G U I D E L I N E S

Telepharmacy: Guidelines

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Telepharmacy: Guidelines

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Introduction

This is the first edition of guidelines from the Canadian Society of Hospital Pharmacists (CSHP) regarding the provision of telepharmacy services. The guidelines were approved by the CSHP Board in 2018.

These guidelines were developed by a group of CSHP members with experience in telepharmacy, in collaboration with CSHP staff. The guidelines are consensus-based, reflecting current best practice in the provision of telepharmacy services.

The term "telepharmacy" refers to the use of telecommunications technology to facilitate or enable the delivery of high-quality pharmacy services in situations where the patient or healthcare team does not have direct (in-person) contact with pharmacy staff. Telehealth, of which telepharmacy is one component, includes 4 domains of application: synchronous video (2-way interaction), asynchronous content (provision of recorded health record, stored audio or video, etc.), remote patient monitoring (e.g., telemetry), and mobile health (using mobile devices). Each of these domains can be extrapolated to telepharmacy.

Telepharmacy is a means of providing pharmacy services to patients so as to enhance or expand the services they receive and to close identified service gaps. Its scope is as broad as the technology can support and legislation allows. Circumstances where telepharmacy is used include, but are not limited to, delivering services in geographically remote areas; covering for absences due to vacation, illness, or vacancy; streamlining operational workflow; and increasing opportunities for direct patient care.

Telepharmacy services may use an intrasystem model, in which pharmacy resources are shared across multiple sites within the same healthcare system, or an intersystem model, in which services are provided through an external facility or vendor.²

The following are examples of pharmacy services that can now be delivered using telepharmacy:

- a) patient care;2
- b) medication order entry and verification;²
- c) medication selection and preparation verification;²
- d) drug information service;2 and
- e) staff education sessions.

Telepharmacy is one approach to improving the quality of patient care. Governments, healthcare leaders, and the public at large have expectations for convenient and timely access to care, patient safety and improved health outcomes, financial sustainability, and appropriate scopes of practice for healthcare professionals. Telepharmacy can address all of these expectations by strengthening the profession's alignment with the healthcare needs of Canadians and responding to stresses on the healthcare system.

1 Scope

These guidelines were developed to support pharmacy personnel in deciding whether to provide or receive services via telepharmacy, in preparing for implementation, and in providing ongoing service support. The guidelines apply to institutional settings such as hospitals, ambulatory care clinics, and long-term care facilities. The information presented here is intended as a general guide, reflecting best or leading practices, and may be adapted to meet the needs of individual pharmacies, within the context of a risk assessment.

These guidelines are intended to complement all relevant legislation (federal/provincial/territorial) and accepted patient safety practices; they should not be used as justification to deviate from practice that is authorized or required by law.

In addition to the legislative frameworks in place in various jurisdictions, individual healthcare organizations may have specific policies and practices that put constraints on the use of telepharmacy. Relevant organizational or site policies will need to be reviewed, and in some cases modified, before a decision is made to implement telepharmacy services. A summary checklist of telepharmacy program requirements is presented in Appendix A.

2 Decision to Use Telepharmacy

The decision to use telepharmacy should be the result of collaboration between the organization's management and pharmacy management. The decision will stem from a desire to improve the quality and safety of patient care by closing one or more gaps (real or anticipated) in pharmacy services or by expanding the provision of direct patient care.

The following aspects of telepharmacy should be taken into account to help the organization's management determine the resources required for implementation:

- a) people;
- b) policies and procedures;
- c) physical space;
- d) technology;
- e) capacity; and
- f) quality.

Various analyses (e.g., needs assessment, cost—benefit analysis, risk assessment, and failure mode and effects analysis), as well as determination of the long-term and short-term consequences for the organization, will help to inform the decision.

The rationale supporting a decision to use telepharmacy should be documented and regularly reassessed to ensure that goals are being met.

For more information about reassessment, refer to section 8: Quality.

2.1 Legal Authority

All pharmacy personnel delivering telepharmacy services shall meet or exceed the comparable standard for in-person care. All aspects of the use of telepharmacy services shall comply with the relevant federal and provincial/territorial legislation, as well as applicable privacy legislation, codes of ethics, standards of practice, and policies and procedures of the relevant pharmacy regulatory authorities.

