



Registered Nurses' Association of Ontario (RNAO)

Submission to: the Standing Committee on Social
Policy

Bill 21, *Safeguarding Health Care Integrity Act, 2014*

December 1, 2014



The Registered Nurses' Association of Ontario (RNAO) is the professional association representing registered nurses (RNs), nurse practitioners (NPs), and nursing students in all roles and sectors across Ontario. Since 1925, RNAO has advocated for healthy public policy, promoted excellence in nursing practice, increased nurses' contributions to shaping the health-care system, and influenced decisions that affect nurses and the public they serve. RNAO appreciates this opportunity to provide feedback to the Standing Committee on Social Policy on Bill 21, *An Act to safeguard health care integrity by enacting the Voluntary Blood Donations Act, 2014 and by amending certain statutes with respect to the regulation of pharmacies and other matters concerning regulated health professions* or the *Safeguarding Health Care Integrity Act, 2014* for short.

RNAO's analysis and recommendations on ways to strengthen the integrity of Ontario's health-care system are divided in three sections: safety of blood supply; access to safe and sustainable pharmaceuticals; and increasing effectiveness of self-regulation of health professionals.

Summary of Recommendations:

- Prohibit for-profit collection of blood and blood products. Instead of moving away from the World Health Organization and Krever Commission recommendations, the Canadian blood supply must build self-sufficiency. This can be done by ensuring the blood and blood products are used responsibly; cost savings generated through a national pharmacare program; and ensuring that blood donor criteria are evidence-based to account for actual risks rather than stereotypes
- Implement recommendation #2 of the Standing Committee on Social Policy's Report on Diluted Drugs. That is,

In order to maintain transparency and accountability, the government of Ontario, through legislative or other means, take those steps necessary to ensure that

- group purchasing organizations and shared services organizations are subject to all aspects of the *Broader Public Sector Accountability Act, 2010*;
- the salaries of employees and executives of group purchasing organizations and shared service organizations are reported under the *Public Sector Salary Disclosures Act, 1996*;
- group purchasing organizations and shared services organizations are subject to audits by the Office of the Auditor General of Ontario;
- public and broader public sector members of group purchasing organizations and shared service organizations pay for the

value of procurement services as opposed to a percentage of purchases; and

- rebates and value adds are discontinued.
- RNAO looks to the government of Ontario to provide leadership for a pan-Canadian standardized, publicly funded and publicly controlled pharmacare program.
- Advance amendments to the *Regulated Health Professions Act* that will promote public safety, confidence in the self-regulatory system and accountability of regulators, while promoting fairness to the health-care professionals involved.

Safety of Canada's Blood Supply

In a globalized world with ever increasing economic inequality worldwide^{1 2 3} including Canada,^{4 5 6 7} there are lessons to be learned from research into the "commodification of the body" or more simply, the selling of the body and its parts.⁸ Driven by the confluence of global capitalism and advancements in medical and biotechnologies, there is a growing demand for the organs, blood, bone, skin, tissue, reproductive and genetic material of others.⁹ Improved technologies of organ retrieval, preservation, and anti-rejection medication promise a longer life and/or a better quality of life for an "ever expanding sick, aging, desperate and dying population."¹⁰ With this infinite demand and extensive media coverage of the needs of recipients, donors are often invisible. Medical anthropologist Nancy Scheper-Hughes describes it as "a deficit or an absence of empathy for the groups we cannot see, those whose lives and suffering remain hidden from view--the population of organs and tissue donors, living and dead."¹¹

A researcher of "living cadavers" in Bangladesh found "poverty forced my research participants to sell one of their body parts."¹² The most common reason given worldwide by kidney vendors for selling a kidney is to feed the family.¹³ Despite being driven by hopes of economic improvements, a systematic review of outcomes of those who sold their kidneys in Pakistan, India, and Iran showed little to no improvement or even a decline in family income after nephrectomy.¹⁴ Instead of a better life, those who sell their kidneys often find their physical and emotional health has deteriorated.^{15 16} Negative social impacts of a commercial kidney market affect not just individuals but their families and communities as well.^{17 18} Two decades of experience in kidney commerce in Pakistan, consistent with trends in Hong Kong, Iran, and Israel, demonstrated a precipitous decline in altruistic donations by family members once purchasing a kidney became an option.¹⁹

