ONTARIO PHARMACISTS ASSOCIATION

Office of the Chief Executive Officer

August 7, 2020

Mr. Patrick Dicerni
Assistant Deputy Minister and Executive Officer, Drugs and Devices Division
Ontario Ministry of Health
438 University Avenue, 10th Floor
Toronto, ON M7A 1N3

Via Email: Patrick.Dicerni@ontario.ca

Dear Patrick;

Re: Proposal No. 20-HLTC033 – Amendments to Regulations 682 and 683 made under the *Laboratory and Specimen Collection Centre Licensing Act, 1990*

On behalf of the Ontario Pharmacists Association ('OPA', the 'Association'), we appreciate the opportunity to provide commentary and recommendations with regard to proposed amendments to Ontario Regulations 682 and 683 made under the *Laboratory and Specimen Collection Centre Licensing Act, 1990* ('LSCCLA').

The Ontario Pharmacists Association is committed to evolving the pharmacy profession and advocating for excellence in practice and patient care. With its 10,000 members, OPA is Canada's largest advocacy organization and continuing professional development provider for pharmacy professionals across Ontario. By leveraging the unique expertise of pharmacy professionals, enabling them to practise to their fullest potential, and making them more accessible to patients, OPA is working to improve the efficiency and effectiveness of the healthcare system.

As expressed in the Ontario budget of 2019 and rearticulated in the 2019 Ontario Economic Outlook and Fiscal Review, efforts to expand scopes of practice for various health professions in ways that maximize and leverage their education, training and experience for improving and optimizing care for Ontarians is highly laudable and fully supported by OPA. Never has this become more important than now during the COVID-19 pandemic, when healthcare resources are being extraordinarily strained and timely access to care in all sectors is being jeopardized. To that end, OPA supports the intent to amend O.Reg. 682 and 683 and offers additional thoughts and recommendations that will optimize access to diagnostic and screening tests.

Point-of-Care Testing by Pharmacy Professionals

The proposed amendments to be considered under an expanded scope of pharmacy practice include allowances for the performance of point-of-care testing ('POCT') relating to the management of diabetes, hyperlipidemia and clotting disorders, notably:

- Blood glucose (diabetes management);
- Hemoglobin A1C (diabetes management);
- Lipids (management of hyperlipidemia); and
- Prothrombin time and International Normalized Ratio (INR) (management of clotting disorders).

The Ontario Pharmacists Association strongly supports these recommendations in the context of POCT as the results from these tests support and better enable the critical role of the pharmacist, as expressed in

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section 3, paragraph (d) of the *Pharmacy Act, 1991*[1], in "[their] promotion of health, prevention and treatment of disease, disorders and dysfunctions through monitoring and management of medication therapy."

However, in recognition of the high degree of accessibility of community pharmacists – much higher than any other frontline healthcare professional – the Association contends that POCT is but one step in terms of leveraging pharmacy professionals to their fullest extent of training and expertise. Monitoring medication therapy is often a critical component on managing disease progression, and more broadly, managing the patient as a whole. Pharmacists need to play a role in managing their patients, not simply their medications, and this speaks to a fundamental shift in thinking as it relates to all health professionals. For decades, pharmacists have been stereotyped in the antiquated role of medication dispensers and as experts in medication management. Now, pharmacists are much more than "medication experts" – they are also exceptionally well-versed in the management of chronic disease and are being increasingly viewed as staunch patient advocates. In consideration of pharmacy standards of practice established by the Ontario College of Pharmacists and with the ongoing support of the two faculties of pharmacy in Ontario as well as post-graduate education providers such as the Ontario Pharmacists Association, pharmacists have evolved to become primary care providers who view patients holistically. Similarly, pharmacists are exceptionally well trained to recognize signs of an acute illness and would benefit greatly from being enabled to order a laboratory test to confirm. If an acute care assessment is deemed to be minor, such as a suspected case of strep throat, then expedited care can be initiated by the pharmacist. Conversely, if deemed more serious or outside of a pharmacist's scope or beyond their self-declared level of competence, then a referral to a medical professional would be warranted. In either case, a pharmacist should not be hindered by restrictive regulations and policies to perform the necessary preliminary assessment. Rather, the pharmacist, armed with the appropriate tools, can effectively and efficiently serve as the patient's first point of contact and, with appropriate judgment and with regard to their scope, can choose to treat or refer based on the level of complexity – consistent with a more holistic approach to patient care.

