

Health Quality Ontario

The provincial advisor on the quality of health care in Ontario



Building an Integrated System for Quality Oversight in Ontario's Non-Hospital Medical Clinics

Contents

Executive Summary	3
Introduction	5
Composition and Scope of the Panel	7
The Panel's Approach.....	8
Principles Underpinning Quality Oversight in Non-Hospital Medical Clinics.....	8
The Review and Recommendation Development Process.....	10
1) Engaging the Public, Patients and Providers.....	10
2) Defining Quality in Out-of-Hospital Programs.....	11
3) Understanding the Current State of Quality Oversight at Non-Hospital Medical Clinics in Ontario..	13
4) Conducting a Jurisdictional Scan.....	16
Learnings from Others.....	21
Important Takeaways of the Panel from their Review Process.....	23
Safety and Appropriateness.....	23
Transparency.....	24
Tools to Support Accountability.....	24
Panel Recommendations	26
Conclusion	32
Consolidated Recommendations	34
Glossary	37
Appendices	39
Appendix 1. Public, Patient and Provider Engagement.....	39
Appendix 2. Key Learnings from Other Jurisdictions.....	41
Appendix 3. References.....	44

Executive Summary

In December 2014, in response to a number of reports of patients suffering serious harm from acquiring infections in a pain clinic and in several endoscopy clinics, the Ontario Minister of Health and Long-Term Care tasked Health Quality Ontario with providing advice to the government on the comprehensiveness and effectiveness of the current quality oversight programs for high-risk medical services being provided in non-hospital medical clinics.

Quality oversight is an essential component of a safe and effective health care system. There is a long tradition in Ontario of regulatory oversight of health care providers and that framework has been updated over the years. However, the existing system of oversight for the premises in which providers deliver care to patients has not kept up with the movement of services out of hospitals into clinics in the community.

Two regimes for regulating non-hospital medical clinics have emerged over time to provide oversight and enhance patient safety. Having two systems introduces unnecessary complexity into an already complex undertaking. Apart from this complexity being a source of risk itself, many procedures and settings are not covered within these two regimes, which may present a concerning gap. Although risk in medicine can never be eliminated, we have a responsibility to mitigate it as much as possible. No patient should be at a relatively higher risk because of where they undergo a medical procedure. A robust system of quality oversight will reassure citizens that their care is required to meet a standard of quality no matter where it is received. A comprehensive set of requirements should be designed to clearly set expectations, proactively reduce exposure to risk, and contain measures for an appropriate response should a lapse in quality occur.

There is a pressing need to modernize our regulatory framework across the spectrum of non-hospital care settings. Lapses in quality in some clinics have raised concerns about the sufficiency of the current system of oversight and have highlighted the need for greater transparency for this sector. As technology increasingly enables services to be delivered in the community setting, and innovative providers are developing models to bring care closer to people's homes, now is the time to ensure that patients will be able to rely on a system of quality oversight designed for both today and tomorrow.

The public, patients and providers are all partners in this effort. Taking their needs into account and making the details of quality goals in non-hospital medical clinics transparent is essential for putting that quality oversight to best possible effect. Consistent quality oversight in non-hospital medical clinics would support the goals of *Ontario's Patients First: Action Plan for Health Care* in the following ways:

Access

- Patients have access to high quality services closer to home.

Inform

- Patients and providers know where to find information that matters to them about the performance of clinics so they can make informed choices.
- Clinic owners and the professionals who work there have information about rules and standards for their clinics, so they know what the expectations are.
- Patients and providers have opportunities to give feedback on their experiences and satisfaction with clinics in one centralized place.
- There is a central registry of all clinics performing high risk procedures.

Connect

- Clinics in the community are linked with other providers and do not operate in an isolated way.

- There are clear channels of communication between public health units, professional regulatory colleges and other authorities responsible for health care quality in these settings.

Protect

- Oversight is complete and covers the clinic, the equipment it uses, and the people who work there.
- Clinics are inspected on schedules based on the kinds of procedures they perform and the possible risks associated.
- A strong regulatory system is in place to uphold the public interest and allow authorities to enforce standards in a way that is flexible and responsive.
- Standards for safety and quality do not change based on who owns or operates a clinic or how it is funded.
- The system is flexible and responsive to adjust to shifts in technology and practice over time.

Having concluded a period of research and discussion, we recommend the creation of a single legislative system for quality oversight in non-hospital medical clinics. To ensure this system is nimble and responsive, we recommend accountability be placed with an independent and appropriately resourced Executive Officer who, with input from experts, has the authority to establish and enforce standards in a way that is transparent, collaborative across the system, responsive to the needs of the public, patients and providers and reflective of ongoing changes in technology and care.

Non-hospital medical clinics should be required to register with the Executive Officer and report performance and quality data, allowing the officer to monitor and respond to quality issues across the system. And, to promote the safest possible care environment, decisions about when and how clinics are inspected should take into account issues of risk, including the kinds of services offered and the performance record of the clinic. In addition, inspection reports should be reviewed in a timely way and an expedited process should be made available for those cases where concerns about safety or risk are greater. Regardless of the status of a review, the Executive Officer should be empowered to order a clinic to cease activity immediately in the interest of public safety.

Patients, providers and the public should be able to make informed decisions about their care and provide feedback, and inspection reports and complaints processes should be designed with this purpose in mind.

We envision this new system of integrated legislative oversight would empower authorities to work collaboratively and communicate transparently, and would encourage organizations to pursue continuous quality improvement.

Introduction

Every day in Ontario, thousands of patients receive procedures, tests and assessments in non-hospital medical clinics. “Non-hospital medical clinics” is a broad term that captures a wide array of settings independent of hospitals, where patients undergo procedures, testing and clinical assessments. Non-hospital medical clinics encompass family physician offices, specialists’ clinics that provide specialized services, some of which may be invasive, and facilities that provide day surgery. These facilities deliver ambulatory or out-patient care, meaning that an over-night hospital stay is not required. This is one of the largest volume patient activities in Canadian health care.¹ The growing volume of services delivered outside of hospitals has been driven by a number of factors, including innovations in technology and care delivery models. The movement of low risk procedures from hospital to the community was expressed as a goal in the *Action Plan for Health Care*,² and providing coordinated and integrated care in the community closer to home was emphasized as a goal in the recently released *Patients First: Action Plan for Health Care*.³

The movement of services away from hospitals and into the community has occurred incrementally over several decades. Non-hospital medical clinics offering specialized services now exist in many parts of the province, and some receive public health care funding while others are privately funded or patients pay out-of-pocket for services. Most offer specialized services such as diagnostic imaging, sleep studies, colonoscopies, gynecology, ophthalmology or plastic surgery. Clinics that specialize may be owned by physicians or non-physicians, or may be attached to hospitals. While all physicians are regulated health professionals, overseen by the College of Physicians and Surgeons of Ontario, the physical premises of non-hospital medical clinics may be regulated under two different systems. Having two regulatory systems for clinics that are all providing medical services creates confusion and unnecessary complexity. Additionally, some clinics operate outside the purview of either regulatory system.⁴ Under the two regulatory frameworks, gaps in oversight persist and are not easily remedied.

In December of 2014, the Ministry of Health and Long-Term Care tasked Health Quality Ontario (HQO) with developing recommendations to achieve comprehensive and effective quality oversight for non-hospital medical clinics. An advisory panel was created to review the current environment of care delivery and to issue a series of recommendations intended to ensure the comprehensiveness and effectiveness of quality oversight of these clinics.

As services and procedures move out of hospitals into the community, how can the public be assured that they meet a high standard of quality?

This report offers a series of recommendations designed to create a consistent and comprehensive system of quality oversight in specified types of non-hospital medical clinics, irrespective of whether the services are paid for publicly or privately.

¹ Canadian Institute for Health Information. (2011). [Data Quality Documentation for External Users: National Ambulatory Care Reporting System, 2010–2011](#).

² Ministry of Health and Long-Term Care. (2012). [Ontario’s Action Plan for Health Care: Better Patient Care Through Better Value for Our Health Care Dollars](#). This policy initiative defines Community-Based Specialty Clinics as “... non-profit health care providers that will offer select OHIP-insured, low-risk procedures that are currently provided in acute hospital settings. Specialty clinics will focus on providing high volume procedures, such as low-risk cataract procedures, colonoscopies, and other procedures that do not require overnight stays in a hospital.”

³ Ministry of Health and Long-Term Care. (2015). [Patients First: Action Plan for Health Care](#).

⁴ This gap in the system refers only to the clinic premises. Most health professionals are regulated under established statutes, for example physicians in Ontario are governed by standards set out under the *Regulated Health Professions Act* and *The Medicine Act*.

Figure 1: Quality as defined by the Ontario public

Thematic word cloud of qualitative responses to online discussion questions received from 35 members of the general population.



Composition and Scope of the Panel

Health Quality Ontario formed a panel composed of health care and health system leaders to guide the process of review and analysis of quality oversight in non-hospital medical clinics.

The panel was composed of:

Co-Chairs

Dr. Joshua Tepper

President and CEO,
Health Quality Ontario

Maureen Taylor

Caregiver Representative

Panel

Tom Closson

Health Care Consultant

Colleen M. Flood

University of Ottawa Research Chair in Health Law and Policy and Director of the Centre for Health Law, Policy and Ethics, University of Ottawa

Dr. Danielle Martin

Vice President, Medical Affairs and Health System Solutions, Women's College Hospital

Dr. David Walker

Professor, School of Medicine and School of Policy Studies, Queen's University

With a focus on the public interest, quality, transparency and accountability, the purpose of the panel was to propose means of strengthening the quality oversight mechanisms for out-of-hospital medical clinics.

The panel was asked to identify strengths, gaps and risks in the current quality oversight structure. The panel was also asked to think about the future and how to build a system that could be responsive to evolving technologies and new practice patterns. The panel was told to be bold in our thinking. The goal is to ensure that patients can be confident that their health care is meeting a consistent high standard of quality in non-hospital medical clinics, regardless of where it is provided and whether it is paid for publicly or privately.

For the sake of patient safety all procedures of a comparable risk should be required to meet a consistent standard of quality, regardless of whether they are publicly or privately funded. Although protecting patients is the most important goal, poor quality in private-pay clinics can also affect the public health care system (e.g., through increased hospital visits due to lapses in quality care). The panel agreed that standards for a particular procedure or service should be set according to best practices and should not change depending on clinic ownership, funding model or location. There was also an acknowledgment that not all non-hospital medical clinics require the same level of oversight; calibrating the degree of oversight to the risk involved to the patient is key.

Throughout its review, the panel remained mindful of initiatives currently under development. Three initiatives of particular note were ongoing policy development related to community-based specialty clinics, the evolution of the Quality Management Partnership led by Cancer Care Ontario and the

College of Physicians and Surgeons of Ontario,⁵ and the development of quality-based procedures in a number of areas such as colonoscopy, dialysis and orthopedics.⁶ All of these initiatives integrate quality considerations in their design and execution.

In scope. The scope of the panel's review included consideration of the quality oversight programs currently operational in non-hospital medical clinics as set out in the *Independent Health Facilities Act, 1990*⁷ and the College of Physicians and Surgeons of Ontario's Out-of-Hospital Premises Inspection Program, which is enabled by a regulation under the *Medicine Act*.⁸ But addressing gaps in the existing system also required the consideration of procedures and settings not currently captured by either program. Additionally, the panel considered how other leading jurisdictions assured quality in similar community-based settings and determined how licensing, inspection, governance and accreditation could be used to best effect.

Out of scope. Out of scope for the panel's review were considerations about where (geographically) services would be performed, service volumes, how funding would be determined, how services should be funded and who delivers funded volumes. The panel did not review the clinical or facility standards set for specific procedures or modalities.

The Panel's Approach

The panel's approach to the review and recommendation development process is depicted below.

Overall, quality as it applies to non-hospital medical clinics was defined and the key features of non-hospital medical programs were compiled. The current state of quality oversight in these clinics in Ontario was also reviewed.

In addition, the panel was informed by interviews with key informants and an environmental scan of comparable jurisdictions that included articles from journals along with available information about other oversight models across different sectors in the health system. Finally, public, patient and provider surveys and engagement sessions were held (see Appendix 1 for an overview of engagement methodology).

Principles Underpinning Quality Oversight in Non-Hospital Medical Clinics

The panel identified the following principles that should guide quality oversight for non-hospital medical clinics.

Integrated. Quality oversight of non-hospital medical clinics is a complex undertaking. The most effective model will have a clear mission and will involve setting out clear accountabilities and authorities for a number of actors.

Consistent. Non-hospital medical clinics and hospitals should be required to meet consistent standards for quality. Although the standard should be the same across the health system, how it is attained and assured may vary depending on facility type or procedure. Quality oversight should apply whether the services are OHIP-funded, being paid for out-of-pocket or by private insurance.

⁵ Refer to the Quality Management Partnership website at: <https://www.qmpontario.ca/>

⁶ Refer to the Health System Funding Reform: Quality-Based Procedures website at: http://www.health.gov.on.ca/en/pro/programs/ecfa/funding/hs_funding_qbp.aspx

⁷ *Independent Health Facilities Act, R.S.O. 1990, c. 1.3*

⁸ *Out-of-Hospital Premises Inspection Program*. The College of Physicians and Surgeons of Ontario. Retrieved June 2015 from: <http://www.cpso.on.ca/cpso-members/out-of-hospital-premises-inspection-program>

Comprehensive. Quality oversight should concern itself with the providers, the clinical care, the outcomes and experience of patients, the premises including infection control and the equipment. The program should be well-functioning, designed to uphold high quality but able to respond thoughtfully and appropriately should something go wrong. Business practices should also be considered, particularly the charging of facility fees or upgrades that can act as barriers to access and/or equity.

