science, its commercial success will largely depend upon the legislative framework governing such treatments, and more particularly the regulation over the following: the concept of "medically required services", the protection of personal information, the administration of medical files, the communication of genetic information, genetic testing, genetic discrimination and insurance contracts. Keeping in mind the tremendous significance and complexity of this topic, this article intends to provide a brief introduction to some legal issues pertaining to genetic testing,

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privacy and human rights issues associated with genetic information.

Genetic Tests

One concern raised by genetic tests is that the regulation of at-home test kits is questionable. Accordingly, patients can purchase such kits online and undertake—without supervision or assistance—tests that could reveal sensitive information regarding their health. While some may attempt to interpret their own test results (giving rise to the risk of misinterpretation), others wishing to have a better understanding could consult a physician. Such consultations could then lead to various duties on the physicians' part (*e.g.*, to provide the medical follow-up required by the patient's condition). However, due to the potential dubious quality of unregulated tests (and results), the duty to provide assistance and follow up could be difficult for physicians to determine.

Another concern raised by genetic tests concerns the ability for patients to control the information added to their medical records once the results of these tests are analysed by a physician. Canadian law generally provides that patients may request the rectification of their medical file if the information contained therein is inexact, incomplete, ambiguous, outdated or unjustified. Provided that the genetic test information is accurate and is in fact included in the patient's medical record a patient will not be able to request the removal of all (or part) of such information. Likewise, medical opinions, interpretations and diagnoses cannot usually be altered within a medical record. Once added,

such results and their interpretation will form an integral part of a patient's medical file and are subject to being communicated to third parties (*e.g.*, when a person agrees that an insurance company may have access to all information in its medical record).

Communication of Genetic Information to Family Members

Another legal issue is that discovery of diseases may have risk implications for patients' relatives, given that in some circumstances genetic information pertaining to a patient may be communicated to family members or third parties.

Even without the consent of the individual, various provincial laws provide that physicians and other persons may communicate personal information contained in a file they hold on that individual to a person to whom the information must be communicated by reason of urgency, such as a life-threatening situation or the health and safety of the individual concerned.

For example, the Manitoba *Personal Health Information Act* permits disclosure when the trustee of personal health information "reasonably believes that the disclosure is necessary to prevent or lessen a serious and immediate threat to […] the health or safety of the individual the information is about or another individual".[1] The law also provides that, "[e]very person whose life or bodily integrity is endangered is entitled to receive the care required by his condition"[2] and any person or any group of persons should be warned should their health condition be threatened by a "significant risk of serious bodily harm". A similar duty is also vested in physicians.[3] While the Canadian Medical Association's code of ethics precludes them from using confidential information to the prejudice of a patient, it nonetheless stresses that "[a] physician's paramount duty is to protect and promote the health and well-being of the persons he attends to, both individually and collectively [emphasis added]". Even if confidentiality has been held to be especially important in respect of genetic disorders as they bear upon present and future consequences on the patient's autonomy and private life, some argue that should a patient refuse to reveal genetic information to his relatives, his physician could, in certain circumstances, take appropriate measures to warn them, provided that this information is important to their health and well-being. Conversely, others took the view that the "serious harm threshold" will not generally be met because the information revealed solely by genetic tests is probabilistic and imprecise *per se*.

Discrimination

One of the advantages of personalized medicine is the ability to stratify patients, so physicians can identify the different forms a disease may take and maximize the effects of drugs by using them on the appropriate patients. However, a downside of such stratification is the possible discrimination it could create. Canadian law does not confer a free-standing protection against genetic discrimination. However, a constitutional guarantee of equality and a prohibition against discrimination on grounds such as disability or handicap is enshrined in the

Canadian Charter of Human Rights and Freedoms as well as in the provincial charters and human rights codes.

In insurance contracts, however, the use of health as a risk determination factor does not constitute discrimination. Recently, the Canadian Life and Health Insurance Association released a position statement on genetic testing. While this statement indicated that "[i]nsurers would not require an applicant for insurance to undergo genetic testing", it also emphasizes that "[i]f genetic testing has been done and the information is available to the applicant for insurance and/or the applicant's physician, the insurer would request access to that information just as it would for other aspects of the applicant's health history". Accordingly, this statement provides for weak guarantees, and given that insurance contracts are "good faith" contracts where the insured has an obligation to divulge any information that may be relevant to the contract, the insured may well be required to disclose the information revealed by such tests. There have been a few legislative attempts in Canada as well as in foreign jurisdictions to deal with the provision of genetic information to insurers, and it will be interesting to follow up on the attempts to deal with non-discrimination and their specific impact on personalized medicine.[4]

Conclusion

The evolution of personalized medicine will be influenced by scientific advances but also by society's perspective on this form of medicine. Many unresolved policy issues are likely to influence the prospects for such treatments. Likewise, with the growing advances in the availability and advantages of these treatments, legislative action will be in various cases necessary to shape the opportunities for companies involved in these technologies, to clarify the rights and protections for Canadians, and to address concerns relating to the potential use of such information by third parties.[5]

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1 *The Personal Health Information Act*, C.C.S.M. c. P33.5.

2 *An Act respecting health services and social services*, CQLR c. S-4.2, s.7.

3 *McInerney v. Macdonald*, [1992] S.C.J. No. 57, [1992] 2 S.C.R. 138.

