Out-of-Hospital Premises Inspection Program Overview

The Out-of-Hospital Premises Inspection Program (OHPIP) supports continuous quality improvement through developing and maintaining standards for the provision of procedures in Ontario out-of-hospital premises (OHPs) and by inspecting premises for safety and quality of care. The OHP Standards are intended to articulate the core requirements for the performance of procedures in certain settings/premises outside a hospital as defined in Ontario Regulation 114/94 under the *Medicine Act, 1991* (hereinafter "the Regulation").

The Standards are used for the inspection of premises and are applicable to all physicians who work in such premises. The standards include information applicable to the range of all procedures performed in OHPs.

The OHPIP is overseen by CPSO's Premises Inspection Committee. 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 legislation (e.g. the Canadian Anesthesiologists' Society *Guidelines to the Practice of Anesthesia*, the *Food and Drugs Act*, etc.), including requirements set out by other regulatory bodies and provincial guidelines.

What is the purpose of the Regulation?

The Regulation creates the framework for the regulation of OHPs in Ontario and sets out which procedures are captured by the OHPIP, along with CPSO's powers and responsibilities in relation to inspection of OHPs.

The Regulation sets out specific criteria regarding the procedures that are captured by the OHPIP. How do I determine which procedures are captured by the OHPIP, and therefore can only be performed in an OHP that meets the requirements set out in the Standards?

Any procedure performed under general or regional anesthesia or parenteral sedation is captured by the program and is therefore subject to the requirements set out in the Standards, including approval of and inspection by CPSO.

Some procedures that are performed using local anesthesia are also captured by the Program. This includes any procedure performed with local anesthetic that is:

- A procedure using tumescent anesthesia[1]
- A nerve block for chronic pain
- A cosmetic procedure involving the alteration or removal of tissue or
- A cosmetic procedure where a substance or material (including tissues from the patient's own body i.e. autologous tissue) is injected or inserted into a patient.

There are some procedures performed with local anesthetic that **are not** captured by the Program, including:

- A minor dermatological procedure such as the removal of skin tags, benign moles and cysts

[1] The practice of injecting a very dilute solution of local anesthetic combined with epinephrine and sodium bicarbonate into tissue until it becomes firm and tense.

- A procedure involving the alteration or removal of tissue where done for clinical and *not* cosmetic reasons
- Procedures using only an external topical anesthetic (e.g. Lasik eye surgery).

Minor cosmetic procedures that do not require local anesthesia (e.g. Botox, sclerotherapy) are not captured by the Program.

How are the different types of anesthesia defined?

The following definitions have been adapted from "Continuum of Depth of Sedation" and "Statement on Safe Use of Propofol" by the American Society of Anesthesiologists (ASA):

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.

Sedation 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.

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.[2]

Moderate Sedation ("Conscious Sedation") is a drug-induced depression of consciousness during which patients respond purposefully[3] 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.

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.

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.

[2] For the purpose of the Standards, sole or minimal use of oral anxiolysis for the purpose of pre-medication is not considered sedation.
[3] Reflex withdrawal from painful stimulus is NOT considered a purposeful response.

General anesthesia is regarded as a continuum of depressed central nervous system function from pharmacologic agents resulting in loss of consciousness, recall, and suppression of somatic and autonomic reflexes.

What are CPSO's responsibilities in relation to regulating OHPs?

CPSO is responsible for considering all issues related to the provision of procedures requiring the use of anesthesia and/or sedation that are performed within OHPs.

CPSO's responsibilities include but are not limited to:

1. Developing and maintaining "OHP Program Standards"
2. Approving any new premises
3. Approving OHP Medical Directors
4. Conducting inspection of the premises and in some cases observing procedures to ensure that services for patients are provided according to the standard of the profession
5. Determining the outcome of inspections
6. Maintaining a current public record of inspection outcomes on the CPSO website
7. Issuing notices for payment of OHP fees.

What does the inspection process involve?

New premises or relocating premises will be inspected within 180 days of notification. All OHPs are inspected every 5 years, or more often if CPSO deems it necessary or advisable.

The inspection may involve but is not limited to:

1. completion of the on-line notification form
2. completion of a pre-visit visit questionnaire
3. a site visit by a nurse inspector appointed by CPSO that includes:
    - a review of records and other documentation
    - review of the OHP's compliance with accepted standards
    - review of any other material deemed relevant to the inspection
4. enquiries or observation of procedures where relevant.

Nurse inspectors provide OHP inspection reports to CPSO, and CPSO provides a copy of the report to the Medical Director.

As outlined in the Regulation, the Premises Inspection Committee determines the inspection outcome and an OHP will be given either a "Pass", "Pass with Conditions", or "Fail" outcome.

What does a "Pass" outcome mean?

A "Pass" outcome means the OHP Standards are met for the specific procedures identified by the OHP at the time of the inspection and that no deficiencies were identified.

What does a "Pass with Conditions" outcome mean?

A "Pass with Conditions" outcome means that deficiencies have been identified in the OHP. If

an OHP receives this outcome they may:

1. be restricted to specific procedures
2. be required to make submissions in writing to CPSO within 14 days of receiving the report
3. be subject to a follow-up inspection at CPSO's discretion within 60 days of receiving the OHP's written submission
4. receive a "Pass" outcome when deficiencies have been corrected to CPSO's satisfaction.

What does a "Fail" outcome mean?

A "Fail" outcome means that significant deficiencies have been identified in the OHP. Where a "Fail" outcome is given:

1. All OHP procedures must cease in the OHP;
2. The OHP may make submissions in writing to CPSO within 14 days of receiving the report; and
3. A follow-up inspection may be conducted at CPSO's discretion within 60 days of receiving the OHP's written submission.

The Medical Director is responsible for ensuring compliance with the OHP Standards and providing any information necessary in relation to the premises. Failure to provide the information may result in an outcome of Fail by the Premises Inspection Committee, in accordance with the *Co-operation with the Out-of-Hospital Premises Inspection Program* Standard and may result in the removal of the Medical Director and direction to appoint a new Medical Director.

Co-operation with the Out-of-Hospital Premises Program Standard

Co-operation with the Out-of-Hospital Premises Inspection Program Standard

Those working in OHPs, including Medical Directors, have an obligation to communicate promptly and accurately with CPSO, to foster a respectful relationship and demonstrate co-operation with the Out-of-Hospital Premises Program (OHPIP). Failure to communicate with or provide information to CPSO in the required manner may result in an outcome of Fail by the Premises Inspection Committee, which requires the OHP to cease operation, or may trigger a reinspection or a referral to CPSO's Inquires, Complaints, and Reports Committee.

Standards

1. All physicians practising in OHPs **must**:

    a. provide accurate information to CPSO, in the form and timeframe specified by CPSO;
    b. co-operate with inspections undertaken by CPSO in order to ensure compliance with the OHP Standards.

2. Medical Directors **must** annually confirm, in the form and manner required by CPSO, their understanding of their responsibilities as set out in the Standards and that they are compliant with these responsibilities. This will include agreement to:

    a. perform their duties with due diligence and in good faith;
    b. ensure that the OHP complies with the Standards and meets its responsibilities,
    c. ensure the OHP provides safe and effective care.

3. Medical Directors **must** respond to CPSO requests for documentation and information in the form and timeframe required, as follows:

    a. within 5 business days for information regarding adverse events;
    b. within 14 days for regular CPSO requests, or
    c. any otherwise specified timeframe as identified by CPSO for other CPSO requests.

4. Medical Directors **must** ensure the OHP does not:

    a. operate in contravention of the Standards;
    b. operate in contravention of any conditions or restrictions imposed by the OHPIP and/or the Premises Inspection Committee.

5. Medical Directors **must** cease operation of an OHP if they receive a fail outcome from an inspection.

6. All physicians planning to practise in an OHP **must** complete the online Staff Affiliation form prior to performing procedures in an OHP.

Notification to CPSO

7. Medical Directors who plan to operate a new OHP **must** notify CPSO of their plans to do so.

8. Medical Directors **must** ensure that no procedures are performed in the OHP until they receive approval from the OHPIP to do so and that only approved OHP procedures are performed.

9. Medical Directors **mus**t notify CPSO of any adverse event in the OHP in writing within 5 business days of learning of the event.[1]

10. Medical Directors **must** notify CPSO in writing at least two weeks prior to any of the following changes to the OHP:

    a. ownership of the OHP
    b. name of the OHP
    c. numbers of procedures performed: any significant increase/decrease (>50% of the last reported inspection)
    d. 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
    e. decision to cease operation of the OHP[2].