In line with this shift in thinking and also to better enable pharmacy professionals to practise to their fullest extent, **it is OPA's recommendation to the Ministry that steps be taken, through the development of new policies, to permit pharmacists to have "read and write" privileges to the Ontario Laboratory Information Service ('OLIS') for the purposes of management of chronic conditions and for screening and early identification of select acute conditions.** This has been a long-standing advocacy request of OPA's to allow pharmacists to order laboratory tests and to access their results. OPA understands that with this ability comes the responsibility and accountability to act on the results. All pharmacists, whether through a Bachelor of Science in Pharmacy curriculum or through the new Doctor of Pharmacy (Pharm.D) degree program, have received training on laboratory monitoring. Unfortunately, community pharmacists have little to no ability at this time to utilize such training due to legacy health policies and their inability to access OLIS data. The Association recognizes that there are other considerations to be made, including broader discussions with other stakeholders, including but not limited to the Ontario Medical Association, the Ontario Association of Medical Laboratories and the Ontario Hospital Association, to ensure that checks and balances are in place to:

- Mitigate duplication of testing;
- Assess and evaluate any intended and unintended impacts of new policies;
- Facilitate interprofessional communications; and
- Identify roles and obligations of all relevant healthcare providers within the patient's circle of care.

[1] Pharmacy Act, 1991, S.O. 1991, Chapter 36. Accessed via e-laws website on August 5, 2020.

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Finally, **it is the recommendation of the Ontario Pharmacists Association that pharmacists should also be enabled to screen and test for select acute health conditions, such as Group A streptococcal infections, Helicobacter pylori (H. pylori), as well as for chronic health conditions not listed in the proposed amendments such as HIV and Hepatitis C**. In addition, **OPA also recommends the enabling of pharmacy professionals (i.e., pharmacists and pharmacy technicians) to perform pandemic-related POCT (i.e., for COVID-19 when available) for asymptomatic Ontarians aged two years or older** through the proposed regulatory amendments to the LSCCLA. Enabling this change now for purposes of broad community-based COVID-19 testing in pharmacies will prepare the province and the profession for future virulent outbreaks, epidemics and pandemics and allow for a much more rapid mobilization of pharmacists and pharmacy technicians – the province's most accessible of all healthcare professionals.

COVID-19 Testing by Pharmacy Professionals

OPA commends the approaches taken by the Ontario government to manage the significant complexities of COVID-19 in Canada's largest province. The ramifications of the pandemic on the health and safety of Ontarians and on our economy are well known, and as we have all seen, it is an "all hands on deck" effort by everyone, including Ontario's healthcare sector. From Day 1, all pharmacy professionals, regardless of their practice setting, remained on the frontline to ensure that patients got the care and support they needed.

As our province begins its slow progression out of the state of emergency, it is recognized that there is still much work to be done. Efforts toward maintaining public vigilance and adherence strategies, such as remaining socially distant when possible and donning protective equipment, are becoming harder to sustain, thereby increasing the risk and severity of a second wave of COVID-19 cases. As such, public testing is becoming more and more important. However, the current assessment centre approach cannot effectively manage a broad-based community testing campaign in a second wave scenario. Accordingly, the Ontario Pharmacists Association recognizes the unique position of its members who practise out of community-based pharmacies and considers these sites collectively as an incredible turnkey solution for the Ontario government.

As previously mentioned, changes that would enable POCT in pharmacies could be expanded to incorporate both polymerase chain reaction ('PCR') testing and POCT for COVID-19 in asymptomatic patients if testing technologies were to be approved for use in Canada. Currently, many U.S. states are leveraging the high degree of accessibility of community-based pharmacy professionals for performance and collection of nasopharyngeal and/or oropharyngeal swab samples. In the province of Alberta, a successful pilot involving 20 community pharmacies performing COVID-19 testing was recently expanded to any pharmacy that opts to participate and meets the safety requirements[2]. Alberta Health has set the bar for the rest of the country in logically turning to community pharmacies to dramatically increase testing capacity. That said, and consistent with the approach adopted in Alberta, OPA acknowledges that pharmacist-administered COVID-19 testing may not be practical or even possible within some community pharmacies due to limitations in physical space, human resources and access to personal protective equipment as well as uncertainty around remuneration. Accordingly, OPA recommends that pharmacist-administered COVID-19 testing should be enabled and introduced using an "opt-in" approach.