Persons or organizations who provide or receive telepharmacy services should align their practice with the applicable pharmacy regulatory authority requirements for telepharmacy services. The most accountable regulated pharmacy personnel must be clearly identified and must be accountable to the provincial/territorial pharmacy regulatory authority. Telepharmacy services involving additional unregulated pharmacy personnel or other regulated (non-pharmacy) healthcare professionals must meet the requirements of the provincial/territorial pharmacy regulatory authority, as well as any applicable organizational policies.

If the telepharmacy services are provided by someone who practises in a provincial or territorial jurisdiction other than the one where the services are received, all relevant pharmacy regulatory authorities should be consulted.

2.2 The Business Case

A business case should be developed to illustrate how incorporating telepharmacy services will change workflow, while improving the quality and safety of patient care.³ It should include the following information:

- a) value proposition of using telepharmacy services;
- b) needs assessment;
- c) possible solutions (including but not limited to telepharmacy);
- d) legal authority and licence requirements;
- e) resources required to support telepharmacy

- i) people
- ii) physical space
- iii) technology and equipment
- iv) funding;
- f) economic analyses;
- g) privacy and security considerations;
- h) underlying assumptions; and
- i) implementation strategy.

Ideally, the business case should be developed through consultation with stakeholders (e.g., pharmacy staff, medical staff, nursing staff, information technology [IT] department).

3 People

3.1 Training and Assessment

All persons involved in telepharmacy services (at both the service provider and recipient sites) shall be trained and shall demonstrate competency in the relevant policies and procedures before using telepharmacy services.⁴

At a minimum, training shall address the following topics:

- a) communication;4
- telepharmacy technology, including procedures for setup, operation, and downtime;
- service delivery processes and expectations of all staff involved in telepharmacy;
- d) relevant privacy and security issues; and
- e) requirements for documentation.

Pharmacy management shall ensure that personnel undergoing training as service providers will work under supervision until the training period is satisfactorily completed.⁴ All service personnel shall remain under the direction of pharmacy management during operations, regardless of where the service providers are physically located.⁴ Training shall be reinforced and refreshed at suitable intervals.⁵

Personnel who use telepharmacy services, either as service providers or recipients, and who have been absent for an extended period, should be reassessed and retrained as needed before resuming their responsibilities, in accordance with the organization's policy.

3.2 Communication

Effective communication skills are critical for the successful delivery of telepharmacy services, to ensure patient

safety and optimal patient care. The provision of critical information about the patient to other healthcare providers must follow applicable laws, regulations, and policies to support safe and effective drug therapy while maintaining patient confidentiality. This requirement for appropriate provision of information includes developing strategies to manage communication with patients and prescribers that is not conducted in person, for the purposes of educating, instructing, offering relevant drug information, and performing other pharmacy processes.

3.3 Accountability

Service providers accept responsibility for ensuring that the practice environment permits the provision of high-quality pharmacy care and services in accordance with the standards of practice outlined by the relevant regulatory authority or authorities. They will work collaboratively with service recipients as required, but will make autonomous decisions within their scope of practice, as outlined in the service delivery agreement (see section 10: Outsourcing). Service providers will adhere to site-specific policies, procedures, and work standards. Requests for technical support (e.g., troubleshooting) should be managed through liaison with service support or IT staff. Incidents of unsafe or unprofessional conduct shall be reported to the responsible pharmacist manager.

4 Policies and Procedures

Policies and procedures for using telepharmacy technologies shall be developed and shall include, but not be limited to, the following topics:

- a) privacy and security;
- b) documentation;
- c) equipment maintenance;
- d) transmission of patient care records;
- e) communication with other healthcare professionals;
- f) communication with patients, with particular focus on patient acceptance and engagement;³
- g) service continuity and contingency planning; and
- h) care at transition points.

All policies and procedures should be validated, approved, and regularly reviewed by designated personnel. Personnel who are expected to comply with the policies and procedures shall be informed of all changes to the policies and procedures.⁵

Pharmacy personnel who are providing direct patient care should ensure that they have verified the patient's identity and location, introduced themselves, and obtained consent for the care.⁶

5 Physical Space

The environments where telepharmacy services are provided or received should complement and improve current workflow, and should protect the privacy and safety of patients and healthcare workers.

The physical environment shall be configured to comply with the legislation and standards of practice relevant to the service being provided. Consideration shall be given to the types of service provided, the supplies and equipment required, and the existing and anticipated workflow.

