

## Position Statement on CSEP-CEP using finger prick blood sample analysis equipment

The drawing of blood is a controlled act.

NOTE: Although the act of phlebotomy is considered an unregulated act in some provinces, CSEP still views it as a controlled act and requires that all CSEP-CEPs who wish to draw finger prick blood samples undergo appropriate training in phlebotomy prior to engaging in the act.

**Table 1.**

**Provincial Summary Table**

Province	Regulated	Unregulated
Alberta		X
British Columbia		X
Manitoba	X	
New Brunswick		X
Newfoundland & Labrador		X
Nova Scotia		X
Ontario	X	
Prince Edward Island		X
Quebec	X	
Saskatchewan	X	

Blood sampling (venipuncture or finger prick) has been defined as: "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"

The increasing availability of affordable fingerpick blood sample analysis equipment for routine monitoring of lactate, blood lipid profiles, A1C, etc. has enabled CSEP-CEPs to expand their services offered to their clients. While finger prick blood draws may appear on the surface to be insignificant and harmless, blood draws are governed by the Provincial/Territorial Governments and may fall under a Controlled Act regulation in the CSEP-CEP's province of practice.

In addition, there are a number of safety concerns for individuals to take into consideration prior to engaging in blood sampling procedures. Such concerns are outlined in the **World Health Organization (WHO) Best Practices for Injections and Related Procedures Toolkit, 2010**<sup>1</sup>:

*"Unsafe phlebotomy can cause adverse effects for patients; such effects are rare, but range from pain or bruising at the site of the puncture, to fainting, nerve damage and haematoma. The adverse events that have been best documents are in blood transfusion services, where poor venipuncture practice or anatomical abnormality has resulted in haematoma and injury to anatomical structures in the vicinity of the needle entry.*

*Another issue for patients is that if a blood sample is poorly collected or destroyed during transportation, the results may be inaccurate and misleading to the clinician, or the patient may have to undergo the inconvenience of repeat testing*<sup>2</sup>.

*Poor infection-control practices can lead to bacterial infection at the site where the needle was inserted into the skin*<sup>3</sup>.

*Both patients and the professionals drawing blood can be exposed through phlebotomy to blood from other people, putting them at risk from blood borne pathogens. These pathogens include*<sup>4</sup>:

- *Viruses, such as HBV, HCV and HIV;*
- *Bacteria, such as syphilis;*
- *Parasites, such as malaria.*

*An example of the spread of blood borne pathogens through phlebotomy is the reporting of outbreaks of hepatitis B associated with the use of glucose meters (devices used to determine blood glucose concentration)*<sup>5</sup>.

*Another issue for health workers is sharps injuries; these commonly occur between the use and disposal of a needle or similar device.*

Given the potential risks associated with phlebotomy, all CSEP-CEPs must obtain the appropriate and required training/certification to ensure insurance coverage. As the regulatory standing on phlebotomy differs by province, a CSEP-CEP will fall into one of two groups outlined below, depending on their province of practice.

**GROUP 1 (Including: Prince Edward Island, Nova Scotia, Newfoundland & Labrador, New Brunswick, Alberta, British Columbia):**

Phlebotomy is an unregulated practice in these provinces and as such, so long as the CSEP-CEP has acquired appropriate training (i.e., a blood collection diploma or certification from an accredited certifying body, or place of education) they are able to collect blood samples. Regular training is required under their CSEP insurance policy for these acts.

For example:

- Within their Health Professionals Act (Alberta HPA, 2000), although unregulated, the province of Alberta re-emphasizes the fact that these acts are restricted to be performed only by an individual who is authorized (trained) to perform them<sup>2</sup>.
- Similarly in British Columbia, although there is no direct legislation or regulations pertaining to blood collection, there are professional practice codes, qualifications and certification requirements. In order to perform these acts one must complete courses through the BC Institute of Technology and attain and maintain a desired standard of competence.

**GROUP 2 (Including: Ontario, Quebec, Manitoba, Saskatchewan):**

Phlebotomy is a regulated practice in these provinces. Please refer to your province of practice below for the specific restrictions and regulations that apply to you.

**Ontario<sup>3</sup>:**

Phlebotomy in Ontario is restricted by the Regulated Health Professions Acts (RHPA, 1991), which states:

*"27. (1) No person shall perform a controlled act set out in subsection (2) in the course of providing health care services to an individual unless, (a) the person is a member authorized by a health profession Act to perform the controlled act; or (b) the performance of the controlled act has been delegated to the person by a member described in clause (a). 1991, c. 18, s. 27 (1); 1998, c. 18, Sched. G, s. 6".*

In these regulations, RHPA includes a number of exceptions that permit persons who are not members of regulated professions to perform controlled act procedures in defined circumstances. The ability to perform controlled acts can be authorized in four ways.

