Applying the Out-of-Hospital Premises Inspection Program (OHPIP) Standards in Induced Abortion Care Premises and Independent Health Facilities (IHFs)

College of Physicians and Surgeons of Ontario

April 2015

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 "Recognition of Non-Family Medicine Specialists" 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 in induced abortion care clinics.

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 "Recognition of Non-Family Medicine Specialists" and "Changing Scope of Practice" policies.

The Purpose of this Document:

This document was developed to help abortion care practitioners plan for and participate in their inspection-assessments. It does not replace the core OHPIP 2013 Standards; rather, it helps the practitioner understand how the OHP Standards will be applied in their abortion care practice. This Guide should be considered a required companion document to the OHP Standards for practitioners as only those Standards requiring guidance and clarification are included.

The information in this guide applies only to new and existing abortion care OHPs/IHFs that are subject to a joint quality assurance program under the OHPIP and the *IHFA*.

The core OHP Standards are available at http://www.cpso.on.ca/uploadedFiles/policies/guidelines/office/ohp_standards.pdf

All 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, national guidelines). This includes requirements set out by other regulatory bodies and provincial guidelines.

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3.1 OHP Levels

Guidance to the Standard

Abortion clinics that satisfy the definition of Anesthesia in the CPSO document Out-of-Hospital Premises Inspection Program Standards, September 2013, p.11 (that they provide intravenous sedation) will be considered Level 2 premises, but with specific exceptions to the Level 2 guidelines identified in this document.

- Clinics that provide sedation with N2O must meet all occupational health and safety requirements including the availability and use of scavenger equipment. Clinics must demonstrate that they meet all Occupational Health &Safety requirements for use of N2O.

Table 02: OHP Levels

OHP Level	Anesthesia	Procedure
OHP Level 1	• Local Infiltration • Minor nerve block (e.g. digital) • Tumescent anesthesia < 500cc of infiltrate solution	Minimally Invasive: • No surgical wound is created **and** • Procedure does not interfere with target organ function or general physiological function.
OHP Level 2	• IV Sedation • Regional anesthesia (e.g., major nerve blocks, spinal, epidural, or caudal) • Tumescent anesthesia ≥ 500cc of infiltrate solution	Limited Invasive: • 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	General Anesthesia	Significantly Invasive: • Surgical wound allows access to a body cavity or viscus (e.g., laparoscopic banding surgery, arthroscopy), **OR** • A significant amount of aspirate is removed 1000-5000cc) **OR** • A large prosthesis is inserted (e.g., augmentation mammoplasty)

4.6 Drugs for Resuscitation

Guidance to the Standard

Abortion clinics are considered Level 2 premises, and are required to have only the Level 2 drugs for resuscitation which are listed in **boldface** in the chart, and these drugs are also listed below:

- Atropine IV
- Benzodiazepine IV
- Dextrose 50% IV
- Diphenhydramine IV
- Flumazenil IV
- Hydrocortisone IV
- Naloxone IV
- Epinephrine for injection
- Oxygen
- Salbutamol

In addition to the drugs required for resuscitation it is an expectation that abortion care clinics have the appropriate drugs/equipment to manage post-abortion hemorrhage. These include:

- Oxytocin
- Methergine
- Carbetocin;
- Misoprostol;
- Carboprost tromehtamine (Hemabate);
- And one of the following mechanical devices providing intrauterine pressure
    - Foley catheter
    - Bakri Balloon; or
    - Vaginal Pack [1]

Parenteral Sedation		
• **Atropine IV** • **Benzodiazepine IV (at least one of: Midazolam, Diazepam, Lorazepam)** • **Dextrose 50% IV** • **Diphenhydramine IV** • **Flumazenil IV (N/A Interv Pain)** • **Hydrocortisone IV 100 mg or 500 mg** • **Naloxone IV (if narcotics are stocked)** • **Epinephrine for injection** • **Oxygen** • **Salbutamol** • BETA Blocker IV (at least one of Metoprolol, Propranolol, Esmolol) (N/A Interv Pain) • Calcium IV (chloride or gluconate) (N/A Interv Pain)	• IV agent for SVT (at least one of Adenosine, Esmolol, Verapimil) (N/A Interv Pain) • MHAUS treatments if triggering agents present, following MHAUS guidelines • Amiodarone IV • Antihypertensive IV (at least one of: Labetalol, Hydralazine) (N/A Interv Pain) • ASA 81 mg po	• Neuromuscular blocking agents, *if qualified staff* available (N/A Interv Pain) • Nitroglycerine spray • Pressor IV (at least two of: Epinephrine, Ephedrine, Vasopressin, Phenylephrine) • Sodium bicarbonate IV (N/A Interv Pain)

[1] National Abortion Federation: 2014 Clinical Policy Guidelines

4.7 Monitoring and Resuscitation Requirements

Guidance to the Standard

Abortion clinics are considered Level 2 premises, and are required to have all of the Level 2 equipment listed in the chart.

In addition, devices for the measurement of pulse and blood pressure must be available for use throughout the clinic.

