Scope of Practice Changes
Submission to the Ministry of Health and Long-Term Care
January 2018
SCOPE OF PRACTICE CHANGES UNDER CONSIDERATION

1. Prescribing controlled drugs and substances
2. Order specified lab tests

Review of 2009 Submission

The Ministry of Health and Long-Term Care (Ministry) has completed a preliminary review of the College’s 2008 submission to the Health Professions Advisory Council (HPRAC). Given the period of time that has elapsed since the drafting of the original submission and the Ministry’s development of a new framework to evaluate scope of practice requests, the Ministry requests additional information in order to proceed with the review.
GENERAL INFORMATION

Please provide the following information:

Question 1: An updated list of laboratory tests the profession is requesting access to and a brief description of the purpose of each test.

Question 2: An updated list of the controlled drugs and substances the profession is requesting access to and a brief description of the purpose for which each drug would be used.

The College of Midwives of Ontario (College) is requesting that the Ministry rescind the current list of laboratory tests midwives are authorized to order in Appendix B of the Laboratories Regulation under the Laboratory and Specimen Collection Centre Licensing Act (Government of Ontario, 2015). Instead, the College is requesting that the Ministry grant midwives the authority to order laboratory tests within their scope of practice as defined by the Midwifery Act, 1991 and the controlled acts authorized to midwives. The College is also requesting that the Ministry rescind the list in the Designated Drugs Regulation made under the Midwifery Act, 1991 and allow midwives access to any drug or substance approved by Health Canada, within the scope of midwifery practice, excluding any drug or substance prohibited to midwives under the New Classes of Practitioner Regulations.

The College is not requesting additions to the current list of laboratory tests and drugs because lists are prone to being outdated. The Ministry and the College cannot predict the tests and drugs that will be part of best practice in the continually evolving field of maternal and newborn healthcare in Ontario. Broader authority to order tests and prescribe within scope will:

1. ensure midwives are able to provide evidence-based care
2. allow midwives to respond to emerging health situations that pose increased risks to their clients
3. decrease the number of consultations with physicians for routine tests and treatments

Rationale

In 2008, the College requested that the Ministry add 20 new laboratory and diagnostic tests to the existing list and grant midwives the authority to prescribe 23 classes of therapeutic drugs, including controlled substances. The College requested the additional tests arguing that the lists at that time, did not include numerous tests and drugs that midwives required to provide care throughout a normal, healthy pregnancy. Based on their research, HPRAC agreed that, “midwives should be able to order and consider the results of diagnostic tests that might indicate a complication in a pregnancy” (Health Professionals Regulatory Advisory Council (HPRAC), 2008) and agreed that increasing access to certain classes of drugs is in the public interest (HPRAC, 2009).
Since 2008, the College has changed its approach to regulation and is in the process of adopting a risk-based approach to regulation based on the work done by the Organization for Economic Co-operation and Development (OECD), the Professional Standards Authority, and other professional authorities in the UK, and Professor Malcolm Sparrow of Harvard’s John F. Kennedy School of Government on regulatory reform. In keeping with a risk-based approach to regulation, the College believes that the public will be best served by midwifery care when clients receive the tests and treatments that are in their midwives’ scope of practice.

There are known risks to ordering laboratory tests and prescribing drugs. Some of the risks are misdiagnoses, incorrect ordering or prescribing, and a lack of follow-up. If we are to understand how broad authority to work according to scope poses greater risks to midwifery clients than the current lists, we must be able to link this broad authority with increased risks and harms to clients. This link is very difficult to make because risks and harms are almost impossible to quantify. Most research does not look at actual harms so linking regulations to client outcomes is challenging (Professional Standards Authority, 2015b). Even when looking at the College’s data, there has been only one referral to discipline alleging the unauthorized prescribing of a controlled substance. Yet even in this case, there was no report of client harm as a result.

Owing to a lack of data, assessing risk of harm for midwifery clients requires the Ministry and the College to predict the risks to the public, and this is an impossible task (Professional Standards Authority, 2015b). No organization can predict if broader authority will put clients at risk. Alternatively, it cannot be predicted if broader authority to work in scope will reduce the risks that currently exist as a result of the current lists of drugs and medications. What the evidence does show is that the only way to generate data showing the safety and efficacy of scope of practice expansion is to make the leap and expand scope (LeBuhn & Swankin, 2010, p. 9) providing further support for the unpredictability about how a change in scope will affect quality of care and patient safety.

What is known is that health care outcomes can be hard to control. No matter what safeguards are put in place, zero risk is impossible to achieve (Better Regulation Commission, 2006; Professional Standards Authority, 2015a). All health care interventions have some degree of risk and eliminating all risk would also “eliminate the possibility of any benefit for the patient” (Professional Standards Authority, 2015c, p. 9). The Better Regulation Commission believes that “governments and regulators must choose certain risks over others” (Professional Standards Authority, 2015b, p. 10). And since risks cannot be predicted, it is important to look at whether the current list structure benefits the public and protects clients from harm. What the literature shows is that rather than appropriately guiding members, unnecessarily prescriptive regulations can exert enormous burdens on members of a profession (Professional Standards Authority, 2015b). This burden is a detriment to their performance and reduces a professional’s reliance on their knowledge and skills (Professional Standards Authority, 2015c). It is, therefore, in the interest of the public to regulate only to the level of risk.
inherent in the act (p.18). Risk-based regulation supports professionals exercising their professional judgment in lieu of overly prescriptive regulating and recognizes that regulators are only one influence on a professional, among many, that keep the public safe. (Professional Standards Authority, 2015a).

