THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

Applying the Out-of-Hospital Premises Inspection Program (OHPIP) Standards in **Endoscopy/Colonoscopy Premises**

September 2014

College of Physicians and Surgeons of Ontario Mandate

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 vision guides our thinking and actions. It defines who we are, what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek.

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.

Healthy System - the trust of the public and our effectiveness as professionals is influenced by the system within which we operate. We demonstrate leadership by active involvement in the design and function of an effective system, one which is accessible, integrated, informed by evidence and sustainable.

Public Trust – we earn trust of the public by ensuring quality professionals and safe care, working collaboratively with partners towards a healthy system, acting in the interests of patients and communities and being accountable and transparent.

Our Guiding Principles – Integrity, Accountability, Leadership and Collaboration

To fulfill our vision of **Quality Professionals, Healthy System, Public Trust** we are guided by the following principles:

Integrity in fulfillment of our mandate and pursuit of our vision, achieved by aligning our goals, behaviours and outcomes and adhering to a high ethical standard.

Accountability to the public and profession achieved through an attitude of service, accepting responsibility, transparency of process and dedication to improvement.

Leadership demonstrated by proactive regulation of our profession, management of risk and service to the public.

Collaboration with health system partners to ensure shared commitment, focus and 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.

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Background:

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 (OHPs), and inspecting and assessing for safety and quality of care. This is mandated by the amendment to Regulation 114/94 under the *Medicine Act* adding **Part XI, Inspection of Premises where Certain Procedures are Performed,** which was enacted on April 9th, 2010.

In November 2009, Council adopted the core Out-of-Hospital Premises Standards which are the basis of inspection-assessments for the variety of procedures performed in OHPs. An external review of the core OHP Standards identified opportunities to provide more practice specific information about the Standards and how they will be applied for the purpose of an inspection- assessment. To meet this opportunity, in 2010 the College engaged a working group consisting of a cross-section of practitioners (including academic and community-based physicians) to provide guidance about the application of the core OHP Standards in this specialty setting.

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 Royal College of Physicians and Surgeons of Canada (RCPSC), or CPSO "Specialist Recognition Criteria in Ontario" and "Changing Scope of Practice" policies.

The Purpose of this Document:

This document was developed to help practitioners plan for and participate in their inspection-assessments. It in no way replaces the core OHP 2013 Standards; rather, it helps the practitioner understand how the OHP Standards will be applied in their practice. This Guide should be considered a required companion document to the OHP Standards for practitioners as only those Standards requiring guidance are included. The core OHP Standards are available at www.cpso.on.ca>cpso members>out of hospital premises inspection program.

Note: *The standards are not intended to either replace a physician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by certain standards and that a particular standard will rarely be the only appropriate approach to a patient's condition.*

Updates have been made to this document in 2014 to incorporate additional quality standards.

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Dr. Stanley Feinberg	Dr. Iain Murray	Dr. Peter Rossos
Dr. Michael Gould	Dr. Gerald O'Leary	Dr. Jill Tinmouth

ACRONYMS

Note: Procedure/OR = Procedure room and/or operating room

ACLS	-Advanced Cardiac Life Support
AED	-automated external defibrillator
ASA	-American Society of Anesthesiologists
BLS	-Basic Life Support
CFPC	-College of Family Physicians of Canada
CNS	-central nervous system
CPSO	-College of Physicians and Surgeons of Ontario
CSA	-Canadian Standards Association
ECG	-electrocardiogram
MHAUS	-Malignant Hyperthermia Association of the United States
MRP	-most responsible physician
OHP	-Out-of-Hospital Premises
OHPIP	-Out-of-Hospital Premises Inspection Program
OR	-Operating Room
PALS	-Paediatric Advanced Life Support
QA	-Quality Assurance
RCPSC	-Royal College of Physicians and Surgeons of Canada
RHP	-Regulated Health Professional
RHPA	-Regulated Health Professions Act
RN	-Registered Nurse
RPN	-Registered Practical Nurse
SVT	-supraventricular tachycardia

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Section I

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Guidance to the Standard

Ventilation, Standard 4.2.2 – Endoscopy/colonoscopy premises must ensure ventilation of any virucide used during reprocessing (whether automated or manual) is in keeping with both occupational health and safety requirements, and the manufacturer's standards.

