***This policy applies at** **All Sites**

Title:	**Development & Approval of a Medical Directive or Clinical Protocol**
Manual:	Clinical
Section:	Interdisciplinary
Approval Body:	Medical Advisory Committee (MAC)
Original Effective Date:	01/2000
Next Revision Date:	04/2027
Policy Lead:	Policy & Risk Associate
Policy Owner:	Program Director, Quality, Patient Safety & Risk

Key Words:	Regulated Health Professions Act, RHPA, medical directive, directive, authorizing mechanism, implementer, co-implementer, -delegation, controlled act
Cross-References:	Development & Approval of Policies & Procedures

POLICY:

A consistent structured process will be utilized in the development and approval of Medical Directives and Clinical Protocols. This process is captured electronically, via PolicyManager™ and outlined in the attached resources.

Medical Directives and Clinical Protocols are developed collaboratively between the physician(s) authorizing the directive and the health care professional(s) authorized to initiate/implement the orders. A Physician Lead must be identified to establish the orders, acquire physician authorization signatures, and present to the endorsement committees where applicable.

Medical Directives are endorsed in writing by the physician(s) who have the legal authority to order the procedure, treatment, drug, or intervention for which they are ultimately accountable. The Physician Chief/Medical Director is accountable for all Medical Directives and Clinical Protocols within their programs. Medical Directives or Clinical Protocols cannot be implemented until all approvals/endorsements are received and the document is published.

Medical Directives

Medical Directives are physician orders used by Regulated Health Care Providers (RHCP) who possess the knowledge, skill, and judgment to initiate the directive in advance of physician assessment. RHCPs will complete the required education associated with each Medical Directive and are individually accountable in doing so.

Orders within a Medical Directive may be initiated by an authorized implementer without a physician order and in advance of physician assessment, in accordance with the procedure below.

A medical directive does not replace physician assessment; it is expected that a delegating physician will assess the patient soon after the directive is enacted. The physician is ultimately responsible for the orders and actions initiated by way of a medical directive (CPSO, 2012; CNO, 2018).

Temporary class licensed Registered Nurse (RN) or Registered Practical Nurse (RPN) are included in roles referred to as nursing (RN/RPN). All medical directives associated with the nursing role would apply to them provided they have successfully completed the initial competency validation process and possess the knowledge, skill, and judgment to implement the medical directive.

All required signatures and authorizations must be completed BEFORE a Medical Directive can advance to committee approvals. Medical directives cannot be implemented until all approvals/endorsements from physicians are received, including the physician authorization/signature list.

Medical Directives must be reviewed annually for approval/authorization and updated each time there is a medical staff change within the department/division which the directive applies (CPSO, 2012). This is captured on the Annual Review Form (contained in the Medical Directive template).

Medical Directives must be revised at least every 3 years, or any time a new order is added. Revisions require the entire PolicyManager workflow, including engaging all mandatory stakeholders and acquiring any required authorization signatures and approvals (See Appendix D).

All new Electronic Medical Record (EMR) orders, or revised orders are required to be reviewed by the Electronic Orders Committee (EOC), prior to approval from the Medical Advisory Committee (MAC). All Medical Directives impact physicians, and therefore require final approval from MAC.

Clinical Protocols

Clinical Protocols are physician orders used by RHCP who possess the knowledge, skill and judgment to implement/enact the orders within the protocol.

Orders within a Clinical Protocol **may not be implemented** without a physician order for the Clinical Protocol itself.

New or Revised Clinical Protocols follow the approval flow required for clinical policies and procedures (Refer to Development & Approval of Policies & Procedures).

All Clinical Protocols impact physicians, and therefore require final approval from MAC.

Delegation of a Controlled Act

If an order in a Medical Directive or Clinical Protocol requires delegation, all requirements for delegation in accordance with CPSO and CNO policies must be adhered to, including evaluation of the authorized implementer/delegate's knowledge, skill, and judgement.

Temporary class licensed Registered Nurse (RN) or Registered Practical Nurse (RPN) must not accept delegation outside of direct order or via medical directive. Temporary class licensed nurses are also not authorized to delegate a controlled or authorized act to any other person.

The Federation of Health Regulatory Colleges of Ontario (FHRCO) provides templates for performance readiness planning and evaluation, including forms to record authorized implementers. These documents do not need to be included with the Medical Directive or Clinical Protocol document; however they are strongly encouraged to be maintained within relevant clinical programs.

