



THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

Out-of-Hospital Premises Inspection Program (OHPIP)

PROGRAM STANDARDS



September 2013

(revised: December 2016)

College of Physicians and Surgeons of Ontario Mandate

Build and maintain an effective system of self-governance.

The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the Regulated Health Professions Act.

Our Vision

Quality Professionals, Healthy System, Public Trust.

Our new vision is the framework by which we organize ourselves.

It guides our thinking and actions into the future. It defines not only who we are, but what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek. Each component of our vision is defined below:

Quality Professionals – as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes.

We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

Healthy System – the trust and confidence of the public and our effectiveness as professionals is influenced by the system within which we operate. Therefore, we as caring professionals are actively involved in the design and function of an effective system including:

- accessibility
- the interdependence of all involved
- measurements and outcomes
- continued sustainability

Public Trust – as individual doctors garner the trust of their patients, as a profession we must aim to have the trust of the public by:

- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system

Our Guiding Principles

Integrity, accountability, leadership and cooperation

The public, through legislation, has empowered the profession to regulate itself through the College. Central to the practice of medicine is the physician-patient relationship and the support of healthy communities. As the physician has responsibility to the patient, the profession has the responsibility to serve the public through the health-care system.

To fulfill our vision of quality professionals, healthy system, public trust we will work to enhance the health of the public guided by professional competence and the following principles:

Integrity – in what we do and how we go about fulfilling our core mandate:

- Coherent alignment of goals, behaviours and outcomes
- Steadfast adherence to a high ethical standard.

Accountability to the public and profession – we will achieve this through:

- An attitude of service
- Accepting responsibility
- Transparency of process
- Dedicated to improvement.

Leadership – leading by proactively regulating our profession, managing risk and serving the public.

Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared resources for the common good of the profession and public.

Guiding Policies

It is expected that physicians will manage medical and surgical conditions within the scope of their certification and experience. For all CPSO members this means practicing with the appropriate qualifications or equivalency subject to requirements set out by the RCPSC, or CPSO “Specialist Recognition Criteria in Ontario” and “Changing Scope of Practice” policies.

Contact Information

Published and distributed by the College of Physicians and Surgeons of Ontario. For more information about the Out-of-Hospital Premises Inspection Program, contact:

Shandelle Johnson
Manager, Practice Assessment and Enhancement
College of Physicians and Surgeons of Ontario
80 College Street, Toronto, ON M5G 2E2

Toll free: 1-800-268-7096 ext. 401
OHP@CPSO.on.ca

Wade Hillier
Director, Quality Management Division
College of Physicians and Surgeons of Ontario
80 College Street, Toronto, ON M5G 2E2

Toll free: 1-800-268-7096 ext. 636
OHP@CPSO.on.ca

1 Introduction

The Out-of-Hospital Premises Inspection Program (OHPIP) supports continuous quality improvement through developing and maintaining standards for the provision of medical care/procedures in Ontario out-of-hospital premises and by inspecting and assessing for safety and quality of care. This document is intended to articulate the core requirements for the performance of procedures involving use of anesthesia as defined in Ontario Regulation 114/94 (see www.cpso.on.ca) in settings/premises outside a hospital that do not fall under another regulatory oversight scheme.

This core standards document will be used for the inspection-assessment of premises and members, and will be applicable to all members of CPSO who work in such premises. The standards include information applicable to the range of all procedures performed in OHPs. Where warranted consideration of specialty-specific working groups (i.e. interventional pain, and endoscopy) have been incorporated into the requirements.

It is expected that physicians will manage medical and surgical conditions within the scope of their certification and experience. For members of the College of Physicians and Surgeons of Ontario (CPSO), this means practicing with the appropriate qualifications or equivalency subject to requirements set by the RCPSC, or CPSO “Specialist Recognition Criteria in Ontario” and “Changing Scope of Practice” policies.

Decisions made by the Premises Inspection Committee will be based on the information within these Standards as well as any additional relevant guidelines, protocols, standards and Acts that are current (i.e. CNO standards, HARP Act). This includes requirements set out by other regulatory bodies and provincial guidelines.

2 OHP Background

In April 2010, Regulation 114/94 provided a 60-day window for all CPSO members performing or assisting in procedures in Out-of-Hospital Premises (OHPs) to notify the College. By June 2012, all premises that existed prior to June 2010 had their inspection-assessment completed. New premises or relocating premises continue to be inspected within 180 days of notification.

Ontario Regulation 114/94¹, made under the **Medicine Act**, 1991 is amended by adding the following:

Part XI: Inspection of Premises and Equipment.

Out-of-Hospital Premises (OHP) means any non-hospital site at which a physician engages or proposes to engage in:

- (a) any act that, when performed in accordance with the accepted standard of practice on a patient, is performed under the administration of,
 - (i) general anesthesia,
 - (ii) parenteral sedation, or
 - (iii) regional anesthesia, except for a digital nerve block; and,
- (b) any act that, when performed in accordance with the accepted standard of practice on a patient, is performed with the administration of a local anaesthetic agent, including, but without being limited to,
 - (i) any tumescent procedure involving the administration of dilute, local anesthetic;
 - (ii) surgical alteration or excision of any lesions or tissue performed for cosmetic purposes;
 - (iii) injection or insertion of any permanent filler, autologous tissue, synthetic device, materials or substances for cosmetic purposes;
 - (iv) a nerve block solely for the treatment or management of chronic pain; or
 - (v) any act that, in the opinion of the College, is similar in nature to those set out in subclauses (i) to (iii) and that is performed for a cosmetic purpose;

but does not include,

- (c) surgical alteration or excision of lesions or tissue for a clinical purpose, including for the purpose of examination, treatment or diagnosis of disease, or
- (d) minor dermatological procedures including without being limited to, the removal of skin tags, benign moles and cysts, nevi, seborrheic keratoses, fibroepithelial polyps, hemangioma and neurofibromata.

¹ Please refer to Appendix 1 for a complete reference to the Regulation.

2.1 CPSO Responsibilities

CPSO is responsible to consider all issues related to the provision of anesthesia/sedation and procedural services within OHPs. The Out-of-Hospital Premises Inspection Program is overseen by the Premises Inspection Committee.

CPSO responsibilities include but are not limited to:

- 1) developing and maintaining “OHP Standards”
- 2) conducting inspection-assessments of the premises and medical procedures to ensure that services for patients are provided according to the standard of the profession
- 3) determining the outcome of inspection-assessments
- 4) maintaining a current public record of Inspection Outcomes (on the CPSO website).

2.1.1 Maintaining the “OHP Standards”

CPSO:

- 1) reviews the “OHP Standards” within a five year cycle, or as required, at the discretion of the Premises Inspection Committee
- 2) prepares revisions of the Standards and associated inspection-assessment tools
- 3) coordinates approval of revisions through an established external review process
- 4) makes revisions available to all relevant parties
- 5) issues notices for payment of OHP fees.

2.1.2 Conducting the Inspection-Assessment

1. **Timeframe:** The timeframe for conducting the inspection-assessment differs for new and existing OHPs.

For:	Inspection-assessment conducted:
CPSO members <i>planning</i> to use a premises for the purpose of performing procedures as defined by O. Reg. 114/94	within 180 days of CPSO receiving the CPSO member’s notice

2. **Process:** The inspection-assessment may involve but is not limited to:
 - 1) completion of the on-line notification process
 - 2) completion of a pre-visit visit questionnaire
 - 3) a site visit by a team of healthcare professionals including one or more physicians (with expertise in the appropriate area of medical practice) appointed by CPSO that includes:
 - a review of records and other documentation
 - observation of procedures performed at the OHP
 - review of the OHP's compliance with accepted standards
 - review of any other material deemed relevant to the inspection-assessment
 - 4) enquiries as may be relevant.
3. **Reports:** OHP assessors provide OHP inspection-assessment reports to CPSO; the CPSO provides a copy of the inspection-assessment report to all members performing procedures in the OHP.

2.1.3 Determining the Outcome of the Inspection-Assessment

1. The **Premises Inspection Committee** is responsible, as outlined in the Ontario Regulation 114/94, for determining the inspection-assessment outcome; see Table 01.

Table 01: Inspection-Assessment Outcomes

Note: Deficiency is anything that can negatively impact the safe and effective provision of medical services for patients.

Outcome	Comments
Pass	<p>“OHP Standards” are met for the specific procedures identified by the OHP at the time of the inspection-assessment; no deficiencies are identified.</p> <p>Note: If a “passed” OHP wishes to add procedures, CPSO must be notified of the intent and conduct an inspection before the new procedures may be performed.</p>
Pass with Conditions	<p>Deficiencies are identified.</p> <ol style="list-style-type: none"> 1) The OHP may be restricted to specific procedures. 2) The OHP may make submissions in writing to CPSO within 14 days of receiving the report. 3) A follow-up inspection-assessment may be conducted at CPSO’s discretion within 60 days of receiving the OHP written submission. 4) A “Pass” will be assigned when deficiencies have been corrected to CPSO’s satisfaction.
Fail	<p>Significant deficiencies are identified.</p> <ol style="list-style-type: none"> 1) The CPSO member(s) cease(s) performance of all procedures. 2) The OHP may make submissions in writing to CPSO within 14 days of receiving the report. 3) A follow-up inspection-assessment may be conducted at CPSO’s discretion within 60 days of receiving the OHP written submission. 4) A “Pass” or “Conditional Pass” will be assigned when deficiencies have been corrected to CPSO’s satisfaction.