4.7 Monitoring and Resuscitation Requirements

Level 1, 2, 3	
• IV setup • Adequate equipment to manage local anesthetic toxicity • Appropriately sized equipment for infants and children, if required	
Level 1	Level 2 &3
Level 1 NA	• Assortment of disposable syringes, needles, and alcohol wipes • AED • ECG monitor • Oral airways • Laryngeal mask airways • Means of giving manual positive pressure ventilation (e.g. manual self-inflating resuscitation device) • Oxygen source • Pulse oximeter • Suction with rigid suction catheter

5 OHP Staff Qualifications

Guidance to the Standard

Standard 5.3 - For the purpose of this requirement a pregnant teenager in an abortion clinic will be considered to be an adult, therefore PALS certification as noted in the core Standards document is not required.

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 other than anesthesiologists who are Royal College certified: 1) who administer sedation, regional anesthesia, or general anesthesia; or 2) who 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 components.

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.

5.5 Physicians Administering Sedation

Guidance to the Standard

Physicians using IV sedation must be competent to manage emergent airway complications.

For the purpose of this requirement a pregnant teenager in an abortion clinic will be considered to be an adult, therefore PALS certification as noted in the core Standards document is not required.

5.5 Physicians Administering Sedation

1. Physicians qualified for administering general anesthesia can administer sedation.

2. Physicians administering deep sedation must hold 1) qualifications to administer general anesthesia (Section 5.3.1) or 2) approval according to CPSO policy, *Changing Scope of Practice.*

3. 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

Guidance to the Standard

Standard 5.6.2 - For the purpose of this requirement a pregnant teenager in an abortion clinic will be considered to be an adult, therefore PALS certification as noted in the core Standards document is not required.

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
c) current BLS certification.
d) must have current ACLS if administering sedation to, monitoring or recovering patients

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

6.3 Pre-Procedure Requirements: OHP Levels 2 and 3

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

Guidance to the Standard

6.3.1; 6.3.2; 6.3.3
Instructions may be provided over the telephone by trained clinic staff or a regulated health professional.

6.3.3 In situations where an adult is not accessible during the duration of the OHP stay it must be documented in the patient record why this was not possible.

Pre-Procedure Requirements: OHP Levels 2 & 3	Responsibility
BEFORE day of procedure:	Physician performing 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)	
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: 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, and body mass index (BMI) 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. 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: 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 and Physician providing anesthesia

6.9 Post-Procedure Patient Care

Guidance to the Standard

If the physician performing the procedure has determined that the patient is alert, oriented and responsive to commands; and is deemed to no longer be sedated, an RPN can care for the patient in Recovery Phase 1 with the presence of an RN onsite.

Available RNs onsite cannot be taken away from situations where they are responsible for the monitoring of a patient during a procedure.

In these settings Recovery Phase 2 and Phase 3 would not be applicable as the patient has already received an Aldrete score 9/10 in Recovery Phase 1.

Table 09: Recovery Area Focus and Requirements

	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**: • 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**: • 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 course

3. The anesthesiologist/physician should stay with the patient until the appropriate recovery-area staff accept responsibility for the patient.

4. Recovery-area staff caring for patients in phase I, II, or III recovery provide care and document it in the patient record; it 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, $Sp0_2$, 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 discharge criteria.

6.10 Patient Discharge

Guidance to the Standard

It is the widely accepted practice in Ontario that patients who receive sedation and in particular intravenous sedation for a procedure must be accompanied home at its conclusion and should not drive a motor vehicle or operate complex machinery for 24 hours. Deviating from this standard potentially puts patients and others at some risk.

In discussions with abortion care stakeholders there were concerns raised about the requirement to be accompanied on discharge. It was acknowledged that this was a special group of patients and that in some cases there may be extenuating circumstances where to make such a demand of a patient might jeopardize access. This is a unique situation that may necessitate a balancing of the risks involved.

This would likely be a rare situation, and decisions must be weighed carefully by the physician. Patient safety must always be the primary consideration .The physician making a decision to waive this requirement should document clearly the circumstances involved, the instructions given, and arrangements made with the patient.

Patients must be given a 24-hour contact number for the clinic or a trained abortion provider on behalf of the clinic and encouraged to call this number first for any problems.

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.

SECTION II –

The following section only applies to facilities that have IHF licences

SECTION II

Independent Health Facilities Act

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, and amended in 1996 with regulation changes in 1999, gives the College of Physicians and Surgeons of Ontario the primary responsibility for carrying out quality assessment in Independent Health Facilities. These facilities may provide some of the following insured services:

- In diagnostic facilities: radiology, ultrasound, computed tomography, magnetic resonance imaging, nuclear medicine, pulmonary function and sleep studies.
- In treatment or surgical facilities: one or more of a variety of procedures in peripheral vascular disease, plastic surgery, obstetrics and gynaecology, dermatology, nephrology, ophthalmology, and their related anaesthetic services and perhaps other specialties.

