COURT FILE NUMBER	2103 14553
COURT	COURT OF QUEEN'S BENCH OF ALBERTA
JUDICIAL CENTRE	EDMONTON
APPLICANT	DAVID THOMAS DICKSON
RESPONDENT	HER MAJESTY THE QUEEN IN RIGHT OF THE PROVINCE OF ALBERTA
DOCUMENT	**AFFIDAVIT OF CHAD MITCHELL**
ADDRESS FOR SERVICE AND CONTACT INFORMATION OF PARTY FILING THIS DOCUMENT	Alberta Justice and Solicitor General Civil Litigation 9th Floor, Peace Hills Trust Tower 10011-109 Street Edmonton, Alberta T5J 3S8 Attention: Redacted

Clerk's Stamp

File No: 7880-1 (LIT-12049)

AFFIDAVIT OF CHAD MITCHELL

Sworn on October 29, 2021

I, Chad Mitchell, of the City of Edmonton, Alberta, MAKE OATH AND SWEAR THAT:

1. I am the Assistant Deputy Minister of the Pharmaceutical and Supplementary Benefits Division of the Ministry of Health ("**Alberta Health**") in the Government of Alberta. As such, I have personal knowledge of the facts and matters in this Affidavit, except those made on information and belief, in which case I believe them to be true.

2. Attached to my affidavit as **Exhibit "A"** is Alberta Health Directive D1-2021, signed January 7, 2021 by Dr. Deena Hinshaw, Alberta's Chief Medical Officer of Health appointed under the *Public Health Act*, RSA 2000, c P-37 (the "**CMOH**").

3. Attached to my affidavit as **Exhibit "B"** is Alberta Health Directive D5-2021, signed February 24, 2021 by the CMOH.

4. Pursuant to Schedule 7.1 of the *Government Organization Act* and the regulations under the *Health Professions Act*, Certified Graduate Nurses, Critical/Advanced Care Paramedics, Dentists, Licensed Practical Nurses, Pharmacists, Midwives, Nurse Practitioners, Physicians, Podiatrists, Registered Psychiatric Nurses and Registered Nurses are authorized to administer a vaccine in Alberta.

5. Attached to my affidavit as **Exhibit "C"** is AHS Policy Document #PRR-01 "Consent to Treatment/Procedure(s)", retrieved from the AHS website on October 28, 2021.

6. Attached to my affidavit as **Exhibit "D"** is the College of Physicians & Surgeons of Alberta's ("**CPSA**") Informed Consent Standard of Practice, retrieved from the CPSA website on October 28, 2021.

7. Attached to my affidavit as **Exhibit "E"** is an excerpt from the College & Association of Registered Nurses of Alberta ("**CARNA**"), Medication Management Standards, retrieved from the CARNA website on October 28, 2021. CARNA is the regulatory college for Certified Graduate Nurses, Nurse Practitioners and Registered Nurses in Alberta.

8. Attached to my affidavit as **Exhibit "F"** is an excerpt from the Standards of Practice for Pharmacists and Pharmacy Technicians respecting informed consent, retrieved from the Alberta College of Pharmacy's website on October 28, 2021.

9. Attached to my affidavit as **Exhibit "G"** is an excerpt from the Standards of Practice for Licensed Practical Nurses on Restricted Activities and Advanced Practice, retrieved from the College of Licensed Practical Nurses of Alberta website on October 28, 2021.

10. Attached to my affidavit as **Exhibit "H"** is an excerpt from the Standard of Practice for dentists respecting informed consent, retrieved from the Alberta Dental Association and College's website on October 28, 2021.

11. Attached to my affidavit as **Exhibit "I"** is an excerpt from the Standards of Practice for paramedics respecting informed consent, retrieved from the Alberta College of Paramedics on October 29, 2021.

12. I make this Affidavit in support of HMQ's Application for an Order striking the Originating Application in this action.

SWORN BEFORE ME at the City of Edmonton, in the Province of Alberta, this 29th day of October, 2021.

Redacted

A Commissioner for Oaths in and for Alberta

Redacted

CHAD MITCHELL

Redacted

This is Exhibit "A" referred to in the
Affidavit of
CHAD MITCHELL

Sworn before me this 29th day
of OCTOBER A.D., 2021

Redacted

A Commissi and for
Alberta

Redacted

Alberta Health

	Directive: D1-2021
Direction to Seek Further Assistance from Regulated Health Practitioners with COVID-19 Immunization	**Effective Date:** December 14, 2020
	Issuer: Chief Medical Officer of Health

TO: Alberta Health Services and All Medical Officers of Health

Whereas pursuant to section 14(1)(d) of the *Public Health Act* (Act), I, Dr. Deena Hinshaw, Chief Medical Officer of Health, have the authority to give directions to the regional health authority, medical officers of health and executive officers in the exercise of their powers and the carrying out of their responsibilities under the Act;

Whereas the Lieutenant Governor in Council made Order in Council 354/2020 under section 52.1(1) of the Act on November 24, 2020 declaring a second state of public health emergency in Alberta due to pandemic COVID-19 and the significant likelihood of pandemic influenza;

Whereas section 7 of the *Communicable Diseases Regulation* (the Regulation) authorizes a medical officer of health, in exercising their powers and carrying out their duties under the Act and the Regulation, to use the assistance of community health nurses and executive officers;

Whereas there is an ongoing need to ensure other qualified persons are available to assist medical officers of health in exercising certain powers and carrying out certain duties under the Act and the Regulation, particularly any powers and duties directly related to COVID-19 immunization;

Therefore, in accordance with section 14(1)(d) of the Act, I hereby give the following directions to Alberta Health Services and all medical officers of health:

1. To employ or engage a sufficient number of regulated health practitioners under the *Health Professions Act*, who are authorized and have the knowledge, skill and competence to administer a vaccine, to assist medical officers of health in exercising their powers and carrying out their duties under the Act and the Regulation with regards to COVID-19 immunization.

2. To ensure that any regulated health practitioners employed or engaged by Alberta Health Services for the purposes of section 1 are trained to administer vaccines in accordance with the relevant provisions of Alberta Health Services' Immunization Program Standards Manual, Alberta Health's Immunization Policy and any other guidance documents issued by Alberta Health Services pertaining to COVID-19 immunizations as well as the *Immunization Regulation* before such individuals are able to assist medical officers of health with the immunization of persons listed in section 1.

3. To remind medical officers of health that they are still responsible for properly exercising their powers and carrying out their duties with regards to carrying out Alberta Health's COVID-19 immunization program despite the assistance of any regulated health practitioners employed or engaged by Alberta Health Services under section 1.

4. To, upon receiving a request from the Chief Medical Officer of Health, provide the Chief Medical Officer of Health, in the form and manner, and within the time specified, any information the Chief Medical Officer of Health may request regarding the implementation of, and any other matter related to, this Directive.

5. This Directive remains in effect until rescinded by the Chief Medical Officer of Health.

Signed at the City of Edmonton, in the Province of Alberta, on this 7 day of January, 2021.

Deena Hinshaw, BSc, MD, MPH, CCFP, FRCPC
Chief Medical Officer of Health
Alberta Health

This is Exhibit "B" referred to in the
Affidavit of
CHAD MITCHELL
Sworn before me this 29th day
of OCTOBER A.D., 20 21
Redacted
A Commissi id for
Alberta

Redacted

Alberta Health

Direction to Seek Further Assistance from Regulated and Other Authorized or Permitted Health Practitioners with COVID-19 Immunization	**Directive: D5-2021** **Effective Date:** February 24, 2021 **Issuer:** Chief Medical Officer of Health

TO: Alberta Health Services and All Medical Officers of Health

Whereas pursuant to section 14(1)(d) of the *Public Health Act* (Act), I, Dr. Deena Hinshaw, Chief Medical Officer of Health, have the authority to give directions to the regional health authority, medical officers of health and executive officers in the exercise of their powers and the carrying out of their responsibilities under the Act;

Whereas the Lieutenant Governor in Council made Order in Council 354/2020 under section 52.1(1) of the Act on November 24, 2020 declaring a second state of public health emergency in Alberta due to pandemic COVID-19 and the significant likelihood of pandemic influenza;

Whereas section 7 of the *Communicable Diseases Regulation* (the Regulation) authorizes a medical officer of health, in exercising their powers and carrying out their duties under the Act and the Regulation, to use the assistance of community health nurses and executive officers;

Whereas CMOH Directive D1-2021 directed Alberta Health Services and all medical officers of health to employ or engage a sufficient number of regulated health practitioners under the *Health Professions Act* to assist with COVID-19 immunization;

Whereas COVID-19 continues to pose a significant risk to the public health despite the lapsing of Order in Council 354/2020;

Whereas there is an ongoing need to ensure additional qualified persons are available to assist medical officers of health in exercising certain powers and carrying out certain duties under the Act and the Regulation, particularly any powers and duties directly related to COVID-19 immunization;

Therefore, in accordance with section 14(1)(d) of the Act, I hereby give the following directions to Alberta Health Services and all medical officers of health:

1. To employ or engage a sufficient number of regulated or other health practitioners, including graduate and student nurses, who are authorized or permitted under the *Health Professions Act* and who have the knowledge, skill and competence to administer a vaccine, to assist medical officers of health in exercising their powers and carrying out their duties under the Act and the Regulation with regards to COVID-19 immunization.

