To: Ontario College of Pharmacists (OCP) Board of Directors & Consultation Committee

From: OnPharm-United

Date: July 30, 2026

Subject: Consultation Feedback – Proposed Amendments to the Standards of Operation for Pharmacies

Executive Summary

Key concerns:

- Unclear legal status of document. The document is not a regulation under DPRA s. 161(1), a by-law under s. 160.1, or a document adopted by reference under s. 161(2). Its obligations should therefore be traceable to the Standards of Accreditation (O. Reg. 264/16), and several proposed provisions are not.
- Subjective compliance triggers. Terms such as "at all times," "professional wellbeing," and privacy "determined to be acceptable by the patient" cannot be objectively inspected or reliably built to, exposing operators to inconsistent enforcement.
- Duplicative enforcement. Accessibility and human rights obligations are already binding under AODA and the Human Rights Code and enforced by their own statutory bodies; the draft would add a third, first-instance layer of accreditation enforcement for the same conduct. Similar dual accountability arises where the draft imports individual professional obligations (privacy of service delivery, clinical documentation) into a facility standard.
- Obligations beyond statute. The draft extends the "undue hardship" accommodation framework to health literacy and digital literacy, which are not accommodation categories in Ontario law.
- Feasibility and safety. A uniform visual-privacy infrastructure requirement disregards leases, building constraints, and capital realities, and full enclosure can work against safety for both patients and pharmacists in premises containing controlled substances and cash.

Key recommendations:

1. Clarify the legal status of the document, rename it to reflect its role as guidance on the Standards of Accreditation or "Operational Policies for Designated Managers", and map each operational expectation to a specific clause of O. Reg. 264/16.
2. Replace the "at all times" staffing standard with a documented, site-specific staffing plan developed by the designated manager or hospital pharmacy administrator and reviewed annually.
3. Reframe the workflow standard around patient safety and the standards of practice rather than the undefined term "professional wellbeing."
4. Retain the existing incentives standard as drafted, with interpretive guidance confirming

Address 2891 Slough Street, Unit 2, Mississauga ON L4T 1G4 **Web** onpharmunited.ca
Phone 1 855 667 4276 **Fax** 1 888 649 2685 **Email** info@onpharmunited.ca

that expectations relating to the provision of pharmacy services do not, in themselves, compromise professional judgement where each service is clinically appropriate.
5. Treat privacy of clinical service delivery as a practice standard; preserve the existing acoustical privacy requirement; remove the "acceptable to the patient" trigger; and confirm that no existing compliant pharmacy is required to modify its premises.
6. Address accessibility and human rights through the Code of Ethics, Standards of Practice, and a Pharmacy Connection article; develop health and digital literacy through clinical guidance rather than a standard.
7. Limit documentation requirements to operational elements (system, training, access) and publish a defined Required Reference Guide for clinical decision support, recognizing dependence on provincial information systems.
8. Use the Equipment and Technology section, objective, measurable, and tied to facility features, as the model for the entire document, and provide an adequate transition period for any standard requiring physical changes.

To the Board of Directors and Consultation Committee,

On behalf of OnPharm-United and the over 600 pharmacist-owned community pharmacies we represent across Ontario, we are submitting our formal feedback regarding the proposed amendments to the *Standards of Operation for Pharmacies*.

Pharmacist Directors and Designated Managers are fully committed to advancing the profession, expanding our scope of practice, and ensuring the highest levels of patient safety. We appreciate the College's efforts to update operational guidelines to reflect modern practice. However, upon reviewing the draft, we have identified several legal, structural, and operational concerns that we believe warrant the committee's careful consideration.

Specifically, the draft appears to occasionally conflate subjective clinical practice standards with objective facility infrastructure requirements, while introducing substantive obligations without clear regulatory anchors. Below is our detailed feedback and our proposed framework for constructively rectifying these issues before the document is finalized.