DEFINITIONS:

Medical Directive: A medical directive is a physician order for a procedure, treatment, drug or intervention that applies to more than one patient when specific conditions are met, and specific circumstances exist. Medical Directives may be initiated to expedite immediate care for a patient prior to physician assessment (CPSO, 2021; CNO, 2018).

Clinical Protocol: An order, or series of orders, for a procedure, treatment, drug, or intervention that applies to an individual patient when specific conditions are met. Orders within a Clinical Protocol may not be implemented by any RHCP without a physician order for the Clinical Protocol.

Controlled Acts: Controlled acts are activities that are potentially harmful if performed by unqualified persons (CNO, 2018). See **Appendix A** for controlled acts under the *Regulated Health Professionals Act.*

Delegation of a Controlled Act: Delegation is a mechanism that allows a physician who is authorized to perform a controlled act to confer that authority to another person (whether regulated or unregulated) who is not independently authorized to perform the act. The accountability and responsibility for the act that has been delegated remain with the physician (CPSO, 2021).

Physician Lead: Although this is most often the Physician Chief/Medical Director, in some cases this may be a division head or physician leader. The authorizing sign-off and accountability resides with the Physician Chief/Medical Directors regardless of who the physician lead is.

PROCEDURE:

For implementing a Clinical Protocol/Medical Directive in EMR:

Authorized implementers will be inputting the order into EMR and ensure that ordering provider and authorizing provider name is the patient's most responsible provider. The name of the authorized implementer will appear in the EMR as the ordering user.

For the development of Clinical Protocols/Medical Directives:

A **Clinical Protocol** may be developed if the order(s) in the protocol:

1. Consistently apply to an identifiable patient group / population; and
2. Can be safely, effectively, and ethically implemented when specific conditions are met in accordance with a standardized approach to routine care.

A **Medical Directive** may be developed if the order(s) in the directive:

1. Consistently apply to an identifiable patient group / population; and
2. Can be safely, effectively, and ethically implemented when specific conditions are met; and
3. Is necessary to expedite immediate care for a patient before direct assessment by the authorizing physician(s).

Medical Directives and Clinical Protocols cannot be implemented until required endorsements are received.

Medical Directives			
Endorsing Group or Committee	**Corporate**	**Departmental**	**Criteria**
Collaborators	REQUIRED	REQUIRED	Member(s) of the team who will assist the Lead in development, review, or revision.
Stakeholders	REQUIRED	REQUIRED	Member(s) of the organization in which the document relates to/affects.
Program Quality Committee(s)	N/A	REQUIRED *(Except Occ. Health)*	Departmental Committee that the document applies to (ex. ED Medical Directive will go to ED Quality Committee).
Professional Practice	REQUIRED	REQUIRED	REQUIRED
EVP, Chief Operating Officer, Chief Nursing Executive	REQUIRED	REQUIRED	REQUIRED

Pharmacy & Therapeutics (P&T) Committee	As Needed	As Needed	The medical directive contains medication usage, practices, or therapeutics implications.
Electronic Order Set Submission to Clinical Informatics	REQUIRED for all new orders & revisions		If the document has changes that will reflect in the order set.
Electronic Orders Committee (EOC)	REQUIRED for all new orders & revisions, submitted by Medical Directive Lead for build & approval		If the document has changes that will reflect in the Medical Directive order.
Final Approval – Medical Advisory Committee (MAC)	REQUIRED	REQUIRED	REQUIRED

Clinical Protocol			
Endorsing Group or Committee	**Corporate**	**Departmental**	**Criteria**
Collaborators	REQUIRED	REQUIRED	Member(s) of the team who will assist the Lead in development, review, or revision.
Stakeholders	REQUIRED	REQUIRED	Member(s) of the organization in which the document relates to/affects.
Program Quality Committee(s)	N/A	REQUIRED *(Except Occ. Health)*	Departmental Committee that the document applies to (ex. ED Medical Directive will go to ED Quality Committee)
Professional Practice	REQUIRED	REQUIRED	REQUIRED
Pharmacy & Therapeutics (P&T) Committee	As Needed	As Needed	All clinical protocols containing medication usage, practices, or therapeutics implications.

Medication Safety Committee (MSC)		As Needed	As Needed	All clinical protocols pertaining to medication management & oxygen.
Final Approval	Medical Advisory Committee (MAC)	REQUIRED	REQUIRED	All clinical protocols **with** physician involvement.
	Executive Leadership Team (ELT)	REQUIRED	REQUIRED	All clinical protocols **without** physician involvement.

