

Feedback on changes to the *Drug and Pharmacies Regulation Act*

Ontario Regulation 58/11

| Quote from Regulation | Comments |
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| <p>Remote dispensing location</p> <p>2. For purposes of the Act and this Regulation, “remote dispensing location” means:</p> <p>(a) in a pharmacy that is accredited as a community pharmacy, a place where drugs are dispensed or sold by retail to the public under the supervision of a pharmacist who is not physically present; and</p> <p>(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.</p> | <p>This definition would include Automated Dispensing Unit's in the patient care areas. This section needs to be clear that the drug is supplied directly to the patient from the machine not via a nurse.</p> |
| <p>Classes of accreditation</p> <p>7. (1) The following classes of accreditation are hereby established:</p> <p>(a) community pharmacy; and</p> <p>(b) hospital pharmacy.</p> | <p>In the act there is also provision for institutional pharmacies why is there no regulations related to these entities described.</p> |
| <p>Classes of accreditation</p> <p>7. (2) A pharmacy that holds a certificate of accreditation to operate a pharmacy as of the date this Regulation comes into force is deemed to be accredited as a community pharmacy.</p> | <p>When a hospital pharmacy holds a certificate of accreditation what is it deemed to be since only community is addressed here.</p> |
| <p>Qualifications for the issuance of a certificate of accreditation of any class</p> <p>8. (1) An applicant is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy of any class if:</p> <p>(4) The past and present conduct of each person who is an applicant, and in the case of a corporation, of each director, and of each shareholder who directly or indirectly owns five percent or more of the voting shares of that corporation, affords reasonable grounds for the belief that the pharmacy will be operated with decency, honesty and integrity and in accordance with the law.</p> | <p>Hospital board of directors do not own shares of the hospital pharmacy and how will their past and present conduct be assessed and do they need to apply for accreditation? Is it all members of the board or just the Chair.</p> |
| <p>Issuance, name and address</p> <p>11. (1) A certificate of accreditation shall be issued in the specific name of the person who owns the pharmacy and for the specific municipal address or addresses at which the pharmacy is to be operated.</p> | <p>For a hospital the owner is defined as the directors of the corporation. Will the certificate be issued in the director's name? If ADU's are remote dispensing locations then will all directors need to be listed?</p> |
| <p>Expiry of certificates of accreditation</p> <p>13. (5) Where the Accreditation Committee directs the Registrar not to renew the certificate of accreditation of a pharmacy, the certificate of accreditation shall be deemed to have expired as of the date the decision of the Accreditation Committee becomes final.</p> | <p>The Minister needs to be informed before any action can be taken.</p> |

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| Qualifications for renewal of any class 14. (1) An owner is qualified for the renewal of a certificate of accreditation if: | Owner is defined as all the directors of the corporation. Do all of them need to sign the application? |
| Qualifications for renewal of any class 14. (2) A certificate of accreditation shall not be renewed where an inspection of the pharmacy or of any of its remote dispensing locations has taken place under the Act and where the inspector identified a failure to conform to the requirements of the Act and its regulations that poses a risk of harm to the public, unless the Registrar is satisfied that such failure has been addressed either to the Registrar's satisfaction or, failing that, to the satisfaction of the Accreditation Committee. | In the act as per section 166.1 of the act the minister needs to be informed before action is taken. |
| Revocation 16. (2) The Accreditation Committee may direct the Registrar to revoke a certificate of accreditation where it is satisfied that it was issued or renewed based on the false or misleading information of an applicant or owner and where it is satisfied that it is appropriate to do so. | Again after the Minister is informed |
| Standards for accreditation of any class 18. (2) Every owner and designated manager shall ensure that the standards for accreditation of a pharmacy are maintained. | Will hospitals require a designated manager and if not then who is ensuring that standards for accreditation are maintained? Will it be the board members? This is not practical. |
| Requirements of a pharmacy 19. Every pharmacy must, | Where do the hospital assessment standards fit into the accreditation process? They are not mentioned here and are not a requirement for accreditation. |
| Requirements of a pharmacy 19. Every pharmacy must, (g) have information management systems that, (i) support the delivery of patient care, (ii) permit information to be recorded, displayed, stored and exchanged; and (iii) facilitate information exchange with external systems, while preserving the confidentiality, security and integrity of all personal information; | Does this mean that every pharmacy must have a computer system or does it mean that if they have a computer system then that system must meet these requirements. |
| Requirements of a pharmacy 19. Every pharmacy must, (j) have the Symbol clearly displayed so as to be easily visible to patients or the public either before or immediately after entering the pharmacy; and | Where would this symbol be located? Often the hospital pharmacy is not clearly identified to the public for security purposes since often they will not need to access the location. If this symbol is displayed outside the pharmacy then there is a risk. If placed inside the pharmacy then no one outside of pharmacy staff will see it. What is the purpose? |
| Requirements of a pharmacy 19. Every pharmacy must, (k) have systems in place to maintain an audit trail of the acquisition and | What does an audit trail mean? We know what we buy and what we send to the units but we do not have full traceability of lot and expiry. Is this required by the time the regulations come |