From a regulatory perspective, amendments that would be required to enable pharmacist-administered COVID-19 testing would depend on the type of test being used. While the Alberta model for pharmacy-based testing incorporates the slightly less sensitive approach of oro-pharyngeal (throat) swabbing for PCR testing,

[2] Press release from Alberta Health, dated July 30, 2020. Accessed online on August 5, 2020

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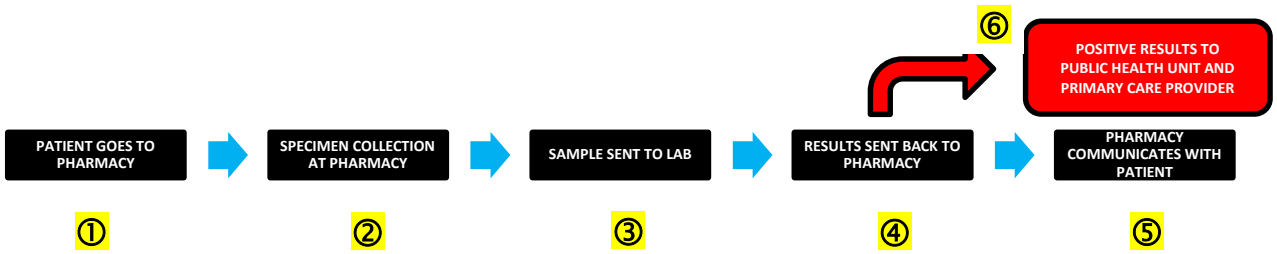
as compared with the more common use of naso-pharyngeal swabs, throat swabbing requires no change in scope of practice as it is not considered as a controlled act under the *Regulated Health Professions Act, 1991*[3].

As articulated in a joint letter from OPA and the Neighbourhood Pharmacy Association of Canada to Deputy Minister Elliott dated June 20, 2020 (see Appendix A), we envision a general 6-step flow for pharmacy-administered COVID-19 testing as depicted below:



As it relates specifically to the *Laboratory and Specimen Collection Centre Licensing Act, 1990*, we anticipate only one minor amendment to the act itself along with some minor regulatory changes to Regulations 682 (Laboratories) and 683 (Specimen Collection Centres). These changes are summarized in the following table and are rearticulated in Appendix B that offers a broader list of our recommended changes for this consultation submission.

LEGISLATION/ REGULATION	RECOMMENDED AMENDMENT	WHAT IT WILL ENABLE
LSCCLA (the Act) These changes would facilitate the following steps: ✓ ① ✓ ② ✓ ③	In the definitions set out in the act in section 5, under "specimen collection centre", a new exclusion from the definition is required, and this requires the addition of paragraph (e) that would read, ***"(e) a place where a member of the Ontario College of Pharmacists is engaged in the practice of pharmacy"***	In a manner that is similar to what the exclusions in the act do for physicians, nurse practitioners, dietitians, and midwives, the addition we are recommending will *permit pharmacists and pharmacy technicians to collect a sample* without the pharmacy practice setting needing to be classified as a formal specimen collection centre. ***Note:*** *While the Associations are proposing that pharmacy technicians be enabled to perform the technical tasks associated with COVID-19 swab testing, any clinical, interpretive and educational work with the patient would be the sole responsibility of the pharmacist.*
Regulation 682 [Laboratories] These changes would facilitate the following steps: ✓ ② ✓ ③ ✓ ④	Replace Section 12 with more current language, including removal of the portion of the clause referencing the performance of immunologic tests for pregnancy. Clause 12 is to be **removed**: ***"All pharmacies and all pharmaceutical chemists employed in a pharmacy are exempt from the provisions of sections 5 to 16 of the Act and from the provisions of this Regulation with respect only to the performance of immunologic tests for pregnancy.*** Clause 12 would be replaced with, ***"All pharmacies and members of the Ontario College of Pharmacists employed in a pharmacy are exempt from the provisions of sections 5 to 16 of the Act and from the provisions of this Regulation."***	Elimination of the portion of the clause referencing immunologic tests for pregnancy is necessary as those tests are long obsolete and are no longer performed. The new clause aligns with language currently used with physicians and naturopaths and enables pharmacy professionals to *practice to their full scope.* This change for pharmacists will also enable changes with respect to *ordering and receiving laboratory tests.* This includes *the ordering of a swab test and obtaining its results* as well as *point-of-care testing onsite in the pharmacy (as per the current regulatory consultation)* that would include a *future serologic test for detection of COVID-19 antibodies*.

[3] Regulated Health Professions Act, 1991, S.O. 1991, Chapter 18. Accessed on the e-laws website on August 5, 2020

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Regulation 683 [Specimen Collection Centres] These changes would facilitate the following steps: ✓ ① ✓ ② ✓ ③ ✓ ④ ✓ ⑤ ✓ ⑥	Addition of paragraph (vi) to Section 4(2)(b) that reads, ***"(vi) a member of the Ontario College of Pharmacists".*** Similarly, addition of paragraph (vi) to Section 5(d) that reads, ***"(vi) a member of the Ontario College of Pharmacists".***	For a specimen is to be collected by the pharmacy professional, processed by a laboratory, and results communicated to the patient (and for positive results, to the public health unit and primary care provider), an official authorization ('order") is required. These changes will *enable the pharmacist to generate ("order") the test that would in turn be recognized by the lab as their authorization to process the sample.* At the same time, the *laboratory would be enabled to contact the pharmacy where the COVID-19 test was performed for communication of results.*

OPA would like to underscore the supplementary role that community pharmacies and their professional staff should play in COVID-19 testing. The Association continues to support the continued need for dedicated provincial assessment centres. However, with an expected second wave, these centres should be dedicated to the testing of *symptomatic patients* as they are best set up to manage these more serious cases. Community pharmacies, however, will be instrumental additions to the provincial testing strategy, as demonstrated in Alberta, to carry the significant work of asymptomatic COVID-19 testing for Ontarians.

