Standard of Practice
Performing Office Based Procedures
Including Cosmetic/Aesthetic and Minor Surgical Procedures, Platelet Rich Plasma Therapy, and Laser Devices)

Initial Approval: December 8, 2021 **Effective Date: January 31, 2022**

Standards of Practice of Medicine set out the requirements related to specific aspects for the quality of the practice of medicine. Standards of Practice of Medicine provide more detailed information than contained in the *Regulated Health Professions Act*, Regulations, and Bylaws. All registrants must comply with Standards of Practice of Medicine, per section 86 of the *Regulated Health Professions Act*.

This Standard of Practice of Medicine is made under the authority of section 82 of the *Regulated Health Professions Act* and section 15 of the CPSM Standards of Practice Regulation.

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PREAMBLE

The College of Physicians and Surgeons of Manitoba sets standards that establish expectations for quality care for patients regardless of whether the care provided is medically required or purely elective. Many registrants perform various in-office procedures on their patients that are medically required or elective. Some of this care is provided in non-hospital medical or surgical facilities and is therefore governed by the Accredited Facilities Bylaw. However, many procedures are performed in non-institutional settings such as established physician offices or medical clinics. When providing this care, registrants must comply with this Standard.

Medical clinic is defined as a medical care facility that is primarily focussed on providing outpatient medical care by CPSM registrants and includes what is commonly known as a physician's office. It does not include a non-medical aesthetic clinic, medi-spa, lash bar, residence, or hospitality facility. It does not include a home office.

APPLICATION

1. This Standard applies to insured and non-insured procedures that are reserved acts under the RHPA performed by a CPSM registrant.[1] These procedures (referred to as "**procedures**") include:
    a. Vasectomy;
    b. Male circumcision, excluding neonatal; (for female see Standard of Practice Female Genital Cutting/Mutilation prohibiting female genital cutting/mutilation)
    c. Cosmetic/aesthetic procedures which may include, but are not limited to:
        1. Application of laser energy and light-based therapies for the removal or ablation of skin lesions and pigmentation; (See Appendix 3)
        2. Soft tissue augmentation – injections of fillers; (See Appendix 1)
        3. Botulinum toxin/Neuromodulators - injectable (See Appendix 1)
    d. Procedures aimed at the treatment of known pathology may include, but are not limited to:
        1. Peripheral stem cell injection as approved by Health Canada; and
        2. Platelet rich plasma injection as approved by Health Canada; (See Appendix 2)

2. This Standard also applies to procedures performed in any location including an Accredited Facility Accredited Facilities Bylaw.

[1] This Standard only applies to CPSM practitioners. It does not apply to other people who perform any of these listed procedures

3. This Standard does NOT apply to:
    a. procedures performed in a hospital or government owned or operated hospital or healthcare facility.
    b. office-based ophthalmic procedures.
    c. Acts that are not reserved acts under the RHPA (examples include facials, peels, microdermabrasion, micro-needling, and laser hair removal).

1. Knowledge, Skill, and Judgment

1.1. Registrants must work only within the limits of their competence and scope of practice and refer a patient to another practitioner if they cannot safely meet the patient's needs.
1.2. If the procedure to be performed was not part of the registrant's medical or specialty education and training, before carrying out the procedure for the first time, registrants must ensure they have the necessary knowledge, skill, and judgment to do so. Registrants must ensure they can: recognize when patients are not suitable to undergo the procedure, safely perform the procedure, and manage potential complications, by undergoing significant training and/or seeking opportunities for supervised practice.
1.3. Competence must be maintained.
1.4. Registrants must practise evidence-informed medicine and maintain a level of understanding of the available evidence supporting the procedure as it evolves.