Transparent. Transparency is necessary to ensure that patients know the quality of services delivered by a facility and can make informed decisions about where to obtain treatment. It is also important in ensuring that providers understand the requirements placed on them when they practice in non-hospital clinics.

Future-oriented. A quality oversight program needs to be nimble and flexible to respond to innovations in technology and practice.

Practical. The cost of the quality oversight program needs to be reasonable and the scale of the program implementable. Enforcement provisions need to be clear and actionable. Barriers to information sharing between organizations are removed in the interest of the patient.

“Make sure a patient is totally comfortable, feels safe, and is 100% aware of what is going on. Make sure all information is EASY to access online.”

—Participant in qualitative online discussion

The Review and Recommendation Development Process

As part of its review process, the panel undertook the following activities.

Engaging the Public, Patients and Providers	Defining Quality in Medical Programs	Understanding the Current State in Ontario	Reviewing Quality Oversight in Context
Conducted quantitative and qualitative surveys of the public, patients and providers to understand preferences and expectations and perspectives on current practice.	Established definition of quality according to six dimensions: safety, effectiveness, patient-centred care, timeliness, efficiency and equity.	Reviewed current state of quality oversight in Ontario to understand the strengths, weaknesses and gaps of the two regulatory systems for non-hospital medical clinics. Conducted key informant interviews.	Surveyed the quality oversight systems of comparable jurisdictions in Canada and internationally. Reviewed how quality oversight is provided in other sectors in Ontario. Examined peer reviewed and grey literature.

1) Engaging the Public, Patients and Providers

The panel felt it was important to learn what the public, patients, referring physicians, and other providers thought about how non-hospital medical clinics that may be providing high risk procedures ought to be overseen and why. In order to avoid making assumptions about the preferences of these groups and to ensure their feedback was embedded in the process, the panel undertook qualitative and quantitative engagement. Some of the findings are below, and a summary of the research into the perspectives, knowledge, priorities and concerns of patients and providers can be found Appendix 1. The complete report is available from Health Quality Ontario.

Public / Patient Engagement. Engagement took two forms: a quantitative survey of a random sample of the population and a qualitative engagement process involving a smaller group of patients, providers and the public. When surveyed, patients made no distinction between the two types of non-hospital medical clinics – independent health facilities (IHF) and out-of-hospital premises (OHP). Ownership information is similarly unimportant.⁹ During qualitative discussions, participants admitted unfamiliarity with the regulation and oversight for these facilities, but were clear that they expected IHFs and OHPs to be regulated in a similar manner as hospitals. Further, the public has a higher confidence in the quality and safety of hospitals than of non-hospital medical clinics. It was not clear what led to that higher degree of confidence.

Survey participants rated transparent information as “very important.” Before their first appointment, patients wanted to receive information about facility cleanliness, accreditations and certifications, clinician credentials and experience, quality control measures, and rates of infections and complications. The majority of respondents felt it was necessary to have information available on the clinic or facility’s website (69%), on a website administered by the provincial government (64%), in the clinic reception or waiting area (62%) and on the websites of professional oversight organizations (61%). Significantly, many patients reported not receiving any information before their appointments, which was confirmed in a survey of family physicians and general practitioners.

⁹ Ownership of the facility was least likely to be endorsed as “important” or “very important.”

Patients were interested too in other aspects of service quality beyond clinical outcomes and safety. These included convenience of location, accessibility, wait times, access to multilingual staff, and cultural sensitivity.

Provider Engagement. The provider engagement process demonstrated similar results. In a survey of Ontario family physicians and general practitioners, more than one third (34%) stated they were unclear on what an IHF is and more than half (51%) responded similarly regarding OHPs. Providers at IHFs and OHPs, while more confident in the care provided at these facilities, expressed confusion regarding existing regulations, with one third (33%) indicating that they were unsure of the frequency at which inspections currently take place.

As part of the qualitative engagement process, family physicians and general practitioners also reported a higher confidence in the quality and safety of hospitals than of non-hospital medical clinics. They indicated that there is not enough information available regarding the cost, safety and overall quality associated with IHFs and OHPs. In addition, the criteria family physicians and general practitioners endorsed most frequently as “very important” when referring patients to a non-hospital medical clinic included physician credentials and experience, cleanliness of the facility, patient feedback, the number of procedures or tests conducted by the physician per year, quality control measures in place, emergency plans related to complications, rates of hospitalizations due to infections and complications and clinic accreditations and certifications. Yet almost half (47%) of respondents indicated they were not certain where to acquire this information.

OHP and IHF providers surveyed indicated that the information their facilities make available to the public does not always align with the information most valued by primary care providers and patients. Only 34% of respondents indicated that their facilities make information available regarding rates of hospitalization, 34% list the number of procedures or tests conducted by physicians per year, 46% provide quality control measures and 52% include facility cleanliness ratings, all measures listed as very important by patients and family physicians and general practitioners alike.

2) Defining Quality in Out-of-Hospital Programs

Although the definition of quality should be nuanced in light of specific treatments or procedures, it is useful to consider a broad understanding of quality. The panel based its considerations on the Institute of Medicine’s six domains of health care quality:¹⁰

Safe. Avoid harm to patients from the care that is intended to help them. Ensuring the safest possible experience for patients requires that:

- Clinicians practice within the scope of their certification and experience.
- Facilities employ best practices in infection control and prevention.
- Critical incidents and adverse events are reported and investigated, with protocols in place for communicating with patients.
- Facilities meet accessibility standards for the disabled
- Consistent oversight is in place, with the facility’s responsibilities and the regulatory environment clearly defined.
- Program standards and inspection protocols are designed to support enhanced patient safety.

Effective. Provide appropriate services based on scientific knowledge and evidence.

- The right services are provided to the right patients, with full transparency around the merits of add-on services that may be offered.

¹⁰ Institute of Medicine (IOM). [Crossing the Quality Chasm: A New Health System for the 21st Century](#). Washington, D.C: National Academy Press; 2001.

- Procedures are performed competently and according to current best practice.
- Referrals are appropriately provided.

Patient Centered. Provide care that is respectful of individual patient preferences, needs, and values.

- Patient values guide all clinical decisions.
- Patients have access to information that helps them make informed choices.
- Patients receive accurate and timely information about their procedure and aftercare.
- Facilities are clean and offer a consistent experience.
- There is a defined and transparent complaint resolution process in place.
- Patients are treated respectfully.

Timely. Reduce wait times and harmful delays for those who receive and those who give care.

- Wait times for procedures are tracked.
- Facilities provide timely turnaround of reports to referring clinicians.

Efficient. Avoid waste, including waste of equipment, supplies, ideas, and energy.

- Facilities make best use of their public funding.
- Data is collected that enables robust performance management of both quality and finances and informed policy-making.
- Accountabilities are clearly defined and are based on a common set of standards and priorities.

Equitable. Provide care that does not vary in quality due to personal characteristics such as gender, ethnicity, geographic location, or socioeconomic status.

- Ontarians who seek insured services are not subject to additional fees.
- Paying for upgrading of services or devices is never a condition of accessing service.

Infection Prevention and Control

The panel also gave careful consideration to infection prevention and control (IPC).

Infection prevention and control is an emerging area of concern to the public, and lapses in this area have had a significant impact on patients, providers, communities and local public health units. IPC standards are important in all medical settings, and are an area of significant focus in IHF and OHP facility standards. Lapses in IPC might be discovered during a premises inspection, or could be identified reactively as infections or outbreaks are reported through the public health system, investigated and traced back to a clinic. There are clear statutory and regulatory requirements for communication related to 'reportable' diseases, and the local medical officer of health is able to investigate and follow-up these cases in all settings.

It is important to note that a lapse does not necessarily mean that any patient has been harmed. All IPC lapses are concerning and understandably very worrying to patients. However, not all lapses pose a serious threat to public health. It is important that the risk is properly assessed and the situation appropriately managed. It is also critical there be clear, formal lines of communication between public health units and the regulatory authority for community medical clinics. This is simple to state but much more complex to execute.

Public health is focused on a wide range of activities that protect and promote the health and wellbeing of whole populations. Legislative and regulatory oversight is provided through the *Health Protection and Promotion Act* and the Ontario Public Health Standards, which set out requirements for the provision of public health services. Local public health services are delivered by 36 boards of health across the province. Each public health unit is headed by a Medical Officer of Health.

At the provincial level, the Public Health Division in the Ministry of Health and Long-Term Care is responsible for setting public health policy. Leadership and clinical experience is also provided through the Office of the Chief Medical Officer of Health. Also at the provincial level is Public Health Ontario, an agency of government that provides expert scientific and technical advice and support relating to matters like infectious diseases, infection prevention and control, surveillance and epidemiology, emergency preparedness and incident response. Public Health Ontario operates 14 Regional Infection Control Networks, voluntary programs that help practitioners implement best practices in IPC, and hosts the Provincial Infectious Diseases Advisory Committees that produce (among other things) evidence-based products related to best practices in infection control (for example, *Infection Prevention and Control for Clinical Office Practice or Cleaning, Disinfection, Sterilization of Medical Equipment and Devices*).

When it comes to lapses or potential lapses in infection prevention and control, the communication channels between public health authorities and the regulator of community medical clinics can be characterized as informal. Roles and responsibilities in investigating, assessing and managing IPC lapses have been the subject of active conversations for some time. In 2011, three of the 36 public health units in Ontario (Ottawa, Peel and Toronto) experienced significant IPC lapses in community-based medical facilities. Of the three lapses, one was identified through the recently introduced Out-of-Hospital Premises Inspection Program. The other two were discovered either because a patient or physician complained to the public health unit about infection control practices or because the public health unit identified clusters of cases of reportable diseases among patients who had been treated at the same facility.

These lapses put patients at risk, weakened public confidence in the health care system and created pressure on the local public health units that had to respond to and manage them.¹¹ Lapses that require trace backs and intensive public communication are not only stressful to communities but are expensive, time-consuming and pull public health unit capacity away from delivering the services they are mandated to provide to their communities.

In 2012, Ontario's Chief Medical Officer of Health at the time, Dr. Arlene King, established the Community Infection Prevention and Control Lapses Task Group to provide advice on improving IPC practices and developing a consistent approach to assessing and managing IPC lapses in the community. The task group returned 12 recommendations designed to help decrease the number of IPC lapses in community clinics and ensure a strong, consistent, appropriate response when they do occur. To date, the MOHLTC has created a working group to identify current education and training practices and is in the process of adding the *Health Protection and Promotion Act* to the list of statutes currently identified within the *Regulated Health Professionals Act* to allow information related to IPC lapses to flow more readily between public health units, the Ministry, the Chief Medical Officer of Health and the CPSO. PHO has convened a working group to develop a framework for risk assessment and processes for communication and has begun compiling educational tools to promote best practices. A number of preliminary discussions, meetings and investigations have been initiated to address remaining recommendations. Moving forward on implementation of the task group's recommendations should be a priority.

3) Understanding the Current State of Quality Oversight at Non-Hospital Medical Clinics in Ontario

Ontario has a model of self-regulation for health professionals. Each health profession has a regulatory college that is responsible among other things for ensuring that professionals deliver services in a safe, effective, and ethical manner. Regardless of the setting in which they practice,

¹¹ Community Infection Prevention and Control Lapses Task Group. (2013). [Report to the Chief Medical Officer of Health](#).

these health professionals are subject to the oversight of their college. The premises in which they practice though, may or may not be subject to oversight. Depending on the services provided or the models under which they are funded, non-hospital medical clinics may not fall under any system of quality oversight. However, there are two different legislative systems which presently regulate those that do:

- 1) **Independent health facilities** (are licensed under the *Independent Health Facilities Act* (IHFA). IHFs deliver services at no charge to patients who are covered by the Ontario Health Insurance Plan (OHIP). The Ministry of Health and Long-Term Care pays the physicians working in IHFs a standard fee for each service (a professional fee), plus the Ministry (or a designated entity) pays facility owners a specified amount for each service that contributes to overhead costs like rent, supplies and equipment (a facility fee). There are approximately 935 IHFs licensed in Ontario, with a large majority being diagnostic imaging facilities.¹² They are independently owned and operated, and most are for-profit corporations.¹³ Approximately half are owned or controlled by physicians, though physician owners may not necessarily operate under the relevant specialty under which an IHF is licensed.
- 2) **Out-of-hospital premises** are established under regulation 114/94 of the *Medicine Act, 1991*.¹⁴ Oversight under this act applies to facilities that provide services to patients where the accepted standard of practice is to use certain types of anaesthesia or sedation.¹⁵ At the time of this report, there were 273 OHPs providing services such as plastic surgery, endoscopy and interventional pain management. OHPs do not receive facility fees, but physicians working in these facilities receive professional fees from OHIP for insured services.

Facilities may fall outside of these two regulatory frameworks, most commonly because they offer services that are not covered by OHIP and do not require anaesthesia or sedation. Although the clinic premises would not be regulated, physicians performing the procedures are subject to the licensing requirements of the College of Physicians and Surgeons on Ontario (CPSO), and the CPSO has the authority to impose restrictions on a member's certificate of registration through the Registration Committee, the Quality Assurance Committee, the Inquiries, Complaints and Reports Committee and/or the Discipline Committee. However, facilities need not be licensed or inspected.

Regulatory Framework for Quality Oversight in Non-Hospital Medical Clinics

Independent Health Facilities

The *Independent Health Facilities Act, 1990* sets out a quality oversight regime for IHFs. The program is developed and administered by the College of Physicians and Surgeons of Ontario under an agreement with the Ministry. Under this program, the CPSO has developed facility standards as well as standards for clinical practices for each IHF procedure offered. Licenses to operate IHFs are granted for five years and, during this period, the facility is inspected by the CPSO at least once.