4 Canada. Parliament. Senate. Bill S-201, *An Act to prohibit and prevent genetic discrimination.* 41st Parliament, 2nd Session, Second Reading (April 1, 2014).

5 If adopted, Bill S-201 will prevent genetic discrimination and will prohibit any person from requiring an individual to undergo a genetic test or to disclose the results of a genetic test as a condition of (1) providing goods or services, (2) entering into (or renew) a contract with such individual, or (3) stipulating specific conditions in a contract. Its enactment will amend other laws (such as the *Canada Labour Code*, R.S.C. 1985, c. L-2, and the *Canadian Human Rights Act*, R.S.C. 1985, c. H-6.

• NEW DEVELOPMENTS IN ONTARIO AND QUEBEC •

Kathryn Walker, University of Toronto

Introduction

Much attention is now being focused on consent, capacity and substitute decision-making. This has been apparent in the months since the Supreme Court of Canada rendered a decision in *Cuthbertson v. Rasouli*,[1] but also more generally through multiple initiatives. The first part of this article examines one of the Law Commission of Ontario's discussion papers.

And while the Canadian debates over assisted dying and end-of-life care may have experienced some amount of quiet in the time following the Supreme Court of Canada's 1993 *Rodriguez*[2] ruling against physician-assisted suicide, recently we have seen courts and law makers in Canada returning to this terrain. In this new round of questioning, many of the issues are similar, if not the same, as those previously settled by the Supreme Court; however, with developments in medical technology, shifting patterns of disease and changing demographics, new areas of concern are now on the table and indeed, have been the genesis for a new Quebec law.

This article aims to provide an overview of two recent legal developments: one on capacity and substitute decision-making, the other on medical aid in dying.

Ontario

The Law Commission of Ontario's [LCO] discussion paper, "Legal Capacity, Decision-Making and Guardianship (May 2014)",[3] considers Ontario's legal approach to capacity and illustrates the contested nature of the law in this area. In doing so, the paper focuses its analysis on two Ontario statutes, the *Health Care Consent Act, 1996* [*HCCA*][4] and the *Substitute Decisions Act, 1992* [*SDA*].[5] The following discussion provides an overview of the LCO's discussion paper, highlighting its analysis of Ontario's legal test for capacity, the province's substitute decision-making system and the manner in which the system is vulnerable to misuse and abuse. While the scope of the paper's consideration of legal capacity is broad, the paper nonetheless has direct and substantial bearing on end-of-life decision making. As much as capacity is a legal concern for many types of persons, the capacity for consent is a major issue for people at the end of life; the reason for this is that health care requires consent, but many end-of-life care decisions emerge once a patient's capacity for consent has been lost or weakened. It was precisely this nexus of end-of-life decision-making and capacity for consent that was the topic of the recent Supreme Court case *Cuthbertson v. Rasouli*.[6]

Capacity

The discussion paper remarks that Ontario's legislative framework on legal capacity and decision-making is guided by a *cognitive and functional* conception of capacity, which interprets capacity as an ability to understand, retain, and evaluate relevant information and to balance that information in order to reach a decision.[7]

Ontario's tests for capacity are based on whether or not a person is able to "understand and appreciate" the information relevant to a given situation. The paper points out that this *cognitive and functional* approach may not square with disability rights and may disadvantage persons suffering from intellectual, language, cognitive, and psychosocial disabilities. Additionally, it notes that this approach may be flawed by an under-appreciation of the role of emotions and interdependent human relationships in our decision-making processes. The discussion paper further points out that there are other ways to approach capacity, such as a non-cognitive will and intent test.[8]

Ontario's Substitute Decision-Making System

The discussion paper notes that Ontario has a relatively modern, coherent and progressive approach to substitute decision-making and applauds the province for the procedural protections it provides for persons lacking legal capacity, the opportunities that the system allows for individuals to choose or have input into the selection of a substitute, its focus on trusting relationships as the foundation for substitute decision-making, and its requirement that substitute decision-makers consider the wishes, preferences, values and beliefs that the individual held or expressed when capable.[9]

Shortcomings of Ontario's System

The discussion paper also considers shortcomings of this approach and contemplates alternative approaches. A major finding of the discussion paper is that if Ontarian substitute decision–makers had supports and oversight to ensure that they thoroughly carried out their duties, the system could work well. The discussion paper notes that Ontario's approach can be criticized for an over-emphasis on cognitive functioning; for fostering a loss of autonomy, which may undermine an individual's well-being; and for taking an all-or-nothing approach that fails to capture the extent to which capacity is of a fluctuating and imprecise quality.

The discussion paper considers possible alternatives, such as "supported decision-making", an approach implemented in various forms in a number of jurisdictions within Canada, including Alberta, British Columbia, the Northwest Territories and the Yukon, and internationally, in England, Wales and Sweden.[10] The distinguishing feature of supported decision-making is that the individual's legal capacity and responsibility remain intact but are supplemented with input from a supporter who can assist the individual in understanding her or his values and preferences, including the consequences of applying such values and preferences. A second alternative is "co-decision-making", a legal concept that moves the locus of decision-making from the single individual to a joint initiative, requiring a collaborative decision be made between the individual and an appointed co-decision-maker. Co-decision-making has received less attention than supported decision-making.