Training and Support

In general, pharmacists are very familiar with POCT technologies, and newer technologies are typically introduced with training and support. As it relates to COVID-19 testing, while the oro-pharyngeal approach is a more turnkey model for engaging community pharmacy professionals as it does not require a change in scope of practice, OPA acknowledges that naso-pharyngeal PCR testing is more sensitive and, thus, the preferred approach for community-based testing.

The Ontario Pharmacists Association is the pre-eminent continuing education provider for pharmacy professionals in Ontario and has a solid track record in training pharmacists quickly but with a gold-standard approach. Examples include our highly successful programs on injections and immunizations, take-home naloxone, medicinal and recreational cannabis, diabetes management, and many more. OPA is fully committed to the development and launch of an education and training program to support all aspects of the proposed changes to the LSCCLA, including naso-pharyngeal swabbing for COVID-19 and other future community viral/bacterial outbreaks.

Remuneration and Additional Supports

As it relates to engaging community pharmacy professionals in the COVID-19 testing strategy, OPA is requesting financial support from the Ontario Government on behalf of participating pharmacies. We are proposing a model that is aligned with that which is in place for pharmacies in the province of Alberta. This is broken down as follows:

- $10 for pick-up of samples from a designated location (e.g., public health unit, hospital assessment centre)
- $20 for patient assessment/questionnaire and associated documentation
- $20 for performance of the naso-pharyngeal swab test by a pharmacist or pharmacy technician
- $10 for drop-off of samples to be processed at a designated location (e.g., public health unit, hospital assessment centre)
- **Total = $60 per assessment** (this assumes provision of government-supplied PPE to participating pharmacies)

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Conclusion

The Ontario Pharmacists Association appreciates the opportunity to respond to this consultation that seeks to enable pharmacy professionals to practise to the full extent of their training and expertise. OPA is also excited about the opportunity to leverage the accessibility of pharmacists at a time when our health system is undergoing unprecedented strain. While point-of-care testing offers an excellent opportunity to allow greater insights into patient care and assisting them in achieving optimal health outcomes, amendments to the *Laboratory and Specimen Collection Centre Licensing Act, 1990* to also enable "read and write" authority for pharmacists within OLIS and to leverage community pharmacies in COVID-19 testing and specimen collection would help drive efficiencies and cost savings to the Ontario government.

In conjunction with our partners at the Neighbourhood Pharmacy Association of Canada and in collaboration with the Ministry and other relevant stakeholders, we look forward to helping to drive significant change in healthcare in Ontario.

Should you have any questions or comments related to this submission, please do not hesitate to contact me at your earliest convenience.

Yours sincerely,

Justin J. Bates
Chief Executive Officer

cc: Neeta Sarta, Director, Laboratories and Genetics, Ministry of Health
Angie Wong, Director, Drug Programs Policy and Strategy, Ministry of Health
Allison Henry, Director, Health Workforce Regulatory Oversight Branch, Ministry of Health
Sean Court, Assistant Deputy Minister, Strategic Policy Planning and French Language Services, Ministry of Health
Rana Shamoon, Director, Health Policy, Office of the Premier of Ontario
Laurel Brazille, Director, Stakeholder Relations, Office of the Minister of Health
Leif Malling, Chief of Staff, Office of the Minister of Health
Tina Yuan, Policy Advisory, Office of the Minister of Health
Catherine Pringle, Special Advisor to the Minister, Office of the Minister of Health
Jen Baker, Chair, Board of Directors, Ontario Pharmacists Association
Allan Malek, EVP and Chief Pharmacy Officer, Ontario Pharmacists Association

Appendices:

- Appendix A – Letter to Deputy Premier Christine Elliott, dated June 20, 2020
- Appendix B – Proposed legislative and regulatory language to support OPA's recommendations

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Appendix A – Letter to Deputy Premier Christine Elliott, dated June 20, 2020

ONTARIO PHARMACISTS ASSOCIATION
Advocating Excellence in Practice and Care

Neighbourhood Pharmacy Association of Canada
Association canadienne des pharmacies de quartier

June 20, 2020

Deputy Premier and Minister of Health Christine Elliott
Ministry of Health, 5th Floor 777 Bay St.
Toronto, ON M7A 2J3

Dear Deputy Premier,

On behalf of the Ontario Pharmacists Association (OPA) and the Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies), and our respective members, we would like to thank you and your government for your relentless efforts to stop the spread of COVID-19. As the voice of more than 10,000 pharmacy professionals in the province we remain committed to supporting you and these efforts however we can.