Overarching Legal and Structural Concerns

Under the *Drug and Pharmacies Regulation Act (DPRA)* s. 161(1)(m), standards for accreditation of pharmacies, "including their operation and the maintenance, space, equipment and facilities required therefor," are made by regulation: the Council makes them subject to Lieutenant Governor in Council approval, and s. 161(5) provides that such a regulation "shall not be made" unless the proposed regulation is circulated to every holder of a certificate of accreditation at least 60 days before Council approves it. The Legislature made that circulation mandatory, and provided only two narrow relief valves, both of which run through the Minister (ss. 161(6) and (7)). Neither applies here.

The current Standards of Operation draft is not a regulation under s. 161(1), a by-law under s. 160.1 (which is confined to the administrative and internal affairs of the College), or an external document adopted by reference under s. 161(2). Substantive operational standards for

accredited pharmacies are precisely the subject matter the Legislature assigned to s. 161(1)(m) and conditioned on the s. 161(5) process. A policy document that imposes the same obligations without that process risks doing indirectly what the statute says shall not be done directly, and leaves accreditation holders without the consultation rights the Legislature expressly gave them.

We therefore suggest that this document can only properly function as an interpretive tool for the existing Standards of Accreditation (O. Reg. 264/16): a guide to what the regulation already requires, not a source of new obligations for pharmacies to maintain accreditation. Any provision that goes beyond O. Reg. 264/16 that relates to premises accreditation belongs in a regulation made through the s. 161 process.

- Rename the Document: To reflect that legal character, we recommend retitling the document from "Standards of Operation" to "Guidance on the Standards of Accreditation" or "Operational Policies for Designated Managers ." The current title suggests a binding instrument with independent legal weight, which the document does not have, and which creates avoidable confusion for operators, inspectors, and the College alike.

Currently, the draft includes new frameworks containing highly subjective terminology (e.g., "patient-determined" privacy, "level of digital literacy," "professional wellbeing"). Operational feasibility becomes challenging when a facility standard relies on subjective, third-party compliance triggers. Pharmacy owners face difficulties underwriting capital expenditures, securing landlord approvals, or designing operational protocols without clear, binary, and objective audit criteria.

We respectfully request that the College clarify the exact legal status of this document and identify the regulatory anchor for each existing and proposed operational standard. This supports regulatory transparency and gives pharmacist directors and designated managers a single, clear source for compliance. We also note that the College's own rationale describes several of the proposed staffing and workflow provisions as providing a foundation for future policy options to be explored; we respectfully advise that such provisions be finalized only once that underlying policy work is complete.

Specific Feedback on Proposed Amendments

Governance and Legal Compliance (Lines 11-17 and 89-91, replacing lines 99-100)

- **Parallel enforcement of existing obligations:**
  - AODA (through O. Reg. 191/11) and the *Ontario Human Rights Code* are already binding on every Ontario pharmacy.
  - Both are enforced by specialized statutory bodies, the AODA Director and the Human Rights Tribunal of Ontario.
  - The College already has powers to act on findings made by these bodies through professional misconduct proceedings against individual pharmacists under the *Pharmacy Act*, and through accreditation action where a finding bears on a pharmacy's fitness to operate.

    - Because the escalation pathway already exists, adding first-instance accreditation enforcement of these obligations would mean a pharmacy could face concurrent proceedings from three different regulators for a single act, without adding to the patient protections already in place under these statutes.
- **Scope of the accommodation framework:**
    - The draft applies the "up to the point of undue hardship" framework, which comes from Human Rights Code accommodation doctrine, to categories that go beyond the protected grounds under either statute.
    - Physical, cognitive, and sensory abilities are recognized accessibility categories under AODA and the Code.
    - Level of health literacy and level of digital literacy, while clinically meaningful, are not currently accommodation categories in Ontario law.
    - We would welcome the College's thinking on these as clinical concepts, but respectfully suggest they may not fit comfortably within an accessibility framework anchored in existing statute.
- **Where the obligation attaches:**
    - Accommodating a patient's abilities, communication needs, or literacy in the delivery of a pharmacy service is something the pharmacist does.
    - This applies in whatever setting the service is delivered: in the pharmacy, at a long-term care home, at a vaccination clinic, or during a home visit.
    - The Standards of Practice and the Code of Ethics already reflect this, and both attach to the professional.
    - The professional-level obligation is the more natural fit for what the College is trying to reinforce, and it avoids duplicating accountability between the pharmacy as an accredited entity and the pharmacist as a regulated professional.

