Ministry of Health:
Proposed Amendments to O. Reg. 45/22 under the *Laboratory and Specimen Collection Centre Licensing Act* (LSCCLA) and Reg. 552 under the *Health Insurance Act* (HIA) to enable pharmacists to order laboratory tests and perform point-of-care tests (POCTs) to support minor ailment assessments

OPA Submission
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Executive Summary

Ontario's health system is under unprecedented strain, marked by significant gaps in access to primary care and rising emergency department volumes. As highly trained and trusted healthcare providers embedded in communities across the province, including rural, remote and underserved areas, pharmacy professionals are uniquely positioned to help. With nearly 100% of community pharmacies participating in Ontario's minor ailments program, the sector has clearly demonstrated readiness, competence, and capacity to safely assume expanded clinical roles.

To fully leverage this workforce and alleviate system pressures, OPA strongly supports the proposed amendments to O. Reg. 45/22 under the *Laboratory and Specimen Collection Centre Licensing Act* to enable pharmacists to requisition laboratory tests for nail fungus infections and sore throat, perform point-of-care tests (POCTs) for sore throat, and collect specimens for these minor ailments. OPA also supports proposed changes to Reg. 552 under the *Health Insurance Act* to allow pharmacists to order OHIP-insured laboratory tests. These proposed changes will support the inclusion of additional minor ailment conditions within pharmacists' scope of practice, strengthening patient access to timely, high-quality care; enhancing system capacity; and improving health outcomes.

To ensure the proposed expanded scope activities are implemented safely, equitably, and sustainably, OPA recommends the following:

- **Establish a Testing Framework for Rapid Strep Tests:** Different test types have distinct advantages and limitations that may have implications on clinical management pathways, feasibility, cost and operations.
- **Expand Scope to Pharmacy Technicians:** Enabling pharmacy technicians to perform POCTs for sore throats would support the technical aspects of testing while maintaining pharmacist oversight, increasing workforce capacity.
- **Issue Guidance on Testing Requirements and Practice Expectations:** Clear guidance on when diagnostic testing is required, and when empiric treatment may be appropriate for onychomycosis, will support evidence-informed practice and consistency in care across practice settings.
- **Establish Publicly Funded Remuneration:** A strong funding framework and availability of resources is essential to support uptake, ensure equitable access for all patients, and promote long-term sustainability.
- **Enhance Continuity of Care and Information Sharing:** Leveraging existing infrastructure will support care coordination while minimizing administrative burden.
- **Allocate Adequate Implementation Time:** Transparent and reasonable timelines are critical to support preparation, planning, and smooth implementation.
- **Build Public and Interprofessional Awareness:** Educating the public and other healthcare providers about pharmacy services will foster system-wide awareness and support integrated, team-based care.

- **Implement Additional Regulatory Changes:** Enabling pharmacists to communicate a diagnosis, order additional laboratory tests, and conduct further POCTs, while ensuring consistent scope of practice across care settings, will enhance patient access to care and support more efficient care delivery.

OPA is committed to collaborating with the Ministry and system partners to ensure a smooth and sustainable implementation of expanded scope. By advancing the proposed changes with the appropriate supports in place to strengthen care delivery while ensuring sustainability of pharmacy services, Ontario can build a more resilient health system that leverages the full expertise of pharmacy professionals and expands equitable access to care for all Ontarians.

Introduction

The Ontario Pharmacists Association ('OPA', the 'Association') is pleased to provide its comments and recommendations to the Ministry of Health Labs Branch ('Ministry') on proposed amendments to O. Reg. 45/22 under the *Laboratory and Specimen Collection Centre Licensing Act* (LSCCLA) and Reg. 552 under the *Health Insurance Act* (HIA), which if approved, will enable pharmacists to order laboratory tests and perform point-of-care tests (POCTs) to support minor ailment assessments.

OPA is committed to evolving the pharmacy profession and advocating for excellence in practice and patient care. With nearly 8,000 members, OPA is Canada's largest pharmacy-based advocacy organization and continuing professional development provider for pharmacy professionals. By leveraging the unique expertise of pharmacy professionals, enabling them to practice to their fullest potential, and making them more accessible to patients, OPA is working to improve the efficiency and effectiveness of the health care system.

