Patient Record Retention

Q: What exactly is meant by a patient record?
A: A patient record is defined in the *Pharmacy Act of Nova Scotia* as including:
   • prescription records
   • medication profiles
   • patient profiles
It is further defined in the regulations as including:
   • any record of information provided by, to or concerning a patient, and
   • a record of any counseling services provided to a patient.
A patient record therefore, is a complete reference of all documentation related to the care of a patient.

Q: So a patient record is different from a prescription record?
A: Yes, a patient record *includes* the patient’s prescription record, along with all of the other documentation related to the care of the patient.

Q: How long do patient records have to be retained?
A: The Registration, Licensing and Professional Accountability Regulations, S.37 require a patient record to be retained for 10 years after the date of the last pharmacy service provided to the patient or, if the patient is a child, 10 years after the date the patient attains the age of majority, whichever is longer.
So, for example, if the patient receives his first prescription (or other pharmacy service) from your pharmacy on Jan 1, 2000 and his last prescription (or other pharmacy service) on Dec 31, 2015, you would need to retain all his patient records/documentation (i.e., from Jan 1, 2000 to Dec 31, 2015) until Dec 31, 2025.

Q: Why do patient records have to be kept for so long now?
A: The primary purpose of patient records is to enable pharmacists to provide optimal care to their patients. Patient records contribute to the consistency and quality of patient care by providing detailed descriptions of a patient’s health status and a rationale for treatment decisions. They promote the continuity of care by enabling other health care professionals to access and understand the patient’s past and current health status and medication profile. Patient records are legal documents that may be needed by the pharmacist to demonstrate evidence of the care provided to the patient in the event of a regulatory, civil or criminal matter; they are also the fundamental components of external reviews assessing patient care, such as those conducted for the purposes of quality improvement, pharmacist self-assessment, or investigations.

The 10 year retention rule brings the patient record requirements for the pharmacy profession in line with those for other health care professions.
Q: How long must I retain electronic immunization records? Compliance packaging records?
A: Records of immunization and compliance packaging records are considered to be part of the patient record and therefore, as with all other forms of documentation for the patient, must be kept for 10 years after the date of the last service provided to the patient.

Q: How can I possibly retain that many paper records?
A: If an original written/paper prescription or record is scanned into a secure electronic database and if the signature and retrieval requirements found in the Regulations are satisfied, the requirement to store the written/paper prescription or record is considered to be met and there is no need to keep the original written/paper prescription or record.

Q: What are the signature requirements found in the Regulations?
A: The Practice Regulations include the following requirements:
S.15(3) The person who receives a verbal or electronic prescription shall sign or initial it and date it.
S.15(6) When a prescription is first dispensed, the pharmacist responsible shall sign or initial and date the prescription and any person involved in the dispensing must also sign or initial.
S.15(8) Every time a prescription is refilled or part-filled, a record to that effect shall be signed or initialed and dated by the pharmacist responsible and by any person involved in the dispensing.

These rules ensure that an audit trail is created that identifies all individuals involved in the processing of a prescription and the dispensing of a drug. Therefore, if a paper prescription or record is scanned into a secure database, the paper prescription cannot be destroyed until the signature(s) noted above are captured. The signature(s) must be individual, intentional, secure and not reproducible. They must confirm that the individual(s) attest to their involvement in filling THAT prescription for THAT patient on THAT date. Depending upon their application, signatures generated biometrically or via a stylus on a screen could meet the signature requirements.

Q: What is meant by a secure electronic database?
A: S.35 of the Registration, Licensing and Professional Accountability Regulations states that patient records (including prescription records) must be stored in a manner that preserves patient confidentiality and facilitates ease of use, sharing and retrieval by authorized persons.
All records must be stored securely to ensure that only persons authorized by the Act and the Regulations have access to the record and that the records are protected from theft, damage or unauthorized access, use or disclosure.
All patient records must be stored in Canada.
All patient records in the electronic form must be backed up at least once a day and the backup preserved in a secure location, outside the pharmacy, where all the following are ensured:
- patient confidentiality is protected
- the records may be easily produced when required
- the records are secure from damage
- the records are protected from theft or unauthorized access, use or disclosure.
Q: With this in mind, if my pharmacy satisfies all the signature requirements and we scan the prescriptions into a secure electronic database, can we then destroy the original/paper prescriptions?
A: Yes. According to Health Canada, the legal requirements to store a “written” prescription is considered to be met if the prescription is scanned into a secure electronic database.
* Before destroying the original/paper record, ensure that necessary notations and documentations are appropriately scanned and that the scanned record cannot be deleted.
* Remember that destruction/disposal must be carried out in a manner that ensures patient privacy and confidentiality.

