Drug and Pharmacies Regulation Act: Regulation Revision Framework

1. Regulations will be performance-based.
2. Regulations will focus on high risk practices, those that impact patient safety
3. The approach to drafting regulations will be high level rather than specific. Standards, policies and guidelines will be utilized to address issues wherever possible.
4. The regulations will support practice evolution and change.
5. The regulations will be drafted without specificity to permit the contemplation of multiple classes of certificates of accreditation.

Regulation Part	Rationale
	The passing of Bill 21: *Safeguarding Health Care Integrity Act, 2014* extends the College's authority to license and inspect pharmacies within public and private hospitals, as well as future authority over institutional pharmacy locations. As a result, the current DPRA regulations, which only address community pharmacy practice needed to be revised. As well, the current regulation is written with a level of specificity which may cause it to become quickly outdated. The new approach sets out the performance expectations of pharmacy practice sites in regulation, but excludes details which may become irrelevant over time. As well, the new approach avoids duplication with other legislation and references national standards as appropriate.
PART I **INTERPRETATION**	All requirements generally indicated for a pharmacy are also indicated for a hospital pharmacy, unless otherwise specified. The proposed regulations clarify that all standards of accreditation that apply to a pharmacy, apply to a remote dispensing location unless otherwise specified. By adopting this approach, a significant amount of duplication was removed from the proposed regulations. The specific provisions that apply to remote dispensing, which are not addressed elsewhere, are retained.
PART II **DRUG SCHEDULES**	The proposed changes update provisions to align to federal legislation regarding the National Drug Schedules and Prescription Drug List. The public interest is protected by ensuring that substances are categorized and located in the community pharmacy according to the risk they pose. The proposed regulations set the standards and objectives that must be met by pharmacy operators. Statements that refer to clinical decision-making, such as approving a drug for sale, have been removed as member practice is guided through the *Pharmacy Act* and *Regulations*, professional ethics, standards of practice, policies and guidelines. The provisions regarding prescription transfers have been moved forward from **Part VI**. Federal provisions govern the rules on prescription transfers and duplicated language has been removed. A College-drafted document on-Prescription Transfers brings together rules established through Federal and Provincial legislation in an up-to-date summary.
PART III **CERTIFICATES OF ACCREDITATION: ISSUANCE AND RENEWAL**	The model for the issuance and renewal of certificates of accreditation has not changed. The Registrar and Accreditation Committee continue to have the authority to refuse to issue and/or renew certificates for a variety of reasons. The Regulations create two classes of pharmacy: community and hospital. Most provisions will apply to both classes; however, as required it is stated when a provision is relevant to one class or another.

Regulation Part	Rationale
	Two different types of documents will be created to support issuance and renewal: 1) policy documents, which define how the regulator will approach a situation; and 2) process documents, which outline the steps that must be taken to achieve a specific goal. Policies will be broadly circulated for input by stakeholders before approval by Council.
PART IV STANDARDS FOR ACCREDITATION AND OPERATION	This section contains both performance-based and prescriptive language. This model will protect patient safety, provide flexibility in regulatory control, and encourage practice innovation without unduly diluting or complicating enforcement capabilities. The regulations serve as a mechanism for raising standards over time while ensuring that minimum operational requirements are being met. The standards are designed to apply to all classes of pharmacy and will support the increasing range of services provided by pharmacies and the staff working within them. The College's oversight will be supported by policies, standards and guidelines which will define specific expectations where necessary. Specialty practices such as sterile compounding or methadone dispensing will be managed through policy, supported by industry-approved provincial or national standards.
PART V LOCK AND LEAVE	This Part is no longer required. The provisions related to **Lock and leave** are moved from the current stand-alone **Part V** to be addressed as a standard of accreditation. The College has published detailed information to support pharmacies in operating a Lock and Leave.
PART VI PRESCRIPTIONS, REFILLS AND TRANSFERS	Prescription transfers are addressed in **Part II** and other provisions are a duplication of information that is addressed elsewhere. As indicated above, member practice is guided through the *Pharmacy Act* and *Regulations*, professional ethics, standards of practice, policies and guidelines.
PART VII CHILD RESISTANT PACKAGING	This Part is no longer required. This topic will be addressed with other operational issues, outside of the Regulations.
PART VIII ADVERTISING	The provisions share commonalities with pharmacy regulations in other Canadian jurisdictions and the requirements of the *Food and Drugs Act*.
PART IX PROPRIETARY MISCONDUCT/ CONFLICT OF INTEREST	With the appropriate adjustment for context, the proprietary misconduct regulations align to the language recently agreed to with the Ministry with respect to professional misconduct. The detail provided in this section ensures clarity for both the proprietor and the regulator in addressing issues related to misconduct and conflict of interest.
PART X RECORDKEEPING	This Part is no longer required. The general requirement to keep records and documents, and the length of retention, is addressed as a Standard of Accreditation.
PART XI INFORMATION, EXAMINATION AND AUDIT	Revised to address only the requirements related to the audit.