2. “Pass” and “Pass with Conditions” outcomes are considered current to a maximum of five years from the date of outcome, but inspections can occur more often if, in CPSO’s opinion, it is necessary or advisable to do so.

2.2 Medical Director Responsibilities

All OHPs must have a Medical Director. The Medical Director is the main contact for the College in relation to information about the premises. The Medical Director is responsible for all duties outlined in this document. In situations where a Medical Director is not present, an “Acting Medical Director” must be appointed. The term “Acting Medical Director” applies in the event that the OHP is being overseen by a physician other than the Medical Director (Refer to section 2.2.3).

2.2.1 Notification to Operate a New OHP

Notification by a Medical Director planning to operate a new OHP shall be made to the CPSO. Notification is accessed through the Member’s Portal log-in on the CPSO website at <https://www.cpso.on.ca/Login.aspx>

All physicians planning to work in an OHP must complete the online Staff Affiliation form by logging in to their membership account on the College Website. Upon completion of the form, an email will be sent to confirm the notification was sent. College staff will review and email the physician when the notification is approved. A copy of this approval email should be shared with the Medical Director prior to performing procedures in an OHP.

2.2.2 Inspection-Assessment Process

The **Medical Director** must inform patient(s) prior to the scheduled inspection-assessment that an observation of the procedure may be a component of the inspection-assessment process.

The **Medical Director** is the main contact for any information related to the premises. Any reports pertaining to the inspection-assessment of an OHP are directed to the Medical Director for review and response. The **Medical Director** must respond to CPSO requests for documentation in the form and timeframe required, as follows:

- Within 24 hours for adverse events submissions (as indicated in College By-law No. 77)
- Within 14 days for regular CPSO requests, or otherwise specified timeframe as identified by the CPSO for other CPSO requests

Failure to provide the information may result in an outcome of Fail by the Premises Inspection Committee.

The **Medical Director** must ensure that patient records are established and maintained, are accurate, legible, complete, follow a consistent format, meet legislative requirements and adhere to the CPSO *Medical Records* policy; a patient record shall include, but is not limited to:

- a) Consent form(s) for the procedure and anesthetic signed by the patient or substitute decision maker/legal guardian and witnessed
- b) Pre-procedure assessment
- c) “Surgical Safety Checklist” – a modified surgical safety checklist is required for endoscopy premises.
- d) “Anesthetic/sedation Record”
- e) Notes about procedural care
- f) Notes about post-procedure care
- g) Adverse event reports as required by CPSO.

The **Medical Director** must ensure that complete records are onsite on the date of the inspection-assessment. In carrying out an inspection of a premises under the regulation, the College may require any or all of the following: Examination and copying of books, accounts, reports, records or similar documents that are, in the opinion of the College, relevant to the performance of a procedure in the practice of the member.

2.2.3 Appointment of Acting Medical Director

In the event the Medical Director is unable or unavailable to perform all of his or her duties due to illness, leave, or other circumstance, then an Acting Medical Director who is acceptable to the CPSO must be appointed. An agreement must be signed by the Acting OHP Medical Director that articulates all responsibilities, with emphasis on the need to respond to CPSO requests for documentation in the form and timeframe required, as follows:

- Within 24 hours for adverse events submissions (as indicated in College By-law No. 77)
- Within 14 days for regular CPSO requests, or otherwise specified timeframe as identified by the CPSO for other CPSO requests

The CPSO encourages Medical Directors to make prior arrangements that identify Acting Medical Director(s) at each of their premises to ensure systematic coverage during absences. The Acting Medical Director is deemed to be the Medical Director of the premises if he or she is in the role for more than three months - unless otherwise directed by the CPSO.

Failure to provide the information may result in an outcome of Fail by the Premises Inspection Committee, which means that the premises can no longer provide the services under the OHPIP regulation.

All staff working at the OHP must be notified in the event an Acting Medical Director is appointed.

In addition, any change to the Medical Director must be reported to the CPSO (see 2.2.4 “Notification of OHP Changes to CPSO”) within 48 hours of the change.

All of the above applies with such modifications as are necessary in the event that the Acting Medical Director is unable or unavailable to perform his or her duties due to illness, leave, or other circumstance.

The Medical Director/Acting Medical Director is professionally accountable for fulfilling all of their obligations and duties to the OHP and the CPSO. In the event that the CPSO determines that the Medical Director or Acting Medical Director is not performing his or her duties in accordance with the legislation, regulations, and policies, the CPSO can require the OHP Medical Director to appoint an Acting Medical Director acceptable to the CPSO and/or take such other steps as deemed necessary.

2.2.4 Notification of OHP changes to the CPSO

The **Medical Director** must notify the CPSO forthwith in writing of any OHP changes with regard to the following:

- a) Ownership of the medical practice
- b) OHP Medical Director (within 48 hours of change)
- c) Name and/or address of the OHP
- d) Structural changes to patient care areas (including equipment)
- e) Types of procedures or practices

- f) Physicians performing procedures or administering anesthesia (additions/deletions)
- g) Numbers of procedures performed: any significant increase/decrease (>50% of the last reported assessment)
- h) A new arrangement to rent space to other physicians for the performance of any surgical or anesthetic technique covered by the OHP policy and procedures
- i) If overnight stays are permitted
- j) Decision to cease operation of the OHP.

2.2.5 Annual Declaration of Responsibilities

The **Medical Director** must review, and sign an annual declaration of his/her responsibilities, which will include agreement to:

- perform his or her duties with due diligence and in good faith;
- ensure that the OHP meets its responsibilities;
- attend and chair QA Committee meetings at the OHP at a minimum of twice per year;
- ensure staff qualifications are current;
- ensure policies and procedures are reviewed and updated when necessary, and in accordance with relevant standards and guidelines including, but not limited to, the CPSO OHPIP Standards, updates to the Provincial Infectious Diseases Advisory Committee's (PIDAC) Infection Prevention and Control for Clinical Office Practice, Malignant Hyperthermia Association of the United States (MHAUS), etc.

2.2.6 OHP Policies and Procedures

1. The Medical Director is responsible for the regular review, update, and implementation of OHP policies and procedures, which must address the following areas:

2.2.6.1.1 Administrative:

- a) responsibility for developing and maintaining the policy and procedure manual
- b) organizational chart
- c) scope and limitations of OHP services provided
- d) overnight stays, if applicable.
- e) ensuring that records kept for each RHP working in the OHP are current and include qualifications, relevant experience, and relevant hospital privileges as appropriate to the RHP.
- f) ensuring all physicians performing OHP procedures at the premises have provided online notification to satisfy the regulation requirements (see section 2.2.1), and documentation verifying approval (emails from College staff) is on file.

2.2.6.1.2 General Response to Emergencies:

Each OHP shall have a policy on management of relevant emergency situations, including, but not limited to:

- a) need to summon additional staff assistance urgently within the OHP
- b) fire
- c) power failure
- d) other emergency evacuation
- e) need to summon help by 911, and coordination of OHP staff with those responders.

2.2.6.1.3 Urgent Transfer of Patients:

The OHP must have an established procedure to facilitate the urgent transfer of patients to the most appropriate acute-care hospital for the management of an urgent- adverse patient event; it should include the following:

- a) The patient must be transferred by appropriate transportation service; in most situations this would mandate transfer by ambulance. It is expected that the most-responsible physician (MRP) will exercise clinical judgment on a case-by-case basis to determine 1) whether transfer by ambulance is required, and 2) whether a regulated health professional or another staff member should accompany the patient during the transfer.
- b) The most-responsible physician (MRP) ensures that essential medical information is sent with the patient (e.g., pre-op history, ECG strips, OR record, anesthesia record, consultation note); however, this information must not delay transfer
- c) The MRP, if not accompanying the patient, must contact the receiving physician/premises immediately, by phone or in person. No other means of communication will be deemed sufficient
- d) If the MRP refers the patient to 1) a specialist or 2) other physician, the MRP must contact the specialist/other physician, by phone or in person, to ensure continuity of care.
- e) The MRP must complete an adverse event report (see Section 8.1.2).

2.2.6.1.4 Job Descriptions:

- a) OHP staff job descriptions that define scope and limitations of functions and responsibilities for patient care
- b) responsibility for supervising staff.