Misuse and Abuse

The most critical part of the discussion concerns the ways in which Ontario's substitute decision-

making system is abused and misused, such as where an attorney for property directly uses that power to carry out financial transactions and impoverish the individual.[11] The paper identifies that the majority of SDMs are close friends or family, and while the intimate nature of these relationships is beneficial because they are typically conducive to trust, it also has a significant impact on the dynamics of abuse and misuse of decision-making authority.[12] Of note, the discussion paper explains that because the SDM is often a close friend or family member, abuse of the role is hidden from detection, where a good deal of abuse may go unreported.[13] The paper also criticizes Ontario's current system in that guardians and attorneys are often unaware of their roles and responsibilities under the *SDA* and that there is a lack of both effective monitoring mechanisms and effective mechanisms for redress.[14]

As part of its consideration of the ways in which the Ontario's system could be improved, the paper tables four avenues for reform:

- an increased understanding of the roles and responsibilities of SDM,
- increased oversight and supervision of SDMs,
- more extensive powers for the reception and investigation of complaints, and
- mechanisms to limit or prevent loss of funds through abuse.[15]

While much of the paper's analysis of the substitute decision-making system is framed in terms of decision-making regarding property and finances, the report's findings also have direct relevance to end-of-life decision-making. In particular, given that under the common law and under Ontario's *HCCA*, health care (*i.e.*, treatment) requires patient consent, and given that this requirement cannot be abrogated but only transferred to an SDM, it is clear that the SDM system, its successes and failures are an intractable feature of end-of-life care. Moreover as the report makes clear, there are important reforms that could improve the system in general and that would also improve the regime of end- of-life decision-making.

Quebec

An Act respecting end of life care

On June 5, 2014, the National Assembly of Quebec passed Bill 52, otherwise known as, *An Act respecting end of life care* [Act],[16] which stipulates rules and guidelines for the implementation Canada's most groundbreaking end-of-life care regime.[17] The preamble recognizes a right to end-of-life care: "[t]he bill specifies rights with respect to end-of-life care, in particular by affirming the right of everyone to end-of-life care that is appropriate to their needs". Its rules apply to local community service centres, hospitals, residential and long-term care centres; for instance, each institution is required by the Act to devise and implement end-of-life care policies. Additionally, the Act emphasizes that its purpose is to ensure that end-of-life patients are provided care in a way that is respectful of their dignity and autonomy. The Act also recognizes the primacy of wishes expressed freely and clearly with respect to end of life.

The Act provides for two types of end-of-life care—namely, continuous palliative sedation and medical aid in dying. Continuous palliative sedation consists of administering medications that will relieve suffering by putting the patient into an unconscious state until death occurs. Continuous palliative sedation may be requested thorough an advance medical directive or by the patient at any time. By contrast, medical aid in dying requires a more stringent request process and does not allow for the use of an advanced medical directive. In order to receive medical aid in dying, the patient must freely and personally request the treatment. Additionally, the patient must be an insured person within Quebec, be of full age and capable of giving consent, be at the end of life, suffer from a serious or incurable illness, be in advanced or irreversible decline in capability and experience constant and unbearable physical or psychological suffering from which relief cannot be attained in a manner the patient deems tolerable. The physician must administer the treatment and must stay with the patient until the patient dies. If a physician declines to administer the treatment, it is required that the physician forward the treatment request so that another physician who is willing to deal with the request can be found.

Of significance to the continuous palliative sedation treatment is the advanced medical directives regime that the Act sets out. This regime enables patient care to be decided with respect to choices made by a patient when he or she was capable of giving consent. Further, this regime allows the patient to name one or more trusted persons who are authorized to give instructions relating to care and requires that advance medical directives be given only by persons of full age and capacity, in writing, and in the presence of witnesses. In cases where the advanced medical directive is given to a health care professional, the regime requires that the professional confirm the accuracy of the directive and file it with the advance medical directives register. The Act further sets out that such directives can be revoked at any time and by any means. Finally, if a person incapable of giving consent refuses treatment to which he or she has previously consented to in advance, the Act through its advanced medical directives regime, requires that the courts authorize the treatment plan in question.

The Act has already been met with legal challenge, which objects to the Act on four distinct grounds.[18] First, the challenge argues that the Act is not properly about health care but criminal activity and is therefore outside of provincial jurisdiction. Second, it argues that the consent requirement attached to the medical aid in dying treatment option is not legitimate on the basis that Quebec suffers from a serious lack of palliative care treatment, without which the choice to die is not properly informed or consensual. Third, the challenge contends that the Act is illegal, violating the *Canadian Charter of Rights and Freedoms*, the *Quebec Charter of Values*, the Constitution of 1868 and s. 222 (the homicide provision) of the *Criminal Code* (Canada). Finally, it objects to the Act on the grounds that it puts doctors at risk of violating the *Criminal Code* and the medical profession's own code of ethics and conduct.

The first of these challenges echoes the legal confrontation between Nova Scotia and Morgentaler,[19] which developed following Nova Scotia's attempt to regulate access to abortion despite the federal decision to decriminalize abortion. In both cases, the provincial government established health care laws that could be interpreted as having duplicated or encroached upon federal criminal law. However, despite this similarity, there is an important distinction between the cases. Where in the abortion case, the province was unable to produce evidence that they were genuinely engaging in a broad-scope health care regulation regime (and not simply restricting abortion for other non-health related motives such as morality), in the present case, there is substantial evidence, including Hansard, which establishes Quebec's intent to create legislation that is health care law in its pith and substance.