Ontario's health system is under unprecedented strain, marked by significant gaps in access to primary care and rising emergency department volumes. Expanding the scopes of practice for pharmacy professionals represents a critical opportunity to enhance system capacity and improve health outcomes. Since the implementation of the publicly funded minor ailments program in January 2023, Ontario's pharmacists have provided over 2.4 million assessments with over 99% of all community pharmacies participating.[1] This demonstrates the sector's readiness, competence, and capacity to safely assume expanded roles, and highlights the integral part pharmacy professionals play in Ontario's primary care system, providing equitable access to care across rural, remote and underserved areas.

OPA strongly supports the proposed amendments to authorize ordering of laboratory tests and conduct more POCTs. Notably, Ontario is only one of two provinces where pharmacists are not authorized to order laboratory tests; all other provinces either already have authority in place or are in the process of enabling this new scope.[2] By aligning with other jurisdictions to authorize lab requisitioning and additional point-of-care testing, Ontario will equip pharmacists with the tools necessary to support the minor ailment expansions and ensure Ontarians receive timely access to care within their communities.

Proposed Amendments

Overall, OPA supports the Ministry's proposed changes to O. Reg. 45/22 under the LSCCLA to:

- **Enable pharmacists to requisition lab tests to support assessment of nail fungus infections and sore throat, and perform POCTs to support assessment of sore throat.**
- **Authorize pharmacists to collect specimens for these minor ailments, as the regulation does not provide broad specimen collection authority.**

In the context of tests required to support the 14 minor ailments proposed for addition to pharmacists' scope of practice in Fall 2025, OPA supports the Ontario College of Pharmacists' (OCP) recommendations to grant pharmacists the authority to perform POCTs to support assessment of sore throat and requisition lab tests and collect specimens to support assessment of fungal nail infections and sore throat. However, regarding onychomycosis, OPA emphasizes that this authority should be utilized at the pharmacist's professional discretion when clinically indicated, rather than strictly mandated for every assessment.

OPA is also supportive of making changes to Reg. 552 under the HIA to **enable pharmacists to order OHIP-insured laboratory tests** as pharmacists are not currently listed as providers who can requisition insured lab services. This will ensure that patients can expect to receive the same level and access to all healthcare services regardless of which healthcare provider they see.

Sector Readiness

Ontario pharmacists have demonstrated their capacity to safely manage testing pathways when supported by a viable infrastructure. During the publicly funded COVID-19 PCR testing services program, pharmacies successfully managed specimen collection, lab requisitioning, and follow-up on the results as appropriate. In addition, pharmacy professionals have been performing POCTs for blood glucose, hemoglobin A1C, lipids, and prothrombin time (PT)/International Normalized Ratio (INR) to support patients with their medication management of certain chronic conditions since 2022. While POCT uptake has been limited due to lack of public funding to support service provision, many pharmacists have gained practical experience with implementation and delivery in clinical practice including conducting, interpreting and sharing the results of POCTs to support patient care.

As with any new scope or change to practice, integration into practice will be staged. Adoption and implementation will depend on the unique practice environment, patient demographics, and the professional autonomy of the individual pharmacy professional to opt-in based on their comfort level. To facilitate a seamless transition, OPA is fully prepared to leverage its extensive experience in developing professional resources and education programs to support implementation of expanded scope initiatives, pharmacy programs and pharmacy services. This also presents an opportunity for pharmacy schools to integrate relevant training into curricula, ensuring graduates are equipped with the necessary knowledge and skills at entry to practice. OPA looks forward to working with the Ministry and other stakeholders to support the needs of pharmacy professionals, as required, to successfully integrate new changes into practice.

Patient and Health System Benefits

Expanding the scope of practice of pharmacy professionals to include lab ordering and POCTs significant streamlines the patient journey, offering convenient, timely access to care without forcing patients to navigate multiple healthcare settings. An evaluation of a Canadian program involving community pharmacists providing point-of-care Strep testing and management found that over 75% of patient survey respondents with severe sore throat visited the pharmacy first and pharmacy-

based testing facilitated prompt and appropriate access to antibiotic therapy, especially if pharmacists had the authority to prescribe.[3]

