CHAPTER 6

Self-Regulation as a Means of Regulating Privately Financed Medicare: What Can We Learn from the Fertility Sector?

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The *Cambie* case, where the plaintiffs are seeking to overturn key sections of the *Medicare Protection Act*, could have a profound impact on Canada's universal health care system and encourage the growth of a second tier of privately financed health care in Canada.[1] As the possibility of greater privately financed health services looms large, this chapter asks what lessons can be learned from the regulation of the fertility sector—one of the few private for-profit health care sectors in Canada that is primarily paid for by private finance (private insurance and out-of-pocket payments) and delivered by for-profit facilities. This chapter examines how the professionals who provide fertility care, as well as the facilities where these services are provided, are regulated, and compares how the regulation of these services differ from publicly funded health care services.[2] This analysis demonstrates that, for the most part, two principal regulatory tools govern this sector: self-regulation (which is a form of internal regulation) through

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1 *Cambie Surgeries v Medical Services Commission of British Columbia* (28 January 2009), Vancouver, British Columbia S-090663 (statement of claim).

2 For the purpose of this chapter, I focus on the professionals and clinics that offer in vitro fertilization, intracytoplasmic sperm injection, intrauterine insemination, and oocyte cryopreservation (whether for medical or non-medical reasons).

physicians' regulatory colleges, and clinical-practice guidelines (CPGs). External regulation by government plays a relatively minor role. Indeed, in Canada, despite the risks associated with various fertility procedures like in vitro fertilization (IVF), provincial governments have only sought to directly regulate the fertility sector where they have extended public funding to assisted reproduction, as occurred in Quebec.[3]

Fertility services are, for the most part, delivered in private for-profit clinics in Canada.[4] Currently, there are thirty-six clinics offering fertility services across Canada; almost half located in Ontario.[5] These clinics offer a number of privately financed services, such as IVF, intracytoplasmic sperm injection (ICSI), as well as sperm and egg freezing. IVF is the most common service that patients pay for out of pocket and, as such, provides a good indication of the marked increase in demand for fertility services. In 2010, there were twenty-eight clinics reporting 18,454 cycles of IVF.[6] By 2017, the number of cycles of IVF performed by Canadian clinics had soared to 32,359.[7] That is an increase of 75 per cent over seven years. Although most fertility services are paid for out of pocket, there has been some limited public coverage for IVF in Quebec[8] and Ontario.[9] Public funding for IVF has been spurred in

3 Esme Kamphius, "Are we overusing IVF?" (2014) 348 British Medical J 15.

4 There are a few exceptions, such as the Mount Sinai Fertility Centre in Toronto.

5 Here is a breakdown from 2018: British Columbia (5), Alberta (2), Saskatchewan (2), Manitoba (1), Ontario (23; notably, there is one centre that has four offices, which have been counted as individual clinics in the total), Quebec (8), New Brunswick (1), and Nova Scotia (1).

6 Joanne Gunby, "Assisted reproductive technologies (ART) in Canada: 2010 results from the Canadian ART Register," online: *Canadian Fertility and Andrology Society* <cfas.ca/_Library/_documents/CARTR_2010.pdf>.

7 "Canadian Assisted Reproductive Technologies Register Plus (CARTR Plus)" (Report Presented at the 64th Annual Meeting of the Canadian Fertility and Andrology Society, Montreal, 13–15 September 2018), online: *Canadian Fertility and Andrology Society* <https://cfas.ca/_Library/cartr_annual_reports/CFAS-CARTR-Plus-presentation-Sept-2018-FINAL-for-CFAS-website.pdf>.

8 François Bissonnette et al, "Working to eliminate multiple pregnancies: a success story in Québec" (2011) 23 Repro BioMed Online 500.

9 Ontario introduced a funding program for IVF treatments in January 2016. Under the program, the province funds one IVF cycle per eligible patient per lifetime. One funded cycle of IVF includes the egg retrieval (as multiple eggs may be retrieved) and single-embryo transfer for the resulting embryos. There are some exclusions: women who are over the age of forty-three, and women

large part by the high incidence of multiple births (twins or triplets) resulting from the transfer of more than one embryo per IVF cycle (multiple-embryo transfer). Patients who pay privately often opt for multiple-embryo transfer as they assume it will increase the chance of pregnancy. As discussed in greater detail below, there are significant health risks for women carrying a multiple pregnancy and increased negative health outcomes for twins and triplets.[10] These poor health outcomes for pregnant women and the resulting children result in significant costs for the public health care system. To reduce these costs, provincial governments tied public funding of IVF to a single-embryo transfer policy. Studies have demonstrated that such an approach is cost effective.[11] This aspect of the program has been a success—multiple births drop dramatically under a mandatory single-embryo transfer policy.[12] Importantly, no such restriction has been imposed on individuals who are paying out of pocket for IVF, although the risks are the same.

An analysis of the legal frameworks governing the private for-profit fertility sector demonstrates that although internal regulation plays an important role, it is an insufficient regulatory tool to protect and promote patient health and safety. CPGs are generally less effective at bringing about change than external standards. Patients have fewer options for bringing complaints about providers and facilities, and these processes offer less effective remedies; and data collection, which is a key tool for promoting patient safety, is less rigorous. By contrast, the statutory frameworks that govern publicly funded services offer a range of more rigorous regulatory tools, such as enforceable clinical standards, various external oversight mechanisms, and mandatory data collection

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who wish to freeze their eggs for non-medical reasons (also known as social egg freezing): Ontario Ministry of Health and Long-Term Care, "Ontario's Fertility Program," online: <www.health.gov.on.ca>. Notably, there is a program cap of 5,000 cycles per year. See also Tamas Gotz & Claire Jones, "Prioritization of Patients for Publicly Funded IVF in Ontario: A Survey of Fertility Centres" (2017) 39:3 JOGC 138.

10 Jocelynn L Cook et al, "Assisted Reproductive Technology-Related Multiple Births: Canada in an International Context" (2011) 33: 2 J Obstetrics & Gynaecology Canada 159.

11 Bissonnette, *supra* note 9. See also W Ombelet, "The Twin Epidemic in Infertility Care—Why do we Persist in Transferring Too Many Embryos?" (2016) 8:4 Facts Views Vis Obgyn 189.

12 Bissonnette, *supra* note 9.

and disclosure. In doing so, government regulation plays a critical role in ensuring patients receive safe, high-quality care. Thus, the story of how the fertility sector is regulated in Canada serves as a cautionary tale should a second tier of privately financed health care take hold in Canada.

In section 1, I offer a brief introduction to the different forms of health care regulation. In section 2, I describe the regulation of the fertility sector in Quebec, Ontario, British Columbia, and Alberta since they are home to the majority of fertility clinics and offer the majority of fertility procedures in Canada.[13] Self-regulation and CPGs are the primary tools for regulating the fertility sector, although there is greater government regulation where fertility services are funded by government. In section 3, I examine three examples to illustrate how self-regulation in the fertility sector has fallen short, as concerns single-embryo transfer, complaints about care, and health-data collection. These examples illustrate that the regulation of the private for-profit fertility sector, which occurs primarily through self-regulation and CPGs, is less rigorous and effective than external regulations, especially provincial legal frameworks governing publicly funded health care services. This analysis also indicates that governments appear to be more reluctant to regulate health care services that they do not fund directly, and failure to do so may put patients at greater risk. In my view, the provincial governments should not leave regulation primarily to health care professionals but should take an active role in regulating all health care services, regardless of who is funding those services. To be clear, I do not support the claim in *Cambie*, nor do I support increasing privately financed health care in Canada. However, if Canada is to make a turn toward more privately financed medical services, provincial governments must carefully consider how to regulate this sector to ensure the quality of these services. Anything less may jeopardize the health and safety of Canadian patients.

13 "IVF Clinics" (last visited 4 October 2019), online: *Canadian Fertility & Andrology Society* <https://cfas.ca/ivf-clinics.html>. There are thirty-eight IVF clinics in Quebec, Ontario, British Columbia, and Alberta.

Health Care Regulation

A range of regulatory tools governing health care professionals and institutions may be employed to promote safe, high-quality, patient-centred health care.[14] As Judith Healy explains, regulation is

> about steering and channeling as well as enforcement, and may be undertaken by state or non-state actors, whether external or internal to the field being regulated. Regulators steer through the use of supports (rewards) and sanctions (punishments).[15]

Generally speaking, health care regulation focuses on two domains: health care professionals and health care facilities or institutions.[16] Health care professionals include members of the health professions, such as physicians, nurses, physiotherapists, and others. By contrast, health care institutions are the facilities where health care is provided, such as hospitals and clinics. Health care institutions are, however, becoming increasingly diverse.[17] In this section, I offer a brief description of how each of these domains are subject to different forms of internal and external regulation.

Internal Regulation

Internal regulation, regulation which flows from members of the health profession, may take different forms, and commonly includes

14 There are two modes of regulation: "input" regulation, which includes measures that control who can practice a particular profession and includes licensure, certification, and registration; and "output" regulation, which is more reactive and includes professional discipline, civil liability, and accountability mechanisms such as the Canadian Institute for Health Information: Amy Zarzeczny, "The Role of Regulation In Health Care—Professional and Institutional Oversight" in Joanna Erdman, Vanessa Gruben & Erin Nelson, eds, *Canadian Health Law and Policy,* 5th ed (Toronto: LexisNexis, 2017) at 161. This chapter focuses on output regulation.

15 Judith Healy, "Regulating the Health Professions: Protecting Professionals or Protecting Patients?" in Stephanie D Short & Fiona McDonald, eds, *Health Workforce Governance: Improved Access, Good Regulatory Practice, Safer Patients* (Burlington, VT: Ashgate, 2012) 205 at 205.

16 Peter D Jacobson, "Regulating Health Care: From Self-Regulation to Self-Regulation?" (2001) 26:5 J Health Pol Pol'y & L 1165 at 1166. See generally Zarzeczny, *supra* note 15.