In sum, other Canadian jurisdictions (and indeed, the international community) will watch with interest to see the outcome of any challenges to the Quebec legislation.

[*Editors' note*: **Kathryn Walker** is a University of Toronto law student.]

1 [2013] S.C.J. No. 53, 2013 SCC 53.
2 *Rodriguez v. British Columbia (Attorney General)*, [1993] S.C.J. No. 94, [1993] 3 SCR 519.
3 *See* <http://lco-cdo.org/capacity-guardianship-discussion-paper.pdf>.
4 S.O. 1996, c. 2, Schedule A.
5 S.O. 1992, c. 30.
6 *Supra* note 1.
7 *Supra* note 36 at 4.
8 *Ibid.* at 5.
9 *Ibid.* at 119–120.
10 *Ibid.* at 9 and 126–130.
11 *Ibid.* at 200.
12 *Ibid*. (*e.g.*, see page 203).
13 *Ibid*. at 218–19.
14 *Ibid.* at 215–217.
15 *Ibid.* at 217–227.
16 RSQ c S-32.0001.
17 This Act will come into force on December 15, 2015.
18 *See* <http://alexschadenberg.blogspot.ca/2014/07/quebec-medical-aid-in-dying-court.html> (last accessed December 10, 2015).
19 *R. v. Morgentaler*, [1993] S.C.J. No. 95, [1993] 3 SCR 463.

• A YEAR IN THE LIFE POST-*RASOULI* •

Mary Jane Dykeman, DDO Health Law, Toronto

On October 18, 2013, the Supreme Court of Canada rendered a landmark decision in *Cuthbertson v. Rasouli*.[1] Chief Justice Beverley McLachlin, speaking for a 5:2 majority, stated that withdrawal of life support is considered "treatment" under the *Health Care Consent Act, 1996*[2] for which consent is required.

Hassan Rasouli underwent surgery in 2010 for a benign brain tumour and developed bacterial meningitis. He was initially determined to be in a persistent vegetative state and was later upgraded to "minimally conscious". Mr. Rasouli's wife and substitute decision-maker took her husband's physicians to court upon learning of their plan to withdraw the ventilator. Ultimately, the Supreme Court reinforced the Ontario Court of Appeal's characterization of a "treatment package" in that withdrawal of life-sustaining equipment such as a ventilator is "treatment" based on the broad manner in which the Act

defines that term (*i.e.*, anything done for a "health-related purpose").

Further, if a physician disagrees with a patient's substitute decision-maker, treatment may not be withdrawn, but the remedy is to apply to the Consent and Capacity Board, a specialized tribunal under the Act. A Form G application is brought by the physician who proposes the treatment (including withdrawal) to determine whether the substitute decision-maker is acting in the patient's best interests according to criteria under the Act.

By contrast, the dissenting opinion held that the Legislature did not intend for the Act to apply to the withdrawal of life support, nor is there a right to insist on continuation of treatment that is "futile, harmful, or contrary to professional medical standards of care". It identified the courts as the appropriate forum to resolve disputes.

End of life decisions (and the attendant consent, capacity and substitute decision-making that accompany these choices) are an increasingly challenging area of law. In this case, Mr. Rasouli's substitute decision-maker did not have the benefit of knowing her husband's prior capable wishes. At present, there are many initiatives underway in Canada, addressing health care consent and advance care planning. Take, for example, the work of the Canadian Medical Association, which as part of its 2014 report *End of Life Care: A National Dialogue*[3] conducted town hall meetings across the country between February and May 2014. CMA made findings about better palliative care and the renewed debate on medical aid in dying/assisted suicide (all of which are under scrutiny in the current legislative and judicial landscape). Its conclusions and a call to action also focused on discussing end-of-life wishes with family and loved ones, and preparation of advance directives. As part of its series on Legal Capacity, Decision-Making and Guardianship, in January 2014, the Law Commission of Ontario published *Health Care Consent and Advance Care Planning in Ontario*[4] by this author and the Advocacy Centre for the Elderly (J. Wahl, M.J. Dykeman and B. Gray), with commentary on the *Rasouli* case.

Out of published decisions of the Consent and Capacity Board, only five refer to *Rasouli*, and only two of these occurred after the Supreme Court rendered its decision in October 2014 (only one of the two was an end-of-life decision). Based on this unscientific evidence, it does not appear that *Rasouli* has specifically led to a marked increase in end-of-life cases at the Board.

It should be acknowledged that however contentious, some cases do not reach the Board but are resolved at the bedside. Hospital legal counsel are periodically asked for advice about withdrawal of treatment at end of life; the *Rasouli* case is now determinative. Somewhat more challenging are the questions around withholding of treatment, facts very different than in *Rasouli*. While arguably, a physician may simply choose not to propose a treatment he or she considers futile, withholding of treatment that has legitimately been part of a "plan of treatment" under the Act would appear to require consent.