Inspections may occur more frequently if requested by the Ministry. IHFs are required to have a quality advisor, a physician who is held accountable for ensuring the facility meets its quality responsibilities under the Act. Similar legislative requirements govern other regulatory colleges as well, including the College of Midwives which appoints assessors for birth centres. A complete list of IHFs, the date of their latest quality assessment and the results are posted on the Ministry website.

¹² The majority of the facilities provide specific classes of diagnostic tests (e.g. diagnostic imaging, nuclear medicine tests, pulmonary function tests and sleep study tests). Twenty-seven are ambulatory facilities providing dialysis, abortion and gynecologic surgery, laser dermatology, ophthalmic/cataract surgery, vascular and plastic surgery. IHFs can also provide surgical, therapeutic and diagnostic procedures that are not included in the OHIP fee paid to physicians.

¹³ Office of the Auditor General of Ontario. (2012). [Independent Health Facilities](#). Chapter 3, Section 3.06.

¹⁴ [O. Reg. 114/94](#).

¹⁵ General, regional and local anaesthesia, as well as parenteral sedation.

The IHFA applies to all facilities licensed under the Act. Recent regulatory changes have empowered the CPSO to also use the Out-of-Hospital Premises Inspection Program assessment approach (discussed in the next section) in cases where the IHF is performing procedures where the standard of care includes the use of anaesthesia or sedation.

Under the Act governing this relationship, the Minister appoints a director of IHFs, who is a Ministry employee, to administer the IHF program. The director may revoke or suspend a license, remove specific services from a license, provide notice of proposal to suspend or provide a warning to address deficiencies.¹⁶ The director is also authorized to issue an immediate suspension where there are reasonable grounds to believe an IHF is or will be operated in a manner that poses an immediate threat to health and safety.

IHF owners (licensees) can appeal decisions to the Health Services Appeal and Review Board and can continue to offer services while the appeal is underway. In some cases, an appeal could last for years. Facilities could theoretically remove themselves from IHFA oversight by forfeiting their license, and hence facility fees, while continuing to operate and collect professional fees for each service.

There is no requirement under the IHFA to report adverse events to the Ministry or the CPSO.

Out-of-Hospital Premises

Regulation 114/94 under the *Medicine Act* grants oversight of some premises to the CPSO, which in response has developed the Out-of-Hospital Premises Inspection Program (OHPIP). The OHPIP includes a process for establishing standards for both the facility and the facility staff, the development of tools for assessments and the appointment of teams of assessors who inspect facilities for compliance with the standards. The CPSO performs an initial inspection prior to the opening of an OHP facility, with a follow-up inspection every cycle of their license—either every three or five years. Inspections may occur more frequently at the discretion of the CPSO. A physician must perform the defined procedures in order for the CPSO to have the authority to conduct inspections. There is no centralized system for monitoring the establishment of new facility locations; instead facility operators must initially identify themselves to the CPSO. Assessment reports are reviewed by a committee and the outcome is posted on the CPSO's public register.¹⁷ OHPs are required to designate a medical director, a physician who is accountable for ensuring the facility meets its responsibilities under the regulation.

The CPSO's oversight is limited to facilities providing procedures that, under the standard of care, require certain types of anaesthesia or sedation. Other procedures performed in the same clinic may fall under the IHFA or outside the jurisdiction of assessors altogether.¹⁸

CPSO assessments may result in a "pass," "pass with conditions" or "fail." CPSO jurisdiction is limited to its members (physicians). If a clinic does not pass its assessment, the CPSO can prohibit any physician from performing the service in question at that clinic, but it does not have the authority to order the premises closed. Once committee review of an assessment report is complete, its determination is final. Any opposition to its determinations would be resolved through application for judicial review.

¹⁶ Considerations include quality and standards of service, contravention of legislation or license condition, dishonesty or discontinued operation.

¹⁷ The College of Physicians and Surgeons of Ontario. Out-of-Hospital Premises. Retrieved June 2015 from: <http://www.cpso.on.ca/Public-Register/Out-of-Hospital-Premises-Listing>

¹⁸ Office of the Auditor General of Ontario. (2012). [Independent Health Facilities](#). Chapter 3, Section 3.06.

The OHPIP recognizes two types of adverse events. Tier 1 events include death on premises or within 10 days of the procedure, transfer to hospital, and surgery on the wrong site or wrong patient. These events must be reported to the CPSO within 24 hours of the physician becoming aware of them. Tier 2 events (including infections) are reported on an annual basis.¹⁹

4) Conducting a Jurisdictional Scan

Quality Oversight Approaches of Other Jurisdictions

In shaping recommendations to strengthen the oversight of non-hospital medical clinics in Ontario, the panel surveyed the quality oversight systems of a number of jurisdictions. Combined, Ontario has over 1,200 IHFs and OHPs, the largest number under quality oversight in any province in Canada. To help ensure that the lessons of other jurisdictions are scalable to Ontario, the panel included the health systems of several other countries.

The following jurisdictions were reviewed: the provinces of Alberta, Saskatchewan and British Columbia, as well as New South Wales, Australia, England, the United States, and the Netherlands.

In all jurisdictions that provide oversight, successful accreditation/inspection is required for facilities to continue providing the services subject to a regulatory program. Because the terms “inspection” and “accreditation” are sometimes used interchangeably, the difference between the two can be difficult to discern. Typically, inspection models are broader in scope, involving assessments of professional clinical performance and observations of particular procedures. However, it is noteworthy that the effectiveness of external review or inspection in enhancing facility compliance with standards has not been thoroughly investigated in the literature.²⁰

Key Features of Canadian Non-Hospital Medical Quality Oversight Programs

Health regulatory colleges are the primary regulators of medical facilities in Canadian provinces. The exceptions appear in provinces where there is no facility regulation. Quebec has replaced its provincial licensing regime with a third-party accreditation requirement. In cases where the regulatory college inspects or accredits facilities, its authority comes through legislation and regulation. The college subsequently establishes by-laws and program standards. This is the case in British Columbia, Alberta, Saskatchewan, Manitoba and Ontario. Some facilities in provinces that do not have a formal regime for quality oversight voluntarily pursue accreditation through third parties such as Accreditation Canada, the Canadian Association for Accreditation of Ambulatory Surgical Facilities, the Commission on Accreditation of Rehabilitation Facilities or the International Organization for Standardization.

Alberta. Alberta has just over 660 facilities under its oversight programs, including 76 surgical facilities. A list of types of procedures covered is provided in regulation. Any facility planning to provide a service from the list is required to obtain accreditation from the College of Physicians and Surgeons of Alberta. In addition, an extensive list of surgical and endoscopic procedures is also set out in the College bylaw. Accredited medical facilities must also safely allow the discharge of patients from medical care within 12 hours of completion of surgical procedures unless those facilities are approved for extended stays. Major surgical services are prohibited from being delivered outside of hospitals.

¹⁹ Tier 1 events include death on the premises, death within 10 days of a procedure, procedures performed on the wrong patient or wrong site and events requiring transfer of the patient to a hospital for care. Tier 2 events, such as infection data or a patient’s unplanned stay for medical reasons longer than 12 hours post-procedure, are tracked for quality improvement purposes.

²⁰ Flodgren, G. Pomey, M.P., Taber, S.A., Eccles, M.P. (2011). Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes. *The Cochrane Library*. Issue 11.

The oversight regime in Alberta addresses the people, the premises and the procedures, including business practices such as extra-billing and the selling of “upgrades.” Evidence-based standards and guidelines for the listed procedures are provided. Clinics must meet the same standards as hospitals for quality assurance, patient satisfaction, reporting on services provided, reporting of incidents and patient concerns, physician qualifications and compliance with medical staff bylaws. Furthermore, all non-hospital surgical facilities must follow the rules set forth in Alberta’s Health Care Protection Act (HCPA) and HCPA regulation regarding the sale of enhanced medical goods and services.

British Columbia. British Columbia has 64 medical clinics and 207 diagnostic facilities and labs. Regulatory authority is provided under the *Health Professions Act* and the College of Physicians and Surgeons of British Columbia bylaw enabled under that Act. The regulator has jurisdiction over both its members (physicians) and the facility. The College administers two programs: the Non-Hospital Medical and Surgical Facilities Program and the Diagnostic Accreditation Program. The regulatory framework applies to surgical facilities that provide anaesthesia. The College’s bylaw also prohibits specific procedures—including major surgery to the head or neck and surgeries that would require the replacement of blood—from being performed in a facility without special permission.

Saskatchewan. Saskatchewan has 12 medical and 34 diagnostic facilities that are governed by the *Health Facilities Licensing Act* and its regulation, the *Health Professions Act*. The College of Physicians and Surgeons of Saskatchewan bylaws are enabled under that Act. An organization operating under the *Health Facilities Licensing Act* requires a licence issued by the provincial government. In general, a facility will require a license if the facility delivers publicly funded health services that were previously provided in a Saskatchewan hospital. The provincial government oversees the licensure process. Non-hospital treatment facilities, which provide both insured and non-insured services, often require both college approval and a license under the *Health Facilities Licensing Act*. Saskatchewan has largely modeled the parameters of their program after Alberta’s.

Key Features of Foreign Non-Hospital Medical Quality Oversight Programs

All four of the international jurisdictions surveyed employ an independent agency in quality oversight.

England. The Care Quality Commission (CQC) is a national program that inspects all healthcare services against national standards,²¹ rates the facilities and reports publicly. As the independent regulator of health and adult social services in England, the CQC’s objective is to promote and protect the health, safety and welfare of people who use those services²². The CQC’s authority is provided under the *Health and Social Care Act, 2008* and regulations under that Act. Almost 15,700 settings fall under the CQC’s jurisdiction, including all hospitals, nursing homes, out-of-hospital clinics, family physicians and general practitioners, office-based practices, dental clinics, social service programs, home care services and other health services (such as ambulances). The CQC has only recently begun inspecting within the independent healthcare sector—those organizations and providers who work exclusively in the private sphere, outside the National Health Service.

The Care Quality Commission recently shifted its monitoring approach from annual inspections for all to a risk-based inspection schedule. Facilities are rated as “inadequate,” “requires improvement,” “good” or “outstanding.” The criteria against which services are evaluated include facility safety, caring staff, responsiveness to patient needs, effectiveness of service and quality of leadership. Re-inspections are conducted regularly to ensure implementation of any required changes. Facilities

²¹ Care Quality Commission. National Standards. Retrieved June 2015 from <http://www.cqc.org.uk/content/national-standards>

²² Report by the Comptroller and Auditor General. The Care Quality Commission: Regulating the quality and safety of health and audit social care (2011) National Audit Office. Retrieved June 2015 from <http://www.nao.org.uk/wp-content/uploads/2011/12/10121665.pdf>.

receiving high ratings may not be re-inspected for up to two years. Enforcement powers include warnings, conditions on registration, suspension and cancellation of registration as well as criminal action. Recent data shows that 5% of inspections have required enforcement, 32% have required improvements and 63% of inspected facilities have met all standards.²³

New South Wales, Australia. The *Private Health Facilities Act, 2007* and the *Private Health Facilities Regulation, 2010* provide for the maintenance of appropriate and consistent standards of health care and professional practice in private health facilities in New South Wales, which are defined as premises where any person is admitted, provided with medical, surgical or other prescribed treatment and then discharged; or premises where a person is provided with prescribed services or treatments (public hospitals and nursing homes are excluded from these categorizations). Facilities covered include anaesthesiology, gastrointestinal endoscopy, maternal, interventional radiology, radiotherapy, medical and surgical facilities (there are 18 types of facilities in total).

In September of 2011, the Australian Health Ministers endorsed the National Safety and Quality Health Service Standards, a national accreditation scheme established by the Australian Commission on Safety and Quality in Health Care (ACSQHC). The ACSQHC is an independent agency that is funded by all governments on a cost sharing basis. Their mandate is to lead and coordinate health care safety and quality improvements in Australia. The standards are intended to protect the public from harm and improve the quality of health service provision.^{24,25} In order to receive a license to operate a private health facility, the facility must engage with the National Standards and Accreditation Scheme of the ACSQHC. The state remains the regulator and receives data on the outcome of the accreditation, but the assessments are carried out by approved third-party accreditation agencies.

The Netherlands. The Health Care Inspectorate, an independent agency of the Ministry of Health, is responsible for the inspection and regulation of all health care settings in the country. Approximately 100 hospitals, 8,500 GP offices, 8,000 dentists, 1,400 homes for the elderly and 40 community public health organizations.

The Health Care Inspectorate analyzes quality information and any additional available data about a care provider (e.g. performance indicators, reported incidents, patient experience data), to develop a risk assessment for that facility, usually based on a comparison with other providers in the same sector. The agency determines which locations and facilities are to receive an inspection visit as well as the timing of those visits.

United States. In 2012, there were 5,260 Ambulatory Surgical Centres (ASCs) in the United States performing approximately 6 million surgical procedures per year. Regulation of ASCs is primarily a state responsibility. Each state has unique licensing regulations with different clauses around eligible procedures and facility requirements (e.g., Pennsylvania limits procedures to those patients requiring fewer than four hours of anaesthesia). Most states require ASCs applying for licensing to be inspected by a state surveyor, after which the ASC is given a (generally time-limited) license. Each state has its own timeline for license renewal and re-inspection (if required). Most ASCs have physician owners

²³ Care Quality Commission. (2014). [Annual Report and Accounts 2013/14](#).