17 See generally John J Morris & Cynthia D Clarke, *Law for Canadian Health Care Administrators*, 2nd ed (Markham, ON: LexisNexis, 2011).

self-regulation and the issuance of CPGs by medical associations and professionals.[18]

In Canada, self-regulation plays an important role in both the public and private health care domains. Self-regulation, where the state confers on health care professionals the authority to regulate members of their own profession, is an important regulatory mechanism for all forms of health care. [19] Physicians, whether they practice in the publicly funded system or provide privately financed health care services, are subject to the regulatory oversight of their respective regulatory colleges. The overarching purpose of self-regulation is to promote patient health and safety, and, in many provinces, to ensure that professionals are regulated and coordinated in the public interest.[20] To achieve this objective, the regulatory colleges exercise a number of functions, including licensing members, setting practice standards, establishing practice guidelines, providing training and continuing education to members, and remediating or disciplining members who do not meet the standards of the profession.[21]

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18 Fleur Beaupert et al, "Regulating Healthcare Complaints: A Literature Review" 27:6 (2014) Intl J Health Care Quality Assurance 505.

19 Tracey Epps, "Regulation of Health Care Professionals" in Jocelyn Downie, Timothy Caulfield & Colleen M Flood, eds, *Canadian Health Law and Policy*, 4th ed (Toronto: Lexis Nexis, 2011) 75 at 83. See generally Margot Priest, "The Privatization of Regulation: Five Models of Self-Regulation" (1997–1998) 29:2 Ottawa L Rev 233; Tracey L Adams, "Regulating Professions in Canada: Interprovincial Differences Across Five Provinces" (2009) 43:3 J Can Stud 194; Donald M Berwick, "Postgraduate Education of Physicians: Professional Self-regulation and External Accountability" (2015) 313:18 J American Medical Assoc 1803.

20 Glenn Regehr & Kevin Eva, "Self-assessment, Self-direction, and the Self-regulating Professional" (2006) 449 Clinical Orthopaedics and Related Research 34; Roger Collier, "Professionalism: The Privilege and Burden of Self-regulation" (2012) 184:14 CMAJ 1559. For example, in Ontario, the *Regulated Health Professions Act*, 1991, SO 1991, c 18, s 3 provides that "[i]t is the duty of the Minister to ensure that the health professions are regulated and co-ordinated in the public interests."

21 David Orentlicher, "The Role of Professional Self-Regulation" in Timothy S Jost, ed, *Regulation of the Healthcare Professions* (Chicago: Health Administration Press, 1997) 129 at 130; Sylvia R Cruess & Richard L Cruess, "The Medical Profession and Self-Regulation: A Current Challenge" (2005) 7 Ethics J of the American Medical Assoc at 1.

The right and obligation of self-regulation can be traced back to the nineteenth century and is rooted in the social contract.[22] As Cruess and Cruess explain: "In return for a physician's commitment to altruistic service, a guarantee of professional competence, the demonstration of morality and integrity in their activities, and their agreement to address issues of social concern, society grants to both individual physicians and the profession considerable autonomy in practice, status in the community, financial rewards, and the privilege of self-regulation."[23]

Several justifications are invoked in support of professional self-regulation. First, self-regulation reflects the strong need for professional autonomy.[24] Second, professionals have the expertise and technical knowledge needed to set standards for medical practice, and to determine whether those standards have been met.[25] Advocates of professional regulation maintain that these standards will be more readily accepted by professionals and the public where they are developed by experts, as opposed to external bodies who do not have the same level of expertise.[26] Third, self-regulation is said to avoid the politicization of medical standards and keeps those standards independent from political processes.[27] Finally, some argue that professionals should be permitted to resolve problems within the profession through self-regulatory mechanisms before resorting to external processes because it is more efficient to do so.[28]

But self-regulation gives rise to several important concerns. Many relate to the oversight and complaints functions—the processes that ensure that professionals meet the standards established by the colleges.[29] These concerns include that complaints must generally be brought by patients;[30] there is no compensation for patient

22 Mary Dixon-Woods, Karen Yeung & Charles L Bosk, "Why is UK Medicine no Longer a Self-regulating Professional? The Role of Scandals Involving 'Bad Apple' Doctors" (2011) 73:10 Social Science & Medicine 1452.

23 Cruess, *supra* note 22 at 1.

24 Orentlicher, *supra* note 22 at 130.

25 *Ibid* at 131.

26 *Ibid* at 131–132; Berwick, *supra* note 20.

27 Orentlicher, *supra* note 22 at 132. He refers to the government's decision to delay the implementation on fetal-tissue transplantation based on political ideologies.

28 *Ibid* at 132–133.

29 Zarzeczny, *supra* note 15 at 172.

30 In certain provinces, colleges can initiate inspections of physicians; e.g., in Ontario, *Regulated Health Professions Act*, *supra* note 21 s 75.

complainants; the complaints processes may not be well known to patients, and may be difficult to navigate; the remedial dispositions or penalties are often considered to be inappropriate or not sufficiently severe; and, the colleges do not provide enough information to the public about professionals who have received an educational or remedial disposition.[31] Further, the regulatory colleges tend to be quite slow in introducing and implementing policy changes.[32] As a result, there is a perception that dispositions are too lenient and professionals are favouring or protecting their own members.[33] Further undermining the public confidence in self-regulation are high-profile media reports of "bad apples," health care professionals who have engaged in egregious misconduct or whose care falls well below the standard of care.[34] These concerns may lead the public to believe that self-regulation is about protecting professionals rather than patients.

The fertility sector increasingly relies on a second form of internal regulation: CPGs. The Canadian Fertility and Andrology Society (CFAS), the professional society that represents fertility practitioners and other allied professionals, is responsible for creating CPGs for Canadian fertility clinicians.[35] Clinical guidelines are intended to promote high-quality, consistent, evidence-based practice.[36] There

31 Cruess, *supra* note 22 at 1; Colleen Flood & Bryan Thomas, "Regulatory Failure: The Case of the Private-for-Profit IVF Sector" in Trudo Lemmens et al, eds, *Regulating Creation: The Law, Ethics and Policy of Assisted Human Reproduction* (Toronto: UTP, 2017) 359 at 369. For criticisms about self-regulation, see generally Fiona McDonald, "Challenging the Regulatory Trinity: Global Trends in Health Professional Regulation" in Fiona McDonald & Stephanie D Short, eds, *Health Workforce Governance: Improved Access, Good Regulatory Practice, Safer Patients* (London: Routledge, 2012) 97.

32 Flood, Thomas & Harrison-Wilson observed that it took several years for the College of Physicians and Surgeons to implement reforms that would provide more rigorous oversight of cosmetic-surgery clinics following the death of Krista Stryland, who died after suffering complications from a liposuction procedure: Colleen Flood, Bryan Thomas & Leigh Harrison-Wilson, "Cosmetic Surgery Regulation and Regulation Enforcement in Ontario" (2010) 36 Queen's L J 31.

33 Cruess, *supra* note 22 at 1.

34 Dixon-Woods, s*upra* note 23 at 1452.

35 For a description of the CFAS, see Canadian Fertility & Andrology Society, online: <https://cfas.ca>.

36 Dylan Kozlick, "Clinical Practice Guidelines and the Legal Standard of Care: Warnings, Predictions, and Interdisciplinary Encounters" (2011) 19 Health LJ 125 at 131. CPGs may be used by a court in establishing the standard of care

is, however, some question about whether CPGs do indeed achieve this goal. First, a CPG may reflect biased views, where members have relationships with industry or institutional affiliations that raise a conflict of interest.[37] There are also concerns about the extent to which health care professionals follow CPGs. Some argue that developing and disseminating CPGs does not, on its own, change physician behaviour.[38] Since they are not binding per se, physicians may disregard these guidelines because they do not agree with them or because of external factors, such as lack of time for implementation.[39]

External Regulation

External authorities, such as governments or private organizations, play a critical role in the regulation of health professionals and facilities. Indeed, as Beaupart notes, external regulation of health care professionals by provincial governments is on the rise.[40] In Canada, one of the most important sources of external regulation is the provincial government. Each province has passed legislation governing various aspects of health care, such as legislation governing public hospitals or non-hospital facilities.[41] For example, under Ontario's *Public Hospitals Act*, the minister of health may appoint an inspector to conduct a review of a hospital, which may include an audit of all or part of the accounts, records, and other affairs of the hospital.[42] Among the act's enforcement provisions is the minister's power to

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owed to the patient. This is one of the four elements that must be established in order to succeed in a negligence claim: Bernard Dickens, "Medical Negligence" in Jocelyn Downie, Timothy Caulfield & Colleen M Flood, eds, *Canadian Health Law and Policy*, 4th ed (Toronto: Lexis Nexis, 2011) 83 at 117.

37 Indeed, most recently, it was revealed that the opioid guidelines endorsed by Health Canada were drafted by a group of experts who had multiple conflicts of interest with industry: Kelly Crowe, "Opioid conflict-of-interest controversy reveals extent of big pharma's ties to doctors," *CBC News* (19 May 2017) online: <https://www.cbc.ca/news/health/opioid-pain-philpott-mcmaster-university-purdue-pharma-drug-industry-conflict-1.4121956>.

38 Orentlicher, *supra* note 22 at 138.

39 Brent Graham, "Clinical Practice Guidelines: What Are They and How Should They Be Disseminated?" (2014) 30:3 Hand Clinics 361 at 362–363.

40 Fleur Beaupart et al, "Regulating Healthcare Complaints: A Literature Review" (2014) 27:6 Intl J Health Care 505.

41 John J Morris & Cynthia D Clarke, *Law for Canadian Health Care Administrators*, 2nd ed (Markham, ON: LexisNexis, 2011) at 2.