A case before Ontario's Health Professions Appeal and Review Board ("HPARB")—*EGJW v. MGC*— has examined this issue.[5] In the *EGJW* case, counsel were offered an opportunity to comment on the applicability of *Rasouli* (paras. 33–35). There was disagreement on this issue, although HPARB accepted the argument that consent was required. In *EGJW,* the complaint centres on a physician's unilaterally changing what was referred to as a "Full Code" to a "Do Not Resuscitate" or "DNR Order" without first seeking consent of the patient's substitute decision-maker. Similar to the court in *Rasouli,* HPARB directed that despite the physician's views on medical futility, the available mechanism to deal with a plan of treatment already discussed with the substitute decision-maker is Consent and Capacity Board (para. 51).

And finally, how broadly has *Rasouli* been understood by the public? In a couple of cases, even where brain death has been clinically confirmed, substitute decision-makers have initially refused to accept this finding and have suggested that *Rasouli* applies to their situation and consent is required to withdraw life support. It is not. Mr. Rasouli was in a persistent vegetative state, and later, a minimally conscious state and was not declared brain dead. Such cases are likely rare, but it shows some awareness of the *Rasouli* case, albeit misapplied. They have resolved with further supports to the substitute decision-makers, and a forum in which to gently put forward the clinical evidence and state of the law post-*Rasouli.*

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1 [2013] S.C.J. No. 53, 2013 SCC 53.

2 S.O. 1996, c. 2, Schedule A.

3 <https://www.cma.ca/Assets/assets-library/document/en/advocacy/end-of-life-care-report-e.pdf>.

4 <http://www.lco-cdo.org/capacity-guardianship-commissioned-paper-ace-ddo.pdf>.

5 2014 CanLII 49888.

• OVER $400 MILLION ONTARIO PRIVACY BREACH CLASS ACTION: IMPLICATIONS FOR CANADIAN HEALTH CARE ORGANIZATIONS •

Priscilla Akyea, Toronto

Introduction

On June 24, 2014, two plaintiffs filed a class action lawsuit in a case involving the alleged sale of patient personal health information for damages of $412 million. The alleged privacy breaches are argued to have affected upward of 8,300 patients.[1]

On August 28, 2014, the Ontario hospital, alleged to be involved in this class action lawsuit, posted a public notice of a possible privacy breach in accordance with the *Personal Health Information Protection Act* [*PHIPA*].[2] According to the notice, two former employees of the Ontario hospital may have disclosed the information of patients who gave birth at Ontario hospital between July 9, 2009, and April 5, 2014.[3] Although not certain, the Ontario hospital suggested that the former employees used the patient index, an electronic list of identifying

information, to obtain patient contact information that was used to sell RESPs or disclose to an RESP company to solicit sales.[4] The patient index provided access to patient names, addresses, phone numbers, health card numbers, gender and date of birth.[5]

Class Action Lawsuit

The plaintiffs are suing for breach of contract, breach of warranty, breach of confidence, intrusion upon seclusion, negligence, and conspiracy in the sum of $332 million. The plaintiffs are also seeking exemplary, punitive and/or aggravated damages in the amount of $80 million in addition to other remedies.[6]

The plaintiffs allege that the Ontario hospital discovered the breaches as early as September 2013 and launched an internal investigation. It is further alleged that a two-month internal investigation was launched in March 2014 when the Ontario hospital discovered the involvement of another employee.[7] The Ontario hospital notified the patients, the Information and Privacy Commissioner and the Ontario Securities Commissioner.

More recently, an internal investigation revealed 6,150 additional breaches at the sister campus of the Ontario hospital, increasing the total number of the alleged privacy breaches to 14,450 patients.[8]

Implications for Canadian Health Care Organizations

Canadian health care organizations must take appropriate measures to ensure compliance with privacy legislation for the collection, use and disclosure of personal health information. In order to meet the standard of care, hospitals should

- establish policies governing the collection, use disclosure and security of personal health information;
- take reasonable steps to ensure that personal health information is not disclosed;
- supervise and monitor staff with respect to accessing patient information;
- implement proper computer programs and/or security systems to prevent privacy breaches;
- conduct proper and timely audits of the electronic medical records;
- inform staff of policies and procedures with respect to maintaining personal health information;
- train staff regarding legislative and regulatory requirements for patient information; and
- advise affected individuals of any privacy breaches in a timely manner.[9]

The Toronto Star reported that the Ontario hospital and its sister campus shared an electronic information system to which the two alleged to be responsible for the breach had access.[10] Added measures must be taken when health care organizations share data system networks, firewalls or other types of databases containing personal health information with another site, or with other health care organizations, which is also increasingly common. More recently, the Ontario Securities Commission has announced that it has charged one of the two staff members implicated in this breach".[11]

Conclusion

Data breaches are increasingly common in both the private and public sectors, and the health sector is no exception. It has been almost ten years since *PHIPA* came into force in Ontario on November 1, 2004. Over the past decade, the proliferation of electronic health records and shared systems has increased exponentially. While that poses opportunities for more seamless and coordinated care, it also raises the prospect of both inadvertent and malicious breaches. Health care organizations must heed the call to properly train their employees, professional staff, students, volunteers and researchers and to contractually bind their third-party vendors to best practices and legal requirements. No health care organization is immune to a breach, but due diligence upfront can set the tone for the organization and gives individual privacy and the security of personal health information the attention they require.

[*Editors' note:* **Priscilla Akyea**, RN, JD, is a Toronto health lawyer.]

