THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

College of Physicians and Surgeons of Ontario

Submission on Bill 160: Strengthening Quality and Accountability for Patients Act, 2017

Standing Committee on General Government

November 20, 2017

Bill 160: Strengthening Quality and Accountability for Patients Act, 2017

Response from the College of Physicians and Surgeons of Ontario

Overview

The College of Physicians and Surgeons of Ontario ("the College") regulates the province's medical profession and has a legal mandate to serve and protect the public interest. College responsibilities include:

- Issuing certificates of registration to doctors to allow them to practice medicine;
- Monitoring and maintaining standards of practice through assessment;
- Investigating complaints about doctors on behalf of the public;
- Disciplining physicians who have committed an act of professional misconduct or who are incompetent;
- Providing guidance to physicians on professionalism, medico-legal, and other issues that are relevant to the practice of medicine through the *Practice Guide* and over fifty College policies.

The role of the College and its authority and powers are set out in the *Regulated Health Professions Act* (RHPA), and the *Health Professions Procedural Code* under the *RHPA* and the *Medicine Act*.

Bill 160 is a significant Bill containing ten schedules. The focus of the College submission is on Schedule 9, *Oversight of Health Facilities and Devices Act, 2017* as it creates a new legislative framework for health facilities and the College is extensively involved in facility regulation. We currently inspect or assess more than 1300 independent health facilities and out of hospital premises. While the College is very supportive of the proposed new legislative framework for health facilities we do suggest a number of amendments which we see as essential to ensuring the effectiveness of the proposed new consolidated framework.

Our submission also contains comments on Schedule 1 and Schedule 4 of the Bill, following the comments below on Schedule 9.

Schedule 9, *Oversight of Health Facilities and Devices Act, 2017*

The College strongly supports Schedule 9, *Oversight of Health Facilities and Devices Act, 2017 (OHFDA). The OHFDA* sets out the government's plan for a single legislative framework for the Independent Health Facilities Program (IHFP), the Out-of-Hospital Premises Inspection Program (OHPIP) and energy applying and detecting medical devices (EADMDs).The *OHFDA* will enhance and consolidate oversight for Ontario's out of hospital facilities and services, better ensure patient safety, and take important steps to increase transparency and public reporting.

The *OHFDA*'s focus on patient safety, transparency, and public reporting are vital changes to a new regulatory system of oversight for community health facilities (CHFs) in Ontario. Specifically, the

College is supportive of the legislation as it provides an inspecting body (IB) with effective tools to take action to protect the public where quality issues are identified by the inspecting body. The College is also supportive of the theoretical flexibility that the new legislation possesses to capture medical services that are delivered in the community and that should be subject to quality oversight.

College involvement in facilities regulation

The College has been involved in facilities regulation since the early 1990s. Under the *Independent Health Facilities Act* (*IHFA*) the College was assigned, through its Registrar, specific duties regarding the regulation of independent health facilities. In 2010, the College expanded its involvement in facilities regulation with the development of the Out of Hospital Premises Inspection Program (OHPIP). The College sought to develop the OHPIP to address a significant threat to patient safety related to facilities providing uninsured, complex surgical interventions for cosmetic purposes, but that were not captured by the IHFA or any other form of oversight. While the College requested a consolidated approach to facilities regulation at the time, ultimately a regulation under the *Medicine Act, 1991* was developed to create a new and separate inspection and enforcement system specific to out of hospital premises (OHPs).

The College's involvement in facilities regulation has continued to grow in scope. In May 2017, the College proposed a regulation amendment, following the Minister's request, to provide the College with authority to enter and inspect premises where fertility services are performed, regardless of whether anesthesia or sedation is used. This program is not yet operating; however, it demonstrates the College's commitment to ensuring a modern system of patient safety and oversight for facilities.

The College's work on facility regulation and, in particular, our approach to quality assurance oversight, is from the perspective of a medical regulator. As a medical regulator, our primary focus is on risk of harm and patient safety as well as the quality of care provided to patients. The College's response to the proposed system of facility regulation under the proposed *OHFDA* is informed by this lens of patient safety and quality care.

While supportive of the *OHFDA*, we offer comments and seek clarification or what we perceive to be important amendments in several areas to ensure clarity and alignment with Schedule 9's objectives. These concerns and proposed revisions are outlined below.

Two general concerns – regulation of "services" and timing of implementation

Regulation of prescribed "services"

As currently drafted, the Bill provides that a community health facility (CHF), for which a license is required, is "a place or a collection of places where one or more services prescribed in regulations made by the Minister are provided".