42 *Public Hospitals Act*, RSO 1990, c P40, s 18.

suspend or the lieutenant-governor's power to revoke a hospital's approval where it is in the public interest.[43]

In addition, private organizations may play a regulatory role; for example, by accrediting professionals or facilities. Accreditation may have different meanings but is generally understood to be a process whereby an independent body issues a certificate indicating that a facility has met certain predetermined standards.[44] For example, Accreditation Canada is a private not-for-profit organization that develops accredited standards and programs for community and home care, health facilities, residential care, and others.[45] As such, accreditation is, in many respects, the privatization of regulation. Although it is beyond the scope of this chapter, Accreditation Canada has sought to fill some of the regulatory gaps in the delivery of fertility services in Canada by establishing three standards relevant to assisted reproduction, including clinical services, laboratory services, and work with third-party donors.[46]

Regulating the Fertility Sector in Canada

Both the funding and regulation of fertility services varies across Canada. While an exhaustive analysis is beyond the scope of this chapter, a brief look at the regulatory frameworks in Quebec, Ontario, Alberta, and British Columbia reveals two trends: first, that self-regulation and CPGs play a significant role in the regulation of the fertility sector, and second, provincial governments seek to more closely regulate the fertility sector when public funding is offered. For example, in Quebec there is extensive government regulation of assisted reproduction, although the Collège des médecins du

43 *Ibid*, at s 4(5).

44 Ontario, Health Quality Ontario, *Building an Integrated System for Quality Oversight in Ontario's Non-Hospital Medical Clinics* (Ontario: Health Quality Ontario, 2016) at 24.

45 See, e.g., Accreditation Canada, "About Accreditation Canada," online: <https://accreditation.ca/about/>.

46 Accreditation Canada, "Assisted Reproductive Technology (ART) Standards for Laboratory Services," online: <https://store.accreditation.ca/products/assisted-reproductive-technology-art-standards-for-laboratory-services>. While accreditation provides patients with an assurance that a clinic has met the requisite standards, there are some concerns about the effectiveness of accreditation as a regulatory tool, including that, since it is voluntary, a clinic that may be in breach of one of the standards may opt not to be accredited.

Québec (CMQ) continues to play a significant role in the regulation of the fertility sector. By contrast, in Ontario, Alberta, and British Columbia, the regulation of the fertility sector falls primarily to the regulatory colleges.

National Standards: The Canadian Fertility and Andrology Society

The regulation of fertility clinics in Canada falls primarily to the provinces, but some national standards do apply. Although the federal government had established a comprehensive regulatory framework, including a licensing and inspection scheme, to govern the fertility sector in the *Assisted Human Reproduction Act* in 2004, these provisions were declared unconstitutional by the Supreme Court of Canada in *Reference re Assisted Human Reproduction Act* in 2010.[47] The impugned provisions were subsequently repealed by Parliament in 2012.[48] As a result, the federal government's regulatory role vis-à-vis fertility clinics is quite limited.[49] While regulation of the health professionals and the clinics themselves now clearly falls largely to the provinces, most provincial governments, with the exception of Quebec, have not stepped in to fill the regulatory void left by the Supreme Court's decision.

In light of the relatively minimal role of the federal government, most national clinical standards are set by the CFAS.[50] The CFAS is a not-for-profit organization representing reproductive specialists, scientists, and allied health professionals in Canada.[51] The CFAS has

47 *Reference re Assisted Human Reproduction Act*, 2010 SCC 61, [2010] 3 SCR 457. The former provisions of the *AHRA* established a licensing and inspection regime: Glenn Rivard & Judy Hunter, *The Law of Assisted Human Reproduction* (Markham, ON: LexisNexis, 2005) at 187–200.

48 The federal government repealed the impugned provisions in 2012: *Jobs, Growth and Long-Term Prosperity Act*, SC 2012, c 19, s 713.

49 Section 10 of the *AHRA* was introduced in 2012 and its purpose is to reduce the health and safety risks arising from the use of third-party sperm and ova. Health Canada recently promulgated regulations under section 10, which were not in force at the time of writing: Safety of Sperm and Ova Regulations: SOR/2019–2192. These regulations impose certain requirements on fertility clinics and other entities in the fertility industry vis-à-vis the importation, storage, and transport of third-party gametes and embryos.

50 One exception is section 8, which sets out the requirements for consent to the reproductive use of a human embryo: *Assisted Human Reproduction Act*, SC 2004, c 2, s 8.

51 Canadian Fertility & Andrology Society, "About," Canadian Fertility & Andrology Society, online:

set a number of CPGs that establish national best practices for the fertility sector, including third-party reproduction, fertility preservation in reproductive-age women who are facing gonadotoxic treatments, the management of ovarian hyperstimulation syndrome, and the number of embryos transferred.[52] The CFAS is also responsible for the collection and disclosure of information about fertility services in Canada. The Canadian Assisted Reproductive Technologies Register, also known as CARTR Plus, has been collecting and reporting aggregate data on assisted-reproduction procedures, such as the number of IVF cycles and their outcome (e.g., pregnancy and multiple birth rate) in Canada since 2001.[53]

Quebec

In Canada, fertility services have been most rigorously regulated in Quebec since 2010 and the advent of public funding for IVF services. Fertility services such as IVF, ICSI, and others are offered in both hospital-based clinics as well as private clinics, both of which are subject to provincial regulation.[54] In 2010, Quebec's provincial legislature introduced a detailed provincial regulatory framework

<https://cfas.ca/about-cfas/>.

52 Canadian Fertility & Andrology Society, "CFAS Clinical Practice Guidelines," Canadian Fertility & Andrology Society, online: <https://cfas.ca/clinical-practice-guidelines/>.

53 While CARTR publishes aggregate data to the general public, "the CARTR outcome-improvement committee has confidential access to clinic-specific data, permitting them to identify and offer help to clinics whose results fall below the national standard." Bissonnette, *supra* note 9 at 501.

54 "There are three public, hospital-based centers for assisted reproduction in Québec, located at the McGill University Health Centre (CUSM), the Centre hospitalier de l'Université de Montréal (CHUM), and the Centre hospitalier universitaire Sainte-Justine. There are currently six centers for assisted reproduction in private facilities: the Clinique Procréa in Montréal and Québec City, the Clinique Ovo in Montréal, the Montreal Fertility Center, the OriginElle Fertility Clinic, and the Fertylis center in Laval. These are private centers under agreement (hereinafter private centers). There are also four regional public centers designated to provide some ART services closer to home to Quebecers living outside major urban centers: Centre de santé et de services sociaux (CSSS) de Chicoutimi, Centre hospitalier régional de Trois-Rivières, Centre hospitalier universitaire de Sherbrooke (CHUS), and Centre hospitalier universitaire de Québec (CHUQ)." Commissaire à la santé et au bien-être Québec, "Summary Advisory on Assisted Reproduction in Québec," (June 2014) online: <https://www.csbe.gouv.qc.ca/fileadmin/www/2014/Procreation_assistee/CSBE_PA_SummaryAdvisory_2014.pdf> at 13.

concurrently with its decision to include assisted reproduction as an insured service.[55] Although the funding program was dismantled at the end of 2015, the regulatory framework has largely remained in place. It would, of course, seem odd if the same services funded by the public system were in fact more lightly regulated if privately financed, given concerns that private for-profit provision may have incentives to skim on quality and safety in pursuit of the profit motive, discussed in more detail below. But that is indeed the Canadian approach now, outside of Quebec.

Quebec's *Act respecting clinical and research activities relating to assisted procreation* (*APA*) is thus an example of direct regulation referenced in part 1 above, and establishes a licensing regime for fertility clinics and practitioners "in order to ensure high-quality, safe, and ethical practices."[56] Under the *APA*, all assisted-reproduction procedures must be carried out in a licensed facility.[57] The *APA* imposes a range of requirements on clinics, including providing an annual report to the minister.[58]

While the provincial government is responsible for licensing,[59] inspection, and oversight,[60] it is the CMQ that sets the applicable clinical standards,[61] with a couple of notable exceptions. First, the *APA* requires physicians to ensure that the treatment chosen for a patient not pose a serious risk to the health of the person or the resulting child, and must document this in the patient record.[62] Further, the

55 The provincial government expanded the provincial health plan to fund up to three cycles of IVF with ovarian stimulation or up to six cycles of natural or modified natural cycle IVF either in hospital-based facilities or private facilities: *Act respecting clinical and research activities relating to assisted procreation*, CQLR c A-5.01, the *Regulation respecting clinical activities related to assisted procreation*, c A-4.01, r 1, and the *Regulation to amend the Regulation respecting the application of the Health Insurance Act*. For a discussion of the scheme, see Stefanie Carsley, "Funding In Vitro Fertilization: Exploring the Health and Justice Implications of Quebec's Policy" (2012) 20:3 Health L Rev 15; and Bissonnette, *supra* note 54 at 501.

56 *Act*, *supra* note 56 at s 1.

57 *Ibid*, ss 6 and 7.

58 *Ibid*, at Chapter III, Division I, s 14.

59 *Ibid*, at Chapter II, Division II, ss 15–22.

60 *Ibid*, at Chapter IV, ss 25–35.

61 *Ibid*, s 10.

62 *Ibid*, s 10.1.

APA mandates, with limited exceptions, that only one embryo may be transferred in an IVF cycle (referred to as single-embryo transfer).[63]

Although Quebec's regulatory scheme for IVF is quite rigorous, a number of regulatory gaps remain. As Flood and Thomas highlight, there does not seem to be a regular inspection mechanism in place to enforce the *APA*; the conditions or suspensions of licenses is at the discretion of the CMQ, and is, therefore, a matter of self-regulation, and the penalties for breaching the act "pale in comparison to the high prices charged for IVF services and the potential for profits."[64]

Ontario

In Ontario, greater regulation of the fertility sector followed the government's decision to introduce a funding program for assisted reproduction in December 2015. As discussed, the provincial government currently funds one stimulated cycle of IVF for every Ontarian.[65] Ontario has more than twenty private for-profit fertility clinics, which offer both publicly and privately funded fertility services.[66] Fertility services are also offered in one public hospital in Ontario, Mount Sinai in Toronto, and as such this clinic falls under the regulatory umbrella of public hospitals.