The College of Physicians and Surgeons of Ontario has a legislative mandate under the Act to perform quality assessment and inspection functions. This responsibility and others set out by agreement with the Ministry of Health & Long-Term Care contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities that will improve the level of quality of care by the majority of physicians. The Independent Health Facilities program helps reach this goal by developing and implementing explicit clinical practice parameters and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients, and as a result, promotes continuous quality improvements.

Link to IHFA http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90i03_e.htm

Responsibilities of the College

Responsibilities of the College include:

- Assessing the quality of care when requested by the Ministry. The College will maintain a roster of physicians, nurses, technologists and others to serve as inspectors and assessors as required.
- Inspecting the illegal charging of facility fees by unlicensed facilities when requested by the Ministry.
- Monitoring services results in facilities. The College's information system will monitor individual and facility outcome performance. This is a unique feature of the legislation, which for the first time in North America requires facility operators to establish and maintain a system to ensure the monitoring of the results of the service or services provided in a facility.
- Providing education and assisting facilities so that they may continually improve the services they provide to patients. The College will work with and assist physicians in these facilities so that they can develop their own quality management programs based

on the parameters and standards, monitor facility performance by conducting quality assessments, work with facilities to continually improve patient services, assist in resolving issues and conducting reassessments as necessary.

Role of the Medical Director

As outlined in the OHPIP Program Standards all OHPs must have a Medical Director. It is an expectation that facilities under the joint regime must have both a Medical Director, to satisfy the requirements of the OHPIP core Standards; and a Quality Advisor to satisfy the requirements of the IHFA.

Please refer to the Medical Director Responsibilities section of the core OHPIP Standards for more information.

Role of the Quality Advisor

As outlined in the IHF Regulations "Every licensee shall appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility".

Every Quality Advisor shall:

- Be FRCP or FRCS qualified (or equivalent), a family physician whose training enables him/her to advise the licensee on matters pertaining to standards or quality of care.
- Be appointed by the licensee to advise on issues of quality and standards of induced abortion care in the IHF
- Seek advice from other health professionals where necessary to ensure that all aspects of the services provided through the IHF are provided in accordance with generally accepted professional standards.
- Chair the Quality Advisory Committee at least semi-annually if the IHF has more than six full-time staff equivalents including the Quality Advisor, otherwise at least annually, and to document the substance of the discussion, the actions agreed upon and the completion date for any actions agreed upon.

The Quality Advisor shall advise the facility licensee and document this advice concerning the following:

- Qualifications, selection and ongoing education of the professional and technical staff working in the independent health facility.
- Whether adequate and appropriate staffing, equipment and procedures are available to ensure patient and staff safety in the independent health facility.
- Testing being performed on a periodic basis to ensure the accuracy and reliability of the independent health facility's equipment

- Proper design of consultation requests, performance protocols, documentation and reports used at the independent health facility.
- Development and maintenance of a quality assurance program for the facility.

Every licensee shall have a written agreement with the Quality Advisor requiring and authorizing the Quality Advisor to fulfill the requirements as set out above.

Note: *Whenever the Quality Advisor has reasonable grounds to believe the conduct of the induced abortion care services might jeopardize the safety of patients or the proper performance of services and where, in the judgment of the Quality Advisor, he or she is constrained from correcting the perceived deficiencies by actions taken or not taken by the licensee, then the Quality Advisor reports those concerns in writing to the Director, Independent Health Facilities as required by the Regulations under the Independent Health Facilities Act.*

It is understood that the sections above do not in any manner remove from the licensee or impose upon the Quality Advisor the obligation or responsibility for operating the facility; it being understood that the Quality Advisor's sole responsibility is to provide advice to the licensee on the matters specified.

IHF Forms – A series of forms that must be completed by the Quality Advisor and Affiliated Physicians can be found at the following link **http://www.health.gov.on.ca/en/public/programs/ihf/forms.aspx**

The following forms must be completed by the Quality Advisor and submitted to the MOH IHF Program at IHFP@ontario.ca and to the OHPIP at OHP@cpso.on.ca .

1. Quality Advisor Acknowledgement Form
   http://www.forms.ssb.gov.on.ca/mbs/ssb/forms/ssbforms.nsf/GetFileAttach/014-4769-85~1/$File/4769-85E.pdf

2. Notice of Appointment of Quality Advisor Form
   http://www.forms.ssb.gov.on.ca/mbs/ssb/forms/ssbforms.nsf/GetFileAttach/014-1563-85~1/$File/1563-85X.pdf

Patient Records

The independent health facility must maintain patient records for the required length of time as outlined in the Independent Health Facilities Act. *(see Independent Health Facilities Act - Ontario Regulation 346/04 Amended O. Reg.57/92).* Paper or electronic record that is accessible and readable is acceptable.

Physicians are expected to comply with the requirements outlined in the CPSO Medical Records Policy. The policy can be found at http://www.cpso.on.ca/Policies-Publications/Policy/Medical-Records

Providing Quality Care

A Quality Advisory Committee is established as per the IHF Act. The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility. Regular meetings are held and minutes maintained (IHF Act Regulation 57/92).

Note: *An exception to this is where the physician is the sole provider of the services, is owner/operator and Quality Advisor, and the services provided are part of his/her office practice.*