2. To ensure that any regulated or other authorized or permitted health practitioners, employed or engaged by Alberta Health Services for the purposes of section 1, are trained to administer vaccines in accordance with the relevant provisions of Alberta Health Services' Immunization Program Standards Manual, Alberta Health's Immunization Policy and any other guidance documents issued by Alberta Health Services pertaining to COVID-19 immunizations, as well as the *Immunization Regulation*, before such individuals are able to assist medical officers of health with COVID-19 immunization.

3. To ensure that any regulated or other authorized or permitted health practitioners, including graduate and student nurses, administer vaccines in accordance with any applicable supervision requirements under the *Health Professions Act*, regulations and any other conditions or requirements imposed by the college or regulatory organization of the health practitioner.

4. To remind medical officers of health that they are still responsible for properly exercising their powers and carrying out their duties with regards to carrying out Alberta Health's COVID-19 immunization program despite the assistance of any regulated or other authorized or permitted health practitioners employed or engaged by Alberta Health Services under section 1.

5. To, upon receiving a request from the Chief Medical Officer of Health, provide the Chief Medical Officer of Health, in the form and manner, and within the time specified, any information the Chief Medical Officer of Health may request regarding the implementation of, and any other matter related to, this Directive.

6. Directive D1-2021 is rescinded.

7. This Directive remains in effect until rescinded by the Chief Medical Officer of Health.

Signed at the City of Edmonton, in the Province of Alberta, on this 24 day of February, 2021.

Deena Hinshaw, BSc, MD, MPH, CCFP, FRCPC
Chief Medical Officer of Health
Alberta Health

This is Exhibit "C" referred to in the
Affidavit of
CHAD MITCHELL
Sworn before me this 29th day
of OCTOBER A.D., 2021
Redacted
A Commiss and for
Alberta

Redacted

Alberta Health Services

POLICY

TITLE
CONSENT TO TREATMENT/PROCEDURE(S)

SCOPE
Provincial

DOCUMENT #
PRR-01

APPROVAL AUTHORITY
Executive Leadership Team

INITIAL EFFECTIVE DATE
October 31, 2010

SPONSOR
Vice President, Health Professions & Practice;
Associate Chief Medical Officer, Quality & Medical Affairs

REVISION EFFECTIVE DATE
January 16, 2020

PARENT DOCUMENT TITLE, TYPE AND NUMBER
Not applicable

SCHEDULED REVIEW DATE
January 16, 2023

NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

If you have any questions or comments regarding the information in this document, please contact the Policy & Forms Department at policy@ahs.ca. The Policy & Forms website is the official source of current approved policies, procedures, directives, standards, protocols and guidelines.

OBJECTIVES

- To facilitate an **informed consent process** within Alberta Health Services (AHS) that reflects good practice, contributes to **patient** safety, and enhances the patient experience.
- To facilitate a fair, respectful process for **informed consent** that is achieved consistently across all care areas within AHS.
- To facilitate compliance with applicable law.

PRINCIPLES

The principle of respect for persons is foundational within this policy and demonstrated by patients being supported in determining what happens to their own bodies, in keeping with their own values and beliefs. Where patients cannot make their own decisions, respect for persons is upheld by recognizing the decision-making role of an appropriate **alternate decision-maker**.

Informed consent:

- requires **capacity**;
- shall be informed;
- shall be specific;
- shall be voluntary;
- requires understanding; and

- shall be documented.

On an exceptional basis, patient-informed consent decisions can be overridden in accordance with legislation such as the *Mental Health Act* and the *Public Health Act*.

The **most responsible health practitioner (MRHP)** providing the **treatment/procedure(s)** to a patient has a duty to obtain informed consent.

AHS is committed to providing continuing education for all personnel to implement this policy and the subsequent procedures.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, Students, Volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Informed Consent is Required

1.1 Before providing a specific treatment/procedure(s) or plan of treatment/procedure(s), the MRHP shall obtain **express informed consent** or **implied informed consent** from the patient, unless a valid exception to informed consent applies (see Section 5 below).

1.2 The MRHP is responsible for determining the most appropriate method of obtaining informed consent (express or implied).

1.3 All consent, whether express or implied, shall be informed.

1.4 Implied informed consent may be presumed in (but is not limited to) circumstances where the patient presents voluntarily for an examination, investigation, or minor or less invasive treatment/procedure(s) which the MRHP determines does not require express informed consent.

a) The MRHP shall be satisfied that the circumstances or the actions of the patient imply permission for the examinations, investigations, and treatment/procedure(s) proposed.

b) If there is any doubt that there is implied informed consent, the MRHP shall obtain express informed consent from the patient.

c) Implied informed consent is encouraged to be documented by the MRHP in the patient's **health record**.

1.5 When the MRHP determines that express informed consent is required to evidence the patient's informed consent to the treatment/procedure(s):

a) verbal consent shall be documented by the MRHP in the patient's health record; or

b) written (signed) consent shall be documented by the MRHP through obtaining the signature of the patient on the applicable **consent form** (see Section 1.7 below), which shall then be attached to the patient's health record. Where a consent form is used, documentation in the patient's health record regarding the informed consent discussion is also recommended.

1.6 Notwithstanding Section 1.2 above, written (signed) consent shall be obtained for:

a) the transfusion of blood and blood products;

b) surgery;

c) invasive investigative procedures;

d) human tissue and organ donation; and

e) medical assistance in dying, consistent with the AHS *Medical Assistance in Dying* Policy.

1.7 The following consent forms shall be used in the following situations or any other treatment/procedure(s) for which the MRHP deems written (signed) consent to be appropriate:

a) The AHS *Consent to Surgery or Invasive Procedure* Form should be used for all surgical or invasive procedures including endoscopy or cardiac catheterization. This form includes sections about possible transfusion and testing for blood-borne viruses in the event of needle-stick injuries or body fluid splashes as well as for the retention of tissue and the involvement of trainees.

b) The AHS *Consent to Treatment Plan/Intervention or Procedure* Form should be used for lesser or non-invasive procedures or treatment plans and interventions that are deemed to reach the threshold of requiring written (signed) consent such as a bedside procedure or blood product transfusion.

c) The AHS *Emergency Health Care: Documentation of Exception to Consent* Form should be used in situations where it is deemed that a procedure, which would otherwise require written (signed) consent, is occurring in an emergency situation where it is not possible to do so.

1.8 Informed consent may be obtained in the MRHP's community office rather than at the applicable **Alberta Health Services (AHS) setting** where the patient will be receiving the treatment/procedure(s). Any completed consent forms shall then

be forwarded to the applicable AHS setting where the patient will be receiving the treatment/procedure(s).

2. Accountability

2.1 The accountability to obtain informed consent shall rest with the MRHP who is providing the specific treatment/procedure(s).

2.2 The MRHP remains accountable for the informed consent process when one (1) or more than one (1) **health care provider** is involved in providing the treatment/procedure(s).

2.3 The MRHP is responsible for confirming the validity of informed consent prior to the delivery of the treatment/procedure(s).

2.4 For programs that offer multiple treatment/procedure(s), each MRHP is accountable for the informed consent process related to the treatment/procedure(s) they are providing.