2. Safety and Quality of Care

2.1. Registrants must not perform, or cause, permit, or enable another person to perform, any procedure in a location other than in a medical clinic.
2.2. Registrants must only perform procedures in a medical clinic that is safe, appropriate, and sanitary, is suitably equipped and staffed, and complies with any relevant regulatory requirements, and the Infection Prevention and Control for Clinical Office Practice.
2.3. Each registrant must take reasonable steps to ensure a system is in place for the proper maintenance, cleaning and calibration of equipment used in the medical care they provide.
2.4. Registrants must also comply with the Standard of Practice - Practice Environment.
2.5. Registrants must ensure the medical clinic has the capability to provide at a minimum, Basic Life Support including appropriate training and certification for staff.
2.6. Registrants must be open and honest with patients in their care and disclose if there is an adverse patient outcome. Registrants must comply with the CPSM Standard of Practice Good Medical Care *(**Section 9. Disclosure of Harm to a Patient**)*. In the event of an adverse patient outcome, the registrant performing, authorizing, or most responsible for the procedure must ensure a care plan is established to mitigate the effects in a satisfactory manner.

2.7. The medical director of the clinic must notify the Assistant Registrar of Quality within one working day of becoming aware of a patient with an **adverse patient outcome** and provide a written report within two weeks.
2.8. An **adverse patient outcome** is defined as an unanticipated significant outcome, either by misadventure, complication, or patient reaction that requires higher level care by an alternate CPSM registrant and includes but is not limited to:
    2.8.1. Transfer to hospital or unanticipated follow-up at a hospital related to how the procedure was performed or how the patient responded to the procedure;
    2.8.2. Third degree burns, disfigurement, or impairment of vision;
    2.8.3. Extreme pain or discomfort causing significant limited function in an ongoing fashion;
    2.8.4. Intra-arterial injection resulting in thrombosis, tissue ischemia, necrosis, or embolism with risk of blindness;
    2.8.5. Injecting or infusing the wrong material than originally intended.

3. Seeking Patients' Consent

3.1. Registrants must comply with the CPSM Standard of Practice Good Medical Care ***(section 5. Informed Consent)***. Consent must be obtained in writing. Registrants must exercise additional scrutiny and caution when considering requests for procedures on minors or those with reduced capacity.
3.2. Registrants must consider the patient's psychological needs and whether referral to another registrant or regulated health professional is appropriate (i.e. body dysmorphic disorder).

4. Practice Management of Procedures Provided by Non-CPSM Registrants

4.1. There must be a registrant identified as most responsible for care for every procedure performed in a medical clinic.
4.2. Registrants most responsible for care or their delegate must assess the indications and potential contraindications for each patient and must personally assess each patient undergoing an invasive procedure.
4.3. The registrant most responsible for care must be available to attend at the same location as the procedure is performed should circumstances arise where they are required to assist non-CPSM registrant providers or to manage misadventure or complications arising from the procedure. "Available to attend" means that in the event of an urgent or semi-urgent episode or complication that exposes the patient to increased risk of harm, the registrant most responsible for care must be available to attend within a reasonable time consistent with the nature of the episode or complication.
4.4. Registrants must ensure that anyone participating in the patient's care has the necessary knowledge, skill, judgment, training, and competence and is appropriately supervised.

Registrants may delegate to non-CPSM registrant providers to perform any procedure in an accredited facility, if the delegation is specific and supervised and under the direction of that physician. This does not apply to regulated health professionals under the *Regulated Health Professions Act* acting within their own scope of practice (i.e. Nurses). (See Contextual Information and Resources).

5. Obligations of Medical Director

5.1. The medical director is responsible for all aspects of the medical clinic which can affect the quality of patient care and is responsible to ensure:

- 5.1.1. the enforcement of this Standard and appropriate standards of care, including the safe, effective, and good medical care of patients in the medical clinic;
- 5.1.2. adequate quality assurance and improvement programs, including the monitoring of infection and medical complications, are in place;
- 5.1.3. a procedures manual is available and maintained for guidance;
- 5.1.4. if procedures are performed at the medical clinic that carry a risk of cardiac arrest or allergic reaction, ensure the availability of appropriate resuscitation equipment and medications and the presence of staff who are appropriately trained to utilize the equipment and medications;
- 5.1.5. a policy is in place for emergent complications, including but not limited to anaphylaxis, allergic reaction or acute embolic event, and the authorized non-physician providers present must be appropriately trained to recognize emergent complications;
- 5.1.6. that all medical devices, equipment, drugs, and other substances utilized in medical care are Health Canada, CSA, or FDA approved.