Expansion of testing authorities also benefits the health system. Being able to initiate antibiotic therapy in a timely manner can have potential clinical and health economic benefits and enabling Strep testing in community pharmacies can help to decrease the workload on physicians in addition to reducing wait times in emergency departments.[3] Furthermore, a cost-minimization analysis of community pharmacy-based point-of-care testing for Strep throat found that Ontario could potentially save an estimated $607,260 - $1,214,500 annually if a publicly funded program for community pharmacy-based Strep throat point-of-care testing was established.[4]

Expanding the scope of pharmacists to include the ordering of laboratory tests and the provision of additional POCTs serves to complement, not replace, other providers. Enabling these services at pharmacies proactively addresses system-wide capacity constraints and fully leverages our workforce capacity. With 1 in 4 Ontarians forecasted to be without a family doctor by 2026,[5] and only 1 in 3 being able to access their primary care provider for a same day or next day appointment,[6] changes are needed to ensure our health system can meet today's challenges. Patients who do not have a designated primary care provider are at a higher risk of clinically decompensating or seeking care at inappropriate locations, such as hospitals, for conditions that could have been managed or prevented in a community setting.[7] In 2022/23, nearly 1 in 4 emergency department (ED) visits in Ontario were for less urgent or non-urgent cases, such as sore throat or cold, often because it was the only immediate option available.[7] These visits contribute to long-wait times (averaging 1.8 hours before a patient's first assessment by a doctor) in addition to high costs to the health care system.[7, 8] Redirecting appropriate cases to community pharmacies preserves critical emergency and laboratory resources for complex medical cases while maintaining a high standard of quality and clinical safety.

Safeguards already exist within Ontario's digital health infrastructure to ensure that testing services provided by pharmacy professionals do not result in unnecessary duplicative testing or fragmented care. Because the results of all laboratory tests ordered are populated into one of Ontario's clinical viewers from the Ontario Laboratories Information System (OLIS), they are available to healthcare professionals.[9] This centralized approach ensures data transparency across settings, preventing the creation of care silos. With respect to POCTs conducted by pharmacy professionals, the administration record of the test, including but not limited to the patient's information, results of the test and the pharmacist's professional decision arising from the results of the test and the rationale for the decision, must be shared with the patient's primary care provider (if any) within a reasonable timeframe.[10] Collectively, these mechanisms facilitate the communication of information between healthcare providers to prevent duplication of testing services and support the delivery of integrated, connected care.

Implementation Considerations

Acute Pharyngitis (Lab Test: Throat Swab Culture; POCT: Rapid Strep Test)

For acute pharyngitis caused by Group A Streptococcus (GAS) colonization, diagnostic accuracy and antibiotic prescribing quality is improved when the assessment involves an investigation of clinical features and, where applicable, laboratory testing.[11] Studies have found that point-of-care testing for Strep A in children and adults with pharyngitis likely reduces the number of individuals prescribed an antibiotic and decreases inappropriate antibiotic prescribing while not likely impacting patient health outcomes.[12] As such, while sore throat is often treated empirically (about 60%),[13] **enabling authority for pharmacists to perform rapid point-of-care Strep tests alongside the ability to order throat swab cultures, if necessary, are critical to supporting antimicrobial stewardship and the appropriate management of patients**.

Type of Rapid Strep Test

POCTs are an important tool to enable rapid detection of Strep A infections to support decision-making in a timely manner.[12] Results are available in less than 15 minutes and specialized laboratory equipment and training are not required.[12] The management of GAS pharyngitis guided by point-of-care testing is also likely cost effective.[13] However, since there are different types of rapid strep tests, i.e., rapid antigen detection tests (RADTs) and nucleic acid amplification tests (NAATs), the Ministry should consider the potential pros and cons associated with each option to maximize patient access and sector participation.

Option A: A Standardized Rapid Antigen Testing Framework

RADTs have high specificity (~95%), meaning in the context of an appropriate clinical presentation, a positive test supports the diagnosis of GAS pharyngitis and routine confirmation is not required.[11,13] However, RADTs have a lower sensitivity compared to NAATs (80-85% compared to 92%, respectively), increasing the likelihood of false negatives.[11,12,13] As a result, confirmatory laboratory testing may still be required in certain populations. For example, current guidelines recommend that a negative RADT result in high-risk patients (e.g., children and adolescents) be confirmed with a throat culture, particularly if risk of acute rheumatic fever (ARF) is a concern.[11] While a negative RADT in adults typically does not require further routine testing, confirmation with a laboratory test may still be required if the patient is at high risk of ARF.[11]

Consequently, reliance on RADTs alone may still require some patients to engage in multiple healthcare encounters before a definitive assessment can be completed. This process may be further complicated by the lack of established workflows for ordering and transporting throat swab

specimens from pharmacies to laboratories, as well as the absence of a remuneration framework to support these activities.