As RNAO explained in correspondence to the federal Minister of Health,²⁰ Health Canada,²¹ and Premier Kathleen Wynne,²² blood is a precious public resource whose safety must be protected. The World Health Organization's position is unequivocal: "the safest blood donors are voluntary, non-remunerated blood donors from low-risk populations."²³ Allowing the commercial plasma industry to harvest blood from vulnerable people in return for payment in Ontario is in direct opposition to explicit evidence-informed policies of the World Health Organization.^{24 25 26} It contravenes the findings of Justice Krever's commission of inquiry into the blood system in Canada that was necessitated by the "public health calamity" of thousands of infections and deaths caused by contaminated blood products collected from paid donors.²⁷

With the fundamental value that blood is a public resource given altruistically by persons in Canada for the benefit of others, Krever concluded "profit should not be made from the blood that is donated in Canada."²⁸ Having a self-sufficient national blood system comprised of altruistic donors with strong Canadian

regulatory enforcement will honour the precautionary principle. A core systemic problem that Krever identified was lack of attention to the precautionary principle:

The slowness in taking appropriate measures to prevent the contamination of the blood supply was in large measure the result of the rejection, or at least the non-acceptance, of an important tenet in the philosophy of public health: action to reduce risk should not await scientific certainty. When there was reasonable evidence that serious infectious diseases could be transmitted by blood, the principal actors in the blood supply system in Canada refrained from taking essential preventive measures until causation had been proven with scientific certainty. The result was a national public health disaster.²⁹

Remaining steadfast to the principles that Krever identified will honour the lives of those who have died and those who are still living with the harm caused by Canada's inattentiveness to the precautionary principle. Following Krever's principles and the expert consensus guidance from the World Health Organization on achieving self-sufficiency in safe blood and blood products, voluntary non-remunerated blood donation is the correct course in the realms of public health science and ethical public policy.

Donations of whole blood and blood components should be truly voluntary as, like any invasive procedure, there is always a potential for harm. The overall incidence of complications directly related to blood donation is one per cent.³⁰ This may seem to be a small number but it is worthy of concern given the large quantities of blood collected each day across the globe.³¹ Adverse effects associated with whole blood donations include vasovagal reactions, sometimes requiring hospitalization due to fall injuries, and iron deficiency linked with anaemia, fatigue, decreased job and physical performance, cognitive changes, and restless legs syndrome.³² Venipuncture-related complications for both whole blood and apheresis donation include sore arm, bruises, nerve injury (with some cases of permanent disability), and arterial puncture.³³

An additional risk associated with apheresis donation (used to collect platelets and plasma) is the necessary use of anticoagulation for extracorporeal circulation. The anticoagulant citrate binds to calcium causing hypocalcaemia, hypomagnesaemia, metabolic alkalosis, prolongation of the QTc prolongation (which might lead to higher risk of ventricular arrhythmia in susceptible donors), secondary hyperparathyroidism, and risk of accelerated bone loss.³⁴ Mild citrate-induced symptoms such as perioral tingling, malaise, nausea, and chills occur in up to 80 per cent of donors.³⁵ More severe but rare (0.4 per cent) citrate-induced symptoms include convulsions, hypertension, chest tightness, and laryngeal spasm.³⁶ Additional adverse events for apheresis donors are exposure to the endocrine disruptor di(2-ethylhexyl) phthalate (DEHP) which might impact fertility, vasovagal reactions, iron deficiency, and protein depletion in high-intensity plasmapheresis.³⁷ In the United States, there were a total of 12 deaths related to

blood donation over 9 years, of which 9 were attributable to plasma or leukocyte donation.³⁸ These deaths are generally thought to be coincidental, however, the "symptoms of acute myocardial ischemia might mimic acute symptomatic hypocalcaemia (hypotension, nausea, chest pain) and transient cardiac symptoms may therefore be underestimated in the absence of further diagnostic procedures."³⁹ The authors of a comprehensive review of adverse events and safety issues in blood donations note that often donors do not receive detailed information on the procedure and possible complications while physicians involved in the donation process often are not aware of less frequent potential risks.⁴⁰