2.2.6.1.5 Procedures:

- a) Adverse events: monitoring, reporting, and reviewing
- b) Adverse events: response to an adverse event
- c) Combustible and Volatile Materials
- d) Delegating controlled acts
- e) Equipment: routine maintenance and calibration
- f) Infection control, including staff responsibilities in relation to the *Occupational Health and Safety Act*
- g) Medications handling and inventory
- h) Medical Directives
- i) Patient booking system
- j) Detailed and clear patient selection/admission/exclusion criteria for services provided at the OHP
- k) Patient consent (written or verbal) based on the scope of the OHP practice
- l) Patient Preparation for OHP procedures
- m) Response to Latex Allergies
- n) Safety precautions regarding electrical, mechanical, fire, and internal disaster.
- o) Urgent transfer of patients (see Section 6.5)
- p) Waste and garbage disposal

2.2.6.1.6 Forms used

2.2.6.1.7 Inventories/Lists of equipment to be maintained

2.2.6.1.8 External (non-OHP) policies: as determined to be necessary by each OHP.

2. The **Medical Director** shall ensure that all staff:
 - a) read the P&P manual upon being hired, and confirm action with signature and date
 - b) review the P&P manual annually, and confirm action with signature and date
 - c) read their individual job descriptions of duties and responsibilities, and sign and date, indicating they have been read and understood.

3. The **Medical Director** is responsible for ensuring that OHP staff who are members of regulated health professions have professional liability protection required by their regulatory body. Physicians need to have professional liability protection in accordance with CPSO bylaws.

2.2.7 CPSO Policies/Procedures & Regulations

The Medical Director is responsible for ensuring all CPSO policies and procedures, as well as applicable laws including Ontario Regulations enacted pursuant to Statute, are adhered to in the operation of the premises.

3 Administration of OHPs

3.1 OHP Levels

The OHP level has two determinants: anesthesia and procedure — the level is decided by the higher ranking of the two, e.g., if the patient is receiving a minor nerve block (level 1) for limited invasive procedure (level 2), the OHP is considered level 2.

Table 02: OHP Levels

OHP Level	Anesthesia	Procedure
OHP Level 1	<ul style="list-style-type: none"> Local infiltration Minor nerve block (e.g. digital) Tumescent anesthesia < 500cc of infiltrate solution 	Minimally Invasive: <ul style="list-style-type: none"> No surgical wound is created and Procedure does not interfere with target organ function or general physiological function.
OHP Level 2	<ul style="list-style-type: none"> IV Sedation Regional anesthesia (e.g., major nerve blocks, spinal, epidural, or caudal) Tumescent anesthesia > 500cc of infiltrate solution 	Limited Invasiveness: <ul style="list-style-type: none"> Surgical wound is created, but not for the purpose of penetration of a body cavity or viscus (e.g., rhinoplasty, facelift) and Procedure has minimal impact on target organ or general physiological response and/or Liposuction 1 to 1000cc of aspirate and/or A small subcutaneous implant is inserted (e.g. lip, chin)
OHP Level 3	<ul style="list-style-type: none"> General anesthesia 	Significantly Invasive: <ul style="list-style-type: none"> Surgical wound allows access to a body cavity or viscus (e.g., laparoscopic banding surgery, arthroscopy), OR A significant amount of liposuction aspirate is removed (1000 - 5000 cc.) OR A large prosthesis is inserted (e.g., augmentation mammoplasty).

3.2 Anesthesia

1. **Local Anesthesia** refers to the application, either topically, intradermally or subcutaneously, of agents that directly interfere with nerve conduction at the site of the procedure.
2. **Sedation**² is an altered or depressed state of awareness or perception of pain brought about by pharmacologic agents and which is accompanied by varying degrees of depression of respiration and protective reflexes.
 - 2.1 **Minimal Sedation** (“Anxiolysis”) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. **Note:** For the purpose of this document, sole or minimal use of oral anxiolysis for the purpose of pre-medication is not considered sedation.
 - 2.2 **Moderate Sedation** (“Conscious Sedation”) is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. **Note:** Reflex withdrawal from painful stimulus is NOT considered a purposeful response.
 - 2.3 **Deep Sedation** is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. **Note:** Due to the potential for rapid and profound changes in sedative/anesthetic depth and the lack of antagonist medications, patients that receive potent intravenous induction agents (including, but not limited to Propofol, Ketamine, Etomidate, and Methohexital) must receive care that is consistent with deep sedation even if moderate sedation is intended. These medications must be administered by a physician qualified to provide deep sedation. Please see section 5.3.
3. **Regional anesthesia:** * Major nerve blocks include, but are not limited to, spinal, epidural, caudal, retrobulbar, stellate, paravertebral, brachial plexus, transcapular, intravenous regional analgesia, celiac, pudendal, hypogastric, sciatic, femoral, obturator, posterior tibial nerve and cranial nerve block.
4. **General anesthesia** is regarded as a continuum of depressed CNS function from pharmacologic agents resulting in loss of consciousness, recall, and suppression of somatic and autonomic reflexes.

² This section is adapted with permission from “Continuum of Depth of Sedation” and “Statement on Safe Use of Propofol” by the American Society of Anesthesiologists (ASA).

* Refer to document on the CPSO website for further direction related to Expectations of Physicians who have changed or plan to change their scope of practice to include interventional pain management (IPM)

4 OHP Physical Standards

Note: Depending on the procedure performed, not all standards may apply.

4.1 General Physical Standards

Note: All documentation relating to physical standards and equipment must be up-to-date.

Table 03: General Physical Standards

	Level 1	Level 2	Level 3
1 Building Codes	OHP site complies with all applicable building codes including fire safety requirements.		
2 Electrical	<ol style="list-style-type: none"> All electrical devices are certified by CSA or licensed for use in Canada. Emergency power supply can provide for safely completing the procedure and recovering the patient. 		
3 Access	<ol style="list-style-type: none"> Access for persons with disabilities complies with provincial legislation and municipal bylaws. Doors and corridors can safely accommodate stretchers and wheelchairs. 		
4 Size	OHP size is adequate for all procedures to be performed.		
5 Layout	<ol style="list-style-type: none"> Layout facilitates safe patient care and patient flow. These areas are functionally separate: <ol style="list-style-type: none"> administration and patient-waiting area procedure room and/or operating room recovery area clean utility area dirty utility room reprocessing room endoscope cabinet staff change room and staff room. 		
6 Emergency Measures	Provisions are in place to ensure <ol style="list-style-type: none"> The safe evacuation of patients and staff in case of an emergency, i.e., stretchers, wheelchairs, or other adequate methods of transport are available, and There is appropriate access to the patient for an ambulance to transfer the patient to a hospital. 		

4.2 Procedure Room/Operating Room Physical Standards

Note: Depending on the procedure performed, not all standards may apply.

Table 04: Procedure Room/Operating Room Physical Standards

	Level 1	Level 2	Level 3
1 Physical Requirements	<ol style="list-style-type: none"> 1. All OHP levels provide: <ol style="list-style-type: none"> a) lighting as required for the specific procedure b) floors, walls and ceilings that can be cleaned to meet infection control requirements c) immediate access to hand-washing facilities and proper towel disposal d) openings to the outside effectively protected against the entrance of insects or animals by self-closing doors, closed windows, screening, controlled air current or other effective means 2. Space can accommodate equipment and staff required for the procedure. 3. Space allows the physician and assisting staff, when sterile, to move around the OR/procedure table with access to both sides of the patient, without contamination. 		

	Level 1	Level 2	Level 3
2 Ventilation	<ol style="list-style-type: none"> 1. Ventilation must ensure patient and staff comfort; and fulfill occupational health and safety requirements. 2. Where applicable, ventilation and air circulation should be augmented to meet manufacturer’s standards and address procedure-related air-quality issues; e.g., cautery smoke, endoscopy, disinfecting agents (e.g., Glutacide venting is separate from the other internal ventilation). 3. Where gas sterilization is used, a positive pressure outbound system is used, vented directly to the outside. 		

	Level 1	Level 2	Level 3
3 Equipment	<ol style="list-style-type: none"> 1. Medical equipment must be maintained and inspected yearly by a qualified biomedical technician. 2. Related documentation for all equipment is available: <ol style="list-style-type: none"> a) equipment operating manuals b) equipment maintenance contracts with an independent and certified biomedical technician c) log for maintenance of all medical devices d) Equipment necessary for emergency situations (i.e. Defibrillators, oxygen supply, suction) should be inspected on a weekly basis and documented. 3. The following equipment is provided: <ol style="list-style-type: none"> a) cleaning equipment as required for the specific procedure b) accessible anesthetic material and equipment c) blood pressure and oxygen saturation monitoring equipment d) sterile supplies and instruments e) table/chair that permits patient restraints and Trendelenberg positioning (level 2 &3) f) table/chair/stretchers that accommodates procedures performed and provides for adequate range of movement for anesthetic procedures g) suction equipment and backup suction, for anesthesia provider's exclusive use. 		

4.2 Procedure Room/Operating Room Physical Standards continued...

	Level 1	Level 2	Level 3
4 Anesthetic and Ancillary Equipment	Level 1 NA	1. Both a) anesthetic and ancillary equipment (selection, installation, maintenance) and b) medical compressed gases and pipelines must comply with: <ul style="list-style-type: none"> • Canadian Standards Association (CSA) or licensed for use in Canada, and • Specific applicable recommendations arising from provincial legislation or as identified in other CPSO requirements 2. A second supply of (full cylinder) oxygen capable of delivering a regulated flow must be present.	
	Level 1 NA	Level 2 NA	3. Level 3 OHP provides: <ul style="list-style-type: none"> a) anesthetic machine b) anesthetic equipment/drug cart.