Despite these limitations, RADTs offer a low cost of entry, ensuring that small, independent, and rural pharmacies can immediately participate in providing testing services without facing prohibitive upfront capital investments. This accessibility supports equitable service delivery and may offer system-level cost advantages, particularly for low-risk patients who can be safely managed based on RADT results.

Option B: A Standardized Molecular Testing Framework

NAATs have a high specificity (~99%), similar to RADTs, meaning a positive result reliably supports the diagnosis of GAS pharyngitis in the appropriate clinical context.[13] Unlike RADTs, NAATs also have a high sensitivity (~92%), and is comparable to that of a throat culture (90-95%) which is considered the gold standard test.[11,13] This high diagnostic sensitivity eliminates the need for downstream laboratory culture confirmation for negative results, providing greater diagnostic certainty across patient populations, including high-risk individuals.

Consequently, the use of NAATs enables a more streamlined patient journey, allowing for definitive assessment and management within a single encounter, without requiring additional follow-up testing.

However, NAATs are generally associated with higher costs compared to RADTs.[12] For example, there may be considerable start-up costs (e.g., capital costs associated with purchasing the molecular instrument to run the test). NAAT devices also require quality control checks and verification based on the manufacturer's recommendations. Without appropriate publicly funded financial supports, these costs may create barriers to adoption, particularly for smaller, independent, and rural pharmacies. This could inadvertently limit participation and contribute to inequities in geographic access for patients to testing services. Consideration should therefore be given to implementing funding mechanisms, such as upfront capital grants or device subsidies, alongside a remuneration model that accounts for both the service and quality assurance requirements (refer to the Financial Sustainability section below for more information).

Option C: A Flexible Framework Permitting Both RADTs and NAATs

Permitting both RADTs and NAATs within a standardized provincial framework would allow individual pharmacies to select the testing modality that best aligns with their practice setting, community demographics, and resource availability. This approach has the potential to leverage the strengths of each test modality while supporting broader sector participation and improving patient access to timely care.

Under this model, RADTs may be used to support rapid, low-cost testing for low-risk patients who can be safely managed based on point-of-care results, while NAATs provide greater diagnostic

sensitivity and may support more definitive assessment and management within a single encounter, particularly for higher-risk individuals.

However, the adoption of a flexible framework may introduce variability in testing practices across pharmacies, which could affect the consistency of patient experiences, diagnostic accuracy, turnaround times, clinical decision-making, and access to appropriate treatment or follow-up. These risks may be mitigated by ensuring the availability of clear provincial standards, evidence-based clinical guidelines and appropriate funding supports.

Inclusion of Pharmacy Technicians

According to the consultation posting, changes are required to O. Reg. 45/22 under the LSCCLA to "*Enable pharmacists…[to] perform POCTs to support assessment of sore throat*". To optimize pharmacy workflows and mitigate operational strain, OPA recommends that **this authority be expanded to include pharmacy technicians**.

Pharmacy technicians in Ontario are already authorized to conduct POCTs for blood glucose, hemoglobin A1C, lipids, and PT/INR to support patients with their medication management of certain chronic conditions (similar to their pharmacist counterparts), provided that the interpretation of the test results is performed by a pharmacist.[14] They can also collect specimens from an individual to conduct a COVID-19 POCT.[15] Expanding the authority for pharmacy technicians to perform POCTs for sore throat is a logical and safe next step. Enabling pharmacy technicians to support the technical aspects of testing, while maintaining pharmacist oversight for clinical assessments and prescribing decisions, alleviates staffing pressures and ensures that pharmacists can focus their time on clinical care.