The College described the goal of these provisions as educational—supporting pharmacy professionals to better understand these obligations. That is a goal we share, and we think there are tools better suited to that purpose than the Standards of Operation. A *Pharmacy Connection* article, developed in the same way the College has communicated other important professional obligations to registrants, would deliver on the educational intent without the enforcement and scope questions that arise when these concepts are placed in an operational standard. The Code of Ethics and Standards of Practice already provide the enduring anchor for these obligations.

We encourage the College to consider:

- That the accessibility and human rights references be considered for inclusion in the Code of Ethics and Standards of Practice, where they attach to the pharmacist delivering the service, and communicated to registrants through a *Pharmacy Connection* article.
- That the health literacy and digital literacy references be developed through a clinical guideline or best-practice document, so that the College's thinking in these areas can evolve without accreditation consequences attaching to concepts that are still being defined.

Management and Employee Relations (Lines 47–50)

- **Staffing:** The draft requires pharmacies to be staffed "at all times" with the number of qualified staff required to maintain the standards of practice. This phrasing provides no objective indicator, making each inspection a discretionary judgment. It also touches upon individual professional judgment about whether staffing on a given shift was adequate—a question properly addressed through the Standards of Practice or a designated manager procedural requirement.
    - *Recommendation:* We recommend anchoring this to an auditable operational tool: *"The pharmacy is staffed in accordance with a written staffing plan, developed by the designated manager or hospital administrator, that reflects the services provided, expected patient volume, and the standards of practice. The plan is reviewed annually or when there is a material change in services or volume."*
- **Wellbeing:** "Professional wellbeing" is being introduced as an operational standard in the draft. Workplace wellbeing in Ontario is regulated under the *Occupational Health and Safety Act (OHSA)* and the *Employment Standards Act (ESA)*, each with its own enforcement body. The term does not have an established operational definition in pharmacy standards.
    - *Recommendation:* We recommend adjusting this to: *"The pharmacy workflow is managed to support patient safety and the standards of practice. Workflow design considers the cognitive and procedural demands of the pharmacy services provided."*

Staff Incentives:

- We recognize this provision is carried forward from the existing Standards rather than newly introduced, and we support its purpose: incentives should never override a professional's clinical assessment of an individual patient
- However, it is important to distinguish the incentive from the service. Ontario funds professional services on a fee-per-service basis precisely to encourage their uptake, so targets or incentives that encourage these services align pharmacy operations with provincial health policy
- This is the standard across all fee-for-service health professions in Ontario. Physicians, dentists, and optometrists all operate with service volume expectations, and none of their regulators treats them as compromising professional judgement
- Where concerns have arisen in the past, the failure was in services that were not clinically warranted or not delivered to standard, and accountability for that already exists through the Standards of Practice and program billing requirements
- We respectfully suggest the standard be retained as drafted, with interpretive guidance (or a single clarifying sentence) confirming: "Expectations relating to the provision of pharmacy services do not, in themselves, compromise professional judgement where each service is clinically appropriate and delivered in accordance with the standards of practice."

Pharmacy Premises (Lines 95-98)

The College's existing operational standard (as seen in the Oct 2025 opening checklist) requires

a separate and distinct patient consultation area offering "acoustical privacy." The draft replaces this with acoustical and visual privacy applied uniformly to every accredited pharmacy, with a compliance trigger of what is "acceptable to the patient."