²⁴ Australian Commission on Safety and Quality of Healthcare. (2012). [National Safety and Quality Health Service Standards](#).

²⁵ Standards address 10 areas of health quality: governance for safety and quality in health service, partnering with consumer, preventing and controlling healthcare associated infections, medication safety, patient identification and procedure matching, clinical handover, blood and blood products, preventing and managing pressure injuries, recognising and responding to clinical deterioration in acute health care, preventing falls and harm from falls.

and are often jointly owned with for-profit health care delivery companies. There are several major U.S. ASC chains.

Medicare maintains national standards and requires that ASCs billing Medicare—a designation that includes nearly all ASCs—be Medicare-certified against these standards. ASCs can choose to become Medicare-certified through either state certification agencies or through a national ASC accreditation body recognized by Medicare. A large majority of ASCs (90%) choose to be certified through state agencies because national accreditation bodies conduct facility inspections every one to three years, whereas state agencies generally inspect less often. Medicare can require ASCs to be re-inspected/re-certified if program standards change.

Quality Oversight Approaches of Other Ontario Non-Hospital Medical Sectors

The Ontario regulatory environment provides for oversight of a number of health care sectors. The panel reviewed four regulated sectors to compare key features. There are a number of lessons to be taken. First, when organizations fail inspections, the premises may not be the primary problem and closing the premises entirely may not best serve the public interest. Second, inspections alone cannot draw a complete picture of the performance of a clinician or facility because representatives of any inspection program can only be present at a moment in time. Third, regardless of ownership models, clear accountability is the key to an effective oversight program.

The Royal College of Dental Surgeons of Ontario is the governing body for dentists in Ontario. Its role is to set standards for the practice of dentistry in Ontario and provide a complaint and investigation process to resolve issues raised by members of the public who feel the standards have not been met. The College examines provider training and facility safety. As of January 2015, there were 1,153 premises involving 1,000 dentists and 275 physicians covered by this program. The College has inspected all dental premises that use anaesthesia since the mid-1990s and regulated oral conscious sedation at a moderate level since 2009. At this level of sedation or deeper, dentists need authorization and a facility permit issued by the College. Though there is a standard for all clinics and an expectation that the standard will always be adhered to, there is no adverse event reporting requirement. Facilities that use anaesthesia and sedation are inspected at least every three years and are provided a pass or fail designation.

The College's approach is mindful of the line between scope of practice and regulated activities. Training, equipment and other items are covered under the professional standards for dentistry, and dentists do not need a facility permit to conduct activities that are within their basic scope of practice (such as administering a local anaesthetic, which is a routine procedure). Dentists have an obligation to maintain the standards of practice of the profession and, accordingly, must ensure that recommended infection prevention and control procedures are carried out in their offices. IPC is therefore not part of the facility inspection program.

The Ontario College of Pharmacists regulates both the practice of members and the practice site. Members are regulated through the *Regulated Health Professions Act*²⁶ and the *Pharmacy Act*.²⁷ Practice sites are regulated through the *Drug and Pharmacies Regulation Act*.²⁸ Pharmacies are generally inspected every three to four years, and the activity risk level is taken into account; for instance, whether a premise is methadone-dispensing or compounding. The College inspects about 1,500 premises per year.

²⁶ [Regulated Health Professions Act, 1991, S.O. 1991, c. 18](#)

²⁷ [Pharmacy Act, 1991, S.O. 1991, c. 36](#)

²⁸ [O. Reg. 58/11](#)

The College has recently introduced a new practice assessment process to evaluate individual practitioner performance against practice standards.²⁹ By bringing together premises inspections and practice assessments, the College ensures that health care professionals have an environment that is conducive to doing their best work.

Under the *Safeguarding Health Care Integrity Act, 2014*, the College is now empowered to inspect and license private and public hospital pharmacies in the same manner it licenses and inspects community pharmacies. This is a new development and the supporting regulations are being drafted.

Long-term care (LTC) homes. LTC homes in Ontario are legislated and regulated under the *Long-Term Care Homes Act, 2007*.³⁰ These facilities are partially publicly funded and provide round-the-clock nursing care to admitted residents. There are 629 LTC homes in Ontario in a mix of for-profit, non-profit and municipal ownership. The Long-Term Care Home Quality Inspection Program safeguards residents' well-being by continuously investigating complaints, concerns and critical incidents, and by ensuring that all homes are inspected at least once per year. Inspections are unannounced. The results of the inspections (redacted to protect resident privacy) are posted on the Ministry website and on the premises of the home. The Ministry administers the inspection program, the inspectors may be either Ministry employees or subcontracted agents. Inspections are detailed and all aspects of non-compliance are documented.

In addition to inspections, Health Quality Ontario reports on 11 long-term care quality indicators for the province of Ontario. Of these 11 indicators, four³¹ are risk-adjusted,³² reported at the level of the home and compared against the provincial average.

LTC homes also collect significant amounts of data, administering comprehensive assessments with the Resident Assessment Instrument – Minimum Data Set 2.0 (RAI-MDS 2.0). Each resident is evaluated with the RAI-MDS 2.0 assessment tool at admission, at the time of discharge, on a quarterly basis and after any significant health changes. The data is reported to the Canadian Institute for Health Information, where it is cleaned and audited for data quality. The assessments provide homes, the Ministry, researchers and analysts with a rich database of information including resident characteristics, health conditions, functional abilities and limitations, current medications, use of restraints and cognitive abilities.

Retirement homes. Retirement homes in Ontario are not publicly funded and do not offer round-the-clock nursing services. By definition, retirement homes are occupied primarily by residents aged 65 years and up, and either directly or indirectly offer at least two care services from among a group of commonly provided forms of assistance, including wound and skin care, continence care, assistance with drugs, assistance with eating, assistance with bathing, dementia and others.

The *Retirement Homes Act, 2010*³³ sets out a framework for quality management in the sector, including the establishment of an independent, not-for-profit regulatory body, the Retirement Homes Regulatory Authority (RHRA) and a set of requirements that retirement homes are required to comply with under the Act. The RHRA has the power to license homes and conduct inspections, investigations and enforcement, including the issuing of financial penalties and revoking licenses. The

²⁹ Ontario College of Pharmacists. (2015). [Practice Assessments](#). *Pharmacy Connection*, Winter, 22(1), 18.

³⁰ [Long-Term Care Homes Act, 2007, S.O. 2007, c. 8](#)

³¹ Incontinence, falls, pressure ulcers and restraints.

³² Risk-adjustment is a statistical practice used to equalize data among homes that may have populations at disparate risk for these conditions. For instance, a home with a greater than average proportion of frail residents is likely have a greater number of falls even if all proper quality assurance measures are in place.

³³ [Retirement Homes Act, 2010, S.O. 2010, c. 11](#)

RHRA is funded through fees collected from retirement homes, primarily licensing and annual fees.

All retirement homes are required to undergo a routine inspection at least once every three years. Complaints can be submitted to the registrar of the RHRA. Retirement homes must report immediately to the registrar if they suspect harm to their residents, including: 1) improper or incompetent treatment or care, 2) abuse by anyone or neglect by a staff member of the home, 3) unlawful conduct or 4) misuse/misappropriation of a resident's money. A report may trigger an inspection.

Quality Oversight in the Hospital Setting in Ontario

Hospitals have historic and well-established governance systems with defined roles and responsibilities for accountability in the quality of care being delivered. Many pieces of provincial legislation guide a hospital's day-to-day operations. The *Public Hospitals Act*³⁴ (PHA) is a key piece of legislation that governs multiple areas, including physician appointments and privileges, reporting requirements, patient admissions, discharge and records and communicable disease protocols. Hospital management regulation under the PHA gives the framework for hospital governance and provides for the establishment of corporate bylaws, professional staff bylaws and the Medical Advisory Committee to make policy and procedure recommendations.

When hospitals operate ambulatory care centres or outpatient clinics, this quality oversight infrastructure extends to those settings as well.

The PHA also empowers the government to appoint an investigator or a supervisor to manage public hospitals in certain circumstances. Among other provisions, the *Excellent Care for All Act*^{35,36} requires hospitals to establish quality committees that report to the board, and to complete annual Quality Improvement Plans. A combination of accountability at the board level, articulation of roles and responsibilities for senior leadership, reporting of data and voluntary accreditation forms the framework for quality oversight in hospitals. Hospitals typically have an established process for receiving and following up on patient concerns and complaints, which can serve as an important tool in ongoing quality oversight.³⁷ Ontario's health care system does not have centralized oversight of quality in hospitals and has not historically held a consolidated view of operations that encompasses the provider, the premises and the clinical quality of the procedure (including patient outcomes) in this sector as a whole.

Learnings from Others

Several observations emerged from the jurisdictional review engaged in by the panel.

Assessment rating scale. In Alberta, facilities can receive full accreditation, provisional accreditation or no accreditation. The CQC in England issues ratings of "outstanding," "good," "requires improvement" and "inadequate." These scales are simple and easy to understand. In contrast, the current CPSO assessments result in "pass," "pass with conditions" or "fail," designations that were not initially developed for the purpose of transparent public reporting (they were designed to support administering the program, where for instance a premise may pass with conditions because some

³⁴ [Public Hospitals Act, RSO 1990, c P.40](#)

³⁵ [Excellent Care for All Act, 2010, S.O. 2010, c. 14](#)

³⁶ There are many other statutes that govern hospital operations, including the *Local Health System Integration Act*, the *Quality of Care Information Protection Act*, the *Personal Health Information Protection Act*, and the *Freedom of Information and Protection of Privacy Act*. See the [OHA's Physician Leadership Resource Manual](#) for a summary of the legislation pertaining to the operation of hospitals.

³⁷ Reader, T.W., Gillespie, A., and Roberts, J. (2014). Patient Complaints in Healthcare Systems: a systematic review and coding taxonomy. *BMJ Qual Saf* doi:10.1136/bmjqs-2013-002437.

paperwork requires completion or signage posted.) “Pass with conditions” gives the public very little guidance when assessing a clinic.

Clinicians practice within the scope of their certification and experience. Some programs credential clinicians to perform certain services in non-hospital medical clinics. Although most programs do not credential, in all cases there is an expectation that clinicians work within the scope of their experience and training. As part of the inspection process, all programs seek to ensure that clinicians have the proper training and licensing.

Detailed standards and processes for keeping them current. This is common to all models. In Ontario, standards and processes for OHPs are developed by expert panels established by the CPSO, and address only those activities that fall under the regulator’s oversight. There is no flexibility allowing these committees to address procedures or premises that fall outside of what is currently specified in legislation and/or regulation. The IHFA permits standards to be designated. England and Australia have established national standards and oversight programs are made to align with those national standards.

Inspection cycle. Most programs in Canada and the United States work on a regular cycle (with provision for shorter intervals in the case of inadequate inspection ratings). In Ontario, inspections occur every license cycle (once per three or five years) unless new activities are undertaken or there are special concerns. England is moving back to a risk-based system after a period of inspecting on an annual cycle.

Program scope and requirement for oversight. There was no consistent or prevalent approach to defining which types of clinics or services should require oversight, or how to enforce compliance. Some jurisdictions set out parameters for requirements for oversight in regulation, others through by-laws, and still others determined theirs through authorities outside of any explicit grant of regulatory authority.

“The regulations should... ‘have teeth’ so that if the clinic is seriously off standards it can be shut down immediately and, similarly, if the operations are raised to or above the standards, a different random health inspector should be able to authorize the re-opening of the clinic as soon as he completes his inspection.”

—Patient respondent in qualitative online discussion

Transparency

The complexity of the existing system impedes transparency. All stakeholders—patients, providers and the general public—value access to comprehensive and timely information. Despite this, when seeking transparent information about non-hospital medical clinics and the physicians who operate within them, stakeholders have limited options.

The College of Physicians and Surgeons of Ontario (CPSO) maintains an online public register with information related to all clinicians overseen by the College, including physician registration status and class, degrees and recognized specialty designations, certification by national examining bodies and any current allegations or previous findings of professional misconduct, incompetence or incapacity. Similarly, information related to assessments of OHPs is also available, including clinics' most recent inspection outcomes. In comparison with other regulatory or oversight bodies for non-hospital medical clinics in other jurisdictions and with bodies regulating professionals in other sectors such as pharmacy or dentistry, the information available from the CPSO is extensive. Of the jurisdictions reviewed, only the Care Quality Commission in England provides more comprehensive data to the public.

“Be transparent about the process. Allow patients to feel in control at all times by ensuring that they are aware of every step, the reasons for each step...”

— *Patient respondent in qualitative online discussion*

Nevertheless, challenges remain with public posting in Ontario. For instance, the Ministry of Health and Long-Term Care recently directed all public health units to publicly disclose more detailed information on non-routine infection prevention and control lapse investigations, but the information is fragmented as it is posted on the website of the local public health unit and is not linked to additional reporting that may be available from the Ministry or the CPSO. The Ministry is developing standard criteria for public health unit reporting and there is an opportunity to consolidate the information so that it is easy to find and contains all relevant information desired by patients.

It is important to note that some quality information is not apparent in real time—for instance, infection prevention and control lapses may become apparent only after the passage

of time. Clear communication about findings and their implications to patients—past, present and future—is essential if patients are to understand the meaning behind public reporting and the implications to their health.

Clear, formal lines of communication between the public, practitioners and facilities is critical to maintaining a clear, safe and effective health system.