Recently proposed regulations by the Ontario government and Ministry of Health are a welcomed step in the right direction that will help enable pharmacists to support even more patients through this challenging time.

While the timing is short, OPA and Neighbourhood Pharmacies (collectively, the Associations) agree that there is a significant window of opportunity to introduce changes that will support the government's response to COVID-19 and help more patients by:

- Enabling pharmacy professionals to participate in conducting COVID-19 testing (short term);
- Setting the stage for future serologic testing for COVID-19 (intermediate term);
- Ensuring that, for any future public health emergencies, pharmacy professionals will be prepared and appropriately positioned to assist at any given moment (long term); and
- Permitting pharmacists to practice to full scope, with 'read and write' access to the Ontario Laboratory Information System (OLIS), to ensure consistency in documentation of test results and to enable pharmacists to order and receive test results to more effectively monitor medication therapy in accordance with their current scope of practice and the expectations of patients, other health professionals and policymakers.

This letter, however, is intended to focus on the immediate short-term goal of identifying regulatory and legislative amendments that will enable pharmacy professionals to participate in conducting COVID-19 testing. With these recommendations, we look forward to working with you, the Ministry and representatives from the Ontario College of Pharmacists to determine a smooth implementation and to ensure that all necessary safeguards are in place to protect pharmacy professionals and the patients to whom they provide care.

Thank you again for the opportunity to work together to support Ontarians through and beyond this pandemic. Please see below our recommendations for your consideration. As always, we would forward to working together collaboratively.

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Recommendations

For the immediate short term, **the Associations recommend that pharmacies support the collection of specimens using non-invasive measures that will not require changes to the controlled acts listed in the *Regulated Health Professions Act*. The preferred approach, therefore, would employ the collection of nasal and throat swabs, saliva and/or capillary blood samples** to quickly and efficiently engage front-line pharmacy professionals. Operationally, we envision a general 6-step flow for pharmacy-administered COVID-19 testing as depicted below:

Our recommendation involves only one minor legislative amendment to the *Laboratory and Specimen Collection Centre Licensing Act, 1990* (LSCCLA) as well as some minor regulatory changes to Regulations 682 [Laboratories] and 683 [Specimen Collection Centres]. These changes are listed in the following table:

	RECOMMENDED AMENDMENT	WHAT IT WILL ENABLE
LSCCLA (the Act) These changes would facilitate the following steps: ✓ ① ✓ ② ✓ ③	In the definitions set out in the act in section 3, under "specimen collection centre", a new exclusion from the definition is required, and this requires the addition of paragraph (e) that would read, *"(e) a place where a member of the Ontario College of Pharmacists is engaged in the practice of pharmacy"*	In a manner that is similar to what the exclusions in the act do for physicians, nurse practitioners, dietitians, and midwives, the addition we are recommending will *permit pharmacists and pharmacy technicians to collect a sample* without the pharmacy practice setting needing to be classified as a formal specimen collection centre. *Note: While the Associations are proposing that pharmacy technicians be enabled to perform the technical tasks associated with COVID-19 swab testing, any clinical, interpretive and educational work with the patient would be the sole responsibility of the pharmacist.*
Regulation 682 [Laboratories] These changes would facilitate the following steps: ✓ ② ✓ ③ ✓ ④	Replace Section 12 with more current language, including removal of the portion of the clause referencing the performance of immunologic tests for pregnancy. Clause 12 is to be **removed**: *"All pharmacies and all pharmaceutical chemists employed in a pharmacy are exempt from the provisions of sections 5 to 16 of the Act and from the provisions of this Regulation with respect only to the performance of immunologic tests for pregnancy.* Clause 12 would be replaced with, *"All pharmacies and members of the Ontario College of Pharmacists employed in a pharmacy are exempt from the provisions of sections 5 to 16 of the Act and from the provisions of this Regulation."*	Elimination of the portion of the clause referencing immunologic tests for pregnancy is necessary as those tests are long obsolete and are no longer performed. The new clause aligns with language currently used with physicians and naturopaths and enables pharmacy professionals to *practice to their full scope.* This change for pharmacists will also enable changes with respect to *ordering and receiving laboratory tests.* This includes *the ordering of a swab test and obtaining its results* as well as *point-of-care testing onsite in the pharmacy (as per the current regulatory consultation)* that would include a *future serologic test for detection of COVID-19 antibodies.*