The approach of regulating "services" to be set out in a regulation poses certain problems. First and foremost, regulating services rather than locations and persons practicing within those locations creates potential gaps in oversight. For example, there may be services delivered at a particular physical location (e.g. a clinic) that are not prescribed services for the purposes of the *OHFDA* and over which the inspecting body (IB) would have no authority. This distinction is unlikely to be apparent to patients or the public, who will assume that the entire physical location is subject to regulatory oversight.

Similarly, the approach of regulating "services" raises the possibility that, depending on the services delivered by the particular licensee at a particular physical location, there might be multiple inspecting bodies responsible for the development of standards and for inspections. This overlapping responsibility has the potential to lead to confusion on the part of patients and break-downs in communication and accountability.

Finally, the College questions whether this approach allows for enough flexibility with respect to new or emerging procedures that the College may become aware are being performed in facilities. By prescribing specific services in regulation, it will be difficult to ensure adequate oversight of these new or emerging procedures until such time as the regulation can be amended.

Timing of implementation

The *OHFDA,* once enacted, will create an entirely new system of oversight for community health facilities. The Act does not specify an enactment date and a substantial amount of detail is to be prescribed in regulation, including the fundamental question of what services will be regulated and who the IB will be in respect of every service.

In order for this system to meet its goals of patient protection and transparency, from the College's perspective **it is essential that the enactment date is, at minimum, a year in the future**.

There is significant preparatory work required in order for the College to function as an inspecting body. This preparatory work includes but is not limited to:

- Developing quality standards for the prescribed services for which the College is responsible as an inspecting body is a significant body of work. This will require convening Working Groups comprised of experts in the area of the particular service or services; consulting with and receiving feedback from stakeholders including licensees; approval of the standards by a Committee or Council; consultation, communication and publication of the standards to the relevant parties. This work will also include the development of tools for inspectors to ensure consistency in evaluating compliance with the quality standards.

- Recruiting, appointing and training inspectors: inspectors under the new legislation will have significantly greater responsibilities and powers than assessors under the IHFA or OHP regulation. The persons who will act as inspectors must be recruited and trained with

respect to the new legislative regime and their responsibilities and powers, and trained with respect to the new standards and tools.

- Creating, recruiting and appointing members of a College Committee to approve standards, appoint Inspectors, review cessation orders and issue decisions.

- Creating internal processes and training staff to run the new inspection program set out in the legislation, including processes related to compliance and cessation orders.

- Developing the necessary information technology systems to allow for the results of inspections and for orders to be made available to the public as required by the legislation.

- Developing an assessment fee model that reflects the services for which the College is responsible as an inspecting body.

- Developing the necessary finance and invoicing systems associated with assessment fees to be prescribed in regulation.

Constructive Feedback and Proposed Revisions

In addition to the two general concerns outlined above, we offer the following comments and seek clarification or amendments in several areas, outlined below.

1. Inspection Reports, Compliance Orders and Cessations Orders

The College believes that transparency must be a defining principle of the *OHFDA*. The College's current public register for OHPs is among the most transparent in Canada and includes a wide breadth of information including whether a current OHP has failed or has passed with conditions, reasons for the fail results, and detail of the conditions the premise must satisfy. We believe that under the new system established by this Bill, the information available must be driven by what patients need when they are seeking safe and quality care from a facility.

The Act has a number of gaps with regards to the regime of reports, compliance, and cessation orders. Amendments are required in order to address these gaps.

a) Currently, while the licensee is required to post inspection reports, there is no requirement for the licensee to post cessation or compliance orders. The College strongly urges an addition to section 34 of the *OHFDA* in order to require licensees to post all cessation and compliance orders while these are in effect. Once an order has been rescinded, the licensee would be permitted to remove the public posting. The requirement to post cessation and compliance orders is necessary for the protection of the public and constitutes a very effective incentive to licensees to address the issues identified in such orders.

b) Currently, the Act requires that every licensee or prospective licensee post copies of inspection reports for the past two years. An amendment to this provision is required as, depending on the inspection schedule, there may not be reports from the last two years. The College recommends that subsection 34(1)(c) be amended so that the last **two reports** are to be posted by the licensee.

c) Section 36(6) of the *OHFDA* requires that every IB keep confidential all information except that which the IB is specifically required to post or make public. Currently, the Act provides, among the responsibilities of the IB set out at subsection 36(3), that IBs are responsible for making reports of inspections available to the public. There is no such responsibility articulated with respect to compliance orders or cessation orders, nor is there any other provision in the Act requiring IBs to make such orders available to the public. If an IB can only make available to the public inspection reports but not compliance orders or cessation orders arising from such reports, this will undermine the transparency and patient autonomy in terms of choice of clinic central to the *OHFDA*. The public must have information about what action was taken in the face of, for example, an inspection reports that details a serious risk of harm to the health and safety of patients.

