RXLAW

Precision Is Protection:
An Enforcement-Based Review of the Draft Standards of Operation for Pharmacies

Consultation Submission on the Ontario College of Pharmacists Draft Standards of Operation for Pharmacies

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Executive Summary

RxLaw is a regulatory defence firm dedicated to healthcare and pharmacy regulation. We are the lawyers in the room when the College's standards are applied to a registrant—in investigations, at screening, and in discipline. We have firsthand experience how standards of practice can enforce, or greatly hinder, self-regulation and professional practice.

In our experience, most College matters are decided on paper, at the screening stage, where a standard's words are applied exactly as written; before they can be interpreted by a Discipline Committee or Court. The outcome can mean a permanent entry on the public register that follows a pharmacist through every job application, insurance or mortgage renewal, and financing review of their career.

There is no moment to argue about what a vague or ambiguous standard means. There is only the text.

That is why our position reduces to one proposition: **a standard is only as protective as it is precise.**

Several of the proposed standards cannot be complied with in advance by any pharmacy, however careful. These include:

- a requirement that the pharmacy be staffed “at all times” to maintain the standards of practice. Adequacy is defined only by the outcome, so when a medication incident occurs, the incident itself becomes the proof that staffing fell short;

- a privacy standard measured by what each patient finds acceptable. The same consultation room can be compliant for one patient and a breach for the next. No pharmacy can be built to a state of mind;

- a workflow standard built around an undefined staff "wellbeing" standard. A pharmacy cannot comply with a single word standard that has no definition or context, and no employer controls the overarching “wellbeing” of its staff; and

- human rights obligations imported into pharmacy regulation without their legal guardrails, assigning accommodation questions to pharmacy screening panels when Ontario already built an expert tribunal to answer them.

Each will be judged after the fact, by someone else, against words that evade any clear definition or certain interpretation.

Standards like these do not fail in consultation. They fail on adjudication, in a matter with a registrant's name on it.

So we offer the College a tool, not just objections. Before adopting any standard, we propose the College ask four questions. We call this the **enforcement test**, which asks four questions:

1. **Knowability:** Can a pharmacy know it complies, in advance?

2. **Auditability:** Would two inspectors come to the same conclusion?

3. **Attachability:** Does the obligation rest on the person who controls it?

4. **Consequence:** Is the consequence of non-compliance clear?

Every recommendation in this submission, and every revision proposed at **Appendix "A"**, comes from applying that test, including a key standard which we propose should be added to the standards to ensure their integrity.

That proposal is our most important request, and it is an addition, not a deletion: **an anti-reprisal standard.** The draft expects pharmacy professionals to raise concerns. It should protect them when they do.

Ontario's pharmacists have accepted the greatest expansion of their responsibilities in a generation.

They have earned rules that say, clearly and in advance, what is being asked of them.

1. Who We Are

RxLaw is a regulatory defence firm dedicated to pharmacy and healthcare regulation. We act for pharmacists, pharmacy technicians, Designated Managers, and pharmacy owners in College investigations, Inquiries, Complaints and Reports Committee ("**ICRC**") proceedings, discipline hearings, and judicial reviews in Ontario, and in pharmacy regulatory matters across Canada.

We write from a specific vantage point: the room where the operational standards being proposed are ultimately applied. Other sector voices have eloquently addressed the draft's legal architecture and operational feasibility in detail, and we do not repeat that analysis.

Our contribution is the enforcement dimension. We focus on how these standards will apply in the context of inspections, investigations, screening decisions, and the files and consequences

that follow. That is where we spend our days, with many of us having sat on both sides of the table.

Nothing in this submission questions the College's objectives. We acknowledge and appreciate that an expanded scope of practice is the most significant development in Ontario pharmacy practice in a generation, and the operational environment must rise to meet it. Our concern is narrower and, we believe, shared: that the standards adopted to support that transition be capable of doing so, in a fair and effective manner.

2. The Proposed Changes in Brief

Because this submission may be read without the draft alongside it, we begin with a plain-language account of what is being proposed.

The Standards of Operation for Pharmacies (the "**Standards**") set the College's expectations for how a pharmacy—as a premises, a system, and a business—is run. They operate alongside the Standards of Practice, which govern the individual professional.

First issued in September 2018, the College is revising the Standards to support Ontario's expanded scope of pharmacy practice, and the current consultation is part of the first substantial reformation of the Standards since their introduction.

The most consequential of the proposed changes fall into three groups:

1. **Clarifications and modernization to the Standards**, including updated terminology ("pharmacy professional" replacing "member," and a new "pharmacy staff" definition covering everyone who works in or supports a pharmacy), a definition of pharmacy services anchored to the *Pharmacy Act*, cleanup of the controlled-substances wording, and a rebuild and clarification of maintenance, calibration, and documentation requirements. Much of this is genuine improvement needed for the effective implementation and regulation of pharmacists' expanded scope of practice.

2. **New obligations imported from other legal regimes,** such as standards requiring that pharmacy services comply with human rights and accessibility legislation—including accommodating a patient's physical, cognitive, and sensory abilities, and their "level of health literacy" and "level of digital literacy," "up to the point of undue hardship"—supported by policies, training, and "monitoring practices." The need and jurisdiction of the College in implementing these measures is unclear.

3. **New subjective and outcome-based tests** that impose new, ambiguous, and unclear standards and requirements on pharmacists and pharmacies. The College has proposed that:

    1. a pharmacy must be staffed "at all times" with the staff needed to maintain the standards of practice;

    2. workflow must support "pharmacy professional wellbeing";

    3. the consultation area must offer acoustical and visual privacy "determined to be acceptable by the patient";

    4. documentation procedures must include protocols for "managing delays in documenting information"; and

    5. clinical decision-support tools and patient health information must be "sufficient."

These groups carry very different compliance enforcement consequences, with the third group being the most problematic, and with respect to which the most scrutiny—and we are hopeful revision—will be required. The first can be complied with in advance, inspected objectively, and enforced consistently. The second and third cannot; their wording leaves compliance to be decided after the fact, by someone other than the pharmacy.

The balance of this submission explains why that distinction matters.