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63 *Ibid*, s 10.3. The *Act* provides: "In the course of an *in vitro* fertilization activity, only one embryo may be transferred into a woman. However, taking into account the quality of embryos, a physician may decide to transfer two embryos if the woman is thirty-seven years of age or over. The reasons for the decision must be entered into the woman's medical record." The *Act* also imposes age restrictions on who may access publicly funded IVF. There is some debate about whether this rationale is justified based on the evidence which is beyond the scope of this chapter. For a discussion about the legitimacy of these policies, see Flood & Thomas, *supra* note 32 at 376–377.

64 Flood & Thomas, *supra* note 32 at 372–373.

65 The Ontario government funds one stimulated cycle of IVF, which includes one at a time transfer for all viable embryos for every Ontarian. Women must be under the age of forty-three. Women who act as a surrogate are eligible for an additional stimulated cycle of IVF. The *Act* also imposes age restrictions on who may access publicly funded IVF. Government of Ontario, "Get fertility treatments" (9 May 2017), Government of Ontario, online: <https://www.ontario.ca/page/get-fertility-treatments>. There is some debate about whether this rationale is justified based on the evidence, which is beyond the scope of this chapter. For a discussion about the legitimacy of these policies, see Flood & Thomas, *supra* note 32 at 376–377.

66 Canadian Fertility & Andrology Society, "IVF Clinics," online: *CFAS* <cfas.ca/ivf-clinics.html>.

The most notable regulatory change that accompanied public funding was a single-embryo transfer requirement: all publicly funded cycles require one-at-a-time embryo transfers, with limited exceptions.[67] Notably, the province has not placed a restriction on IVF cycles that patients pay for out of pocket. For privately funded cycles, it is up to the treating physician to follow the CFAS's CPG on multiple-embryo transfers. Since there is no hard and fast rule, there is more discretion here for physicians to transfer multiple embryos.[68]

The Ontario government also called for a regulatory framework tailored to fertility services following the introduction of the funding program. This enhanced regulatory model will, however, continue to fall within the jurisdiction of the College of Physicians and Surgeons of Ontario (CPSO) through the Out-of-Hospitals Premises Inspection Program (OHPIP). The OHPIP is a program mandated by the province but designed and administered by the CPSO.[69] OHPIP establishes standards for premises where procedures are performed using anesthesia where the premises do not fall under another provincial regulatory oversight scheme.[70] These other regulatory schemes include the *Public Hospitals Act*,[71] the *Excellent Care for All Act* (*ECFAA*),[72] and the *Independent Health Facilities Act*[73]—the latter provides a licensing and oversight framework for facilities that offer diagnostic facilities that are funded by the Ministry of Health, and ambulatory-care facilities that provide surgical, therapeutic, and diagnostic procedures, such as dialysis and plastic surgery.[74]

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67 Government of Ontario, *supra* note 66.

68 Joint SOGC-CFAS Clinical Practice Guideline, "Elective Single Embryo Transfer Following In Vitro Fertilization" (2010) 241 J Obstetrics & Gynaecology Canada 363, online: <https://www.jogc.com/article/S1701-2163(16)34482-6/pdf>.

69 *Medicine Act*, *1991*, SO 1991, c 30.

70 *Ibid*.

71 *Public Hospitals Act*, RSO 1990, c P 40.

72 *Excellent Care for All Act*, *2010*, SO 2010, c 14. The *Act* applies to public hospitals in Ontario and requires hospitals to, among others things, establish quality committees that report on quality-related issues, create annual quality-improvement plans and make these available to the public, and establish a patient-relations process to address and improve the patient experience.

73 *Independent Health Facilities Act*, RSO 1990, c I 3. The *IHFA* program is administered by the Ministry of Health and Long-Term Care but the minister may request more frequent inspections of IHFs and IHFs are posted on the ministry website: Ontario, *supra* note 45 at 14.

74 Flood & Thomas, *supra* note 32.

Although fertility clinics are subject to OHPIP, its requirements are ill-suited to fertility clinics and practitioners delivering IVF, IUI, and ICSI, as well as gamete and embryo retrieval and storage, as the guidelines do not establish standards for these specialized procedures.[75]

Following the introduction of the public funding program, the Ontario government asked the CPSO to develop and implement a quality and inspection framework to specifically govern fertility services.[76] The proposed standards for fertility services apply to IVF, IUI, and fertility preservation for medical purposes (all of which are fully or partially funded services).[77] Notably, the standards do not apply to fertility preservation for non-medical purposes, or social egg freezing (e.g., where a woman freezes her eggs for later reproductive use).[78] It is unclear why this is the case as the health and safety risks for women are similar, regardless of the reason for oocyte preservation. Perhaps it is because the government does not consider social egg freezing to be a health service, although it begs the question why this would matter given the associated health risks.

The proposed OHPIP for fertility-services premises sets detailed standards for fertility services in Ontario.[79] The program contains comprehensive standards on a range of aspects of fertility practice, including the handling of human gametes and transfer of cryopreserved human cells and tissues for assisted reproduction;[80] physical

75 *Ibid.* Indeed, as the Health Quality Ontario panel explained: "OHP oversight enforcement is limited to particular procedures. Facilities failing to receive a pass rating could continue to perform procedures that do not require anaesthesia or sedation even if the cause of the failed inspection may affect the facility as a whole (e.g., substandard infection control practices)." Ontario, *supra* note 45 at 27.

76 The CPSO released a draft of the standards that would apply to fertility-services premises in September 2016: The College of Physicians & Surgeons of Ontario, *Applying the Out-of-Hospital Premises Inspection Program (OHPIP) Standards in Fertility Services Premises*, CPSO, 2016, online: <http://policyconsult.cpso.on.ca/wp-content/uploads/2016/11/Fertility-Services-Draft-Companion-OHPIP.pdf>.

77 The revised standards will amend section 44 of O Reg 114/94, Part XI.

78 O Reg 114/94, *ibid*, s 44(1)(b.1) includes (i) in vitro fertilization, (ii) intra uterine insemination; (iii) fertility preservation for medical purposes.

79 CPSO Draft Standards, *supra* note 77 at iii. The standards are broadly divided into two parts, IVF units and ovulation induction/intracervical insemination/intrauterine insemination units, to reflect the types of services offered by fertility-services premises.

80 *Ibid* at 2, 2.2.6.1.5ff.

standards for fertility premises (e.g., layout for the IVF laboratory and the procedure room);[81] nurse and laboratory staff qualifications;[82] clinical standards (e.g., taking a focused history and physical examination before the procedure[83] and including certain documents in the medical record);[84] and verification processes to ensure patients receive the correct gametes or embryos.[85] Further, OHPIP establishes "essential outcome measures" for monitoring quality of care, including reporting information regarding access (e.g., patient criteria for acceptance consultation, wait times for first appointments, and first fertility treatments), patient population (e.g., age and reason for treatment), and fertility preservation.[86] However, there is no requirement to submit this information to CARTR Plus or to any federal or provincial agency, nor is there any requirement to disclose it to the public.[87]

The proposed OHPIP for fertility-services premises is a significant improvement to the current regulation of Ontario's fertility sector. By creating a regime tailored to fertility services it better promotes the health and safety of fertility patients. Yet there are important gaps. Its principal weakness is that the standards are set and enforced by a self-regulatory body.[88]

While the Ontario fertility sector currently falls outside of provincial oversight, it appears that this may change with the new *Oversight of Health Facilities and Devices Act* (*OHFDA*), 2017.[89] Following recommendations by Health Quality Ontario, the province's health-quality watchdog, the *OHFDA* will establish a single legislative framework to govern independent health facilities and non-hospital medical clinics that provide privately financed care (known as "community health facilities").[90] In other words, the same regulatory framework would apply to both publicly and privately financed care. The proposed integrated framework will establish a licensing and inspections process, as well as a complaints and

81 *Ibid* at 4–5, 4.1 and 4.2ff.
82 *Ibid* at 9, 5.6ff.
83 *Ibid* at 12, 6.2ff.
84 *Ibid* at 11, 6.1ff.
85 *Ibid* at 14–15, 6.4–6.6ff.
86 *Ibid* at 21–22.
87 *Ibid* at 20, 8.1ff.
88 *Public Hospitals Act*, *supra* note 72.
89 *Oversight of Health Facilities and Devices Act*, *2017*, SO 2017, c 25, Schedule 9.
90 Health Quality Ontario, *supra* note 45.

independent review process, together with a mechanism for disclosing this information.[91] The act is not yet in force and the regulations are not yet available, but the *OHFDA* may well provide a consistent, comprehensive, and transparent regulatory framework for both publicly and privately financed health care services, which may well serve as a model for the better regulation of privately financed care. Unfortunately, it appears that these important regulatory changes have been shelved, likely as a result of a change in government and the introduction of legislation that will overhaul the delivery of health care services in Ontario.[92]

Alberta

The College of Physicians and Surgeons of Alberta (CPSA) is responsible for the regulation of non-hospital surgical facilities, regardless of whether they provide insured or uninsured services. In Alberta, most assisted-reproduction services are uninsured and are offered in one of two private for-profit fertility clinics.[93] Although there are some important differences between the regulation of insured and uninsured services in non-hospital surgical facilities, the regulation of Alberta's fertility clinics that offer IVF and other assisted reproduction, an uninsured service, is quite similar to the regulation of facilities that provide insured services.