Tools to Support Accountability

There are several tools to support accountability and the following is an assessment of each:

Accreditation: Generally, the term accreditation means different things in different contexts, as observed through jurisdictional review. Regulation and accreditation also have different meanings. Regulation involves rules that must be followed, while accreditation is a seal of approval from an independent accrediting body indicating that an organization has met certain standards.³⁸

³⁸Warburton, R. N. (2009). Accreditation and Regulation: Can They Help Improve Patient Safety? Agency for Healthcare Research and Quality. Retrieved June 2015 from <http://webmm.ahrq.gov/perspective.aspx?perspectiveID=74>

Accreditation is a common voluntary pursuit for Ontario hospitals, and can serve as a seal of approval from an independent accrediting body indicating that an organization has met certain standards. However, accreditation is more commonly used in Ontario to guide continuous quality improvement efforts, rather than as a quality assurance mechanism or a tool for transparency for patients or clients. When accreditation is an option rather than a requirement, posting the results of the outcome of the accreditation process is also voluntary. Though a worthwhile pursuit, accreditation alone is insufficient in replacing regulatory oversight.

Contracts: Contracts to fund the provision of volumes of services are powerful tools that can be used for both funding accountability and performance purposes. As a quality assurance tool they can only work for publicly funded services, as no public funder would be contracting for privately paid services. Contracts to provide insured health services can reinforce quality measures but alone would be insufficient for oversight.

Inspections: Inspections may be powerful tools for holding non-hospital medical clinics accountable as licensing is contingent on successful inspections. Inspections that occur under the IHF program and OHPIP are, in the main, proactive: premises are inspected before they are able to open, when they add new services to their offerings or when a previous inspection has noted the need for a follow-up visit.

Information Sharing: Essential to effective regulation is information sharing, knowing where services are happening and who is performing them. The regulator of non-hospital clinics must be able to convey information to the professional colleges of regulated health professionals. If there are concerns about a regulated health professional's performance or competency in a specific setting, their college needs to be able to assess that professional's performance in other settings where they practice. For instance, if a physician's competence is found to be substandard in the hospital where they practice and they also practice in an IHF or OHP, the complaint about their hospital performance should trigger an inspection of the community-based clinic where they also provide services. This principle should apply to all regulated health professionals including nurses and medical radiation technologists for example, not just physicians.

“Patient safety is the utmost top priority in any health care clinics and facilities. In order to protect the health and safety of clients, greater transparency and openness will strengthen the trust in any health care clinics and facilities. This includes complete access and disclosure to information requested by regulatory bodies, clients and auditors.”

—IHF/OHP provider in qualitative online discussion

Panel Recommendations

The panel considered a number of regulatory approaches to quality oversight across jurisdictions and sectors. No single model would entirely support the principles the panel agreed should underpin a renewed program for quality oversight in non-hospital medical clinics. For this reason, the panel has proposed a novel approach that sets out a structure of roles, responsibilities and authorities. This approach offers a number of implementation options that could be informed by policy-makers and be considered by government.

RECOMMENDATION 1. The Independent Health Facilities and Out-of-Hospital Premises quality programs should be consolidated into a single regulatory model that can easily encompass procedures not currently regulated in existing programs.

There is an insufficient difference between IHFs and OHPs to warrant separate oversight regimes. There are also many procedures with potential risk not covered by either program. To eliminate unnecessary complexity, the panel recommends that the programs be consolidated through legislation that places quality oversight for non-hospital medical clinics under one regulatory authority.

RECOMMENDATION 2. The regulatory model for all non-hospital medical clinics needs to be integrated, consistent, comprehensive, transparent, future-oriented and practical.

Health care service delivery requires a clear regulatory framework set out in law to serve the public's best interest and build a culture of quality. There was strong consensus that the oversight program should minimize lapses in quality proactively through assessing the clinic premises and equipment as well as the professionals working there, and reactively through inspections and enforcement to remediate lapses after they occur.

An appropriate regulatory balance should be struck in non-hospital medical clinics by focusing on the essential—that the regulatory mechanism be a key lever for embedding essential standards, enabling performance monitoring and reporting through data, tracking patient complaints and adverse events and assigning the authority to assess and enforce. The goal of regulation would be to embed a culture of quality and protect patients from substandard care and to ensure the provision of accurate information that the public and others can use to make decisions.

Important contributions to quality oversight can also come from non-regulatory measures. Effective tools need to be employed alongside regulation in embedding a culture of quality in non-hospital medical clinics. These include clinician and employer leadership, contract management in the case of procured services, and in all cases patients engaged in conversations about their treatment options and about considerations around the management of their health care. The Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry, examining serious failings in the protection of patients, observed:

“The reality is that it is not the setting of national standards in itself which will ‘catch’ a Mid Staffordshire but having effective methods of policing those standards. It is important that such policing is not confined to one method applied to a single organization, but is undertaken in as many different ways as possible, through provider internal leadership, external but local public scrutiny, commissioning, and the regulator all working to a common set of values, standards, and priorities. The Department of Health has struggled to get the

balance right between 'light touch' regulation and the need to protect service users from harm.”³⁹

Ontario is fortunate to have a number of opportunities to provide essential, multi-layered oversight of non-hospital medical clinics. Clinicians, facility owners, regulatory colleges, the Ministry of Health and Long-Term Care, the Local Health Integration Networks, agencies like Health Quality Ontario and Cancer Care Ontario, accreditors and, importantly, patients themselves are all contributors to assuring high quality care.

RECOMMENDATION 3. New quality oversight legislation should consolidate the models, rather than amending the current patchwork of legislation and regulation. Legislation and regulation should set out only what is essential so that it is nimble, responsive and attuned to patient needs.

A new model that encompasses both IHF and OHP settings can build on the strengths of the current system while also remedying the shortcomings. The new legislative vehicle should enable the Ministry to keep separate the funding provisions captured in the IHFA, which apply only to some premises, from the quality oversight provisions, which would apply to all. The development of a new legislative framework would provide the opportunity to revisit key aspects of the regulatory system for improved effectiveness.

Inspection intervals. The inspection schedule should be aligned to patient risk and clinic performance rather than at set calendar-based trigger points.

Standards and accountability. Standards and tools for assessment currently in place are consistent and key aspects of the programs are similar. For example, IHFs and OHPs both must have a physician who is held accountable for the facility meeting the quality standards. This physician need not be an owner, but their accountability under regulation is very clear. Under the recommended standards, quality professional practice must take precedence over the business practices and priorities of the facility owners and oversight legislation should require processes that ensure the health care professional accountable for quality is not in conflict should they also be the owner-operator.

Enforcement. Enforcement tools under the existing programs should be harmonized and key gaps eliminated. For instance, under the current quality oversight programs, IHFs not receiving a pass rating can continue to operate outside the program, which would mean they forfeit their facility fees. It may be unlikely given the financial impact, but it is possible. Facilities can also delay enforcement for extended periods of time through a lengthy appeal, during which they may continue to offer unsafe procedures. OHP oversight enforcement is limited to particular procedures. Facilities failing to receive a pass rating could continue to perform procedures that do not require anaesthesia or sedation even if the cause of the failed inspection may affect the facility as a whole (e.g., substandard infection control practices).

Program reach. Neither the *Independent Health Facilities Act* nor regulation 114/94 of the *Medicine Act, 1991* are sufficiently nimble instruments for quality oversight. The IHF program applies only to facilities licensed under the IHFA. The OHP/IP applies to procedures rather than to the entire facility. Procedures such as in vitro fertilization, cystoscopy, Lasik eye surgery, sclerotherapy and non-permanent fillers fall beyond existing oversight measures under the current regime, despite posing

³⁹ Francis, R. (2013). [Executive Summary](#). Report of The Mid Staffordshire NHS Foundation Trust Public Inquiry, p. 63

relatively higher risks that may include infection, disfigurement and blindness.⁴⁰ The ability to add services or procedures to the regulatory regime only after a need is identified may leave a lag in quality oversight that prevents quick response to evolving practices patterns and new risks. As a reform example under the current regime, the Ministry of Health and Long-Term Care, Cancer Care Ontario (CCO) and the College of Physicians and Surgeons of Ontario recently collaborated to offer colonoscopy clinics the opportunity to apply for IHF licenses. This move was undertaken to align the provision of colonoscopy services with a recent colonoscopy funding reform measure. To ensure that this shift from OHP to IHF did not result in less oversight and compliance levers some additional measures needed to be put in place. It is an example of positive collaboration around a shared goal of patient safety, but also illustrated the advantage of having a common quality oversight framework.

Accountability and Authority. Inspectors and regulators should have the authority to act on the outcomes and hold professionals and facilities accountable. The public expects that regulators have the authority to act on concerns both within and without the regulated areas of a clinic and would have the power to close a clinic where there were concerns around patient safety. The reality is that it is difficult for authorities to act on activities that are beyond the scope of the oversight programs. Ensuring that all parties have the necessary authority to exercise their accountability is essential in an improved system.

A new program offers the opportunity to focus on enhancing critical elements of an oversight program, including:

- Authority for the regulator to take action when standards are not met.
- Formalized relationships that improve communication between other authorities and the regulator.
- Improved performance monitoring and transparency through reporting outcome measures and adverse events/critical events.
- Public reporting to ensure patients and providers are able to make informed choices.
- Enshrinement of the precautionary principle so that the regulator is empowered to act to protect public safety when there is a reasonable apprehension of harm.

Adverse event reporting. Under the current quality oversight programs, IHFs are not required to report adverse events, except for procedures involving certain types of anaesthesia and sedation. OHPs are required to report adverse events to the CPSO. There is no obligation to report them publicly. Because adverse event reporting is a new requirement, the CPSO has just begun to acquire data. Under a consolidated system, clinics should be required to report adverse events to the regulator in a standardized manner, and should be held accountable for investigating incidents and communicating with patients according to best practices. Information about trends in adverse events should be used to inform program requirements and as an opportunity for learning and improvement across the system.

RECOMMENDATION 4. The new legislation should establish a senior role who will be the regulatory authority (“the Executive Officer”). The Executive Officer would have the authority to establish rules and criteria for the program, act on inspection findings (e.g. order a premises to cease providing a service), and communicate information and coordinate between services (e.g. to regulatory colleges, Chief Medical Officer of Health). The Executive Officer must be independent and appropriately resourced.

⁴⁰ Community Infection Prevention and Control Lapses Task Group. (2013). [Report to the Chief Medical Officer of Health](#).

The panel recommends that, in the interests of building a responsive and independent oversight program, the authority to establish program rules and criteria be assigned through legislation to a senior position (referred to in the document as an “Executive Officer”) that is the single point of accountability for ensuring the effective execution of the program. This individual would be empowered to make the kinds of responsive program decisions that are currently only possible through a regulatory process, and would have the authority to enforce those decisions. The Executive Officer would be able to register facilities that pass inspection. In addition to establishing program rules, the Executive Officer would be empowered to order premises to cease activities, communicate information, order inspections, require the submission of specified data from clinics and take other necessary actions as a condition of facility registration. The Executive Officer would not make funding decisions. His or her authority would focus on regulating the quality of the clinics.

A key feature of a strong oversight program for non-hospital medical clinics is the ability to share information. Clear communication channels should be open among all individuals in a position to observe the administration of care in the facility. Communication policies should account for the fact that any inspection team is in a clinic for a short period time. Other actors who are visiting the clinics in a professional capacity (e.g., x-ray licensing inspectors or infection prevention and control educators) should also have a responsibility to report problematic observations or findings to the regulator in a timely fashion. The critical importance of information sharing becomes apparent when concerns arise mid-inspection cycle and an appropriate response needs to be organized.

To achieve a full picture of the care provided, the Executive Officer needs to be able to share information with other bodies such as public health authorities and regulatory colleges overseeing the professionals working in the facilities. Sharing information in a timely manner is in the best interest of patients and should take precedence over institutional barriers or concerns around the business interest of the facility.

Best practice in regulation from other jurisdictions shows that independence of the regulator is required. They need to be autonomous from government and other regulators and associations but work together to achieve effective oversight.

RECOMMENDATION 5. A permanent expert committee should be established in legislation, to provide the Executive Officer with independent specialized advice. Membership should include patients.

- **The Committee would have the authority to commission specialized subcommittees, including subcommittees that would review inspection reports and make recommendations to the Executive Officer about registering premises or revoking registrations**
- **Recommendations should be transparent and prepared with the intent to publicly post**

An appropriately constituted expert panel or committee would be empowered through legislation to advise the executive officer on necessary adjustments to the program. These might include recommendations on the addition of procedures not currently under oversight or determining appropriate inspection intervals for facilities based on the risks associated with a procedure or provider. To ensure a range of perspectives are represented, review committees could include representatives from the clinical community, provincial organizations such as Public Health Ontario, Health Quality Ontario, Cancer Care Ontario, health regulatory colleges such as the CPSO and the College of Nurses of Ontario, the LHINs, patients, the public and the Ministry of Health and Long-Term Care.

Essential to the success of this model is widespread transparency, review mechanisms that are based on expertise and that promote fairness, and a robust appeals mechanism that puts patient safety first while supporting due process.

RECOMMENDATION 6. This program should be the foundation for quality oversight for non-hospital medical clinics. Other system levers such as contracts and accountability agreements should be used to reinforce quality requirements.

Accreditation and contracts are useful and appropriate tools for documenting performance requirements and other accountabilities. They can be used to reinforce quality priorities but cannot replace a robust regulatory system.

As noted, accreditation is often pursued voluntarily by Ontario hospitals, many of whom engage Accreditation Canada. Other organizations—for example, the laboratory quality oversight program (IQMH)—accredit to an industry standard (in the case of laboratories, ISO 15189) and this accreditation is a requirement of operation.