6 Technology

The pharmacy director or manager shall engage and involve information systems staff, the organization's privacy officer, and other key stakeholders to ensure that any technology introduced to support telepharmacy services meets the requirements set out in the following:

- a) federal and provincial/territorial legislation;
- b) national and provincial/territorial standards of practice for pharmacy (e.g., Model Standards of Practice for Canadian Pharmacists⁵ and Model Standards of Practice for Canadian Pharmacy Technicians⁷); and
- c) organizational policies and procedures.

In particular, the privacy and security standards set out by the above legislation, standards, and policies shall be met by the service provider and by service recipient organizations implementing telepharmacy systems. These standards shall be discussed and agreed upon, and should be documented in the contract. In meeting these standards, the quality and safety of patient care should be maintained or improved.

The design of an IT system should begin with a gap analysis of the current state of pharmacy services and the desired future state of these services after implementation of telepharmacy technology.

In designing the IT requirements, the workflow that will be affected by telepharmacy should be mapped out. This process will help to identify the minimum IT requirements to implement the telepharmacy service while still meeting applicable legislation and standards. For instance, during transmission of patient information, the requirements for privacy of health information and the national standards for pharmacy practice management systems must be met.⁸

The organization should implement risk mitigation strategies to ensure that the equipment and communication systems are operating correctly. These strategies should include

procedures during downtime; timely access to IT resources or help desk services; protection from vandalism, loss, or damage; protection software and protocols for viruses and hacking; and user acceptance testing. Appendix B identifies some components of telepharmacy that should be considered before any use of telepharmacy technology.

6.1 Equipment

The pharmacy management team should be aware of the current trends in equipment applications and the organization's processes to procure and select equipment that is routinely used with telepharmacy technology, to ensure that the equipment will be supported in the future.

The equipment used with telepharmacy technology shall be fit for purpose and shall be capable of supporting the delivery of high-quality services provided via telepharmacy.

All equipment shall be operated only for its intended and designated use. Staff shall be supported through training and through availability of documentation on safe and appropriate use of equipment.

All equipment shall be inspected and maintained at required intervals to prevent it from affecting the integrity of the services provided or causing harm to those involved in that service provision. Any equipment that fails inspection should be removed and replaced or repaired. If it cannot be removed or repaired promptly, it shall be labelled to indicate non-usability. Documentation supporting such actions shall be kept on site.

Responsibilities for inspecting, maintaining, cleaning, and replacing equipment shall be clearly specified in the policies and procedures.

7 Capacity for Service Provision

The development and implementation of telepharmacy services requires a capacity plan to ensure that the services can handle the anticipated demand in an efficient manner that maintains a minimum level of quality and patient safety. The capacity plan should describe the service delivery model (and its scope) and the configuration for current or anticipated demand (daily, monthly, and annually), should define the limits (or constraints) in the system, and should include a sensitivity analysis to allow development of a strategy for managing fluctuations and growth in service demand. A risk assessment should be performed to support the capacity plan.

The plan shall be regularly reviewed and updated, as needed, by the service provider and the service recipient, against measures of quality, workload, and resources.

7.1 Contingency Planning

It is essential to have a documented plan for any type of service disruption, regardless of duration. This plan shall be supported by communications directives.

The contingency plan should provide information on the following topics:

- a) activation of the plan;
- b) attention to critical systems;
- c) responsibilities during each phase of the plan;
- d) contact information for logistical support;
- e) alternative service providers (local or remote) in case of service disruption or staff shortage;
- f) recovery plans;
- g) return to normal operations;
- h) relevant training; and
- i) documentation of situations requiring activation of the plan.

Contingency plans should be outlined for circumstances such as the following:

- a) planned and unplanned interruptions in data, video, or audio links, including hacking or virus attacks;
- b) unavailability of network or server;
- c) absence of trained staff on short notice; and
- d) weather-related emergencies, power outages, or events involving mass casualties.

8 Quality

The use of telepharmacy technology shall be supported by a quality management program employing a risk management framework. Quality and safety shall be incorporated in every step of the design and maintenance of telepharmacy technology. A multidisciplinary team approach to managing quality improvement is important.⁹

The quality management program shall be documented and should include the following interrelated components, all of which should be assessed regularly for their effectiveness and suitability:

- a) quality assurance;
- b) change control;
- c) quality control; and
- d) quality improvement.