3. How Standards Are Actually Applied

Four realities of College enforcement shape everything that follows. They converge on a single test, which anchors the changes we propose in this consultation.

3.1. The Text Governs, Not the Label

The formal nature of the Standards will matter less than the words on the page.

Whatever their formal legal status—and their legality more broadly—the text will be applied by College assessors at inspection, imported into investigations through the professional misconduct regulation under the *Pharmacy Act* and its regulations, and engaged in proprietary misconduct and accreditation proceedings under the *Drug and Pharmacies Regulation Act* and its regulations.

This is not speculation. The College's published discipline decisions routinely particularize operational and record-keeping failures, measured explicitly against College policies and standards, as professional and proprietary misconduct.

College committees—notably the ICRC and the Discipline and Accreditation Committees—will treat the Standards as the authoritative statement of the minimum standards that must be met by a properly operated pharmacy. The Standards will inform decisions on investigations, complaints, accreditation issues, and allegations of professional misconduct.

In these circumstances, a committee is not collaborating with a registrant toward an amicable resolution. It is applying standards—on a registrant's written submissions and without the benefit of oral argument—to adjudicate a matter and, ultimately, to impose a remedial or disciplinary outcome.

Ambiguous and unclear standards—as with the second and third groups above—are at their most dangerous in exactly this setting.

3.2. Screening Decides Most Matters

The overwhelming majority of College investigations and complaints conclude on screening by the ICRC, without necessitating a hearing. Screening is a paper process: there is no cross-examination, no testing of expert evidence, and no forum in which a registrant can litigate what a standard means before it is applied to them.

Outcomes at that stage—advice, cautions, specified continuing education or remediation programs, undertakings—are shaped almost entirely by how the applicable standard reads on its face.

At screening, standards are not tested. They are applied. Challenging their application afterward means review proceedings—the Health Professions Appeal and Review Board where that route exists, the Divisional Court where it does not—which are slow, costly, and usually only available after the notation is made.

The logical moment to remediate the Standards is proactively, before they are adopted, and before they effect lasting consequences for registrants and the public.

3.3. Public and Permanent Consequences

Screening outcomes divide sharply between their private and public outcomes. An ICRC decision to take no action, or to issue advice or recommendations, remains confidential. A caution or a specified continuing education or remediation program does not. Since the

Protecting Patients Act, 2017, remedial measures have been posted to the College's public register, with no real statutory provision or mechanism for removal.

But it means the same investigation can end on either side of a permanent publicity line.

In our practice, we routinely see how much the public side matters, and the disproportionately deteriorative effect it has on registrants' practices and businesses.

Register notations are weighed in hiring decisions, insurer renewals, banner and credentialing reviews, and financing due diligence; whether or not the underlying subject matter has anything to do with the question being assessed. Most people viewing the Register only see the notation—the "exclamation mark"—not the nuance.

The gap in consequence between "advice or recommendation" and "caution" is now measured in careers, and the choice between them turns on how a panel reads the applicable standard.

3.4. Consistency and Predictability

A single incident routinely produces multiple respondents. The same dispensing error can ground allegations against the staff pharmacist under the Standards of Practice, the pharmacy's Designated Manager under the operational standards, and the owner or directors under the pharmacy accreditation framework.

Standards drafted at the facility level in ambiguous, outcome-based language do not clarify responsibility; they multiply respondents.

Who is made to answer to the allegations of a standard's breach is unpredictable. In our practice, the same fact pattern yields an investigation against the dispensing pharmacist alone in one investigation, and against a pharmacist, the Designated Manager, and the directors in the next. A registrant cannot predict the consequences of their conduct, which ultimately depend on choices the drafting leaves open.

A standard that does not say who owns an obligation invites the College to name, or attempt to name, everyone. And the College routinely does exactly this.

Nor does the inconsistency and unpredictability end with the College's selection of a respondent to a complaint or report. Every file passes through a series of discretionary judgments: the College assessor who decides what to flag, the investigator who decides how far to pursue the matter, the panel that decide where the matter lands. Those actors change from file to file, even for multiple respondents to the same investigation.

A precise standard disciplines that discretion toward consistency and predictability. A vague one scatters it. Similar pharmacies, on similar facts, meet different findings at inspection, different investigative scope, different dispositions, and—given the public nature of the register—different permanent records with real consequences.

We see this routinely in our practice based on the current Standards. The proposed revisions increasingly multiply that risk because they multiply the subjective surface of the Standards using subjective, amorphous and ambiguous language like:

- "at all times";
- "acceptable to the patient";
- "pharmacy professional wellbeing";
- "abides by provincial human rights legislation";
- "sufficient"; and
- "monitoring practices."

Divergence, once it begins, does not correct itself. Screening outcomes at the ICRC stage are not published as reasoned decisions. There is no public body of interpretation that registrants can consult. Each panel reads the words fresh.

A vague standard therefore never converges on a settled meaning through use: whatever meaning it is to have must be written into the text at the outset, or it will be supplied case by case, invisibly, and differently.

Uncertainty also has a distributional cost. Where a standard's meaning is genuinely contestable, outcomes begin to track representation rather than risk. The well-resourced respondent retains counsel and contests the interpretation, and is able to seek judicial review of an unreasonable interpretation of a standard. The registrant unable to afford counsel, meanwhile, has no choice but to accept that unreasonable interpretation. We see both types of files.

The registrants who depend on an untarnished public record to secure employment are the least able to absorb a permanent register notation, and also the least equipped to challenge one built on ambiguous text. Unfortunately, those are often the registrants who overwhelmingly (in our experience) have to contend with investigations.

None of this serves the public, or the College for that matter.

Consistent application is what makes screening decisions defensible, inspections credible, and the register meaningful. An operator cannot build a compliance program to a standard that means different things to different inspectors, and a registrant cannot fairly carry a permanent notation that a different panel, reading the same words, would never have imposed. A register populated by drafting ambiguity rather than genuine risk is a weaker tool for the public it exists to protect.

3.5. Standards for Standards

For these reasons, we assess every proposed standard against four questions. In our practice, when consulting on policy or legislative matters, we call this framework the "enforcement test." The test consists of four components which tests a provision's robustness and defensibility:

1. **Knowability:** Can a Designated Manager determine with certainty, before an inspector arrives or a complaint is filed, whether the pharmacy is compliant?