- **Dual accountability and inconsistency with the model used by every other regulated health profession:** Every other regulated health profession in Ontario handles privacy of the clinical encounter as a practice standard applied to the individual professional. Physicians (CPSO), nurses (CNO), dentists (RCDSO), optometrists (COO), and physiotherapists (CPO) all address this through professional conduct standards, not through facility-level infrastructure requirements. The OCP itself already uses this model for pharmacists in adjacent areas. Confidentiality of personal health information is covered under the Standards of Practice for Pharmacists and the Code of Ethics, applying to the pharmacist in whatever setting they deliver care, including off-site vaccination clinics, LTC visits, and home visits, where there is no OCP-inspected premises. Duplicating this obligation in the Standards of Operation as a facility standard departs from that model, and creates concurrent accountability: the pharmacist is accountable as a professional under the *Pharmacy Act*, and the pharmacy is accountable as an accredited entity under the DPRA, for the same conduct. It also produces requirements untethered from actual service delivery. A central-fill pharmacy, or a pharmacy that delivers injections only at off-site clinics, would still be expected to build an enclosed counselling room in the pharmacy, even though the privacy concern the room addresses never arises there.
    - *We respectfully suggest the College align its approach to privacy of clinical service delivery with the model used across the regulated health professions: through the Standards of Practice for Pharmacists, applied to the professional, in whatever setting service is delivered.*

- **Visibility as a safety feature for patients and for pharmacists:** The draft assumes full acoustical and visual privacy is always the desired standard. In practice, visibility supports safety in situations that are common in pharmacy work.
    - *Patient safety:* Injections are safer where the pharmacist is visible to colleagues in case of an adverse reaction. Services delivered with a caregiver or support person, pediatric services, patients with cognitive impairment, and situations where coercion or power-imbalance may be a concern all work better with visual openness.
    - *Pharmacist safety:* Community pharmacies contain Schedule I, II, and III drugs, controlled substances, and cash—a risk profile the College's own Pharmacy Safety Initiative, time-delayed safe requirement, and lock-and-leave provisions recognize. Requiring pharmacists to conduct one-on-one clinical encounters in fully enclosed rooms, isolated from colleagues and with no sightline to the dispensary or retail area, is inconsistent with that security posture and could be exploited in robbery scenarios and pharmacist statutory responsibility to supervise the pharmacy. Determining the appropriate level of visual privacy for a given service is a matter of clinical and situational judgment, properly a practice standard, not a facility standard.

- **Subjective compliance trigger:** The phrase "acceptable to the patient" makes compliance a third-party subjective judgment rather than a feature of the pharmacy, outside the pharmacy's control. Because patients may prefer less enclosure as well as more, the test can cut in both directions: the same fully enclosed room could be found compliant or non-compliant depending on the individual patient on a given day. This is not a standard a pharmacy can operationally build to.
- **Operational feasibility:** Modifying commercial retail spaces involves landlord approvals, structural permits, and significant capital investment. Many pharmacies operate in leased premises with contractual constraints on alteration, and some occupy older buildings where structural changes are not feasible without extensive redesign. Applied uniformly and without a transition period, this standard could risk the continued accreditation of pharmacies that have served the public safely for years, on the basis of physical constraints unrelated to service quality.

We respectfully advise that:

- Privacy of clinical service delivery be treated as a practice standard under the Standards of Practice for Pharmacists, consistent with how every other regulated health profession in Ontario handles this concern.
- The existing acoustical privacy standard be preserved, without adding a fixed visual privacy requirement.
- Where a pharmacy offers expanded-scope services on-site, the design of the counselling area allows the pharmacist to determine the appropriate level of privacy in the moment of service, recognizing that visibility supports safety in many situations.
- The "acceptable to the patient" language be removed, as the underlying obligation already exists in the Standards of Practice and Code of Ethics.
- No existing compliant pharmacy should be required to modify its premises. Where a pharmacy chooses to offer expanded-scope clinical services on-site, it may invest in the infrastructure to do so; where it does not, it should be able to continue operating under the existing standard, delivering those services off-site or not at all.