8.1 Quality Assurance

Quality assurance ensures that

- a) personnel are adequately trained and competent to execute their responsibilities using the telepharmacy technology (see section 3: People);
- b) equipment and IT are fit for use;
- c) critical procedures are validated;
- d) the services provided are evidence-based and suitable to promote patient and staff safety; and
- e) risk management processes are followed.

8.2 Change Control

Change control practices should be defined and implemented, to ensure that changes to the system are introduced and managed in a systematic, controlled fashion, without unwanted consequences.

All changes that might affect the services provided using remote technology should be assessed, validated, and formally approved by the appropriate individual(s). Corresponding changes to policies and procedures should be made accordingly.

8.3 Quality Control

The pharmacy department should have a quality control program that incorporates key performance indicators (KPIs) to assess the quality of the telepharmacy service and compliance with legislation, standards of practice, and policies.

8.4 Quality Improvement

KPIs should be measured at all critical points. Methods should be established to regularly collect and analyze the data for these indicators.

The pharmacy department should regularly monitor KPIs to identify opportunities for improving the provision of pharmacy services through telepharmacy.

The pharmacy department should develop and implement plans to continually improve the quality and performance of telepharmacy services according to the analysis of outcome measures. The department should also assess the relevance and appropriateness of its KPIs and adjust them accordingly.

9 Implementation

An interprofessional team should be created to develop and implement a strategy to help attain the desired vision for telepharmacy services. The team may include IT staff, privacy officers, and others, in addition to representatives from pharmacy, medicine, and nursing. The strategy to implement telepharmacy services should include the following elements:

- a) defining a clear vision of the scope of telepharmacy services;
- b) designing the telepharmacy workflow;
- c) establishing critical paths and milestones;
- d) assigning responsibilities and accountabilities;
- e) choosing the staffing model for the provision of telepharmacy;
- f) developing policies and procedures;
- g) training all staff involved;
- h) ensuring that security protocols are met;
- i) conducting end-user acceptance testing; and
- i) developing a quality management program.

10 Outsourcing

When a pharmacy department is unable to meet a minimum standard of pharmacy services or enhance its existing pharmacy services, outsourcing the service(s) should be considered. The pharmacy management should be involved in any decision to outsource the service(s).

Refer to the CSHP publication *Outsourcing: Guidelines* for *Pharmacy Practice*¹⁰ for information about additional provisions when a request for proposals is issued or a contract is awarded.

10.1 Request for Proposal

The request for proposal for telepharmacy services should provide the following information for potential vendors:

- a) description of the organization (e.g., number of patients served in a defined period, number of beds, level and type of care provided);
- b) description of the pharmacy department;
- architecture of the existing IT system (e.g., security, network servers, privacy measures, pharmacy operational software, organizational information system);
- d) service-level agreement, which should include but is not limited to the following:
 - i) services to be provided, including urgent or emergent services;
 - ii) performance standards; and
 - iii) service provision schedule.

The request for proposal should ask the potential vendor to provide the following additional information, in writing:

- a) name and location of all sites that would provide the pharmacy services via telepharmacy technology;
- b) licences held by the vendor;
- applicable licences held by the vendor's staff members who would be providing services to the organization;
- d) results of all regulatory inspections and accreditation surveys, including citations and status thereof;
- e) evidence that the vendor's IT system is compatible and will align with the buyer's system(s), and that it meets the required specifications;
- evidence of the vendor's commitment to continually improve the quality and safety of its services;
- g) evidence of the vendor's risk management program (e.g., quality assurance system, quality control, equipment and supplies, policies and procedures, emergency preparedness, recall procedures, equipment maintenance program, and reporting systems);
- h) notarized statements that the check of every employee's criminal record satisfies the requirements of the service recipient;
- i) description of the vendor's solution to providing the services; and
- j) ability to offer potential solutions for services that the vendor is unable to provide (if applicable).