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1 *Broutzas and Ware v. Rouge Valley Health System et al*., Court File No. CV-14-507026-00CP.

2 S.O. 2004, c. 3, Schedule A.

3 *See* <http://www.rougevalley.ca/public-disclosures> (last accessed December 5, 2014).

4 *Ibid*.

5 *Ibid*.

6 *Supra* note 1.

7 *Ibid*.

8 Joel Eastwood, "Rouge Valley Hospital Privacy Breach Expands to Affect 14,450 Patients", Toronto Star, August 27, 2014. In that article, it was also noted that in a somewhat related matter, Rouge Valley and five other hospitals were subject to a privacy breach involving disclosure of personal health information to a third-party photography services provider. <http://www.thestar.com/news/gta/2014/08/27/rouge_valley_hospital_privacy_breach_affects_6000_more_patients.html>.

9 Section 12 of *PHIPA* requires that a health information custodian give notice to an affected individual in the case of theft, loss or unauthorized access to the individual's record of personal health information.

10 Ibid.

11 <http://www.osc.gov.on.ca/en/NewsEvents_nr_20141124_shaida-bandali-charged.htm>.

• THE TIMES THEY ARE A-CHANGIN': NEW CONFLICT OF INTEREST PROVISIONS GOVERNING OPTOMETRISTS •

Lindsay Kantor, Torkin Manes LLP, Toronto

For years, opticians and optometrists have been advocating for greater flexibility with respect to their relationships with their counterparts on the other side of the glass. Unfortunately, their hands have historically been tied in this egard, primarily by the regulations governing optometrists.

After years of advocating, at long last, the new professional misconduct regulation governing optometrists came into effect on April 15, 2014.[1,2] While the College of Optometrists of Ontario has voiced its belief that this regulation heralds "modernized conflict-of-interest provisions",[3] these new provisions may not be as clear, or as far reaching, as both opticians and optometrists may have desired.

It is clear that the requirement that there be separate entrances between an optical dispensary and an optometry office no longer exist. This will certainly benefit both professions and the

public, since optometrists and opticians will be able to work together in a more collaborative way. This collaboration, however, is not without its limits. While opticians and optometrists working out of the same area will be able to share personnel for some purposes, such as the collection of fees, the optometrist must pay for the personnel's performance of these tasks. In addition, optometric records must be kept separate for custodianship purposes.

So if the physical walls between optometrists and opticians are starting to come down, what about the more invisible walls, such as those pertaining to financial arrangements? That's where the water gets a little more murky.

Many will be happy to know that the old regulation prohibiting optometrists from working "in association" with opticians no longer exists. An optometrist may now have an ownership interest in an optical dispensary located outside his or her office.[4] However, the new regulation expressly states that optometrists cannot "practice [their] profession in a working arrangement with another person". While there are express exceptions to this prohibition, an arrangement with an optician is not one of them.

Do not fret just yet! The new regulation goes on to say that there will be no conflict of interest (*i.e.*, an optometrist can practice in a working arrangement with another individual such as an optician) so long as the optometrist practises (1) as an independent contractor, and (2) pursuant to a written agreement.

This leads to the next obvious question: what does that written agreement need to say? Is it sufficient to expressly say that the optometrist is an independent contractor? No. The title assigned to the position, even if reduced to writing, does not matter in the slightest. Rather, the new regulation sets out a list of provisions that must be included in the agreement (and followed) including, but not limited to the following:

- The optometrist must control whom he or she may accept as a patient.
- The optometrist must set the fee charged or collected in respect of any professional service.
- The optometrist, and his or her staff, must have access to the premises where he or she practises (and where the practice's books and records are kept) at any time—day or night.

If the required provisions are not reduced to writing and/or are not followed, the optometrist will be in breach of the new regulation and could be charged with having committed professional misconduct.

The same does not apply the other way around (*i.e.*, an optometrist can now hire an optician to be his or her employee). It seems then, that what is good for the goose is not necessarily good for the gander after all.

Before leaving you, just to muddy the waters a little more, I will simply remind you that the regulations to the *Opticianry Act, 1991*[5] also stipulate that it is an act of professional misconduct for an optician to practise while in a conflict of interest. We have yet to see how the College of Opticians will interpret this provision

in light of the recent changes to the optometry conflict of interest provisions.

Confused? Frustrated? You are not alone. While the new regulation certainly assists in modernizing the practices of optometry and opticianry, it is still a far cry from the equal playing field for which opticians have been advocating for years. The new regulation makes it clear that there are many nuances to the ever-expanding realm of optometrist/optician working arrangements and that a failure to strictly abide by these nuances could lead to trouble for all parties involved. Make sure your working arrangements with other professionals are properly executed. Do your research, take your time, and seek legal advice where appropriate.

[*Editor's note*: A version of this article was originally published by *Focus*—Ontario Opticians Association Newsletter.

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[1] <http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_940119_e.htm>.

[2] This article is not meant to be a comprehensive review of the new regulation.

[3] <http://www.collegeoptom.on.ca/index.php/resources/news/244-guidelines-for-the-new-professional-misconduct-regulation>.

[4] So long as that interest is disclosed to patients who are referred to that dispensary.

[5] S.O. 1991, c. 34.