However, when accreditation is an option rather than a requirement, as in the case of many hospitals, posting the results of the outcome of the accreditation process is also voluntary. Generally, accreditation is more commonly used in Ontario to guide continuous quality improvement efforts, rather than as a quality assurance mechanism or a tool for transparency to patients or clients. Overall, the panel acknowledged that accreditation in the content of medical clinics is a worthwhile pursuit, but that it alone is insufficient to replace the need for regulatory oversight.

Similarly, contracts cannot serve as the sole mechanism for oversight, but they are powerful tools that can be used for both funding accountability and performance purposes. Because one of the principles articulated by the panel was that oversight should apply equally to publicly funded and non-publicly funded services, contracts could not be the primary mechanism for oversight as not all clinics would have a funding relationship with the Ministry or LHIN.

RECOMMENDATION 7. Owners of non-hospital medical clinics should be required to apply for registration with the Executive Officer and registration should be made contingent on passing inspection. Clinics must have a single point of accountability for quality oversight and in all cases that person should be a regulated health professional as specified by the Executive Officer.

With a clear definition of which medical services delivered in non-hospital clinics are subject to oversight, facility owners will need to identify themselves to the regulator. Knowing where services are happening and who is performing them will be key. Standardized facility registration will aid in maintaining a complete picture of the facility and the practices of the clinicians within it. Currently, premises are inspected before they are able to open, when they add new services to their offerings and when a previous inspection has noted the need for a follow-up visit. This approach should be maintained.

The quality advisor or medical director in an IHF or OHP is typically a physician (in the two birth centres licensed as IHFs it is a midwife). Under the new model, this may continue to be the right requirement or it may be appropriate to designate a different type of regulated health professional as the quality advisor, such as a nurse, depending on the activity.

RECOMMENDATION 8. Regulated non-hospital medical clinics should be required to report utilization, performance and quality data as specified by the Executive Officer.

Planning, policy-making, public reporting and risk analysis all depend on the collection and availability of reliable data. IHF and OHP data currently collected is insufficient to these tasks. With the advice of experts, the Executive Officer should establish data submission requirements as a condition of facility registration. Data related to adverse events, critical incidents and near misses should be collected consistently, reported to the necessary authorities promptly, openly disclosed to the public when appropriate in a convenient logical location and monitored over time to allow for system-wide improvements. Consistent with other sectors, some data may become integrated into public reporting.

RECOMMENDATION 9. Turnaround times for inspection reports should be established to ensure timely and transparent response. Reports should be centrally reviewed by a committee for consistency and in the interests of fairness. The regulations should set out conditions under which the Executive Officer can act before the process is finalized or require an expedited review.

In order for the inspection regime to fulfill its purpose, substandard conditions must be addressed without undue delay. The time lag from discovery of the problem to the determination of appropriate enforcement and the correction of the condition must be minimized. In addition, enforcement should be standardized such that similar infractions across facilities are dealt with similarly. The process should be clear and consistent so that determinations can be made by the proper authority in a fair and timely manner.

RECOMMENDATION 10. Standardized plain-language summaries of inspection reports should be posted in clinic waiting rooms and online.

Inspection reports are designed to document findings that support the determination of the outcome of the inspection. They can be quite technical documents and not necessarily useful tools for patients and the public. In the current system, the date and outcome of each facility's most recent quality assessment are posted on the website.

With the collaboration of patients and providers, the province should lead the development of a standardized plain-language report template designed for patients. A simple, one-page summary of results should be posted in clinics, and a more detailed version should be made available online. The Care Quality Commission in England provides the most comprehensive and patient-friendly reports across all jurisdictions examined and would be a useful model to consider.

RECOMMENDATION 11. A clear and transparent process for patient and provider complaints is needed. Non-hospital medical clinics should prominently post the complaints process and this communication should be consistent across clinics. In developing a standardized complaints process communication, the Executive Officer should ensure alignment and coordination with existing complaints mechanisms set out by the health professions regulatory colleges.

In interviews conducted as part of this report, patients indicated a strong desire for a clear and understandable complaint process. They also expressed a lack of certainty regarding the current process for registering complaints related to experiences at non-hospital medical clinics. Patients and referring providers should have opportunities to give feedback on their experiences. Because complaints, investigations and discipline of regulated health professionals is the responsibility of their college, patients should be informed about the need to make a complaint with a provider's regulatory college when their concern is about a professional. The Executive Officer will therefore need to collaborate closely with the regulatory colleges when developing a complaint process and the materials for communicating this process. Nothing about the development of a standard process and communication for that process changes the role of the regulatory colleges in managing complaints about providers.

Consideration should be given though to ensuring the appropriate flow of information between the two regulators so patients have a seamless experience and potential issues are not missed because the patient has gone to the wrong oversight body. Patients should be able to find out who the clinic owner is and where to reach them should they have a concern about the clinic itself. They should know that if they are unsatisfied by the follow up to their complaint about the premise, they can escalate their matter to the Executive Officer.

This is a complex system, so it should clearly describe the process for patients, family members and caregivers and help direct them to the right place when necessary. Important information about areas for improvement could also be gathered through consolidated public input.

RECOMMENDATION 12. Facilities should be required to complete and post Quality Improvement Plans.

With growing volumes and types of procedures happening in non-hospital medical clinics, it is important that these clinics deliver care in an integrated fashion with the rest of the health care system. There is an opportunity to ensure that they are well integrated with health system priorities and the quality agenda. Under the *Excellent Care for All Act*, hospitals, long term care homes, Community Care Access Centres and primary care organizations such as Family Health Teams and Community Health Centres are required to complete an annual Quality Improvement Plan. As one mechanism for ensuring alignment with the broader health care system, this requirement should be extended to non-hospital medical clinics. Each facility's plan should be posted publicly.

“A properly, well set-up non-hospital clinic that has a short waiting list, procedures done efficiently and effectively and good follow up and communication with the referring doctor and patient.”

—A general practitioner's answer to what good quality in a non-hospital medical clinic looks like

Conclusion

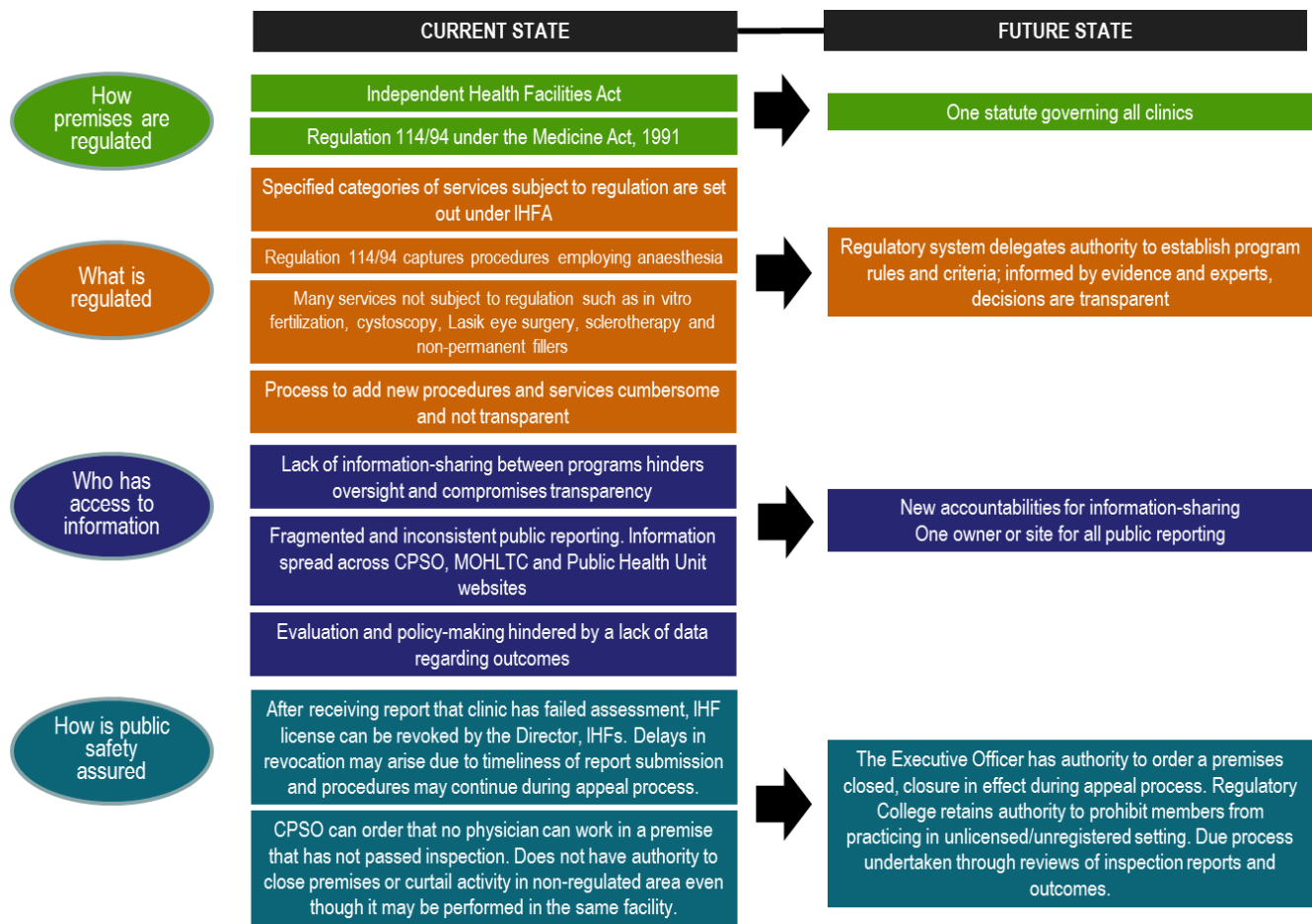
The safe and effective provision of services outside of hospitals, in settings close to home, has been articulated by government as a priority for the health care system. Procedures delivered outside of hospitals have come to represent a significant segment of all health care in the province. Further, the *Patients First* action plan names transparency as a focus, with the goal of allowing patients to make informed decisions about their care.

Improving the oversight of non-hospital medical clinics is a goal of many jurisdictions throughout Canada and the developed world. Many health agencies are grappling with the same issues Ontario is focused on: who and what to regulate, how often to inspect and how to communicate information to the public in a user-friendly fashion. Decisions around oversight are being made in an environment where innovation and technology are rapid but regulatory change can be slow, while the public has an expectation that safety will be just as high a priority in the non-hospital medical setting as in the hospital. Nothing in medicine can ever be risk free, but we have a responsibility to minimize risk to the greatest extent possible.

In this report, we have proposed a series of recommendations that will contribute to a quality oversight system that is both simplified and strengthened, integrated and transparent, with clear accountability and responsibility. A system where patients and the public, as well as practitioners and regulators will have access to the information they need to make the best decisions – where regulations can accommodate the changing landscape of service migration out of hospitals and into communities.

The proposed regulations are carefully calibrated to take the ‘right touch’ while integrating non-hospital medical clinics into the overall quality agenda, with its focus on culture, leadership and building capacity to deliver high quality care. We continuously look for opportunities to improve.

Figure 3: Comparison between current state and proposed future state



Consolidated Recommendations

RECOMMENDATION 1. The Independent Health Facilities and Out-of-Hospital Premises quality programs should be consolidated into a single regulatory model that can easily encompass procedures not currently regulated in existing programs.

RECOMMENDATION 2. The regulatory model for all non-hospital medical clinics needs to be integrated, consistent, comprehensive, transparent, future-oriented and practical.

RECOMMENDATION 3. New quality oversight legislation should consolidate the models, rather than amending the current patchwork of legislation and regulation. Legislation and regulation should set out only what is essential so that it is nimble, responsive and attuned to patient needs.

RECOMMENDATION 4. The new legislation should establish a senior role who will be the regulatory authority (“the Executive Officer”). The Executive Officer would have the authority to establish rules and criteria for the program, act on inspection findings (e.g. order a premises to cease providing a service), and communicate information and coordinate between services (e.g. to regulatory colleges, Chief Medical Officer of Health). The Executive Officer must be independent and appropriately resourced.

RECOMMENDATION 5. A permanent expert committee should be established in legislation, to provide the Executive Officer with independent specialized advice. Membership should include patients.

- The Committee would have the authority to commission specialized subcommittees, including subcommittees that would review inspection reports and make recommendations to the Executive Officer about registering premises or revoking registrations
- Recommendations should be transparent and prepared with the intent to publicly post

RECOMMENDATION 6. This program should be the foundation for quality oversight for non-hospital medical clinics. Other system levers such as contracts and accountability agreements should be used to reinforce quality requirements.

RECOMMENDATION 7. Owners of non-hospital medical clinics should be required to apply for registration with the Executive Officer and registration should be made contingent on passing inspection. Clinics must have a single point of accountability for quality oversight and in all cases that person should be a regulated health professional as specified by the Executive Officer.

RECOMMENDATION 8. Regulated non-hospital medical clinics should be required to report utilization, performance and quality data as specified by the Executive Officer.

RECOMMENDATION 9. Turnaround times for inspection reports should be established to ensure timely and transparent response. Reports should be centrally reviewed by a committee for consistency and in the interests of fairness. The regulations should set out conditions under which the Executive Officer can act before the process is finalized or require an expedited review.

RECOMMENDATION 10. Standardized plain-language summaries of inspection reports should be posted in clinic waiting rooms and online.

RECOMMENDATION 11. A clear and transparent process for patient and provider complaints is needed. Non-hospital medical clinics should prominently post the complaints process and this communication should be consistent across clinics. In developing a standardized complaints process

communication, the Executive Officer should ensure alignment and coordination with existing complaints mechanisms set out by the health professions regulatory colleges.

RECOMMENDATION 12. Facilities should be required to complete and post Quality Improvement Plans.

