

Electronic Transmission and Storage of Prescriptions

Policy Statement and Guidelines for Pharmacists and Pharmacy Technicians

Current Exemptions Under Section 56 of the *Controlled Drugs and Substances Act* (CDSA) and Prescription Review Program (PRP)

Given the emergency exemptions that may be in place during the COVID-19 pandemic, members should review the following documents and monitor communications from the SCPP for exemptions that may impact this policy when enacted:

- [SCPP's Section 56 Exemption Communication](#)
- [Joint Statement on the Section 56 Exemption for CDSA Drugs](#)
- [Practice Changes for Community Pharmacy During COVID-19 Pandemic](#)

PREAMBLE

Current legislation allows some prescriptions to be provided verbally or in writing, except for Prescription Review Program drugs for which [time-limited](#) exemptions have permitted verbal orders to be accepted only as a last resort when a written prescription is not possible. (See text box above for more details.) A written prescription is signed by the prescriber. This provides a method for the prescriber to authenticate the prescription as well as a method for the pharmacist or pharmacy technician to verify the authenticity of the order. However, advances in technology have provided opportunities for prescribers to generate prescriptions electronically (electronic medical record – EMR). Such opportunities purport to be safer and more secure than conventional handwritten or verbal prescriptions.

The College of Physicians and Surgeons of Saskatchewan (CPSS) outlines requirements for “wet signature” as per Regulatory Bylaw 17.1 (cps.sk.ca). Therefore, the purpose of this statement and guideline is to describe when electronic prescribing which is safer and more secure is acceptable.

This document is intended to provide guidance to pharmacists and pharmacy technicians in the interpretation of prevailing law. Where questions arise, the official text of the relevant legislation should be consulted, and that law takes precedence over this document.

DEFINITIONS

In this document:

- Unless the context indicates otherwise, “**member(s)**” includes licensed pharmacist(s) and pharmacy technician(s).
- “**Electronic transmission of prescriptions**” means the transmission of a prescription by any electronic means, except verbally by telephone, including and without limiting the generality of the foregoing, by facsimile, secure electronic mail or internet or other network communications system, and “e-prescribing” has the same meaning.
- “**Facsimile transmission**” means transmission of the exact visual image of a document by way of electronic equipment.
- “**Prescription**” as defined in *The Pharmacy and Pharmacy Disciplines Act*, means “an authorization given by a practitioner directing that a stated amount of any drug or mixture of drugs specified in it be dispensed for the person or animal named in the authorization.”
- “**Record**” as defined in the *Pharmacy and Pharmacy Disciplines Act* includes any information that is recorded or stored in any medium or by means of any device, including a computer or electronic media.

POLICY

On December 21, 2007, Health Canada released the following:

Policy Statement on e-Prescribing¹

e-Prescribing (e-Rx) is a means of streamlining the prescription process by enabling prescriptions to be created, signed, and transmitted electronically. There are significant benefits associated with the implementation of e-Rx including the potential to reduce the incidence of medication and dispensing errors caused by illegible prescriptions, a potential decline in adverse drug reactions and the timely transmission of prescription information from practitioner to pharmacist. Health Canada recognizes these benefits and supports the implementation of e-Rx.

Until recently, it was the position of Health Canada that, to allow for e-Rx, amendments to Part C of the Food and Drugs Regulations made under the Food and Drugs Act, regulations made under the Controlled Drugs and Substances Act and possibly regulations made under Personal Information Protection and Electronic Documents Act would be required.

¹ As printed by the Canadian Pharmacists Association, Health Canada “Policy Statement on e-Prescribing” December 21, 2007: <https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/PPRecommendationsElectronicPrescriptions.pdf>.

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 prescription.

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 signed¹ by the practitioner before selling or providing drugs containing controlled substances to a patient.

