Medical Hyperbaric Oxygen Therapy Private Facility

Standards & Guidelines

March 2014 v8

College of Physicians & Surgeons of Alberta

Serving the public by guiding the medical profession

Revision Date: **March 2014 v8**

Approval Date: September 1999

Originating Committee: Medical Facility Accreditation Committee

Table of Contents

Medical Hyperbaric Oxygen Therapy Private Facility

1.0 Introduction

Alberta's *Health Professions Act* provides for the accreditation of medical services in non-hospital facilities by the College of Physicians and Surgeons of Alberta. Section 8.1 in Schedule 21 of the *Act* states:

> **8.1 (1)** A regulated member shall not provide a prescribed health service, or cause a prescribed health service to be provided, in a facility unless the facility is an accredited medical facility or a facility referred to in subsection (2).
>
> **(2)** Subsection (1) does not apply with respect to a prescribed health service provided in
>
> (a) an approved hospital within the meaning of the *Hospitals Act*,
>
> (b) a hospital operated by the Government of Canada,
>
> (c) a health care facility operated by the Government of Canada or the Government of Alberta,
>
> (d) a hospital, clinic or centre operated by a regional health authority under the *Regional Health Authorities Act*,
>
> (e) a facility within the meaning of the *Mental Health Act* or an accredited health centre established for the purpose of section 49(b) of the *Mental Health Act*, or
>
> (f) a facility that is prescribed in the regulations.

Medical Hyperbaric Oxygen Therapy services are one of many health services for which the College requires accreditation. A complete list of prescribed health services is contained in the College's by-laws and available on the College's website.

The Medical Facility Accreditation Committee considers any issues regarding the provision of hyperbaric oxygen therapy services in private facilities, including, but not necessarily limited to the following:

1. Advise Council on accreditation standards for the ownership and operation of diagnostic and treatment facilities in Alberta;
2. Investigate and assess the ownership and operation of such facilities;
3. Establish, develop and administer a program of review and assessment of such facilities;
4. Confirm that the practice of medicine conducted in such facilities and the financial arrangements pertaining thereto are in accordance with the College's bylaws and Council's policies;
5. Advise Council on matters referred to the Committee regarding standards of practice for the use of new health technology in medical practice;
6. Advise Council on matters referred to the Committee regarding the qualifications of physicians for medical practice in addition to their recognized specialties.

Note: This document incorporates standards and guidelines in a diagnostic and treatment facility approved by the MFAC/Council:

- **"shall" is used when a section is a <u>requirement</u> for accreditation;**
- **"should" is used when a section is <u>recommended</u>; and**
- **"may" is used when a section is <u>discretionary</u>.**

2.0 Role of the College

2.1 Accreditation of Facilities

2.1.1 All private medical hyperbaric oxygen therapy facilities shall register with and maintain accreditation by the College.

2.1.2 Applications for accreditation of new facilities shall be made to the College.

2.1.3 The Standard of Practice #20 – Direction and Control of Medical Practice as established by the Council of the College are applicable for privately owned facilities.

2.1.4 Accreditation involves an on-site assessment to:

- assess facility appearance
- observe procedures
- assess quality assurance procedures and documentation
- review manuals
- assess equipment
- assess facility safety

2.1.5 The assessment is completed by a physician (with expertise in the appropriate area of medical practice) designated by the College. An appropriate team is selected by the designated physician.

2.1.6 Following the assessment, a report which outlines the details of the assessment is prepared and subsequently reviewed by the Medical Facility Accreditation Committee.

2.1.7 "Full Accreditation" is granted to those facilities with no identified deficiencies.

2.1.8 "Provisional Accreditation" may be granted for a 30-day period to those facilities with minor deficiencies to allow for their correction. A written response to each deficiency is required from the medical director of the facility. A follow-up assessment may be required at the sole discretion of the College. "Full Accreditation" will be granted when deficiencies have been corrected to the satisfaction of the College.

2.1.9 Requirements shall be met before accreditation will be granted or renewed by the College.

2.1.10 The College may revoke accreditation if practice in the facility is considered unsafe.

2.1.11 A "Certificate of Accreditation" will be issued by the College to all facilities with "Full Accreditation".

2.1.12 Accreditation of Medical HBO therapy facilities shall be renewable after four years upon successful re-assessment of the facility and its documentation by the College.

2.1.13 Payment to the College for the cost of the assessment is the responsibility of the Medical Director of the facility.