2. **Auditability:** Would two different inspectors, applying the standard to the same pharmacy on the same day, reach the same conclusion?

3. **Attachability:** Does the obligation rest on the person who actually controls the variable it describes?

4. **Consequence:** Is it clear what consequence follows from non-compliance—accreditation action, a misconduct referral, or guidance—and through which process?

A standard that fails these questions will not fail here, in consultation. It will fail on adjudication of a file, with a registrant's name on it, a panel reading it, and a register or the Discipline Committee waiting.

4. What the Draft Standards Get Right

4.1. Equipment and Technology (lines 218–223)

This section meets all of the requirements of the "enforcement test."

It requires a pharmacy to have standard operating procedures for maintenance, calibration, and certification, performed to manufacturer instructions, with documentation that is retrievable. Every element is knowable in advance, auditable on inspection, attached to the operator, and clear in consequence.

This section should serve as the drafting template for the rest of the document. It is proof that operational standards can be both rigorous and fair; and that the College has the capacity and ability to address the issues we raise below.

4.2. Definitions: Pharmacy Professional and Pharmacy Staff

Precision about who in a pharmacy's operations bears which obligation is the foundation of fair enforcement. This proposed change supplies the certainty that was missing in the current regulatory framework.

We support it. It is a move in the right direction.

4.3. Clinical Decision Support and Patient Health Information (lines 169–171)

We strongly support this standard. Of the provisions in the third group we noted above, it is the only one which can be cured relatively simply by clarifying a definitional term.

In our defence practice, we regularly see professionals held to the standards of practice without the tools those standards presuppose. A pharmacy that requires its professionals to deliver expanded-scope services must resource them to do so.

We encourage the College to specify and define what "sufficient" means for each element the standard lists, including clinical decision support tools, reference databases, and patient health information. Because much patient health information resides in provincially administered systems, the "sufficiency" standard should be assessed against what the pharmacy itself provides and maintains, not infrastructure it does not control.

This gap can be remediated simply, by defining what "sufficient" means for the services a pharmacy offers.

4.4. Incentives and targets (lines 62–63)

We support retaining this standard. It is not new; it is carried forward from the existing Standards, and its purpose—that no target should ever override a professional's clinical assessment of an individual patient—is sound.

Retention should not, however, be mistaken as a carte blanche rule against service expectations.

The Province of Ontario funds pharmacy services on a fee-per-service basis precisely to encourage their accessibility and use to the public, as it does across fee-for-service health professions. A pharmacy that expects its professionals to offer funded services where clinically

appropriate, and where that is within the professional's judgment, is aligning its operations with provincial health policy, not compromising judgement.

What the standard should properly police is narrower: pressure that overrides the clinical judgment of a pharmacy professional, or negatively affects the assessment of an individual patient. Where a service was not clinically warranted, but nevertheless provided (and billed), accountability already exists under the Standards of Practice.

What those instruments cannot reach is the operational structure above the encounter. Regulation of that overarching infrastructure that imposes pressure on clinical judgment is where the standard should be operative.

The pharmacy professionals we defend are far more often the subjects of volume pressure than the authors of it. This standard is one of the few instruments that reaches the people who design negative incentive and pressure structures; including, critically, corporate actors who are not themselves registrants but who are reachable through the accreditation framework of the pharmacy. The standard should be applied there, at the level where targets are actually set, not against the professionals subject to them.

Two clarifications, by guidance or a single sentence, would let the standard do that work consistently: that clinically appropriate service expectations do not, of themselves, compromise professional judgement; and that where an incentive or target does, responsibility rests at the level where it is set. Our proposed wording is at **Appendix "A"**.

4.4.1. The Board's Candour on Workload

The Board's documented reasoning acknowledges that expanding scope will exacerbate workload concerns.

That candour is welcome and, from where we sit, overdue. Workload is the unstated context of a substantial share of the medication-incident files we defend.

The question is not whether the College should address staffing and workflow, but how and whether these provisions, as worded, can.

As drafted, we believe they will generate proceedings rather than protection and, in the case of the College's amorphous concept of "professional wellbeing," attempt to regulate the employment, franchise, or other business relationship rather than the operation of a pharmacy.

This brings us to our serious concerns with the proposed Standards, as drafted.

5. Where the Standards Fail

5.1. Staffing "at all times" (lines 47–48)

5.1.1. The Defect: "Adequacy" Defined Only by Outcome

The draft requires the pharmacy to be staffed "at all times" with the number of qualified and trained staff required for pharmacy professionals to maintain the Standards of Practice.

This fails the first two questions of the enforcement test:

1. **Knowability:** no Designated Manager can determine in advance whether a given shift complies, because adequacy is defined only by outcome; and

2. **Auditability:** two inspectors reviewing the same shift would have no transparent, common measure to apply.

The circularity is built into the text itself: the draft defines adequate staffing as the number "required for pharmacy professionals to maintain the standards of practice." No quantitative criteria are mentioned: no hours, no ratios, no coverage floor, no measure of adequacy that exists independently of the outcome.

Because compliance can only be judged after the fact, the standard, as written, will necessarily be applied retrospectively. A Designated Manager scheduling next week's shifts has no way to know whether that schedule complies with the standard. The answer arrives only after something goes wrong, when an assessor or a panel looks backward from the incident and decides.

In other words, the standard cannot guide or inform staffing decisions; it can only judge them after a breach has been identified.

5.1.2. The Dangerous Inference Chain

When a medication error occurs, the chain of inference the text invites is clear:

1. An error or incident occurred;

2. Therefore, the standards of practice were not maintained; and

3. Therefore—by the standard's own definition—staffing was inadequate.

The incident becomes its own proof of the breach. Under that reasoning, no evidence of careful scheduling can answer the allegation. The only complete defence is that the incident never occurred, which is precisely the fact under investigation.

We note what this chain never asks:

- how many staff were actually on shift;
- what the volume was that day;
- whether staffing played any role in the error; or
- whether the same error would have occurred with twice the coverage.

This is precisely the root cause of the flaw: the standard is not consistent with the realities of practice.