Minimizing or not fully disclosing all the potential risks of blood donation to prospective donors reinforces a notion that the lives and well-being of the recipients are of greater significance than unseen donors. This is particularly alarming given the iatrogenic history of the commercial plasma industry globally. Since the 1970's into the 1990's, outbreaks of blood-borne diseases such as HIV, Hepatitis B, and Hepatitis C have been attributed to commercial plasmapheresis centres in Austria,⁴¹ Mexico, India, and China.⁴² The Chinese government acknowledged in 2004 that the commercial collection of plasma accounted for a quarter of all cases of HIV infection in China.⁴³ Those who became infected in the early to mid 1990's in central China were "primarily poor, rural farmers," their partners and newborn children.⁴⁴ To help imagine the scope of the impact, consider just one community. In a study of one village in central China of 1,632 residents, 197 people were found to be HIV positive.⁴⁵ Most HIV positive people in this village (180 individuals, 91.4 per cent) had a history of paid blood donation.⁴⁶ The overall HIV infection rate in the village was 15.3 per cent and the HIV infection rate among paid blood donors was 38.6 per cent.⁴⁷ Of the 197 HIV positive individuals, 170 (86.3 per cent) had progressed to AIDS.⁴⁸ Many thousands of paid donors in impoverished areas have died in the transition from being farmers to being farmed for their blood with contaminated equipment and dangerous collection processes.

Historically, commercial plasma clinics in the United States were five to eight times more likely to be geographically located in areas that were economically disadvantaged, had higher residential mobility, and active drug sales than would be expected by chance.⁴⁹ Chris Healey of Grifols, a global plasma therapies producer, has argued that "the idea that our industry targets poor and low-income neighbourhoods is false" and a "holdover from the 1970's."⁵⁰ The evidence is that as late as 1995, commercial plasma clinics were continuing to pay cash in "the midst of active drug markets and poverty."⁵¹ First person accounts of individuals in the United States who sell their plasma describe being motivated by financial need and desperation,^{52 53 54} just as were the kidney vendors and rural farmers.

The value of the global pharmaceutical market is forecasted to reach \$1 trillion in 2014.⁵⁵ Since 2008, the plasma pharmaceuticals market has jumped from \$4 billion to more than \$11 billion annually.⁵⁶ With 100 new plasma centres opening

in the United States during the recession, plasma donations increased from 12.5 million in 2006 to more than 23 million in 2011.⁵⁷ There are immense economic interests in play that are known to distort both medicine and politics.^{58 59} There is even a growing understanding for the need for transparency to address potential conflicts of interest with respect to industry funding for patient advocacy groups.⁶⁰

RNAO urges the Standing Committee on Social Policy to resist market forces that would compromise our blood supply for profit by joining the province of Québec in **prohibiting for-profit collection of blood and blood products. Instead of moving away from the World Health Organization and Krever Commission recommendations, the Canadian blood supply must build self-sufficiency. This can be done by ensuring the blood and blood products are used responsibly; cost savings generated through a national pharmacare program; and ensuring that blood donor criteria are evidence-based to account for actual risks rather than stereotypes.** Until 2013, Canada had a lifetime deferral for men who have had sex with men that was in force for almost 30 years until it was changed to a five- year ban.^{63 64} This contrasts with Argentina, Australia, Hungary, Japan, and Sweden that have one-year deferrals and the more effective approach of Italy and Spain screening on a case-by-case basis for high-risk sexual practices.⁶⁵

Safe and Sustainable Pharmaceuticals

As you know, Schedule 2 of the *Safeguarding Health Care Integrity Act*, 2014 is in response to the discovery that 1,202 patients from February 2012 to March 2013 received diluted chemotherapy medications at one hospital in New Brunswick and four hospitals in Ontario.⁶⁶ Upon review, the best estimate is that the average actual cyclophosphamide concentration was 10 per cent lower than stated on the medication label while the actual concentration of gemcitabine was 7 per cent lower than labeled.⁶⁷ In addition to the review by Jake Thiessen, this incident prompted the Standing Committee on Social Policy to investigate and reported on procurement practices of hospitals; the oversight, monitoring and regulation of non-accredited pharmacies; and other concerns such as labeling, communications, and best practices.⁶⁸

While all the recommendations presented by the Standing Committee on Social Policy seemed reasonable, the **RNAO would particularly like to urge the provincial government to implement recommendation #2:**

In order to maintain transparency and accountability, the government of Ontario, through legislative or other means, take those steps necessary to ensure that

- **group purchasing organizations and shared services organizations are subject to all aspects of the *Broader Public Sector Accountability Act, 2010*;**
- **the salaries of employees and executives of group purchasing organizations and shared service organizations are reported under the *Public Sector Salary Disclosures Act, 1996*;**
- **group purchasing organizations and shared services organizations are subject to audits by the Office of the Auditor General of Ontario;**
- **public and broader public sector members of group purchasing organizations and shared service organizations pay for the value of procurement services as opposed to a percentage of purchases; and**
- **rebates and value adds are discontinued.**⁶⁹