• MORE ISN'T ALWAYS BETTER: WHAT CAN HAPPEN WHEN EMPLOYERS RECEIVE TOO MUCH MEDICAL INFORMATION •

Christine Thomlinson, Rubin Thomlinson LLP, Toronto

In a case recently reported by the CBC, a Yellowknife woman said that she was distraught after a detailed report about her mental health was released to her employer.[1] The woman has a mental illness and agreed to a psychiatric assessment because she was seeking various workplace accommodations. She said that she never agreed that the full report could be released and she was shocked to learn that her employer had read a report that included information about her drinking habit, sexual past, mental health diagnosis and feelings about her employer.

The employee, in this case, believed that her work environment with the NWT government was harmful to her health and that her employer was ignoring suggestions from her doctor on how to accommodate her illness. The employee's own doctor actually suggested the psychiatric assessment as a way that she might strengthen her case for her desired accommodation. She expected that the psychiatrist would simply send a letter to her employer after the assessment, confirming her need for accommodation. The employee says that she never agreed that the full report could be sent to her employer and says that she even received an assurance that this would not be done.

The woman's doctor disagreed, saying that the employee gave verbal consent. The employee said that even if she had given this consent

(which she denies), she would have expected a physician to caution her against doing so. Six months after the report was received by the employer, the woman was laid off by the NWT government, and she continues to believe that the contents of the report (*i.e.*, her private and sensitive personal and medical information) influenced this decision.

The facts of this case are probably shocking to most, and so it likely comes as no surprise that we would say there are definite lessons to be learned from this employee's experience.

1. Ask specifically where medical assessment results will be sent and in what form.

This advice applies to both employees and employers. If an employee attends a medical appointment on their own initiative with the intent of obtaining medical advice to provide to their employer, they should ask about the exact nature of the information that will be produced from the assessment, how that information will be presented (in report or summary form) and to whom. If the employee has sought out the assessment, it might seem logical that the report would be provided directly to the employee who can then provide it to their employer, but this may not always be the case, and so it's worth confirming.

Employers should be equally vigilant if they are requesting that an employee attend for an independent medical examination of some kind. Instead of requesting a generic report on the outcome of the assessment, employers would be wise to consider the exact nature of the information they are seeking and to request that only this be provided. One effective way to do this is through the preparation of a questionnaire, often compiled with the assistance of legal counsel so that legal advice can be sought about the appropriateness of the desired information. It would seem far easier for a physician to answer an employer's direct and targeted questions rather than to prepare a lengthy, generic report on the outcome of the appointment. The problem with employers receiving excess information about an employee's medical condition is that subsequent employment decisions relating to the employee may be perceived as being tied to the receipt of the information, as was the case here with the Yellowknife employee.

2. Beware the verbal consent.

It seems astounding that, in today's age of privacy hypersensitivity, any physician would rely on a patient's verbal consent as a basis for releasing confidential medical information to an employer. Lawyers will always tell you that the problem with any agreement reached verbally is that, later on, when there's a problem, there may not be consensus about the nature of that agreement. Inasmuch as the physician seems to have said in this case that the woman's consent was given verbally, she clearly disputed this later, and, in the absence of a written authorization form, it may be impossible for the physician to establish that consent was actually given. It's always important to get it in writing.

3. Recognize that sometimes medical assessments are a necessary part of the accommodation process.

I was extremely surprised to read that Dr. Chris Summerville, a board member for the Mental

Health Commission of Canada and the Chair of the Manitoba Schizophrenia Society, was quoted as saying in relation to this case, "A person should not have to go and get a psychiatric report to demonstrate that they need workplace accommodation".[2] He goes on to say, and I don't disagree, that "accommodation is necessary for many people in the workplace, including people with mental illness".[3] However, I do disagree that employees should never be asked to get psychiatric assessments as part of the accommodation process.

First of all, human rights jurisprudence makes clear that accommodation is a "two-way street" and that both employees and employers need to participate in this process of identifying and providing appropriate accommodation in the workplace. To expect an employer to do so without adequate access to relevant medical information, and especially in the case of mental illness, is to set an employee up for failure and possible exacerbation of their medical condition.

Sometimes, the only way the employer can truly understand the employee's medical needs is to request information from a medical assessment, and, in the case of mental illness, this could very well be a psychiatric assessment. When we work with our employer clients, we find them overwhelmingly supportive of their employees' accommodation rights and willing to work constructively to explore accommodation options. However, employers cannot and should not operate in a vacuum. Very often, specialized medical information is necessary to inform the process of considering reasonable accommodation that meets an employee's medical needs and restrictions.

[*Editor's note*: **Christine Thomlinson** is co-founder and co-managing Partner of Rubin Thomlinson LLP, a boutique law firm specializing in employment law, human rights and workplace investigation services.]

1 E. Brohman, "Yellowknife Woman's Psychiatric Report Lands in Employer's Hands", *CBC News*, October 21, 2014, <www.cbc.ca/news/canada/north/yellowknife-woman-s-psychiatric-report-lands-in-employer-s-hands-1.2806853>.

2 *Ibid.*

3 *Ibid.*

• MATH CAN KILL •

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Background

On August 22, 2006, Denise Marie Melanson died of a fatal chemotherapy overdose. Melanson was 43 years old and began receiving chemotherapy and radiation for treatment of nasopharyngeal cancer in May 2006. She was being treated at the Cross Care Cancer Institute, Edmonton, Canada, and while Melanson's cancer was advanced, the prescribed treatment was being given with the expectation of effectiveness.