10.2 Elements of the Contract

In addition to the contract elements described in the CSHP publication *Outsourcing: Guidelines for Pharmacy Practice*, ¹⁰ a contract for outsourcing telepharmacy activities should include the following provisions:

- a) evidence that the service provider offers high-quality pharmacy services that meet or exceed regulatory standards and will complement the organization's delivery of pharmacy services;
- b) evidence that the service provider has the human and technological resources to support telepharmacy services with no anticipated interruptions;
- evidence that the service provider can comply with relevant federal and provincial/territorial privacy legislation;
- d) description of responsibilities of the service provider and service recipient for ensuring that the telepharmacy technologies and equipment used shall be fit for purpose at all times;
- e) evidence that the service provider contributes data that will supplement performance data needed by the service recipient (e.g., hospital) to strategically and operationally manage its pharmacy services (e.g., clinical pharmacy KPIs, drug-distribution KPIs); and
- expectations regarding the provision of goods or services on an urgent or emergent basis.

11 Glossary

Capacity plan	A plan that establishes the minimum and maximum output or production that can be achieved by a defined set of resources. It also describes the amount and type of resources needed to produce a certain level of output in the event of demand for output changes.
Change control practices	A set of written procedures describing the processes to be undertaken if a change is requested (or planned) that will affect the physical environment, equipment, supplies, or processes, or that may affect the quality of a good or service provided. These procedures ensure that changes are considered and approved before being implemented, that the changes either address a problem or improve the system, and that services are not disrupted.
Quality assurance	"[The] planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality." 11
Quality control	"[The] operational techniques and activities used to fulfill requirements for quality."11
Quality improvement	"[A] systematic approach to making changes that lead to better patient outcomes and stronger health system performance."9
Quality management program	A systematic process designed to help those who plan, lead, and execute the provisior of goods or services that are of sufficient quality to meet or exceed the needs of the end-user. It includes quality improvement, quality control, quality assurance, and change control practices.
Service provider	The person or organization that delivers telepharmacy services. Also known as the "remote site."
Service recipient	The person or organization receiving pharmacy services via telepharmacy. Also known as the "central site" or "the client."
Shall	A mandatory requirement.
Should	A recommendation, something that is advised but not mandatory.
Telepharmacy	The use of telecommunications technology to facilitate or enable the delivery of high-quality pharmacy services in situations where the patient or healthcare team does not have direct (in-person) contact with pharmacy staff.

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Appendix A: Checklist of Program Requirements

Working collaboratively, the service provider and the service recipient shall ensure that the following criteria are addressed before implementation and throughout service delivery:

- a) operational needs are met;
- b) the scope of services required has been defined;
- the service complies with requirements of the relevant regulatory authority;
- d) job descriptions hold staff using telepharmacy services accountable for professional performance consistent with standards of practice, including measurable performance indicators;
- e) appropriate computer access to the pharmacy information system is available;
- f) policies and procedures ensure that a safe and effective system of medication supply is maintained at all times;
- g) staffing and workflow support pharmacy staff in fulfilling their professional obligations;
- staff members have access to required information and resources;
- i) staff members, or support personnel working under their direct supervision, are delegated to undertake (as permitted) pharmacy-related activities appropriate to their training and consistent with legislation, regulations, and policies;
- j) staff members, or support personnel working under their direct supervision, competently perform delegated pharmacy-related activities;
- k) communications are prepared and distributed to all applicable site staff in advance of each scheduled telepharmacy service;
- policies and procedures are developed to support staff members' ability to continuously improve the safety and quality of patient care provided; and
- m) practice change models are developed and implemented on the basis of measurements and desired improvement in the quality of care and services provided by pharmacists.

Appendix B: Telepharmacy Components to be Considered

Topic	Aspects to Consider
Remote Access	Secure login with validation and audit trail
	Roles and permissions: permission given to specific groups of users to perform certain tasks (e.g., access, modify, remove) for particular content
	Virtual private networks
	Firewalls
Transmission of data	Quality of information that is transmitted (e.g., electronic scan versus fax)
	Data encryption during transmission
	Mode of transmission (e.g., telephone, internet versus Bluetooth versus satellite, internal hospital networks)
Hardware	Workstations and mobile devices: Minimum specifications Encryption Data storage Network
	Video cameras: Quality of digital images (high definition) ² Storage retention period and recall procedures
	Robots
Communication	Telephone, video, and mobile applications: Encryption 2-factor authentication Privacy and security of communication
Software solution	Type of software: cloud versus hosted server
	Legislative requirements for privacy and confidentiality (including a privacy impact assessment)
	Data retention and recovery

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Additional Reading

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