Medication incidents have many causes—look-alike/sound-alike products, software defaults, interruptions at the counter—and they occur in fully staffed pharmacies.

We have defended enough of these files to say it plainly: hindsight is the natural habitat of outcome-based standards.

5.1.3. A Standard at War with Itself

The College's draft itself knows better. Its "Safe Medication Management" section requires a quality-improvement process for "detecting, recording, analysing, correcting and sharing lessons learned from medication incidents." This framework, in line with the Institute for Safe Medication Practices, presumes incidents will occur even in well-run pharmacies and treats them as signals to learn from.

A staffing standard that converts every reported incident into presumptive proof of a breach works directly against a framework that invites candour, and encourages remediation and compliance.

The College cannot ask for a culture of openness, honesty and learning at line 51 while lines 47–48, immediately above, make every learning opportunity a significant liability.

5.1.4. Multiplication of Respondents

The standard also multiplies respondents to a complaint or investigation if an incident occurs. The same incident grounds allegations against the dispensing pharmacist, the Designated Manager, and the directors or owners; regardless of who actually controlled the labour budget, or what the staffing circumstances were, on the day.

5.1.5. Neither Vague Words nor a Universal Number

It may be said that this standard merely carries forward the existing expectation that staffing must be adequate to maintain the Standards of Practice, and that assessment has always rested on professional judgment.

With respect, that is the concern stated plainly: a standard whose content cannot be quantified in advance can only be assessed by working backward from the very incidents it was meant to prevent. Adding, “at all times” does not cure that defect; it makes it substantially worse.

Nor is the answer a single provincial number. Every practice environment is different. A ratio suited to a high-volume urban dispensary would be meaningless in a rural pharmacy running clinics. A universal figure would simply fail the enforcement test in the opposite direction, penalizing pharmacies safely staffed for their own practice.

5.1.6. An Instrument that Resolves both Defects

The instrument that resolves both defects is a mandatory written, pharmacy-specific staffing plan.

Such a plan would be developed by the Designated Manager or hospital administrator, and quantified through their professional judgment based on the pharmacy’s services and work volume, in a way that is justifiable and auditable by the College.

This meets the needs of all stakeholders: it gives the College defined variables inspect and assess, it gives the pharmacy an unambiguous standard it can meet, and creates a justified plan based on professional judgment and the practical realities of pharmacy practice, which serves the public interest.

We note that the invocation of “professional judgment” does not provide pharmacy management carte blanche to create an arbitrary staffing plan. Professional judgement must necessarily be justified, and a written staffing plan can be assessed by a panel of peers and public appointees should an issue arise. This is what the legislature envisioned.

A necessary corollary is that any written staffing plan should include a **deviation protocol** requiring a documented response when planned pharmacy professional coverage fails through illness, resignation, or emergency.

A plan without a deviation pathway becomes a tripwire. It allows a significant gap that would allow the pharmacy’s own document to be cited against it the first day practice reality departs from the paper standard. A plan with a defined expectation of deviation becomes evidence of a managed system, assessed on how the pharmacy responds when things go wrong rather than on the fact that they sometimes do; this is what such a standard should be.

5.2. Privacy “determined to be acceptable by the patient” (lines 95–98)

The proposed consultation-area standard deems a pharmacy's counselling area to be acoustical and visual privacy compliant when “determined to be acceptable by the patient.”

This fails our enforcement test at every step:

1. **Knowability:** No pharmacy can comply in advance. The measure of compliance—a patient's acceptance—does not exist until after the encounter.

2. **Auditability:** Two inspectors examining the same consultation area have no common measure to apply. The same room can satisfy one patient and fail the next, and the text makes both results correct.

3. **Attachability:** The obligation attaches to the pharmacy, but the deciding variable—what a patient finds acceptable—is controlled by no one there. The standard holds the operator answerable for the state of mind of the patient.

4. **Consequence:** The draft does not say what follows from failure. Our practice does: a complaint.

Consider how this arrives at the College.

A patient who felt overheard files a complaint. A screening panel deciding on a paper record has no yardstick against which to weigh the reasonableness of the pharmacy’s layout; the standard’s own text has already made the patient’s dissatisfaction the measure of the breach.

As drafted, the complaint and the contravention are identical, and there is no configuration of premises an operator can build that ensures compliance in advance of a breach.

Taken to its logical extreme, a disgruntled patient who raises their voice could only be accommodated by a fully soundproof vault if that is what is “determined to be acceptable by the patient” in the circumstances. This creates a result as unworkable as it is unreasonable.

The privacy of the clinical encounter should be addressed as a practice standard attached to the professional, consistent with the model used across Ontario’s regulated health professions, and that the existing acoustical privacy requirement be preserved at the facility level.

If the College concludes that the premises must nonetheless be addressed directly—and we accept that an environment can enable or defeat privacy—then the standard should describe the **capability of the premises**, not the state of patient satisfaction.

For example:

"The pharmacy has a consultation area capable of providing acoustical privacy and, where required by the services offered, visual privacy."

A pharmacy can be built or renovated to meet that standard. Whether and how that capability is used in a given encounter is the professional's judgment, exercised with the patient and governed by the Standards of Practice.

This preserves the College's patient-centred intent while giving operators a standard they can actually meet.

5.3. Human rights and accessibility (lines 11–17 and 89–91)

5.3.1. The Values Are Not in Question

We want to be precise here, because the underlying values are not in question. The *Ontario Human Rights Code* and the *Accessibility for Ontarians with Disabilities Act, 2005* bind every pharmacy in the province today.

The obligations are real, are being enforced by regulators with jurisdiction over them, and pharmacies must meet them.The existing Standards already require compliance with the law in general terms, and we take no issue with that.

The difficulty with the Standards is different in kind: the draft writes another legal regime's balancing doctrine—accommodation "up to the point of undue hardship" into a pharmacy's regulator's accreditation criterion, and assigns its administration to committees that were never designed for it.

This does not make sense, legally or practically.

5.3.2. Ontario Has Already Built the Forum

Ontario did not leave human rights to generalists. The legislature created a dedicated, specialized tribunal, the Human Rights Tribunal of Ontario (the "**HRTO**"), with expert adjudicators, full evidentiary hearings, a developed body of jurisprudence on discrimination and accommodation, and remedial powers that include compensation for the person wronged.