1. By direct authorization
2. By delegation or medical directive (**only this option applies to CSEP-CEPs**)
3. Through exceptions
4. Through exemptions

**Direct Authorization:** The governing statutes of some regulated health professions directly authorize them to perform controlled acts or components of controlled acts. Registrants of these professions may perform these controlled acts when

they are practicing within their professions' scopes of practice, and when they have the appropriate knowledge, skills and judgement to perform them according to the standard of practice of the profession.

**Delegation or Medical Directive:** A Delegation or Medical Directive is the process by which a person who is a member of a regulated health profession that is authorized to perform controlled acts within their profession, delegates the authority to perform one or more of these controlled acts or components of the controlled acts to another person, who is then authorized to perform these acts.

Delegation or Medical Directives must be:

1. given in advance by physicians/ordering authorizers to enable an implementer to decide to perform the ordered procedure(s) under specific conditions without a direct assessment by the physician or authorizer at the time.
2. written and have essential components. See the Appendix A for a copy of a sample Medical Directive and/or Delegation Template.

**Exception:** Exceptions are circumstances, defined in law, where the restrictions on performing controlled acts do not apply (i.e. in an emergency).

**Exemptions:** Exemptions are controlled acts, or components of controlled acts, that are exempted from the performance restrictions on these acts. The current exemptions for controlled acts are contained in a regulation made under the authority of the RHPA.

**Other:** The taking of a blood sample from a vein or by pricking the skin is exempt from subsection 27 (1) of the Act if the person taking the blood sample is employed by a laboratory or specimen collection centre licensed under the Laboratory and Specimen Collection Centre Licensing Act. Most CSEP-CEPs are not working in these licensed laboratories.

In order to be covered by their CSEP insurance policy for acts of phlebotomy, CSEP-CEPs practicing in Ontario that wish to engage in blood sampling procedures are **required** to:

1. Achieve competence and obtain certification through examination and demonstration of hands-on ability to perform the act competently.
2. Provide documentation annually at the time of their CSEP-CEP renewal, or as requested by CSEP, of their certification and authorization to perform the act from the delegator that specifies the range of clients and conditions under which the act can be performed.
3. Have their blood sampling competence be re-certified annually to ensure continued competence. Those members who do not obtain the appropriate training, certification (and/or recertification) and the requisite authorization from a delegator are not permitted to carry out blood sampling procedures; failure to obtain the appropriate training, certification (and/or recertification) and the requisite authorization from a delegator voids insurance coverage for this service,

#### Quebec<sup>4</sup>:

Phlebotomy is restricted through the Ordre professionnel des technologistes médicaux du Québec. And in order to practice phlebotomy you must be a member of the Ordre professionnel des technologistes médicaux du Québec

However, Chapter C-26, r.238 (Chapter C-26, s. 94, para.h) of the Professional Code covering the regulation of professional activities, outlines that certain restricted activities, including phlebotomy, may be performed by persons other than medical technologists **only** if they fall into one of these three categories:

1. A registered student in a program leading to a diploma which will enable them to obtain a permit issued by the Ordre professionnel des technologistes médicaux du Québec may practice the professional activities that are performed by medical technologists if/as required for the completion of their program, provided that they do so under the supervision of a clinical professor/teacher who is available to immediately intervene if required. (D.770-2004, a.1).
2. Individuals that fall under the third paragraph of Article 9 of the Regulation on Standards for Equivalence or Training for the licensing of Medical Technologists through the Ordre professionnel des technologistes médicaux du Québec (chapter C- 26, r. 250) may, practice the professional activities that are performed by Medical Technologists if/as required for the completion of the training that would allow the individual to receive a diploma of equivalence/training, provided that they do so under the supervision of a teacher or tutor who is available to immediately intervene if required. (D.770-2004, a.2,D.472-2006, a.1).
3. An individual who does not meet the requirements for obtaining a permit from the Order professionnel des technologistes médicaux du Québec may continue to perform the following professional activities listed in subparagraphs *a* and *c* of paragraph 6 of Article 37.1 of the Professional Code (Chapter C-26), if the person was legally engaging in those activities prior to June 11, 1980 and meets the following conditions that were applicable at that time:
  1. take samples;
  2. introduce an instrument, according to a prescription, into a peripheral vein. (D.770-2004, a.3).

Given these requirements, in order to be covered by their CSEP insurance policy for acts of phlebotomy, CSEP-CEPs practicing in Quebec that wish to engage in blood sampling procedures **are required to**:

- be registered as a Medical Technologist in Quebec
- OR
- fall under one of the three categories outlined above

#### **Manitoba<sup>5</sup>:**

Phlebotomy is restricted in Manitoba by the Provincial Regulated Health Professionals Act (Manitoba RHPA, 2009). The RHPA regulates the performance of activities, which present a risk of harm to the public in the provision of health care. This includes performing a procedure below the dermis, such as venous and capillary blood draws.