3. Required Components of Informed Consent

3.1 Capacity:

a) The MRHP is responsible to conduct initial assessment of the patient for determination of capacity to make treatment and care decisions.

(i) Where the MRHP cannot complete an assessment of the patient for the determination of capacity to make treatment decisions, the MRHP shall ensure assessment of the patient's capacity by an appropriate clinical expert (refer to list of approved capacity assessors).

b) An **adult** patient is presumed to have capacity to make treatment/procedure(s) decisions unless the patient is determined to lack capacity.

(i) When an adult patient lacks capacity to consent to a treatment/procedure(s), the authority of a co-decision-maker or an alternate decision-maker shall be recognized in accordance with the AHS *Consent to Treatment/Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity* Procedure.

(ii) Capacity for a **minor** patient shall be determined in accordance with the AHS *Consent to Treatment/Procedure(s): Minors / Mature Minors* Procedure.

c) The MRHP shall be satisfied that the patient has the capacity to make each treatment/procedure(s) decision.

(i) If a patient is considered to have capacity and consents to the proposed treatment/procedure(s), they may be treated.

(ii) A patient's capacity can change depending on changes to their mental and physical health.

(iii) The determination of capacity shall relate to each specific treatment/procedure(s) or plan of treatment/procedure(s).

(iv) Informed consent shall be obtained prior to the administration of any medication that may significantly affect the patient's capacity to make an informed decision (i.e., analgesic, narcotic, or anaesthetic).

(v) A patient may have capacity even if they are unable to communicate verbally. Communication with the patient shall be facilitated by any means that enables understanding (see Section 3.5 below).

(vi) The patient's choice to make decisions based on their values and beliefs shall be supported, subject to exceptions (see Section 5 below).

3.2 Informed:

a) The MRHP shall ensure all necessary information has been provided to the patient so that the patient can make an informed decision about the treatment/procedure(s). Necessary information shall include but is not limited to:

(i) the condition for which the treatment/procedure(s) is proposed;

(ii) the treatment/procedure(s) plans/interventions and/or list of agreed upon treatment/procedure(s), that are clinically indicated and approved for the condition;

(iii) the potential risks and benefits of the proposed treatment/procedure(s);

(iv) information applicable to the patient's particular circumstances or as specifically requested by the patient;

- If the patient alerts the MRHP of particular circumstances that might affect the information the patient would want for their treatment/procedure(s), the MRHP shall be responsible for addressing those particular circumstances with further information as requested by the patient.

(v) alternatives to the proposed treatment/procedure(s);

(vi) the potential consequences of both providing consent or refusing to provide consent for the proposed treatment/procedure(s); and

(vii) who will perform the treatment/procedure(s) and who may provide assistance, including whether the treatment/procedure(s) will include health care providers in training (i.e., residents, students).

3.3 Specific:

a) The provision of informed consent shall relate to each specific treatment/procedure(s) or a plan of treatment/procedure(s).

b) Treatment/procedure(s) that:

(i) are in addition to the treatment/procedure(s) already consented to;

(ii) are different from the treatment/procedure(s) consented to;

(iii) were unanticipated at the time informed consent was obtained;

(iv) may be convenient to do; or

(v) may be beneficial to the patient,

shall not be performed without obtaining further informed consent, unless a valid exception to informed consent applies (see Section 5 below).

c) New informed consent shall be obtained when one (1) or more of the following occurs:

(i) the patient's condition has materially changed;

(ii) the medical knowledge about the patient's condition or the treatment/procedure(s) available has materially changed;

(iii) when the treatment/procedure(s) for the patient changes;

(iv) the previously given consent and/or any portion of the previously given consent has been withdrawn (see Section 4 below); and

(v) the patient has refused the involvement of particular individuals in their treatment/procedures(s) (i.e., medical students).

d) If the previous informed consent was evidenced using a consent form, then the new or subsequent informed consent should also be evidenced using a consent form.

3.4 Voluntary:

a) The patient shall have the opportunity, without undue influence, to accept or refuse a treatment/procedure(s).

b) As time permits in the clinical circumstance, informed consent discussions shall occur when the patient has a reasonable opportunity to reflect on the decision and ask questions.

c) When appropriate to do so, informed consent discussions should not take place in the operating room or the operating room environment.

d) The patient shall be given an opportunity to take the time required to reflect on the information and to consult with whom they choose prior to making a decision.

e) A patient's decision to accept or refuse a treatment/procedure(s) shall not prejudice their access to ongoing or future health care.

3.5 Understanding:

a) The MRHP accountable for the informed consent process shall:

(i) provide the patient with the opportunity to ask questions;

(ii) provide responses to the questions asked by the patient; and

(iii) ensure the patient has understood the information sufficiently to proceed with the informed consent discussion.

b) The informed consent discussion is a shared process between the patient and the MRHP, resulting in the patient's decision to accept or refuse the proposed treatment/procedure(s).

c) The MRHP shall communicate with the patient in a manner that supports the patient's ability to understand and shall address all communication barriers including, but not limited to:

(i) hearing;

(ii) sight;

(iii) language;

(iv) culture;

(v) literacy;

(vi) level of education;

(vii) level of anxiety and stress; and

(viii) environmental factors, including location of discussion.

d) If the patient is having difficulty understanding the discussion or reading and completing the consent form (if applicable), the discussion and contents of the consent form shall be read and explained to the patient in the presence of a witness and with the assistance of an interpreter, as necessary. Documentation of this process is recommended. The MRHP may allow, at the patient's request, their **family** to accompany the patient and offer their assistance to help the patient to understand or demonstrate an understanding of the information provided.

4. Refusal of Treatment/Procedure(s) and Withdrawal of Informed Consent

4.1 Subject to situations in which a treatment/procedure(s) is ordered in accordance with applicable legislation, an adult patient with capacity to consent to a treatment/procedure(s) may at any time:

a) refuse to consent to all or a portion of a proposed treatment/procedure(s); or

b) withdraw previously given informed consent to any or all of the treatment/procedure(s) at any time prior to or during the treatment/procedure(s).

4.2 Subject to situations in which a treatment/procedure(s) is ordered in accordance with applicable legislation, an adult patient with capacity may refuse to consent to a treatment/procedure(s) or withdraw informed consent on any grounds prior to the start of the treatment/procedure(s), even when it is clear that the treatment/procedure(s) is necessary to preserve their life or health. In such an instance, the treatment/procedure(s) shall not be carried out, even if failure to provide such a treatment/procedure(s) may result in the patient's death.

a) The alternate decision-maker for an adult patient lacking capacity may refuse a treatment/procedure(s) or withdraw previously given informed consent in accordance with the AHS *Consent to Treatment/Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity* Procedure.

b) A **mature minor** or a minor's **legal representative** may refuse a treatment/procedure(s) or withdraw previously given informed consent in accordance with the AHS *Consent to Treatment/Procedure(s): Minors / Mature Minors* Procedure.

4.3 After a treatment/procedure(s) has been commenced, the MRHP shall stop providing the treatment/procedure(s) immediately upon the withdrawal of the informed consent and shall revisit the informed consent process with new or additional information that should be shared with the patient.

a) If the termination of the treatment/procedure(s) will result in immediate and serious risk to the patient, the MRHP may be required to continue with the originally consented to treatment/procedure(s) to the extent required to limit the immediate and serious risk to the patient.

4.4 Where a patient refuses to consent to a treatment/procedure(s) or withdraws previously given informed consent, the MRHP shall explain the potential risks and consequences of the refusal or withdrawal of informed consent, without undue influence.

a) This explanation can be witnessed by a second **health care professional** to confirm patient identity and confirm the discussion occurred.

b) The MRHP shall document on the patient's health record:

(i) the refusal or withdrawal of informed consent;

(ii) the circumstances of the refusal, including the patient's reasons for withdrawing informed consent or refusing the treatment/procedure(s);

(iii) a summary of the discussion with the patient about the patient's clinical condition, the planned treatment/procedure(s) or interventions, the expected outcomes, material risks, and potential consequences of withdrawing informed consent or refusing the treatment/procedure(s);

(iv) the outcome of the discussion;

(v) the presence of witnesses, if any; and

(vi) where written (signed) informed consent was previously given, withdrawal of consent shall be documented in the 'withdrawal' section of the consent form.