Accessibility under the *Accommodations for Ontarians with Disability Act* (the "**AODA**") carries its own enforcement and review structures. Undue hardship is assessed in those forums against defined statutory considerations—cost, outside sources of funding, and health and safety requirements—on an evidentiary record.

That legislative architecture is not an accident. It reflects the basic allocation on which administrative law is built: specialized questions go to the specialized bodies constituted with the relevant experience and expertise to answer them.[1]

5.3.3. A Pharmacy Regulator's Screening Panel is Not That Forum

To be precise about what is and is not new: the College can, and does, treat discriminatory conduct as professional misconduct. Indeed, the College is able to address findings made by the HRTO and under the AODA as part of its current complaints and investigations machinery.

That is regulatory action based on findings made by another body against a registrant; and it sits squarely within the College's inherent ambit under the professional misconduct regulations.

What the draft standard proposes is different. It makes the Human Rights Code's accommodation analysis—a balancing exercise the legislature assigned to the HRTO—a criterion of pharmacy accreditation, assessed by screening panels applying the standard "abides by provincial human rights legislation" on a paper record.

There is no evidentiary hearing, no accommodation jurisprudence to draw on, and no institutional experience of the doctrine, because no part of the College's mandate has ever required it.

The likely result is not better human rights adjudication. Instead, the result is rougher, and potentially incongruous rulings, potentially at odds with decades of established jurisprudence; all delivered by a decision making body engineered for pharmacy regulation, not human rights law.

5.3.4. Self Regulation Cuts Both Ways

The College's own authority rests on the same allocation principle.

Pharmacy is self-regulated because the legislature concluded that pharmacy questions belong with those who know pharmacy. That is exactly why human rights questions were given to the HRTO, given its expertise in the Human Rights Code and related jurisprudence.

A regulator that writes another tribunal's mandate into its accreditation criteria is not extending patient or public protection; it is working against the division of expertise on which its own legitimacy depends. Whether or not such a standard is within the College's formal powers—our view is that it is not—it is outside its institutional design.

While the other provisions in this part fail the enforcement test's questions, this one fails before the questions begin by assigning the test to the wrong institution.

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[1]See: *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65, at para 119

5.3.5. The Public is Not Better Protected

The duplication of proceedings does not help the public interest the College's empowering legislation was designed to protect.

A patient with a genuine discrimination claim against a pharmacy has, at the HRTO, a forum that can hear their evidence and order remedies for them, including compensation.

A pharmacy accreditation process can do none of this. In a College file, the patient is not a party seeking a remedy; they are the complainant in someone else's proceeding, and nothing a screening panel orders restores anything to them.

And the HRTO's jurisdiction does not evaporate because the College gained a sudden interest in human rights.

Nothing in a pharmacy accreditation standard displaces the HRTO's jurisdiction, nor could it.

The proposed standard therefore does not move rights claims to the College; it adds a second forum alongside the first. The same encounter can generate an HRTO application against the operator and a College complaint against the pharmacy, its Designated Manager, and its pharmacy professionals—with AODA compliance processes besides, where premises are involved—each with its own record, its own timeline, and its own cost.

The Danger of Inconsistent Decisions

Parallel forums invite inconsistent results, and the law forbids reconciling them. Section 36(3) of the *Regulated Health Professions Act, 1991* seals College proceedings off from the civil courts (the "**Confidentiality Provision**"). No record, report, statement, or decision from a College matter can be used in a civil proceeding.

The HRTO has held that a human-rights application is a civil proceeding, and the courts have called the bar absolute.

The Tribunal confirmed this only months ago, in a case involving the College.

A pharmacist brought a human-rights application about the College's own assessments of their practice. It was dismissed because everything needed to decide it was sealed behind s. 36(3). The College itself raised the seal to bar consideration of the claim by the HRTO: *Yoshizawa v. Ontario College of Pharmacists*, 2026 HRTO 687.

Application of this to the proposed Standard is extremely concerning. If human-rights compliance becomes an accreditation criterion, the College will start deciding accommodation

questions. Under the Confidentiality provision, no discrimination claim arising from those decisions can ever be heard by the province's expert human-rights tribunal.

The evidence is sealed before the claim begins. That is not speculation; it is exactly what happened in *Yoshizawa*.

The seal runs one way. The College can read the HRTO's public decisions; the Tribunal can never receive the College's. The expert body on human rights is the one kept blind. So the two could reach opposite conclusions on the same facts—a pharmacy cleared by the Tribunal but carrying a permanent register notation, or cleared by the College and later found by the Tribunal to have discriminated—and no process exists to reconcile them.

The proposed standard does not add protection. It builds a second decision-maker for human-rights questions that is neither as qualified nor as capable, sealed off from the expert tribunal the legislature built to answer them.

5.3.6. Undefined Categories, Undefined Monitoring

The Standards extend the undue-hardship formula to health literacy and digital literacy, concepts that are clinically meaningful but are not accommodation categories in Ontario law.

This creates complaint categories with no settled content. A patient directed to an app-based refill system who complains that their digital literacy was not accommodated presents a screening panel with a question no statute, tribunal, or guideline has yet answered. Registrants should not be the test cases through which these concepts acquire meaning.

Line 11 of the Standards also requires that staff be supported by "monitoring practices" without defining what monitoring entails. An obligation whose method of compliance is unknown will be assessed by absence: no monitoring program on paper results in breach; regardless of the pharmacy's actual conduct.

5.3.7. Where These Obligations Belong

Human rights and accessibility obligations are already binding and enforceable on pharmacies by specialized regulators and adjudicators (i.e. the HRTO, and the Accessibility Directorate of Ontario which enforces the AODA).

Should the College wish to address these obligations further, they should be anchored where they attach within the College's competence and jurisdiction—the Code of Ethics and the Standards of Practice—*after* findings have been made by the proper authority.

Should the College see a systemic gap with respect to these issues in pharmacy practice—of which there is no evidence—it should be addressed and communicated through the College's

established educational channels, with the literacy concepts developed in clinical guidance where the College's creative thinking can mature without accreditation consequences attaching to it.