4.3 Recovery-Area Physical Standards

Table 05: Recovery-Area Physical Standards

	Level 1	Level 2	Level 3
1 Physical Requirements	1. A sink for hand washing is accessible.		
2 Size and Layout	Level 1 NA	1. The size of the recovery area depends on planned use: it must accommodate the volume of patients expected for a minimum of two hours operating room time, i.e., <ul style="list-style-type: none"> • 1 hour procedure = 2 patients • 0.5 hour procedure = 4 patients. 2. The recovery area allows for transfer of patients to/from a stretcher and performance of emergency procedures.	
3 Equipment	Level 1 NA	Monitoring, suction, oxygen, and bag-valve mask devices, intravenous and other medical supplies are immediately available.	

4.4 General Medication Standards

1. OHPs should:
 - a) maintain a general medication inventory record
 - b) periodically inspect all medications for viability
 - c) date multidose vials of medication on opening and dispose according to manufacturer's guidelines
 - d) label medications in accordance with the *Food and Drug Act* (FDA) and the *Controlled Drugs and Substances Act* (CDSA) and its regulations
 - e) store medications:
 - i) according to the manufacturer's recommendations (e.g., refrigeration if required)
 - ii) in a manner suitable for security and restocking
 - f) store emergency drugs in a common location. In facilities where procedures are done in multiple procedure rooms, a crash cart is advisable
 - g) document administration of medications in the patient record
 - h) dispense medications at discharge accompanied by verbal and written instructions that are given to the patient and/or accompanying adult
 - i) make available resources to determine appropriate drug dosages and usage.
2. If services are provided to infants and children, the required drugs must be available and appropriate for that population.

4.5 Controlled Substances Standards

1. Controlled substances are handled and administered in accordance with *Food and Drug Act* (FDA) and the *Controlled Drugs and Substances Act* (CDSA) and its regulations.
2. The OHP ensures that controlled substances are:
 - a) accessed by a qualified designated staff (RN, RPN with medication skills, physician)
 - b) stored in a designated, fixed locked cabinet
 - c) accounted for in a "Log of Controlled Substances" that specifies:
 - for each controlled substance: name, quantity, date received; expiry date; loss (damaged, expired, spilled) date and quantity; and
 - for patient administration:
 - 1) patient name
 - 2) drug name and amount removed from inventory
 - 3) date and time
 - 4) name of staff administering the medication.
3. At the beginning and end of each day that controlled substances are used, a balance of the inventory of controlled substances must be calculated by physical count and verified. In the event of a discrepancy, an investigation must be conducted and documented with the action taken.

4.6 Drugs for Resuscitation

Note: The requirements for drugs for resuscitation are dependent on the level of anesthesia used at the OHP (i.e. local, IV sedation or general)

Level 1	Level 2	Level 3
<ul style="list-style-type: none"> Diphenhydramine Intralipid if Bupivacaine/Ropivacaine is used 		<ul style="list-style-type: none"> Epinephrine for injection Oxygen Salbutamol
Level 1	Level 2	Level 3
NA for Level 1	<ul style="list-style-type: none"> Amiodarone IV Antihypertensive IV (at least one of Labetalol, Hydralazine)(N/A Interv Pain) ASA 81mg po Atropine IV Benzodiazepine IV (at least one of: Midazolam, Diazepam, Lorazepam) BETA Blocker IV (at least one of Metoprolol, Propranolol, Esmolol)(N/A Interv Pain) Calcium IV (chloride or gluconate)(N/A Interv Pain) 	<ul style="list-style-type: none"> Dextrose 50% IV Diphenhydramine IV Flumazenil IV(N/A Interv Pain) Hydrocortisone IV 100mg or 500mg IV agent for SVT (at least one of Adenosine, Esmolol, Verapamil) (N/A Interv Pain) MHAUS treatments if triggering agents present, following MHAUS guidelines Naloxone IV (if narcotics are stocked) Neuromuscular blocking agents, <i>if qualified staff available</i> (N/A Interv Pain) Nitroglycerine spray Pressor IV (at least two of: Epinephrine, Ephedrine, Vasopressin, Phenylephrine) Sodium bicarbonate IV (N/A Interv Pain)
	Level 2	Level 3
	NA for Level 2	<ul style="list-style-type: none"> Antihypertensive IV (at least two of Labetalol, Hydralazine or Nitroglycerine) IV agent for SVT (at least three of Adenosine, Esmolol, Verapamil, Metoprolol) Lasix IV Lidocaine 2% (pre-filled syringe) Magnesium Sulfate IV

4.7 Monitoring and Resuscitation Requirements

Level 1		
•AED		
Level 1	Level 2	Level 3
<ul style="list-style-type: none"> •IV setup •Adequate equipment to manage local anesthetic toxicity •Appropriately sized equipment for infants and children, if required. 		
Level 1	Level 2	Level 3
Level 1 NA	<ul style="list-style-type: none"> • Assortment of disposable syringes, needles, and alcohol wipes • Cardiopulmonary resuscitation equipment with current ACLS/PALS-compatible defibrillator • ECG monitor • Intubation tray with a variety of appropriately sized blades, endotracheal tubes, and oral airways 	<ul style="list-style-type: none"> • Laryngeal mask airways • Means of giving manual positive pressure ventilation (e.g., manual self-inflating resuscitation device) • Qualitative and quantitative means to verify end-tidal CO₂ • Oxygen source • Pulse oximeter • Suction with rigid suction catheter • Torso backboard

5 OHP Staff Qualifications

1. It is expected that physicians will manage medical and surgical conditions within the scope of their specialty training, certification and experience.
2. All staff who: 1) administer sedation, regional anesthesia, or general anesthesia; or 2) monitor or recover such patients, must maintain a current ACLS certification.
Note: Basic (BLS), advanced (ACLS) or paediatric (PALS) life-saving training, as referenced in these standards, includes certification in both theory and hands-on components³.
3. If services are provided to infants and children, staff must be trained to handle paediatric emergencies and maintain a current PALS certification.
4. Physicians who do not meet OHP Physician Qualification standards must successfully complete a Change in Scope of Practice application process, which may include the necessity to demonstrate education, training, and/or competency in the area of practice. This may include physicians who are currently engaged in a CPSO approved change in scope of practice process.
5. Qualifications of all regulated health professionals (RHPs) must meet requirements of their respective regulatory college, and they must practice within their scope of practice.

Note: Change in Scope of Practice. For any Change in Scope of Practice requests from physicians that involve procedures or anesthetic in Out-of-Hospital Premises, the College's Quality Assurance Committee will provide oversight to the decision regarding the suitability of the request. The College may (based on the nature of the request) establish training and supervision requirements that must be completed before a final assessment is conducted to formally approve the physician in his/her new scope of practice.

5.1 OHP Medical Director Qualifications

A physician who is applying to become a Medical Director must hold a valid CPSO certificate of registration and must **not** be the subject of any disciplinary or incapacity proceeding in any jurisdiction.

If, during the course of serving as a Medical Director, the Medical Director becomes the subject of a disciplinary or incapacity proceeding, the Medical Director must inform the Out-of-Hospital Premises program staff at the CPSO, and may be required to appoint a substitute Medical Director at the discretion of the CPSO. The Medical Director may only resume the role upon CPSO approval.

Additional consideration will be made by CPSO regarding the ability of a physician to serve in the role of Medical Director. Considerations may include, but will not be limited to:

- A physician who is the subject of a Specified Continuing Education Remediation Program (SCERP);
- A physician who has signed an undertaking with the College to resolve a clinical complaint that may include supervision;
- A physician who is the subject of a complaint; where the complaint may have a specific impact on the ability to perform in the role; and
- A physician who is the subject of a discipline finding.

The OHP must have a Medical Director appointed at all times. Failure to have an appointed Medical Director will result in an outcome of Fail.

³ To identify training courses, contact the Heart and Stroke Foundation of Ontario.

5.2 Physician Performing Procedures Qualifications

All physicians who perform procedures using local anesthesia in OHPs, as set out in O. Reg. 114/94, shall hold:

- 1) Valid CPSO certificate of registration
and
- 2) **One** of the following:
 - a) RCPSC or CFPC certification that confirms training and specialty designation pertinent to the procedures performed.
 - b) CPSO recognition as a specialist that would include, by training and experience, the procedures performed (as confirmed by the CPSO “Specialist Recognition Criteria in Ontario” policy).
 - c) Satisfactory completion of all CPSO requirements for a physician requesting a change in their scope of practice (based on the CPSO policy, *Changing Scope of Practice*). This may include physicians who are currently engaged in a CPSO approved change in scope of practice process.

Physician Administering Anesthesia Qualifications

5.3 Physicians Administering General Anesthesia

Physicians administering general anesthesia shall hold:

- 1) Valid CPSO certificate of registration
and
 - 2) RCPSC designation as a specialist in anesthesia **OR one** of the following:
 - a) Completion of a 12-month rotation in a program accredited by the College of Family Physicians of Canada (CFPC) under the category of “Family Medicine Anesthesia”.
 - b) CPSO recognition as a specialist in anesthesia as confirmed by CPSO “Specialist Recognition Criteria in Ontario” policy.
 - c) Satisfactory completion of all CPSO requirements for a physician requesting a change in their scope of practice (based on CPSO policy, *Changing Scope of Practice*). This may include physicians who are currently engaged in a CPSO approved change in scope of practice process.
- and**
- 3) Current ACLS certification, and PALS certification if providing care for patients fourteen (14) years and younger.