5.2. The medical director must be in attendance in-person at the medical clinic for sufficient time to ensure that all their obligations are discharged satisfactorily to ensure patient safety.

5.3. The medical director must ensure that the medical clinic, or registrants or other persons performing procedures do not function to increase profit at the expense of good medical care.

5.4. Registrants must only be medical directors of medical clinics in which they actively practice. Registrants must not be medical directors of non-medical clinics or other entities.

6. Liability coverage

6.1. Any registrant performing procedures or who is involved in authorizing non-CPSM registrant providers to provide or assist in procedures must ensure they have appropriate professional liability protection.

7. Communicating Information about Procedures Offered

7.1. When advertising or promoting procedures, including through the use of social media, registrants must follow the applicable provisions in the Standard of Practice Advertising, Standard of Practice Conflict of Interest, and the Code of Ethics and Professionalism.
7.2. Registrants must ensure information being communicated is responsible, factual, does not exploit patients' vulnerability or lack of medical knowledge, is not capable of misleading or misinforming the public, and does not minimise or trivialize the risks of procedures or claim that procedures are risk free.
7.3. Registrants must not mislead about the likely results of a procedure. They must not falsely claim or imply that certain results are guaranteed from a procedure.

8. Honesty in Financial Dealings

8.1. Registrants offering procedures must be open and honest with patients about financial or commercial interests that could be seen to affect the way they care for patients.
8.2. Registrants must not allow financial or commercial interests to affect good medical care.
8.3. Registrants must comply with the Standard of Practice on Conflict of Interest and the Code of Ethics and Professionalism.

APPENDIX 1 – INJECTION OF FILLERS – SOFT TISSUE AUGMENTATION AND BOTULINUM TOXIN/ NEUROMODULATORS

1. In addition to complying with the above Standard of Practice requirements, registrants who provide, authorize, delegate, or enable injections of botulinum toxin, dermal fillers, fillers of any sort injected below the dermis, or neuromodulators, controlled products, of other injectable cosmetic substances (all defined as substances) must comply with this Appendix.
2. Registrants must ensure only substances approved by Health Canada are injected.
3. Registrants who inject substances must have completed relevant and significant procedure specific medical education and training prior to performing such procedures.
4. Registrants must not themselves, nor may they permit or enable any other person to inject these substances in a location other than their medical clinic and then only as part of good medical care.
5. Registrants may permit a regulated health professional acting within their scope of practice to inject these substances in their medical clinic. Registrants must not permit or enable any other persons to inject these substances.
6. Registrants must not authorize the purchase, distribution, or dispensing of these substances, for use by other persons outside their medical clinic, whether regulated health professionals or not.
7. Registrants must perform an assessment and provide a client specific order for *Schedule 1 drugs under the National Drug Schedules* when collaborating with a regulated health care professional to administer the drug where that regulated health care professional is not authorized to prescribe.
8. Registrants must have appropriate antidotes present when performing these injections.

APPENDIX 2 – PERFORMANCE OF AUTOLOGOUS PLATELET RICH PLASMA THERAPY

Platelet rich plasma (PRP) therapy is based on the theory that the use of patient's own blood factors may improve tissue repair and healing. The validity of any potential beneficial effects of PRP therapy continues to undergo further definition and evaluation. This also includes the variability with: technique, number and spacing of injections, number/concentration/exogenous activation of platelets, with/without leukocytes and a definition of the appropriate candidate.