In addition to the principles of risk-based regulation, the work on scope optimization presents a compelling argument for broader authority for midwives to work according to an optimal scope. In Managing the Oversight of the Health Workforce in Ontario, current scopes of practice and controlled acts were recognized as being potential barriers to providing individualized care, working collaboratively with other health care providers and keeping up with an evolving health care system (Waddell, Moat, & Lavis, 2017). A review of successful models of collaboration between midwives and physicians found that “regulation allowing the full scope of midwifery practicing…was essential to successful collaborative practice” (Avery, Montgomery, & Brandl-Salutz, 2012). The Canadian Medical Association (CMA) believes that the scope of practice of every health professional should enable them to contribute optimally to providing high quality patient-centred care without compromising patient safety and that ideally, every health care provider should have a scope of practice that is consistent with his or her education and training, and that the health care system should enable them to practice to the fullest extent of this scope (Canadian Medical Association, 2015) (p. 3).

**Question 3: Updated profile of the profession and its practice, specifically addressing the following considerations**

- **How many members are registered to practice with the College?**
  
  On September 30, 2017, at the end of the last quarter, there were 746 members registered in the general class and eligible to practice. An additional 149 members were registered in the inactive class, some of whom will be returning to practice in the immediate future.

- **How many registered members will be impacted by this change?**
  
  The entire practicing membership will be affected by this change because members practice to the limits of midwifery defined by the *Midwifery Act, 1991* which involves ordering laboratory tests and prescribing medications for routine prenatal, intrapartum, postpartum and postnatal care. For the 2016/17 fiscal year, the membership provided midwifery care to 22,627 Ontario women who may be influenced by the change.

- **Practice Setting (e.g., % of members practicing in community or acute settings)**
  
  Owing to the midwifery scope of practice, 100% of midwives practice in what would be considered a community setting. While a handful of midwives work with physicians using the hospital as their primary practice location, they do not provide acute inpatient care.
**Practice Characteristics (e.g., % in independent practice, % practicing in interprofessional teams)**
There are 96 midwifery practice groups (MPG) in the province where the majority of midwives belong. Of these MPG, 4 are solo practitioners providing midwifery care as the only midwife in the practice. The remaining midwives work with at least one other midwife. Twenty-nine midwives, representing nine different MPG work interprofessionally with physicians.

**Geographical Distribution (e.g., % practicing in rural/remote locations, % in urban locations)**
Using the Rurality Index of Ontario (RIO), a 2015 report showed that approximately 15% of MPG designated rural and approximately 8% of MPG designated remote (Association of Ontario Midwives, 2015).

**General Demographics of principal patient groups treated by the profession (e.g., age, morbidities, geographic distribution).**
Data from the Better Outcomes Registry and Network (BORN), the provincial database that collects maternal and newborn data from Ontario, shows that for the 2016/17 fiscal year (April 1, 2016 to March 31, 2017), 83.6% (19, 434) of clients in midwifery care had an urban postal code and 17.4 % (4,087) had a rural postal code (Better Outcomes Registry and Network, 2017)

The general demographics of the client group is women of childbearing age who are considered healthy with healthy pregnancies. While women and their newborns may develop morbidities during their care, midwives accept into care women who are healthy in accordance with their scope as defined by the Midwifery Act, 1991. For the 2016/17 fiscal year, the age of midwifery clients by rural or urban postal code is found in the following table:

<table>
<thead>
<tr>
<th>Maternal Age At Birth (Years)</th>
<th>Urban</th>
<th>Rural</th>
<th>Missing Data</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>14-17 Years</td>
<td>61</td>
<td>19</td>
<td>0</td>
<td>80</td>
</tr>
<tr>
<td>18-19 Years</td>
<td>192</td>
<td>44</td>
<td>0</td>
<td>236</td>
</tr>
<tr>
<td>20-24 Years</td>
<td>1,646</td>
<td>517</td>
<td>&lt;6</td>
<td>2,165</td>
</tr>
<tr>
<td>25-29 Years</td>
<td>5,266</td>
<td>1,451</td>
<td>13</td>
<td>6,730</td>
</tr>
<tr>
<td>30-34 Years</td>
<td>8,035</td>
<td>1,486</td>
<td>8</td>
<td>9,529</td>
</tr>
<tr>
<td>35-39 Years</td>
<td>3,708</td>
<td>493</td>
<td>8</td>
<td>4,209</td>
</tr>
<tr>
<td>40-44 Years</td>
<td>494</td>
<td>76</td>
<td>&lt;6</td>
<td>573</td>
</tr>
<tr>
<td>&gt;45 Years</td>
<td>31</td>
<td>&lt;6</td>
<td>0</td>
<td>32</td>
</tr>
<tr>
<td>Missing Data</td>
<td>&lt;6</td>
<td>0</td>
<td>0</td>
<td>&lt;6</td>
</tr>
<tr>
<td>Total</td>
<td>19,434</td>
<td>4,087</td>
<td>34</td>
<td>23,555</td>
</tr>
</tbody>
</table>

**Description of remuneration model for the profession (e.g., % OHIP-insured services, % privately insured services, % uninsured services):**
Midwifery is a managed program under the Ministry. The Ontario Midwifery Program (OMP) funds each MPG through a transfer payment agency (TPA).
Each MPG has a funding arrangement with a Ministry-approved TPA to provide midwifery care in a particular geographical location.
PATIENT AND/OR SYSTEM NEED

The 2008 policy submission links the expanded scope to the various patient and system needs listed below. The Ministry is seeking more information and supporting evidence on how the proposed changes to scope of practice impact these needs.