11. Medical Directors **must** notify CPSO in writing at least two weeks prior to any of the following intended changes to the OHP and receive approval (and where necessary undergo a re/inspection):

    a. OHP Medical Director (in accordance with the *Medical Director* Standard);
    b. OHP location/address;
    c. structural changes to patient care areas (including equipment);
    d. new types of procedures or practices;
    e. permitting overnight stays.

Inspection Process

12. Medical Directors and physicians practising in the OHP **must** participate fully in the inspection process and comply with CPSO requests in relation to this process, including:

    a. submitting to an inspection of the OHP;
    b. promptly answering any questions or complying with any requirement of the inspector that is relevant to the inspection;
    c. co-operating fully with CPSO and the inspector who is conducting the inspection;
    d. providing the inspector with any requested records;
    e. allowing direct observation of a physician, including direct observation by an inspector of the physician performing a procedure on a patient;

[1] Please see the *Adverse Events* Standard for more information.
[2] For more information on the appropriate steps to follow when ceasing operation, please see CPSO's *Closing a Medical Practice* policy.

i. Where observation will be occurring, Medical Directors **must** inform the patient prior to the scheduled procedure that an observation of the procedure may take place as a component of the inspection process.

13. Medical Directors **must** ensure that complete records are onsite on the date of planned inspections, including all books, accounts, reports, records or similar documents that are relevant to the performance of a procedure done in the OHP.

14. Medical Directors **must** participate in any requested post inspection processes (e.g., an exit interview with the inspector, completion of a post inspection questionnaire, and providing any required follow-up documentation).

Advice to the Profession: Co-Operation with the Out-of-Hospital Premises Inspection Program Standard

As the Medical Director, how do I need to annually confirm my understanding of my responsibilities?

Medical Directors will need to confirm their understanding of their responsibilities through an Annual Attestation. This attestation is made as part of the annual premises renewal process and is done through the Member Portal.

If I am planning to operate a new OHP, what do I need to do?

Before you can perform any procedures at a new OHP you will need to complete and submit a New Premise Application, pay the required fee and pass a premise inspection, which will be conducted within 180 days of receiving your notice. To complete the application:

1. log into the CPSO Member Portal,
2. click on the OHP tile,
3. click on the New Premises Application button.

Where I am required to notify CPSO of specific changes to the OHP, how do I do this?

You will need to complete a New Request or Notification form and include as many details as possible regarding the change to the OHP. CPSO will then decide if your OHP needs to be re-inspected. To complete a New Request or Notification form:

1. log into the CPSO Member Portal,
2. click on the OHP tile,
3. click on the OHP number of the OHP for which you wish to make changes,
4. click on OHP Requests/Notifications on the left-hand navigation,
5. select the appropriate request or notification button.

What information needs to be available for inspections?

The Standard requires that the Medical Director ensures that complete records are onsite on the date of the inspection. In carrying out an inspection of an OHP, the inspector may require any examination and copies of books, accounts, reports, records or similar documents that are, in the opinion of CPSO, relevant to the performance of the OHP.

More information related to inspections can be found in the *Out of Hospital Premises Inspection Program Overview* document.

CPSO

Medical Director Standard

Medical Director Standard

Definitions

Medical Director: The Medical Director is the CPSO approved physician responsible for the management and oversight of the OHP.

Acting Medical Director: An "Acting Medical Director" refers to a CPSO approved physician who is overseeing the OHP in the absence of the Medical Director.

Standards

1. All OHPs **must** have a Medical Director or an Acting Medical Director who has been approved by CPSO, and who is responsible for oversight of the OHP, including ensuring compliance with all applicable legislation, regulations, by-laws, CPSO policies, and the requirements in the Standards.

2. Medical Directors **must** annually confirm their understanding of their responsibilities in relation to the OHP, in the manner and form required by CPSO (e.g., sign an annual declaration of responsibilities[1]).

Qualifications

3. Physicians acting as a Medical Director in an OHP **must** have the skills and experience necessary to effectively oversee the OHP[2] and **must** at minimum meet the following criteria:

    a. reside in Ontario;
    b. hold a valid and active CPSO certificate of registration;
    c. not be the subject of any disciplinary or incapacity proceeding in any jurisdiction;
    d. not have lost their hospital privileges or been terminated from employment for reasons of professional misconduct, incompetence, or incapacity; and
    e. not have any terms, conditions or limitations on their certificate of registration that would impact their ability to fulfill the role of a Medical Director.[3]

4. Medical Directors **must** inform the CPSO if, during the course of serving as a Medical Director, they become the subject of a disciplinary or incapacity proceeding and may be required to appoint an Acting Medical Director at the discretion of CPSO.

    a. The Medical Director **must** only resume the role upon CPSO approval.

[1] Please see the *Co-operation with the Out-of-Hospital Premises Inspection Program* Standard for more information
[2] For more information about the types of skills and experience necessary to effectively oversee an OHP, please see the *Advice to the Profession* document.
[3] For additional considerations please see the *Advice to the Profession* document.

Appointment of Acting Medical Director

5. Medical Directors **must** ensure that whenever they are unable or unavailable to perform all of their duties, they have designated another physician practising in the OHP to do so.

6. Medical Directors who plan to take an extended leave of absence or who will be unable to fulfill the duties of their role for an extended period of time (i.e., greater than one month) **must** inform CPSO, who will then determine whether an Acting Medical Director needs to be appointed.

7. Where an Acting Medical Director needs to be appointed, Medical Directors **must** ensure the Acting Medical Director who is appointed:

    a. meets the criteria set out in provision 3 above; and
    b. is approved by CPSO.

8. Where an Acting Medical Director is appointed, the Acting Medical Director **must** sign an agreement with the Medical Director that articulates all of their responsibilities.

9. The Medical Director or Acting Medical Director **must** ensure that all staff working in the OHP are notified when an Acting Medical Director is appointed.

Credentialing and Ensuring Competence

Ensuring competence is a key component of the role of the Medical Director and Medical Directors are ultimately accountable and responsible for all the care provided in the OHP (i.e., for the care provided by the staff practising in the OHP).

10. Medical Directors **must** ensure that all staff practising within the OHP have the requisite knowledge, skill, and judgment to do so competently and safely and that they are practising within their scope of practice and any limitations of their certificate of registration.

11. Medical Directors **must** ensure all staff practising in the OHP have the appropriate qualifications[4] and competence prior to working in the OHP, by at minimum, ensuring the following:

    a. the training and credentials of all staff who wish to practise in the OHP have been reviewed and verified;
    b. all staff are in good standing with their regulatory body, where applicable (i.e., a Certificate of Professional Conduct has been reviewed) including that they:

        i. have a valid and active certificate of registration with their regulatory body;
        ii. are not the subject of any disciplinary or incapacity proceeding in any jurisdiction;
        iii. have not lost their hospital privileges or been terminated from employment for reasons of professional misconduct, incompetence, or incapacity;

[4] For additional information on appropriate qualifications please see Appendix A.

iv. do not have any terms, conditions or limitations on their certificate of registration that would impact their ability to practise in an OHP.

12. Medical Directors **must** ensure that all staff:

    a. read the Policies and Procedures (P&P) manual upon being hired and annually, or where there is a change, and confirm this action (e.g., with a signature and date);
    b. read their individual job descriptions of duties and responsibilities, indicating they have been read and understood (e.g., with a signature and date); and
    c. have professional liability protection as required by their regulatory body, where applicable.

Appropriate Supervision

13. Medical Directors **must** provide a level of supervision and support that ensures safe and effective care within the OHP.

14. Medical Directors **must:**

    a. be on site as needed, to oversee the premises and ensure the OHP is operating safely and effectively, at least one day per month; and
    b. be readily available to provide appropriate oversight and assistance, when necessary.

15. Medical Directors **must** be satisfied that all staff practising within the OHP:

    a. understand the extent of their responsibilities; and
    b. know when and who to ask for assistance, if necessary.

16. Medical Directors **must:**

    a. take reasonable steps to ensure that all staff are practising in accordance with the standard of care; and
    b. take appropriate action where there are concerns about the conduct or care of any staff practising in the OHP (e.g., concerns about the number of adverse events), including:

        i. Addressing and documenting the issue with the individual;
        ii. Ensuring appropriate remediation;
        iii. Suspending or terminating the individual, where appropriate;
        iv. Reporting to the professional's regulatory body, where necessary.

Appendix A: Staff Qualifications

Appropriate qualifications generally include the following:

If pediatric care is provided to children 12 and under, staff will:

a. be trained to handle pediatric emergencies; and
b. maintain a current PALS certification.

If administering or recovering pediatric patients from general or regional anesthesia or sedation, staff will need to have recent clinical experience doing so (i.e., within 2 years).