Nomenclature: All Medical Directives & Clinical Protocols must follow the nomenclature as described below:

- Action/Order for which patients, and by whom.
- Must not include special characters (i.e. \ / : * ? " < > |).
- Must not include abbreviations.
- Ex. “Advanced Airway in Adults by Respiratory Therapist”

The document folder path in PolicyManager™ and the document title must not exceed 225 words for all Policies and Medical Directives.

Review Cycle: Refers to the review of a medical directive or clinical protocol. Documents are reviewed **annually**, by the Policy Lead to ensure all content is current. Changes during a review may include:

- Updates to Policy Lead/Owner Title, References, Cross-References, Appendices and Version History.
- Evaluation of the medical directive or policy’s relevance.
- Minor changes to procedure that do not require education/notification to staff.

The Policy Lead is responsible for ensuring a review is completed offline. Once the medical directive or clinical procedure has been reviewed and deemed complete, the Policy Lead will provide the finished copy to the Policy Associate to upload onto PolicyManager™.

If the Policy Lead reviews the document and determines that additional changes are required, they may proceed with a revision of the document.

All medical directives must be approved by the Policy Owner and Physician Chief annually. Any additional Physician(s) not included in the previous review/revision must also approve when reviewing the document.

Steps guiding a review:

1. The Policy Lead will download and review the current document for changes.
2. The Policy Lead determines if changes reflect a review cycle.
    a. If additional changes, not reflected in the review cycle, the Policy Lead will proceed with a revision of their document.
3. The Policy Lead will connect with their policy manager and owner for their awareness.
    a. The Policy Lead will make any necessary changes to the document based on feedback from their policy manager and/or owner.
4. The Policy Lead will obtain approval signatures of the Policy Owner, Physician Chief and any physicians not captured in the previous revision.
5. The Policy Lead will provide the completed document to the Policy Associate for upload to PolicyManager™.

Revision Cycle: Refers to the mandatory review and update of the content of a medical directive or clinical protocol, at minimum, **every three (3) years**, from the last revision date. Revisions can include, but are not limited to:

- Updates to Policy Lead/Owner Title, References, Cross-References, Appendices and Version History.
- Evaluation of the document's relevance.
- Any changes to the document, including procedures, roles, and responsibilities.

During a revision, the document will be subject to review and approval via PolicyManager™ by mandatory stakeholders. The mandatory stakeholders are determined based on document type and content (see appropriate workflow). Mandatory stakeholder approval may include:

- Program Quality Committee(s)
- Director or AVP
- Executive Leadership Team (ELT) Member
- Policy & Procedure Committee
- Acute Resuscitation Committee (ARC)
- Medication Safety Committee (MSC)
- Pharmacy & Therapeutics (P&T) Committee
- Medical Advisory Committee (MAC)

Steps guiding a revision:

1. The Policy Lead will receive a notification from PolicyManager™ that their Medical Directive is upcoming or overdue.
2. The Policy Lead will download and review the current document for changes.
3. The Policy Lead will present their Medical Directive for collaborative review. A collaborative review contains the programs interdisciplinary team, including, but not limited to:
    a. Program Manager(s)
    b. Program Director or AVP
    c. Nurse Educator(s)

d. Professional Practice Leaders (Interprofessional)
e. Program Leads
f. Program Physician Chief/Medical Director

4. The Policy Lead will present their Medical Directive for stakeholder review (if applicable). A stakeholder review contains representatives from other areas within the Hospital that the Medical Directive or Procedure affects.
5. The Policy Lead will provide the completed document to the Policy Associate to put into "Full Edit" or "Project Mode" in PolicyManager™.
6. The Medical Directive or Clinical Protocol will flow through the workflow approvals within PolicyManager™:
    a. Policy Associate Review
    b. Program Director Approval
        i. Corporate directives: All program directors that the document affects.
        ii. Departmental directives: Only 1 program director required.
    c. Professional Practice Review
        i. If changes are identified by the Professional Practice team, they will add a comment in PolicyManager™ and communicate with the Policy Lead via email regarding changes to be addressed.
        ii. The Policy Lead will review the changes from the Professional Practice team and update as necessary.
        iii. The Policy Lead will re-upload their updated document to PolicyManager™ and advise the Professional Practice Lead that they may review and approve via PolicyManager™.
    d. The Policy Lead will obtain program physician sign off.
        i. This task is to be completed offline via email.
        ii. The Policy Lead will re-upload the updated document to PolicyManager™, as needed.
            - **Corporate directives:** All department Chiefs must sign off electronically. (10 Chiefs total).
                - **For adult only directives:** All physician Chiefs minus Chief of Paediatrics.
            - **Departmental directives:** The department Chief and all department physicians must sign off.
    e. CNE/EVP/COO & Director of Professional Practice approval.
    f. Pharmacy & Therapeutics Committee review
        i. Applicable only if the document contains medication and oxygen components.
    g. Electronic Orders Committee (EOC), MyLearning & tentative go-live review
        i. The Policy Lead will communicate with EOC representative of any updates and/or new build required to the electronic medical directive order set in EMR.