**Question 1: Impact on timely access to care**

According to Health Quality Ontario (HQO), access can be measured as the percent of patients who report that they were able to get a same or next-day appointment when they were sick or needed medical attention (2012). In Ontario, 56% of adults are unable to access care when they need it despite the fact that 94% have primary care physicians (Health Quality Ontario, 2017). Health Quality Ontario’s best practice states that in order to address timely access to care, we must reduce the demand for health care visits and reduce the number and type of appointments. Midwives ordering lab tests and prescribing in scope is an important part of ensuring timely access for clients in their care because it prevents unnecessary physician visits. Midwives with broader authority to order and prescribe in their scope will reduce the wait times for clients who must be referred to their family physician or obstetrician to receive the care that could be provided by their midwife. Rather than having to wait, on average, one to two weeks to see their own physician (Health Quality Ontario, 2012), the lab test or medication can be ordered the moment its need is identified during the midwifery visit, in the midwife’s office.

Clients often choose midwifery care because midwives are the only professionals with the skills and training to provide home birth and one of the only professionals competent to provide postpartum primary care at home for women and newborns. Many women choose this care because of these unique components of care. Women in midwifery care should have the same access to new and approved laboratory tests and drugs as women in the care of a family physician.

In rural and remote areas of the province, concerns about access are exacerbated because of the limited care options available to women and newborns in these communities (Ministry of Health and Long Term Care, 2010). With fewer physicians in practice, and the health human resource shortage in many rural and remote communities, there is greater potential for longer than average times to appointments. In some cases, clients will not even have a family physician to be referred to. As a result, they may choose not to have testing done or obtain a prescription, or they may end up in the closest hospital emergency department, possibly in another community, to access the care.

**Question 2: Impact on quality of care and patient safety**

The only way to show that expanding scope of practice is safe requires expanding the scope and evaluating it after the change is made (LeBuhn & Swankin, 2010, p. 9). This suggests that there is no way of knowing, prior to changes in scope, how the change
will affect quality of care and patient safety. All health care interventions have risks attached and no amount of safeguarding can prevent these risks (Professional Standards Authority, 2015c). There is no research to demonstrate changes to the quality and safety of midwifery care in Ontario after a change in scope so other sources must be looked at for answers. There is research on other non-physician care providers working in expanded scope that shows positive results. Non-physician health care professionals can competently provide care that adheres to the same patient safety standards as that provided by physicians in the same discipline (LeBuhn & Swankin, 2010). A 2009 Cochrane review found that nurses can provide care of equal quality as physicians with good health outcomes (Colorado Health Institute, 2008). Hwang, Koleba & Mabasa (2013) found that more and more studies are demonstrating improved patient outcomes when pharmacists practice in an expanded scope. In addition, pharmacists’ job satisfaction is enhanced. This body of literature on expanding scopes shows it works in the best interest of clients and the professionals working in the new scope.

HPRAC’s recommendations about the College’s 2008 submission support the findings above regarding optimizing or expanding scope. Through their literature review and jurisdictional scan, HPRAC recommended that granting midwives more tests and medications was in the best interest of the public:

*Authorizing midwives to order the additional laboratory tests and diagnostics may result in better patient care by enabling a midwife to identify potential risk factors earlier. In its analysis, HPRAC agreed with the CMO’s position that midwives should be able to order and consider the results of diagnostic tests that might indicate a complication in the pregnancy, so they can determine whether a referral to a specialist is required, or if they should continue with the course of care. Patients would consider this responsible care, and an expected professional duty.”* (HPRAC, 2008, p. 17)

HPRAC’s review of non-physician prescribing found…. ‘midwives currently have prescribing rights, and in HPRAC’s view, midwives are educated and trained on an ongoing basis to prescribe the most current drugs to treat conditions within their scope of practice’ (HPRAC, 2009, p. 238).

There is a body of research supporting the benefits to patients when they get the care they need when they need it. Studies on advanced access, which is based on client-driven appointment scheduling rather than pre-arranged appointments, shows that patient care improves, patient anxiety is reduced and care providers are happier as they “no longer feel they are on that proverbial treadmill” (Health Quality Ontario, 2012). The Ministry’s focus on advanced access could be the sole rationale for midwives having broader laboratory testing and prescribing authority to provide care for clients at the moment the need is identified. However, some of the most salient points for broadening the scope are provided below.
• **Best Practice and Clinical Practice Guidelines**
  A list of laboratory tests or prescription drugs is prone to being outdated because future gold standard testing and evidence-based prescribing cannot be predicted. Midwifery clients are at risk of receiving sub-optimal care when midwives are not able to provide clients with best practice and follow the recommendations of constantly changing clinical practice guidelines. An example of this occurred when the Zika virus became a public health concern in Ontario in the summer of 2016. At this time, midwives spent a great deal of time contacting the College and laboratories to advocate for clients at risk who required Zika virus testing which was not in Appendix B (Public Health Agency of Canada, 2016). Another example occurred in 2003, when ergonovine maleate, a drug specified in the College’s Designated Drugs Regulation to treat postpartum hemorrhage, became temporarily unavailable to the health care sector for a prolonged period of time. There was no alternative medication available through the regulation that allowed midwives to treat postpartum hemorrhage in situations where the first-line treatment failed.

The Ministry has clearly stated that all health system partners have a role to play during the response to an influenza pandemic (Province of Ontario, 2013). Primary care providers, including midwives, must be able to prescribe and administer influenza vaccines as well as antiviral medications such as Tamiflu. Data from the 2009-2010 H1N1 influenza pandemic revealed a relationship between administration of the influenza vaccine in pregnancy and improved fetal and neonatal outcomes (Fell, 2012). With only a third of Canadians receiving the influenza vaccine, and Ontario showing a decline in acceptance in past years (Statistics Canada), facilitating access should be a public health priority and midwives can be an integral part of implementing this recommendation.