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Regulation 683 [Specimen Collection Centres] These changes would facilitate the following steps: ✓ ① ✓ ② ✓ ③ ✓ ④ ✓ ⑤ ✓ ⑥	Addition of paragraph (vi) to Section 4(2)(b) that reads, *"(vi) a member of the Ontario College of Pharmacists".* Similarly, addition of paragraph (vi) to Section 5(d) that reads, *"(vi) a member of the Ontario College of Pharmacists".*	For a specimen is to be collected by the pharmacy professional, processed by a laboratory, and results communicated to the patient (and for positive results, to the public health unit and primary care provider), an official authorization ("order") is required. These changes will *enable the pharmacist to generate ("order the test") that would be in turn be recognized by the lab as their authorization to process the sample.* At the same time, the *laboratory would be enabled to contact the pharmacy where the COVID-19 test was performed for communication of results.*

As you will see from Appendix A (see separate attachment), the broader scope of practice public consultation (Proposal 20-HLTC025 posted on the Regulatory Registry on June 12, 2020) will require other legislative, regulatory and policy considerations. Regarding legislative and regulatory changes, the Associations will be making a series of recommendations for further amendments to the *Pharmacy Act*, *Regulated Health Professions Act* and the *Health Protection and Promotion Act* in our respective submissions along with the aforementioned proposed amendments to the *Laboratory and Specimen Collection Centre and Licensing Act*. However, in addition to these recommendations, we urge the Ministry to begin exploring other policy and technical changes immediately, as these will need to be addressed so as to quickly operationalize an expanded scope of pharmacy practice that includes point-of-care testing, laboratory screening and ordering/receiving laboratory tests for purposes of medication and disease management. Such changes would include pharmacists' read and write access to OLIS.

To most effectively expand access to testing across Ontario by leveraging the infrastructure and accessibility of community pharmacies, we recommend an inclusive model in which participating pharmacies would be encouraged to meet certain criteria to protect the safety of the public as well as the safety of pharmacy staff. We welcome the opportunity to work with government to establish conditions and criteria that must be met by pharmacies to become COVID-19 testing sites. We propose consideration of the following recommendations:

A. **Physical Conditions:** A separate space outside the pharmacy (e.g., an adjacent parking lot) is available to collect specimens so that patients will not enter the pharmacy itself. Patients waiting for their test must be enabled to maintain physical distancing according to local public health guidelines. The testing space must be cordoned off to the general public and clearly marked so that the public cannot inadvertently enter the testing zone. Drive-up testing may also present an option to meet the physical conditions required.

B. **Personnel Conditions:** Pharmacy staff must be provided with adequate PPE and must be properly trained in the collection techniques, testing procedures and the proper use and disposal of PPE in accordance with guidelines from Public Health Ontario and the Canadian Pharmacists Association. Pharmacy professionals who approach within two metres of patients must wear full PPE, including a medical/procedural mask, gown, gloves, and eye protection[i]. Pharmacy personnel who can maintain a distance of two metres or more from patients should wear gloves and a medical/procedural mask. Note that collection of a nasopharyngeal or throat swab is not considered an aerosol-generating medical procedure and thus, an N95 respirator would not be required.[ii]

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C. **Procedural Conditions:** A system must be in place to ensure an orderly process for specimen collection that minimizes the exposure time for staff and ensures 100% accuracy in matching the specimen with the patient. The system must be able to screen patients so that only those meeting local public health criteria are eligible for an appointment[iii]. Specimens are to be collected only on an appointment basis in order to minimize exposure time and avoid large congregations of patients. Patient history and contact information should be collected prior to the appointment in order to minimize the time spent in the testing space. Prior to collecting the sample, pharmacy personnel must positively identify each patient and match them against the patient information provided to them. Systems must be in place to accurately label specimens and record all information in accordance with Public Health Ontario guidelines[iv]. All personal health information must be managed and secured in accordance with provincial privacy legislation at all times.

OPA and Neighbourhood Pharmacies recognize some of the technical and policy challenges that need to be addressed and are eager to discuss and mitigate them in collaboration with Ministry officials. Finally, in order to effectively operationalize this program and enable pharmacies to best support the government's testing objectives, remuneration for testing should consider the cost of the test and other materials (including but not limited to PPE), as well as the cost of the labour required to administer the tests. We hope to arrange a meeting within the coming weeks to begin the process of enabling pharmacy professionals to assist you and all Ontarians as quickly and as efficiently as possible.

Once again, thank you for the opportunity to present our thoughts, ideas and recommendations to help your government with its testing strategy. Please contact us at your earliest convenience to discuss these recommendations and next steps.