In Alberta, the *Health Care Protection Act* (*HCPA*) establishes the regulatory frameworks for facilities that provide insured surgical

91 See *supra* note 90. The definition of "community health facilities" includes (a) a place or collection of places where one or more services prescribed in regulations made by the minister are provided, and includes any part of such a place; and (b) a place or collection of places in regulations made by the minister. The *OHFDA* creates a licensing process for CHFs under the oversight of an "executive officer" (EO) appointed by cabinet (s 2). The EO has the discretion to decide whether to issue a license and to impose conditions on the license (ss 5–7); the OHFDA requires CHFS to have a complaints process to receive and respond to complaints from patients & services providers (s 35), an incident-review process (s 36), and a disclosure-of-information process (s 37–38). The regulation will designate inspecting bodies for CHFs (s 40) and inspections will be carried out by inspectors. Inspectors and the EO can impose compliance orders (s 54), cessation orders (s 55), and administrative monetary penalties (s 58). All orders made by the EO must be made public (s 67).

92 *The People's Health Care Act*, SO 2019, c 5.

93 At present, Alberta has only two clinics: see www.cfas.ca.

services and facilities that provide uninsured surgical services.[94] The *HCPA* establishes a number of standards common to both facilities. The CPSA is primarily responsible for the oversight of all non-hospital surgical facilities. All facilities must be accredited by the CPSA before they can be designated as such by Alberta's minister of health.[95] Also common to both is that "significant mishaps" or "reportable incidents" must be reported to the CPSA and the health authority.[96] Similarly, the CPSA has established a common set of standards that apply to all non-hospital surgical facilities, including standards for personnel, patient care, infection prevention and control, and others.[97] The CPSA also establishes a process for granting privileges to members to practice in non-hospital surgical facilities.[98] Notably, clinics must also meet many of the same standards as public hospitals, including reporting of incidents, physician qualifications, and compliance with medical staff bylaws.[99]

However, a couple of important differences exist. First, public reporting of the facilities' performance differs. The non-hospital surgical facilities that provide insured services must enter into agreements with regional health authorities, which in turn require annual performance reports from the facility, which must be made public.[100] A similar requirement for an annual performance report does not appear to exist for public hospitals under Alberta's *Hospital Act*.[101] The second difference is the disclosure of health data. A range of data about insured surgical services for outpatient services must be disclosed to the provincial reporting authority and for inpatient services to the Canadian Institute of Health Information (CIHI).[102] Yet, there is no equivalent requirement to report data about

94 *Health Care Protection Act*, RSA 2000, c H-1. For non-hospital surgical facilities providing insured services see s 11(1)(b) and for uninsured services see s 15(2).

95 *Ibid*, ss 11, 15 and 21.

96 *Health Care Protection Regulation,* AR 208/2000 at s 17.

97 College of Physicians and Surgeons of Alberta, *Non-Hospital Surgical Facility: Standards & Guidelines*, CPSA, March 2016 v 23, online: <http://cpsa.ca/wp-content/uploads/2015/03/NHSF_Standards.pdf>.

98 *Ibid.*

99 Health Quality Ontario, *supra* note 45 at 17.

100 CPSA, s*upra* note 98 at s 16.

101 *Hospitals Act*, RSA 2000, c H2. See also, *Operation of Approved Hospitals Regulation,* A/R 247/1990.

102 *Ibid*, at s 15(2).

uninsured services to any provincial authority or federal agency, which is discussed in greater detail below.[103]

Notably, the CPSA has established a set of standards specific to assisted reproductive technologies.[104] Unlike the proposed OHPIP for fertility premises, these standards are quite brief: they establish specific qualifications for medical directors, physicians, and assisting personnel who provide fertility services; and requirements for information that must be included in a patient's medical record. In addition, the CPSA standard requires clinics to submit data about fertility services to CARTR Plus and the college.[105]

In my view, Alberta's integrated regulatory framework for surgical facilities, whether publicly or privately financed, is the right approach. Regulatory frameworks should not differ solely on the basis of who is paying for the health care service. But Alberta's system suffers from two important problems: much of the regime falls to a self-regulating body, and there is insufficient data reporting and disclosure for privately financed clinics.

British Columbia

Like Ontario and Alberta, the College of Physicians and Surgeons of British Columbia (CPSBC) is primarily responsible for the regulation of private for-profit facilities and professionals who work in these facilities. In British Columbia, IVF is an uninsured service and is delivered in private for-profit clinics.[106] The CPSBC, pursuant to college bylaws under BC's *Health Professions Act*, has established a framework for the accreditation for private non-hospital medical and surgical facilities: the Non-Hospital Medical and Surgical Facilities Accreditation Program (NHMSFAP).[107]

The NHMSFAP establishes a number of standards and an accreditation program for private non-hospital facilities and health care professionals working in those facilities. For example, the CPSBC

103 See Part C, Regulatory Gaps, c. Health information: Evaluating and improving health systems and outcomes.

104 College of Physicians and Surgeons of Alberta, *Assisted Reproductive Technology: Standards & Guidelines*, CPSA, May 2017, v 2, online: <http://www.cpsa.ca/wp-content/uploads/2017/11/Assisted-Reproductive-Technology-Standards-and-Guidelines.pdf>.

105 *Ibid.*

106 See IVF Clinics, *supra* note 14.

107 *Health Professions Act*, RSBC 1996, c 183, s 25.5(1)(e).

has established a policy for patient-safety incidents, reporting to the NHMSFAP's committee.[108] Importantly, the medical director of a facility must notify the committee within twenty-four hours of becoming aware of a patient-safety incident or a death that occurred within twenty-eight days of a facility procedure.[109] The CPSBC also sets a number of standards that clinics must meet to be accredited.[110] The standards address a range of elements including physical standards, patient care, medical record keeping, and facility governance.[111]

The CPSBC also establishes an appointment process for medical staff[112] who work in non-hospital medical and surgical facilities. The NHMSFAP authorizes the medical director of the facility to approve applications from medical staff for appointment and reappointment to non-hospital medical surgical facilities.[113] It also establishes a series of standards, rules, policies, and guidelines respecting the skills and training necessary for the appointment of medical staff.[114]

Although there is a list of accredited non-hospital medical and surgical facilities available on the CPSBC website, there is no other information provided to the public about the facility, such as when they were accredited. Thus, while there are provisions that require reporting of patient safety incidents or death, it does not appear that this information is made available to the public. This information would likely be of interest to patients choosing between surgical facilities.

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108 College of Physicians and Surgeons of British Columbia—Non-Hospital Medical and Surgical Facilities Accreditation Program, *Bylaw Policy: Patient Safety Incidents Reporting*, CPSBC, 2018, online: <https://www.cpsbc.ca/files/pdf/NHMSFAP-BP-Patient-Safety-Incidents-Reporting.pdf>.

109 The NHMSF requires that each clinic have a medical director: *Ibid.*

110 College of Physicians and Surgeons of British Columbia—Non-Hospital Medical and Surgical Facilities Accreditation Program, *Bylaw Policy: Terms of Accreditation*, CPSBC, 2017, online: <https://www.cpsbc.ca/files/pdf/NHMSFAP-BP-Terms-of-Accreditation.pdf>.

111 For a list of the various standards, see College of Physicians and Surgeons of British Columbia, "Standards" CPSBC, online: <https://www.cpsbc.ca/programs/nhmsfap/standards>.

112 Medical staff includes physicians and allied health care professionals.

113 College of Physicians and Surgeons of British Columbia—Non-Hospital Medical and Surgical Facilities Accreditation Program, *Bylaw Policy: Appointment of Medical Staff to Facilities*, CPSBC, 2018, online: <https://www.cpsbc.ca/files/pdf/NHMSFAP-BP-Appointment-of-Medical-Staff.pdf>.

114 *Ibid.*

In summary, in most provinces, self-regulated bodies are the principal regulators of the fertility sector. As described, the colleges have, to varying degrees, introduced a number of tools—such as setting basic clinical standards, requiring critical-incident reporting, and introducing a process for physician privileges—that promote patient health and safety. But because these regulatory frameworks are set and enforced by a self-regulating body, they are subject to a range of criticisms described above, including that these processes and decisions are not sufficiently transparent, and that, because they are administered and overseen by members of the profession, they are inherently self-interested and are not well suited to protecting patient health. As such, greater external oversight is needed, whether through an integrated system such as that proposed in Ontario or a specific/separate regulatory framework created, implemented, and enforced by government, like certain aspects of Quebec's approach.

Fertility Services: The Regulatory Gaps

While internal regulation is an important form of regulation, it is insufficient to protect and promote patient health and safety. There are general concerns about the safety and quality of care in the private for-profit health care sector. Although there is no Canadian study comparing the delivery of IVF services in publicly funded as opposed to privately funded clinics, there are studies from other sectors that compare quality and safety in private for-profit facilities and public not-for-profit facilities. For example, Devereaux et al found that private for-profit hospitals and facilities are associated with an increased risk of death when compared to their not-for-profit counterparts.[115] The authors explain that the difference in quality of care may be explained by various cost-cutting practices, such as staffing or duration of procedures. More recently, there are reports of observational evidence which demonstrate that publicly funded care in *for-profit* long-term care facilities is inferior to publicly funded

115 PJ Devereaux et al, "A Systematic Review and Meta-Analysis of Studies Comparing Mortality Rates of Private For-Profit and Private Not-for-Profit Hospitals" (2002) 166:11 CMAJ 1399 at 1400. See also PJ Devereaux et al, "Comparison of Mortality between Private For-Profit and Private Not-for-Profit Hemodialysis Centres: A Systematic Review and Meta-analysis" (2002) 288:19 JAMA 2449.

care in *not-for-profit* long-term care facilities.[116] However, there is not unanimous consent on this question. Flood and Thomas note there is disagreement between scholars regarding the connection between profit status and quality of care.[117] In addition to quality and safety concerns in the for-profit sector, there are concerns about potential conflicts of interests. Although a detailed examination of these concerns in the fertility sector is beyond our scope here, they have been highlighted by Flood and Thomas[118] and others.[119]

Below, I focus on three examples that illustrate how regulation of the privately financed fertility sector is less rigorous and effective than government regulation of publicly funded health care. First, although CPGs have had some impact on physician practice, they have not proven to be nearly as effective as legislative mandates in Quebec and Ontario. The legal rule in Quebec mandating single-embryo transfer had a swift and profound impact on clinical practice. By contrast, the CPG recommending single-embryo transfer has resulted in fewer multiple births, but the change in practice has been much more gradual. Second, there are fewer complaints processes available for patients who receive privately financed health care services, and the college complaints and investigation process suffers from several shortcomings. Third, although the CFAS has taken steps to collect and disclose some aggregate data about assisted reproduction in Canada, information collection and disclosure for privately financed care is less rigorous than for publicly funded care. Of course, there are other regulatory challenges unique to this sector, such as the

116 See Lisa A. Ronald, "Observational Evidence of For-Profit Delivery and Inferior Nursing Home Care: When Is There Enough Evidence for Policy Change" (2016) 13(4) PLoS Med e1001995.