• **Delays in Care**
  Currently, the inability of midwives to order and prescribe to scope can subject clients to risks to their health and their newborns health when there is delay in performing some laboratory tests. One example is ordering tests to determine why a pregnant or postpartum client has elevated blood pressure measurements (see the Society of Obstetricians and Gynaecologists of Canada (SOGC) guidelines on hypertensive disorders of pregnancy) (Magee, Pels, Helewa, Rey, & von Dadelszen, 2014). High blood pressure in pregnancy can be a precursor to serious problems for women and newborns and is a significant risk factor for maternal morbidity and mortality internationally (Bilano, Ota, Ganchimeg, Mori, & Souza, 2014; Ghulmiyyah & Sibai, 2012; Magee et al., 2014). In high income countries like Canada however, this has largely been prevented because of timely access to care and proper management (Ghulmiyyah & Sibai, 2012). Canadian research shows that poor coordination during prenatal care can lead to evolving conditions, such as preeclampsia, and that earlier interventions may result in better management (Canadian Medical Protective Agency, 2016). As such, timely laboratory tests for these conditions, at the moment a concern is identified, may prevent them from developing into full blown diagnoses and
improve patient outcomes. Other tests, such as the Non-Invasive Prenatal Test (NIPT) which is current best practice to determine if a fetus has specific aneuploidies are equally time sensitive. While no inherent harm will come to the pregnant client if testing is delayed, their values and preferences are not respected and the goals of continuity and person-centred care are compromised. This is a particularly important acknowledgement in a profession that clients often choose because of its approach to informed choice and continuity of care.

Another example of delays in care that can lead to unwanted outcomes is prescribing contraceptives. Midwives routinely counsel postpartum clients on contraceptive choices yet are unable to prescribe them. Instead, midwifery clients must arrange care from another provider. This inability to receive contraceptives prior to discharge from midwifery care is a barrier to clients accessing the right care at the right time from the right provider. This delay also puts the client at risk of an unwanted pregnancy.

- **Seamless care**
  Most laboratory errors (46-68%) occur during the pre-analytic stage (i.e. before the samples are analyzed). A number of these errors are more apt to be avoided when the primary care provider is ordering the test. These problems include order entry errors and misidentification of patients, all of which would be avoided with continuity of care provider where the same provider identifies the need for testing, performs the testing and receives the results (Hammerling, 2012). This lack of continuity can further compromise care when laboratory tests ordered by a physician are not received by the midwife’s practice. With two care providers from different practices now part of an individual’s care plan, there is greater potential for gaps to exist in the system of information sharing that negatively affect patient outcomes (Canadian Medical Protective Agency, 2016; HIROC, 2017).

  When clients choose midwives as their primary care providers, they are likely to be most satisfied if their midwife can provide the full range of care and support their preferences and values. Research shows that continuity of care and continuity of carer improve client outcomes (Sandall, Gates, Shennan, & Devane, 2016) and increases client satisfaction (Saultz & Albedaiwi, 2005).

  The College receives reports from clients who are dissatisfied with having to go to their physician to have a test ordered when their midwife has the knowledge to discuss the test, offer informed choice, and arrange follow up, but not actually order the test.

- **Client choice**
  Clients often choose midwifery care because midwives are the only professional that provides the option of a home birth and provides postpartum primary care at home for women and newborns. Many women choose this care because of these unique components of care. Women in midwifery care should have their choice in
care provider respected and not penalized by the limits imposed on their care providers tests and medications. Clients should have access to the same tests and medications as women who choose to have their care delivered by a family physician. A consequence of having to refer clients on for certain tests or prescriptions is that clients may simply choose not to access the care at all. This is not in line with the goals of the Ministry’s Excellent Care for All Act, 2010 to support a health care system that is accessible, appropriate, effective, efficient, equitable, integrated [and] patient-centred (Ministry of Health and Long Term Care, 2010).

Requiring midwives to consult with a physician only to order a laboratory test or prescribe a medication that is in scope also has the potential to undermine the clients trust in their midwife. The College receives inquiries from clients asking why their midwife, who they trust to deliver their care and their newborn’s care, is not allowed to order a blood test or prescribe a medication. From the provider’s experience, the College receives reports from midwives concerned about having to consult for a prescription for narcotics in early labour which is an increasing part of their care.

- **Enhancing inter-professional collaboration**

  Interprofessional care is an expectation in the current health care environment and is cited as a minimum requirement in the Regulated Health Professions Act, 1991 (RHPA) (Ministry of Health and Long Term Care, 2017), for quality assurance programs. The College recognizes that interprofessional collaboration serves the public interest, and has a position statement with the College of Physicians and Surgeons of Ontario (CPSO) (CPSO, 2012). Limiting the laboratory tests and drugs authorized to midwives, however, can put collaborative efforts at risk. While consultation and referral are known to be effective ways to collaborate, poor or ineffective consultation can strain these relationships and lead to frustrated care providers according to the Canadian Medical Protective Agency (Canadian Medical Protective Agency, 2012). When midwives consult with physicians and request a test that is in a midwife’s scope of practice, this can strain these professional relationships by pushing the limits of the physician’s resources and time. It can also cause “responsibility overload”, all of which are known barriers to interprofessional collaboration (Registered Nurses' Association of Ontario, 2013). Responsibility overload might be exacerbated when physicians are providing care to women who they do not have a pre-existing relationship with and are simply responding to a midwife’s need for them to order a simple test and to prescribe a medication. Responsibility overload is also exacerbated when rural physicians are woken in the night to provide orders for tests or treatments that the midwife has the knowledge and skills to perform.