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| movement of drugs. | into force? |
| Recordkeeping 20. (2) The records and documents referred to in subsection (1) shall be maintained in the pharmacy in an electronic format and in a manner that is secure, auditable, traceable and allows for their easy retrieval. | There is no electronic system on the market that supports electronic retention of records that is auditable and traceable. Are hospital pharmacies expected to scan all their documents related to dispensing? Where would they scan the documents and where would they be kept? |
| Length of retention 21. Subject to the Act, records and other documents relating to the care of a patient shall be maintained for a period of at least 10 years from the last recorded pharmacy service provided to the patient, or until 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer. | Patients come and go from the hospital therefore it is unknown when the last recorded pharmacy service will be therefore this would mean that hospitals would need to know when patients die since that is the only guarantee that they will not return and keep the records for 10 years after that. This is not the standard for record retention in health records. |
| Access and supervision 24. A remote dispensing location shall only be accessible to the public or to hospital patients, as applicable, when a pharmacist: | Is this the ADU? Public and hospital patients would never have access. |
| Controlled drugs, narcotic drugs and targeted substances 26. No controlled drugs, narcotic drugs, verbal prescription narcotics or targeted substances shall be located at or available from a remote dispensing location. | ADU's need to contain narcotics and controlled drugs and targeted substances. |
| Information and notices to be displayed 27. (1) At every remote dispensing location, contact information for the pharmacy under whose certificate of accreditation the remote dispensing location operates shall be clearly and prominently displayed. | This whole section does not make sense for ADU's. They are unit dose medications removed from the machine by nurses at the point of administration and therefore the signage on the machine and the product would not make sense. |
| Acts of proprietary misconduct 32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act: 4. Failing to co-operate with an inspector of the College. | They are no longer called inspectors but rather advisors |
| Acts of proprietary misconduct 32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act: 7. Failing to keep records as required respecting the operation of the pharmacy and the patients and practice of members practising in the pharmacy. | Currently no hospital pharmacy can comply with the records outlined above. |
| Acts of proprietary misconduct 32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act: | Prescription information is always disclosed to those members in the circle of care for the patient. For example when a patient is transferred to another institution. In addition prescription information needs to be available to the nurse administering the medication. In a retail store prescription information is always |

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| <p>11. Disclosing prescription information to another person unless: (i) the disclosure is made in accordance with a written agreement between the owner and the person to whom the disclosure is made, and that agreement requires that any prescription information that is disclosed will not include anything that would be reasonably expected to identify a patient; and</p> | <p>disclosed to the payor of the prescription.</p> |
| <p>Acts of proprietary misconduct</p> <p>32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act:</p> <p>18. Entering into any agreement that restricts a person’s choice of a pharmacy or pharmacist without the consent of that person.</p> | <p>Patients in a hospital do not have a choice of pharmacy or pharmacist. Therefore this section would be contravened in a hospital.</p> |
| <p>Acts of proprietary misconduct</p> <p>32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act:</p> <p>20. In a pharmacy that is accredited as a hospital pharmacy, returning to stock or selling or dispensing again a drug, that was previously sold or dispensed, except that it will not be proprietary misconduct to return to stock or re-sell or re-dispense a drug (i) that is returned to the pharmacy in a sealed dosage unit or container as originally dispensed,</p> <p>(ii) that is returned with the labelling intact and includes a legible drug lot number and expiry date, and</p> <p>(iii) the integrity of which can be verified.</p> <p>21. Dispensing, selling or compounding a drug, or administering a substance, that is not of good quality or does not meet the standards required by law, or, in the case of a drug, does not contain a substance that the drug is meant to contain.</p> | <p>This would only be possible in a unit dose system. If a traditional or ward stock system were used in the hospital which is very common, then this could not be done because vials would be redispensed and these are not sealed. Oral liquid syringes are also not sealed. ie. does it mean a sealed container or just the original container?</p> |
| <p>Acts of proprietary misconduct</p> <p>32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act:</p> <p>27. Contravening any federal, provincial or territorial law or any municipal by-law, (i) with respect to the distribution, purchase, sale, or dispensing or prescribing of any drug product, the administering of any substance, or the piercing of the dermis,</p> | <p>Pharmacists can administer the flu shot therefore why is it professional misconduct to pierce the dermis?</p> |
| <p>Conflict of interest, definitions</p> <p>33. In this section, and in sections 34 and 35,</p> <p>“responsible person” means the designated manager and the owner of the pharmacy;</p> | <p>Hospitals do not have designated managers.</p> |