Figure 4: Proposed quality oversight structure

The Executive Officer is a senior decision-making role established in statute. Through an Expert Committee, the Executive Officer's decisions are informed by best available evidence, clinician input, health system stakeholder advice, and patients and the public. The Executive Officer has the authority to:

The Executive Officer

- Make types of services or procedures performed in non-hospital settings subject to the quality oversight program
- Establish rules and criteria (e.g. data submission) for the non-hospital setting quality oversight program
- Upon recommendation from the Expert Committee, approve premises to operate, or order a premises to cease providing services should they fail to meet requirements
- Publicly post inspection findings
- Communicate and coordinate information with the inspectorate, the chief medical officer of health, and professional regulatory colleges

The Expert Committee provides independent specialized advice to the Executive Officer. The Committee could:

Expert Committee

- Establish, maintain and apply criteria to determine whether a clinical activity should be subject to the quality oversight program
- Recommend to the Executive Officer medical services or procedures that should be subject to quality oversight and advise of any special considerations related to the service or procedure
- Establish subcommittees to review inspection reports and submit recommendations to the Executive Officer (e.g. to register a clinic or take enforcement action)
- Provide reasons for every recommendation, for public dissemination
- Provide advice at the request of the Minister or Executive Officer on program enhancements or communications protocols
- Committee membership should include practicing clinicians from a range of specialities, health system stakeholders and public members

Inspectorate

- Facilitates clinical expert panels to design inspection standards and clinical parameters, as required
- Communicates program requirements to clinics
- Operationalizes inspections (employs and trains inspectors/assessors, designs tools and processes, schedules inspections, deploys inspectors, submits inspection reports to the subcommittees of the Expert Committee for review)
- Investigates complaints referred by the Executive Officer

Chief Medical Officer of Health

Public Health Ontario

36 Public Health Units

- Reactive role in investigating outbreaks or responding to lapses at the local level
- Expertise in infection prevention and control risk assessment and best practice can be leveraged
- Clear communication protocols between the Executive Officer, the Inspectorate and the CMOH are essential

Health Professional Regulatory Colleges

- Responsible for ensuring that regulated health professionals provide health services in a safe, professional and ethical manner. This includes, among other things, setting standards of practice for the profession and investigating complaints about members of the profession and, where appropriate, disciplining them
- Also have a legislated mandate to continuously improve the quality of care provided by their members and administer a number of programs to do so (such as peer assessment in the case of physicians and practice assessment in the case of nurses)

Glossary

College of Physicians and Surgeons of Ontario (CPSO)

Doctors in Ontario have been granted a degree of authority for self-regulation under provincial law. The College of Physicians and Surgeons of Ontario is the body that regulates the practice of medicine to protect and serve the public interest. This system of self-regulation is based on the premise that the College must act first and foremost in the interest of the public. All doctors in Ontario must be members of the College in order to practise medicine.

Health Quality Ontario (HQO)

HQO is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care and better outcomes for Ontarians and better value for money. HQO's legislated mandate under the *Excellent Care for All Act, 2010* is to evaluate the effectiveness of new health care technologies and services, report to the public on the quality of the health care system, support quality improvement activities and make evidence-based recommendations on health care funding. HQO is the provincial advisor on health care quality.

Independent Health Facilities (IHF):

IHFs are licensed and funded by the Ministry of Health and Long-Term Care and are governed by the *Independent Health Facilities Act (IHFA)*. Facilities may be established in a variety of settings, for example, they may be completely free-standing, located within a public hospital, located in a multi-office complex or operated on a mobile basis at specifically approved sites.

IHFs may be:

- Diagnostic facilities that are funded by the Ministry to provide specific classes of diagnostic imaging, pulmonary function or sleep study tests, or
- Ambulatory care facilities providing surgical, therapeutic and diagnostic procedures for which the costs of carrying out the procedure are not included in the OHIP fee paid to physicians. Currently licensed facilities include dialysis, abortion, laser dermatologic surgery and ophthalmic, vascular, plastic and gynaecologic surgery, MRI/CT and PET/CT scans.

An IHF may be for profit or not-for-profit. The licensee of an IHF may be either an individual or a corporation, but may not be a corporation that operates a public hospital.

Ministry of Health and Long-Term Care (MOHLTC)

The Ministry of Health and Long-Term Care is working to establish a patient-focused, results-driven, integrated and sustainable publicly funded health system. Its plan for building a sustainable public health care system in Ontario is based on helping people stay healthy, delivering good care when people need it, and protecting the health system for future generations. The Ministry is involved in:

- Establishing overall strategic direction and provincial priorities for the health system.
- Developing legislation, regulations, standards, policies, and directives to support those strategic directions.
- Monitoring and reporting on the performance of the health system and the health of Ontarians.
- Planning for and establishing funding models and levels of funding for the health care system.
- Ensuring that Ministry and system strategic directions and expectations are fulfilled.

Out of Hospital Premises (OHPs)

OHPs are defined by use of anesthesia and sedation.

- General anesthesia for parenteral sedation or regional anesthesia.

- Local anesthesia for tumescent procedures, injection or insertion of permanent fillers, autologous tissue, synthetic devices for cosmetic purposes or nerve blocks for management of chronic pain.

Out of Hospital Premises Inspection Program (OHPIP)

The Out-of-Hospital Premises Inspection Program (OHPIP) supports continuous quality improvement through developing and maintaining standards for the provision of medical care/procedures in Ontario out-of-hospital premises and by inspecting and assessing for safety and quality of care.

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

Appendices

Appendix 1. Public, Patient and Provider Engagement

Health Quality Ontario engaged Pollara Strategic Insights to conduct a public, patient and provider engagement process to ensure that the perspectives, knowledge, priorities and concerns of key stakeholders regarding health services delivered outside hospitals were taken into account and represented in final recommendations to the Minister of Health and Long-Term Care.

Public and Patient Engagement

From March 4 to 8, 2015, a random sample of 794 Ontarians aged 18 years and older completed an online survey of their knowledge and opinions of independent health facilities and out-of-hospital premises. Responses were weighted by region, gender and age based on the most recent census figures for Ontario to ensure that the sample was representative of the actual population. Survey participants were invited to continue discussing the topic in an online qualitative setting. This qualitative dialogue took place between March 15 and April 9, 2015. There were 35 active participants who shared their sentiments around confidence in care; quality, safety and risk; information sharing and access; issues and complaints and regulation.

Summary of public engagement findings:

- Quality, safety and risk:
 - Ontarians are generally confident in the province's health care system and its quality.
 - Confidence in hospitals was higher as compared with non-hospital specialty health care clinics/facilities in terms of both quality and safety—primarily due to unfamiliarity with non-hospital settings; qualitative research revealed that many are uncertain or apprehensive about IHFs/OHPs.
 - Experiences with these clinics are primarily driven by doctor recommendations, which represent the biggest reason individuals visit these facilities and are important to the public's overall level of confidence.
 - The qualitative discussion characterized quality care as professional, respectful, skilled, clean, safe and up-to-date.
- Information sharing and access:
 - Patients report not receiving information about IHFs/OHPs, but there is a strong desire for more.
 - Respondents indicated a desire to have information posted on clinic/facility websites, on government websites, in waiting rooms and reception areas and on websites hosted by professional organizations.
 - Though the internet, word-of-mouth and professional organizations were identified as possible information sources, referring physicians were found to be the preferred source. Qualitative discussions indicated that patients would like to have detailed discussions with their family physicians and general practitioners well in advance of clinic appointments and want to walk away with papers or be directed to information online.
- Issues, complaints and regulation:
 - Unsurprisingly, there was much confusion among the public about IHF/OHP regulation and inspection.
 - There was consensus, however, that IHFs/OHPs should be inspected at least annually.
 - In the qualitative discussion, patients expressed a desire for the government to be involved in regulation. Patients had no complaints to report related to IHFs/OHPs, but they did indicate a desire for a formal complaint process.
 - Suggestions regarding how to improve or enhance the quality of care delivered centered on setting high standards and increasing transparency.

Provider Engagement

From March 16 to 25, 2015, a sample of 85 family physicians (FPs) and general practitioners (GPs) and 106 IHF/OHP providers were surveyed. Regional representation from across Ontario was sought. FP and GP survey participants were invited to continue discussing the topic in an online qualitative setting. This qualitative dialogue took place between March 23 and April 16, 2015. There were eight

active FP and GP participants who shared their sentiments around confidence, referrals, patient feedback, continuity of care and regulation. In a separate discussion, 16 active IHF/OHP providers offered opinions related to confidence, infection control, complaints and regulation.

Summary of FP and GP engagement findings:

- Confidence:
 - Confidence in hospitals was higher as compared with non-hospital specialty health care clinics/facilities in terms of both quality and safety—primarily due to unfamiliarity with non-hospital settings. Many expressed uncertainty regarding the definitions of IHF and OHP.
- Information sharing and access:
 - The majority of FPs and GPs indicated that there is not enough information available regarding IHFs and OHPs.
 - Respondents suggested that a wide range of information was valuable when choosing where to refer patients including physician credentials and experience, facility cleanliness, patient feedback, quality control, emergency measures in place and rates of hospitalization. Facility ownership was the criteria endorsed least frequently.
 - Despite desiring this information, the majority of FPs and GPs indicated that they did not know where to acquire it. Increased communication was a dominant suggestion in the qualitative research.
- Regulation and inspection:
 - FPs and GPs indicated uncertainty regarding how frequently IHFs/OHPs are inspected, but the majority expressed a preference for this to be done on a yearly basis.
 - The majority also felt that all non-hospital facilities should be regulated and licensed. During the qualitative discussion, respondents felt this should be done by the OMA and/or the CPSO.

Summary of IHF/OHP provider engagement findings:

- Information sharing and access:
 - The majority of providers indicate that their facilities share information related to physician credentials, clinic accreditations and certifications and emergency contacts and plans for complications. Relatively few share information regarding rates of patient hospitalization, how many procedures are completed by physicians per year and chart review/quality control measures.
- Regulation and inspection:
 - Providers expressed confusion regarding when inspections currently take place, though the majority indicated that they should occur annually or at least every two to four years. Equal numbers of survey respondents indicated that this should be done by the CPSO, the MOHLTC or qualified colleagues or peers.
 - The majority agreed that IHFs/OHPs should be regulated—in the qualitative discussion respondents most frequently mentioned the Ministry/government as an appropriate regulator.
 - Qualitative dialogue participants suggested several approaches to improving transparency regarding regulations including posting on front doors of clinics, providing an up-to-date registry of clinics on a government website and conducting random inspections or accreditation checks.

Appendix 2. Key Learnings from Other Jurisdictions

Dimension of Oversight	Key Learnings
Legislative, regulatory and/or policy authority	<ul style="list-style-type: none"> • <u>Ontario</u>: Two sources currently; there are gaps in oversight of procedures and facilities and lack of clarity for patients and providers in terms of responsibility. • <u>International</u>: Single authorities act as independent agents of government. • Single authority is preferred to ensure clarity in accountability.
Governance structure	<ul style="list-style-type: none"> • <u>Ontario</u>: Differs depending on regulatory authority (MOHLTC or CPSO). • <u>International</u>: Single authorities act as independent agents of government. • <u>Nationally</u>: The trend (in many but not all cases) is for authority to be assigned to physician regulators. • Preference for decision-making authority to rest with a named individual who is informed by appropriate decision-making processes and supports.
Definition of scope of quality standards and activities of the program	<ul style="list-style-type: none"> • <u>Ontario</u>: In some cases, scope is set out in regulation, in others it is established through by-laws (e.g. details of adverse event reporting or posting to public registers) or determined by authorities besides the regulatory authority. • <u>England, Australia and the Netherlands</u>: Independent quality agencies define national standards; in some cases, sets out in regulations what facilities are covered and in others covers all care settings. • Program scope should be responsive to changes; should ultimately be defined by regulatory authority, with input from experts.
Development of detailed standards	<ul style="list-style-type: none"> • <u>Ontario</u>: Developed currently by expert panels established by CPSO for activities falling within oversight; no flexibility to address procedures beyond what is specified in legislation and/or regulation. Services can also be designated under the IHFA, which is not a legislative or regulatory process. • <u>England and Australia</u>: National standards are established and oversight programs align with those national standards. • Standards should continue to be set by experts in the field, with flexibility built into method for changing or updating.
Assurance that clinicians practice within scope of certification/experience	<ul style="list-style-type: none"> • <u>Ontario</u>: No credentialing of professionals, but there is an expectation that clinicians will work within the scope of their experience and training; all programs ensure as part of inspection process that clinicians hold proper training and licenses. • <u>Alberta</u>: Clinicians credentialed to work in non-hospital premises, granted specific certification to perform services. • Inspections should continue to assure that staff are appropriately trained and licensed; regulation of the profession is the responsibility of the CPSO
Identification of facilities and/or practitioners	<ul style="list-style-type: none"> • <u>Ontario</u>: IHFs require a license from the Ministry to operate and receive facility fees. CPSO requires members to self-report certain types of activities, meaning that all non-IHFs subject to the OHPIP must also self-identify to CPSO. • Physician oversight is the responsibility of the CPSO.