Onychomycosis (Lab Test: Nail Clipping/Scraping for Culture and Microscopy)

OPA supports the proposed changes to authorize pharmacists to order lab tests to facilitate the assessment of nail fungus infections. According to the Fungal Nail Infections chapter of *Therapeutic Choices*, the diagnosis of onychomycosis should include a physical exam and be confirmed with further testing (a combination of fungal culture and direct microscopy using potassium chloride) to determine the optimal treatment for the infection.[16]

However, consideration should be given to whether testing will be a mandatory requirement for pharmacist-led assessments of fungal nail infections. Guidance on testing may differ between guidelines, with only half of Canadian guidelines recommending laboratory confirmation prior to treatment.[17] In practice, despite the potential value of confirmatory testing, many clinicians (36%-47%) initiate treatment without it.[18] This suggests that while the ability to order these tests is an important tool, **it should remain an option based on the pharmacist's professional judgement**.

Mandating specimen collection within the pharmacy setting for laboratory confirmation may limit uptake given additional operational considerations such as infection prevention and control, specimen handling and workflow integration. Meanwhile, empiric treatment is already common practice, occurring in approximately one-third to one-half of cases managed by other healthcare providers. Ensuring alignment in practice expectations and consistency in care across providers is important to ensure that patients receive equitable, evidence-based care across practice settings. This reduces unwarranted variation in clinical practice, supports optimal patient outcomes, promotes patient confidence and facilitates efficient use of health system resources.

Financial Sustainability

To support service provision, it is imperative that services are accompanied by **fair and reasonable publicly funded remuneration.** A public funding framework is essential to promote widespread sector uptake, ensure equitable access for all patients, and avoid creating a two-tiered system where only those able to pay out-of-pocket can access the services.

The current remuneration of $19 for an in-person minor ailment assessment and $15 for a virtual assessment were established based on the following being provided as past of the minor ailment service:[19]

- Obtaining informed consent to provide the minor ailment service
- Collecting and reviewing all relevant patient information to evaluate them and the situation (e.g., history of presenting complaint, patient's health and medication history, etc.)
- Assessing the patient to verify the patient's self-diagnosis and identifying the best course of action
- Determining through a shared decision-making process the appropriate care plan
- Implementing the care plan which may include issuing a prescription (if applicable), or referring the eligible person to their primary care provider, providing education for the patient, documentation, and notification of the patient's primary care provider (if any) if an allowable medication is prescribed
- Following up with the patient to establish monitoring parameters, evaluate safety and efficacy of the care plan and additional next steps as required

As the clinical time, infrastructure, and technical execution required to perform point-of-care testing or manage lab requisitions are entirely outside the scope of the current minor ailments service fee, OPA recommends establishing a separate remuneration framework to ensure the financial viability of these testing services.

While establishing these services requires an initial public investment, these costs must be balanced against the significant downstream financial and systemic benefits they will deliver. Dedicated public funding is essential to guarantee equitable access to testing services for all patients. Failure to do this risks creating a two-tiered system, where only those able to pay out-of-

pocket can access services and may exclude marginalized and vulnerable populations. Furthermore, enabling publicly funded POCTs within community pharmacies will actively reduce the need for laboratory-based testing, allowing the Ministry to redirect existing diagnostic funding into more efficient community channels rather than requiring entirely net new funding. Ultimately, shifting uncomplicated, appropriate care to the pharmacy sector generates substantial, long-term cost savings for the broader health system by diverting low-acuity cases away from overburdened emergency departments.[4]

Strep Throat POCT Remuneration

OPA recommends keeping the established $19 fee for the clinical assessment component and introducing a separate **professional service fee of $16 for the testing component,** bringing the total service fee to $35 for a Strep throat assessment with a POCT. This fee supports the time and expertise required to provide and document the professional service and is aligned with remuneration that was provided for publicly funded in-pharmacy point-of-care PCR testing for COVID-19 in Ontario ($22.00 specimen collection fee and $20 assessment fee) as well as insured and uninsured services in other provincial jurisdictions (Table 1).