- If there are no changes to the order set, the EOC must be made aware as an FYI.
- If there are changes to the order set, approval from the EOC must be added to the PolicyManager™ workflow.

ii. The Policy Lead will communicate with the MyLearning representative of and updates and/or new build required for the MyLearning Module associated with the Medical Directive.

iii. The Policy Lead will collaborate with EOC representative, MyLearning representative, Professional Practice and the Policy Associate to determine a tentative go-Live date.

iv. The Policy Lead will complete this task once all groups have been engaged.

h. Medical Advisory Committee (MAC) review

i. The Policy Lead will provide a short summary of changes to the Policy Associate along with confirmation that the Physician Chief is aware and able to present at the next MAC meeting.

7. Go-Live & communication
   a. The Policy Associate will confirm if EOC/MyLearn is complete and publish the document to PolicyManager™.
   b. MyLearn module will be uploaded.
   c. EPIC go-live.
   d. The Policy Lead will communicate to all staff affected of the revision/ net-new document.

If changes or feedback are identified, the reviewer/approver must communicate to the Policy Lead and await confirmation that the feedback has been addressed before proceeding to "approve" or "complete task" in PolicyManager™. The reviewer/approver should NOT "reject" the document.

Archival of a Policy and Procedure: When archiving a Medical Directive or Clinical Protocol the Policy Lead will refer to the Development & Approval of a Policy & Procedure, Procedure C. Archival of a Policy and Procedure.

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APPENDICES:

APPENDIX A: Controlled Acts under RHPA

Controlled acts are activities that are considered to be potentially harmful if performed by unqualified persons. The 14 controlled acts established in the *Regulated Health Professionals Act* are:

1. Communicating to the individual or his/her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his/her personal representative will rely on the diagnosis.
2. Performing a procedure on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, or in or below the surfaces of the teeth, including the scaling of teeth.
3. Setting or casting a fracture of a bone or dislocation of a joint.
4. Moving the joints of the spine beyond the individual's usual physiological range of motion using a fast, low amplitude thrust.
5. Administering a substance by injection or inhalation.
6. Putting an instrument, hand or finger:
    i. beyond the external ear canal,
    ii. beyond the point in the nasal passages where they normally narrow,
    iii. beyond the larynx,
    iv. beyond the opening of the urethra,
    v. beyond the labia majora,
    vi. beyond the anal verge, or
    vii. into an artificial opening into the body.

7. Applying or ordering the application of a form of energy prescribed by the regulations under this Act.
8. Prescribing, dispensing, selling, or compounding a drug as defined in the Drug and Pharmacies Regulation Act or supervising the part of a pharmacy where such drugs are kept.
9. Prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eyeglasses other than simple magnifiers.
10. Prescribing a hearing aid for a hearing-impaired person.
11. Fitting or dispensing a dental prosthesis, orthodontic or periodontal appliance or a device used inside the mouth to protect teeth from abnormal functioning.
12. Managing labor or conducting the delivery of a baby.
13. Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.
14. Treating, by means of psychotherapy technique, delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception, or memory that may seriously impair the individual's judgment, insight, behaviour, communication, or social functioning.
15. Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.

APPENDIX B: Workflows & Blank Templates

Medical Directive

- Medical Directive Workflow
- Medical Directive Blank Template

Clinical Procedure: Refer to the appropriate policy workflow.

- Clinical – ELT Final Approval Workflow
- Clinical – MAC Final Approval Workflow
- Departmental Policy Workflow
- Policy & Procedure Blank Template

Policy Archival

- Policy & Medical Directive Archival Workflow
- Policy & Medical Directive Archival Form

VERSION HISTORY:

Review:	03/2019; 10/2023
Revision:	12/2017; 11/2021; 04/2024