Dimension of Oversight	Key Learnings
Inspection cycle	<ul style="list-style-type: none"> • <u>Canada and the United States</u>: Inspections operate on a cycle, occurring at regular intervals unless new activities/concerns arise (e.g. every three or five years in Ontario). • <u>England and the Netherlands</u>: England moving from annual cycle to a risk-based model. The Netherlands also uses risk-based assessment. • Ontario model should tailor inspection cycle to the risk involved in the activity.
Design of assessment process	<ul style="list-style-type: none"> • Inspection process (e.g. records review, observation of practice) and development of tools similar across jurisdictions; should continue as such.
Trained assessors to inspect against established standards	<ul style="list-style-type: none"> • Process aligned across jurisdictions. • Scaling up program to include more facilities will require more trained assessors.
Framework for determining assessment outcome	<ul style="list-style-type: none"> • <u>Alberta</u>: Facilities receive full accreditation, provisional accreditation or no accreditation. • <u>England</u>: Outcomes range from “outstanding” to “inadequate”. • <u>Ontario</u>: OHPs receive categorizations (e.g. “pass”); IHFs receive warning letters, proposals to suspend license/amend services, suspension of license. • Outcomes designed for administering program and not descriptive for public reporting; new system should focus on transparent communication and clarity of meaning.
Process for reviewing assessment/inspection reports and allowing facilities to comment	<ul style="list-style-type: none"> • <u>Ontario</u>: CPSO committee reviews outcomes of inspection reports before they are finalized. Facilities can comment on outcomes of inspections during this process. Helps resolve issues without the need to proceed to a hearing. Balance between due process for clinic operators and public interest is required. • Maintain ability to review reports, but ensure that public interest prevails over facility right to continue to operate during appeal process.
Authority to take action for non-compliance or failure to meet standards	<ul style="list-style-type: none"> • <u>Ontario</u>: Authority to take action mixed—CPSO has jurisdiction over only its members and activities under regulation 114/94; facilities regulated under the IHFA may continue offering procedures during the appeal of a revocation or suspension of license. • Authority must be empowered to take immediate action on non-compliance that puts patients at immediate risk.
Pathway to respond to incidents affecting patient safety	<ul style="list-style-type: none"> • <u>Ontario</u>: Physicians expected to disclose harm and provide follow-up care in case of incidents;⁴¹ however, clinicians or facilities are not always equipped to manage required response and patients may be uncomfortable with further interaction. Process by which these cases should be governed is currently unclear. • Non-compliance issues will arise (e.g., IPC lapses) and patients may need to be informed and followed up with. Responsibility and accountability for this must be considered as part of oversight regime

⁴¹ The College of Physicians and Surgeons of Ontario. Disclosure of Harm. Retrieved June 2014 from <http://www.cpso.on.ca/policies-publications/policy/disclosure-of-harm>

Dimension of Oversight	Key Learnings
Barrier-free communication channels	<ul style="list-style-type: none"> • <u>Ontario:</u> Communication channels between regulator and other authorities (e.g., between public health units, regulatory colleges) are largely informal. • Formalizing roles, communication channels and processes is essential to ensuring patient safety.
Approach to public reporting	<ul style="list-style-type: none"> • <u>Ontario:</u> Leads most jurisdictions (except England) in posting information to public register or website, but there is room for improvement. More information could be provided and the reports made easier to find. • Future reporting should include posting of plain-language summary reports to a central website (e.g., up-to-date comprehensive public registry of clinics), and visibly in clinics.
System for reporting, tracking and investigating critical incidents and adverse events	<ul style="list-style-type: none"> • <u>Ontario:</u> OHPIP requires adverse events to be reported to CPSO (added by CPSO through bylaw); no requirement under IHFA to report adverse events to Ministry or CPSO, except those providing anaesthesia (practice standards specify they should be reported to local Quality Advisors). • Clear system and accountabilities for managing, reporting and monitoring adverse events required.
Requirements for data submission	<ul style="list-style-type: none"> • <u>Ontario:</u> Currently limited data collected from OHPs and IHFs. • Additional data needed to support improved planning, policy-making, public reporting (e.g., key adverse event indicators such as infection rates and transfers to hospital) and risk analysis.

Appendix 3. References

- 1) A fresh start for the regulation of independent healthcare. Working together to change how we regulate independent healthcare. (2014). Care Quality Commission. Retrieved from http://www.cqc.org.uk/sites/default/files/20140415_independent_health_signposting_document.pdf
- 2) Alharbi, O., Rabeneck, L., Paszat, L. F., Wijeyesundera, D. N., Sutradhar, R., Yun, L., Tinmouth, J. (2010). Factors associated with colonoscopy performed in nonhospital settings. *Canadian Journal of Gastroenterology*, 24(7), 419–424.
- 3) Amalberti, R., Auroy, Y., Berwick, D., Barach, P. (2005). Five System Barriers to Achieving Ultra safe Health Care. *Annals of Internal Medicine*. Volume 142.
- 4) Ambulatory Surgery Centers: Big Business Little Data (June 2013). California Health Care Almanac.
- 5) Ambulatory Surgical Center Quality Reporting Program. (2014). Center for Medicare and Medicaid Services: Quality Measures Specifications Manual. Washington, D. C. Retrieved: http://ascrs.org/sites/default/files/ASC%20Specs%20Manual_v3_0c.pdf
- 6) Baker, G. R., Denis, J. L., Pomey, M. P., Macintosh-Murray, A. (2010). Effective Governance for Quality & Patient Safety in Canadian Healthcare Organizations. Canadian Health Services Research Foundation: Retrieved from www.patientsafetyinstitute.ca
- 7) Bishop, T. F., Ryan, A. M., Casalino, L. P. (2011). Paid Malpractice Claims for Adverse Events in Inpatient and Outpatient Settings. *The Journal of American Medical Association*.
- 8) Bridging the Gap: A patient Safety Imperative. The Out-of-Hospital Premises Inspection Program Report. (2012). The College of Physicians and Surgeons of Ontario.
- 9) Casalino, L. P., Devers, K. J., Brewster, L. R. Focused factories? Physician-owned specialty facilities. (2003). *Health Affairs (Millwood)*, 22: 56–67.
- 10) Chung, F., Shnaider, I. (2006). Outcomes in day Surgery. *Current Opinion in Anesthesiology*. 19 (6), 622-9.
- 11) Coglianese, C. (2012). Measuring Regulatory Performance: Evaluating the Impact of Regulation and Regulatory Policy. Organization for Economic Co-operation and Development. Retrieved from http://www.oecd.org/gov/regulatory-policy/1_coglianese%20web.pdf
- 12) Cook, D., Thompson, J. E., Habermann, E. B., Visscher, S. L., Dearani, J. A., Roger, V. L., Borah, B. J. (2014). From 'Solution Shop' Model To 'Focused Factory' In Hospital Surgery: Increasing Care Value and Predictability. *Health Affairs*, 33 (5).
- 13) Creating Community-Based Specialty Clinics in Ontario, Evidence Brief (May 2013). McMaster Health Forum.
- 14) Establishing comprehensive Quality Management Programs for Mammography, Colonoscopy and Pathology in Ontario (2014). Quality Management Partnership 2013/14 Report.
- 15) Findings of the Community Infection Prevention and Control Lapses Task Group. (2013). Report to the Chief Medical Officer of Health, Ministry of Health and Long-Term Care. Retrieved from <http://www.oha.com/News/Misc%20Documents/Findings%20of%20the%20Community%20Infection%20Prevention%20and%20Control%20Lapses%20Task%20Group%20%282%29.pdf>
- 16) Flodgren, G., Pompey, M. P., Taber, S. A., Eccles, M. P. (2011). Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes. *The Cochrane Library*. Issue 11.
- 17) Flood, C., Thomas, B., Wilson, L. H. (2010). Cosmetic Surgery Regulation and Enforcement in Ontario. *The Queens Law Journal*.
- 18) For Health or Wealth? The evidence regarding private clinics and user fees in Ontario. (2014). Ontario Health Coalition. Retrieved from

<http://www.ontariohealthcoalition.ca/index.php/private-health-clinics-using-manipulative-tactics-to-over-bill-patients-ontario-health-coalition-report/>

- 19) Francis, R. (2013). QC The Mid Staffordshire NHS Foundation Trust Public Inquiry.
- 20) Gilmour, J. M. (2003). Regulation of Free-Standing Health Facilities: An Entrée for Privatization and For-Profit Delivery in Healthcare. Health Law Journal Special edition.
- 21) Gregory, R., Roski, J. (2001) Performance measurement for ambulatory care: moving towards a new agenda. International Journal for Quality in Health Care, Volume 13 (6), 447-453.
- 22) High Quality Care for All, NHS Next Stage Review Final Report. (2008). Department of Health, National Health Service.
- 23) Howlett, K., Mickleburgh, R., Moore, O., Pickard, A. (2010). How provinces have experimented in the private sphere. The Globe and Mail.
- 24) IHF Report by Location. (2015). Ministry of Health and Long-Term Care. Retrieved from http://www.health.gov.on.ca/en/public/programs/ihf/docs/ihf_assessment_report.pdf
- 25) Incident Reporting. (2014). New South Wales Government. Retrieved from <http://www.health.nsw.gov.au/Hospitals/privatehealth/Pages/Incident-reporting.aspx>
- 26) Independent Health Facilities. (2014). Annual Report of the Office of the Auditor General of Ontario.
- 27) Independent Health Facilities and Out of Hospital Premises. (2014) Presentation made by Negotiations and Accountability Management Division Ministry of Health and Long-Term Care, Ontario.
- 28) Infection Prevention and Control for Clinical Office Practice (June 2013). Provincial Infectious Disease Advisory Committee (PIDAC). Public Health Ontario.
- 29) Institute of Medicine (IOM). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C: National Academy Press; 2001.
- 30) Ivers, N. Schwandt, M. Hum, S. Martin, D., Timmouth, J., Pimlott, N. (2011). A comparison of hospital and nonhospital colonoscopy: Wait times, fees and guideline adherence to follow-up interval. *Canadian Journal of Gastroenterology*, 25(2), 78–82.
- 31) Jurisdictional Review of Out-of Hospital Facilities: Oversight and Transparency (2014). College of Physicians and Surgeons of Ontario.
- 32) Kinney, D. E. (1994). Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When Is It Appropriate? *Law and Contemporary Problems* 47-74. Retrieved from: <http://scholarship.law.duke.edu/lcp/vol57/iss4/3>
- 33) Los Angeles Independent Diagnostic Testing Facilities Compliance with Medicare Standards (2011). Department of Health and Human Services.
- 34) Mitchel, J. M. (2012). The influence of Physician ownership on practice in U.S ambulatory surgical centers. *Canadian Doctors for Medicare*.
- 35) Naylor, C., Gregory, S. (2009). Independent sector treatment centres. (2009). The King's Fund.
- 36) Non-Hospital Surgical Facility Standards and Guidelines (June 2014). College of Physicians and Surgeons of Alberta.
- 37) Out-of-Hospital Premises Inspection Program (OHPIP). (2013). Program Standards. College of Physicians and Surgeons of Ontario.
- 38) Pomey, M. P., Lemieux-Charles, L., Champagne, F., Angus, D., Shabah, A., Contandriopoulos, A. P. (2010). Does accreditation stimulate change? A study of the impact of the accreditation process on Canadian healthcare organizations. *Implementation Science*, 5:31. Retrieved from <http://www.implementationscience.com/content/5/1/31>.
- 39) Private Health Facilities Act 2007 No 9. (2014). New South Wales Government. Retrieved from <http://www.legislation.nsw.gov.au/maintop/view/inforce/act+9+2007+cd+0+N>

- 40) Private Hospital licensing and data collection (2012). Private Hospital Data collection Review Final Report. The Department of Health, Australian Government. Retrieved from http://www.health.gov.au/internet/publications/publishing.nsf/Content/phdcreview~phdcreview_curr~phdcreview_curr_3
- 41) Quality and accreditation in health services: A Global Review. (2003). World Health Organization Geneva.
- 42) Reader, T. W., Gillespie, A., Roberts, J. (2013). Patient complaints in healthcare systems: a systematic review and coding taxonomy. BMJ Quality & Safety.
- 43) Reader, T., Gillespie, A., Roberts, J. (2014). Patient complaints in healthcare systems: a systemic review and coding taxonomy. BMJ Quality and Safety
- 44) Report and Recommendation on Day Surgery. (2004). Australian Day Surgery Council.
- 45) Report by the Comptroller and Auditor General. The Care Quality Commission: Regulating the quality and safety of health and audit social care (2011) National Audit Office. Retrieved June 2015 from <http://www.nao.org.uk/wp-content/uploads/2011/12/10121665.pdf>.
- 46) Report of the Working Group on Defining High-risk Medical Procedures/Practices performed in Ambulatory Setting. (2014). Department of Health Hong-Kong. Retrieved from http://www.hpdo.gov.hk/doc/fhsd/WG2%20Final%20Report_e.pdf
- 47) Right-touch regulation. (2010). Council for Healthcare Regulatory Excellence.
- 48) Rules and regulations for licensure of freestanding diagnostic testing centers: Chapter 8. (2007). Retrieved from <http://soswy.state.wy.us/Rules/RULES/3226.pdf>
- 49) Section 1.2- Key Legislative and Regulatory Agreements Governing the Ontario Health System. Module 1: Health Care in Ontario. Physician Leadership Resource Manual. Ontario Hospital Association.
- 50) Standards and Checklist. (2014) American Association for Accreditation of Ambulatory Surgical Facilities. Retrieved from http://www.aaaasf.org/Surveyor/cms_web/PDF%20FILES/ASC%20PDFS/ASC%20Standards.pdf
- 51) The Regulation of Facilities Looking Forward (February 2015). College of Physicians and Surgeons of Ontario.
- 52) Transforming the safety and quality of health care (2014). NSQHS Standards. Australian Commission on Safety and Quality in Health Care.
- 53) Warburton, R. (2009). Accreditation and Regulation: Can they help improve patient safety. Agency for Healthcare Research and Quality. U.S Department of Health and Human Services.