2.1.14 "Spot" assessments without prior notice may also be conducted. These are at no cost to the facility.

2.2 Administration

2.2.1 A record of each facility shall be kept on file at the College.

2.2.2 The College shall be advised of any change of ownership of the medical practice or Medical Director of the facility.

2.2.3 Each facility is required to pay an annual fee, set by Council, for the administration of the accreditation program.

3.0 Personnel

3.1 Medical Director

3.1.1 Qualifications

3.1.1.1 The Medical Director shall be licensed to practice in Alberta, qualified to supervise HBO therapy.

3.1.2 Responsibilities

1. The responsibilities of the Medical Director include but are not limited to the following:

a. Ensuring the safe and ethical care of patients in the facility.
b. Ensuring the facility's structure, procedures and equipment are appropriate and safe and comply with CAN/CSA Z 275.1-93.
c. Ensuring personnel working in the facility are qualified to perform their duties and knowledgeable in the risks and hazards in the facility.
d. Ensuring policy and procedure manuals for the administration of the facility, the operation of equipment, and the management of patients are prepared, maintained and readily accessible to staff.
e. Ensuring the advertising and marketing of services offered by the facility meet the ethical guidelines of the medical profession.
f. Ensuring procedures for billing patients and third parties for services provided in the facility meet the ethical guidelines of the medical profession.
g. Ensuring complete and accurate confidential patient records are created and kept secure for a minimum of ten years after the date of last treatment or two years beyond the age of majority, whichever is longer.
h. Ensuring documentation relating to the operation of the facility and procedures performed is kept in accordance with accreditation standards.
i. Ensuring physicians supervising patient care in the facility are qualified to provide HBO therapy.
j. Ensuring a qualified physician is immediately available whenever patients are being treated in the facility.
k. Ensuring compliance with bylaws of the College of Physicians and Surgeons governing Principles of Ownership of medical practices and Conflict of Interest.
l. Ensuring documentation and fees are submitted to the College as required.

3.2 Physicians Supervising HBO Therapy

3.2.1 Qualifications

1. Physicians supervising HBO therapy shall:

a. Have completed at a minimum, a 40-hour course approved by the Undersea & Hyperbaric Medical Society. A record of completion of the course of training shall be kept on file in the facility

and

b. Be certified specialists in anesthesiology or maintain a current certificate in Advanced Cardiac Life Support (ACLS)

and

d. Be licensed to practice in Alberta

3.2.2 Responsibilities

1. A physician supervising HBO therapy shall:

   a. Perform an assessment of the appropriateness of HBO therapy and the fitness of the patient for HBO therapy before the first dive.
   b. Remain in the facility during a patient's first dive.
   c. Be available within five minutes during the treatment of any patient in the facility.

3.3 Technologists

3.3.1 Qualifications

1. Technologists shall:

   a. Be registered respiratory technologists and shall have completed at a minimum, a 40-hour course approved by the Undersea & Hyperbaric Medical Society. A record of completion of the course of training shall be kept on file in the facility

   and

   b. Maintain a current certificate in cardiopulmonary resuscitation.

3.3.2 Responsibilities

1. A technologist shall:

   a. Remain in continuous attendance on patients in the facility when a supervising physician is not in attendance.
   b. Maintain visual and audio contact with patient during dives when a physician is not in attendance.
   c. Perform pre-dive assessments.
   d. Monitor dives.
   e. Maintain and order equipment and supplies.
   f. Ensure documentation is complete.

4.0 Patient Selection

4.1 The list of indications for which HBO therapy is offered shall be stated in the facility's Policy Manual.

4.2 Indications for HBO therapy in the facility shall be limited to those accepted by the Undersea and Hyperbaric Medical Society or otherwise as approved by the College and based on scientific evidence for therapeutic effectiveness. (Appendix A)

4.3 The medical status of patients shall be commensurate with the medical and support services available in the facility.

4.3.1 The referring physician and the accepting HBO physician must discuss and document the appropriateness of the setting and care for all patients with the following:

a. assisted ventilation
b. unconscious
c. uncooperative
d. hemodynamically unstable (must have satisfactory BP and stable cardiac rhythm)
e. undiagnosed fever
f. heavy requirements for narcotics or other drugs that can impair consciousness or respiration
g. unstable diabetes
h. cardiopulmonary arrest within the previous 12 weeks

4.4 HBO therapy on critically ill or unstable patients shall be carried out only in hospital-based facilities unless, subject to 4.3.1, a determination is made by both the referring and HBO physician that the risk of treatment at a private HBOT is less than the risk of delays associated with the transfer of the patient to a hospital based facility.