*Health Canada has collaborated with Canada Health Infoway on the development of a technical document entitled *Ensuring the Authenticity of Electronic Prescriptions*, in order to provide advice about how to ensure the authenticity of electronic signatures. Although this document (and annexes) was not subject to widespread consultation, it could be of use to provincial and territorial Ministries of Health in moving forward with e-prescribing.*

Health Canada has also initiated discussions with provincial and territorial pharmacy and medical regulatory authorities in order to determine how it can be of assistance in facilitating collaboration between provincial and territorial stakeholders regarding e-Rx implementation.

¹Sign: whatever is determined to be necessary to authenticate and validate the order in that pharmacists must have a high degree of certainty that the identified practitioner (in the electronic message) has ordered the prescription.

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Electronic Storage of Prescriptions

On July 14, 2014, the Health Products and Food Branch of Health Canada released the following information in a letter to the Canadian Pharmacists Association and the Canadian Association of Chain Drug Stores:

The term ‘written’ prescription as per section C.01.041 (2) and (3) of the Regulations can be interpreted to include: (1) the original written prescription, or (2) the electronically-scanned copy of the original prescription. If the original written prescription is scanned into a secure electronic database, then the requirement to store a “written prescription” is considered to be met and there is no need to keep the original hand-written prescription.²

Relying upon Health Canada policies, and based upon our interpretation of *The Pharmacy and Pharmacy Disciplines Act*, and SPP Bylaws and standards governing pharmacy practice, the electronic transmission of a prescription for any drug is equivalent to the written format and is acceptable, provided that:

1. Members are able to fulfill their professional obligations of Principles 1, 2, 3, 4 and 5 below to verify the authenticity of the prescription; and,
2. The principles governing shared onus between the prescriber and member for patient confidentiality, authenticity, validity, security, and patient choice of pharmacy as described below are met to ensure accountability for the authenticity of the electronically transmitted prescription, as follows:

Principle #1: The process must maintain patient confidentiality.

Principle #2: The process must be able to verify the authenticity of the prescription (i.e., verify the identity of the practitioner/health care professional authorized to issue the prescription).

Principle #3: The accuracy of the prescription must be able to be validated, including a mechanism to prevent forgeries.

Principle #4: The process must incorporate a mechanism to prevent diversion, so that the prescription authorization cannot be transmitted to more than one pharmacy.

Principle #5: Patient choice must be protected; that is, the patient must determine the pharmacy to receive the prescription authority.

² Letter from Anne Lamar, Assistant Deputy Minister, Health Products and Food Branch of Health Canada, “Electronic Storage of Prescriptions”, July 14, 2014: <http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/ElecPrescriptionStorageHCLetter14July14.pdf>

Consistent with earlier guidelines respecting facsimile transmission of prescriptions, the facsimile represents the original prescription. A faxed prescription can be interpreted as either a written prescription or a digitally (computer) generated prescription that has been transmitted electronically.

Electronically transmitted prescriptions must contain the signature of the prescriber as defined by Health Canada in the “Policy Statement on e-Prescribing.” A prescription with an electronic signature of the prescriber represents authority for the member to sell the drug. Without limiting the generality of the foregoing, examples of acceptable electronic signatures are:

1. Original signature of the prescriber on the facsimile transmitted to the pharmacy;
2. A digital reproduction of the prescriber’s original signature where the prescriber is the only person authorized to generate his/her signature in the electronic device reproducing his signature, and provided that the prescriber’s identity can be verified by the member filling the prescription;
3. A code or identifier that uniquely identifies that particular prescriber where the prescriber is the only person authorized to generate his/her code from an electronic device designed for this purpose; or,
4. The name of the prescriber is associated with an order for a drug issued within a secure electronic environment or network to which that prescriber has secure access.