	Level 1	Level 2	Level 3
2 Ventilation	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.		

6.4 Verification Process, Page 28

Guidance to the Standard

Second verification, Standard 6.4.1 – A two-stage verification process where the patient and the intended procedure is verified and documented by two different premises staff is sufficient for endoscopy/colonoscopy premises (see Standards 6.5 and 6.6, pg 25). A "time-out" or "surgical pause" is not required for endoscopy/colonoscopy premises.

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.

6.8 Intra-Procedure Patient Care for Sedation, Regional Anesthesia or General Anesthesia, Page 30

Guidance to the Standard

Standard 6.8 –
Note: In addition to this standard, the OHP Medical Director must ensure appropriate staffing flow for patient safety.

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:
   - O_2 saturation must be continuously monitored and documented at frequent intervals. In addition, if the trachea is intubated or an LMA [5] 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

8. Quality Assurance (QA), Page 35

Guidance to the Standard:

Monitoring OHP Activity, Standard 8.1.2 – In addition to this Standard, it is required:

- That endoscopy/colonoscopy premises document which scope, including serial number, was used on which patient if not done automatically by the endoscope technology, and;
- That when reprocessing scopes the serial number of the scope and which patient it was used on be documented.

8 Quality Assurance (QA)

The Medical Director is responsible for OHP compliance with external regulatory requirements including all Acts relevant to the practise of Medicine[1], 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)

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).

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[1] RHPA, Medicine Act, etc.

Section II

Additional Quality Standards

Equipment

1. All equipment used for a colonoscopy and/or GI endoscopy procedure (e.g. cleaners and reprocessors) must be:
    a. Tracked and maintained with a log to ensure full equipment functionality and safety.
    b. Subject to compliance testing and certification where required by the Canadian Standards Association (CSA) or licensed for use in Canada.
    c. Subject to a regular quality control program. In addition, the specific piece of equipment used for a particular procedure is documented and readily accessible in the form of a log book.
    d. Replaced where necessary to maintain an up-to-date and high standard of service.

2. All Clinics must:
    a. Have standard equipment to remove polyps and manage complications; including but not limited to: thermal devices, vasoconstricting agents, clipping devices and tattooing equipment.
    b. Use automatic endoscopic reprocessors (AERs) for all procedures.
    c. Have enough AER capacity to ensure that the necessary endoscopes are cleaned and ready for use before the next scheduled patient.
    d. Have an automatic irrigator available for every patient.
    e. Have technology to capture, store and review clinically relevant landmarks or pathology during endoscopy procedures.

3. All colonoscopy procedures must be performed using a video colonoscope that must be maintained within manufacturer specifications.

Policies and Procedures

1. Clinics must have a documented process for the storage and retrieval of endoscopic images that identifies how each image is linked with a patient.

2. Clinics must have a policy for:
    - Following up on pathology as outlined in the CPSO test results policy: http://www.cpso.on.ca/policies-publications/policy/test-results-management.
    - Documented identification of a care path to follow up on findings where subsequent therapy or surgery is required.

3. Clinics must manage the continuum of care for their patients and have processes or procedures in place to promote quality patient care, including:
    - Referral criteria that are readily available to referring physicians and the public to ensure that the appropriate patients have their procedures in the appropriate setting.
    - An internal process to review referrals to ensure the appropriateness of the:
        a. Indication/reason for the endoscopy.
        b. Timing of the endoscopy.
        c. Procedure to be completed in an out-of-hospital facility).
    - A policy that guides the criteria and conditions 'direct to procedure' (i.e. open access) referrals to the clinic, as opposed to consultation prior to the procedure. A policy in place to ensure that post endoscopy, any findings and recommendations are communicated to the referring and other physicians.
    - Recommendations regarding the timing for the next colonoscopy.

Quality Improvement

1. Clinics must prescribe and document individual quality improvement processes to address any identified quality issues (i.e. from quality assurance and other).