117 Flood & Thomas, *supra* note 32 at 364 citing to Mark B McClellan & Douglas O Staiger, "Comparing Hospital Quality at For-Profit and Not-for-Profit Hospitals" in David M Cutler, ed, *The Changing Hospital Industry: Comparing For-Profit and Not-for-profit Institutions* (Chicago: University of Chicago Press, 2000) 93.

118 Flood & Thomas, *supra* note 32 at 366 and 371.

119 For example, a recent study in Denmark demonstrated that while meniscal procedures increased in both public and private sectors in Denmark between 2000 and 2011, the incidence of meniscal procedures was "particularly conspicuous in the private sector" as its proportion increased in private clinics from 1 per cent to 32 per cent: Kristoffer Borbjerg Hare et al, "Large regional differences in incidence of arthroscopic meniscal procedures in the public and private sector in Denmark" (2015) BMJ Open e006659.

concerns about conflicts of interest and advertising highlighted by Flood and Thomas, but these are beyond the scope of this chapter.[120]

Enforcing Clinical Standards: Single-Embryo Transfer Policies

Clinical-practice guidelines appear to be less effective than legal rules mandating clinical care. There is some debate about the efficacy of CPGs and the extent to which they impact clinical practice has been questioned.[121] The relative inefficacy of CPGs as compared to a legal mandate is well illustrated by single-embryo transfer policies.

Single-embryo transfer policies are intended to address the disproportionately high rates of multiple pregnancies resulting from IVF. Multiple pregnancies increase the health risks for pregnant women, including an increase in cardiac complications, preeclampsia, gestational diabetes, postpartum hemorrhage, and the possibility of a surgical intervention such as a hysterectomy.[122] Multiple pregnancies also increase the chance of poor outcomes for the resulting children, including preterm birth, which is associated with a number of adverse outcomes such as lung and eye disorders, and the possibility of neurodevelopmental conditions such as cerebral palsy.[123] Traditionally, multiple embryos were transferred during a cycle of IVF in order to maximize the chance of pregnancy. Where patients are paying out of pocket, patients may choose to transfer more than one embryo in the hopes that they will become pregnant and will not have to pay for additional cycles.[124] Clinics may also have an incentive to transfer more than one embryo to boost their success rates.[125] As discussed at the outset, this has prompted some governments to fund IVF and, in exchange for public funding, impose a single-embryo transfer requirement, which ultimately reduces the costs associated with multiple pregnancies and births in the public system.[126] Prior to regulatory efforts, Canada had one of the high-

120 Flood & Thomas, *supra* note 32 at 367.

121 See above, section 1.

122 Jocelyn L Cook et al, *supra* note 11 at 159.

123 *Ibid.*

124 Bissonnette, *supra* note 9 at 501.

125 *Ibid.*

126 Jason G Bromer et al, "Preterm Deliveries that Result from Multiple Pregnancies Associated with Assisted Reproductive Technologies in the USA: A Cost Analysis" (2011) 23:3 Current Opinions in Obstetrics & Gynecology 168; Patricia Fauque et al, "Cumulative results including obstetrical and neonatal outcome of fresh and frozen-thawed cycles in elective single versus double fresh embryo

est multiple-birth rates resulting from assisted reproduction in the world.[127]

In 2010, the Society of Obstetrics and Gynaecology of Canada (SOGC) and the CFAS, recognizing the health risks with multiple-embryo transfer, introduced a joint CPG that recommended single-embryo transfer in the majority of IVF cycles.[128] This followed the Quebec government's decision to require single-embryo transfer for publicly funded cycles, described above. The SOGC/CFAS's CPG on single-embryo transfer has had a gradual, but notable, impact on multiple births resulting from assisted reproduction. In 2010, CARTR reported that the multiple birth rate was 23.8 per cent of all assisted-reproduction cycles.[129] In 2016, the multiple pregnancy rate had decreased to 9.7 per cent of all assisted-reproduction cycles.[130] By contrast, the legislated limit in Quebec had an immediate and profound impact on multiple pregnancy rates. In 2009, the year prior to the introduction of the IVF-funding program, the multiple pregnancy rate in Quebec was 25.6 per cent. Six months after the introduction of the program, the multiple pregnancy rate plummeted to 3.7 per cent.[131] Although it increased slightly, it remained relatively low, at 6.9 per cent.[132]

At the time of writing, we do not yet know the impact of the single-embryo transfer requirement in most publicly funded cycles of IVF in Ontario. It is likely that there will be a drop in Ontario's

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transfers" (2010) 94:3 Fertility & Sterility 927; Jan Gerris, "Single-embryo Transfer Versus Multiple-embryo Transfer" (2009) 18 Reproductive BioMedicine Online (Supplementary 2) 63; Abha Maheshwari, Siriol Griffiths & Siladitya Bhattacharya, "Global Variations in the Uptake of Single Embryo Transfer" (2011) 17:1 Human Reproduction Update 107; Bissonnette, *supra* note 9 at 501.

127 Jocelyn L Cook et al, *supra* note 11 at 165.

128 Jason K Min, Ed Hughes & David Young, "Joint SOGC-CFAS Clinical Practice Guideline: Elective Single Embryo Transfer Following In Vitro Fertilization" (2010) 32 J Obstetrics & Gynaecology Canada 363.

129 Canadian Fertility & Andrology Society, "CARTR Annual Report—2010," Canadian Fertility and Andrology Society, online: <https://cfas.ca/_Library/_documents/CARTR_2010.pdf>.

130 Canadian Fertility & Andrology Society, "CARTR Annual Report—CARTR Plus 2016 Report—Powerpoint Presentation," Canadian Fertility & Andrology Society, online: <https://cfas.ca/_Library/cartr_annual_reports/CFAS-CARTR-Plus-presentation-Sept-2017-for-CFAS-website.pdf>.

131 Bissonnette, *supra* note 9 at 504.

132 M P Vélez et al, "Universal Coverage of IVF pays off" (2014) 29:6 Human Reproduction 1313 at 1316.

multiple-birth rate. But will the drop be as pronounced as in Quebec? Because single-embryo transfer is only required in publicly funded cycles, it is difficult to predict the impact on the multiple-birth rate overall. Will physicians and patients adopt the same clinical practice for privately funded cycles? If not, it may also spur the provincial government to take regulatory action. How will the provincial government justify allowing a practice it considers unsafe for women and children to continue solely because it is paid for out of pocket? If there is a disparity between clinical practice in publicly and privately funded cycles, it is imperative that the provincial government addresses it. If not, it may send a message that the government is willing to tolerate greater health risks in the context of privately financed care.

Complaints Processes: The College's Complaint Investigating Authority as the Only Resort

Another significant difference between the regulation of publicly and privately financed care is the extent to which patients have access to processes and procedures for raising concerns about the conduct of a health professional or an incident at a health facility. Generally, there are more opportunities for patients to complain about publicly funded as opposed to privately funded health care services. As discussed, complaints processes are critical to ensure that clinical standards are being met and that patients receive high-quality health care.[133] Complaints or disciplinary processes are "key elements" of self-regulation, as they ensure that health care professionals meet the standards set by the profession.[134] However, these processes are often lacking—in most cases they are patient-initiated, they may fail to adequately address the unsatisfactory practice of a member, they do not make enough information available to the public,[135] they are often ill-equipped to make systemic remedies, and they tend to

133 Tom W Reader, Alex Gillespie & Jane Roberts "Patient Complaints in Healthcare Systems: A Systemic Review and Coding Taxonomy" (2014) 23:8 British Medical J Quality & Safety 678.

134 Zarzecnzy, *supra* note 15 at 165. See also Epps, *supra* note 20 at 81–82.

135 Julie Maciura & Lonny J Rosen, "A New Era of Transparency in Health Care Regulation" (Paper delivered at the OBA's Institute—Health Law Update: Privacy, Transparency & Class Action, 4 February 2016) (Toronto: OBA Continuing Professional Development, 2016) 1.

address the conduct of professionals rather than facilities. Two cases illustrate the shortcomings of the college's complaints process.

In *Applicant v AA*, the applicant brought a complaint to the CPSO against her obstetrician, A.A., who provided her fertility care and treatment.[136] The applicant underwent IVF with an egg donor, L.T., who was located in Washington state in the United States.[137] The applicant paid between $8,000 and $10,000 in fees to the donor. The applicant brought a number of complaints against the physician, including that he prescribed medication to the egg donor, L.T., who resided outside of the jurisdiction in which he was licensed without first examining her to determine whether she was an appropriate candidate to be an egg donor; and he provided the applicant with a copy of L.T.'s confidential medical record at the conclusion of her care and treatment, thereby breaching her privacy. The CPSO's inquiries, complaints, and reports committee investigated the complaint and decided to require A.A. to attend at the college to be cautioned in person,[138] and to take a continuing-education or remedial program that would include a preceptorship and reassessment. In its decision, the committee noted that the powerful medications prescribed to L.T. were associated with a significant risk of dangerous complications. Nevertheless, the committee did not decide to refer the patient's complaint to the discipline committee, which can issue more severe sanctions.[139] Nor did the college choose to carry out an inspection of the physician's clinic.[140]

Despite the severity of the case, the public does not know this physician's identity. Because this case was commenced prior to 1 January 2015, neither the caution nor the educational order appears on the physician's public record on the physician's registry.[141] Therefore, potential patients have no way of identifying this

136 *Applicant v. A.A.*, 2016 CanLII 30077, File # 14-CRV-0386, online: (ON HPARB) <https://www.canlii.org/en/on/onhparb/doc/2016/2016canlii30077/2016canlii30077.html?searchUrlHash=AAAAAQALImVnZyBkb25vciIAAAAAAQ&resultIndex=1>.