Table 1: Comparison of Provincial Publicly Funded Programs for Strep Throat Assessments with POCTs[20,21,22,23]

Public Funding	Saskatchewan	Nova Scotia*	Prince Edward Island
Strep Throat Assessment with POCT	$35	$35.70~	$25
Test Cartridge Reimbursement	Actual Acquisition Cost	Actual Acquisition Cost + 10%	Actual Acquisition Cost + 10%

*In designated pharmacies
~To increase to $36.41 on April 1, 2027

To protect this funding model from being eroded by hidden operational expenses, the provincial framework must also incorporate the following financial safeguards:

- **Reimbursement for materials (e.g., testing cartridges) at actual acquisition cost plus 10%**: The cost of materials to perform the POCT should be considered separately from the remuneration provided for the professional pharmacy service which compensates for the pharmacy professional's expertise, time and cognitive elements of testing (e.g., interpretation of the results). Establishing a reimbursement framework for materials aligns with publicly funded programs in other Canadian provinces (Table 1).
- **Provision of a molecular POCT device quality assurance fee:** NAATs require ongoing device quality control checks and verification based on the manufacturer's recommendations. These costs should be supported by a testing device quality assurance fee, similar to the one established for in-store point-of-care PCR testing for COVID-19 under the publicly funded testing program in Ontario pharmacies. In that program, the actual quality control swabs (kit box) costs were reimbursed up to $732.40 (calculated based on

the cost per box of positive and negative control swabs ($250), 12-pack box of external positive COVID-19 swabs ($470.40) and universal printer labels ($12)). The amount paid included completing the device quality control check for all POCT devices when a new person was trained to perform the test, when a new device shipment was received, when there was a change in lot number, after the device was moved and after an update of the device software; reimbursement for the quality control swabs used; investigation of failed device quality control checks; and documentation of device quality control checks.

- **Funding to support overhead costs:** As there may be considerable start-up costs associated with providing POCTs (e.g., capital costs associated with purchasing the molecular instrument to run the test cartridges and consumables such as throat swabs and tongue depressors, infrastructure changes to ensure a private consultation area), consideration should also be given to funding these initial investments to encourage participation. There are also considerable ongoing costs including but not limited to waste disposal (e.g., biohazardous bins, disposal services), training and competency, maintenance and calibration requirements, inventory loss, and insurance. To support implementation of Strep pharyngitis assessment and prescribing in Prince Edward Island, grant funding was available to participating pharmacies to cover expenses related to Strep A testing equipment, swabs, and administrative or operational start-up costs.[22] This support is essential to alleviating some of the pressures associated with offering this new service including increased workload, staffing pressures and financial investments that could make adoption of the service challenging, especially for small, independent and rural pharmacies.

Lab Ordering Remuneration

For the proposed laboratory tests, **OPA recommends establishing a specimen collection fee and transportation fee** for transportation of the specimen from the pharmacy to the lab, similar to the remuneration framework that was established for the publicly funded COVID-19 testing program in Ontario pharmacies:

- **In-Store Specimen Collection Fee for Lab-Based PCR COVID-19 Test ($20.00 for screening + $22 for specimen collection = $42 total):** Amount paid included patient eligibility screening, collection of the specimen, completion of the test requisition form (input data into the Ontario Laboratories Information System – Mobile Order Result Entry (OLIS-MORE) platform), notification of results to the patient and public health unit, documentation requirements and reimbursement for any privately purchased personal protective equipment by the pharmacy.[24]
- **Transportation Fee (COVID-19 Specimen) for Lab-Based PCR Tests (actual transportation costs, up to $140):** Amount paid included the daily transportation of the specimens from the pharmacy to the designated laboratory and included the costs of shipping materials.[24]

Continuity of Care and Information Sharing

To facilitate continuity of care and avoid duplication of services, sharing of information between healthcare providers is essential. At the same time, it is **critical that any reporting requirements leverage existing digital infrastructure to support care coordination without adding unnecessary administrative burden to pharmacies**.

Since OLIS includes all laboratory test orders and results from hospitals, community labs and public health labs, any tests ordered by pharmacists, if enabled, would be accessible to other authorized healthcare providers through OLIS. As such, additional reporting requirements are not necessary as the available information already supports care decisions and helps prevent duplication of services.

For POCTs conducted physically within the pharmacy, results are generated outside of the centralized laboratory infrastructure. Currently, pharmacy professionals are required to share results with the patient's primary care provider (if available) to facilitate continuity of care, which creates significant administrative burden for all providers. To resolve this operational burden, OPA recommends two integrated solutions:

- **HNS Claim Documentation**: If POCTs are included within a publicly funded framework, these services would require claim submission through the Health Network System (HNS) for reimbursement. This process automatically documents the encounter within the patient's electronic health record, making it visible through Ontario's clinical viewers.
- **OLIS Writing Privileges**: To ensure POCT results are fully integrated into the province's digital health ecosystem, OPA recommends granting pharmacists writing privileges to OLIS. This can mirror the successful framework utilized during the pandemic, where pharmacies that performed in-store point-of-care PCR testing for COVID-19 utilized the OLIS-MORE platform to report results directly into the provincial record.