  As laboratory testing and prescribing become more advanced and increasingly unmanageable through a list, more clients will be sent to physicians or hospitals for episodic care that is within the scope of midwifery as defined by the Midwifery
**Act, 1991.** This will put increasing pressure on interprofessional relationships. In addition, physicians have expressed frustration with midwives when they receive referrals for what is a common pregnancy-related test or a drug. This can lead to physicians believing that midwives are skirting their own responsibilities and workload. For example, Appendix B under the *Laboratory and Specimen Collection Centre Licensing Act, 1990*, permits midwives to order laboratory testing to diagnose both Chlamydia and Gonorrhea. Midwives also have the authority to diagnose Chlamydia and Gonorrhea under the *Midwifery Act, 1991* through the controlled act of communicating a diagnosis (Government of Ontario, 1991). However, the current Designated Drug Regulation does not permit midwives to prescribe the first-line treatment for Chlamydia as per the current Canadian guidelines (Government of Ontario, 2010; Public Health Agency of Canada, 2015).

A review of the literature did not uncover any known barriers or facilitators to interprofessional care among primary care providers that would apply to midwives moving from lists to an optimized scope. Rather funding models, resistance to changing practice, education (Morgan, Carson, Gagnon, & Blake, 2014) and restrictions to scopes of practice are factors shown to influence collaboration between health care providers (Avery, Montgomery, & Brandl-Salutz, 2012). Avery et al. found that "regulation allowing the full scope of midwifery practicing...was essential to successful collaborative practice" (p. 427).

While the College exerts little control over funding models and education, it is eliminating standards that make it difficult for midwives to work in interprofessional models. In the spring of 2018, the College is set to rescind its restrictive standards that require midwives to only work with other midwives and replace them with a new professional standard that focusses on person-centred care, professional behaviour and integrity. The College is applying the evidence in support of risk-based regulation to revise its standards and expects that, with an optimized scope, there will be an important growth in positive collaborative efforts and interprofessional models of care.

**Question 4: Enhancing access to maternity care.**

The College does not believe broader authority to order tests and prescribe according to scope of practice will enhance access to maternity care for individuals seeking maternity care. However, for clients already in midwifery care, their access to elements of care will be enhanced as noted above.
IMPACT ASSESSMENT

The Ministry is seeking further information for an evidence-informed impact assessment of each change in scope of practice. The Ministry is particularly interested in getting more information in the following areas:

Patient Impact

Question 1: The 2008 submission argues that scope enhancements would address issues in patient access to care. Please elaborate on how these proposed scope changes would address the following areas:

a. Delays in care: The proposed changes would reduce delays in care as noted above under Question 2: Impact on quality of care and patient safety.

b. Care in rural and remote locations: The proposed changes would improve access to laboratory testing and drugs as noted above under Question 1: Question 1: Impact on timely access to care

Economic Impact

Question 2: What is the anticipated economic impact of the proposed change on:

• Patients:
  Midwives are funded to provide care to Ontario residents, regardless of insurance status. There are no financial costs associated with midwives having broader authority to order tests or prescribe medications including controlled substances. In fact, there would be some associated cost savings because clients would not incur any out-of-pocket expenses by having to go to another location, such as a physician’s office, to get a laboratory test or have a prescription written. For uninsured clients, while some consultation and laboratory fees are reimbursed by the Ontario Midwifery Program budget, other fees are not, and these out-of-pocket expenses would also be prevented. Our literature review did not provide the financial costs to individuals who have been referred to physicians, costs that might include transportation to the care provider, parking, childcare, and lost wages if taking time off work.

• Other providers:
  The College does not anticipate other care providers incurring additional costs as a result of the proposed changes. Because of the funding model for physicians, any decrease in fees owing to this proposed change is likely to be insignificant for them.

• Public resources:
  The use of public resources is largely dependent on current funding mechanisms and the salary differences between midwives and physicians. Midwives are paid per course of care and all publicly funded laboratory tests and prescription
medications are included in this billable course of care regardless of how many hours are spent or how complex the care is (Ministry of Health and Long Term Care, 2017). When midwives consult with physicians for the purpose of ordering or prescribing, additional charges are incurred by the health care system. In these situations, the physician can charge for the consultation visit, laboratory tests, and follow up care (Ministry of Health and Long Term Care, 2015). In addition, for some tests, women might be sent to their local hospital for consultation and testing where it is likely to be more expensive than community laboratory testing (Ministry of Health and Long Term Care, 2015). Midwives billing by course of care means some of these hospital costs would not be incurred by the health care system but would be included in the midwives’ fee. In cases where a client seeks care in a facility funded through an overarching budget, such as a Community Health Centre or Public Health Unit, using their funds for this kind of care may leave them fewer resources to treat clients who are not being served by midwifery care.

Public resources are also used when the Ministry and College need to coordinate urgent changes to the regulations because of the limits inherent in the current drug and prescribing lists. When the College and Ministry needed to work together revise the Designated Drug regulation during the ergonovine maleate shortage, the process took more than a year and consumed considerable human and financial resources to address this risk to public safety. With an optimized scope, resources will be saved because negotiations to ensure access to new testing or prescription medications will not be necessary. There will also be fewer resources required for future regulatory amendments.