4.5 The patient may provide informed consent again at any time following a subsequent informed consent discussion.

4.6 Adult patients who carry written and signed statements refusing the infusion of blood products shall have their wishes respected. This includes situations where the patient presents to an AHS setting for emergency health care.

5. Exceptions to Informed Consent

5.1 Emergency Health Care Exception:

a) For adult patients:

(i) If an adult patient requires emergency treatment/procedure(s) but the adult lacks the capacity to provide informed consent or refuses informed consent due to altered consciousness from trauma, drugs, alcohol, or any other cause, or where informed consent cannot be immediately obtained from the adult's alternate decision-maker, emergency health care may be provided by a MRHP:

- only where it is immediately necessary to preserve the patient's life, prevent serious physical or mental harm to the patient, or to alleviate serious pain; and
- where there is no knowledge that the patient would have objected to the treatment/procedure(s).
- If a Physician is not available, a Nurse Practitioner or Registered Nurse may initiate emergency health care as per their scope of practice.

(ii) The MRHP shall document that an emergency situation exists by completing the relevant section of the AHS *Emergency Health Care: Documentation of Exception to Consent* Form. In all possible situations, a second Physician or MRHP shall confirm the existence of the emergency situation, although it is recognized that in rural settings there may not always be a second Physician available.

- If a second Physician is not available, a Nurse Practitioner or Registered Nurse may confirm the existence of the emergency situation and document the same on the AHS *Emergency Health Care: Documentation of Exception to Consent* Form.
- Resident Physicians are not permitted to provide a written opinion to confirm the criteria for emergency health care.

(iii) The details of the emergency situation and all treatment/procedure(s) decisions shall be documented in the patient's health record. All reasonable efforts shall be made to contact the patient's alternate decision-maker or next of kin, as appropriate, to advise that emergency treatment/procedure(s) was provided.

(iv) The Emergency Health Care Exception is only valid during the emergency situation. All future treatment/procedure(s) provided outside of the emergency situation shall require informed consent.

b) For minor patients:

(i) The applicability of the Emergency Health Care Exception for a minor patient shall be determined in accordance with the AHS *Consent to Treatment/Procedure(s): Minors / Mature Minors* Procedure.

5.2 Exceptional Circumstances:

a) The requirement for informed consent may be overridden by a warrant, subpoena, court order, or applicable legislation (e.g., a review panel's treatment order under the *Mental Health Act*, orders under the *Public Health Act*, orders under the *Mandatory Testing and Disclosure Act*, etc.).

6. Documentation

6.1 The MRHP is responsible for ensuring appropriate documentation of the informed consent process and outcomes in the patient's health record. Specifically, the following outcomes shall be documented:

a) agreement with informed consent to the treatment/procedure(s);

b) refusal of the treatment/procedure(s) (refer to Section 4 above); and

c) withdrawal of consent previously given (refer to Section 4 above).

6.2 All relevant legal documents including, but not limited to, court orders, warrants, subpoenas, **personal directives**, capacity assessments, and evidence of the formal status of alternate decision-makers, shall be documented on the patient's health record.

6.3 While the requirements for documentation outlined in Section 6.1 above are met by appropriately filling in the applicable consent form where written (signed) consent has been deemed necessary, documentation in the patient's health record regarding the consent discussion is recommended.

6.4 Completed consent forms required for treatment/procedure(s) may be faxed or scanned (refer to the AHS *Transmission of Information by Facsimile or Electronic Mail* Policy). When possible, and at the earliest opportunity, the original consent form shall be obtained and placed on the patient's health record.

6.5 When an interpreter is used to assist in obtaining consent, the interpreter shall complete the relevant documentation on the consent form.

a) The MRHP shall follow up to ensure the consent form has been completed as required.

6.6 A blind or disabled person's 'mark' is recognized as a valid signature on the consent form.

6.7 Witness documentation of informed consent:

a) A written (signed) consent form should be witnessed.

b) Any person, other than a relative of the patient, the MRHP, or the interpreter for the patient, may witness the signing of a consent form.

(i) Before acting as a witness or signing the consent form as a witness, confirmation of the patient's identity by the witness shall be required.

(ii) If the signee is not the patient, the witness shall request to see a form of the signee's identification and confirm that the person making a mark on behalf of the patient has been asked to do so by the patient.

c) Witnessing a consent form indicates only that the witness observed the consent form being signed and is not evidence of the consent process.

d) In the event that the patient expresses doubt about the consent process and/or requests further explanation, the witness shall not sign the consent form and the MRHP shall be notified.

DEFINITIONS

Adult means a person aged 18 years and older.

Agent means the person(s) named in a personal directive who can make decisions on personal matters according to the wishes expressed by the patient.

Alberta Health Services (AHS) setting means any environment where treatment/procedures and other health services are delivered by, on behalf of or in conjunction with, Alberta Health Services.

Alternate decision-maker means a person who is authorized to make decisions with or on behalf of the patient. These may include, specific decision-maker, a minor's legal representative, a guardian, a 'nearest relative' in accordance with the *Mental Health Act* (Alberta) or an agent in accordance with a personal directive or a person designated in accordance with the *Human Tissue and Organ Donation Act* (Alberta). This also includes what was previously known as the substitute decision-maker.

Capacity means the ability for the patient to 1) understand the nature, risks, and benefits of the procedure and the consequences of consenting or refusing; and 2) understand that this explanation applies to them.

Consent form means an Alberta Health Services approved form of documentation that can be used to provide evidence of the outcome of the consent process, that is, agreement to or refusal of a treatment/procedure.

Express informed consent means direct, explicit agreement to undergo treatment/procedure(s), given either verbally or in writing (signed).

Family means one or more individuals identified by the patient as an important support, and who the patient wishes to be included in any encounters with the health care system, including, but not limited to, family members, legal guardians, friends, and informal caregivers.

Guardian means, where applicable:
For a minor:

a) A guardian as defined by the *Family Law Act* (Alberta), a divorced parent with custody of the minor, or a person appointed pursuant to a will, personal directive, court order, agreement or by authorization of legislation (e.g., *Child, Youth and Family Enhancement Act* [Alberta]).

For an adult:

a) An individual appointed by the Court in accordance with the *Adult Guardianship and Trusteeship Act* (Alberta) to make decisions on behalf of the adult patient when the adult patient lacks capacity.

Health care professional means an individual who is a member of a regulated health discipline, as defined by the *Health Disciplines Act* (Alberta) or the *Health Professions Act* (Alberta), and who practises within scope and role.

Health care provider means any person who provides goods or services to a patient, inclusive of health care professionals, staff, students, volunteers and other persons acting on behalf of or in conjunction with Alberta Health Services.

Health record means the collection of all records documenting individually identifying health information in relation to a single person.

Implied informed consent means consent inferred from the patient's or alternate decision-maker's (if applicable) actions and surrounding circumstances.

Informed consent means the patient's agreement (or alternate decision-maker) to undergo a treatment/procedure after being provided, in a manner the patient can understand, with the relevant information about the nature of the treatment/procedure(s), its benefits, potential risks and alternatives, and the potential consequences of refusal.

Informed consent process means a discussion or series of discussions and interactions that may occur over a period of time between the most responsible health practitioner and patient or their alternate decision-maker (if applicable) including: i) the determination of capacity, as necessary, ii) the provision of relevant information, iii) the verification of understanding, iv) the decision-making and v) documentation of the consent process and outcome.

Legal representative means the following in relation to a minor, as applicable:

a) guardian; or

b) nearest relative as defined in the *Mental Health Act* (Alberta), who has the authority to consent to treatment for a minor formal patient or minor who is subject to a Community Treatment Order.

Mature minor means a person aged less than 18 years, who has been assessed and determined as having the intelligence and maturity to appreciate the nature, risks, benefits, consequences, and alternatives of the proposed treatment/procedure(s), including the ethical, emotional, and physical aspects.

Minor means a person aged less than 18 years.

Most responsible health practitioner (MRHP) means the health practitioner who has responsibility and accountability for the specific treatment/procedure(s) provided to a patient and who is authorized by Alberta Health Services to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.

Patient means all persons, inclusive of residents and clients, who receive or have requested health care or services from Alberta Health Services and its health care providers. Patient also means, where applicable:

a) a co-decision-maker with the person; or
b) an alternate decision-maker on behalf of the person.