The onus is upon the prescriber to ensure that adequate security measures are in place to protect the electronic signature from unauthorized use. When the signature of the prescriber is unknown to the member, or where the member is concerned with the authenticity of the prescription or prescriber, **the member must verify the prescription with the prescriber.**

A prescription produced in a secure electronic environment or network to which both the prescriber and the member have secure access, such as the Pharmaceutical Information Program (PIP), meets the principles in this document. Appropriate security measures, authentication processes and tracking mechanisms are in place in PIP. Therefore, electronic prescriptions issued within PIP represent sufficient authority for the member to dispense the prescription. In this case, even though the signature may not be affixed to the prescription itself, it is deemed to be associated with the prescription because the prescriber can only access the system that generates the prescription via secure means attributed to that particular prescriber. For further information on PIP, consult <https://www.ehealthsask.ca/services/pip>.

CONCLUSION

Use of electronic transmissions is common in most business and health practices. Often, the transfer of prescriptions by electronic means may be safer and more secure than through verbal or written transmission. When safer, use of such technologies to accommodate health professionals in meeting patient needs should be permitted and supported.

As the College has been working with eHealth Saskatchewan, the Saskatchewan Ministry of Health, and others, SPCP concludes that prescriptions issued and retained within the electronic

prescribing capability of the Pharmaceutical Information Program meet this policy statement and members may dispense prescriptions from the electronic prescription record generated by the prescriber in PIP.

The member is left to determine if other electronic prescribing methods meet this policy statement.

Supplementary Guidelines

1. Electronic Prescriptions

An electronic prescription must contain a name, code, identifier, or electronic signature that uniquely identifies a particular prescriber and prescribing event where the prescriber is the only person authorized to generate his/her electronic signature, code or identifier from an electronic device designed for the purpose. This could occur in the following ways:

The electronic prescription has an electronic record that is unique to the issuance of that prescription, which would include a specific time of day the prescription was issued and can be verified using this time of day or another electronic locator; and,

- A totally secure network (like hospitals) where only prescribers can, through security measures within the system, access the system to prescribe and therefore the prescription does not require a direct physical signature or an electronic signature; or
- In electronic prescription systems that are not within a secure network, there must be an electronic verification of authenticity that is included with the electronic prescription; or
- An electronic prescription could be issued using handheld technology that allows for an electronic written signature to accompany the prescription.

Electronic prescribing of PRP drugs using the PIP system is acceptable because the system conforms to this policy and such prescriptions meet the information requirements that the prescriber must include in all PRP prescriptions.

Please note that the integration of electronic health records and/or EMRs may occur within the e-Health viewer of SaskHealth and could require further steps for authentication.

2. Prescription Transfers

Prescriptions for most Schedule I Drugs under *The Pharmacy and Pharmacy Disciplines Act* may be transferred from one member to another member when all the requirements under the relevant legislation are met. Prescriptions for Narcotic and Controlled Drugs cannot be transferred, while prescriptions for Benzodiazepines and other Targeted Substances may only be transferred once. The basic requirement interpreted from the law is member to member communication. This may be achieved through facsimile or other electronic transmission provided that the principles in this policy statement are met. Transferring prescriptions electronically by fax requires the transferring member to include his/her name, and the name

and address of the pharmacy with all the required documentation, as well as knowing and recording the name of the pharmacist and pharmacy to which the prescription is being transferred. The member receiving the facsimile transmission transfer must ensure the authenticity of the transmission and must fulfill their requirements to complete the transfer process, including documentation of his/her name/initials on the facsimile transmission.

3. Facsimile Transmission

Guidelines for facsimile transmission of prescriptions permit the faxing of all legal classifications of drugs. This includes those drugs monitored under the Prescription Review Program. All required documentation must be included on the PRP prescription. The following is intended to clarify issues arising from experience with faxed prescriptions.

