Association of Ontario Midwives
Delivering what matters.

May 24, 2024

Laboratories and Diagnostics Branch
Health Programs and Delivery Division
Ministry of Health
438 University Avenue, 4th Floor
Toronto ON M7A 1N3

Re: **Proposed Amendments to Ontario Regulation 45/22 (General) under the Laboratory and Specimen Collection Centre Licensing Act**

To whom it may concern,

Thank you for the opportunity to respond to the proposed changes to the Laboratory and Specimen Collection Centre Licensing Act, 1990. The Association of Ontario Midwives (AOM) has two major overarching concerns with this proposed Regulation:

1. The Ministry of Health (MOH) must undertake fulsome consultation with Indigenous (Aboriginal) Midwives working within the Exemption Clause and First Nation, Metis, Inuit communities regarding proposed regulation of laboratory tests that can be ordered by Indigenous (Aboriginal) Midwives. This consultation process should be Indigenous led. The Indigenous Midwifery department at the AOM can help facilitate the necessary consultations. Consultation with the College of Midwives of Ontario (CMO) does not satisfy a requirement for consultation with Indigenous Midwives as they are not members of the CMO or regulated by the CMO. Indigenous Midwives are community-governed through distinctions-based approaches. The current open public consultation does not fulfill the commitment to reconciliation with Indigenous Peoples made by the Government of Ontario to design programs that apply to Indigenous Peoples with the input and support of Indigenous Peoples.[1]

2. The MOH continues to embed in the Regulation a list of specific tests midwifery clients can access through their midwives, an approach which has proven to be a barrier to safe, cost-effective, client-centered care. This approach to regulation must be stopped.

Midwives should be enabled to order any laboratory test within their scope of practice, rather than being limited by a list that is quickly outdated and not responsive to the needs of clients. It is imperative that the Ontario Government promptly adopt a new approach to regulation.

[1] Government of Ontario, Ontario's commitment to reconciliation with Indigenous peoples, Accessed at https://www.ontario.ca/document/spirit-reconciliation-ministry-indigenous-relations-and-reconciliation-first-10-years/ontarios-commitment-reconciliation-indigenous-peoples , April 30, 2024

While the AOM has significant concerns as outlined above, we acknowledge that, in the interest of immediate improvements to client care, the proposed changes to the Regulation should be adopted. However, **prior to the adoption of the proposed changes, Indigenous (Aboriginal) Midwives must be added to the list of those authorized to provide point-of-care testing** under Section 25.1. At a minimum, Indigenous Midwives practicing within the Exemption in section 8 (3) of the Midwifery Act must be authorized to provide their clients all of the tests authorized to Registered Midwives.

The pages that follow will highlight additional problems with and potential alternatives to the proposed changes, specifically:

1. The regulation of Indigenous Midwives
   1.1. Access to point-of-care testing for Indigenous Midwives
2. How regulating by embedding a list of specific tests in the Regulation is a barrier to safe, cost-effective and client-centered care
   2.1. The problem with the list of tests in Schedule 2
   2.2. The contradiction to the government's "Your Health: A Plan for Connected and Convenient Care"
   2.3. Alternatives to naming specific tests midwives can order in the Regulation

1.0 The regulation of Indigenous Midwives

In an effort to enhance equity and improve Indigenous midwifery clients' experiences, the MOH provided Indigenous Midwives with Ontario Health Insurance Plan (OHIP) identification numbers. This change came into effect on July 1, 2022, and grants Indigenous Midwives access to directly refer clients for laboratory tests and diagnostic services within the midwifery scope of practice. Language which is inclusive of Indigenous Midwives must be added to all regulations and regulatory proposals to reflect this change in practice.

1.1 Access to point-of-care testing for Indigenous Midwives

As per the background above, Indigenous Midwives must be added to section 25.1 (1) which allows for point-of-care testing within this proposal.