   The College strongly urges that amendments be made to subsection 36(3), and sections 45, 50 and 51 to provide that IBs shall make public all inspection reports, compliance orders and cessation orders. Moreover, and as opposed to the recommended amendment to provide that the licensee must post only those orders currently in effect, the College urges that the requirement of the IB apply to <u>all</u> orders, even those no longer in effect. It is the College's position that all orders must be made publicly available by the IB so that the public has access to an accurate history of the CHF in question.

d) The Act restricts IBs from making available to the public reports of inspections that include "personally identifiable information about a person". The College believes that the intention of this language was to ensure that no <u>personal **health** information</u> is disclosed in reports of inspections made available to the public. As currently written, however, the provision would not allow relevant information to be made available to the executive officer or to the public, such as, for example, the fact that a particular employee does not possess the required qualifications to practice at a facility or that the quality advisor has failed to abide by his or her responsibilities. The College recommends amendments to clarify that the information that cannot be made available to the public is personal health information, not "personally identifiable information".

e) The Act stipulates that a cessation order must include a <u>period of time</u> that the CHF must cease from operating or cease from providing a service. More realistically, a cessation order should be in effect until certain conditions are met. Accordingly, the College recommends that an amendment is made to subsection 51(1) in order to clarify that the limitation on the cessation order is not for a period of time but rather for a "defined period".

f) In order to be effective, notice of a compliance order or cessation order issued by an inspector or IB must be served on the licensee. Presumably it will be the responsibility of the inspector or IB to effect service of such orders in such circumstances. However, as currently drafted, service is to be made on the last address, fax number, etc. appearing on the records of the executive officer. Given that the IB will be responsible for effecting service on the licensee and that, particularly in the case of cessation orders, it will be important to effect such service as quickly as possible. As such, the College strongly urges an amendment to subsection 70(1) of the *OHFDA* to provide that service shall be made on the last address, fax number, etc. appearing on the records of the executive officer or IB. A consequential amendment may be required in regulation under section 35 to stipulate that a licensee is required to ensure that the IB is provided with current contact information for service.

g) The Act outlines the manner in which notice can be served. Absent from this list is notice by electronic means. Given that electronic communication is increasingly the default method of contact; the College strongly urges an amendment to subsections 70(1) and (2) to provide for service by email which shall be deemed to be effective on the next business day.

Proposed Revisions

Posting

34 (1) Every licensee and prospective licensee in respect of a community health facility shall post, in a prominent place clearly visible to members of the public, at or near the entrance of the community health facility, and in compliance with the requirements provided for in the regulations, if any,

(c) copies of the past two inspection reports ~~for the past two years~~ with respect to the community health facility;

(c.1) a copy of any compliance order issued and in effect under subsection 50(3) and cessation order issued and in effect under subsection 51(1) and 51(4);

Responsibilities of inspecting bodies

36 (3) Subject to the regulations, an inspecting body has the following powers and responsibilities with respect to the community health facilities provided for in the regulations:

6. Making reports of inspections, which shall not include ~~personally identifiable information about a person~~, personal health information, available to the public.

7. Making orders under sections 50 and 51 and making such orders and decisions related to such orders, which shall not include personal health information, available to the public.

Reports

45 (1) Promptly after completing an inspection of a community health facility,

(a) an inspector appointed by an inspecting body shall make a written report to the inspecting body; and

(b) an inspector appointed by the executive officer shall make a written report to the executive officer.

Same

(2) An inspecting body shall, on request, provide to the executive officer, in the form and at times satisfactory to the executive officer, copies of,

(a) every report made by an inspector under clause (1) (a);

(b) a written summary of every report made under clause (1) (a); and

(c) every order made by the inspecting body or an inspector appointed by the inspecting body under this Act.

Inspecting body to make reports available to public

(3) An inspecting body shall make available to the public copies of every report made by an inspector under clause (1) (a), which shall not include personal health information.

Time of validity

(6) A compliance order issued under clause (1) (c) is valid until the date set out in the order or until the conditions specified in the order have been met, whichever is earlier.

