Ontario Hospital Association Submission Regarding the Proposed Regulation 58/11 (General) under the *Drug and Pharmacies Regulation Act*

**Supporting Ontario’s Health System**

The Ontario Hospital Association (OHA) is pleased to have the opportunity to provide comments on behalf of its members on the proposed Regulation 58/11 under the *Drug and Pharmacies Regulation Act* (DPRA). Access to safe and effective drugs and pharmacies are fundamental parts of providing quality health care in Ontario, and the OHA believes that it is essential that any regulations impacting drugs enhance patient care.

Hospital drug supply and medication-use chains are already subject to a number of rigorous oversight mechanisms, including: existing oversight for the Ontario College of Pharmacists (College) over pharmacists and pharmacy technicians; Accreditation Canada’s accreditation program; and oversight mechanisms under the *Public Hospitals Act* (PHA) and the *Excellent Care for All Act* (ECFAA). The OHA and our members are committed to working with the College to ensure the smooth implementation of its new oversight; however, we emphasize that the College’s oversight should enhance and build upon existing practices to minimize duplication.

The following input is based on a consultation of more than 70 hospital pharmacy leads and hospital administrators. The OHA has several recommendations regarding the proposed regulatory framework generally, as well as a number of specific recommendations. Our recommendations are set out in detail below.

I. **Proposed Regulatory Framework**

   i. **Processes ensuring collaboration**

   The OHA welcomes the College’s collaborative approach in the development of the accreditation standards and believes there is an opportunity to enshrine this collaborative approach in the regulation. This will ensure an ongoing dialogue between the College and the sector, and will help to ensure standards are developed to reflect the needs and capacity of hospitals within realistic timeframes. The OHA also believes that a more codified standards development process will offer some procedural protections to hospitals as new standards are developed and implemented over time.

   The College has opted for a flexible regulatory framework that has left specific accreditation standards to be developed in policy. While this makes sense as it allows standards to be adopted over time, and decreases the need for amendments to the regulation, it also means that there is some uncertainty with respect to how and when new standards come into force.

   The OHA believes that it is important to balance this new flexibility with procedures that ensure the viewpoints of hospital pharmacists and administrators are accounted for more formally in the development and implementation of new standards. Without this kind of mechanism, hospitals may have no way of helping to shape emerging standards, as they have no formal role in the College Council or the standards development process. We believe that such procedural safeguards will help to protect
hospitals from unintended consequences, including unforeseen infrastructure and human resources costs.

This is important as, depending on standards implemented, costs to comply with new requirements could be substantial (infrastructure costs and human resources costs in particular). New standards may have associated physical infrastructure costs,¹ may require upgrades to IT systems² or require additional human resources.³

It will also be important that any standards prescribed by the College recognize the various unique characteristics and circumstances of hospitals, in particular those of small and rural hospitals, and provide hospitals with the flexibility to ensure safe pharmacy practice within their operating budgets.

Recommendation #1:
That the regulation include provisions setting out a process that provides hospital pharmacists and administrators with the opportunity to help shape the development and updating of content of new hospital pharmacy standards/assessment criteria. This could take a number of forms, including:
- A hospital standards advisory committee composed of hospital representatives;
- A formal consultation process detailed in the regulation; and
- Representatives of hospital administration on the College’s governing Council.

Note that Part II of this submission outlines a number of issues that require additional clarification. **All of the issues outlined below warrant a process of rigorous consultation with hospitals on an ongoing basis.**

**ii. Formal process for addressing issues**

In addition to a more formal process respecting the development of standards and policies impacting hospital pharmacies, the OHA believes there is also a need for a more formal process addressing issues that arise through the inspection process. Formal hearings regarding accreditation and revocation of certificates are addressed through the Accreditation Committee under the DPRA and the procedures under the Regulated Health Professions Act and the Ministry must be notified where revocation of a hospital pharmacy certificate is being contemplated. The OHA and its members believe that it is desirable to have a process to resolve matters before they reach that level.

The current process in relation to issues identified during inspections of community pharmacies incorporates the creation of an action plan to resolve issues. The OHA recommends that the regulation include a commitment to collaboration in the development of action plans for hospitals with an ability to escalate disputes where that is necessary.