2.0 How regulating by embedding a list of specific tests in the Regulation is a barrier to safe, cost-effective and client-centered care

2.1 The problem with the list of tests in Schedule 2

Midwifery clients face barriers to accessing testing because of the government's insistence on writing regulations which list specific tests midwives can order. The history of harm this has caused can be understood by reviewing the 42 tests added in the current proposal for Schedule 2 and the additional tests that were recommended by the CMO but remain omitted from the proposed list. Each one of these tests represents missed opportunities for a higher standard of care for countless midwifery clients. These lists of tests tell the story of care that should have been accessible to pregnant Ontarians from their midwives for a decade or longer. That some tests recommended by the CMO have been added while others have not, even though they are clearly all within the scope of midwifery, demonstrates the randomness of this approach and the ongoing inequity in access to care. Here are a few examples:

Tests added to the proposed list in Schedule 2 (and for which midwifery clients have experienced barriers to access for a decade or more):

1. **Fetal fibronectin testing** for threatened preterm labour has been a standard of care funded by the MOH since 2009, and is proposed to be added to Schedule 2 in 2024. The Provincial Council for Maternal and Child Health (PCMHC) provides a detailed clinical protocol for ordering and performing the test. PCMCH reported:

   "Evaluation of the testing protocol revealed significant cost savings to health provider organizations and the system as a whole, and suggested increased quality and safety of care to birthing individuals and their newborns."[2]

   Threatened preterm labour is an urgent time-sensitive condition that must be tested for as soon as possible to initiate life-saving treatments. Prompt diagnosis improves outcomes and safety of care, and saves health-care dollars. For the past 15 years, midwifery clients have needlessly waited and worried while costly physician consultations were arranged to order a test which could have been ordered by a midwife using the same PCMHC protocol followed by physicians. The AOM welcomes this test being added to midwives' scope of practice; however, this gap in care demonstrates how the list of tests quickly goes out of date and forces midwives to find workarounds that are not efficient for the system or in the best interest of clients.

[2] Provincial Council for Maternal and Child Health, https://www.pcmch.on.ca/fetal-fibronectin-testing/, accessed April 30, 2024.

2. **Non-invasive prenatal testing (NIPT)** was the chosen method of screening for 17,802 of 146,947 pregnant Ontarians in 2020. Prenatal Screening Ontario states, *"NIPT should be offered to all pregnant individuals prior to initiating prenatal genetic screening along with other available options."* [3] Although the MOH has funded the test for a selected population since 2014, and it has been available for those who choose to self-pay since 2011, midwives have not been able to order the test. Tens of thousands of midwifery clients have suffered the consequences. Again, this test is a welcome addition but the options for prenatal screening will evolve and midwives must be given the authority to provide the latest evidence-based care without finding workarounds.

3. **Zika virus testing** for pregnant people became an urgent concern in 2014 when a large epidemic in Brazil showed Zika to be associated with microcephaly in newborns. Zika testing in pregnancy for those with potential exposure or symptoms became a standard of care in Ontario in 2015, yet the test will not become readily accessible to midwifery clients until later in 2024.[4] There will be outbreaks of new infectious diseases beyond Zika; lists of specific tests that will not include the latest infectious threat limits midwives' ability to actively participate in the public health response.

Tests omitted from the proposed list in Schedule 2 (tests for which midwifery clients will continue to face barriers to access):

4. **Parvo virus tests** for infection or immunity do not appear on the proposed Schedule 2 list, despite the addition of testing for Zika, which is much rarer in the Ontario population. Parvo infection in pregnancy is associated with non-immune hydrops and fetal death. Parvo outbreaks occur annually in Ontario with larger epidemics occurring every four to five years. The Society of Obstetricians and Gynecologists of Canada (SOGC) recommends:

   "Pregnant women who are exposed to, or who develop symptoms of, parvovirus B19 infection should be assessed to determine whether they are susceptible to infection (non-immune) or have a current infection by determining their parvovirus B19 immunoglobulin G and immunoglobulin M status."[5]

---

[3] Prenatal Screening Ontario, https://www.prenatalscreeningontario.ca/en/pso/resources/Remediated-PDFs-2020/PSO-Program-Report---FINAL-Dec-8-2021.pdf, accessed April 30, 2024.
[4] Public Health Ontario, Zika, Accessed at https://www.publichealthontario.ca/en/Diseases-and-Conditions/Infectious-Diseases/Vector-Borne-Zoonotic-Diseases/Zika-virus , April 30, 2024.
[5] Society of Obstetricians and Gynecologists of Canada, Clinical Practice Guideline, Parvovirus B19 Infection in Pregnancy, J Obstet Gynaecol Can 2014;36(12):1107–1116.