5.4 Physicians Administering Regional Anesthesia

Physicians administering regional anesthesia shall hold:

- 1) Valid CPSO certificate of registration
and
 - 2) **One** of the following:
 - a) RCPSC designation as a specialist in anesthesia.
 - b) Completion of a 12-month rotation in a program accredited by the College of Family Physicians of Canada (CFPC) under the category of "Family Medicine Anesthesia".
 - c) CPSO recognition as a specialist in anesthesia, or other specialty pertinent to the regional anesthesia performed, as confirmed by CPSO "Specialist Recognition Criteria in Ontario" policy.
 - d) Satisfactory completion of all CPSO requirements for a physician requesting a change in their scope of practice (based on CPSO policy, *Changing Scope of Practice*). This may include physicians who are currently engaged in a CPSO approved change in scope of practice process.
- and**
- 3) Current ACLS certification, and PALS certification if providing care for patients fourteen (14) years and younger.

5.5 Physicians Administering Sedation

1. Physicians administering deep sedation must hold qualifications to administer general anesthesia (Section 5.3).
2. Physicians **not** qualified for administering general anesthesia or deep sedation, but administering minimal-to-moderate sedation, shall hold:
 - a) Valid CPSO certificate of registration
 - b) Education and experience to manage the potential medical complications of sedation/anesthesia, including ability to 1) identify and manage the airway and cardiovascular changes which occur in a patient who enters a state of general anesthesia, 2) assist in the management of complications, and 3) understand the pharmacology of the drugs used, and
 - c) Current ACLS certification, and PALS certification if providing care for patients fourteen (14) years and younger.

5.6 Nurse Qualifications

1. Registered nurses (RNs) and registered practical nurses (RPNs) working within their scope of practice in OHPs must hold:
 - a) current registration with the College of Nurses of Ontario
 - b) additional training and appropriate experience as required for procedures performed
 - c) current BLS certification
 - d) must have current ACLS if administering sedation to, monitoring or recovering patients (RNs only).

2. Registered Nurses (RNs) working with a pediatric population (14 years and younger), who are involved in monitoring, administering sedation or recovering patients must maintain a current PALS certification.

5.7 Other Staff Qualifications

Staff from other regulated health professions must be adequately trained and registered with their regulatory body.

Staff responsible for the sterilization and reprocessing of medical equipment must be adequately educated and trained. Please contact the College for an approved list of courses specific to reprocessing and sterilization in an OHP.

6 Procedure Standards for all OHPs

The ultimate judgment regarding the care of a particular patient and selection of procedure must be made by the physician considering all the circumstances presented in an individual case. Risk factors that should be considered as having the potential to jeopardize patient safety in an OHP include but should not be limited to:

- 1) State of patient health, including co-morbidities (ASA physical status)
- 2) Potential complication from a specific procedure
- 3) Complications in surgical management if more than one procedure is performed during a single operation
- 4) Anesthetic factors that place patient at higher risk
- 5) Necessity for prolonged recovery period
- 6) Duration of procedure
- 7) Availability of anti-hyperthermia measures
- 8) Anticipated blood loss
- 9) Hypothermia

6.1 Pre-Procedure Patient-Care Standards

1. The physician must:
 - I. assess the risks inherent in each procedure or combination of procedures to determine if the OHP setting is safe; and
 - II. appraise each patient's medical risk factors and capacity to undergo anesthesia
2. Documentation:

All actions taken for pre-procedure patient care are entered in the patient record; separate forms, e.g., consent form, are placed in the patient record.

6.2 Pre-Procedure Requirements: OHP Level 1

Pre-procedure requirements for OHP Level 1 are shown in Table 06.

Where appropriate, the responsibility for the actions listed in the chart below may be performed by appropriately qualified providers under the direction of the Most Responsible Physician (MRP).

Table 06: Pre-Procedure Requirements: OHP Level 1

Pre-Procedure Requirements: OHP Level 1		Responsibility
BEFORE day of procedure:		Physician performing procedure
1. Provide fasting instructions as required.		
2. Advise patient that a responsible adult should be accessible during the duration of the OHP stay.		
BEFORE or ON day of procedure:		
3. Conduct pre-procedure assessment , which includes, but is not limited to: <ul style="list-style-type: none"> a) focused history and physical examination that includes findings indicating the rationale for the proposed procedure b) blood pressure and pulse c) allergies. 		
4. The physician is responsible for obtaining informed consent and a procedure consent form signed by the patient or substitute decision maker and witnessed.		
ON day of procedure:		
5. Complete admission assessment: Confirm baseline history and physical as in point 3 above.		

6.3 Pre-Procedure Requirements: OHP Levels 2 and 3

The physician providing anesthesia assigns an ASA classification for all prospective patients requiring anesthesia for OHP procedures; Class ASA4 and above are not generally acceptable for OHPs.

The pre-procedure anesthetic/sedation assessment includes but is not limited to the following:

- 1) ASA classification
- 2) a review of the patient’s clinical record (including pre-procedure assessment)
- 3) an interview with the patient
- 4) a physical examination relative to anesthetic aspects of care
- 5) a review and ordering of tests as indicated
- 6) a review or request for medical consultations as necessary for patient assessment and planning of care
- 7) orders for pre-procedure preparation such as fasting, medication, or other instructions as indicated.

Table 07: Corresponding Grade in each ASA Classification⁴

	Description
ASA1	A normal healthy patient
ASA2	A patient with mild systemic disease
ASA3	A patient with severe systemic disease
ASA4	A patient with severe systemic disease that is a constant threat to life
ASA5	A moribund patient who is not expected to survive without the operation
ASA6	A declared brain-dead patient whose organs are being removed for donor purposes

Table 08: Pre-Procedure Requirements: OHP Levels 2 and 3

Where appropriate, the responsibility for the actions listed in the chart below may be performed by appropriately qualified providers under the direction of the MRP.

Pre-Procedure Requirements: OHP Levels 2 and 3	Responsibility
BEFORE day of procedure:	
1. Provide fasting instructions as required for the procedure, specific conditions, (e.g., diabetes), and for medications the patient routinely takes (e.g., diabetic medications, antihypertensives, antiplatelets).	Physician performing procedure
2. Advise patients if they will require adult accompaniment on leaving OHP after the procedure.	
3. Advise patient that a responsible adult must be accessible during the duration of the OHP stay.	
BEFORE or ON day of procedure:	
4. Conduct pre-procedure assessment that includes, but is not limited to: <ul style="list-style-type: none"> a) history and physical examination that includes findings indicating the rationale for the proposed procedure b) all current medications (prescribed and non-traditional, e.g., herbal remedies) c) weight, height, body mass index (BMI), blood pressure, and pulse d) allergies e) ECG, laboratory tests, x-rays, pre-procedure consultation, and investigations (all as indicated). 	Physician performing procedure
5. For patients with significant co-morbidities (including sleep apnea), arrange a consultation with an anesthesiologist, and other medical specialists as required, prior to procedure acceptance. <ul style="list-style-type: none"> 5.1 If classified as ASA3, patients may be accepted only if the disease entity could not reasonably be expected to be affected adversely by the anesthetic or procedure. 5.2 The physician and anesthesiologist should discuss all Class ASA3 cases well in advance of the scheduled procedure, with regard to the: <ul style="list-style-type: none"> a) pre-procedure assessment and care required, b) intra-procedure and post-procedure requirements, and c) appropriateness of OHP setting for the safe performance of the procedure. 	Physician performing procedure or Physician providing anesthesia

⁴ American Society of Anesthesiologists: www.asahq.org/clinical/physicalstatus.htm

<p>6. Obtain informed consent and a procedural consent form signed by the patient. A rolling patient consent (which requires specific information to be documented) is suitable for the same procedure performed consecutively and should be documented in the patient’s chart.</p>	<p>Physician performing procedure</p>
<p>7. Provide adequate explanation to the patient about the proposed anesthesia including anticipated outcome, significant risks, and alternatives available. This may be included in the procedure consent form.</p>	<p>Physician performing procedure or Physician providing anesthesia</p>

ON day of procedure:

<p>8. Complete admission assessment: Confirm pre-procedure anesthetic/sedation assessment (may be unnecessary if anesthesiologist conducts pre-procedure anesthetic/sedation assessment on same day as procedure).</p>	<p>Physician providing anesthesia</p>
<p>9. Complete admission assessment: Confirm baseline history and physical as in point 4 above; update if >14 days. Take vital signs (BP, pulse, respiration, oxygen saturation, temperature), and glucometer reading for diabetic patients where appropriate.</p>	<p>Health care provider</p>

6.4 Verification Process

The verification process (prevention of wrong site, wrong procedure, or wrong patient) ensures that the correct patient has the correct procedure performed on the correct site.

NOTE: If the patient is unable to verify the information him/herself (e.g., minor, incompetent), the legal guardian/substitute decision maker provides and verifies the appropriate information.