Q: How are refills now handled? Do we need a paper (hard) copy?
A: The requirement for paper records to be maintained has been removed.

Q: Is it permissible to delete or modify patient records?
A: The Standards of Practice: General Pharmacy Practice (3.2.1) require that any documentation be made so that it is a permanent and non-erasable part of the record and that any alterations made to the record enable an audit trail.

Q: Do the electronic patient records need to be “active” in my pharmacy software system for the entire retention period? This could use up a significant amount of space.
A: No, the electronic records do not need to be “active” in your system for the entire retention period; however you do need to be able to access them if necessary for 10 years beyond the date of the last pharmacy service provided. The regulations state that a patient record must be producible within 30 minutes from when the request was made if the record is less than 3 years old and within 48 hours from when the request was made if the record is 3 years or older.

Q: Do I need to store electronic patient records in my pharmacy?
A: No, s. 35 (1)(d) of the Registration, Licensing and Professional Accountability Regulations states that patient records must be stored in Canada.

Q: What about security issues associated with patient records if they are not stored in my pharmacy?
A: The Regulations require that patient records must be stored in a manner that preserves patient confidentiality and that also facilitates the ease of use, sharing when required, and retrieval by authorized persons. They must be stored securely to ensure that only persons authorized by the Act and Regulations (and by privacy legislation) have access and also that the records are protected from theft, damage, unauthorized access, use or disclosure.

Q: If I destroy the paper copies of prescriptions, what happens if the electronic versions are lost due to system problems?
A: The Registration, Licensing and Professional Accountability Regulations, S. 37(3) require that all patient information in electronic form must be backed up at least once daily and the backup preserved in a secure location, outside the pharmacy, where patient confidentiality is protected and records are secure from damage, loss, unauthorized access, use or disclosure.
The Standards of Practice: General Pharmacy Practice (3.3.1) require records to be kept in a manner that ensures their permanence, safety and security.
Q: Is scanning now a requirement or is it still an option to keep prescription records in the traditional paper-based manner?
A: Scanning is not mandatory. Health Canada now interprets the term “written” prescription in the Food and Drug Regulations to include the original written prescription or the electronically scanned copy of the original prescription for the purposes a record storage. If scanning is not being used, then the pharmacy must retain (paper) prescription records.

Q: What about third party insurers? Will they recognize scanned prescriptions as being the same as paper prescriptions?
A: It is your responsibility to confirm with your third party insurers/payors that they will recognize scanned prescriptions as being the same as original/paper prescriptions.

Q: Can you recommend software that I can use to scan my prescriptions?
A: Your software vendor should be contacted for direction on how to integrate new software into your system so that you can convert your paper prescriptions into electronic form in a manner that meets legal requirements.

Q: Will the NSCP approve specific technology that meets the requirements of the regulations?
A: There are a variety of ways in which a pharmacy can achieve compliance with the new record retention regulations. The NSCP is not prescribing, nor approving, any specific method. Pharmacies need to work with their software vendors to choose the mechanism that is suitable for the pharmacy while also meeting the requirements of the regulations. As with other systems and processes, the pharmacy manager is responsible and accountable for ensuring that the chosen mechanism and the associated policies and procedures for scanning and record keeping meet all the applicable standards and is compliant with relevant federal and provincial legislation and regulations.

Q: Where can I find the rules regarding patient records?
A: There are rules pertaining to patient records in various federal and provincial regulatory frameworks, including:

- the Food and Drug Regulations (s.C.01.041 - C.01.043, C.01.049 and G.03.001-G.03.015),
- the Narcotic Control Regulations (s.38-45)
- the Benzodiazepines and Other Targeted Substances Regulations s. 50-55).
- the Pharmacy Act (s.36.40),
- the Pharmacy Act and Regulations Definitions Regulations (s.3),
- the Registration, Licensing and Professional Accountability Regulations (s.35 to 39)
- the Pharmacy Practice Regulations (s. 35-41) and
- assorted Nova Scotia College of Pharmacists standards and policies

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