¹ For example, the OHA’s members informally estimate the costs of fully implementing USP 795 and USP 797 to be anywhere from $100,000.00 to more than $1 million per hospital pharmacy site. Further, several members indicated that the renovations required to fully implement USP 797 may be physically impossible given the current size and structure of their facilities.

² For example, improved medication traceability may be quite challenging as the IT and hospital pharmacy distribution infrastructure investments at hospitals are impacted by ongoing provincial budget pressures, including flat-lined hospital funding for operating budgets while expenses are rising.

³ For example, the proposed baseline standards may require expanded clinical pharmacist coverage, additional annual training for certification costs and supplies required for sterile compounding, etc.
**Recommendation #2:**
That the regulation include a more formal process for resolution of disputes regarding the inspection process and specific results. This process should include an ability to make formal representations and permit requests for written reasons or requests for reconsideration/re-inspection.

**iii. Management of complaints**
As noted above, hospitals are subject to a number of oversight mechanisms. It is important that there is certainty with respect to who has authority to hear which complaints so as to avoid duplication and conflicting decisions. While the College indisputably has jurisdiction to hear complaints respecting pharmacists and pharmacy technicians, the OHA believes that the College should defer to other complaints mechanisms where the policies, procedures, and operations of the hospital are in question. Hospitals have mandatory patient relations processes pursuant to ECFAA and will soon be subject to the jurisdiction of the new Patient Ombudsman. Further, the Information and Privacy Commissioner has jurisdiction over privacy-related complaints. In our view, deferring to these other authorities in instances where there may be broader impacts on the hospital allows for a more systemic approach, and where conduct of an individual pharmacist or pharmacy technician is at issue, these matters will be referred to the College.

**Recommendation #3:**
That the College not hear complaints respecting hospital corporations generally but limit their processes to address the conduct of individual pharmacists and pharmacy technicians.

**II. Standards Setting, Inspection and Accreditation of Hospital Pharmacies**

**i. Development of Standards**
The OHA recommends that as new standards are being considered, the lead time before full compliance will be expected should account for the potential time to meet the standards, including staffing requirements and infrastructure costs. This would be consistent with the approach Accreditation Canada has taken with their Required Organizational Practices (ROPs), which allow the system a cycle or two before expecting full compliance. In the same vein, current required standards must be clearly delineated from aspirational or prospective standards. Hospitals need certainty respecting what standards they will be required to meet and in what timeframe. This issue is discussed further below in terms of reporting.

This, coupled with the recommendation that hospital pharmacies be represented on the College’s Council; the development of a hospital pharmacy committee to support development and update of the standards; and a formal consultation on standards, will help to ensure that all new standards are subject to a rigorous development process that reflects the needs of the sector.

**ii. Scope, fees and term of accreditation**
As noted above, there are several oversight mechanisms in place, and while the College’s hospital assessment criteria refers to and incorporates Accreditation Canada standards, it would be helpful to address where there is overlap in the scope and how the College’s process could enhance the oversight process rather than duplicate it. Further, there is an opportunity for the College inspection template to provide additional clarity on the weighting of individual assessment criteria (e.g., Accreditation Canada
outlines minor and major criteria), and to provide details on how the overall score is calculated and certificate issued.

The OHA understands that hospitals will be required to pay a fee as part of the inspection and accreditation process. We are seeking clarity as to whether this refers to the annual renewal fee due to the College, or if there will be additional associated costs for the inspections (e.g., travel costs for inspectors to assess hospital pharmacies). Given that hospital budgets continue to operate in a zero per cent increase environment and that inspections will be mandatory for all hospitals with pharmacies, we recommend that a fee model for inspection similar to the inspection and accreditation of hospital medical laboratories be considered.

Finally, while we understand that the College is moving to a performance-based model for inspections, OHA members noted that there is a need to clarify the timelines for inspections. For instance, members informed us that inspections every year would be impractical. The OHA believes that Accreditation Canada’s Qmentum program provides a useful framework; it recently switched from a three-year to four-year term. The OHA recommends that the College include reference to a minimum set timeline (e.g., every four years). This set timeline could be coupled with the ability to link back individually with specific hospitals where particular performance issues have been identified by the College.

iii. Issuance of certificate by site and subclasses

The OHA recommends the College consider issuing licenses that better reflect the organizational structures of hospital pharmacies. For example, various license subclasses could consider hospital corporations with multiple sites (e.g., certificate offered to each site, but tied to the corporation as a whole, or a certificate that is linked to one primary hospital pharmacy with other sites considered as branches of that primary pharmacy).