Prescriptions may be transmitted by facsimile from the prescriber to a pharmacy, provided that the following requirements are met:

- a) The prescription must be sent only to the pharmacy of the patient's choice;
- b) The prescription must be sent directly from the prescriber's office, office computer or directly from a health institution for a patient of that institution.
- c) Prescriptions for drugs included in the Prescription Review Program may be faxed to the pharmacy. Please note, the quantity is not required to be written as both a numerical value and a written value when the prescription is faxed;
- d) Always verify the facsimile number before sending the documentation to ensure that patient privacy is maintained. If you receive a fax in error, please notify the sender as soon as possible. The facsimile equipment at the pharmacy must be under the control of the member so that the transmission is received and only handled by staff in the pharmacy in a manner which protects the patient's privacy and the confidential information on the transmission;
- e) The prescription must include the following:
 1. Date (the date of facsimile transmission is acceptable);
 2. Name of the person for whose benefit the prescription is being issued. The patient's address is required on prescriptions for Prescription Review Program drugs;
 3. Name of the drug or ingredient(s) and strength where applicable;
 4. Quantity of the drug which may be dispensed;
 5. Dosage instructions for use by the patient;
 6. Refill authorization where applicable, which shall include the number of refills (and interval between refills, when so required);
 7. Prescriber's name, address, fax number and telephone number;

8. Prescriber's signature in a manner that complies with this policy statement if issued or generated electronically; and,
 9. Time and date of transmission;
- f) The member is responsible for verifying the origin of the transmission, the authenticity of the prescription, and if not known to the member, the signature of the prescriber;

Ensuring Authenticity and Origin of a Faxed Prescription

Pharmacists must make every effort to ensure any facsimile transmission has been sent to the pharmacy by a practitioner and to verify any prescriptions when the practitioner is unknown to the pharmacy, or if there is a concern that the prescription has been altered to ensure the safety and care of the patient. (See the SCPP's [Forgeries](#) document.)

- g) For guidance on records, refer to "6. Record Keeping" below;
- h) Facsimile transmissions can be accepted for all schedules of drugs;
- i) Facsimile transmissions can be accepted from a practitioner registered to practice in a province of Canada;
- j) A unique number is assigned to the prescription and will not be re-used or re-produced on any other prescription;
- k) For guidance on filing, refer to "6. Recording Keeping" below.

4. Scanned Prescriptions

Prescriptions may be scanned, and an electronic copy may be maintained and/or stored electronically. This is acceptable provided that the process meets the principles and policies in this document as well as privacy policies of SCPP (see section 6) Record Keeping for more information).

5. No Substitution

Section 54 of *The Pharmacy and Pharmacy Disciplines Act*³, requires that the member dispense the product prescribed when the prescriber instructs “no substitution”, either verbally or in their own handwriting.” As per section 17.1(h) of the CPSS Regulatory Bylaws, pre-printed instructions must be accompanied by the prescriber’s initials.

6. Record Keeping

So that it is available for patient care purposes and for legally authorized auditing, inspection, or other accountability purposes such as quality assurance, in the pharmacy; the electronic prescription must be printed and retained on permanent quality paper, or saved electronically if:

- a) the record can be accessed and viewed on the system; AND
- b) the system is capable of producing the record on paper if needed.

All other record keeping requirements must be met. For example, prescriptions for Narcotic and Controlled Drugs must be filed in a separate file in sequence as to date and number. If the pharmacy’s software system cannot meet this requirement electronically, then the original prescription must be retained and filed accordingly. For further guidance, refer to the document “Record Keeping Requirements for CDSA Drugs” in the [SCPP Reference Manual](#).

Documentation must be kept for a minimum of two (2) years from the last entry (refill, transfer, review) and SCPP’s recommendation is to save documentation longer, as per directions from third parties such as NIHB, CRA, etc.

There are additional record keeping elements to take into account beyond the principles and policies in this document. The onus is on the pharmacy manager to ensure the pharmacy’s records meet all other record keeping requirements. The following are examples to consider:

- a) Can your computer software provider conform to the provincial and federal regulations for record keeping?
- b) Does your record keeping system meet and maintain privacy legislation (i.e., HIPA and PIPEDA)?
- c) Have you verified with your accountant Canada Revenue Agency’s requirements and whether electronic documents are adequate?
- d) Have you ensured that the requirements of third party payer contracts are met?