Personal directive means a written document in accordance with the requirements of the *Personal Directives Act* (Alberta), in which an adult names an agent(s) or provides instruction regarding their personal decisions, including the provision, refusal, and/or withdrawal of consent to treatments/procedures. A personal directive (or part of) has effect with respect to a personal matter only when the maker lacks capacity with respect to that matter.

Physician means a person licensed in independent practice and in good standing with the College of Physicians and Surgeons of Alberta pursuant to the *Health Professions Act* (Alberta).

Specific Decision-Maker means a nearest relative who may be selected from a hierarchy of relatives to make a specific decision on behalf of the patient according to the *Adult Guardianship and Trusteeship Act.*

Treatment/procedure(s) means a specific assessment, treatment, investigative procedure(s), or series of treatments/procedures planned to manage a clinical condition; these can be presented as a treatment plan/intervention.

REFERENCES

- Alberta Health Services Governance Documents:
  - *Consent to Mental Health Treatment/Procedure(s): Formal Patients and Persons Subject to Community Treatment Orders Under the Mental Health Act* Policy (#PRR-01-04)
  - *Consent to Treatment/Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity* Procedure (#PRR-01-02)
  - *Consent to Treatment/Procedure(s): Deceased Donation of Human Organs and Tissues* Policy (#PRR-01-05)
  - *Consent to Treatment/Procedure(s): Minors / Mature Minors* Procedure (#PRR-01-03)
  - *Medical Assistance in Dying* Policy (#HCS-165-01)
  - *Transmission of Information by Facsimile or Electronic Mail* Policy (#1113)
- Alberta Health Services Forms:
  - *Consent and Declaration for Treatment/Procedure (on Behalf of a Formal Patient or Person Subject to a Community Treatment Order who lacks capacity)* Form (#09565)
  - *Tissue and/or Organ Donation Consent (Human Tissue and Organ Donation Act of Alberta)* Form (#09816)
  - *Consent to Surgery or Invasive Procedure* Form (#18628)
  - *Consent to Treatment Plan/Intervention or Procedure* Form (#09741)
  - *Emergency Health Care: Documentation of Exception to Consent* Form (#18629)
- Non-Alberta Health Services Documents:
  - *Adult Guardianship and Trusteeship Act* (Alberta)
  - *Child, Youth and Family Enhancement Act* (Alberta)
  - *College of Physicians and Surgeons of Alberta: Standards of Practice* (Alberta)
  - *Family Law Act* (Alberta)
  - *Health Information Act* (Alberta)
  - *Health Professions Act* (Alberta)
  - *Human Tissue and Organ Donation Act* (Alberta)
  - *Mandatory Testing and Disclosure Act* (Alberta)
  - *Mental Health Act* (Alberta)
  - *Personal Directives Act* (Alberta)
  - *Protection for Persons in Care Act* (Alberta)
  - *Protection of Children Abusing Drugs Act* (Alberta)
  - *Public Health Act* (Alberta)

VERSION HISTORY

Date	Action Taken
August 01, 2011	Revised
February 27, 2012	Non-substantive change
January 16, 2020	Revised

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COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

STANDARDS OF PRACTICE

Informed Consent

Under Review: No
Issued By: Council: January 1, 2010
Reissued by Council: June 1, 2016

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COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

The ***Standards of Practice*** of the College of Physicians & Surgeons of Alberta ("CPSA") are the **minimum** standards of professional behavior and ethical conduct expected of all regulated members registered in Alberta. Standards of Practice are enforceable under the *Health Professions Act* and will be referenced in the management of complaints and in discipline hearings. CPSA also provides **Advice to the Profession** to support the implementation of the Standards of Practice.

1. A regulated member **must** obtain a patient's informed consent[1] prior to an examination, assessment, treatment or procedure; such consent may be implied, expressed orally or in writing as appropriate.

2. If a patient is under the age of 18 years, a regulated member **must:**

   a. determine whether the patient is a mature minor with the capacity to give informed consent[1]; and

   b. if the patient is not a mature minor, seek informed consent from the patient's legal guardian, in accordance with legislation[1].

3. If an adult patient lacks capacity to give informed consent, a regulated member **must** seek informed consent from the patient's legal guardian or substitute decision maker, in accordance with legislation[1].

4. A regulated member who has reasonable grounds to believe an informed consent decision by a legal guardian or substitute decision maker is not in the best interests of the patient **must** seek legal advice, such as from the Canadian Medical Protective Association, or advice from CPSA.

5. A regulated member obtaining informed consent from a patient, or the patient's legal guardian or substitute decision maker, **must** ensure the decision maker:

   a. is aware of his/her right to withdraw consent at any time;

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[1] See CPSA's Advice to the Profession: Informed Consent for Adults and Informed Consent for Minors.

Terms used in the *Standards of Practice*:

- "Regulated member" means any person who is registered or who is required to be registered as a member of this College. The College regulates physicians, surgeons and osteopaths.
- "Must" refers to a mandatory requirement.
- "May" means that the physician may exercise reasonable discretion.

b. is free of undue influence, duress or coercion in making the consent decision;

c. receives a proper explanation that includes, but is not limited to:

   i. diagnosis reached;

   ii. advised interventions and treatments;

   iii. exact nature and anticipated benefits of the proposed examination, assessment, treatment or procedure;

   iv. common risks and significant risks;

   v. reasonable alternative treatments available, and the associated common risks and significant risks;

   vi. natural history of the condition and the consequences of forgoing treatment; and

d. demonstrates a reasonable understanding of the information provided and the reasonably foreseeable consequences of both a decision and a failure to make a decision.

6. A regulated member who assesses the capacity of a patient to give informed consent **must:**

   a. use accepted capacity assessment processes;

   b. to the extent possible, conduct the capacity assessment at a time and under circumstances in which the patient is likely to be able to demonstrate full capacity; and

   c. inform the patient of the nature and consequences of the capacity assessment.

7. A regulated member obtaining informed consent for a patient to participate in health research **must** comply with CPSA's ***Human Health Research*** standard of practice.

Terms used in the Standards of Practice:

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- "Must" refers to a mandatory requirement.
- "May" means that the physician may exercise reasonable discretion.

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(8) A regulated member **may** delegate responsibility for obtaining informed consent to another healthcare professional only when confident the delegate has the appropriate knowledge, skill and judgment to meet the expectations of this standard.

RELATED STANDARDS OF PRACTICE

- *Code of Ethics & Professionalism*
- *Human Health Research*
- *Medical Assistance in Dying*
- *Responsibility for a Medical Practice*
- *Supervision of Restricted Activities*

COMPANION RESOURCES

- Advice to the Profession: Informed Consent for Adults
- Advice to the Profession: Informed Consent for Minors
- Advice to the Profession: Legislated Reporting & Release of Medical Information
- Office of the Public Guardian's Guide to Capacity Assessment under the Personal Directives Act
- Office of the Public Guardian's Resources for Capacity Assessors
- CMPA's Consent: A guide for Canadian Physicians
- CMPA's Informed consent: Overview and objectives
- CMPA's Informed consent: Why and when do we need consent?

Terms used in the Standards of Practice:

- "Regulated member" means any person who is registered or who is required to be registered as a member of this College. The College regulates physicians, surgeons and osteopaths.
- "Must" refers to a mandatory requirement.
- "May" means that the physician may exercise reasonable discretion.
- "Patient" includes, where applicable, the patient's legal guardian or [illegible]

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Standards

College & Association of
Registered Nurses of Alberta

Medication Management Standards

March 2021

1.29 ***store***, handle, transport, and dispose of medications safely and follow employer requirements;

1.30 ***transcribe*** medication orders completely, accurately and according to employer requirements; and

1.31 assess if the medication is appropriate for the client.

Standard 2: Authority

Regulated members follow current legislation, standards, and policies about medication management.

