Computer Requirements for Pharmacy Practice

These Guidelines describe the elements required to meet the standards of current legislation and pharmacy practice.

1. All systems should incorporate secure access to activate the system. Passwords and codes should be unique to the individual users and not shared amongst staff.

2. All systems must incorporate a code for individual pharmacists for each new or refilled prescriptions authorized to be dispensed under their supervision. A forcing function for pharmacist initials is recommended. The pharmacist whose initials are captured in the computer records will be accountable for the accuracy and safe dispensing of the prescription.

3. All systems must record the transaction date for the original prescription and each refill.

4. All systems must record all prescription information as set out by Federal and Provincial laws, including but not limited to:
   - *The Pharmacy and Pharmacy Disciplines Act*
   - *The Prescription Drugs Act*
   - *The Controlled Drugs and Substance Act*
   - Narcotic Control Regulations
   - The Benzodiazepines and Targeted Substances Regulations
   - *The Food and Drugs Act*
   - The Food and Drugs Regulations

5. Systems should be capable of complying with the legal requirements of recording and storing all required information for prescriptions/patient profiles including all patient notes, and relevant documents such as SMAPs, etc. for two years from the date of the last prescription fill.

6. All systems must be capable of ensuring that each new dispensed prescription has a unique number assigned to it and that this number cannot be re-issued or re-used.

7. All systems must be capable of producing a hard copy of each and every patient's profile in a format which is readily available to an SCPP field officer or to an inspector from Health Canada.

8. Drug interaction programs must be up to date.

9. All systems must require a deliberate procedure by the pharmacist for any “purging” of data from the system to occur. If this authority is delegated it must be clearly defined with a standard operating procedure.

10. All basic patient information fields, such as name, address, date of birth, health services number, allergies, medical conditions, special information, etc. may be open fields. Changes or corrections should be dated when documentation of the information occurs.
11. Any systems that utilize patient registration numbers to access patient medication profiles must also have the capability of retrieving these medication profiles through an alphabetical search.

12. The pharmacist is responsible for monitoring the patient profile. Therefore, all systems will provide the function of viewing the patient medication profile during the dispensing process. Pharmacists must view the DIS (integrated Drug Information Screen) of the Pharmaceutical Information Program (PIP) prior to filling a prescription.

13. The system must automatically alert the pharmacist when the authorized refills have expired and must not allow further refills of the prescription. Further, a system must not allow refills beyond the one year “life” of a prescription.

14. A record of the drug product (by the Drug Identification Number) must be retained. If the drug product is to be changed (BRAND) the change must be documented and the date of the change captured in the system.

15. All systems must comply with the requirements to constitute a legal prescription transfer for a Prescription Drug List Drug (formerly Schedule F), including:
   a) an indication that original prescription is void once transferred and that no further transactions will occur with that prescription
   b) the date of the transfer
   c) the pharmacy name and phone numbers, the pharmacist’s name to whom the transfer was provided and the pharmacist’s initials who completed the transfer

16. All systems must have back-up capabilities (which are offsite and secured). Any third party agencies involved in records management must sign a privacy and confidentiality agreement.

17. Inventory adjustments must be capable of being traced to the person who adjusted the inventory and should include the reason for the adjustment. This process should only be completed by authorized personnel under a password protected process.

18. As per the policy “Electronic Transmission of Prescription Policy Statement and Guidelines for Pharmacists,” prescription and patient information may be retained in an electronic format (paperless system) if it meets health Canada requirements.

After further review, Health Canada has concluded that there are currently no regulatory impediments to moving ahead with electronically generated and transmitted prescriptions and that these are permissible to the extent that they achieve the same objectives as written prescriptions. Provinces and territories wishing to proceed with e-Rx are obligated to ensure that electronic prescriptions meet existing regulatory requirements and achieve the same objectives as written prescriptions. For example, there must be evidence of a genuine practitioner/patient relationship, and in the case of controlled substances, pharmacists filling prescriptions must verify prescriptions are signed by the practitioner before selling or providing drugs containing controlled substances to a patient.
Please refer the NAPRA “Pharmacy Practice Management Systems: Requirements to Support NAPRA’s “Model Standards of Practice for Canadian Pharmacists” for more detailed information.