Regards,

Justin J. Bates
Chief Executive Officer
Ontario Pharmacists Association

Sandra Hanna, RPh.
Chief Executive Officer
Neighbourhood Pharmacy Association of Canada

cc: Allan Malek, EVP and Chief Pharmacy Officer, Ontario Pharmacists Association
Jeff Mehltretter, VP, Pharmacy and Business Development, Neighbourhood Pharmacy Association of Canada
Leif Malling, Chief of Staff, Office of the Deputy Premier and Minister of Health
Rana Shamoon, Director, Health Policy, Office of the Premier of Ontario

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[i] Personal Protective Equipment (PPE), Suggested Best Practices for Pharmacies During the COVID-19 Pandemic, Canadian Pharmacists Association, https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/PPE-Best-Practice-Suggestions.pdf, accessed June 18, 2020

[ii] IPAC Recommendations for Use of Personal Protective Equipment for Care of Individuals with Suspect or Confirmed COVID-19, Public Health Ontario, https://www.publichealthontario.ca/-/media/documents/ncov/updated-ipac-measures-covid-19.pdf?la=en, accessed June 18,2020

[iii] COVID-19 Provincial Testing Guidance Update, Ministry of Health, http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/2019_covid_testing_guidance.pdf, accessed June 18, 2020

[iv] Criteria for Acceptance of Patient Specimens, Public Health Ontario, https://www.publichealthontario.ca/en/laboratory-services/about-laboratory-services/specimen-acceptance-criteria, accessed June 18, 2020

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Appendix B – Proposed Legislative and Regulatory Language to Support OPA's Recommendations

The following is proposed language for regulatory amendments to the *Laboratory and Specimen Collection Centre Licensing Act, 1990*, as drafted by the Ontario Pharmacists Association, for purposes of enabling point-of-care testing by pharmacy professionals in accordance with the Ministry's consultation document.

In addition, OPA has also drafted some proposed legislative and regulatory language that would enable PCR and point-of-care testing for the current COVID-19 pandemic as well as for any future virulent outbreak, epidemic or pandemic.

Please note that all **proposed additions** to current legislative or regulatory language are presented in *red italicized font* while all **proposed deletions** to current language are presented in ~~*green italicized font*~~ with a strikethrough.

Pharmacy Act, 1991 - Legislation

- The scope of practice section in the Act requires the addition of a clause in subsection 4(1) and numbered as paragraph 6, which would read as follows (red font for additions):

> *"4 (1) In the course of engaging in the practice of pharmacy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:*
>
> *[…] 6. Putting an instrument, hand or finger beyond the point in the nasal passages where they normally narrow."*

Pharmacy Act, 1991 – Regulation 202/94

- Section 39 of the regulation would require several changes as outlined below (red font for additions, green font for strikethrough):

> *39. (1) For the purposes of paragraphs 5 and 6 of subsection 4 (1) of the Act, and subject to subsection (3), a member referred to in subsection (2) who meets all the requirements in subsection (4) is authorized to perform the act of piercing a patient's dermis with a lancet-type device to obtain blood and putting an instrument, hand or finger beyond the point in the nasal passages where they normally narrow.*
>
> *(2) A member who is a Part A pharmacist, an intern, a registered pharmacy student or a pharmacy technician is authorized to perform the act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration.*
>
> *(3) A pharmacy technician shall not perform the act provided for in subsection (1) unless,*
>
> *(a) a Part A pharmacist is physically present on the premises at the time when the pharmacy technician performs the act; ~~and~~*
>
> *(b) the pharmacy technician is under the direction of a Part A pharmacist at the time when the pharmacy technician performs the act, and*
>
> *(c) where the act is performed to administer a point of care test, a Part A pharmacist interprets the results of the test and makes the professional decision arising from the results of the test.*
>
> *(4) A member may only perform the act provided for in subsection (1) if he or she complies with the following:*
>
> *1. ~~The member may only perform the act for the purpose of demonstrating the appropriate use of lancet-type devices for the patient's self care and education or for the patient's self-monitoring of his or her chronic disease, and before performing the act,~~ Where there are applicable regulations under the Laboratory and Specimen Collection Centre Licensing Act, the member shall only perform the act in accordance with those regulations.*
>
> *~~i. shall explain that purpose to the patient or his or her authorized agent, and ii. shall The~~*

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~~member must~~

~~ii.~~ 2. *The member shall receive an informed consent from the patient or his or her authorized agent before performing the act.*

~~2.~~ 3. *The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient.*

~~3.~~ 4. *The member shall ensure that appropriate infection control procedures are in place.*

~~4.~~ 5. *The member must possess the knowledge, skill and judgment respecting the performance of the act and understand the condition of the patient, to perform it safely and effectively.*

~~5.~~ 6. *The member must consider whether performing the act on the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome and any other relevant circumstances.*

~~6.~~ 7. *The member must maintain a patient record that includes,*

i. the name and address of the patient ~~and the member~~,

ii. the ~~date~~ name and address of the member,

iii. the date the act was performed, ~~and~~

~~iii.~~ *iv. the circumstances relating to the act and any adverse reaction experienced by the patient,*

v. where the member performed the act to administer a point of care test, the results of the test,

vi. the professional decision arising from the results of the point of care test and the rationale for the decision, and

vii. confirmation that an informed consent was given by the patient or his or her authorized agent.