Criteria

The regulated member must

2.1 only administer Schedule 1 medications when there is a client specific order from an authorized prescriber;

2.2 follow employer requirements when administering medications that do not require an order from an authorized prescriber: Schedule 2, 3, and unscheduled drugs (see Appendix B) and natural health products;

2.3 follow employer requirements for vaccine, biological, blood and blood product administration;

2.4 administer medications only within their competence, scope of practice, and when supported by employer requirements;

2.5 ***compound*** medication according to the ACP's *Standards of Practice for Pharmacists and Pharmacy Technicians* and *Standards for Pharmacy Compounding of Non-Sterile Preparations* (2018), and employer requirements;

2.6 ***dispense*** medication only:

- **a.** following a comprehensive assessment and medication review,
- **b.** when a pharmacist is not available,
- **c.** when there is a medication order,
- **d.** according to employer requirements,
- **e.** based on client need, and
- **f.** when following the ACP's *Standards of Practice for Pharmacists and Pharmacy Technicians* for dispensing;

2.7 in addition to 2.6 when dispensing drug samples:

a) ensure there is a record of the drug dispensed, preferably in the Pharmaceutical Information Network;

b) document any collaborative discussions with authorized prescribers about dispensing the drug sample;

c) ensure dispensing decisions about drug samples are based solely on the client's health and need;

2.8 only accept drug samples as authorized in the *Prescribing Standards for Nurse Practitioners;*

2.9 follow federal legislation and regulations, and employer requirements related to the acquisition, access, counts (including documentation of withdrawals and administration, and discrepancies) of controlled drugs and substances; and

2.10 question policy that does not reflect current evidence and information from reputable organizations.

Standard 3: Knowledge

Regulated members are knowledgeable about the medications they administer and those that their clients are taking, whether prescribed, over-the-counter, or natural health products.

Criteria

The regulated member must

3.1 be knowledgeable about the therapeutic effects and side effects of the medication, its interactions with other medications, and contraindications;

3.2 provide education, and counselling where necessary, to clients and their families about the medications they are taking, including:

a. the reason why it has been ordered,

b. possible side effects,

c. what the medication does,

d. how it works,

e. probability of effectiveness,

f. the risks of not taking it,

g. how the medication will interact with other medications,

h. when and how to seek medical attention, and

i. how to self-administer (e.g. preparation and routes);

3.3 be knowledgeable and competent to administer the medication via the specified route;

3.4 follow employer requirements for use of the ***client's own medication*** and self-administration;

3.5 obtain and document a ***best possible medication history,*** including the client's use of non-prescription and natural health products, as outlined in employer requirements;

3.6 address concerns of ***problematic polypharmacy*** with the client, the inter-professional team and the authorized prescriber or ***most responsible health practitioner***;

3.7 have the knowledge, skill and competence to recommend an appropriate ***over the counter medication*** in accordance with employer requirements;

3.8 evaluate and document the therapeutic effect of the medication;

3.9 assess the client for any adverse reaction to a medication, take immediate action to remedy harm, inform the authorized prescriber and document;

3.10 withhold a medication when it would pose a risk of harm to the client and consult the authorized prescriber immediately or as soon as possible;

3.11 document and sign for the administration of a medication in the medication administration record, including: the client name, medication name, dose, route, site (if applicable), date and time of administration, signature and designation, and other relevant information;

3.12 follow employer requirements for documenting ***medication administration*** when a designated recorder is used in urgent or emergent circumstances;

3.13 prepare medications at time of administration. Medication should not be ***pre-poured***;

3.14 communicate to the authorized prescriber and document when a client refuses a medication (including the reason); and

3.15 document the initiation and completion of medications administered over time (e.g. intravenous medications).

Standard 4: Ethics

Regulated members follow the *Code of Ethics for Registered Nurses* and ethical principles in all aspects of medication management.

Criteria

A regulated member must

4.1 assess the client's understanding of the medication to be taken and obtain ***informed consent*** prior to medication administration; use a ***decision maker*** when the client is unable to provide informed consent as outlined in legislation and in employer requirements;

4.2 not administer any medication without informed consent unless in urgent or emergent circumstances as outlined in employer requirements;

4.3 respect the client's decision and right to refuse a medication where the client has capacity and makes an informed decision;

4.4 follow employer requirements when using ***covert medication administration***;

4.5 incorporate principles of ***harm reduction*** into medication management with respect to a client who has a substance use disorder; and

4.6 interact with the client from a place of ***cultural humility*** and support a ***culturally safe*** environment during medication management.

Glossary

Adverse reaction – A noxious and unintended effect caused by a health product (Health Canada, 2019).

Antimicrobial stewardship – An interdisciplinary activity that promotes appropriate selection, dosing, route and duration of antimicrobial therapy to:

- optimize patient clinical outcomes,
- minimize antibiotic adverse effects/toxicity,
- reduce the selection of certain pathogenic organisms (e.g. Clostridium difficile), and
- reduce or stabilize antimicrobial resistance (Alberta Health Services, 2013).

Authorized prescriber – A health-care professional authorized in Alberta to perform the restricted activity of prescribing a Schedule 1 medication.

Best possible medication history (BPMH) – A medication history created using a systematic process of interviewing the client/family and a review of at least one other reliable source of information to obtain and verify the client's use of prescribed and non-prescribed medication, including natural health products (Institute for Safe Medication Practices (ISMP), 2019; Potter, Astle, Stockert, & Hall, 2019).

Care transition – The points when a patient moves to, or returns from, a particular physical location or contact with a particular health-care professional to ensure safe and effective coordination and continuity of care. This includes between home, hospitals, long term care, out patients, clinics etc. It is more than a clinical handover (World Health Organization, 2016).

Clients – The people, patients or residents who benefit from registered nursing care. A client may be an individual, a family, group, community or population.

Close calls – Also known as near miss; an event, situation, or incident that took place but caught before reaching the client (ISMP, 2009).

Client's own medication – Medications brought into a facility by the client.

Compound – The preparation and mixing of two or more ingredients of which at least one is a medication for the purposes of dispensing a medication, but does not include reconstituting a medication with only water (Government Organization Act, R.S.A. 2000, c. G-10, Sch. 7.1, 1[b]). Compounding a medication is a restricted activity that regulated members are authorized to perform in certain circumstances, e.g. adding a medication to an intravenous solution for administration.

Covert medication administration – The administration of medication to a client without their knowledge or consent, in a disguised or deceptive form, when they lack the capacity to take medicines or to understand the consequences of refusing to take medicines. It requires a complex, multidisciplinary assessment, and employer requirements which are based in sound ethical and legal principles that must be followed (Kelly-Fatemi, 2016).

Cultural humility – A process of openness, self-awareness, being egoless, and incorporating self-reflection and critique after willingly interacting with diverse individuals (Foronda, Baptiste, Reinholdt, & Ousman, 2016).

Culturally safe – An outcome based on respectful engagement free from racism and discrimination so that patient is a powerful player, not a passive receiver, of health care (Yeung, 2016).

Decision-maker – A decision maker may be an alternate decision maker, co-decision maker, or specific decision. The type of decision maker is outlined in employer requirements according to legislation.

Dispense – With respect to drugs, to provide a drug pursuant to a prescription for a person, but does not include the administration of a drug to a person. To dispense, compound, provide for selling or sell a Schedule 1 drug or Schedule 2 drug within the meaning of the Pharmacy and Drug Act (Government of Alberta, 2019); This is a restricted activity that regulated members are authorized to perform.

Electronic medication orders – The use of electronic means to communicate medication orders which are then kept as a part of the client record.

Harm reduction – Policies, programs and practices to reduce the adverse health, social, and economic consequences of legal and illegal psychoactive drugs without necessarily reducing drug consumption (CNA, 2017).

High alert medications – Medications that have an increased risk of harming a client when used in error and require special employer safeguards to reduce the risk of incidents and minimize harm (ISMP, 2018).

Independent Double-Checks – A process where a second health-care professional (HCP) verifies a medication before it is administered to a patient. The result from the first check is not communicated with the HCP performing the second check and the second check must be performed independently (Institute for Safe Medication Practices, 2019).

Intermediary – A person who communicates prescriptions between a prescriber and a pharmacist or pharmacy technician.

Informed consent – The informed agreement of a client or alternate decision maker (if applicable) prior to the client undergoing a treatment or procedure after being provided with the relevant information about the treatment or procedure, its risks, alternatives, and the consequences of refusal (Alberta Health Services, 2011).

Investigational medication – Medication(s) not available in the Canadian market, which are used in human clinical trials to determine their safety and effectiveness

Medication – In this document, *medication* refers to all scheduled drugs, over the counter medication, blood and blood products, biologics, vaccines, and natural health products.