The human rights system will continue to do what it was built to do. The College should keep doing what it was built to do.

Patients are best protected when both institutions stay within their expertise and legislative mandate.

5.4. "Pharmacy professional wellbeing" (lines 49–50)

5.4.1. An Undefined Term Protects No One

We make this point with care, because we defend the people this term is meant to protect.

An undefined term in an enforceable standard protects no one. It generates disputes about its meaning, and those disputes arrive at the College as complaints; frequently, in our experience, complaints that originate in employment conflict and migrate into the regulatory forum, where the resignation letter becomes the exhibit.

This standard fails our enforcement test at every step:

1. **Knowability:** No Designated Manager can determine whether a workflow "supported" wellbeing. The term has no content to comply with in advance.

2. **Auditability:** Two inspectors reviewing the same workflow have no common measure to apply. Wellbeing is internal, and it varies by person and by day.

3. **Attachability:** The pharmacy operator controls the schedule and the workflow. It does not control the state of being the Standard makes it answerable for, which is shaped by workload, but also by everything else in a pharmacy professional's life.

4. **Consequence:** The draft does not say what follows from failure. Our practice does: a complaint, with an employment dispute inside it.

5.4.2. Where the Complaints Will Come From

An operational standard is supposed to describe the pharmacy and its operations.

This Standard describes the employment relationship, and employment disputes do not stay in employment forums once a regulatory door is opened to them.

An undefined term generates disputes about its meaning, and those disputes arrive at the College as complaints; frequently, in our experience, complaints that originate in workplace conflict and migrate into the regulatory forum. The scheduling grievance becomes an accreditation question. The dismissal becomes an allegation that the workflow failed to support wellbeing. The resignation letter becomes the exhibit.

The migration runs in both directions. Section 36(3) of the *Regulated Health Professions Act, 1991* makes College records, reports, and decisions inadmissible in civil proceedings. However, it governs admissibility, not incentive.

A College complaint remains a costless way to test an employment claim: the complainant files, and the registrant must respond in writing, in detail, on a deadline—producing the schedules, the correspondence, and the operator's full account of the workplace—all of which the complainant reads before any statement of claim is issued.

The complaint functions as early, unilateral discovery: the registrant is compelled to disclose everything; the complainant discloses nothing.

In our practice, we see regulatory files opened in the shadow of civil disputes, and civil claims sharpened by what the regulatory response revealed. Section 36 polices the courtroom; it cannot police the strategy. An undefined "wellbeing" standard hands that strategy its subject matter to be leveraged unfairly.

5.4.3. Policy First, Standard Second

The College's own rationale describes these provisions as "a foundation for future policy options to be explored."

We respectfully suggest the sequence be reversed: policy should be developed and refined first, a standard should be imposed second.

A standard adopted before its content has been developed asks registrants to comply with obligations the College itself has not yet defined. This creates an impossible position for the registrant, and an uncomfortable one for the College when the first contested case arrives.

5.4.4. The Strongest Reason to Draft with Precision and Care

There is also a reason the College should want to get this right rather than let it go off the rails. Pharmacists fall outside many of the hours-of-work protections that the *Employment Standards Act, 2000* extends to other workers.

If employment law will not police workload in a pharmacy, the College's operational standards may be the only instrument that can. This is the strongest argument we know for drafting that instrument with precision rather than reckless aspiration.

5.4.5. Two Paths that Preserve the Intent

If the College wishes to act now, two paths preserve the intent in a justifiable manner:

1. define wellbeing through measurable operational proxies, including scheduled rest breaks, coverage overlap, protected time for expanded-scope services; or

2. Situate the concept in properly developed guidance and evidence-based research while the underlying policy work completes.

We close on this section where we began: with care. The concern behind this standard is real, and the profession the College regulates is carrying it.

That is precisely why the standard must be built to hold weight. "Wellbeing" written as aspiration will be litigated as ambiguity, and the people caught in that litigation will be the ones the word was meant to protect.

Define it, or stage it; either path keeps faith with the intent, and we would gladly support that work.

5.5. "Procedures are in place" (lines 163–167 and related)

The draft's recurring formula—"procedures are in place"—appears across infection prevention, documentation, equipment, and records management.

The formula is not inherently defective. The Equipment section shows this framework working effectively, anchored to manufacturer instructions and confined to operational matters. The defect appears where the same words float without the same anchors.

Unanchored, the proposed standard becomes knowable and auditable, although relating to fundamentally flawed variables. What a pharmacy can know in advance, and what two inspectors can verify, is whether procedures are in place. Whether the practice is sound is a different question, and the standard never considers it.

The absence of the written procedure becomes the breach, independent of actual practice. A pharmacy delivering careful, well-documented patient care without a written protocol for "managing delays in documenting information" is offside; a pharmacy with a handsome binder and poor practice may pass.

Documentation standards should verify systems, not substitute for them.

The standard also imports clinical obligations, including "who must document" and "the information that must be documented," that already attach to the professional under the Standards of Practice and the Documentation Guideline, making the operator and the professional answerable twice for the same conduct. This is redundant and unnecessary.

We support the operational core of the documentation standard—the records system, training on it, and access to it—and join OnPharm-United's recommendation that the content of clinical documentation remain where it already lives, in the Standards of Practice and the Documentation Guideline.

Our proposed wording is at **Appendix "A"**.

Point-of-care testing deserves particular attention. As calibration and log requirements attach to new devices, a missing log entry should prompt correction, not ground a misconduct theory where device accuracy was never in doubt.

5.6. Orientation of all pharmacy staff (lines 42–43)

The new "Pharmacy Staff" definition reaches every individual who supports the operation of a pharmacy. Lines 42-43 require that all of them be "oriented to the regulatory framework that governs both the place and the practice of pharmacy."

We support the intent. But drafted without qualification, the inspection risk writes itself in a manner that is not fit for purpose. An inspector asks whoever is at the dispensary counter what orientation they received, and the evening or weekend cashier's answer becomes the finding and the lynchpin that grounds misconduct..

The weekend cashier and the staff pharmacist do not require the same orientation, and an inspection standard should not imply they do in any way.