The pharmacy manager is responsible to ensure that all patient records are stored, whether on paper or electronically, in a manner that protects the privacy and confidentiality of the patient.

³ The Pharmacy and Pharmacy Disciplines Act, Section 54: “Dispensing an interchangeable pharmaceutical product,” p. 37: https://scp.in1touch.org/document/3530/The_Pharmacy_and_Pharmacy_Disciplines_Act.pdf.

This includes protection from privacy threats (robbery, “snooping” etc.) and physical threats (fire, water, etc.). **The less direct the oversight is on the area of record storage, the more security and safeguards that need to be in place.** The area of storage must be accessible to the pharmacy staff only, and the records therein need to be easily reproducible upon request in a timely manner. The pharmacy manager is to determine what is considered reasonable storage based on the regulatory requirements.

Pharmaceutical Information Program (PIP)

For prescriptions which are prescribed in the Pharmaceutical Information Program, the pharmacy staff must first print the prescription using the “Print Prescription” function within the PIP system.

Saving the prescription electronically does not mean saving it in the PIP system. Rather, it means saving it in the pharmacy’s computer system if that capability is provided by the pharmacy’s computer system vendor according to this policy and guidelines.

CONTACTS FOR FURTHER INFORMATION

Pharmaceutical Information Program (PIP)

<https://www.ehealthsask.ca/services/pip>

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APPENDIX A

The following information was provided to another provincial regulatory authority by the Therapeutic Products Directorate of Health Canada in November 2015 as a response to a request for information on prescription record retention.

A. Retaining Paper (original) Prescription Records in Electronic Format

Where original prescriptions are received in a paper format:

1. Can the original be scanned and stored electronically?

Yes. However, the provinces and territories are responsible for delivery of healthcare and as such, set their respective requirements with respect to eHealth.

More pharmacists are moving to a paperless environment and filing prescriptions electronically. Health Canada has no objection to this transition provided that the electronic files are saved in a secure high resolution format to ensure the information is easily readable. Pharmacists should ensure that there is an appropriate backup system to avoid any loss of relevant information.

For narcotics and controlled drugs, pharmacists must be able to meet section 40(1) of the Narcotic Control Regulations and G.03.009 of Part G of the Food and Drug Regulations which requires pharmacists to maintain a special controlled drugs and narcotic prescription file.

2. If so, how long does the electronic record need to be stored?

Electronic records (including those for controlled drug substances) must be retained for at least two years after the day they were filled as per sections C.01.041(3) and G.03.010 of the Food and Drug Regulations. Beyond the two-year period, it is up to your provincial/territorial professional college or the respective provincial Ministry of Health to determine if the records required by Regulations under the CDSA and the Food and Drug Regulations are needed/required to be kept for a longer period based on other sets of federal or provincial legislation.

3. Can the original paper prescription be destroyed upon being electronically recorded and stored?

Yes. However, the provinces and territories are responsible for delivery of healthcare and as such, set their respective requirements with respect to eHealth.

B. Retaining Prescriptions that Are Received Electronically by Facsimile or Comparative technology

1. Can a copy of a paper based prescription be scanned and transmitted by facsimile to a pharmacy?

There is nothing preventing this in the Food and Drug Regulations or in the Regulations under the CDSA; however, the provinces and territories are responsible for delivery of healthcare and as such, set their respective requirements with respect to eHealth.

2. Can an electronic copy of a prescription be sent by facsimile to a pharmacy?

There is nothing preventing this in the Food and Drug Regulations or in the Regulations under the CDSA; however, provinces and territories are responsible for delivery of healthcare and as such, set their respective requirements with respect to eHealth.