1. The PRP procedure involves multiple steps requiring handling blood products. Registrants must pay special attention to maintaining the sterility of technique and product to ensure patient safety. The risk of contamination reflects the number of steps within the PRP procedure. Contamination can easily occur during venipuncture, selection/handling of collection devices, separation containers, multiple centrifugation runs to isolate the PRP layer and the injection of the concentrated aliquot. Registrants must ensure the critical ability to perform all steps of the PRP procedures without contamination due to the inability to filter-sterilize the end product prior to injection. The entire procedure must take place at one patient visit.
2. Registrants must ensure compliance with the Standard of Practice Good Medical Care. ***(Section 11. Non-Traditional Therapies)***
3. Registrants who offer and perform platelet rich plasma services must comply with the College of Physicians and Surgeons of Alberta's Guideline "Performance of Autologous Platelet Rich Plasma Therapy in Unaccredited Settings: A Guideline for Physician Office/Clinic Setting".

APPENDIX 3 – LASER SAFETY

1. In addition to complying with the above Standard of Practice requirements, registrants who use a laser device for patient care and/or treatment must comply with this Appendix.
2. Registrants who use a laser device for patient care and/or treatment must have completed relevant and significant specific laser operation education and training prior to performing procedures with a laser.
3. Registrants must ensure that unregulated health care workers or technicians applying laser in their clinics have documented relevant and significant specific training and possess the requisite knowledge, skill and competence to safely perform the laser procedure. Registrants must define the degree of medical supervision required and must perform, at a minimum, annual competency assessments of each individual performing laser treatments that include observed procedures with feedback and must maintain a record of those assessments.
4. Registrants utilizing regulated health professionals who require additional education to authorize performance of the reserved act must ensure the additional education received meets requirements as outlined by that regulated health professional's College.
5. Registrants must use lasers in compliance with existing standards and occupational health and safety regulations and must keep current with the standards as they are updated from time to time. Registrants must refer to CSA Z386-2014 *Safe Use of lasers in health care*, and ANSI Z136.3-2018 *Safe use of lasers in health care*, and both are current at the time of this standard in 2021.
6. In addition to the above-mentioned standards, registrants must comply with CPSBC's Practice Direction on Laser Safety for Physician Practice and the CPSBC's Laser Safety for Member Practice Summary.

Contextual Information and Resources Performing Office Based Procedures

Effective Date: January 31, 2022

The Contextual Information and Resources are provided to support registrants in implementing this Standard of Practice. The Contextual Information and Resources do not define this Standard of Practice, nor should it be interpreted as legal advice. It is not compulsory, unlike a Standard of Practice. The Contextual Information and Resources are dynamic and may be edited or updated for clarity, new developments, or new resources at any time.

Relevant and Significant Training

Patients are entitled to receive safe medical care by knowledgeable, skillful, and competent medical practitioners. Many procedures are performed by plastic surgeons or dermatologists, or family physicians with an added competency. While many years of training is not required for every procedure, a weekend course(s) is not sufficient for family physicians, other regulated health professionals or staff in the medical clinic performing or participating in the procedures.

It is incumbent upon registrants to ensure their knowledge, skill, judgment, and competency prior to performing any procedures. This is an objective, not subjective standard. Registrants should take numerous courses and perform a number of procedures under supervision prior to performing procedures independently to ensure they will provide good medical care to their patients.

CPSM can not establish what is the exact training or courses required for each registrant to determine knowledge, skill, judgment, and competency. The training is dependent upon the procedure to be performed, the education, scope of practice, specialization, and experience of each physician. CPSM can only say that the training must be relevant and significant and that registrants should seek to invest both the time and cost to establish the required knowledge, skill, judgment, and competency.

Medical Director and Purchasing

Registrants may be asked by non-physicians to purchase substances or medical devices which can only be sold to a physician by law. For clarity, CPSM registrants are not permitted to purchase injectables or other substances or medical devices for any person, clinic, or entity other than their

own medical clinic in which they actively practice. This means no purchasing of substances or medical devices for nursing clinics or other aesthetic clinics.

CPSM registrants may not be medical directors of nursing clinics or other aesthetic clinics in which they do not actively practice medicine.

Medical Clinics

The definition of medical clinic is provided in the Standard. For greater clarity, if the medical practice is located inside a major retail or grocery store or pharmacy, then that would be defined as a medical clinic, and the procedures listed in the Standard may occur in that location. These procedures must not be performed in a home, hotel, club, vehicle, at "botox parties", etc.