137 *Ibid* at para 7.

138 A caution is ordered when the committee has a significant concern about conduct or practice that can have a direct impact on patient care, safety, or the public interest: *Regulated Health Professions Act*, *supra* note 21 Schedule 2, s 10.

139 *Ibid*, Schedule 2, s 36.

140 *Ibid*, Schedule 2, s 75.

141 Cases commenced after 1 January 2015, cautions, specified continuing education or remedial program, and undertakings will appear on the CPSO public

physician, and, as such, cannot choose not to see him.[142] Although the CPSO has sought to increase transparency of its decisions since January 2015, important information is still not disclosed to the public, including when a physician has entered into a voluntary remedial agreement with the CPSO, or when the committee states its expectation of a physician.[143]

A second case further illustrates the limitations of the college's complaints process and its failure to adequately address a member's misconduct. Norman Barwin was a fertility doctor who practiced in Ontario until his retirement in August 2014. Dr. Barwin was disciplined by the CPSO in 2013 (discipline decision) and is the defendant in a class-action lawsuit.[144] Both the discipline decision and the class-action lawsuit arise from Dr. Barwin's use of sperm other than the sperm chosen by his patients and their partners for the purposes of artificial insemination. In many cases, the evidence indicates that Dr. Barwin used his own sperm rather than that of the intended parent or anonymous donor. The agreed statement of facts from the discipline decision reveals that Dr. Barwin engaged in a long-standing pattern of misconduct beginning in the mid-1980s and had been the subject of numerous patient complaints. The college notified Dr. Barwin of an error he had made in his insemination of a patient (Patient E) in the mid- to late 1990s. Patient E, following the birth of her child in 1995, had discovered that her child was not conceived with the donor sperm she had instructed Dr. Barwin to use. This error did not appear on Dr. Barwin's public record.

Three similar complaints followed: Patient A, following DNA testing of her child in 2007, discovered that she had been inseminated with sperm other than the donor sperm she had instructed

register: The College of Physicians and Surgeons of Ontario, "Transparency of Physician-Specific Information," CPSO, online: <https://www.cpso.on.ca/>.

142 The only reason there is any public information about this case is because the applicant asked the Health Professions Appeal and Review Board to review the CPSO's decision.

143 In 2012, the six health-professional colleges (medicine, nursing, dentistry, optometry, pharmacy, and physiotherapy) formed a working group on transparency called the Advisory Group for Excellence, which has resulted in greater information sharing on college websites. However, important information remains private: CPSO, *supra* note 142.

144 *Re Barwin*, [2013] OCPSD No 5 (Ontario College of Physicians and Surgeons Discipline Committee) and *Dixon, Dixon and Dixon v Barwin*, Statement of Claim, File No 16-70454CP (Ontario Superior Court of Justice).

Dr. Barwin to use in 2003; Patient C, who was acting as a surrogate for her sister (Patient B), discovered in 2008 that the resulting child (born in 2007) was not biologically related to the intended father; and Patient D discovered in 2011 that her child, who was born in 1986, was not conceived with her husband's sperm (which he had frozen prior to cancer treatments in 1984).[145] The discipline committee accepted an order proposed jointly by Dr. Barwin and counsel for the college and found that Dr. Barwin had engaged in professional misconduct, suspended him for two months, and issued a public reprimand and a costs order of $3,650.

In 2016, eleven plaintiffs launched a class action against Dr. Barwin, alleging he engaged in similar misconduct, namely using sperm other than that chosen by the plaintiffs for the purpose of artificial insemination.[146] Shortly thereafter, the CPSO announced that it would launch a third investigation into Dr. Barwin's conduct.[147] As one former patient stated: "This is the third time the college has investigated. Why did they not take his license away? Why didn't they test the children back then to see how widespread this was? As far as I am concerned, they should be investigating themselves."[148]

It was not until 25 June 2019 that the CPSO revoked Dr. Barwin's licence in response to his serious misconduct.[149]

Not only is Dr. Barwin's conduct deeply troubling, the CPSO's failure to adequately address Dr. Barwin's long-standing misconduct is also concerning and illustrates a number of shortcomings of the college's complaints process. First, the complaints process is slow and lacks transparency. Despite numerous complaints of a similar nature, beginning in 2007 and 2008, the discipline committee did not issue a decision until 2013. During this five-year

145 *Re Barwin, ibid* at para 5.

146 *Dixon, supra* note 145 at paras 25 and 27. The representative plaintiff in the class action was born in 1990 and refers to another woman born in 1991, both of whom were conceived at Dr. Barwin's clinic and who discovered in 2015 and 2016, respectively, that they were conceived using his sperm.

147 Elizabeth Payne, "College of Physicians Investigating Former Fertility Doctor Norman Barwin—Again," *Ottawa Citizen* (18 June 2018), online: <https://ottawacitizen.com/news/local-news/college-of-physicians-investigating-former-fertility-doctor-norman-barwin-again>.

148 *Ibid*.

149 *Ontario (College of Physicians and Surgeons of Ontario) v Barwin*, 2019 ONCPSD 39.

period, many patients continued to be treated by Dr. Barwin and were unknowingly put at risk of harm or were subject to his acts of misconduct.

Second, the CPSO's initial investigation appears to have been deficient. If the allegations in the class action are proven, the college failed to identify a number of additional cases of misconduct. Because there is little public information available about the nature of the investigation, it is difficult to identify what steps the college took in investigating these complaints. But the discipline committee's brief reasons seem to indicate that the committee was focused on investigating Dr. Barwin's role in these individual complaints rather than engaging in a wider investigation into the storage and use of sperm in the clinic. A number of systemic failures appear to have facilitated Dr. Barwin's misconduct, including a lack of clinic policies and procedures regarding patient and donor record keeping, and the identification, preservation, and storage of sperm.[150] A broader investigation of the clinic may have uncovered systemic problems such as Dr. Barwin's failure to put much-needed policies and procedures in place at his fertility clinic, and may have exposed additional cases of misconduct. The current investigatory process appears to be ill-equipped to deal with systemic or facility-level problems, because the committee relies heavily on an *ex post* response of patients initiating complaints, and its mandate under the *RHPA* is to investigate a professional rather than the facility.

Third, the finding and penalty in this case, a two-month suspension, strike many as woefully inadequate. The discipline committee accepted an agreement between Dr. Barwin and counsel for the college, whereby Dr. Barwin admitted to committing an act of professional misconduct and counsel for the college withdrew a second allegation of professional misconduct, as well as an allegation of incompetence.[151] Such a weak finding and penalty in the face of this egregious conduct leaves the impression that the college is focused on protecting its members rather than patients and the public.

It is impossible to say whether Dr. Barwin's misconduct would have been uncovered earlier or would not have happened at all if fertility services were delivered in a public hospital or if they were publicly funded and subject to the applicable provincial frameworks.

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150 *Dixon*, *supra* note 145 at para 43.

151 *Re Barwin*, *supra* note 145 at para 4.

However, the additional safeguards in place at public hospitals as a result of the *Public Hospitals Act*,[152] and at health care organizations that receive public funding which are subject to the *ECFAA*,[153] may well have reduced the likelihood of harm to patients. These safeguards include detailed requirements for patient record keeping,[154] as well as internal supervisory mechanisms over physicians in hospital[155] and broader quality committee processes in health care organizations that receive public funding.[156]

Another safeguard for patients receiving publicly funded care is access to additional processes for raising concerns and filing complaints about health professionals and facilities. Two examples of external quality-of-care processes established by the government and administered by independent third-party agencies are facility-based patient-relations processes,[157] and ombudspersons or quality review boards.[158]

Ontario has created two additional processes for patients who receive publicly funded care in health care organizations pursuant to the 2010 *ECFAA*.[159] First, the *ECFAA* requires health care

152 *Public Hospitals Act*, *supra* note 72.

153 *Excellent Care for All Act*, *2010*, SO 2010, c 14.

154 *Hospital Management*, RRO 1990, Reg 965, s 19.

155 For example, in Ontario there are processes for an officer of the medical staff who becomes aware that if, in his or her opinion, a serious problem exists in the diagnosis, care, or treatment of a patient, the officer shall forthwith discuss the condition, diagnosis, care, and treatment of the patient with the attending physician, and may relieve the attending physician of his duties with respect to the physician and advise the medical advisory committee of the problem with the attending physician: *Supra* note 72, s 34. Further, physicians are supervised by the medical advisory committee, which determines hospital privileges and which are empowered to revoke or suspend privileges where appropriate: *Ibid*, ss 35–36.

156 *Excellent Care for All Act*, *supra* note 153 s 4. Notably, the *ECFAA* only applies to health care organizations that are public hospitals or receive public funding: *Ibid*, s 1.

157 In Ontario, see *ECFAA*, *supra* note 153 s 6 requires all health care organizations to have a patient relations process and make information about that process available to the public.