If the MOH persists with listing every virus test that can be ordered by midwives in Schedule 2, midwives will not be able to provide this recommended care to their clients. The selection of viral tests which appear in Schedule 2 is not comprehensive when compared to Ontario Public Health recommendations for pregnant people. As new viral threats to health for pregnant people and their newborns emerge, midwives will not be able to follow public health directives for testing due to the limitations of the list approach.

5. **Electrolyte tests**, including serum sodium, chloride and magnesium, which were on the list of tests recommended by the CMO, have been omitted from the proposed Schedule 2 list. Dehydration is a serious health concern for the pregnant person and fetus, and can result from hyperemesis gravidarum or vomiting and diarrhea caused by viral or bacterial infections. Electrolyte testing may be indicated to determine if the client requires intravenous fluid replacement and/or hospitalization.[6] As these are not rare problems, and can suddenly impact an otherwise healthy pregnancy, it is unclear why tests needed in the diagnosis of dehydration should not be performed by midwives.

The above offers a small sample of the many examples illustrating needless, harmful and inequitable barriers to care for midwifery clients. The delays and gaps in care, as well as the extra costs created by regulating through a specific list of tests are unconscionable. **Any assertion that restricting midwifery practice through a list of tests protects the public by ensuring that midwives do not practice outside their scope must be weighed against the proven harms of this type of regulation to midwifery clients and the Ontario health-care system,** including:

- increased **clinical risk** to midwifery clients and their newborns
- **gaps, delays, and roadblocks in services** for thousands of people receiving perinatal and newborn health care in Ontario
- adding to the burden of an already struggling health-care system with **extra appointments, ER visits and hospital stays**
- burdens on taxpayers for the **unnecessary additional cost of these extra visits and services**

[6] Jansen LA, Shaw V, Grooten IJ, Koot MH, Dean CR, Painter RC. Diagnosis and treatment of hyperemesis gravidarum. CMAJ. 2024 Apr 15;196(14):E477-85

- **unnecessary inconvenience for midwifery clients** who must juggle time off from work, pay for childcare and transportation, and experience delays in care to get appointments with other practitioners (who are often overbooked or not available close to home), for care they could and should have received directly from their midwives. This is an equity issue, as the added burden too often results in clients not accessing the recommended testing at all, potentially endangering their health and resulting in greater costs to the health-care system down the line.

2.2 The contradiction to the government's "Your Health: A Plan for Connected and Convenient Care"

The 42 tests the MOH proposes to add to Schedule 2 are not an expansion of the midwifery scope of practice, but rather are proof that the current and proposed lists in Schedule 2 are harmful restrictions on midwifery scope of practice. Logically, any test being added in the current proposal should have been recognized as being within the midwifery scope of practice since the very beginning of regulated midwifery in Ontario, or since the test became recommended as a standard of care in Ontario. Midwives have had the qualifications and competence to order these tests all along, and should have been able to provide these tests to their clients long before 2024. The MOH must acknowledge that equitable access to care has been unnecessarily denied to midwifery clients. **Regulation through a list of specific tests has failed Ontarians. Continuing the same approach will not produce a different result. It does not fulfill the promise of Pillar One of "Your Health: A Plan for Connected and Convenient Care" because midwifery clients will continue to face barriers to receiving the right care in the right place.**

The proposed Regulation is a failure to achieve the MOH's stated goal to work with the CMO to increase access to the right care in the right place through the ordering of lab tests by midwives.[7] The scope of practice statement in the Midwifery Act, 1991, S.O. 1991, c. 31 begins with the phrase: "The practice of midwifery is the assessment and monitoring of women during pregnancy, labour and the post-partum period and of their newborn babies[8]." Midwives are trained to provide this assessment and monitoring, which always requires lab tests, and midwives are regulated by the Midwifery Act and the CMO to practice within scope. Embedding a list of specific tests in regulation, which has proven to be insufficient for the care needs of clients, is unnecessary. There are better approaches the MOH can adopt to deliver "connected and convenient care."