For responses 1 and 2 of this section, please note that for controlled drug substances, pharmacists are required to verify the signature of the prescribing practitioner (if not known).

3. In either of these situations, can the electronic version that is received by the pharmacy be considered the original prescription and stored to meet Health Canada prescription storage requirements? OR does the document need to be printed and retained for the required period?

Storing the electronic version of the original prescription would suffice to meet the requirements under the Food and Drug Regulations and in the regulations under the CDSA. However, as the provincial and territorial governments have primary jurisdiction over the administration and delivery of health care services, the provincial/territorial authorities may set other requirements.

4. Are any audit logs required; and if so, what information must they include?

This question is outside the scope of the Food and Drug Regulations. Presumably, whatever was required in the various provincial/territorial jurisdictions regarding audit logs of paper prescription, will now apply to the scanned electronic copy of the paper prescription. However, the provinces and territories are responsible for delivery of healthcare and as such, set their respective requirements with respect to eHealth.

We also note that Part 2, Electronic Documents, Personal Information Protection and Electronic Documents Act (PIPEDA) (Retention of documents, section 37) states that:

"A requirement under a provision of a federal law to retain a document for a specified period is satisfied, with respect to an electronic document, by the retention of the electronic document if:

(a) the electronic document is retained for the specified period in the format in which it was made, sent, or received, or in a format that does not change the information contained in the electronic document that was originally made, sent, or received;

(b) the information in the electronic document will be readable or perceivable by any person who is entitled to have access to the electronic document or who is authorized to require the production of the electronic document; and

(c) if the electronic document was sent or received, any information that identifies the origin and destination of the electronic document and the date and time when it was sent or received is also retained."

C. Retaining Prescriptions that are received electronically through e-prescribing (i.e., electronic encrypted orders)

1. Can an encrypted/secure version of a prescription including a digital signature be transmitted to a pharmacy?

There is nothing preventing this in the Food and Drug Regulations or in the regulations under the CDSA; however, the provinces and territories are responsible for delivery of healthcare and may have their respective requirements with respect to eHealth.

2. If so, must the electronic version be printed, and then scanned back into the system to comply with federal requirements? OR does the e-version of the prescription meet federal requirements so long as it is stored and retrievable for 2 years?

Yes, the e-version of the prescription is sufficient so long as it is stored and retrievable for two years. However, the provinces and territories are responsible for delivery of healthcare and as such, set their respective requirements with respect to eHealth.

For controlled drugs, please refer to the policy statement on the electronic ordering of controlled substances at www.hc-sc.gc.ca/hc-ps/substancontrol/pol/pol-docs/electronic-eng.php.

3. Are any audit logs required; and if so, what information must they include?

Please see comment above re: PIPEDA, part 2, section 37.

D. Site of Storage

- 1. Please clarify whether original prescriptions must be stored on-site? Can a pharmacy have a management agreement with an off-site repository to retain original prescriptions; in paper or electronic format?**

It is our understanding that provincial health information acts set out rules for electronic data storage. However, the regulations under the CDSA require that all records must be maintained for a period of at least two years. Pharmacists must always retain knowledge of, and control over any records that are subject to a record-keeping requirement.

- 2. Can an off-site repository be located outside of Canada? If so, are there any requirements that must be met to accommodate this?**

Some provinces/territories have legislation requiring that personal health information storage sites be located in Canada, and this is generally considered to be a good practice. However, some provinces do allow personal health information to be stored outside of Canada and provide guidelines or regulations for data custodians to follow.

- 3. Given the growth in non-traditional practice models, if off-site record storage is permitted by Health Canada (including OCS), how will this be harmonized between provinces? Will Health Canada (including OCS) define the criteria (i.e., specifically for cross border provincial or international storage) or leave it up to the individual provinces to determine accessibility, retrievability and security criteria?**

We have no comment on this. Each provincial/territorial regulatory authority has primary jurisdiction in this area and may impose specific requirements.

Questions?

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