The OHA also strongly suggests that the College consider classes of licenses that align to the practices and services provided at the hospital. This would provide needed flexibility, as not all hospitals pharmacies may need to be in compliance with all standards given the services they provide. This would better support prioritization of resources and consideration to different types of hospitals. This issue is discussed further below in respect of small and rural hospitals. (See Section IV.)

iv. Transparency and reporting of results

The OHA and its members support transparency and accountability in all aspects of their operations including pharmacy accreditation. However, it is important to consider how results will be communicated to patients and the public as this will have direct implications respecting confidence in hospitals. At present, it is likely unnecessary to publish the full inspection reports in respect of individual hospital pharmacies, as the most critical information relates to accreditation status and the College has not had the opportunity to set baseline expectations with the broader public.

A useful model to consider is that which would be similar to the Drug Preparation Premises process, which would result with posting the following information:

- A template of the hospital inspection/assessment criteria template;
- A chart listing the name of every Ontario hospital site/corporation;
- The status of accreditation (pass/pass with conditions/fail); and
- Timeline for accreditation (expiration).
As noted above, the OHA believes that the distinction between the standards against which hospitals are measured (i.e. those impacting their accreditation) and those standards that are more aspirational must be clearly delineated. It is currently not possible to meet some of the “emerging standards” in the College’s proposed assessment criteria. Hospitals are concerned about the impact on patient confidence where the hospital fails to meet standards that are not directly applicable to passing College accreditation.

The OHA believes that any inspection reports that are made public should be structured in such a way so that the relevant binding assessment criteria are distinct from those that are not current measures impacting the hospital pharmacy’s accreditation.

Recommendation #4:
That a high-level inspection report (similar to inspection reports for a drug preparation premise) is the document made public; and

That the hospital assessment criteria only contain required standards, with emerging or aspirational standards being included as an appendix or separate document that outlines future vision for the pharmacy practice.

III. Technical Amendments

i. Sections 1 and 2: Definitions

There are several definitions that could be clarified or could be amended to better reflect hospitals.

“Owner”
The OHA agrees that accountability for meeting legislative requirements, including ensuring that standards for hospital pharmacy are met, lies with the hospitals’ Board of Directors. However, the current definition of owner as it is applied throughout the proposed regulation can be incongruent with how hospitals are organized. Specifically, while hospital boards oversee the operations of the hospital, this function is more strategic and flows from ensuring appropriate policies, procedures and processes are in place. Also, reference to shareholders in section 8 would not be relevant in a hospital context. The OHA believes that further guidance is needed regarding the role of directors in respect of such issues as applications for accreditation and ensuring pharmacy standards are met. In particular, additional guidance outlining the information that the College will require regarding volunteer hospital directors is required.

“Remote Dispensing Location”
The OHA and its members are concerned that the current definition of “remote dispensing location” (RDL) is too broad and would captures automated dispensing units, telepharmacy arrangements with other hospitals, as well as small hospitals that do not have pharmacists on site full-time, etc. Insofar as the RDL requirements prevent hospital sites from having controlled drugs, narcotics, verbal prescription narcotics or targeted substances, this may have a significant impact on hospitals’ abilities to provide patient care. The RDL definition should be restricted to ensure that only the concerning activity (i.e. the direct sale to individuals without the supervision of a pharmacist) is captured.
Recommended amendment:  
"Remote dispensing location"

2. For purposes of the Act and this Regulation, “remote dispensing location” means: 
(a) in a pharmacy that is accredited as a community pharmacy, a place where drugs are dispensed supplied or sold by retail directly to the public or patients of a hospital under the supervision of a pharmacist who is not physically present. For greater certainty, a place in a hospital where drugs are supplied directly to patients by a regulated health professional is not considered a remote dispensing location; and 
(b) in a pharmacy that is accredited as a hospital pharmacy, a place where drugs are dispensed or supplied to patients of the hospital under the supervision of a pharmacist who is not physically present.

ii. Sections 20 and 21: Recordkeeping

There is some confusion regarding the recordkeeping requirements set out in sections 20 and 21 of the draft regulation. Given that sections 153 and 156 of the DPRA have not been applied to hospitals, it is unclear whether subsection 20(1)(a) would apply to hospital pharmacies. Also, it is unclear whether section 20(2) allows for retention a paper records – some hospitals have yet to transition to a fully electronic system for all of their records, including pharmacy records.