158 In Ontario, see *ibid*, s 13.1.

159 *Ibid*, s 1. The *ECFAA* applies to "health care organizations" and "health sector organizations," which include public hospitals as well as organizations that receive public funding and does not include complains regarding privately financed care.

organizations to have a patient-relations process.[160] These processes allow patients or caregivers to bring complaints directly to the health care organization. Second, the *ECFAA* creates a "patient ombudsman" in order to improve quality of health care and to promote the health of patients.[161] The patient ombudsman is charged with undertaking an investigation either as a result of a patient complaint or on her own initiative.[162] The patient ombudsman must report to the minister of health, the LHIN, and the public on her activities and recommendations.[163] Although there have been calls for greater independence and more robust powers, the patient ombudsman is an important avenue for redress for patients receiving publicly funded health care.[164]

Similarly, patients in British Columbia may bring a "care quality complaint" to one of British Columbia's Patient Care Quality Review Boards.[165] These complaints may not duplicate the complaints investigation authority of the professional bodies, but they do provide patients with an opportunity to complain about the quality of publicly funded health care services.[166] Like Ontario's patient ombudsman, a patient-care quality review board is restricted to making recommendations.

The complaints and investigation processes available through self-regulated bodies play an important role in determining whether health care professionals meet clinical standards and in addressing conduct that does not. However, the current gaps in the process may put patients' health at risk. Although these concerns exist for both publicly and privately funded care, they are almost

160 *Ibid*, s 6.

161 *Ibid*, s 13.1.

162 *Ibid*, s 13.1(2). David Watts & David Solomon, "Day-to-Day Operations of Hospitals and Other Health Institutions: The Impact of Recent Legislative Amendments and Regulatory College Initiatives" (Paper delivered at the OBA's Institute—Health Law Update: Privacy, Transparency & Class Action, 4 February 2016) (Toronto: OBA Continuing Professional Development, 2016) 1 at 2.

163 *Excellent Care for All Act*, *supra* note 153, s 13.5.

164 Watts & Solomon, *supra* note 162 at 1.

165 *Patient Care Quality Review Boards Act*, SBC 2008, c 35.

166 These review boards will not consider complaints regarding health care services that are paid for entirely by the patient or the patient and a private insurer; British Columbia—Patient Care Quality Review Boards, "Frequently Asked Questions"; British Columbia—Patient Care Quality Review Boards, online: <https://www.patientcarequalityreviewboard.ca/faqs.html#Q1>.

certainly less acute where self-regulation is buttressed by external oversight mechanisms. Although patient-relations processes and independent review bodies are intended to complement rather than replace self-regulation, they effectively shore up the college's complaints process and offer additional oversight of professionals and facilities.

Health Information: Evaluating and Improving Health Systems and Outcomes

Finally, there are important differences in terms of the collection and disclosure of publicly funded and privately financed health care information. Health information is also essential to measure population health, to evaluate and improve health systems, and to engage in evidence-based decision making.[167] As Collier notes, data is critical for physicians to offer high-quality, consistent health care as it ensures they provide appropriate care to patients.[168] Publicly available health information is also critical for patients to make informed health care decisions. While there is a robust legislative framework for data collection, use, and disclosure of publicly funded health care services, the collection and disclosure of information about privately financed services like fertility services has fallen to health care professionals and their regulatory bodies. Data collection for Quebec and Ontario's publicly funded IVF services improved following public funding but, unfortunately, still falls short.

All provincial governments have legislation requiring the collection of certain health information from patients and authorizing the disclosure of non-identifying information in certain circumstances.[169] This legislation applies to publicly funded health care services—the province has comprehensive information because

167 Gregory P Marchildon, *Health Systems in Transition*, 2nd ed (Toronto: World Health Organization, 2013) at 124.

168 Collier, *supra* note 21.

169 For example, in Ontario, the minister and the general manager may directly or indirectly collect, use, and disclose personal information for purposes related to the administration of this *Act*, the *Commitment to the Future of Medicare Act, 2004*, SO 2004, c 5, the *Independent Health Facilities Act*, *supra* note 74 or *Health Insurance Act*, RSO 1990, c H 6. As described above, in Alberta, although many common standards apply to non-hospital surgical facilities, the information-disclosure requirements apply only to facilities offering insured services.

it pays for the health care service. Robust pan-Canadian data on publicly funded health care services also exists. CIHI, an agency created through a federal, provincial, and territorial partnership, is responsible for the collection and disclosure of pan-Canadian health data and information, and is generally considered to be one of the world's "premier national health information repositories."[170] Notably, CIHI primarily receives data from the provincial and territorial health care insurance plans, and as such its pan-Canadian databases generally contain information on publicly funded health services.[171]

By contrast, the CFAS is primarily responsible for information collection and disclosure of information regarding fertility services in Canada. As mentioned above, the CFAS, through the initiative of the medical directors of the fertility clinics, is responsible for collecting and disclosing information for assisted-reproduction services through CARTR Plus.[172] Fertility clinics may disclose a range of information about assisted-reproduction services, including patient information and history, details about the type and number of IVF cycles undertaken, the number of embryos transferred per IVF cycle, the use of donor eggs, the number of gestational surrogacies, and live-birth rates to CARTR Plus.[173] The CFAS also publishes an annual report that provides aggregate data from the CARTR Plus database.[174]

CARTR Plus offers important information about assisted-reproduction services in Canada; but it is not nearly as robust as data collection about publicly funded health care. First, disclosure is voluntary. While most fertility clinics disclose information to CARTR Plus, it is not mandatory, and therefore clinics may opt out

170 Marchildon, *supra* note 167 at 124.

171 For a list of CIHI's data holdings, see www.cihi.ca/en/access-data-and-reports/make-a-data-request/data-holdings.

172 The federal government had established a national registry for the information collection, use, and disclosure system in the *Assisted Human Reproduction Act*, *supra* note 51 ss 14–18. These provisions were declared unconstitutional by the Supreme Court of Canada in 2010: *Reference re Assisted Human Reproduction Act*, *supra* note 48.

173 Born Ontario, "Data Elements in CARTR Plus through BORN Ontario—April 2013" on file with author.

174 The CFAS annual reports are available at Canadian Fertility & Andrology Society, "CARTR Annual Report," Canadian Fertility & Andrology Society, online: <https://cfas.ca/cartr-annual-reports/>.

of disclosure without penalty.[175] Only the CPSA requires clinics to disclose information to CARTR Plus.[176] Second, there appears to be no process for the data disclosed to CARTR Plus to be verified and, as a result, there may be some question about its reliability. Third, while the CFAS discloses some aggregated data to the public, clinic-specific data is generally not available. As Dr. François Bissonette explains, the clinic-specific data is available to the CARTR outcome-improvement committee in order for them "to identify and offer help to clinics whose results fall below the national standard."[177] It is troubling that clinic-level data is not made available to patients, as one would expect that this information would be relevant to patients when deciding which fertility clinic to attend. Further, the directors of the fertility clinics have taken the position that they own the data and, as such, will only consider requests for more detailed data on a case-by-case basis, and, in most cases, charge a fee for disclosure.

Both the Quebec and Ontario governments have taken steps to improve information collection for publicly funded fertility services, but a number of gaps remain. In Quebec, the ministère de la Santé et des Services sociaux set up an information registry for assisted reproduction, but it has been criticized for failing to meet international standards, failing to accurately calculate success rates, and being limited in scope.[178] Work is underway to improve data collection and monitoring of assisted reproduction, but there is little information about the progress of this initiative.[179]

In Ontario, it appears the provincial government is collecting information about publicly funded fertility services, although it is unclear how the government plans to disclose this information.[180] OHPIP for fertility-service premises has proposed better data collection for all fertility services regardless of who pays. In particular,

175 For example, in 2012, thirty-two of the thirty-three clinics participated in CARTR: Joanne Gunby, "Assisted Reproductive Technologies (ART) in Canada: 2012 Results from the Canadian ART Register," Canadian Fertility & Andrology Society, online: <https://cfas.ca/public-affairs/canadian-art-register/report-2012/>.

176 CPSA, *supra* note 105.

177 Bissonnette, *supra* note 9.

178 Summary Advisory, *supra* note 55 at 35.

179 *Ibid* at 36.

180 One scholar has obtained this information through a freedom-of-information request.

it proposes that fertility-service premises provide the CARTR Plus patient data to an assessor who is reviewing the premises. However, there is no requirement to disclose information to CARTR Plus or a provincial registry, as in Quebec.

Conclusion: What Lessons can be Learned?

The regulation of the fertility sector in Canada offers important lessons about the steps governments should take to regulate privately financed care, which may become more of a necessity if the *Cambie* litigation is successful in striking down laws protective of public medicare. First, while self-regulation plays an important role, external regulation of health care professionals and facilities is necessary to promote patient health and safety. However, as evidenced by the privately financed fertility sector, the present Canadian approach is to leave the privately financed sector lightly regulated via self-regulating bodies and CPGs. This has resulted in regulatory gaps in terms of clinical standards, complaints, and investigation processes, and with information collection and disclosure.

There are a number of legislative frameworks that buttress self-regulation, such as additional complaints processes and rigorous data-collection frameworks; but these are only applicable to health care services that are publicly funded. The fertility sector demonstrates that health law and policy-makers should be wary of leaving privately financed health care services to self-regulation and the enormous challenges, both in terms of access as well as quality and safety, that will arise if greater privatization is permitted.

Second, provincial governments appear reluctant to directly regulate privately financed fertility services. The Quebec and Ontario governments only took steps to regulate the fertility sector more tightly after it decided to fund these services. While greater external oversight of the fertility sector is laudable, it has led to a concerning practice in Ontario, where the government has different clinical standards and oversight for the same clinical practices, in this case single-embryo transfer, depending on who is paying for the service. This may leave the impression that governments are willing to tolerate higher risks for patients who are receiving privately financed health care services.

Finally, provincial governments should take steps to regulate all health care, regardless of who pays. To reiterate, I do not support

increasing privately financed health care in Canada. However, should this come to pass, governments must address the quality of privately financed services and the safety of patients who received these services. Governments should strive to introduce integrated frameworks that establish the same set of regulations for both publicly and privately financed care, such as that occurs for certain standards in Alberta and as proposed in Ontario's *Oversight Act*.[181] In my view, this is the best way to ensure that the overall objective of health care regulation, to ensure patients receive safe, high-quality health care, is met.

181 *The People's Health Care Act, 2019*, SO 2019, c 5-Bill 74.

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