Qualifications for Physicians Performing Procedures

Physicians who perform procedures using local anesthesia in OHPs will hold one of the following:

a. Royal College of Physicians and Surgeons of Canada (RCPSC) or College of Family Physicians of Canada 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's *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, *Ensuring Competence: Changing Scope of Practice and/or Re-entering Practice*). This may include physicians who are currently engaged in a CPSO approved change in scope of practice process.

Qualifications for Physicians Administering Anesthesia

Physicians Administering General or Regional Anesthesia or Deep Sedation

Physicians administering general or regional anesthesia or deep sedation will hold:

a. RCPSC designation[5] as a specialist in anesthesia or one of the following:
    i. Completion of a program accredited by the College of Family Physicians of Canada under the category of "Family Practice Anesthesia";
    ii. CPSO recognition as a specialist in anesthesia, or other specialty pertinent to the regional anesthesia performed, as confirmed by CPSO's *Specialist Recognition Criteria in Ontario* policy.

[5] Physicians who are trained in general or regional anesthesia or deep sedation but who have not been practising in this area for two years or more would be subject to CPSO's *Ensuring Competence: Changing Scope of Practice and/or Re-entering Practice* policy, if they wished to return to this area of practice.

Physicians Administering Minimal to Moderate Sedation

Where a physician is not qualified to administer general anesthesia or deep sedation, but is administering minimal-to-moderate sedation, the physician will hold:

- Education and experience to manage the potential medical complications of sedation/anesthesia, including ability to:
    i. identify and manage the airway and cardiovascular changes which occur in a patient who enters a state of general anesthesia,
    ii. assist in the management of complications, and
    iii. understand the pharmacology of the drugs used, and
- Current ACLS certification.

Nurse Qualifications

Nurses working in OHPs will have training, certification, and appropriate experience as required for the procedures performed, including holding qualifications in accordance with those set out in the National Association PeriAnesthesia Nurses of Canada's *Standards for Practice*, where applicable, as well as current ACLS if administering sedation to, monitoring or recovering patients (RNs only).

Appendix B: OHP Policies and Procedures

The OHP policies and procedures, which must be regularly reviewed, updated, and implemented include the following:

Administrative issues and responsibilities, including:
a. responsibility for developing and maintaining the policy and procedure manual,
b. scope and limitations of OHP services provided,
c. overnight stays, if applicable,
d. staff qualifications, hospital privileges, and records.

Response to emergencies, including those related 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.

Urgent transfer of patients, including:
a. appropriate transportation (e.g., ambulance) and accompaniment (e.g., Most Responsible Physician, OHP staff, etc.), and
b. timely transfer of relevant documentation/medical records.

Job Descriptions, including:
a. OHP staff job descriptions that define scope and limitations of functions and responsibilities for patient care; and
b. Responsibility for supervising staff.

Procedures related to:
a. Adverse events (i.e., monitoring, reporting, reviewing and response)
b. Combustible and Volatile Materials
c. Delegating controlled acts and medical directives
d. Routine maintenance and calibration of equipment
e. Infection control, including staff responsibilities in relation to the *Occupational Health and Safety Act*
f. Medications handling and inventory
g. Patient booking system
h. Detailed and clear patient selection/admission/exclusion criteria for services provided
i. Patient consent in accordance with CPSO's *Consent to Treatment* policy
j. Patient preparation for OHP procedures
k. Response to allergic reactions (e.g., latex)
l. Safety precautions regarding electrical, mechanical, fire, and internal disaster
m. Waste and garbage disposal

Forms used

Inventories/Lists of equipment to be maintained

Advice to the Profession: Medical Director Standard

The role of the Medical Director is central to ensuring safe and quality care within an OHP. The quality of the leadership and oversight of the OHP correlates with the quality of the care provided within the OHP.

Accordingly, many of the expectations set out within the Standards are the responsibility of the Medical Director. This companion *Advice* document is intended to help Medical Directors interpret their obligations as set out in the *Medical Director* Standard and provide guidance around how the expectations may be effectively discharged.

The Medical Director Standard sets out minimum criteria that must be met in order to be a Medical Director. If I meet the minimum criteria, will I automatically be approved to be a Medical Director?

No. Satisfaction of minimum criteria does not guarantee approval to be a Medical Director. CPSO will exercise reasonable discretion in approving Medical Directors. Additional considerations may include, but will not be limited to, whether:

- a physician has active investigation(s) and the nature of the investigation(s) (e.g. whether the complaint has a specific impact on the ability to perform in the role);
- a physician is subject to any other regulatory activity or condition that may be relevant to the role;
- a physician is the subject of a discipline finding;
- a physician has had their certificate of registration revoked or suspended.

The Medical Director Standard requires that Medical Directors have the skills and experience necessary to effectively oversee the OHP. What are the skills and experience necessary to oversee an OHP?

The role of a Medical Director is key to ensuring safe and quality care within an OHP. Relevant skills needed to be effective in the role include strong leadership skills, relevant clinical expertise, and knowledge of relevant clinical practice guidelines, quality improvement, and infection prevention and control standards. There are a variety of ways in which the necessary skills and experience can be acquired. While some Medical Directors may have such knowledge, skills and experience before taking on this role, others may acquire the skills over time. For those seeking additional training to help develop the necessary skills, professional development is available. For example, leadership training is offered through programs such as the Canadian Medical Association's The Physician Leadership Institute.

I'm considering hiring a regulated health professional whose certificate of professional conduct (CPC) indicates they have an active investigation. Am I permitted to hire them?

It depends. The *Medical Director* Standard sets out minimum criteria that must be met for staff practising in an OHP. Given that Medical Directors are responsible for their staff

and all of the care provided in the OHP, even if these criteria are met, Medical Directors will need to use their professional judgement and carefully consider the nature and seriousness of the complaint or investigation and how quickly it will be resolved.

Medical Directors are responsible for ensuring their staff are appropriately qualified and have the competence necessary to practise safely in an OHP. Depending on the nature and seriousness of the complaint or investigation (e.g., whether there are concerns about clinical competence) Medical Directors may wish to hold off on hiring the individual until the outcome of the investigation is known, or to take additional steps to satisfy your obligation to ensure the individual's competence. Medical Directors are ultimately responsible for the care provided in the OHP and for exercising due diligence when hiring.

What happens if CPSO determines that a Medical Director cannot fulfill their duties?

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

If I go on vacation do I need to appoint an Acting Medical Director to fulfill my duties?

Whenever a Medical Director is unable to fulfill their duties as set out in the Standards, they are required to ensure that another physician practising in the OHP can fulfil these duties. If the Medical Director will be unavailable or unable to fulfill their duties for an extended period of time (i.e., more than a month) they are required to notify the CPSO and where deemed necessary, appoint an Acting Medical Director who meets the criteria set out in the Standard and who is approved by CPSO. Temporary or short term absences (less than a month) do not require undergoing the process of appointing an Acting Medical Director that is approved by CPSO, but do require the Medical Director to appoint a physician within the OHP to perform their role while they are unavailable.

Medical Directors are required to be on site as needed, but at least one day per month, to oversee the premises and ensure the OHP is operating safely and effectively. What kind of things would a Medical Director be doing when they are on site?

There are a number of responsibilities that Medical Directors have with respect to the OHP, including those related to supervision, quality assurance, and infection prevention and control. In order to effectively fulfill these duties, it is important that Medical Directors are on site as needed to oversee the premises, ensure that policies and procedures are being adhered to and to ensure that safe, quality care is being provided. The more present and involved a Medical Director is within the OHP, the better the patient care tends to be.

CPSO

Physicians Practising in Out-of-Hospital Premises Standard

Physicians Practising in Out-of-Hospital Premises Standard

Standards

1. All physicians practising in an Out-of-Hospital Premises (OHP) **must**:
    a. have completed the online Staff Affiliation form for each OHP they wish to practise in, prior to practising in that OHP;
    b. meet the standard of practice of the profession, which applies regardless of the setting in which care is being provided;
    c. practise within their scope of practice and within the limits of their knowledge, skill and judgement;
    d. comply with all applicable requirements in the Standards, including:
        i. cooperating with and providing information to CPSO in accordance with the *Co-operation with the Out-of-Hospital Premises Inspection Program* Standard;
        ii. being appropriately qualified to perform all procedures they perform in that OHP, in accordance with Appendix A of the *Medical Director* Standard;
        iii. complying with pre-procedure, intra-procedure and post-procedure care requirements when performing procedures in accordance with the *Procedures Standard*;
        iv. complying with all infection prevention and control standards and requirements in accordance with the *Infection Prevention and Control* Standard;
        v. managing and reporting all adverse events in accordance with the requirements in the *Adverse Events* Standard;
        vi. participating in quality assurance processes within the OHP, in accordance with the *Quality Assurance* Standard;
        vii. complying with all applicable policies and procedures of the OHP, as set out in Appendix B of the *Medical Director* Standard;
    e. comply with all applicable CPSO policies[1];
    f. comply with the requirements for the OHP set out by the Medical Director and in the OHP's policies and procedures; and
    g. comply with existing standards or guidelines from applicable specialty societies.