While the 10-year retention period for patient care records in section 21 matches the record retention period in the PHA, there is uncertainty regarding what is contemplated by “records and other documents relating to the care of a patient”. In particular, the interplay between sections 20 and 21 is unclear as there is uncertainty as to whether all records noted in section 20 relate to patient care. If section 21 relates primarily to the records enumerated in section 20, the OHA suggests that section 21 specifically reference that provision. If not, the proposed regulation should contemplate the applicable retention period.

Regulation 965 under the PHA specifically enumerates the content of medical records that must be maintained and pharmacy records are not currently contemplated under Regulation 965. The OHA recommends that the specific types of pharmacy records required to be maintain under the proposed regulation are also more specifically enumerated.

Recommendation #5: 
That the College commit to developing, in consultation with hospitals, a recordkeeping schedule outlining the specific documents that the College would like access to, and amending section 20(2) to allow for the retention of paper records.

iii. Section 32: Proprietary Misconduct

Privacy Breaches

The OHA and its members are fully committed to ensuring patient privacy is protected so acknowledge the importance of safeguards in this respect. All hospitals are governed in respect of personal health information and personal information under the Personal Health Information Protection Act and the Freedom of Information and Protection of Privacy Act respectively. As such, where hospitals are concerned, these matters fall squarely within the purview of the Information and Privacy Commissioner.
Given that there might be integrated information systems and a breach may include a variety of non-pharmacy related information, we suggest limiting the application of section 32 paragraph 10 to community pharmacies because an oversight mechanism already exists for hospitals. Additionally, we understand that mandatory reporting of regulated health professionals responsible for privacy breaches to their respective Colleges is being considered by the Ministry of Health and Long-Term Care as an amendment to the Personal Health Information Protection Act so the College will be apprised of individual instances of misconduct by pharmacists in relation to privacy breaches.

**Recommended amendment:**

10. *In a pharmacy that is accredited as a community pharmacy,* failing to keep confidential personal health information or other personal information concerning a patient, except with the consent of the patient or the patient’s authorized representative or as otherwise permitted or required by law.

**Agreements**

There is some confusion with respect to section 32 paragraph 18 respecting agreements limiting the choice of pharmacists. A number of hospitals sign agreements with community pharmacies to supply drugs to the hospital and to patients, and a number of community pharmacies have leased space on hospital property. While the OHA understands that the intent of this provision is not to impact on hospitals, it would be helpful to confirm its application is only to community pharmacies.

**Recommended amendment:**

18. *In a pharmacy that is accredited as a community pharmacy,* entering into any agreement that restricts a person’s choice of a pharmacy or pharmacist without the consent of that person.

**IV. Additional Considerations for Small and Rural Hospitals**

As noted above, there are potentially large costs where new standards change infrastructure or human resources requirements. Even relatively small increases in costs may have an acute impact on the pharmacy services of small and rural hospitals. Small and rural hospitals generally have fewer resources and a lesser ability to retain pharmacy professionals. As such, these hospitals rely to a much greater extent on different models of pharmacy, including telepharmacy, partnerships with community pharmacies, partnerships between hospitals, other health professionals doing pharmacy work, etc.

The OHA firmly believes that standards should not prevent hospitals from developing safe and effective practices that meet the needs of their patients. This is especially true in northern Ontario where patients may be required to travel hundreds of kilometres for necessary drugs and treatments if local hospitals can no longer offer them.

**Recommendation #6:**

That the College issue subclasses of hospital pharmacy licenses based on hospital size and services offered. Especially in small and rural hospitals, accreditation requirements should focus on the particular services that a hospital offers and recognize that a one-size-fits-all approach may impact hospitals’ continued ability to provide pharmacy services and patients access to drugs.
Final Comments

We appreciate the opportunity to provide written comments on the proposed regulation and look forward to continuing to work with the College and the Ministry to ensure a smooth transition to the oversight of hospital pharmacies by the College. The OHA will continue to work to ensure that Ontario’s drug supply chain is as safe and effective as possible, and that patient care is improved.

We trust that our comments and suggestions will be of assistance to you as you consider finalize the new regulation. We are happy to work with you on language that addresses our recommendations. Please do not hesitate to contact us for additional information, as required.