Melanson was to start three cycles of chemotherapy, using two drugs, cisplatin and fluorouracil. On July 31, 2006, Melanson arrived at the medical day care unit and was given the appropriate dose of cisplatin. What followed was a fatal miscalculation. Melanson received the dose

of fluorouracil, which was supposed to be delivered over the next four days. Instructions were given for her to return for infusion pump disconnection after the aforementioned time period, and she was discharged from the clinic and returned home for the duration of her treatment regimen.

After a few hours, Melanson noticed that the infusion pump started beeping, indicating that the infusion was complete. Upon discovering that the fluorouracil bag was empty, she immediately headed to the hospital. Upon examination, it was discovered that the infusion pump had been programmed at an incorrect rate. Four days' worth of fluorouracil, a drug used to treat tumours, had been incorrectly administered to Melanson in just four hours. Melanson's health rapidly deteriorated culminating in multi-organ system failure. Three weeks after the lethal initial overdose, life support was removed and Melanson was pronounced dead due to "sequelae of fluorouracil toxicity", leaving behind her husband and children.

How Did It Happen?

Infusion pumps deliver fluid at a designated rate. A nurse receives orders from a physician for a specific drug or drugs along with the intended dosage individualized for each patient. The nurse then sets in the infusion rate on the pump. While scenarios vary slightly according to policy and procedure at institutions, there are standard protocols for the administration of chemotherapy.

Melanson did not die as a result of the cancer she had been diagnosed with six months prior but from the miscalculation of the infusion rate of her chemotherapy medication. The error was so egregious that two inquiries were made, one of which included an inquiry by the Alberta Cancer Board. While the cause of Melanson's chemotherapy overdose was determined to be tri-fold and consisting of (1) fluorouracil overdose, (2) design of the chemotherapy protocol, and (3) inability to mitigate harm from the fluorouracil and cisplatin, one finding relating to the overdosing of Melanson is particularly unsettling: "Nursing staff were required to complete a complex calculation involving multiple dimensions at the bedside (specifically, dose in milligrams divided by days, divided by hours, divided by concentration) to determine the infusion rate for administration".

What is striking to me about this finding is that this type of calculation is taught in nursing school. It is one of the few mathematical requirements I recall being impressed upon me, and its application continues to be widespread to this day. The dosage of drug ordered for Melanson was 5,250 mg, diluted in 105 mL of fluid to be administered intravenously over four days. This calculation requires the total amount (105 mL) be divided over 24 hours per day over four days. The primary nurse calculated the medication pump to be infused at a rate of 28.8 mL per hour, exactly 24 times the ordered dosage of 1.2 mL/hour over four days. In other words, the nurse was supposed to divide the 28.8 figure by 24 and produce an hourly dosage rate.

Neither the first nurse who calculated the dosage rate nor the second nurse who checked the

calculation discovered the fatal error. What ought to resonate with nurses and risk managers alike is that indeed a second nurse "checked" the first nurse's calculations or at least she tried to "but couldn't find a calculator and ended up doing the mathematical equation mentally and on a piece of paper. She didn't catch the mistake". Neither nurse "twigged" to the fact that 105 mL of fluid infused at 28.8 mL/hour could not possibly be a correct dosage intended to last over four days, as had been ordered.

Conclusion

Could miscalculation warrant more attention in health care practitioner training to prevent further fatal outcomes for patients and their families? The fact that the primary nurse's calculations were "double-checked" becomes irrelevant if neither nurse can perform the necessary calculation to administer the drug as required. When the other contributing matters are factored in, the question is still begged: if the two nurses were not sure of the correctness of their calculation and were not familiar with this drug or the dosage prescribed, did it not became incumbent upon them, as prudent practitioners, to further check with knowledgeable parties? In particular, large hospitals generally provide 24-hour resource support (from pharmacy and nursing supervisors).

According to the Institute for Safe Medication Practices Canada,[1] seven similar fatalities have been reported since 2000. This is, possibly, just the tip of the proverbial iceberg if you expand the scope of medications to include all types of oral and intravenous pharmaceuticals administered in hospitals in the course of treating all patients. And that number might still be dwarfed were the number of undocumented or unreported medication errors to be added to this mix.

So how then can health care practitioners mitigate such risk to patients? The lessons in the Melanson case appear to be two-fold. First, the risk reduction via double-checking is most substantial when the verification is done completely independently—nothing less will do. And second, even with more and more advanced technology, there is still no substitute for basic mathematical skills among health care practitioners. While life presents us with circumstances we sometimes have no control over, losing a loved one by virtue of a health care practitioner's miscalculation should not be in the equation.

[*Editors' note:* **Sondra Rutman** has been President of Legal Nurse Atlantic Inc., a consulting firm that assists both plaintiff and defense lawyers by providing reports for medically related files across Canada. With more than 25 years of broadly based nursing experience, she assesses and evaluates cases for merit and provides expert opinion based on comprehensive research of applicable standards of care. Sondra can be reached at <srutman@eastlink.ca>.]

[1] *The Canadian Journal of Hospital Pharmacy* 60, no. 4 (September 2007).

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