8. Where the act is performed for a purpose other than patient education and demonstration, the member must notify the patient's primary care provider (if any) within a reasonable time that the member performed the act and provide details respecting the act.

Regulated Health Professions Act (RHPA) – Legislation

- No changes are required for the RHPA legislation

Regulated Health Professions Act (RHPA) – Regulation 107/96

- In lieu of an amendment to the *Pharmacy Act, 1991* legislation, OPA proposes that an exemption clause be added to O.Reg. 107/96 under the RHPA, as follows (red font for additions):

> *15. A member of the Ontario College of Pharmacists is exempt from subsection 27 (1) of the Act for the purpose of putting an instrument, hand or finger beyond the point in the nasal passages where they normally narrow.*

***Laboratory and Specimen Collection Centre Licensing Act (LSCCLA)* - Legislation**

- An amendment is required to the definition section of the Act as it relates to "specimen collection centre", whereby new clause (e) is added that reads (red font for additions):

> *"(e) a place where a member of the Ontario College of Pharmacists is engaged in the practice of pharmacy,".*

- With this addition, current clauses (e) and (f) would be renumbered as (f) and (g), respectively.
- This should enable pharmacy professionals to perform tests permitted in the regulations by the Lieutenant Governor in Council.

***Laboratory and Specimen Collection Centre Licensing Act (LSCCLA)* – Regulation 682 (Laboratories)**

- In accordance with subsection 18 (a.2) of the Act, it is worth noting that the Lieutenant Governor in Council may:

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"[provide] for additional places that are specimen collection centres for the purposes of the definition of 'specimen collection centre' in section 5, and excluding places from that definition".

- In the event that a laboratory test is required on a human sample collected by a pharmacy professional for purposes of screening, monitoring or assessing a pharmacist's patient, a clause needs to be added to Section 9(1)(a) and numbered as (vii) that reads as follows (red font for additions):

  "(vii) at the request of a member of the Ontario College of Pharmacists."

- Note that subsection (vi) would need the addition of a comma and the word "and" added to allow for addition of subsection (vii) listed above.
- With the change in the definition of "specimen collection centre" in the Act, and to enable pharmacy professionals to support their patients in accordance with their scope of practice, Section 12 of Regulation 682 should be amended to the following (red font for additions, green font for deletions):

  "12. All pharmacies and ~~all pharmaceutical chemists~~ members of the Ontario College of Pharmacists employed in a pharmacy are exempt from the provisions of sections 5 to 16 of the Act and from the provisions of this Regulation ~~with respect only to the performance of immunologic tests for pregnancy. R.R.O. 1990, Reg. 682, s. 12; O. Reg. 169/15, s. 2~~.

***Laboratory and Specimen Collection Centre Licensing Act (LSCCLA)* – Regulation 683 (Specimen Collection Centres)**

- In accordance with subsection 18 (a.2) of the Act, it is worth noting that the Lieutenant Governor in Council may:

  "[provide] for additional places that are specimen collection centres for the purposes of the definition of 'specimen collection centre' in section 5, and excluding places from that definition".

- In the event that a specimen is collected and/or a test is requested by a pharmacy professional to be performed for purposes of prevention, a clause needs to be added to Section 4(2)(b) and numbered as (vi) that reads as follows:

  "(vi) a member of the Ontario College of Pharmacists"

- Note that subsection (v) would need a comma and the word "and" added to allow for addition of subsection (vi).
- The same would apply to Section 5(d) whereby a clause needs to be added and numbered as (vi) that reads as follows:

  "(vi) a member of the Ontario College of Pharmacists"

- Note that subsection (v) would need a comma and the word "and" added to allow for addition of subsection (vi).

***Health Protection and Promotion Act, 1990* – Legislation**

- No changes are required for the HPPA legislation

***Health Protection and Promotion Act, 1990* – Regulation 569 (Reports)**

- Amendments throughout the regulation to add the word "pharmacist" to the list of health professionals who are responsible to report *"information respecting the disease of public health significance or communicable disease, as the case may be, as the medical officer of health considers necessary."*

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