[1] This includes but is not limited to the following: *Availability and Coverage*, *Consent to Treatment*, *Delegation of Controlled Acts*, *Disclosure of Harm*, *Physician Behaviour in the Professional Environment*, *Prescribing Drugs*, *Managing Tests.*

CPSO

Physical Space Standard

Physical Space Standard

Standards

General

1. Medical Directors **must** ensure that the requirements in Public Health Ontario's *Infection Prevention and Control for Clinical Office Practice* document regarding physical spaces, including the surgical space and reprocessing space, are met.

2. Medical Directors **must** ensure:

    a. The OHP complies with all applicable building codes including fire and safety requirements;
    b. All electrical devices are certified by the Canadian Standards Association (CSA) or are licensed for use in Canada;
    c. There is an emergency power supply that allows for safely completing a procedure that is underway and for recovering the patient;
    d. Access for persons with disabilities complies with provincial legislation[1] and municipal bylaws;
    e. Necessary spaces can be accessed by and accommodate stretchers and wheelchairs;
    f. The size of the OHP is adequate for all the procedures that will be performed within it;
    g. The OHP layout facilitates safe patient care and patient flow; and
    h. The following areas of the OHP are functionally separate:
        i. administration and patient-waiting area
        ii. procedure room and/or operating room
        iii. recovery area
        iv. clean utility area
        v. dirty utility room
        vi. reprocessing room
        vii. endoscope cabinet (where applicable)
        viii. staff change room and staff room.

3. Medical Directors **must** ensure the physical space allows for appropriate movement of patients in an emergency, including:

    a. safely evacuating patients and staff if necessary (i.e. stretchers, wheelchairs, or other adequate methods of transport are available), and
    b. appropriate access to the patient for an ambulance to transfer the patient to a hospital.

[1] *Accessibility for Ontarians with Disabilities Act, 2005*, S.O. 2005, c. 11.

Procedure Room/Operating Room Physical Standards

Physical Requirements

4. Medical Directors **must** ensure the OHP has:

    a. lighting as required for the specific procedure being performed;
    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; and
    e. space sufficient to accommodate equipment and staff required for the procedure, and to move around while sterile, without contamination.

Ventilation

5. Medical Directors **must** ensure:

    a. there is ventilation sufficient to ensure patient and staff comfort, and fulfill occupational health and safety requirements;
    b. there is ventilation and air circulation augmented to meet manufacturer's standards and address procedure-related air-quality issues (e.g., cauterysmoke, endoscopy, disinfecting agents, anesthesia gases), where applicable; and
    c. air exchanges meet infection control standards[2] for the type of procedure being performed;
    d. if using gas sterilization for reprocessing, a positive pressure outbound system is used, vented directly to the outside.

Equipment

6. Medical Directors **must** ensure:

    a. Medical equipment is maintained and inspected yearly by a qualified biomedical technician and has an active service contract;
    b. Equipment necessary for emergency situations (i.e., defibrillators, oxygen supply, suction) is inspected on a weekly basis and documented;
    c. Related documentation for all equipment is available, including:
        i. record of certification of medical equipment by a qualified biomedical technician,
        ii. equipment operating manuals,
        iii. equipment maintenance contracts with an independent and certified biomedicaltechnician,
        iv. log for maintenance of all medical devices, and
    d. The following equipment is available:
        i. cleaning equipment as required for the specific procedure,
        ii. accessible anesthetic drugs and equipment,
        iii. blood pressure and oxygen saturation monitoring equipment,

[2] For more information see Public Health Ontario's *Infection Prevention and Control for Clinical Office Practice.*

iv. sterile supplies and instruments,
v. table/chair that permits patient restraints and Trendelenberg positioning, where applicable,
vi. table/chair/stretcher that accommodates procedures performed and provides for adequate range of movement for anesthetic procedures,
vii. suction equipment and backup suction, for anesthesia provider's exclusive use.

Anesthetic and Ancillary Equipment

7. Where an OHP administers general anesthesia, regional anesthesia or sedation, Medical Directors **must** ensure:

    a. Both anesthetic and ancillary equipment and medical compressed gases and pipelines comply with the Canadian Standards Association (CSA) or are licensed for use in Canada;
    b. A second supply of (full cylinder) oxygen capable of delivering a regulated flow is present;
    c. An anesthetic machine and anesthetic cart with appropriate drugs[3] and equipment is provided, where general anesthesia is being administered.
        i. In accordance with the Canadian Anesthesiologists' Society *Guidelines to the Practice of Anesthesia*, appropriate equipment includes at minimum:
            - Pulse oximeter;
            - Apparatus to measure blood pressure, either directly or noninvasively;
            - Electrocardiography;
            - Apparatus to measure temperature;
            - Neuromuscular blockade monitor when neuromuscular blocking drugs are used;
            - Capnography for general anesthesia and to assess the adequacy of ventilation for moderate or deep procedural sedation; and
            - Agent-specific anesthetic gas monitor, when inhalational anesthetic agents are used.

Recovery Area Physical Standards

8. Medical Directors **must** ensure a sink is available for hand washing.

9. Where an OHP provides general anesthesia, regional anesthesia or sedation, Medical Directors **must** ensure:

    a. The size of the recovery area can accommodate the number of patients for two hours of operating room time (i.e., 1 hour procedure = 2 patients, 0.5 hour procedure = 4 patients);
    b. The recovery area allows for transfer of patients to/from a stretcher and performance

[3] For more information on what drugs are needed, see the *Drugs and Equipment* Standard.

of emergency procedures; and

c. Monitoring, suction, oxygen, bag-valve mask devices, and other emergency airway equipment, intravenous and other medical supplies are immediately available.

CPSO

Drugs and Equipment Standard

Drugs and Equipment Standard

Standards

General

1. Medical Directors **must** ensure the following practices are undertaken in the OHP:

    a. a general drug inventory record is maintained;
    b. periodic inspection of all drugs is undertaken to ensure drugs are not expired;
    c. single dose vials of drugs are used wherever possible;
    d. if multidose vials of drugs must be used, they are dated on opening, disposed of according to manufacturer's guidelines, and are used in accordance with Public Health Ontario's *Updated Guidance on the Use of Multidose Vials*[1];
    e. drugs are labelled in accordance with the *Food and Drug Act*[2] and the *Controlled Drugs and Substances Act*[3] and any regulations made under those statutes;
    f. drugs are stored securely and in accordance with the manufacturer's recommendations (e.g., refrigeration if required); and
    g. emergency drugs are stored in a common location[4].

Controlled Substances

2. Medical Directors **must** ensure that controlled substances are:

    a. handled, stored, and administered in accordance with *Food and Drug Act* and the *Controlled Drugs and Substances Act* and any regulations made under those statutes;
    b. accessed by a qualified designated staff member[5];
    c. stored securely and appropriately to prevent theft and loss; and
    d. accounted for in a "Log of Controlled Substances".[6]

3. Medical Directors **must** ensure that at the beginning and end of each day that controlled substances are used, a balance of the inventory is calculated by physical count and verified.

4. In the event of a discrepancy, Medical Directors **must** ensure that an investigation is conducted and documented with the action taken.

Drugs and Equipment for Urgent or Emergency Situations

5. Medical Directors **must** ensure that staff are prepared to address urgent or

[1] For more information on appropriate use of multidose vials see Public Health Ontario's *Updated Guidance on the Use of Multidose Vials*.
[2] *Food and Drug Act* R.S.C., 1985, c. F-27, s. 1
[3] *Controlled Drugs and Substances Act* (CDSA)S.C. 1996, c.19
[4] A crash cart may be appropriate in OHPs where procedures are done in multiple procedure rooms.
[5] For example, an RN, RPN with medication skills, or a physician.
[6] For additional information on appropriate practices please see the Canadian Society of Hospital Pharmacist's *Controlled Drugs and Substances in Hospitals and Healthcare Facilities: Guidelines on Secure Management and Diversion Prevention.*

emergency situations or resuscitate a patient using appropriate equipment[7] and current drugs, when necessary.

6. Medical Directors **must** ensure that, at minimum, the OHP has the following drugs immediately available:

    a. Oxygen
    b. H1 antihistamines (e.g., Diphenhydramine)
    c. Epinephrine for injection
    d. Bronchodilators (e.g., Salbutamol)
    e. Atropine
    f. Intralipid if using Lidocaine/Bupivacaine/Ropivacaine.