4.5 Other than in situations outlined in 4.4, the minimum age of patients treated in the facility shall be fourteen (14) years.

5.0 Access to HBO Therapy

5.1 Patients treated in the facility shall be referred by a physician, dentist, oral surgeon or podiatrist.

5.2 All referrals shall be assessed by a physician with privileges in the facility for the appropriateness of and fitness for HBO therapy.

6.0 Facility Structure

6.1 The HBO therapy facility shall maintain:

1. Efficient access for emergency extrication
2. Anti-static precautions
3. Ambient humidity of >40%
4. Protection of patients from fast-flicker lighting during dives
5. Safe storage of compressed gases
6. Precautions to prevent unauthorized entry

7.0 Fire Safety

7.1 Fire extinguishers shall be immediately available.

7.2 Clothing and linen in the HBO chamber shall be 100% cotton only.

7.3 Policies and procedures shall prohibit metal, Velcro™, synthetic materials, oil and cosmetics in the chamber.

8.0 HBO Chamber

8.1 The HBO chamber shall be approved for medical use in Canada.

8.2 The HBO chamber shall be installed and assessed by a qualified service representative. Documentation of installation and assessment shall be kept in the facility.

8.3 The facility shall keep a record of the following:

1. Installation checklist
2. Assessment checklist
3. Operational checklist
4. Cleaning checklist
5. Maintenance log
6. Log of use of the chamber

9.0 Safety Equipment and Supplies

9.1 The facility shall have and maintain the following:

1. Apparatus to measure blood pressure with an appropriately sized cuff inside and outside of the HBO chamber
2. Equipment for electrocardiographic monitoring inside and outside of the HBO chamber
3. IV supplies and accessory equipment such as syringes, needles, tape, etc.
4. Emergency drugs and supplies with procedures to review expiry date

9.2 Required Drugs:

9.2.1 Basic list for emergency treatment:

1. Oral
   a. Acetylsalicylic acid;
   b. Nitroglycerin spray.

2. Inhaled
   a. Salbutamol (with spacer device)

3. Intravenous
   a. Atropine;
   b. Benzodiazepine, either midazolam or diazepam;
   c. Diphenhydramine;
   d. Epinephrine, subcutaneous and intravenous;
   e. Naloxone, when parenteral narcotics are used.
   f. 50% glucose

10.0 Patient Information – Medical Records

10.1 A clinical record shall be created at the first visit by each patient and shall be kept for the prescribed period which contains the following:

1. Identifying information
2. History, physical examination, investigations, medication list
3. Name of Referring physician
4. Treatment plan
5. Consent for HBO therapy
6. Pre-dive assessments
7. Record of HBO and pressure equalization teaching
8. Dive monitoring
9. Letter to referring physician
10. Results of any physical assessments during and upon completion of HBO therapy

10.2 All reports containing interpretations shall indicate authorship and whether or not the contents of the report have been verified by the author. (A signature means that the contents have been verified by the signator).

11.0 Quality Assurance

11.1 The facility shall follow the Guidelines for Clinical Hyperbaric Facilities and the Quality Assurance recommendation of the Undersea & Hyperbaric Medical Society, including any subsequent amendments or additions.

11.2 Records of the quality assurance program shall be maintained for a minimum of two years.

11.3 An external review of the quality assurance program shall be undertaken by the College after the first twelve months of the facility's operation.

12.0 Infection Prevention and Control

These standards have been adapted from *Health Canada – Infection Control Guidelines – Hand Washing, Cleaning, Disinfection and Sterilization in Health Care* and *Health Canada – Infection Control Guidelines – Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care.*

Routine infection control practices should be incorporated into everyday patient/resident/client care. Institutional policy should provide for education of every care provider in the principles of routine precautions, provision of adequate equipment to implement them, and a means by which compliance with practice can be monitored and audited.

To minimize the risk of transmission of infection, patients/residents/clients (referred to henceforth as "patients") should be assessed for infection or potential infections upon admission. Each facility should endeavor to have some assessment procedure in place; the results should be communicated to other personnel providing care and should be documented in the patient record.