1. Procedures Included

Procedures with any of the following components require a verification process; a) intravenous sedation; b) surgical incision (of any size); c) removal of tissue; d) primary procedure is itself an injection of any kind. This requires verification of the correct patient, procedure, and correct site at two different times and locations, as follows:

	When	Where
First verification	before entering the procedure room/ operating room	the pre-procedure area
Second verification	during the time-out	in the procedure room/ operating room

Note: Procedures exempted from site marking still require a verification process.

6.5 First Verification

1. The first verification takes place in the pre-procedure area.
2. The patient is awake and aware.
3. The nurse preparing the patient for the procedure:
 - a) confirms the patient identity, procedure, site and/or side with the patient/substitute decision-maker/legal guardian
 - b) documents the first verification on the *Surgical Safety Checklist*.

6.6 Second Verification

1. The second verification must be conducted during the time-out in the location where the procedure takes place, immediately before starting the procedure.
2. The patient is not required to be awake.
3. The entire procedure team confirms the patient identity, procedure, site and/or side and acknowledges their agreement: nurse(s), attending physician, attending anesthesiologist (if applicable), and physician-assistant (if applicable).

6.7 Site Marking

1. Marking must take place with the patient awake and aware, if possible.
2. The physician performing the procedure marks at or near the incision/insertion site. Site- sensitive areas must be marked above or lateral to the procedure site (e.g., scrotal surgery sites are marked on the groin area on the appropriate side of the body; breast sites are marked on the breast or above the breast on the upper chest area).
3. Procedures involving right/left distinction or multiple structures (fingers, toes) must be marked.
4. The mark must be:
 - a) placed using a permanent marker
 - b) visible at the time of patient preparation and visible at time of incision
 - c) explicit (e.g., initials) to indicate the intended site of incision or insertion or actual incision line.
5. Site marking is exempted in the following situations:
 - a) The procedure requires a surgical measurement to the operative part when applied on an awake and oriented patient.
 - b) Patient refuses to allow site marking. In this situation, a risk report is completed and placed in the patient's record.

6.8 Intra-Procedure Care for Sedation, Regional Anesthesia, or General Anesthesia

Requirements for managing patients undergoing sedation, regional anesthesia, or general anesthesia, are as follows. Note: See physician qualification as well.

1. If the physician administering the sedation or regional anesthesia is also performing the procedure, the patient must be attended by a second individual (physician, respiratory therapist, RN or anesthesia assistant) 1) who is NOT assisting in the procedure and 2) who is trained to monitor patients undergoing sedation or regional anesthesia.
 - 1.1 The second physician, respiratory therapist, RN or anesthesia assistant shall hold ACLS (and PALS if pediatric patients are being treated) certification and the following skills:
 - 1) assessing and maintaining patient airway
 - 2) monitoring vital signs
 - 3) venipuncture
 - 4) administering medications as required
 - 5) assisting in emergency procedures including the use of a bag-valve-mask device
 - 6) documenting in the Anesthesia/Sedation Record
2. Note: If assistance is required during the procedure, a third HCP must be available. The person monitoring the anesthetic shall remain with the patient at all times throughout the duration of anesthetic care until the patient is transferred to the care of a recovery-area staff in the recovery area.
3. Patients shall be attended for the duration of the anesthetic care as follows:
 - 3.1 O₂ saturation must be continuously monitored and documented at frequent intervals. In addition, if the trachea is intubated or an LMA is used, end-tidal carbon dioxide concentration must be continuously monitored and documented at frequent intervals. Capnography must be available at the premises for use, where appropriate, on patients receiving deep sedation. Capnography is always required for patients receiving general anesthesia as defined in section 3.2.
 - 3.2 Pulse, blood pressure and electrocardiography must be in continuous use during the duration of anesthetic care. Heart rate and blood pressure shall be documented at least every 5 minutes. During sedation (see section 3.2) in healthy patients without cardiac disease and for whom no cardiovascular disturbance is anticipated, it may be acceptable to waive ECG monitoring as long as pulse oximetry is in continuous use and ECG monitoring is immediately available.
 - 3.3 Audible and visual alarms must not be indefinitely disabled. The variable pitch pulse tone and the low-threshold alarm of the pulse oximeter and the capnograph alarm must give an audible and visual alarm. Variable pitch tone pulse oximeter must be clearly audible at all times.

4. The **Anesthesia/Sedation Record** is completed; it includes the following:
 - 1) pre-procedure anesthetic/sedation assessment
 - 2) all drugs administered including dose, time, and route of administration
 - 3) type and volume of fluids administered, and time of administration
 - 4) fluids lost (e.g., blood, urine) where it can be measured or estimated
 - 5) measurements made by the required monitors:
 - O₂ saturation must be continuously monitored and documented at frequent intervals. In addition, if the trachea is intubated or an LMA⁵ is used, end-tidal carbon dioxide concentration must be continuously monitored and documented at frequent intervals
 - Pulse, blood pressure documented at least every 5 minutes until patient is recovered from sedation
 - 6) complications and incidents (if applicable)
 - 7) name of the physician responsible (and the name of the person monitoring the patient, if applicable)
 - 8) start and stop time for anesthesia/sedation care

⁵ Laryngeal mask airway

CAS Guidelines can be found in *Merchant, R., Chartrand, D., Dain, S., et al. Guidelines to the Practice of Anesthesia Revised Edition 2012. Can J Anesth 2012;59; 63-102*

6.9 Post-procedure Patient Care

1. Recovery area focus and staff requirements are as shown in Table 09. Depending on the invasiveness of the procedure and the level of anesthesia, the staffing requirements may be increased at the discretion of the most responsible physician as appropriate. This must ensure the safe recovery and discharge of the patients.

Table 09: Recovery area Focus and Staff Requirements⁶

	OHP Level 1	OHP Level 2	OHP Level 3
Recovery Phase I (most acute) Focus: monitoring recovery of the patient to a state requiring less acute nursing interventions.	NA	Staff required: <ul style="list-style-type: none"> • One RN in the same room at all times with the patient • A second RN or RPN available on site 	
Recovery Phase II Focus: Preparing the patient for self/family care in the home or for care in Phase III.	NA	Staff required: <ul style="list-style-type: none"> • Minimum of 2 nurses of which one must be an RN, competent in post- procedure care. 	
Recovery Phase III Focus: ongoing care for the patient requiring or requesting extended observation and intervention prior to discharge.			

2. Following sedation/regional anesthesia/general anesthesia, the anesthesiologist/physician must accompany the patient to the recovery area and communicate the appropriate information to the appropriate recovery-area staff. This verbal report includes, but is not limited to:
 - a) name and age of patient
 - b) procedure performed
 - c) pertinent history including allergies, medical/physical limitations
 - d) type of anesthesia/sedation used
 - e) other medications given
 - f) any unusual or adverse events pertaining to patient
 - g) estimated fluid or blood loss
 - h) anesthetic progression.
3. The anesthesiologist/physician should stay with the patient until the appropriate recovery-area staff accepts responsibility for the patient.

⁶ Adapted from Ontario PeriAnesthesia Nurses Association (OPANA).

4. Recovery-area staff caring for patients in phase I, II, or III recovery provide care and document it in the patient record; this includes but is not limited to:
 - a) patient identification, date and time of transfer to recovery area, initial and routine monitoring of: blood pressure, pulse, respirations, SpO₂, temperature, level of consciousness, pain score, procedure site and general status
 - b) continuous monitoring of vital signs until the patient has met requirements of discharge criteria using an objective scoring system from time of transfer to recovery area until discharge from Phase II recovery
 - c) medication administered: time, dose, route, reason, and effect
 - d) treatments given and effects of such treatment
 - e) status of drains, dressings, and catheters including amount and description of drainage
 - f) summary of fluid balance.

5. An anesthesiologist/physician must remain on site until the patient has met Phase 1 discharge criteria. Where there is an overnight stay at an OHP, all of the following conditions must be met:
 - a) The physician or designate physician, appropriately qualified in accordance with Section 5 of the OHP core standards, shall be immediately available by telephone and shall be available onsite at the premises within thirty minutes for urgent medical matters; and,
 - b) The minimum staffing requirements at the premises for overnight stays will be: a minimum of two nurses, one must be a RN with ACLS certification. The second nurse can be a RN or a RPN. The second individual cannot be a Personal Support Worker.

6.10 Patient Discharge

For OHP levels 2 and 3:

1. An anesthesiologist or physician is responsible for writing the discharge order. However, the actual decision for discharge from the recovery area must be based on discharge criteria using an objective scoring system; the decision can be delegated to recovery-area staff.
2. All patients should be accompanied by an adult when leaving the OHP. Patients having received sedation or general anesthesia must be accompanied by a responsible adult.
3. Appropriate verbal and written post-discharge instructions are given to the patient and the accompanying adult.
4. The patient and accompanying adult are instructed to notify the OHP of any unexpected admission to a hospital within 10 days of the procedure.