7. Medical Directors **must** ensure that other appropriate equipment and drugs are immediately available to respond to the following situations, proportionate to the level of anesthesia or sedation being administered[8]:

    a. Hypertension
    b. Hypotension
    c. Anaphylaxis
    d. Cardiac events, including those covered in the ACLS Algorithms
    e. Respiratory Events
    f. Malignant Hyperthermia, if using triggering agents [9]
    g. Benzodiazepine reversal
    h. Opioid reversal
    i. Neuromuscular blockade reversal, if using nondepolarizing muscle relaxants
    j. Acidosis
    k. Relevant potential electrolyte disturbances
    l. Hyper and Hypoglycemia
    m. Emesis.

8. If services are provided to infants and children, the Medical Director **must** ensure that required drugs are available and appropriate for that population.

[7] Please see the *Advice* document for more information on the equipment that would be typically required within an OHP.
[8] The drugs required will depend on the type of anesthesia used at the OHP (i.e., local, IV sedation or general). Please see the *Advice* document for more information on the drugs typically used to respond to the listed conditions.
[9] For more information see Malignant Hyperthermia Association of the United States' *What should be on an MH cart?*

Advice to the Profession: Drugs and Equipment Standard

Where can I find more information on how to appropriately store and handle controlled substances?

Additional information on appropriate practices relating to controlled substances can be found in the Canadian Society of Hospital Pharmacists' document *Controlled Drugs and Substances in Hospitals and Healthcare Facilities: Guidelines on Secure Management and Diversion Prevention.*

The Drugs and Equipment Standard requires drugs to be immediately available to respond to a number of situations – which specific drugs are recommended?

Medical Directors are responsible for ensuring that the OHP has the appropriate drugs needed to address the situations outlined in the Standard. This may be achieved in a number of ways but generally speaking the following drugs will support physicians in managing urgent and emergency situations:

Hypertension

- Antihypertensive IV such as Labetalol, Hydralazine or Nitroglycerine (at least 1 for circumstances where sedation or regional anesthesia is being administered, and at least 2 where general anesthesia is being administered)
- BETA Blocker IV such as Metoprolol, Propranolol, Esmolol
- Lasix IV

Hypotension

- At least 2 of:
    - Epinephrine
    - Ephedrine
    - Vasopressin
    - Phenylephrine

Anaphylaxis

- Diphenhydramine IV
- Hydrocortisone IV

Cardiac Events

- Epinephrine
- Amiodarone IV
- ASA
- IV agent for supraventricular tachycardia such as Adenosine, Esmolol, Verapamil, or Metoprolol (at least 2 for circumstances where sedation or regional anesthesia is being administered, and at least 3 where general anesthesia is being administered)
- Nitroglycerine spray
- Atropine IV
- Benzodiazepine IV such as Midazolam, Diazepam, or Lorazepam
- Calcium IV

- Lidocaine 2% pre-filled syringe

Respiratory Events

- Bronchodilators

Malignant hyperthermia

- An adequate supply of Dantrolene, and other appropriate drugs as per MHAUS guidelines

Benzodiazepine Reversal

- Flumazenil IV

Opioid Reversal

- Naloxone IV - if narcotics are stocked

Electrolyte Disturbances

- Magnesium Sulfate IV

Hypoglycemia

- Dextrose 50% IV

Other

- Neuromuscular blocking reversal agents
- Sodium bicarbonate IV

What kind of equipment is appropriate to have immediately available for urgent or emergency situations?

Medical Directors are responsible for ensuring that the OHP has the appropriate equipment needed to address the situations outlined in the Standard. This may be achieved in a number of ways but generally speaking the following equipment will support physicians in managing urgent and emergency situations:

- AED
- IV setup
- Adequate equipment to manage local anesthetic toxicity
- Appropriately sized equipment for infants and children, if required
- Assortment of disposable syringes, needles, and alcohol wipes
- Laryngeal mask airways
- Means of giving manual positive pressure ventilation (e.g., manual - self-inflating resuscitation device)
- Cardiopulmonary resuscitation equipment with current ACLS/PALS - compatible defibrillator
- Qualitative and quantitative means to verify end-tidal CO2
- ECG monitor

- Intubation tray with a variety of appropriately sized blades, endotracheal tubes, and oral airways
- Oxygen source
- Pulse oximeter
- Suction with rigid suction catheter
- Devices to provide active warming
- Torso backboard
- Cognitive Aids (for example, for difficult airways, ACLS algorithms, Malignant Hyperthermia, etc)

The *Physical Space* Standard contains requirements around maintaining and inspecting equipment. Please see that Standard for more information.

CPSO

Patient Selection Standard

Patient Selection Standard

Patient selection is a crucial component of ensuring procedures performed in an OHP are safe. The appropriateness of performing a procedure in the OHP setting depends on ensuring that the proposed procedure can be performed safely for that particular patient and their particular circumstances.

Standards

1. Physicians **must** use their professional judgement to determine whether a procedure can be provided to a particular patient safely and effectively in an OHP, on a case by case basis.

2. Physicians **must** only perform a procedure on a patient where they are satisfied that the procedure can be safely and effectively performed in the OHP, and it is in the patient's best interest to do so, taking into account:

    a. the patient's existing health status (e.g., any co-morbidities, frailty, stability of any existing conditions), their specific health-care needs and the specific circumstances;
    b. the potential complications that could arise from that specific procedure, including potential complications in surgical management if more than one procedure is to be performed at a time;
    c. anesthetic or sedation factors that may place the patient at a higher risk;
    d. the resources that may be required to perform a procedure on that particular patient;
    e. the duration of the procedure and the potential for a prolonged recovery period; and
    f. the location of the OHP and its proximity to emergency services or hospitals[1], should complications arise from the procedure.

3. Where a prospective patient would be required to undergo general or regional anesthesia or sedation, the physician administering the anesthesia or sedation **must** assign an ASA classification[2] for that prospective patient.

    a. Generally, only patients with ASA classifications of I and II are appropriate for procedures in an OHP setting. Physicians **must** only perform procedures involving the administration of general or regional anesthesia or sedation on patients classified as ASA III if:
        i. the comorbid condition is unlikely to add significant risk to the anesthetic, sedation or procedure; and
        ii. the comorbid condition could not reasonably be expected to be adversely affected by the anesthetic, sedation, or procedure;
    b. The physician administering the anesthesia or sedation and the physician performing the procedure **must** discuss all potential ASA III cases well in advance of the scheduled procedure, with regard to the:

[1] The *Adverse Events* Standard requires OHPs to have an established protocol to facilitate the urgent transfer of patients to the most appropriate hospital for the management of an urgent adverse patient event.
[2] For more information on ASA classifications see the *Advice to the Profession* document.

i. appropriateness of OHP setting for the safe performance of the procedure (including the factors listed in Provision 2 above),
ii. pre-procedure assessment and care required, and
iii. intra-procedure and post-procedure requirements.

Advice to the Profession: Patient Selection Standard

Why is patient selection so important in an OHP?

Appropriate patient selection is critical to help ensure that patients can receive safe care in OHPs. The Out-of-Hospital Premises Inspection Program has historically seen a number of adverse events that result from inappropriate patient selection. The *Patient Selection* Standard requires physicians to classify patients, prior to a procedure where general or regional anesthesia or sedation will be used, using the American Society of Anesthesiologists' Physical Status Classification System and only perform procedures on patients who are classified as ASA I, ASA II or, in some circumstances, ASA III.

The process of determining suitability of a patient to undergo a procedure in an OHP involves the complex interplay of several factors, and there can be a significant difference in the way physicians classify patients and determine which ASA III patients they consider appropriate to treat in an OHP. This Standard is intended to help physicians appropriately exercise professional judgment in relation to these patients.

How do I determine which ASA classification a patient should have?

In determining the appropriate ASA classification for a patient there are a number of factors that need to be considered. The table below[1] outlines some examples of conditions or diseases that would influence the determination of a patient's ASA classification.

ASA Classification	**Definition**	**Adult Examples**
I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): • current smoker, • well-controlled diabetes mellitus or hypertension, • mild lung disease
III	A patient with severe systemic disease	Substantive functional limitations; 1 or more moderate to severe diseases. Examples include (but not limited to): • poorly controlled diabetes mellitus or hypertension, • chronic obstructive pulmonary disease, • transient ischemic attack, • coronary artery disease/stents

[1] Modified from Rajan, N, Rosero E, and Joshi, G 2021, 'Patient Selection for Adult Ambulatory Surgery: A Narrative Review', *International Anesthesia Research Society*, vol. 133, no. 6, pp 1415-1430. Please see this article for more information.

What kind of comorbidities may make a patient inappropriate to perform a procedure on in an OHP?