The RHPA permits the following individuals to perform this regulated act:

1. Regulated health professionals who are authorized under the RHPA or under an existing profession-specific act to perform the reserved act
2. Individuals to whom the performance of a reserved act is delegated or who are supervised by a regulated health professional with authority to perform the reserved act

3. Individuals who fit with an exemption from the restriction on the performance of the reserved act set out in the RHPA or a regulation made under the RHPA.

Section 2 would apply most directly to CSEP-CEPs, for which a CSEP-CEP who has received the appropriate training/certification can be delegated permission to perform these acts.

**Delegation or Medical Directive:** A Delegation or Medical Directive is the process by which a person who is a member of a regulated health profession that is authorized to perform controlled acts within their profession, delegates the authority to perform one or more of these controlled acts or components of the controlled acts to another person, who is then authorized to perform these acts.

Delegation or Medical Directives must be:

1. given in advance by physicians/ordering authorizers to enable an implementer to decide to perform the ordered procedure(s) under specific conditions without a direct assessment by the physician or authorizer at the time.
2. written and have essential components. See the appendix for a copy of a sample Medical Directive and/or Delegation Template.

In order to be covered by their CSEP insurance policy for acts of phlebotomy, CSEP-CEP's practicing in Manitoba that wish to engage in blood sampling procedure are **required** to:

1. Achieve competence and obtain certification through examination and demonstration of hands-on ability to perform the act competently.
2. Provide documentation annually at the time of their CSEP-CEP renewal, or as requested by CSEP, of their certification and authorization to perform the act from the delegator that specifies the range of clients and conditions under which the act can be performed.
3. Have their blood sampling competence be re-certified annually to ensure continued competence. Those members who do not obtain the appropriate training, certification (and/or recertification) and the requisite authorization from a delegator are not permitted to carry out blood sampling procedures; failure to obtain the appropriate training, certification (and/or recertification) and the requisite authorization from a delegator voids insurance coverage for this service.

#### **Saskatchewan<sup>6,7</sup>:**

Phlebotomy is restricted by the Medical Laboratory Licensing Regulations (Saskatchewan Medical Laboratory Licensing Regulating, 1995) in Saskatchewan, from which it is established that:

*Blood drawn for screening, diagnosis, prophylaxis, treatment or any other health-related purpose requires a Medical Laboratory Licence granted through The Medical Laboratory Licensing Act, 1994. This must be requested by a physician unless exempted by regulatory permission.*

*Blood drawn for non-medical reasons such as insurance or employment drug and alcohol testing does not require a Medical Laboratory Licence.*

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9(1) Subject to subsection (2), a person employed to perform tests in a Category II, Category III, Category IV, Category V, Category VI, Category VII, or Category VIII medical laboratory must be:

- a. A registered nurse, a registered psychiatric nurse, a license practical nurse, or a duly qualified medical practitioner;
- b. A certified combined laboratory and X-ray technician;
- c. A medical laboratory technologist;
- d. The holder of an academic bachelors, masters, or doctoral degree in a relevant chemical or biological science as approved in the license; or
- e. A medical director

Given these requirements, a CSEP-CEP practicing in Saskatchewan would generally fall under Category D above so long as they have received the appropriate training for these acts and are recognized as accredited by The College of Physicians and Surgeons of Saskatchewan.

In order to be covered by their CSEP insurance policy for acts of phlebotomy, CSEP-CEP's practicing in Saskatchewan that wish to engage in blood sampling procedures are **required** to:

1. Achieve competence and obtain certification through examination and demonstration of hands-on ability to perform the act competently.
2. Provide documentation annually at the time of their CSEP-CEP renewal, or as requested by CSEP, of their certification and authorization to perform the act from the delegator that specifies the range of clients and conditions under which the act can be performed.
3. Have their blood sampling competence be re-certified annually to ensure continued competence. Those members who do not obtain the appropriate training, certification (and/or recertification) and the requisite authorization from a delegator are not permitted to carry out blood sampling procedures; failure to obtain the appropriate training, certification (and/or recertification) and the requisite authorization from a delegator voids insurance coverage for this service.

## References

1. World Health Organization (WHO) (2010), *WHO Best Practices for Injections and Related Procedures Toolkit*, WHO Press, Switzerland
2. *The Government Organization Act, schedule 7.1 (section 2.1a)*. Revised Statutes of Alberta 2000 Chapter G-10. Published by Alberta Queen
3. *Regulated Health Professions Act, 1991, Schedule 27 (Sections 1-2)*. Service Ontario 1991, Chapter 18, as amended;
4. *Ordre professionnel des technologistes m.* Chapter C-26, r.238 (Chapter C-26, s. 94, para.h) of the Professional Code.
5. *Regulated Health Professionals Act (Manitoba RHPA, 2009)*. Part 2, Reserved Acts. Province of Manitoba, June 11, 2009.
6. *The Medical Laboratory Licensing Act, 1994*. Chapter M-9.2 of the Statutes of Saskatchewan, 1994. The Queen
7. *The Medical Laboratory Licensing Regulations, 1995*. Chapter M-9.2 Reg 1. The Queen

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