In situations requiring additional precautions, these precautions must be instituted as soon as indicated by triggering mechanisms such as diagnosis, symptoms of infection, laboratory information, or assessment of risk factors.

The institution/facility is responsible for ensuring that appropriate precautions are taken for specific patients.

All personnel (physicians, nurses, technologists/technicians, students, volunteers and others) are responsible for complying with routine and additional precautions and for tactfully calling observed infractions to the attention of all offenders. There are no hierarchical exceptions to precautions, and everyone has a responsibility to monitor his or her own practice as well as the practice of other care providers. There are no exceptions, and all should teach by example.

12.1 Occupational Health/Immunization

The *Occupational Health and Safety Act, Regulation and Code* will also apply. Copies of the OHS Act, Regulation and Code, and *"A Physician's Guide to Occupational Health and Safety Responsibilities"* are available on-line at www.worksafely.org.

1. All personnel, including physicians should have their immunization status reviewed and documented at the time they commence employment at the facility and periodically thereafter.

2. Personnel that are unable to provide acceptable evidence of adequate immunity against hepatitis B, influenza, measles, mumps, rubella, and varicella; should be advised to speak to their physician about immunization.

3. Employers should consider measles, mumps, rubella, hepatitis B and varicella immunity as a condition of employment.

4. Tuberculin skin testing is recommended for all personnel at the beginning of their employment.

5. All personnel shall understand and adhere to *"Routine Practices"* which incorporate universal blood and body fluid precautions such as described in the *"Health Canada Infection Control Guideline: Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care*. (This guideline is available on-line at *http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/99pdf/cdr25s4e.pdf).*

6. There shall be a policy and procedure for the management of significant exposures (e.g. needle-stick injuries).

7. Consultation with a specialist in infectious disease shall be obtained prior to workers with blood-borne pathogens starting work in the facility. *"Health care workers who perform exposure-prone procedures*

have an ethical obligation to know their serologic status for hepatitis B virus (HBV), human immunodeficiency virus (HIV) or hepatitis C virus (HCV) and to follow the recommendations in 'Proceedings of the Consensus Conference on Infected Health Care Workers: Risk for Transmission of Bloodborne Pathogens,' (This document is available on-line at http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/98vol24/24s4/24s4b_e.html*).*

12.2 General Infection Prevention Measures

1. Adequate hand washing sinks shall be appropriately located throughout the facility. Waterless, alcohol based antiseptic hand agents are an acceptable alternative to soap and water, if there is no visible soiling.

2. Hands shall be washed between patients, after removal of gloves, when visibly soiled and after contact with any contaminated objects.

3. Hand washing with an antiseptic agent shall be used:

   a. before performing invasive procedures;
   b. before contact with immunocompromised patients;
   c. before contact with patients with extensive skin damage.

4. There shall be no re-use of critical or semi-critical medical equipment labeled as single-use by the manufacturer.

5. Masks, eye protection and face shields shall be worn for protection of mucous membranes of the eyes, nose and mouth during procedures likely to generate splashes or sprays of blood, body fluids, secretions or excretions.

6. Clean non-sterile gloves shall be worn:

   a. for contact with blood, body fluids, secretions and excretions, mucous membranes, draining wounds or non-intact skin (open skin lesions or exudative rash);
   b. when handling items visibly soiled with blood, body fluids, secretions or excretions;
   c. when the healthcare worker has open lesions on the hands.

7. Gloves are to be changed between care activities and procedures with the same patient after contact with materials that may contain high concentrations of microorganisms.

8. Gloves are to be removed immediately after completion of care or procedure, at point of use and before touching clean environment surfaces.

9. There should be a designated person responsible for the maintenance and enforcement of infection control and occupational health standards in the facility.

12.3 Additional Precautions

1. Airborne Transmission Precautions

   a. Patients with known or suspected infectious tuberculosis, measles, varicella or disseminated zoster should be placed directly in a single examination room and the door shall remain closed.
   b. Those patients shall wear a surgical/procedure mask during transport and movement through the facility.
   d. High efficiency dust/mist masks shall be worn by all healthcare workers who enter the examination room of a patient with infectious tuberculosis.

e. High efficiency dust/mist masks shall be worn by non-immune healthcare workers who absolutely must enter the examination room of a patient with varicella, disseminated zoster or measles.