7 Infection Control

The CPSO, in partnership with Public Health Ontario (PHO), have developed accepted standards of practice for OHPs and physician offices for infection control. The document can be found at the following link: www.publichealthontario.ca/ClinicalPractice

The Medical Director is responsible for compliance with the requirements set out in the Provincial Infectious Diseases Advisory Committee (PIDAC) document. He or she is also responsible for ensuring periodic reviews of the CPSO and PHO website documents by the Medical Director, staff and physicians working in the OHP. All OHP staff, including the Medical Director must stay current with standards for infection prevention and control. The Medical Director is responsible for ensuring implementation and compliance by all physicians and staff of the OHP with the PHO requirements.

OHPs shall adhere to the following:

- 1) Accepted standard(s) of infection control practices that are pertinent to the specific procedures performed at the OHP.
- 2) The *Routine Practice* approach to infection control. According to the concept of Routine Practices, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV and other blood borne pathogens.
- 3) Actions that minimize risk of infection in the operating room:
 - a) adherence to proper use of disinfectants
 - b) proper maintenance of medical equipment that uses water (e.g., automated endoscope reprocessors)
 - c) proper ventilation standards for specialized care environments (i.e., airborne infection isolation, protective environment, and operating rooms)
 - d) prompt management of water intrusion into OHP structural elements.
- 4) Accepted standards of handling regulated waste.
“Regulated Waste” means:
 - a) liquid or semi-liquid or other potential infectious material
 - b) contaminated items that would release blood or other potential infectious materials in a liquid or semi-liquid state are compressed
 - c) items that contain dried blood or other potential infectious materials and are capable of releasing these materials during handling
 - d) contaminated sharps
 - e) pathological and microbiological wastes containing blood or other potentially infectious materials.

8 Quality Assurance (QA)

The Medical Director is responsible for OHP compliance with external regulatory requirements including all Acts relevant to the practise of Medicine¹, including the CPSO OHP Standards, Companion documents to the Standards, and other guidelines, such as, the Provincial Infectious Diseases Advisory Committee's (PIDAC) *Infection Prevention and Control for Clinical Office Practice*, Malignant Hyperthermia Association of the United States (MHAUS), etc. The Medical Director is also individually responsible for OHP compliance with all internal CPSO policies, guidelines and directives within their Policy and Procedure Manual.

The Medical Director is responsible for appointing other individuals as necessary to **assist** with OHP staff compliance with policies and procedures set out by the Medical Director, especially as it relates to monitoring and reporting on the quality of anesthetic and surgical procedures.

OHP Quality Assurance Committee

Each OHP must have a Quality Assurance (QA) committee for the purpose of creating processes to establish standards, monitor activity, and improve performance so that the care provided will satisfy requirements as appropriate to the volume and scope of service provided.

The Medical Director must attend and chair, at a minimum, two QA Committee meetings at each OHP site, per year. Meetings must include representation from all staff providing patient care for every type of anesthetic or surgical procedure. All meetings must be documented. The documentation of the QA Committee meetings must be available upon request by the Premises Inspection Committee and be available for OHP assessors to review.

At minimum, every QA Committee meeting must address the following topics:

- 1) Reports on Quality of Care for each service (8.1)
- 2) Infection Control– duties as set out in Section 7
- 3) Adverse Events
- 4) Staffing credentials

8.1 Monitoring Quality of Care

The purpose of monitoring activity is to identify problems and frequency, assess severity, and develop remedial action as required to prevent or mitigate harm from adverse events.

Monitoring OHP Activity

The OHP must have a documented process in place to regularly monitor the quality of care provided to patients. These activities include, but are not limited to, the following:

- 1) Review of non-medical staff performance
- 2) Review of individual physician care to assess
 - a) patient and procedure selection are appropriate
 - b) patient outcomes are appropriate
 - c) adverse events (see 8.2)

¹ RHPA, Medicine Act, etc.

The suggested protocol is, annually, random selection of 5-10 patient records to review:

- i) record completion and documentation of informed consent
 - ii) percentage and type of procedures
 - iii) appropriate patient selection
 - iv) appropriate patient procedure
 - v) where required, reporting results in a timely fashion
 - vi) evaluation of complications (see 8.2)
 - vii) assessment of transfer to hospital, where required
 - viii) follow up of abnormal pathology and laboratory results
- 3) Review a selection of individual patient records to assess completeness and accuracy of entries by all staff
 - 4) Review of activity related to cleaning, sterilization, maintenance, and storage of equipment
 - 5) Documentation of the numbers of procedures performed: any significant increase/decrease (>50% of the last reported assessment).

8.2 Monitoring and Reporting Adverse Events

1. All OHP staff must monitor adverse events. Indicators of adverse events generally include complications related to the use of sedation/anesthesia or to the procedure.
2. Every member who performs a procedure in an OHP shall report the following events to the College within 24 hours of learning of the event. These events are termed 'Tier 1 Events' to denote the potential serious nature of the event and the need to prevent a recurrence.

Tier 1 events are:

- a) Death within the premises;
 - b) Death within ten (10) days of a procedure performed at the premises;
 - c) Any procedure performed on the wrong patient, site or side; or,
 - d) Transfer of a patient from the premises directly to a hospital for care.
3. Members performing procedures in an OHP are required to document other quality assurance incidents (Tier 2) which are deemed less critical for immediate action. The premises' QA Committee and the Medical Director must submit Tier 2 events to the College after review (on an annual basis). Failure to do so may result in an outcome of Fail by the Premises Inspection Committee.

Tier 2 events include, but are **not limited to**:

- a) unscheduled treatment of a patient in a hospital within ten(10) days of a procedure performed at a premises
- b) complications such as infection, bleeding or injury to other body structures
- c) cardiac or respiratory problems during the patient's stay at the OHP
- d) allergic reactions
- e) medication-related adverse events

4. All OHP staff should report adverse events as follows:
 - 4.1 The member must report Tier 1 adverse events (see above) to the Medical Director and to the College in writing within 24 hours of learning of the event using the form provided on the College website. To access the form, the reporting physician must log in to his/her CPSO member portal on the CPSO website at <https://www.cpso.on.ca/Login.aspx>
 - 4.2 Death occurring within the OHP must also be reported to the coroner.
 - 4.3 The member should report in writing any Tier 2 adverse event (see above) to the Medical Director within 24 hours of the event.
The written report should include the following:
 - a) name, age, and sex of the person(s) involved in the incident; includes staff and patients
 - b) name of witness(es) to the event (if applicable)
 - c) time, date, and location of event
 - d) description of the incident and treatment rendered
 - e) date and type of procedure (if applicable)
 - f) analysis of reasons for the incident
 - g) outcome.

Note: OHPs should identify and adhere to quality indicators specific to procedures performed in their premises.

8.3 Review of Adverse Events and other QA Monitoring Activities

The Medical Director must:

- 1) Review all adverse events reports and QA monitoring findings occurring over a 12-month period
- 2) Document the review and any relevant corrective actions and quality improvement initiatives taken
- 3) Provide feedback to all staff regarding identified adverse events.

APPENDIX

Appendix 1: Ontario Regulation 114/94

ONTARIO REGULATION 134/10

made under the

MEDICINE ACT, 1991

Made: February 1, 2010

Approved: March 31, 2010

Filed: April 6, 2010

Published on e-Laws: April 8, 2010

Printed in *The Ontario Gazette*: April 24, 2010

Amending O. Reg. 114/94

(General)

Note: Ontario Regulation 114/94 has previously been amended. For the legislative history of the Regulation, see the Table of Consolidated Regulations – Detailed Legislative History at www.e-Laws.gov.on.ca.

1. (1) Ontario Regulation 114/94 is amended by adding the following Part: PART XI

INSPECTION OF PREMISES WHERE CERTAIN PROCEDURES ARE PERFORMED

44. (1) In this Part,

"inspector" means a person designated by the College to carry out an inspection under this Part on behalf of the College;

"premises" means any place where a member performs or may perform a procedure on a patient but does not include a health care facility governed by or funded under any of the following Acts:

1. The *Charitable Institutions Act*.

Note: On the day section 1 of the *Long-Term Care Homes Act, 2007* comes into force, paragraph 1 is revoked and the following substituted:

1. The *Long-Term Care Homes Act, 2007*.

See: O. Reg. 134/10, ss. 1 (2), 2 (2).

2. The *Developmental Services Act*.
3. The *Homes for Special Care Act*.
4. The *Homes for the Aged and Rest Homes Act*.

Note: On the day section 1 of the *Long-Term Care Homes Act, 2007* comes into force, paragraph 4 is revoked. See: O. Reg. 134/10, ss. 1 (2), 2 (2).

5. The *Independent Health Facilities Act*.
6. The *Ministry of Community and Social Services Act*.
7. The *Ministry of Correctional Services Act*.
8. The *Ministry of Health and Long-Term Care Act*.
9. The *Nursing Homes Act*.

Note: On the day section 1 of the *Long-Term Care Homes Act, 2007* comes into force, paragraph 9 is revoked. See: O. Reg. 134/10, ss. 1 (2), 2 (2).