[7] Letter from Dr. Eric Hoskins, Minister of Health to Tiffany Haidon, Present of the College of Midwives of Ontario, September 20, 2017, accessed at https://cmo.on.ca/wp-content/uploads/2017/09/2017-Scope-of-Practice-Minister-Letter-Midwives1.pdf , April 30, 2024

[8] Government of Ontario, Midwifery Act, 1991, S.O. 1991, c. 31. Accessed at https://www.ontario.ca/laws/statute/91m31 , May 24, 2024

2.3 Alternatives to naming specific tests midwives can order in regulation

In June 2016, the CMO met with the MOH to propose regulatory changes, including removing lists of drugs and laboratory tests and replacing the lists with the ability to prescribe and administer drugs and order laboratory tests in accordance with the midwifery scope of practice.[9] When these proposals were rejected by the MOH, both the CMO and the AOM worked to provide a model for drug regulation which would specify *categories* of drugs rather than *a specific list* of drugs. Had this model of regulation using categories been acceptable to the MOH, the same approach of using categories instead of naming specific tests could have been applied to Schedule 2 in the General Regulation under the Laboratory and Specimen Collection Centre Licensing Act, 1990.

Other Canadian jurisdictions have adopted the use of categories as a more patient-focused approach to regulating both the tests and drugs that are accessible to midwifery clients. The categories of tests in Table 2 of the Saskatchewan *Midwifery Act, M-14.1*[10] have been unchanged since 2008. **If Ontario had used these categories, the problems caused by listing specific tests in Schedule 2 would be avoided.** Midwifery clients would not need an urgent physician consultation for assessment of dehydration. Midwives would be able to follow all, instead of an apparently random selection, of the recommendations of Public Health Ontario for virus testing in pregnancy. This would provide better, safer care for tens of thousands of Ontarians.

Saskatchewan is now applying the same principles to midwifery ordering and administering of drugs that successfully served Saskatchewan's midwifery clients in the regulation of ordering tests. **The government of Saskatchewan recently amended their Midwifery Act to use categories to regulate the drugs that can be used and prescribed by midwives, replacing a list of specific drugs.** The Saskatchewan government press release announcing the change to categories rather than specific lists stated, "This change removes regulatory barriers to safe and appropriate patient care." [11]

The problems inherent to the list-based approach are summed up in that statement, and a solution which works within a regulatory framework for midwifery has been identified. Resistance by the Ontario Government to this improvement in patient care, which will also

---

[9] College of Midwives of Ontario, Recent Timeline on the Proposed Changes to the Designated Drugs Regulation and Laboratory and Specimen Collection Centre Licensing Act, 1990, accessed at https://cmo.on.ca/recent-timeline-on-the-changes-to-the-designated-drugs-regulation-and-laboratory-and-specimen-collection-centre-licensing-act-1990/ , April 30, 2024.
[10] Government of Saskatchewan, Midwifery Act, M-14.1, Accessed at https://publications.saskatchewan.ca/#/products/23016 , April 30, 2024.
[11] Government of Saskatchewan, Changes to the Midwifery Regulations, https://www.saskatchewan.ca/government/news-and-media/2024/april/15/changes-to-the-midwifery-regulations, accessed April 30, 2024.

reduce system costs, is a disservice to Ontarians.

In summary, while adoption of the proposed changes to the Laboratory and Specimen Collection Centre Licensing Act, 1990, will improve the care received by midwifery clients in Ontario, **the addition of a few more laboratory tests is not enough**. The list-based system of regulation will continue to endanger the health and well-being of childbearing Ontarians and their newborns, and place unnecessary financial and human resources burdens on the health-care system.

The AOM urges the MOH to ensure that:

- The process for development and consultation for regulatory proposals that impact the health of Indigenous communities honours the commitment of the Ontario Government to reconciliation
- Language which is inclusive of Indigenous Midwives be added to all regulations and regulatory proposals
- Specifically for this proposal, Indigenous Midwives must be added to section 25.1 (1) which allows for point-of-care testing
- Work begins immediately to create new regulations which do not list the specific tests authorized to midwives

We look forward to the opportunity to work with the Ministry of Health to achieve these goals.

Sincerely,

Althea Jones

Alexa Minichiello

Althea Jones, RM
President

Alexa Minichiello
Acting CEO

CC: Allyson Booth, Director, Quality Risk Management, AOM
Megan Bobier Acting Director, Clinical Knowledge Translation, AOM
Kelly Dobbin, Registrar, CMO
Claire Ramlogan-Salanga, President, CMO