By utilizing these existing digital channels, Ontario can maintain robust interprofessional communication, protect patient safety, and avoid the manual alert fatigue that often contributes to administrative burden and friction between pharmacy professionals and physicians.

Communication and Awareness

A critical priority for the successful rollout of these testing authorities is ensuring a **clear and consistent communication plan, including transparent and adequate implementation timelines**. Providing sufficient lead time is essential to support operational planning within the pharmacy sector, promote service uptake and manage public expectations effectively. OPA has a strong track record of collaborating with the Ministry and other stakeholders and stands ready to support implementation planning and successful integration into practice.

A potential barrier to accessing care in community pharmacies is limited patient awareness of available services and how to access them. This barrier may be particularly acute for newcomers to the province or individuals with low health literacy who may not be aware of the full range of services offered by pharmacists, and may not understand program details, such as the availability of virtual care. OPA recommends that the Ministry fund and execute a **targeted public awareness campaign to educate Ontarians on the availability of pharmacy services, access points, and what to expect during an encounter** to help patients navigate their care options more confidently.

Similarly, **increased engagement and education for other healthcare providers** is equally important to mitigate potential misconceptions and foster collaborative, team-based care. For instance, when emergency department staff, urgent care centres, and family physicians are fully aware of available pharmacy services, they can confidently redirect patients presenting with minor symptoms (such as an acute sore throat) to community pharmacies for assessment. This collaborative triaging frees up critical primary and emergency care capacity for more complex cases, reduces broader health system costs, and ensures patients receive timely access to care.

Additional Considerations

Authority to Communicate a Diagnosis

To support the effective provision of care under these expanded testing frameworks, OPA urges the Ministry to grant pharmacists the **authority to communicate a diagnosis** for all minor ailments within scope. While the proposed scope expansions could continue to proceed without this change, enabling pharmacists to explicitly communicate a diagnosis may help to increase patient understanding and clarity, strengthen patient trust and satisfaction with the care they receive, and improve patient adherence to treatment protocols.

As defined by the *Regulated Health Professions Act, 1991,* the controlled act of diagnosing refers to "*Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis*".[25] In practice, prior to initiating or recommending treatment for a minor ailment, a pharmacist performs a differential diagnosis based on their clinical knowledge (supported by the results of any available/applicable tests and physical examinations) to identify the most likely indication and to rule out other conditions that may require a referral to another healthcare provider. This indication is then communicated to the patient to either confirm the patient's self-diagnosis or to inform them of the most likely indication based on the assessment results – a process that directly aligns with the definition of diagnosing. Recognizing this clinical reality, an October 2023 letter from Shenda Tanchuk, Registrar and CEO of OCP to the Hon. Sylvia Jones, Deputy Premier and Minister

of Health, noted that some of the assessments that will be undertaken by pharmacists for some of the proposed minor ailments is difficult not to characterize as diagnosing based on the required level of assessment and/or reliance on test results.[26] For example, the identification of acute pharyngitis would require the results of point-of-care testing using a throat swab to contribute to a diagnosis of the patient's condition.[26] Continuing to label this activity as an "assessment" creates unnecessary confusion and ambiguity around the pharmacist's role. It may also inadvertently diminish patient confidence, leaving them with the impression that they did not receive a definitive diagnosis.

There are precedents for pharmacists having the authority to diagnose conditions in Canada. Currently, the regulations in three Canadian provinces (British Columbia, Nova Scotia and Prince Edward Island) include diagnosis in their pharmacy regulations (Table 2). Furthermore, in certain provinces (e.g., New Brunswick, Newfoundland and Labrador), "diagnosis" is not a protected term, and the inclusion of diagnosis is not required in regulation for pharmacists to have the ability to diagnose specific minor ailments.