10. The *Private Hospitals Act*.
11. The *Public Hospitals Act*;

"procedure" means,

- (a) any act that, when performed in accordance with the accepted standard of practice on a patient, is performed under the administration of,
 - (i) general anaesthesia,
 - (ii) parenteral sedation, or
 - (iii) regional anaesthesia, except for a digital nerve block, and
- (b) any act that, when performed in accordance with the accepted standard of practice on a patient, is performed with the administration of a local anaesthetic agent, including, but without being limited to,
 - (i) any tumescent procedure involving the administration of dilute, local anaesthetic,
 - (ii) surgical alteration or excision of any lesions or tissue performed for cosmetic purposes,
 - (iii) injection or insertion of any permanent filler, autologous tissue, synthetic device, materials or substances for cosmetic purposes,
 - (iv) a nerve block solely for the treatment or management of chronic pain, or
 - (v) any act that, in the opinion of the College, is similar in nature to those set out in subclauses (i) to (iii) and that is performed for a cosmetic purpose,

but does not include,

- (c) surgical alteration or excision of lesions or tissue for a clinical purpose, including for the purpose of examination, treatment or diagnosis of disease, or
- (d) minor dermatological procedures including without being limited to, the removal of skin tags, benign moles and cysts, nevi, seborrheic keratoses, fibroepithelial polyps, hemangioma and neurofibromata. O. Reg. 134/10, s. 1 (1).

(2) Anything that may be done by the College under this Part may be done by the Council or by a committee established under clause 94 (1) (i) of the Health Professions Procedural Code. O. Reg. 134/10, s. 1 (1).

45. (1) All premises where a procedure is or may be performed on a patient by a member in connection with his or her practice are subject to inspection by the College in accordance with

this Part. O. Reg. 134/10, s. 1 (1).

(2) In carrying out an inspection of a premises under subsection (1), the College may also require any or all of the following:

1. Inspection, examination or tests regarding any equipment, instrument, materials or any other thing that may be used in the performance of a procedure.
2. Examination and copying of books, accounts, reports, records or similar documents that are, in the opinion of the College, relevant to the performance of a procedure in the practice of the member.
3. Inquiries or questions to be answered by the member that are relevant to the performance of a procedure on a patient.
4. Direct observation of a member in his or her practice, including direct observation by an inspector of the member performing a procedure on a patient. O. Reg. 134/10, s. 1 (1).

46. An inspector may, on the production of information identifying him or her as an inspector, enter and have access to any premises where a procedure is or may be performed by a member at reasonable times and may inspect the premises and do any of the things mentioned in subsection 45 (2) on behalf of the College. O. Reg. 134/10, s. 1 (1).

- 47.** It is the duty of every member whose premises are subject to an inspection to,
- (a) submit to an inspection of the premises where he or she performs or may perform a procedure on a patient in accordance with this Part;
 - (b) promptly answer a question or comply with a requirement of the inspector that is relevant to an inspection under this Part; and
 - (c) co-operate fully with the College and the inspector who is conducting an inspection of a premises in accordance with this Part. O. Reg. 134/10, s. 1 (1).

48. Where, as part of the inspection, an inspector directly observes a member in their practice, or directly observes the member performing a procedure on a patient, before the observation occurs, the inspector shall,

- (a) identify himself or herself to the patient as an inspector appointed by the College;
- (b) explain the purpose of the direct observation to the patient;
- (c) inform the patient that information obtained from the direct observation, including personally identifiable information about the patient, may be used in proceedings under this Part or any other proceeding under the Act;
- (d) answer any questions that the patient asks; and
- (e) obtain the patient's written consent to the direct observation of the patient by the inspector. O. Reg. 134/10, s. 1 (1).

49. (1) No member shall commence using premises for the purposes of performing procedures unless the member has previously given notice in writing to the College in accordance with subsection (5) of the member's intention to do so and the premises pass an inspection or pass an inspection with conditions. O. Reg. 134/10, s. 1 (1).

(2) The College shall ensure that an inspection of the premises of a member referred to in subsection (1) is performed within 180 days from the day the College receives the member's notice. O. Reg. 134/10, s. 1 (1).

- (3) A member whose practice includes the performance of a procedure on a patient in

any premises on the day this Part comes into force shall give a notice in writing to the College in accordance with subsection (5) within 60 days from the day this Part comes into force. O. Reg. 134/10, s. 1 (1).

(4) The College shall ensure that an inspection of the premises of a member referred to in subsection (3) is performed within 24 months from the day this Part comes into force. O. Reg. 134/10, s. 1 (1).

(5) The notice required in subsections (1) and (3) shall include the following information, submitted in the form and manner required by the College:

1. The full name of the member giving the notice and the full name of the owner or occupier of the premises, if he or she is not the member who is required to give notice under this section.
2. The full name of any other member who is practising or may practise in the premises with the member giving the notice.
3. The name of any health profession corporation that is practising at the premises.
4. The full name of any hospital where the member or other members at the premises have privileges or where arrangements have been made to handle emergency situations involving patients.
5. The full name of any other regulated health professional who is practising or may practise in the premises with a member at the premises, along with the name of the College where the regulated health professional is a member.
6. The full address of the premises.
7. The date when the member first performed a procedure on a patient in the premises or the proposed date when the member or another member intends to perform a procedure on a patient at the premises.
8. A description of all procedures that are or may be performed by a member or other members at the premises and of procedures that may be delegated by the member or other members at the premises.
9. A description of any equipment or materials to be used in the performance of the procedures.
10. The full name of the individual or corporation who is the owner or occupier of the premises, if different from the member giving the notice.
11. Any other information the College requires that is relevant to an inspection conducted at the premises in accordance with this Part. O. Reg. 134/10, s. 1 (1).

50. All premises where a member performs or may perform a procedure on a patient are subject to an inspection by the College once every five years after its initial inspection or more often if, in the opinion of the College, it is necessary or advisable to do so. O. Reg. 134/10, s. 1 (1).

51. (1) After an inspection of a premises, the College shall determine, in accordance with the accepted standards of practice, whether the premises pass, pass with conditions, or fail. O. Reg. 134/10, s. 1 (1).

(2) In determining whether premises pass, pass with conditions or fail an inspection, the College may consider,

- (a) the inspection results provided to the College by the inspector;
- (b) information provided by one or more members who perform or may perform procedures in the premises respecting the inspection, including the answers given by them in response to inquiries or questions asked by the inspector;
- (c) the information contained in a notice given by a member under subsection 49 (1) or

(3); (d) any submissions made by the member or members practising in the premises that are relevant to the inspection; and

(e) any other information that is directly relevant to the inspection of the premises conducted under this Part. O. Reg. 134/10, s. 1 (1).

(3) The College shall deliver a report, in writing, to the owner or occupier of the premises and to every member who performs or may perform a procedure on a patient in the premises, within a reasonable time after the inspection is completed, in accordance with section 39 of the *Regulated Health Professions Act, 1991*. O. Reg. 134/10, s. 1 (1).

(4) Any report made by the College respecting an inspection of premises where a procedure is or may be performed shall make a finding that the premises passed, passed with conditions, or failed the inspection and shall provide reasons where the premises passed with conditions or failed the inspection. O. Reg. 134/10, s. 1 (1).

(5) Any report made by the College that makes a finding that the premises failed an inspection or passed with conditions is effective on the day that it is received by one or more members who perform or may perform a procedure within the premises, in accordance with section 39 of the *Regulated Health Professions Act, 1991*. O. Reg. 134/10, s. 1 (1).

(6) A member shall not perform a procedure on a patient in premises that fail an inspection until,

- (a) the College delivers a report indicating that the premises passed a subsequent inspection, or passed with conditions; or
- (b) after considering submissions under subsection (8), the College substitutes a finding that the premises pass or pass with conditions. O. Reg. 134/10, s. 1 (1).

(7) A member shall not perform a procedure on a patient in premises that pass an inspection with conditions except in accordance with the conditions set out in the report until,

- (a)) the College delivers a report indicating that the premises passed a subsequent inspection; or
- (b) after considering submissions under subsection (8), the College substitutes a finding that the premises pass. O. Reg. 134/10, s. 1 (1).

(8) A member may make submissions in writing to the College within 14 days from the day he or she receives a report made by the College that finds that the premises passed with conditions or failed the inspection. O. Reg. 134/10, s. 1 (1).

(9) The College may or may not elect to re-inspect the premises after receiving a member's submissions, but no more than 60 days after a member provides his or her submissions, the College shall do one or more of the following:

1. Confirm its finding that the premises failed the inspection or passed with conditions.
2. Make a report and find that the premises pass with conditions.
3. Make a report and find that the premises passed the inspection. O. Reg. 134/10, s. 1

(1). (10) Premises that fail an inspection or pass with conditions may be subject to one or more further inspections within a reasonable time after the College delivers its report, at the request of a member, any other person to whom the College gave the report, or at any time at the discretion

of the College. O. Reg. 134/10, s. 1 (1).

(11) Where, as a result of an inspection carried out under this Part, a report made by the College finds that a member's knowledge, skill or judgment is unsatisfactory, the College may direct the Registrar to refer the report to the Quality Assurance Committee. O. Reg. 134/10, s. 1 (1).

(12) Where, as a result of an inspection carried out under this Part, a report made by the College finds that a member may have committed an act of professional misconduct or may be incompetent or incapacitated, the College may direct the Registrar to refer the report to the Inquiries, Complaints and Reports Committee. O. Reg. 134/10, s. 1 (1).