We recommend the College's own formula from lines 153–154— "commensurate with their role"—be to be applied here for internal consistency and logical practicality. Our proposed wording on this point is included in **Appendix "A".**

5.7. "Equally enforces" (Introduction)

The Introduction states that the College "equally enforces the clearly outlined responsibilities accorded to each role." We recommend a single word change: "proportionately."

The staff pharmacist who inherits a schedule and the corporate director who sets the labour budget do not share the same responsibility in relation to a staffing standard. Yet "equally" is the word an investigator reads before naming every registrant in the building to the same allegation; it is a free license for the multiplication of respondents to an investigation described above.

Enforcement proportionate to control is a principle screening panels can apply, respondents can understand, and the public can trust. Our proposed wording is included in **Appendix "A"**.

6. A Missing Standard: Protecting Those Who Raise Concerns

The draft asks a great deal of individual pharmacy professionals. The Introduction expects pharmacists and pharmacy technicians to raise concerns with management where standards are not being met.

The Standards require and encourage reporting. Lines 27–28 require mechanisms for concerns to be raised and acted upon. Lines 64–65 empower professionals to provide feedback about how services are organized and delivered. We support every one of these provisions.

But the draft is silent on what happens to the professional who does what it asks or, put more colloquially, a "whistleblower."

We are not silent to this unpleasant reality of pharmacy practice. We see those files: the pharmacist who flagged understaffing and watched their hours contract; the technician who documented a concern and was scheduled out of employment.

Professionals should not have to choose between their obligations and their employment. An expectation to speak, unaccompanied by protection for those who do, is a burden; not a safeguard.

We therefore propose what we regard as the draft's single most important addition, a new standard under Management and Employee Relations:

No member of pharmacy staff is subject to reprisal for raising, in good faith, a legitimate concern about compliance with these standards or a risk to patient safety.

We have run every contested provision in this submission through the enforcement test. Fairness requires that our own proposal face it too:

1. **Knowability:** The obligation is complete on its face and is easily understood: pharmacy staff should not be penalized for raising a good-faith concern. An operator knows today what compliance will require tomorrow.

2. **Auditability:** Unlike "wellbeing," reprisal has settled content in Ontario law. The *Occupational Health and Safety Act* has prohibited it for decades (s. 50), the *Employment Standards Act, 2000* does the same (s. 74), and adjudicators apply well-developed indicia: timing, departure from past practice, and the quality of the explanation offered. A panel applying this standard would not be reading the word fresh.

3. **Attachability:** The obligation rests on the operator, who alone controls the response to a concern: the schedule, the hours, the assignment of shifts. It holds the pharmacy answerable for its own conduct, and not, as the "wellbeing" and privacy standards do, for someone else's state of mind.

4. **Consequence:** A breach is an operational matter, assessed at accreditation like any other standard in this document, and the conduct it captures sits squarely within the College's ambit of how a pharmacy is run.

Nor is this accountability mechanism novel in healthcare. Ontario's long-term care legislation has protected those who raise care concerns from reprisal since 2010, first under the *Long-Term Care Homes Act, 2007*, and now under the *Fixing Long-Term Care Act, 2021*, which prohibits retaliation "whether by action or omission" and even places the burden on the employer to disprove an alleged reprisal. The logic is that residents are safest where people are empowered to speak out.

Patients in pharmacies deserve the same logic. And the standard costs a compliant pharmacy nothing. This addition would convert the draft's culture language—openness, honesty, and learning, at line 51—from aspiration into architecture.

If the College adopts one recommendation from this submission, we ask that it be this one.

7. Consolidated Recommendations

Each recommendation below follows from the enforcement test applied throughout this submission. Where we propose alternative wording, it is collected at **Appendix "A"**.

1. **Before adoption, put every new or revised standard to the four questions of the enforcement test:** is compliance knowable in advance, auditable on inspection, attached

to the person who controls it, and clear in consequence? A standard that fails any of them is not ready.

2. **Define the "sufficient" threshold in the clinical decision support standard (lines 169–171)** for each element it names—clinical decision support tools, reference databases, and patient health information—and assess sufficiency against what the pharmacy itself provides and maintains, not provincially administered infrastructure it does not control.

3. **Retain the incentives and targets standard (lines 62–63), clarified by guidance** to confirm that clinically appropriate service expectations do not, of themselves, compromise professional judgement. Where an incentive or target does compromise judgement, the standard should be applied at the level where it is set; reaching, through the accreditation framework, those who design incentive structures rather than the professionals subject to them.

4. **Replace "staffed at all times" (lines 47–48) with a written, pharmacy-specific staffing plan** developed by the Designated Manager or hospital administrator and including a deviation protocol for when planned coverage fails. Neither outcome-based wording nor a universal quantum passes the enforcement test; the plan resolves both defects.

5. **Remove "determined to be acceptable by the patient" as a compliance measure (lines 95–98).** Address privacy of the clinical encounter as a practice standard attached to the professional, preserve the existing acoustical privacy requirement at the facility level and, if a facility-level standard is retained frame it as a capability of the premises, not a state of patient satisfaction.

6. **Withdraw the human rights and accessibility standards (lines 11–17 and 89–91) from the accreditation criteria.** Anchor these obligations where they attach and within the College's competence—the Code of Ethics and the Standards of Practice—communicate them through the College's established educational channels, and leave accommodation questions with the expert tribunals the legislature built to answer them.

7. **Develop the health literacy and digital literacy concepts in clinical guidance** before any accreditation consequence attaches to them, and define what "monitoring practices" requires before enforcing its absence.

8. **Define "pharmacy professional wellbeing" (lines 49–50) through measurable operational proxies** such as scheduled rest breaks, coverage overlap, protected time for

expanded-scope services. Alternatively, situate the concept in guidance until the underlying policy work is complete.

9. **Limit the documentation standard (lines 163–167) to its operational elements** including the records management system, training on it, and access to it. Leave the content of clinical documentation to the Standards of Practice and the College's Documentation Guideline.

10. **Qualify the orientation of pharmacy staff (lines 42–43) as "commensurate with their role,"** consistent with the College's own formula at lines 153–154.