Delivering Services (Lines 163-171)

- **Documentation (lines 163-167):** The proposed documentation procedures contain a genuinely operational core, ensuring the pharmacy provides a records management system and training on its use, which we support. Elements such as protocols for the information that must be documented import individual professional obligations that already exist under the Standards of Practice and the Documentation Guideline, creating the same dual accountability noted above.
    - *Recommendation:* We respectfully suggest the standard be limited to the operational elements (the system, training, and access), leaving the content of clinical documentation to the Standards of Practice.
- **Clinical decision support and patient health information (lines 169-171):** We support the intent of this standard and the Board's direction on access to patient health information.
    - *Recommendation:* We encourage the College to publish a defined Required Reference Guide and clarify how compliance interacts with provincial clinical information systems, so that accreditation risk does not attach to infrastructure outside an operator's control.

Equipment and Technology (Lines 197-223)

OnPharm-United strongly supports the amendments in this section. By focusing on physical assets, manufacturer calibration instructions, and retrievable maintenance logs, this section effectively captures the proper operational intent of a facility standard. It is objective, measurable, and translates cleanly into clear inspection criteria. We believe this section should serve as the model for how the other operational standards in this document are framed.

3. Holistic Recommendations for Document Revision

To support the College in developing a document that is legally sound, fair to pharmacist directors and designated managers, and helpful for College inspectors, OnPharm-United respectfully offers the following holistic recommendations for the Board's consideration prior to approval:

1. **Rename the Document:** To support regulatory clarity, we suggest the Board consider renaming this document from "Standards of Operation" to "Guidelines to the Standards of Accreditation" or "Operational Policies for Designated Managers and Pharmacist Directors." A revised name would help reflect the document's role as guidance operationalizing O. Reg. 264/16, and would help distinguish it from the underlying regulatory instrument.
2. **Connect Every Point to Legislation:** We recommend each operational expectation in this document be explicitly mapped back to a specific clause within O. Reg. 264/16. Making the regulatory chain transparent to pharmacist directors and designated managers, both for new provisions in the draft and for operational criteria already in use, would support fair and consistent compliance across the sector.
3. **Consolidate Existing Operational Criteria into a Single Source:** The College currently maintains several helpful operational tools, including the *Checklist for Opening a New Pharmacy* and the *Community Pharmacy Assessment Criteria*. We would welcome the College's consideration of consolidating these into the renamed guidance document, so that pharmacist directors and designated managers have a single, transparent source for what is required and where each requirement comes from in law or in professional standards.
4. **Clarify the Designated Manager's Role:** We suggest the College consider developing a dedicated resource that clearly outlines the operational policies and expectations specific to the Designated Manager's role. Organizing facility-level processes and accountabilities around that role would give Designated Managers a coherent framework to work from and would support them in preparing for accreditation.

This approach would align with well-established regulatory models such as Health Canada's "Person in Charge" under GMP requirements and the CPSO's "Medical Director" role for Out-of-Hospital Premises. Both models thoughtfully separate objective facility standards from professional and clinical accountability, and both give the individual responsible for the facility a clear set of operational expectations. We think a similar structure for Designated Managers would give the College a familiar and defensible framework, and would give Designated Managers the clarity they need to serve patients well and prepare for inspections with

confidence.

By focusing operational standards on facility-level enablers, and framing each expectation in a way that supports clear and consistent inspection, the College would provide Designated Managers with a fair and workable operational framework.

We would welcome the opportunity to discuss these recommendations further with the Consultation Committee, and we are grateful for the College's willingness to engage with the sector on this important work.

Sincerely,

Michael Nashat

OnPharm-United

(On behalf of the OnPharm-United Leadership Team and Member Pharmacies)

Address 2891 Slough Street, Unit 2, Mississauga ON L4T 1G4 **Web** onpharmunited.ca
Phone 1 855 667 4276 **Fax** 1 888 649 2685 **Email** info@onpharmunited.ca