Performance of Procedures By Non-CPSM Registrants

Many medical clinics utilize nurses (NP, RN, LPN) and non-regulated health professionals to perform a variety of health care procedures on patients. Registrants must understand the implications, responsibilities, and processes for having other regulated professionals and non-regulated health professionals perform procedures in a medical clinic prior to permitting them to do so.

The Regulated Health Professions Act sets out a way of regulating who does what in the provision of health services based on the concept of controlling potentially dangerous acts. Those activities, known as reserved acts, pose a significant risk of harm or possible harm to the health, safety or well-being of the public. Reserved acts may be performed in the course of providing health care by competent, regulated health care professionals that have been granted specific legislative authority to do so, based on their competence and skills. There are 21 categories of reserved acts and CPSM registrants can perform all 21 reserved acts subject to their knowledge, skill, and judgment and being within the registrant's scope of practice. Examples of reserved acts are – prescribing drugs, cutting into tissue, applying a form of energy for diagnosis (ex: x-rays, CT scans). Many of the reserved acts can be performed by more than one profession, and most notably, members of the College of Registered Nurses of Manitoba, including Nurse Practitioners, can perform many reserved acts.

This approach supports enhanced inter-professional and multidisciplinary practice while maintaining patient safety and public protection. It also ensures that members of each regulated health profession can practice to the maximum level of their scope of practice.

Delegation

There are circumstances where it is necessary for a registrant to delegate tasks to unregulated care providers in order to provide access to care. Delegation is the extension of authority by a registrant to another regulated health care professional or health care provider who does not have the authority to perform the reserved act. Delegation is always patient-specific and the task cannot be further delegated or transferred to another patient.

There is no need to delegate tasks to a regulated health professional acting within their profession's authorized scope of practice. Regulated health professionals may or may not be able to accept delegation outside their legislated scope of practice depending upon the direction provided by their respective regulatory college. Registrants should be aware of other regulated health profession regulations pertaining to accepting delegation prior to delegating a task.

Delegation does not apply to clinical assistants and physician assistants since they are supervised classes of practitioners under their Contract of Supervision.

Making the Decision to Delegate

In delegating a reserved act, the registrant should:

1. Confirm the employer (if any) supports this delegation and follow applicable policies and procedures.
2. Be competent and authorized to perform the task they are delegating.
3. Assess the competence of the person in relation to the delegated task on the specific patient.
4. Identify the risk to the patient through an assessment of the patient, task, person providing the care and environment.
5. Be satisfied the decision to delegate is appropriate in the context of the specific patient, task, person being delegated to provide the care, and environment.
6. Include information about the decision to delegate and process of delegation when obtaining informed consent from the patient for the task.
7. Document the decision to delegate.

Engaging in the Process of Delegation

While engaging in the process of delegation the registrant should:

1. Provide patient-specific teaching to the person providing the care until the registrant is satisfied the person providing the care is competent to perform the task in the context of the task, patient and environment.
2. Ensure support and consultation is available during the performance of the task.
3. Provide periodic monitoring and evaluation of the competence of the person providing the care.

4. Remain responsible for the decision to delegate and the ongoing assessment of the patient's health status and plan of care.
5. Determine appropriate monitoring and evaluation of the plan of care based on assessment of the patient, task, environment and person providing the care.
6. Terminate the delegation if a change in patient status or the competence of the person providing the care indicates the delegation is no longer appropriate or acceptable to the patient.

RESOURCES

The College of Licensed Practical Nurses has a Practice Direction on Aesthetic Nursing to assist in understanding their responsibilities and legal obligations and enabling them to make safe and ethical decisions within their practice.

CPSM gratefully acknowledges the College of Registered Nurses of Manitoba for the use of its materials in the Making the Decision to Delegate and Engaging in the Process of Delegation sections, and the College of Physicians and Surgeons of Saskatchewan for the use of some of its materials in the Standard.