Medication administration – The supplying of a dose of a drug to a person for the purpose of immediate ingestion, application, inhalation, insertion, instillation, or injection (Government of Alberta, 2019).

Medication administration records (MAR) – A list of specific medications based on current prescriber orders and is a permanent part of their health record. The health-care professional, documents immediately after the drug or device is administered. The MAR serves as a legal record of the drugs administered to a client by a health-care professional (Alberta Health Services, 2014).

Medication incident(s) – Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use (ISMP, 2019).

Medication order(s) – A means to communicate a desired treatment or diagnostic test with other health-care professionals and can include medications, devices, laboratory tests, procedures, etc.

Medication reconciliation – The systematic and comprehensive review of all the medications a client is taking (best possible medication history) (ISMP, 2019).

Most responsible health practitioner – The health practitioner responsible and accountable for the specific treatment/procedure(s) provided to a client, and who is authorized to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within their scope of practice (Alberta Health Services, 2016).

Off-label – The use of a medication beyond what Health Canada has reviewed and authorized to be marketed in Canada and as indicated on the product label: i.e. using the medication for an illness or disease other than what it was authorized for. The

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Standards of Practice for Pharmacists and Pharmacy Technicians

Alberta College of Pharmacy

Introduction

These standards are made under the authority of Section 133 of the *Health Professions Act*. They are one component of the law that governs the practice of pharmacy in Alberta.

These standards are part of and must be read in the overall legislative scheme that regulates the practice of pharmacists, the practice of pharmacy technicians and the operation of pharmacies which includes:

- the *Health Professions Act*,
- the Pharmacists and Pharmacy Technicians Profession Regulation,
- the Alberta College of Pharmacy Code of Ethics,
- the *Pharmacy and Drug Act*,
- the Pharmacy and Drug Regulation, and
- the Standards for the Operation of Licensed Pharmacies.

Pharmacists and pharmacy technicians practising in Alberta must know, understand and comply with this overall legislative scheme.

These standards are mandatory. They set out the minimum acceptable standard of practice for pharmacists and pharmacy technicians.

For each standard, there is a basic statement of principle followed by detailed rules set out in the *Application of Standard*. Both the basic statement of principle and the detailed rules are mandatory.

Ensure patient safety when administering a drug, blood product or vaccine

STANDARD 17:

A pharmacist who administers a drug, blood product or vaccine must have proper regard for the interests of the patient and take all steps necessary to ensure that the drug, blood product or vaccine is administered safely.

APPLICATION OF STANDARD 17

Steps required for the safe administration of a drug, blood product or vaccine

17.1 A pharmacist who administers a drug, blood product or vaccine to a patient must:

a) obtain informed consent from the patient;

b) be satisfied that there has been compliance with Standard 6 in relation to the appropriateness of the drug, blood product or vaccine that will be administered;

c) take appropriate steps to ensure the patient is given the right drug, blood product or vaccine, for the right reason, in the right dose, at the right time, using the right route.

17.2 In addition to the requirements in Standard 17.1, a pharmacist who is authorized to administer drugs by injection who administers an injection to a patient must:

a) ensure that:

i. there is ready access to drugs and health care products, aids and devices used to treat reactions to injectable drugs, blood products and vaccines; and

ii. the pharmacist is trained to administer the drugs and use the health care products, aids and devices used to treat reactions to injectable drugs, blood products and vaccines, and to manage reactions to injectable drugs, blood products, and vaccines;

b) be satisfied that the drug, blood product or vaccine to be administered:

i. has been prepared for administration using aseptic technique,

ii. is stable, and

iii. has been stored and labeled appropriately prior to and following reconstitution or mixing,

c) observe routine precautions for infection control; and

d) use aseptic technique.

Routine precautions for infection control defined

17.3 For the purpose of Standard 17(2)(c), routine precautions for infection control include precautions to help prevent the spread of infection, including but not limited to:

a) handling all body fluids and tissues as if they were infectious, regardless of the patient's diagnosis;

b) washing hands before and after caring for the patient, and after removing gloves; and

c) wearing gloves when required to prevent contact with body fluids, excretions or contaminated surfaces or objects.

Steps required after administration

17.4 Following the administration of a drug, blood product or vaccine, a pharmacist must:

a) ensure the patient is appropriately monitored;

b) respond appropriately to complications of therapy if they arise;

c) ensure devices, equipment and any remaining drug, blood product or vaccine is disposed of safely and appropriately;

d) document the administration in the patient record as required in Standard 18 and Appendix A; and

e) provide relevant information to other regulated health professionals and provincial health agencies as appropriate.

No injection for a child younger than five years

17.5 A pharmacist authorized to administer drugs by injection must not administer an injection to a child younger than five years old.

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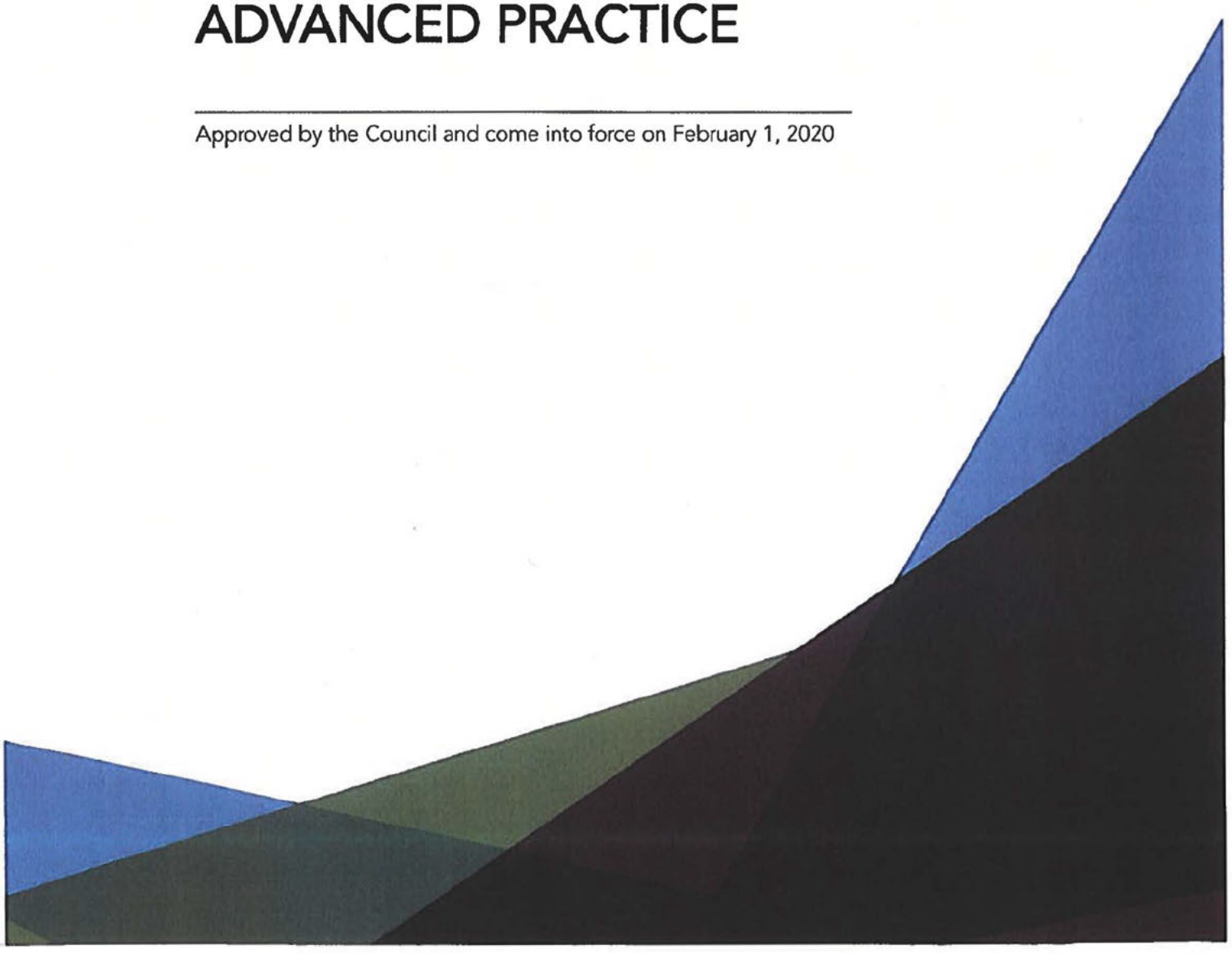
COLLEGE OF
LICENSED PRACTICAL NURSES
OF ALBERTA

STANDARDS OF PRACTICE FOR LICENSED PRACTICAL NURSES ON RESTRICTED ACTIVITIES AND ADVANCED PRACTICE

Approved by the Council and come into force on February 1, 2020



COMMON STANDARDS FOR ALL RESTRICTED ACTIVITIES AND AREAS OF ADVANCED PRACTICE

An LPN must follow all standards of practice that apply to the individual restricted activity they are performing. Below are Education and Practice Standards that are common across all restricted activities and areas of advanced practice.