Several comorbid conditions have been demonstrated to have an effect on patient outcomes after procedures in an OHP type setting and therefore need to play a major role in patient selection. Independent factors identified by a majority of studies include:

- advanced age
- obesity
- obstructive sleep apnea
- cardiac disease,
- chronic obstructive pulmonary disease
- diabetes mellitus
- end-stage renal disease
- transient ischemic attack/stroke,
- chronic opioid use or opioid use disorder, and
- malignant hyperthermia.[2]

Generally, patients would be unsuitable for a procedure in an OHP where they:

- have unstable or poorly managed chronic illnesses such as diabetes, hypertension, hepatitis, etc.;
- have unmanaged alcohol or substance use disorders; or
- are undergoing active immunosuppressant cancer treatment.

Physicians are required to exercise their professional judgement when determining the appropriateness of performing procedures on patients in an OHP, and where they are unsure or where the patient is classified as ASA III, are required to consult with the physician administering the anesthesia or sedation well in advance of the procedure.

Why do physicians need to discuss ASA III cases well in advance?

The *Patient Selection* Standard does allow room for professional judgement when it comes to determining which ASA III patients may be appropriate to have a procedure in an OHP. However, it is important that professional judgment in these circumstances be exercised in a considered way. Requiring that discussions take place between the physician who will be performing the procedure and the physician administering the anesthesia or sedation will help to ensure that both physicians have thought through the potential complicating factors of performing a procedure on the patient in the OHP setting, and both agree that it is appropriate to do so in the circumstances. It is important for discussions to take place in advance in order to manage patient expectations and avoid any pressure to perform a procedure that has been scheduled where it might not be appropriate.

[2] Rajan, N, Rosero E, and Joshi, G 2021, 'Patient Selection for Adult Ambulatory Surgery: A Narrative Review', *International Anesthesia Research Society*, vol. 133, no. 6, pp 1415-1430.

CPSO

Procedures Standard

Procedures Standard

Standards[1]

1. Physicians **must** meet the standard of practice of the profession, which applies regardless of the setting in which care is being provided.

2. Physicians administering anesthesia or sedation **must** do so in accordance with the Canadian Anesthesiologists' Society *Guidelines to the Practice of Anesthesia,* including requirements for patient assessment, pre-procedural testing, fasting guidelines, patient monitoring, documentation of care in the patient record, and anesthesia support personnel.

    a. Where a physician is administering anesthesia or sedation to a pediatric patient they **must** do so in accordance with the Canadian Pediatric Society's *Recommendations for procedural sedation in infants, children, and adolescents*.

3. Physicians **must** use the Surgical Safety Checklist for all surgical procedures.

4. The Medical Director **must** ensure that nursing staff comply with National Association of PeriAnesthesia Nurses of Canada *Standards for Practice*, including requirements for appropriate staffing, discharge of patients from recovery phases, documentation of care in the patient record and appropriate discharge instructions.

5. Prior to procedure acceptance, physicians **must** have assessed the suitability of the patient to undergo the procedure in the OHP setting in accordance with the *Patient Selection* Standard.

    a. For patients with significant co-morbidities, physicians **must** undertake appropriate consultation (for example, with an anesthesiologist or other specialists) as required, prior to making a decision to proceed with the procedure in the OHP setting.

6. Physicians **must** ensure all elements of patient care are appropriately documented in accordance with CPSO's *Medical Records Documentation* policy. For more information on appropriate documentation, please see the *Advice to the Profession* document.

Pre-Procedure Requirements

7. Physicians **must** provide appropriate pre-procedure instructions to patients including any fasting instructions, and whether they will require adult accompaniment upon discharge from the OHP.

8. The physician performing the procedure **must** undertake an appropriate pre-procedure assessment and ensure a baseline history and physical has been taken.

9. Where anesthesia or sedation will be administered, the physician administering the anesthesia or sedation **must**, on the day of the procedure, undertake a pre-anesthetic

[1] Where this standard uses the term "physician" the expectation can be fulfilled by either the physician performing the procedure, or the physician administering the anesthesia or sedation. Expectations that must be fulfilled by a specific physician state this explicitly.

assessment.

10. Physicians **must** ensure informed consent has been obtained for the procedure, including the use of anesthesia or sedation where applicable, in accordance with CPSO's *Consent to Treatment* policy.

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

11. If the physician administering the regional anesthesia or sedation is also performing the procedure, the physician **must** ensure the patient is attended by a second individual[2] who is not assisting in the procedure, and is appropriately qualified, in accordance with Appendix A of the *Medical Director* Standard, to monitor patients undergoing regional anesthesia or sedation.

Post-Procedure Patient Care

12. A physician **must** remain on site until the patient has met discharge criteria for the most acute phase of recovery, in accordance with the National Association of PeriAnesthesia Nurses of Canada *Standards for Practice*.

13. Medical Directors **must** ensure that where there is an overnight stay at an OHP, all of the following conditions are met:

    a. A physician, appropriately qualified in accordance with Appendix A of the *Medical Director* Standard, is immediately available by telephone and can be available onsite at the premises within thirty minutes for urgent medical matters; and
    b. A minimum of two nurses appropriately qualified to monitor and recover patients from anesthesia or sedation are on premises.

Patient Discharge After General or Regional Anesthesia or Sedation

14. When a patient is being discharged, a physician **must:**

    a. write the discharge order for a patient, and
    b. direct that the discharge summary be distributed to the patient's primary care provider, if there is one and, the patient has provided consent.

15. Recovery area staff **must** ensure that patients are:

    a. Provided with appropriate written discharge instructions[3];
    b. accompanied by an adult when leaving the OHP, and are advised to have an adult stay with the patient during the postoperative period (most commonly 24 hours);
    c. informed that they need to notify the OHP of any unexpected admission to a hospital within 10 days of the procedure.

[2] Such as a physician, respiratory therapist, RN or anesthesia assistant.
[3] For example, no driving for 24 hours, who to contact for routine and emergency follow-up, and instructions for pain management, wound care, and activity.

Advice to the Profession: Procedures Standard

What kind of pre-procedure assessments are appropriate to undertake before performing a procedure on a patient in an OHP?

The *Procedures* Standard requires that an appropriate pre-procedure assessment is undertaken including a baseline history and physical examination.

Where anesthesia or sedation will be administered, the Standard also requires the physician administering the anesthesia or sedation to complete a pre-anesthetic assessment. Such an assessment would typically include the following:

- American Society of Anesthesiologists' (ASA) physical status classification of the patient
- a review of the patient's clinical record (including pre-procedure assessment)
- an interview with the patient
- a physical examination relative to anesthetic aspects of care
- a review and ordering of tests as indicated
- a review or request for medical consultations as necessary for patient assessment and planning of care
- a review of pre-procedure preparation such as fasting, medication, or other instructions that were given to the patient.

When determining which tests are indicated or appropriate for a particular patient, physicians may wish to consult Choosing Wisely Canada's recommendations in relation to anesthesia.

What elements of patient care need to be documented when administering anesthesia or sedation in an OHP?

As the *Procedures* Standard states, physicians must comply with *Medical Records Documentation* policy.

When anesthesia or sedation is administered, an Anesthesia/Sedation Record is required to be completed. A typical Anesthesia/Sedation record includes the following information:

a. pre-procedure anesthetic/sedation assessment
b. all drugs administered including dose, time, and route of administration
c. type and volume of fluids administered, and time of administration
d. fluids lost (e.g., blood, urine) where it can be measured or estimated
e. measurements made by the required monitors:
    - Oxygen saturation must be continuously monitored and documented at frequent intervals. In addition, if the trachea is intubated, a supraglottic airway is used, or moderate to deep sedation is being administered, end-tidal carbon dioxide concentration must be continuously monitored and documented at frequent intervals
    - Pulse and blood pressure documented at least every 5 minutes until patient is recovered from sedation
    - Temperature and neuromuscular blockade monitors
f. complications and incidents (if applicable)
g. name of the physician responsible (and the name of the person monitoring the patient, if applicable)

h. start and stop time for anesthesia/sedation care.[1]

What elements of care need to be documented during the recovery period?

In relation to care provided during the recovery period appropriate documentation would typically include:

a. patient identification
b. date and time of transfer to recovery area
c. initial and routine monitoring of: blood pressure, pulse, respirations, oxygen saturation, temperature, level of consciousness, pain score, procedure site and general status
d. 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
e. medication administered: time, dose, route, reason, and effect
f. treatments given and effects of such treatment
g. status of drains, dressings, and catheters including amount and description of drainage
h. summary of fluid balance
i. discharge score using a verified discharge scoring system.

What other documents or notes would typically be included in the patient record?