Table 2: Inclusion of Diagnosis in Regulation for Pharmacists Across Canadian Provinces[27,28,29,30,31,32,33,34,35,36,37,38]

	BC	AB	SK	MB	ON	QC	NB	NS	PEI	NL
Authority to Diagnose	☑	☒	☒	☒	☒	☒	N/A	☑^	☑	N/A

N/A refers to "diagnosis" not being a protected term, therefore the inclusion of diagnosis is not required in regulation for pharmacists to have the ability to diagnose specific minor ailments

^Only under specific situations (e.g., prescribing for a diagnosis supported by a protocol, pharmacists participating in the Community Pharmacy Primary Care Clinic Project for hypertension and Type 2 diabetes)

Ordering Other Lab Tests and Conducting Additional POCTs

Rather than utilizing a restrictive, list-based approach to specify which individual laboratory tests and POCTs are within scope, OPA recommends that changes be made to enable pharmacists to **order all laboratory tests and conduct all POCTs** for acute and chronic conditions that are relevant and recommended to support the provision of patient care based on clinical practice guidelines and professional judgement. This will help to future-proof the regulations and policies. When clinical practice guidelines evolve to recommend a new "gold standard" test for a particular condition, a less restrictive approach ensures that pharmacists can immediately adopt evidence-based changes without waiting for lengthy regulatory amendments. Most importantly, it empowers the pharmacist to fully exercise their professional judgement to determine which tests are required to optimize care for each individual patient.

Scope of Practice Alignment Across All Practice Settings

As Ontario continues to evolve our health care system to be patient-centred rather than provider-centred, it is essential that patients can access the full range of services pharmacists are authorized to provide, regardless of the care setting. Across Ontario, pharmacists continually demonstrate that they do more than just dispense medications. Pharmacists are stepping up to support and deliver care to patients in their homes, in the community, in congregate settings like long-term care (LTC) homes, and in hospitals to provide the care they need to lead healthy and full lives. To continue to support better care for all patients, **pharmacists should be enabled to work to their full potential across the entire health care system**.

While scope changes in regulations apply to all pharmacy professionals regardless of their place of practice, other regulatory and policy barriers exist that impede pharmacy professionals from practicing to full scope in all settings. This in turn creates additional administrative burden for these practice settings to find workarounds to the current barriers, such as establishing medical directives, which may require multiple reviews and annual updates, to enable pharmacists to practice to full scope. For example, the *Public Hospitals Act, 1990* remains a primary barrier to pharmacists being able to practice to full scope in hospital settings. Modernizing this antiquated piece of legislation is critical to reflecting today's collaborative care models and giving hospitals the operational flexibility to best utilize their pharmacy health workforce. OPA strongly recommends that the Ministry undertake the necessary work to modernize and align scope of practice across all settings so that pharmacists working in hospitals, primary care teams and LTC homes can practise to the same full scope as their community-based colleagues.

Conclusion

The Ontario Pharmacists Association appreciates the opportunity to participate in this consultation on behalf of Ontario's pharmacy professionals. Ontario's health care system remains under strain and there is a need to modernize current processes and care pathways to increase equitable and convenient access to health services while enabling greater capacity across the health system. Pharmacy professionals are well positioned to play an expanded role in helping to close these gaps so that all Ontarians can access the care they need, when and where they need it, particularly in rural or underserved communities.

Overall, OPA supports the proposed regulatory changes under the LSCCLA and HIA. Enabling pharmacists to requisition additional laboratory tests and perform POCTs for acute pharyngitis and onychomycosis, as applicable, may contribute to the safe and timely delivery of these minor ailment assessments. To ensure successful implementation, the Ministry must establish a clear testing framework for point-of-care Strep tests that reflects the advantages and limitations of RADTs and NAATs while supporting patient access and sector participation. This should be accompanied by

clear guidance on testing and practice expectations for both acute pharyngitis and onychomycosis. Establishing a fair and reasonable remuneration framework and providing operational supports will also be critical to promoting uptake and ensuring long-term sustainability. Consideration of additional regulatory changes to further enhance access and care delivery is also warranted.

OPA looks forward to collaborating with the Ministry of Health and system partners to advance these changes and modernize the health system. Together, we can enhance access and equity, improve patient care, increase efficiency, reduce system pressures and strengthen resilience, ensuring that pharmacy services continue to deliver meaningful and sustainable benefits for all Ontarians.

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