In order to ensure access to a safe and sustainable supply of needed pharmaceuticals, RNAO also continues to recommend action on a national pharmacare program.⁷⁰ **RNAO looks to the government of Ontario to provide leadership for a pan-Canadian standardized, publicly funded and publicly controlled pharmacare program.** A recent review of the evidence in support of a pharmacare policy in Canada has been released by our colleagues at the Canadian Federation of Nurses Unions⁷¹ as well as the C. D. Howe Institute.⁷² With a recent groundswell for pharmacare reflected in Canada's media, now is the time to act on fulfilling medicare's promise by providing equitable and cost-effective access to prescription medications.^{73 74 75}

Effective Self-Regulation

RNAO supports the following amendments to the *Regulated Health Professions Act*:

(1) The Lieutenant Governor in Council may appoint a person as a College supervisor, on the recommendation of the Minister, where the Minister considers it appropriate or necessary.

The Minister of Health and Long-Term Care should have the ability to appoint a supervisor in any circumstance where he/she feels that it is necessary to do so. Ontario is very fortunate to have established an effective model of self-regulation for health-care professionals that is studied and rivaled by other jurisdictions. Overall, the work of the regulatory bodies is well aligned with the interests of public safety. However, the sustainability of a self-regulatory model requires ongoing public confidence and it is important that the Minister retains tools to promote accountability and to support regulators when needed.

10(d.1) for a prescribed purpose, to a public hospital that employs or provides privileges to a member of a College, where the College

is investigating a complaint about that member or where the information was obtained by an investigator appointed pursuant to subsection 75 (1) or (2) of the Code, subject to the limitations, if any, provided for in regulations made under section 43; and

(d.2) for a prescribed purpose, to a person other than a public hospital who belongs to a class provided for in regulations made under section 43, where a College is investigating a complaint about a member of the College or where the information was obtained by an investigator appointed pursuant to subsection 75 (1) or (2) of the Code, subject to the limitations, if any, provided for in the regulations;

These provisions are important for ensuring public safety. We urge nurses and other health-care professionals to be forthcoming in disclosing to an employer if they are subject to an investigation by a regulatory body. However, this does not always happen for a number of reasons including fear of the employment implications. More detail is needed on what the prescribed purpose would be for this type of disclosure.

12 (7) Despite subsection (1), the chair of the Inquiries, Complaints and Reports Committee shall not select a panel of the Committee to investigate a complaint where the Registrar has determined that it is not reasonable to believe the allegations contained in the complaint, if established, could constitute professional misconduct, incompetence or incapacity on the part of the member.

This provides regulators with the mechanism to triage frivolous complaints so that resources can be better targeted to investigations related to genuine public safety concerns.

12 (9) Where, within 30 days of receiving notice under subsection (8), the complainant makes a request in writing to the Registrar seeking a review of the Registrar's determination, the chair of the Inquiries, Complaints and Reports Committee shall select a panel of the Committee to review the Registrar's determination.

MPP Bill Walker reported that he received a letter from the Federation of Health Regulatory Colleges of Ontario recommending that "complainants be given 14 days to decide on whether to request a review."⁷⁶ A fair process for complainants must not be compromised by the requirement to resolve complaints in 150 days.

RNAO is concerned with the current wording of of the Bill stating:

(2) Where a member resigns, or voluntarily relinquishes or restricts his or her privileges or practice, a person referred to in subsection (3) who has reasonable grounds to believe that the resignation, relinquishment or restriction, as the case may be, is related to the member's professional misconduct, incompetence or incapacity, shall file with the Registrar within 30 days after the resignation, relinquishment or restriction a written report setting out the grounds upon which the person's belief is based.

First, RNAO would like the committee to ensure that this provision applies to all settings where health-care is delivered, not just hospitals. Second, RNAO is unclear what reasonable grounds means and suggests greater clarity be added.

RNAO Recommendations:

- Prohibit for-profit collection of blood and blood products. Instead of moving away from the World Health Organization and Krever Commission recommendations, the Canadian blood supply must build self-sufficiency. This can be done by ensuring the blood and blood products are used responsibly; cost savings generated through a national pharmacare program; and ensuring that blood donor criteria are evidence-based to account for actual risks rather than stereotypes
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- rebates and value adds are discontinued.
- RNAO looks to the government of Ontario to provide leadership for a pan-Canadian standardized, publicly funded and publicly controlled pharmacare program.
- Advance amendments to the *Public Hospital Act* and *Regulated Health Professions Act* that will promote public safety, confidence in the self-regulatory system and accountability of regulators, while promoting fairness to the health-care professionals involved.

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