Appendix D contains the "Overview Table for Standards of Practice on Restricted Activities and Advanced Practice". LPNs are required to know all information contained within these standards of practice, but the table provides a quick reference guide on requirements and where to find all pertinent information in this document.

STANDARD 1: Common Education Standards

Prior to performing any restricted activity or area of advanced practice, **the LPN must**:

1.1 have education or training to perform the restricted activity attained through:

- 1.1.1 a CLPNA Council approved practical nurse entry-level education program or equivalent entry-level training that includes education for the restricted activity they are performing; or
- 1.1.2 post entry-level training or education for the restricted activity they are performing;

1.2 pass the CLPNA module, *Understanding Restricted Activities*, or have graduated from a practical nurse entry-level education program in Alberta after June 2022;

1.3 possess and maintain the competencies as set out in the CLPNA Competency Profile for the individual restricted activity; and

1.4 have the knowledge and competence to perform the restricted activity safely, including the competence to use the specific equipment and technology required to perform the restricted activity.

STANDARD 2: Common Practice Standards

When performing any restricted activity or area of advanced practice, **the LPN must**:

2.1 have CLPNA authorization to perform the individual restricted activity;

2.2 be accountable for their practice including safe and competent performance;

2.3 only perform restricted activities that are appropriate to the LPN's area of practice and the procedures being performed;

2.4 identify and respond to risks, indications, contraindications, and required precautions prior to performing the individual restricted activity;

2.5 follow employer requirements and best practices related to performing the individual restricted activity;

2.6 inform and educate the client regarding the nature, purpose, and expected outcomes including any required follow up care;

2.7 obtain informed consent from the client or alternate decision maker prior to performing the individual restricted activity;

2.7.1 In rare or emergent situations, it may not be possible to obtain consent prior to the LPN performing the restricted activity. In this situation, the consent must be obtained as soon as possible from the patient or alternate decision maker;

2.8 apply infection prevention and control best practices in accordance with legislative requirements, CLPNA standards, and employer requirements;

2.9 monitor and evaluate the client's response to the restricted activity;

2.10 competently respond to any adverse event and ensure it is communicated to the appropriate health care professional in a timely manner;

2.11 report and document according to legislation, employer requirements, and CLPNA policies related to any aspect of performing the individual restricted activity;

2.12 be responsible and accountable in ensuring safe, ethical, and competent care; and

2.13 adhere to all CLPNA standards of practice and the CLPNA code of ethics.

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association & college

Standard of Practice:

Informed Consent

2015

Introduction

All regulated members of the Alberta Dental Association and College (dentists) must discuss treatment options including no treatment with the patient in order to allow the patient to make an informed choice.

The ethical obligations of dentists with respect to obtaining the informed consent of patients are embodied in the Alberta Dental Association and College Code of Ethics. This document builds on the Code of Ethics and identifies standards for obtaining informed consent.

Standards for Informed Consent

1. The dentist is responsible and accountable for ensuring that consent is obtained from a patient before performing an examination or treatment, except where permitted by law to act without consent.

2. Consent for examination or treatment may be implied, or may be expressed orally or in writing. A dentist must:

    a) consider the risks to the patient, the potential for bleeding, infection, pain and discomfort, and the invasiveness of the procedure when deciding on the type of consent required,

    b) if relying on implied consent, be certain that the actions of the patient would be interpreted by others as having implied permission for the dentist's actions,

    c) ensure that written consent is obtained before initiating and/or performing treatment of a more complex nature.

3. A dentist must determine a patient's legal and mental capacity to give consent.

4. A dentist who obtains consent from a substitute decision maker on behalf of a patient must comply with applicable laws.

5. A dentist is responsible to ensure that the cost of treatment or procedures is explained to the patient.

6. A dentist must ensure that all of the dentist's staff involved in the informed consent process are given adequate direction and training to perform their functions in the consent process and only delegate the role where there is adequate knowledge and expertise.

7. A dentist must document informed consent in the patient record.

8. Dentist must recognize informed consent is not a onetime event.

    a) In the case of ongoing care, continuation of consent needs to be verified throughout the treatment period.

b) When consent is given for a coordinated series of procedures as part of a complex treatment plan, the consent remains valid until that treatment plan is changed or the patient withdraws consent.

c) A dentist must respect the right of the patient to withdraw consent at any time.

9. A dentist in obtaining informed consent for treatment must discuss:

a) The diagnosis or differential diagnosis,

b) the exact nature and the anticipated benefits of the proposed procedures, tests or treatments and the cost,

c) reasonable and accepted alternative procedures, tests, or treatments that are generally available, including no treatment and their estimated cost,

d) the consequences of not undertaking the proposed procedures, tests or treatments,

e) the common and significant risks of the proposed procedures, tests or treatments,

f) serious risks, even if unlikely,

g) future costs of care and life expectancy of treatment,

h) special risks, that although uncommon, may have particular relevance to the patient, and

i) responses to any questions the patient may have about their medical history and dental treatment.

10. These Standards must be followed by dentists who are members of the Alberta Dental Association and College. Failure to do so constitutes unprofessional conduct and may result in disciplinary action by the Alberta Dental Association and College.

This is Exhibit "I" referred to in the
Affidavit of
CHAD MITCHELL
Sworn before me this 29th day
of OCTOBER A.D. 20 21
Redacted
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Alberta

Redacted

ALBERTA COLLEGE OF PARAMEDICS

Standards of Practice

Revised and Effective July 2021, Adopted September 2016

2.0 PATIENT RELATIONSHIP

Paramedic professionals form a provider-patient relationship from the first point of care that must be respected and managed appropriately to ensure public safety and public trust is maintained. As a regulated member of a healthcare profession in Alberta, paramedic professionals are responsible for ensuring appropriate boundaries are established and that the relationship is one of trust and accountability.

2.1 Privacy and Confidentiality

A regulated member upholds a patient's rights to privacy and confidentiality by:

1. Complying with all relevant privacy legislation.
2. Maintaining an environment and engage in practices that protect the privacy and confidentiality of patient information.
3. Accessing records, information and archival systems only as required for the provision of professional services.
4. Ensuring any risks to privacy and confidentiality of patient information involved in the transport of records from one location or medium to another are minimized.
5. Limiting information disclosed and the number of people informed while still fulfilling medical, legal and research obligations.
6. Not disclosing or using the name or identifying features of a patient unless the regulated member has obtained the patient's prior written consent to disclose or use the information for purposes unrelated to the patient's care, or unless otherwise required or permitted to do so by law.

2.2 Consent

Consent in paramedicine can be achieved by either informed or implied consent.

2.2.1 Informed Consent

Regulated members must communicate to and discuss with the patient the indications, risk of harm and contraindications of treatment (including medication) to enable the patient/alternate decision maker to be able to provide informed consent prior to treatment.

A regulated member must:

1. Disclose the nature of the proposed examination and give the patient/alternate decision maker the opportunity to ask questions.
2. Inform the patient/alternate decision maker of the assessment/diagnosis and proposed treatment.
3. Inform the patient/alternate decision maker of the benefits and any potential risks of the proposed treatment.
4. Address any questions the patient/alternate decision maker has about the assessment/diagnosis and proposed treatment and any risks.
5. Receive informed consent either written or verbally or allow the patient/alternate decision maker to refuse care by not providing consent.
6. Respect the patient/alternate decision maker's right to withdraw consent at any time.