The *Medical Records Documentation* policy states that the goal of the medical record is to "tell the story" of the patient's health care journey. In order to ensure that a full picture of the patient's health care journey is reflected in their record, the following documents or notes would typically be included:

- Documentation of the consent process in accordance with CPSO's *Consent to Treatment* policy, including a record of any forms that were used
- Pre-procedure assessment
- A copy of the completed Surgical Safety Checklist
- The Anesthetic/Sedation Record
- Discharge summary, where applicable
- Any adverse event reports, as required by CPSO.

[1] For more information see the Canadian Anesthesiologists' Society *Guidelines to the Practice of Anesthesia*.

CPSO

Infection Prevention and Control Standard

Infection Prevention and Control (IPAC) Standard

All OHP staff are responsible for complying with appropriate IPAC practices and for taking action where inappropriate practices are occurring (i.e., those that are out of line with infection prevention and control standards). Everyone has a responsibility to monitor their own practice as well as the practice of the other health care providers working in the OHP to ensure patient safety.

Standards

1. Medical Directors **must** ensure appropriate infection prevention and control practices are occurring within the OHP, including compliance with all applicable legislation and regulations[1], as well as with Public Health Ontario's *Infection Prevention and Control for Clinical Office Practice*[2].[3]

2. In particular, Medical Directors **must** ensure that the following is occurring within the OHP:

    a. Adherence to Routine Practices[4] and Additional Precautions[5];
    b. Compliance with safe medication practices;[6]
    c. Maintenance of a clean and safe health care environment with environmental cleaning and disinfection appropriate to the clinical setting performed on a routine and consistent basis;
        i. Areas where surgery and invasive procedures are performed are cleaned and disinfected according to standards set by the Operating Room Nurses Association of Canada (ORNAC);[7]
    d. Reprocessing of medical equipment is done in accordance with the manufacturer's instructions and/or accepted standards and reflects the intended use of the

[1] This includes, for example, the *Occupational Health and Safety Act* (hereinafter OHSA), as well as the *Needle Safety Regulation (O. Reg 474/07)* under the *OHSA,* and the Workplace Hazardous Materials Information System (WHMIS).
[2] Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. *Infection Prevention and Control for Clinical Office Practice*. 1st Revision. Toronto, ON: Queen's Printer for Ontario; April 2015.
[3] A summary of mandatory practices and best practice recommendations for clinical office practice is set out on page 72 of *Infection Prevention and Control for Clinical Office Practice*.
[4] Routine Practices are based on the premise that all patients are potentially infectious, even when asymptomatic, and that the same standards of practice must be used routinely with all patients to prevent exposure to blood, body fluids, secretions, excretions, mucous membranes, non-intact skin or soiled items and to prevent the spread of microorganisms.
[5] "Additional Precautions" refer to IPAC interventions (e.g., barrier equipment, accommodation, additional environmental controls) to be used in addition to Routine Practices to protect staff and patients and interrupt transmission of certain infectious agents that are suspected or identified in a patient.
[6] For additional information see *Appendix H: Checklist for Safe Medication Practices* set out in *Infection Prevention and Control for Clinical Office Practice*.
[7] For more information about environmental cleaning in surgical areas refer to the Operating Room Nurses Association of Canada (ORNAC) standards, which are now under the auspices of the Canadian Standards Association.

equipment or device and the potential risk of infection involved in the use of the equipment or device[8];

e. Accepted standards of handling regulated waste are adhered to[9].

3. Medical Directors **must** ensure the following is in place to support appropriate IPAC practices:

   a. well documented policies and procedures which are periodically reviewed by staff;
   b. all staff are properly trained and are provided with regular education and support to assist with consistent implementation of appropriate IPAC practices;
   c. responsibility for specific obligations are clearly defined in writing and understood by all staff; and
   d. mechanisms are in place for ensuring a healthy workplace, appropriate staff immunizations and written protocols for exposure to infectious diseases, including a blood-borne pathogen exposure protocol.[10]

4. Where substandard IPAC practices are occurring, all staff **must** take appropriate action, including advising the Medical Director, addressing the issue with the individual responsible for the infraction, and/or reporting to Public Health, where required.

[8] For additional information see *Appendix I: Recommended Minimum Cleaning and Disinfection Level and Frequency for Medical Equipment* set out in *Infection Prevention and Control for Clinical Office Practice*.
[9] "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.
[10] For additional information see *Appendix J: Checklist for Office Infection Prevention and Control* set out in *Infection Prevention and Control for Clinical Office Practice*.

Advice to the Profession: Infection Prevention and Control (IPAC) Standard

Why is it important to ensure OHPs are complying with IPAC standards?

IPAC is an important element of care in any health care institution. Given the nature of the procedures done in OHPs, for example the level of invasiveness, it is important to ensure that appropriate IPAC practices are in place and that standards are met. Failure to do so can have serious consequences for both patients and staff.

What are common IPAC infractions observed during inspections?

Many OHPs that fail their inspections do so from a failure to comply with IPAC standards. Common IPAC deficiencies seen during inspections include the following:

- Sinks with no backsplash
- Items stored underneath sinks
- Aerosol or spray trigger cleaning chemicals
- Cloth furniture that is porous
- Biomedical waste that is stored with other supplies
- Refrigerator used for medications with no temperature log
- Multi-use gel or cleaning solutions not dated upon opening
- Multi-use medications not dated upon opening
- Housekeeping supplies not stored in a designated space
- Reprocessing issues (e.g. technician not appropriately trained, reprocessing done incorrectly, missing items essential to reprocessing, reprocessing brushes that are not designed for re-use being used multiple times).

Medical Directors are responsible for compliance with the requirements set out in Public Health Ontario's *Infection Prevention and Control for Clinical Office Practice*[1] and for ensuring the practices within the OHP are current and reflect any changes in requirements relating to IPAC.

What are some actions that minimize risk of infection in the operating room?

Actions that minimize risk of infection in the operating room include adherence to proper use of disinfectants, proper maintenance of medical equipment that uses water (e.g., automated endoscope reprocessors), proper ventilation standards for specialized care environments (i.e., airborne infection isolation, protective environment, and operating rooms), and prompt management of water intrusion into OHP structural elements.

[1] Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. *Infection Prevention and Control for Clinical Office Practice*. 1st Revision. Toronto, ON: Queen's Printer for Ontario; April 2015.

CPSO

Adverse Events Standard

Adverse Events Standard

Definitions

Adverse Event: An incident that has resulted in harm to the patient as a result of the care provided in the OHP (also known as a "harmful incident"). For specific examples, please see the *Advice to the Profession* document.

Standards

Preparing for Adverse Events

1. Medical Directors **must:**

    a. ensure there are written protocols in place to support the recognition and reporting of adverse events and to appropriately manage any adverse events that occur;
    b. ensure there is an established protocol to facilitate the urgent transfer of patients to the most appropriate hospital for the management of an urgent adverse patient event;
    c. ensure there is a formalized transfer agreement with a local hospital;
    d. be available to provide assistance in managing any adverse events, if necessary;
    e. be satisfied that staff practising within the OHP are capable of managing any adverse events themselves, if necessary; and
    f. have a communication plan in place to keep informed of any adverse events that take place and any actions taken to manage them.

Managing Adverse Events

2. When an adverse event occurs, physicians involved in the adverse event **must** take appropriate and timely action, including:

    a. managing any urgent adverse events appropriately by:
        i. providing any necessary care to address the patient's immediate needs;
        ii. ensuring timely initiation of emergency care or services, where necessary (i.e., where the patient is experiencing severe suffering or is at risk of sustaining serious bodily harm if treatment is not administered promptly);
        iii. initiating a timely transfer to hospital, where necessary;
        iv. accompanying the patient to hospital, where necessary;
        v. communicating with the receiving physician or premises to notify them of the transfer, where the patient is unaccompanied;
        vi. ensuring essential medical information and the referring physician's contact information is sent with the patient to support continuity of care;
    b. caring for, supporting, and following-up with patients, family, and caregivers as necessary.

Documenting and Reporting Adverse Events

3. When an adverse event occurs, physicians involved in the adverse event **must**:

    a. document the details of the adverse event in the patient's medical record;

b. provide a written report to the Medical Director within 24 hours of learning of the event which includes the following information:
    - name, age, and gender of the person(s) involved in the incident, including staff and patients
    - name of witness(es) to the event (if applicable)
    - time, date, and location of event
    - description of the incident and treatment rendered
    - date and type of procedure (if applicable)
    - analysis of reasons for the incident
    - outcome;
c. report the incident, including the details captured in provision 3b, to CPSO in writing within 5 business days of learning of the event;
d. provide CPSO with any relevant medical records and additional information as requested;
e. ensure appropriate disclosure to the patient, in accordance with CPSO's *Disclosure of Harm* policy; and
f. where a death occurs, make a report to the Coroner.