- **Other stakeholders and Ontario businesses:**
  The College does not anticipate a situation where another stakeholder or Ontario business would incur a cost as a result of the proposed changes to Appendix B. However, there will be a small impact on the consortium of three Midwifery Education Programs (MEP) in Ontario when rescinding the list of drugs midwives are authorized to prescribe. The MEP will incur a one-time cost of further curriculum development to ensure that full midwifery scope, including prescribing controlled substances, is covered in the education program. However, it is likely that the end result will be a cost savings because the MEP will not need to continually revise its curriculum when new tests or medications are added to the list. Instead, an ongoing investment in curriculum focussing on the principles of safe ordering and prescribing will provide midwifery students with the necessary education to apply this theoretical foundation to any indication or condition within the scope of midwifery practice.
Professional Competency

Question 3: Do members of the profession currently have the competencies to perform the proposed change to the scope of practice? Describe these competencies:

At entry to practice, midwives have demonstrated competencies in ordering, performing and interpreting results of screening and diagnostic tests in accordance with provincial and territorial regulations and standards (Canadian Midwifery Regulators Consortium, 2008). In practice, midwives order a range of laboratory screening and diagnostic tests on their own authority in accordance with Appendix B (Government of Ontario, 2015). Ordering laboratory tests and understanding the crucial nature of appropriate testing, timely testing, receiving the test results and following up, and making referrals based on abnormal results will not be new skills to midwives; midwives currently have the knowledge, skills and judgement to do provide this care when clinically indicated. In addition, the Colleges Consultation and Transfer of Care Standard (CTCS) provides clear guidelines about when things need to be referred to another care provider (College of Midwives of Ontario, 2014). As such, the proposed changes to laboratory testing would not require additional competencies.

At entry to practice, midwives are competent to prescribe, in every province and territory where midwifery is regulated (Canadian Midwifery Regulators Consortium, 2008). Information gathered for the 2008 HPRAC submission describes how the competencies for pharmacotherapy are taught and tested in the MEP. The pharmacotherapy course includes an overview of the basic concepts in pharmacy, pharmacology and treatments relevant to midwifery. The midwifery curriculum includes pharmacokinetics, toxicology, adverse drug reactions and drug transfer through lactation and students learn the concepts of microbial control and virology and all major families of antivirals, antibiotics and antifungals. HPRAC was of the view that “midwives are educated and trained on an on-going basis to prescribe the most current drugs to treat conditions within their scope of practice…. (HPRAC, 2009) Prescribing is a core element of midwifery education (Wainman, McDonald, & Murray-Davis, 2017) and is reflected in the national core competencies. In practice, the controlled act of prescribing is not a discrete and isolated activity connected to a specific list of itemized drugs and substances. Prescribing is integral to providing comprehensive midwifery care to clients, within a therapeutic relationship. Like all other providers, before prescribing a drug, a midwife assesses a client’s health by taking a health history, formulating a differential diagnosis, and narrowing down the list of potential diagnoses and treatment options. The midwife also takes inventory of all the medications the client is taking to reduce the risk of interactions. The midwife then decides on the most appropriate course of action. In addition to the curriculum and practice, all midwifery applicants sit a national exam that tests their midwifery knowledge and they must successfully complete the College’s jurisprudence exam. As such, midwives are knowledgeable not only about the national competencies related to clinical practice but must understand their ethical and professional obligations to practice in accordance with their knowledge, skills and judgment and the overarching regulations and standards that guide the profession.
Broadening their authority to order lab tests and prescribe medications in scope allows midwives to work to the full extent of their competence as it relates to laboratory testing and prescribing.

When considering what is required to obtain and maintain competence in ordering tests and prescribing medications, it is essential to recognize that other practitioners with authority to prescribe and order tests have vast scopes of practice compared with midwives. These practitioners do not have the prior knowledge or experience of prescribing every drug or substance available. Instead, they limit their prescribing or ordering to reflect their competence and refer when the clients requires care that exceeds their knowledge, skills or judgment. This is the way midwives currently practice. There is also no known correlation between a list of drugs and substances and safe prescribing. There are currently dozens of lab tests and over 50 drugs and substances on the midwife’s drug list (Government of Ontario, 2010) and each has the potential to cause harm if prescribed or administered incorrectly or without sufficient knowledge, skill or judgment. The list does not ensure safety or protection from harm, rather it is midwifery competencies and professional practice standards that promote and guide safe prescribing and administration.

**Question 4: Describe the impact of the proposal on entry-to-practice (didactic and clinical) education and training requirements of the profession.**

There are insignificant impacts on the didactic and clinical instruction that would be required to adapt to the proposed changes to laboratory testing and prescribing. As noted above, midwives have the clinical skills required to perform the tests that might be included in their scope. They currently order and perform a range of screening and diagnostic tests and this is already an important part of their didactic and clinical training. Midwifery students learn to draw blood for routine prenatal blood tests, perform pap smears for cervical cancer screening and sterile speculum exams for determining rupture of membranes, perform charcoal swabs for Group B Strep and perform blood spot tests for congenital newborn screening.

The MEP also includes broad pharmacology education, principles of prescribing, and teaches all the medications required for care in pregnancy, even if current care is outside scope (Wainman, McDonald, & Murray-Davis, 2017). Where didactic instruction would need to be adjusted is in the design and integration of curriculum around safe prescribing practices for controlled substances and teach the new regulations.

The College regularly meets with the MEP and International Midwifery Pre-Registration Program (IMPP) and has been in contact with these institutions this past year about implementing the new professional standards. This is an excellent time to review how laboratory testing and prescribing are taught in these programs while looking for guidance in the education research and in pre-existing frameworks such as the Royal College of Physicians and Surgeons’ CanMEDS (Royal College of Physicians and Surgeons, 2017).
Question 5: Describe the impact of the proposal on members of the profession already in practice.

Midwives already order laboratory tests; they write requisitions, review results and consult when results are abnormal. They have all the skills and training required to do this at entry to practice (Canadian Midwifery Regulators Consortium, 2008). The proposed changes to their authority to order laboratory tests and prescribe medications provides more flexibility to optimize their current scope of practice. In optimizing scope, the proposed changes may slightly increase the midwifery clinical workload as they will have the authority to order a greater number of tests and write additional prescriptions. However, the proposed changes will decrease the administrative midwifery workload because it will reduce the midwife’s time in consultations and following up on the consultant’s laboratory tests and plans of care. We could find no research that dealt with this specific situation. However, similar to the findings of Hwang et al. (2013), where pharmacists experienced greater job satisfaction after their scope was expanded, this may lead to greater job satisfaction for members who will spend more time practicing midwifery and less time in the administrative aspects of practice.