2. Droplet Transmission Precautions

a. Patients with known or suspected meningococcal infection,, rubella, mumps, pertussis, diphtheria, or hemorrhagic fevers should be placed in a single examination room. If this is not possible the patient shall maintain a one meter spatial separation between other patients.
b. Surgical/procedure masks should be worn by all healthcare workers that must come within one meter of the patient.
c. The patient shall wear a surgical/procedure mask during transport and movement through the facility.

3. Contact Transmission Precautions

a. Patients with know or suspected diarrhea, extensive skin or wound infection not contained by dressings, hemorrhagic fevers, meningitis, hepatitis, herpes simplex-disseminated, scabies (extensive or Norwegian/crusted), varicella, disseminated or extensive uncovered zoster and Antibiotic Resistant Organisms (ARO) should be placed in a single examination room. If this is not possible, a spatial separation of one meter shall be maintained between patients.
b. Gloves should be worn when entering the patient's room or designated examination space.
c. Gloves shall be removed before leaving the patient's room or designated examination space.
d. Hands shall be washed immediately, first with soap and water if visibly soiled, then an antiseptic agent.
e. Equipment and surfaces in direct contact with the patient or infective materials shall be cleaned before the room is used by another patient.

12.4 General Environmental and Equipment Cleaning

1. Chairs, cabinets and charts are not usually an infection risk, but should be cleaned on a regular basis.

2. Walls, blinds and curtains should be cleaned regularly and when soiled.

3. Floors should be cleaned regularly, with damp mopping preferred.

4. Carpets/upholstery should be vacuumed regularly and shampooed as necessary.

5. Toys shall be regularly cleaned, disinfected with a low level disinfectant, thoroughly rinsed and dried.

13.0 Manuals

13.1 The facility shall have current and comprehensive manuals in place

13.2 Manuals shall be site specific

13.3 All procedures shall initially be reviewed and signed by the medical director.

13.4 Manuals shall contain the date of the original writing and dates of revisions.

13.5 Manuals shall contain the name and signature of the person who wrote the manuals and who performed each revision.

13.6 The manuals shall be readily accessible and all staff shall be aware of its content.

13.7 All procedures shall be reviewed annually and signed by the medical director or designate.

13.8 Any changes in the interim shall be approved and initialled by the director.

13.9 The following manuals shall be available in the laboratory

13.9.1 HBO Therapy Manual

The facility shall maintain an organized manual containing at a minimum, details of each of the following:

1. Indications for HBO therapy in the facility
2. Contraindications to HBO therapy
3. Treatment protocols
4. Side effects and complications of HBO therapy
5. Operation and maintenance of the HBO chamber and ancillary equipment
6. Operation and maintenance of patient monitoring equipment and emergency treatment equipment

13.9.2 Infection Prevention and Control Manual

An Infection Prevention and Control Manual shall contain at a minimum, the following policies and procedures:

1. Management of patients with open wounds, infectious diseases and infections or colonization with antibiotic-resistant organisms
2. Management of sharps and bio-hazardous wastes
3. Immunization of staff in the facility
4. Cleaning and sterilization of equipment, linen and structures in the facility

13.9.3 Safety Manual

A Safety Manual shall contain at a minimum, a detailed description of the management of the following:

1. Medical Emergencies
   - Cardiopulmonary arrest procedure
   - Pneumothorax

- Cerebral embolism
- Sudden decompression
- Seizures
- Acute management of hypoglycemia including blood glucose monitoring for patients in attendance at the facility
- List of emergency supplies/equipment to be kept in stock
- List of emergency phone numbers

2. Fire
3. Electrical failure
4. Explosion
5. Hazards from compressed gases
6. Incidents

13.9.4 Policy Manual

This manual shall include, as a minimum, the following sections:

1. Organizational chart
2. Staff/office policies
3. Procedure policies

Appendix A - Approved Uses
(see standards for restrictions)

1. Air or gas embolism
2. Carbon monoxide poisoning and smoke inhalation
3. Clostridial myonecrosis (gas gangrene)
4. Crush injury, compartment syndrome, and other acute traumatic ischemia
5. Decompression sickness
6. Enhancement of healing in selected problem wounds
7. Exceptional blood loss (anemia)
8. Necrotizing soft tissue infections (subcutaneous tissue, muscle, fascia)
9. Osteomyelitis (refractory)
10. Radiation tissue damage (osteoradionecrosis)
11. Skin grafts and flaps (compromised)
12. Thermal burns
13. Adjunctive hyperbaric oxygen in intracranial abscess