4. Where an adverse event occurs, Medical Directors **must** ensure the reporting obligations set out above are complied with (e.g., that the adverse event has been reported to the CPSO within 5 business days).[1]

Incident Analysis

5. Once the adverse event has been appropriately managed, Medical Directors **must** initiate a process to analyze and learn from the event, including:

    a. undertaking an investigation to understand how and/or why the incident occurred;
    b. developing recommendations to help prevent similar incidents from occurring;
    c. sharing the learnings and recommendations with other staff in the OHP.

6. Medical Directors **must** ensure that recommendations are implemented within the OHP and are monitored over time to assess their effectiveness.

Analyzing and Learning from Adverse Events

7. Medical Directors **must**:

    a. critically review all adverse events that have occurred over a 12 month period and evaluate the effectiveness of the OHP's practices and procedures to improve patient safety;
    b. document the review and any relevant corrective actions and quality improvement initiatives taken; and
    c. provide feedback to all staff regarding identified patterns of adverse events.

[1] Failure to report an adverse event may result in an outcome of Fail by the Premises Inspection Committee.

Advice to the Profession: Adverse Events Standard

An adverse event is defined as an incident that has resulted in harm to the patient as a result of care provided in the OHP. What are some specific examples of adverse events that must be reported to CPSO?

A key component of the definition is that the adverse event must be related to the procedure performed in the OHP. Indicators of adverse events generally include complications related to the use of sedation/anesthesia or to the procedure itself. This includes both serious complications, such as:

- Death within the premises;
- Death within 10 days of a procedure performed at the premises;
- Any procedure performed on the wrong patient, site, or side; or
- Transfer of a patient from the premises directly to a hospital for care.

It also includes other quality assurance incidents which are deemed less critical for immediate action, such as:

- Unscheduled treatment of a patient in a hospital within 10 days of a procedure performed at a premises in relation to the procedure;
- Complications such as infection, bleeding, or injury to other body structures;
- Cardiac or respiratory problems during the patient's stay at the OHP;
- Allergic reactions; or
- Medication-related adverse events.

Patient harm that occurs as a result of an unrelated activity is not considered an adverse event as defined by the Standard and does not need to be reported to CPSO. For example, if a patient has an injury that results in a hospital stay within 10 days of the procedure performed in the OHP but is unrelated to the OHP procedure, this would not be considered an adverse event.

Why is it important for Medical Directors to track adverse events?

Adverse events can serve as a good indicator of where quality improvement can occur in an OHP, both with respect to policies and procedures in the OHP, and with respect to an individual physician's practices. Keeping track of this information is intended to assist OHPs with learning from and improving patient safety within the premises. Reviews of adverse events (and near misses) are considered an effective approach to improving patient safety.

What is the purpose of reporting adverse events to CPSO? What will you do with this information?

CPSO is responsible for the effective oversight of OHPs. Reviewing the severity and frequency of adverse events within each OHP helps CPSO to fulfill this duty by helping to identify any concerning trends. In order to fulfill CPSO's obligation to monitor for higher risk events, and to fulfill their own obligations, Medical Directors are accountable to CPSO for reporting this information and for taking any appropriate corrective action.

CPSO recognizes that adverse events can result from a variety of factors, including risks inherent in the procedure, system failures, or even performance issues with individual

physicians, however they offer opportunity for learning and improvement and can offer insight into areas which might benefit from practice improvement or additional safety measures. Depending on the nature and frequency of adverse events, they are not necessarily an indication of poor practice. However, lack of reporting of adverse events may serve as indication that OHPs are failing to comply with their obligations as set out in the *Adverse Events* Standard.

CPSO is committed to assisting OHPs with improving their practices and collecting information regarding adverse events helps us to do so.

How can I report adverse events and what information needs to be submitted to CPSO?

Adverse events can be reported through the Member Portal on CPSO's website. Physicians involved in the adverse event are required to submit a report with the following information:

- name, age, and gender of the person(s) involved, including staff and patients;
- name of witness(es) to the event (if applicable);
- time, date, and location of event;
- description of the incident and treatment rendered;
- date and type of procedure (if applicable);
- analysis of reasons for the incident;
- outcome;
- any additional information as requested by CPSO.

Physicians will also be asked to submit relevant medical records, including any referral letters, pre- and post-operative notes and tests, surgical notes, the anesthesia record, and an updated memo of the patient's outcome.

Why has CPSO moved away from distinguishing between Tier 1 and Tier 2 adverse events?

With the implementation of CPSO's new Member Portal, you are now required to report all adverse events as they occur, so the distinction between Tier 1 and Tier 2 adverse events no longer serves a purpose. CPSO will continue to review all adverse events that occur within OHPs and respond accordingly.

Where can I learn more about adverse events?

The CMPA's Good Practices Guide and *Learning from adverse events: Fostering a just culture of safety in Canadian hospitals and health care institutions* have additional guidance related to adverse events, including the best approach for reviewing these events.

CPSO

Quality Assurance Standard

Quality Assurance Standard

Standards

Creating a Culture of Safety and Quality

1. Medical Directors **must** foster a culture of safety and quality within the OHP.

2. Medical Directors **must** ensure that the OHP maintains a Quality Assurance program and that it undertakes initiatives to improve the quality of care within the premises.

3. Medical Directors **must** ensure the OHP has a Quality Assurance (QA) committee for the purpose of creating processes to establish standards, monitor activity, and improve performance to ensure appropriate volume and scope of services provided.

4. Medical Directors **must:**

    a. hold, at a minimum, two QA committee meetings at each OHP site per year, that address quality issues (e.g., infection control, adverse events, etc.);
    b. ensure meetings are attended by all staff providing patient care where possible, and that all staff who are unable to attend are updated on the meeting discussions and outcomes;
    c. ensure all meetings, including the staff who were in attendance, are documented and that the documentation is available to CPSO upon request.

5. Medical Directors **must** hold periodic staff meetings to review policies and procedures, challenging cases, near misses[1], adverse events, and protocols as appropriate to minimize adverse events.

6. Medical Directors **must** ensure that members of staff undertake continuing education relevant to their practice in the OHP, in accordance with applicable regulatory requirements, to maintain clinical competency and knowledge of best practices.

Monitoring Quality of Care

7. Medical Directors **must** ensure there is a documented process in place to regularly monitor the quality of care provided to patients through activities, including the following:

    a. review of all staff performance (i.e., both medical and non-medical staff);
    b. review of individual physician care to assess:
        - patient and procedure selection are appropriate
        - patient outcomes are appropriate
        - adverse events;
    c. review a selection of individual patient records to assess completeness and accuracy of entries by all staff;

[1] Near miss incident is defined in CPSO's *Disclosure of Harm* policy as an incident with the potential for harm that did not reach the patient due to timely intervention or good fortune (also known as a "close call"). For specific examples, please see the *Advice to the Profession: Disclosure of Harm*.

d. review of activity related to cleaning, sterilization, maintenance, and storage of equipment;
e. documentation of the numbers of procedures performed (i.e., any significant increase/decrease (>50% of the last reported assessment)).

Advice to the Profession: Quality Assurance Standard

What is "Quality Assurance" and what does it mean to foster a culture of safety and quality within the OHP?

The term "Quality Assurance" generally refers to the identification, assessment, correction, and monitoring of important aspects of patient care. The *Quality Assurance* Standard sets out a number of quality assurance activities that must be undertaken in an OHP which, when undertaken effectively, can help to foster a culture of safety and quality within the OHP.

The CMPA's *Learning from adverse events: Fostering a just culture of safety in Canadian hospitals and health care institutions*[1] also has guidance around fostering a just culture of safety within an institution.

The Quality Assurance Standard requires that Medical Directors hold periodic staff meetings to review policies and procedures, challenging cases, near misses, adverse events, and protocols as appropriate to minimize adverse events. How often should staff meetings be held?

Medical Directors can determine the frequency of staff meetings based on the needs of the OHP and its staff, any updates or changes in polices and procedures, or any adverse events, near misses, or challenging cases that may need to be reviewed.

Medical Directors are required to regularly monitor the quality of care provided to patients through activities such as reviewing a selection of patient records. What are best practices with respect to this quality assurance activity?

An annual review of a random selection of medical records (e.g., 5-10 records) can help to monitor the quality of care within an OHP, including review of the following:

- record completion[2] and documentation of informed consent
- percentage and type of procedures
- appropriate patient selection[3]
- appropriate patient procedure
- where required, reporting results in a timely fashion
- evaluation of complications
- assessment of transfer to hospital, where required
- follow up of abnormal pathology and laboratory results.

[1] *Learning from adverse events: Fostering a just culture of safety in Canadian hospitals and health care institutions*. Ottawa, ON: Canadian Medical Protective Association; 2009.
[2] For more information see the *Advice to the Profession: Procedures Standard* document.
[3] For more information see the *Patient Selection* Standard.