Another potential impact of the proposed changes is the possible requirement for further training regarding controlled substances, a decision that will be made in close consultation with the Ministry, the MEP and other midwifery stakeholders, as well as with the membership. Should additional training be required, there will be an investment of time and money from each member. There are, however, courses already developed for midwives in other jurisdictions which could be adapted for the Ontario context. Using the course developed for midwives in British Columbia as an example, the cost to midwives would be approximately $300 and require 10-12 hours of study time (University of British Columbia, 2016).

Patient Safety

Question 6: How does the proposed scope change impact risks of over-testing and over-utilisation? How does the profession intend to mitigate these risks?

Evidence from a recent meta-analysis shows that over-utilization of laboratory testing was approximately 21% (Zhi & Ding, 2013). Factors that contribute to over-utilization of laboratory testing include a care provider’s uncertainty about what to test for, trying to meet client expectations (Cadogan, Browne, Bradley, & Cahill, 2015), fear of litigation and a clinician’s failure to implement the newest clinical practice guidelines (Freedman, 2015). Some of the solutions provided to address over-testing include decreasing tests that are not medically necessary and limiting tests to only those that can be conducted in the inpatient setting in order to direct patient care (Freedman, 2015), both of which are routine practices for Ontario midwives. Midwives only order laboratory tests that are a part of routine prenatal care and any tests ordered beyond that would be in response to a clinical indication. As such the College has no data to help us understand over-testing in midwifery practice and our review of the literature did not find any studies specifically addressing facilitators to over-testing when more authority to order
laboratory tests is granted. For midwives, even with an expanded ordering authority, the scope of practice remains very limited which implies the range of tests that will be in scope will also be limited. This leaves much less room for the rates of over-testing that appear in the literature among other professions.

One of the most over-utilized test in obstetrical care, and one midwives currently have the authority to order, is routine urinalysis for protein and glucose (Choosing Wisely Canada, 2017). Its existence in Appendix B suggests that midwives should be utilizing this test when in fact it is no longer current evidence. An argument could be made that the list is actually encouraging over-testing of routine urinalysis rather than a list limiting over-testing. As with all clinical practice, laboratory tests should be ordered using the best available evidence and client choice. All care providers should order tests in response to a clinical question and for midwives, many of these tests will be to rule out specific pregnancy related pathologies. These tests will have clinical indications to perform them and often a clinical practice guideline, for example from the Association of Ontario Midwives and SOGC, directing them.

There is no known solution to preventing over-testing and evidence shows that individuals have their own ordering practices and that no one mechanism will prevent over-testing (Freedman, 2015). As a result, there are studies, reviews and editorials all seeking to understand and address over-utilization of laboratory tests (Freedman, 2015; Cadogan, Browne, Bradley, & Cahill, 2015; Zhi & Ding, 2013; Wilson, 2015; CADTH, 2014). Evidence-based formularies or algorithms to guide midwives’ decisions about laboratory tests may also prevent, to an extent, overuse of laboratory testing and the College is currently working on a framework for this (see Question 8 below).

Prescribing within scope is unlikely to lead to over-utilization of prescription medications. Most prescribing will happen within the realm of treating infections, prescribing contraception and managing the labour pain. The College is aware of the opioid crisis in the province and that controlled substances, which are susceptible to diversion, misuse, and abuse, may present a risk of addiction and overdose (CPSO, 2017). Since opioid addiction is generally related to the treatment of chronic non-cancer pain, this is not in the midwifery scope and does not pose a great risk to midwifery clients. The College will however address the risk of opioid over-use and addiction through adequate student and member training and will recommend and make available screening tools for the risk of addiction and diversion. The College will revise its Prescribing and Administering Drugs Standard which will provide oversight in the mitigation of these risks.

Given the findings from the literature, it is reasonable to believe that the limited scope of midwifery practice naturally limits the tests that can be ordered and the drugs that can be prescribed and that high rates of over-utilization are unlikely to result. College complaints from the past 5 years show only one case of over-testing where a midwife allegedly ordered an inappropriate test. In terms of prescribing, only one related allegation has occurred in the past 5 years. The allegation was about a midwife prescribing a medication that was not on the list of drugs midwives are authorized to
order but which would otherwise be considered in scope. If midwives are granted broader lab testing authority, the College will investigate ways to understand and address any possible over-testing and over-utilization in order to guide future standards and policies.

Question 7: What new or amended oversight mechanisms are necessary to ensure continued safety and quality of the care provided by the profession?

As mentioned throughout this document, it is ultimately professionalism that keeps the public safe (PSA, 2015), and the College will be implementing its new Professional Standards for Midwives that uses a principles-based approach and guides the professionalism of midwives in the spring of 2018.

Other mechanisms are already in place. The College’s Quality Assurance Program expects that midwives maintain their clinical competency through their continuing professional development activities, during case reviews with peers and through self-reflection and evaluation. Like all other health regulatory colleges in Ontario, the College has a Professional Misconduct Regulation, which lists the recognized types of professional misconduct. It is based on a general framework used by the Ministry, and is consistent with professional misconduct provisions for other health professions regulated by the RHPA.

For laboratory testing specifically, the College supports the recommendations presented in the Ministry's Laboratory Services Expert Panel Review (2015):

> This program should be informed by best evidence and developed with leadership from the community laboratories in conjunction with professional organizations. Ideally, a mechanism to build standard diagnosis codes into laboratory requisitions could be developed to support appropriateness assessment over the long term. A series of electronic prompts should be implemented to confirm the physician’s intention to order, with embedded guidelines where available (p.33)

Until these systems are in place to support the clinical decision making of midwives, the College believes that midwives currently have the knowledge, skills and judgment to order tests.