11. **Replace "equally enforces" with "proportionately enforces" in the Introduction.** Enforcement proportionate to control is a principle panels can apply, respondents can understand, and the public can trust.

12. **Add an anti-reprisal standard under Management and Employee Relations**, protecting pharmacy staff who raise good-faith concerns about compliance or patient safety. If the College adopts one recommendation from this submission, we ask that it be this one.

13. **Publish, with the final document, a plain-language map of consequences** such as which standards are assessed at inspection, which may ground accreditation action, and which may found a misconduct referral. Also, publish any interpretive guidance concurrently with the Standards, not after the first cases are adjudicated. Because screening outcomes are not published, the meaning of a standard must either live in its text and its published guidance.

14. **State expressly that the revised Standards apply prospectively from their effective date**, with a reasonable transition period, and that no currently accredited pharmacy is required to modify compliant premises. Provisions the College has itself described as a foundation for future policy options should be finalized only once that policy work is complete.

8. Closing

Everything in this submission reduces to a single proposition: a standard is only as protective as it is precise.

Vague and ambiguous standards are the worst of both worlds. They are difficult to enforce against those who fail patients, and easy to wield against those who serve them well.

Precision is not a concession to the regulated. It is the condition of regulation that is fair, consistent, and effective at protecting and serving the public interest.

We wish to be clear: we have not argued that the College is wrong to modernize the Standards. Much of the draft deserves adoption. The Equipment and Technology section proves the College can write operational standards that are rigorous, fair, and enforceable. We respectfully suggest that the same discipline be applied throughout.

The stakes are not abstract. A flawed standard does not fail in this consultation; it fails in a real matter, with a registrant's name on it and a career in the balance.

Ontario's pharmacists have accepted the most significant expansion of their responsibilities in a generation. The rules that govern them should say, clearly and in advance, what is being asked and what standards must be met.

And where the draft asks professionals to speak up, it should protect them when they do. If the College adopts one recommendation from this submission, we ask that it be the anti-reprisal standard.

Our proposed wording is collected at **Appendix "A"**. We would welcome the opportunity to discuss any of these recommendations with the College, and to assist as that work proceeds.

Ontario's pharmacy profession is being asked to do more than ever before. It is entitled to know, in advance, what compliance looks like.

All of which is respectfully submitted.

Appendix A

9. Appendix A: Proposed Wording of Standards

For the Board's convenience, the alternative wording discussed in this submission is collected below, marked against the draft's text. Each proposal is drafted to pass the enforcement test: knowable in advance, auditable on inspection, attached to the actor who controls it, and clear in consequence.

Standard	Lines	Redline of draft wording	Proposed wording
Incentives and targets (interpretive guidance)	62–63	*No change to the current standard's text.*	Service expectations do not, of themselves, compromise professional judgement where each service is clinically indicated and delivered in accordance with the standards of practice. Where an incentive or target does compromise professional judgement, responsibility rests at the level where it is set.
Staffing	47–48	The pharmacy is staffed ~~at all times with the number of qualified and trained staff required for pharmacy professionals to maintain the standards of practice while~~	The pharmacy is staffed in accordance with a written staffing plan, developed by the Designated Manager or hospital administrator, that sets out the staffing required for the

Standard	Lines	Redline of draft wording	Proposed wording
		~~providing pharmacy services~~ **in accordance with a written staffing plan, developed by the Designated Manager or hospital administrator, that sets out the staffing required for the services offered and the volumes anticipated, consistent with the standards of practice. The plan includes a protocol for responding to unplanned staffing shortfalls, and is reviewed annually and upon any material change in services or volume**.	services offered and the volumes anticipated, consistent with the standards of practice. The plan includes a protocol for responding to unplanned staffing shortfalls, and is reviewed annually and upon any material change in services or volume.
Workflow *(if the College elects to proceed before the underlying policy work is complete)*	49–50	The pharmacy workflow is managed**, consistent with the staffing plan, to support patient safety and** to permit pharmacy professionals ~~adequate~~ **the** time **required** to ~~maintain~~ **meet** the standards of practice ~~and to support pharmacy professional~~	The pharmacy workflow is managed, consistent with the staffing plan, to support patient safety and to permit pharmacy professionals the time required to meet the standards of practice for each service provided.

Standard	Lines	Redline of draft wording	Proposed wording
		~~wellbeing~~ **for each service provided**.	
Consultation-area privacy *(if a facility-level standard is retained)*	95–98	The pharmacy has a ~~separate and distinct area for patient consultation where the provision of pharmacy services may take place without being overheard by others and which respects the privacy needs of each patient. This includes both acoustical and visual privacy, as appropriate for the pharmacy service provided and determined to be acceptable by the patient~~ **consultation area capable of providing acoustical privacy and, where required by the services offered, visual privacy**.	The pharmacy has a consultation area capable of providing acoustical privacy and, where required by the services offered, visual privacy.
Documentation	163–167	Procedures are in place that enable pharmacy professionals to document the care and services provided in a timely	Procedures are in place that enable pharmacy professionals to document the care and services provided in a timely

Standard	Lines	Redline of draft wording	Proposed wording
		and consistent manner, ~~and include: Training requirements for how to use the pharmacy's records management system; Protocols regarding who must document, the information that must be documented, and options for managing delays in documenting information~~ **including training on the pharmacy's records management system and access to that system during service delivery**.	and consistent manner, including training on the pharmacy's records management system and access to that system during service delivery.
Orientation of pharmacy staff	42–43	All pharmacy staff are oriented to the regulatory framework that governs both the place and the practice of pharmacy**, commensurate with their role**.	All pharmacy staff are oriented to the regulatory framework that governs both the place and the practice of pharmacy, commensurate with their role.
Enforcement statement	Introduction	… and ~~equally~~ **proportionately** enforces the clearly outlined responsibilities accorded to each role.	… and proportionately enforces the clearly outlined responsibilities accorded to each role.

Standard	Lines	Redline of draft wording	Proposed wording
Protection for raising concerns *(new standard)*	New	*No existing text.*	No member of pharmacy staff is subject to reprisal for raising, in good faith, a concern about compliance with these standards or a risk to patient safety.