Question 8: Identify whether any new standards of practice or policy guidelines would need to be developed by the College relating to the change in scope of practice, especially as they relate to the prescribing of controlled drugs and substances.

The College will work closely with the Ministry during this process. Once the College has the Ministry’s response to the submission, we will do an assessment and develop regulatory tools as needed. The College needs to understand the outcome of this submission in order to dedicate resources to researching what would need to be developed and implemented. With this information, the College would like to ensure that
any new standards or guidelines are only developed once the need has been identified. Allocating resources where required once the need has been identified ensures that our regulatory response is proportionate, targeted and accountable.

Currently the College has a laboratory testing standard that simply articulates Appendix B of the *Laboratory and Specimen Collection Centre Licensing Act* (Government of Ontario, 2015) and a prescribing and administering standard. If the proposed changes are approved, the College will consult with the Quality Assurance Committee and Council to determine the best way to ensure public protection with scope optimization. Research shows that evidence-based algorithms to guide decision making about appropriate testing can contribute to better practices (Laposata & Dighe, 2007). The College is currently developing a guide about the scope of practice and authorized acts to carefully articulate how to make decisions in accordance with this approach. Similarly, both the Nursing and Midwifery Board of Ireland and the Nursing and Midwifery Board of Australia have decision-making flow charts that can be used as templates for the College (Nursing and Midwifery Board of Ireland; Nursing and Midwifery Board of Australia). The College will also clarify for members that the approved controlled substances only include narcotics and benzodiazepines and will set additional conditions and limits to ensure prescribing is safe and ethical.

The College is also developing a new Quality Assurance Program (QAP) that includes a self-assessments and reflection, and peer and practice assessments. This is an ideal time for the College to build into the QAP assessments of broader authorities to order and prescribe and the critical thinking required to do this compared with practicing according to lists.
CONSULTATIONS

Please provide the following information regarding consultation activities:

Question 1: The submission references a consultation, could you please provide more information on who was consulted and the results, including support for and opposition to the proposed changes?

As the Ministry knows, in 2008 the College conducted a broad consultation with its membership. Of the 264 respondents, 252 (95%) supported increasing access to additional tests for their clients. The reason provided by respondents was to improve continuity of care with their clients and interprofessional collaboration with consultants. Respondents described ordering the tests in order to have the information prior to the consultation in cases such as gestational hypertension where consultants require the results of the laboratory diagnostic tests in order to provide a care management plan. Not having that information delays potential treatment. Conversely, midwives having the ability to order these tests means physicians will not be disturbed from work or sleep to order tests that may ultimately be normal and not require their care. In addition, increased costs to the health care system was cited by many respondents, as the result of limited access to tests and medications.

Question 2: Given the time that has elapsed since the development of the initial proposal, the Ministry encourages the College to seek updated perspectives from its stakeholders, including but not limited to:

a. Patients
b. Members of the profession in Ontario
c. Members of other affected health professions in Ontario (unregulated and regulated)
d. Other affected third-parties

There has been insufficient time to launch another consultation regarding laboratory testing and prescribing medications. During the College’s most recent public consultation regarding the Professional Standards for Midwives, the membership has supported the replacement of prescriptive standards with an overarching document that will form the foundation for midwifery practice. This document has been well received by the membership, public and other stakeholders because of its focus on midwives’ accountabilities and professionalism and its move away from lists and rules that go quickly out of date. The membership has cited concerns with the current prescriptive rules and regulations because the current approach poses barriers to positive client care, continuity of care and interprofessional collaboration. The support for this document suggests that the membership agrees with the general direction the College is taking to protect the public through managing risk proportionately and holding midwives accountable to the principles such as person-centred care and integrity.
LABORATORY TESTS REQUESTED

Question 1: In the list of laboratory tests requested, please provide the following information:

a) Brief description how the test is relevant to the provision of midwifery care within its current scope, and how it relates to other controlled acts and authorities that midwives currently have.

The College is requesting all laboratory tests within the midwifery scope of practice rather than a list. Midwives are primary care providers with the authority to order a range of screening and diagnostic tests that are designed to protect and promote the health of the women and newborns in their care.

b) Cost to patients, if any, of undergoing each test:

There is no cost to patients if having any OHIP test providing it is covered by OHIP or any other insurance plan. There are tests that may cost money if not covered by OHIP (e.g. NIPT prior to its approval for OHIP funding) despite being in the scope of practice. In this situation, all clients have a choice and would not be required to agree to any testing, either publicly funded or not funded.

c) Impact on public resources, if any, of ordering each test:

As is clear from the previous sections of this report, all tests are publicly funded. Midwives providing publicly funded laboratory tests on their own authority will reduce duplication of services. This will result in reducing public resources.

d) Within the current typical patient pathway, how do patients currently receive each test listed in the submission and who usually interprets them? How would the pathway change should midwives gain the authority to order the proposed laboratory tests?

Currently, clients would receive these tests through consultation with a family physician, obstetrician or other specialist physician and these physicians would interpret the results. With approval of the proposed changes, midwives would order the tests and consult with a family physician, obstetrician or specialist physician if the results put the client in a category that is not in the scope of midwifery practice. The scope of practice is defined by the Midwifery Act, 1991, the authorized acts and is further articulated in College standards. In addition, the College’s Consultation and Transfer of Care Standard (CTCS) clearly articulates when a midwife must consult or transfer care.
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Scope of Practice Changes Submission
College of Midwives of Ontario