Inspecting body to make orders available to public

(7) An inspecting body shall make available to the public copies of every compliance order made under subsection (3), which shall not include personal health information.

Cessation orders

51 (1) An inspector or inspecting body or the executive officer may order a licensee or a prospective licensee in respect of a community health facility to cease from operating or to cease from providing a service for a defined period ~~period of time~~ set out in the order or provided for in the regulations.

Grounds, cessation order

(2) A cessation order may be made if, in the opinion of the inspector, inspecting body or the executive officer, after considering any factors provided for in this Act or the regulations, the licensee or prospective licensee has not complied with a requirement under this Act and the non-compliance poses a serious risk of harm to the health and safety of any person.

Restrictions

(3) A cessation order made by an inspecting body or an inspector appointed by an inspecting body may only be with regard to requirements under this Act respecting the functions for which the inspecting body is responsible under its designation in the regulations or that is reasonably connected to such a requirement.

Cessation order by certain inspectors

(4) The following applies with respect to a cessation order made by an inspector appointed by an inspecting body:

1. The order must be reviewed by the inspecting body within the time provided for in the regulations and the inspecting body must make a decision with respect to the order within a time provided for in the regulations. If the inspecting body does not make a decision within that time, the order ceases to be valid.
2. The licensee or prospective licensee may make submissions in writing to the inspecting body within the time specified by the inspecting body.
3. In its review, the inspecting body must consider the cessation order made by the inspector, the inspector's report and any submissions received from the licensee or prospective licensee.
4. In its decision, the inspecting body may confirm, alter or rescind the order made by the inspector and may also,
    i. substitute another order for that of the inspector, including issuing a compliance order in accordance with section 50, and
    ii. require an additional inspection to be carried out in accordance with its instructions.
5. The inspecting body shall serve the licensee or prospective licensee with notice of the decision, which shall include written reasons if the order is confirmed or altered or another order is substituted.

Copy

(5) An inspector or inspecting body that issues a cessation order shall promptly provide the executive officer with a copy of the order.

Funding

(6) Where, under a cessation order, a licensee or prospective licensee is required to cease providing any service, no funding shall be provided by the Minister or any other person out of public money with respect to the service that was the subject of the cessation order until the cessation order is terminated by an order issued under subsection (7).

Order valid

(7) A cessation order is valid until terminated by further order of the inspector, inspecting body or executive officer.

Copy

(8) An inspector or inspecting body that terminates a cessation order shall promptly provide the executive officer with a copy of the order.

Inspecting body to make orders and decisions available to public

(9) An inspecting body shall make available to the public copies of every cessation order made under subsection (1) and subsection (4), every decision and written reasons of the inspecting body under subsection (4), and every further order terminating a cessation order under subsection (7), which shall not include personal health information.

Service

70 (1) Any notice that is required to be served under this Act may be served,

(a) by personal service;

(b) by sending the notice by registered mail addressed to the person or entity to be served at their last address appearing on the records of the executive officer or inspecting body;

(c) by sending the notice by fax to the person or entity to be served at their last fax number appearing on the records of the executive officer or inspecting body;

(c.1) by sending the notice by email to the person or entity to be served at their last email address appearing on the records of the executive officer or inspecting body;

(d) by sending the notice by commercial courier to the person or entity to be served at their last address appearing on the records of the executive officer or inspecting body; or

(e) by any other prescribed method of delivery.

Deemed receipt

(2) Where notice is served in a manner described in subsection (1), the person or entity shall be deemed to have received the notice,

(a) in the case of a notice sent by registered mail, on the fifth business day after the day is was mailed;

(b) in the case of a notice sent by personal delivery, fax or email, on the first business day after the day it was sent;

(b) in the case of a notice sent by commercial courier, on the second business day after the commercial courier received the document; or

(d) in the case of a notice sent by any other prescribed methods, on a day provided for in the regulations.

Same, community health facilities

72 (3) The Lieutenant Governor in Council may make regulations governing community health facilities and their licensing and, without restricting the generality of the foregoing, may make regulations,

(l) respecting and governing reports, decisions and orders that are required to be made publicly available and the persons responsible for making such reports available;

2. Assessment Fees

The Act relies on IBs to perform the critical task of ensuring the safety and quality of services delivered at CHFs. In order to be able to perform this critical task, the IB must be able to establish and collect fees from licensees for the activities (and associated administrative and overhead costs) that the IB is required to perform. While the Act contains regulation-making authority in s. 72(3)(t) that would allow the IB to establish and collect fees to fund its activities, there are currently gaps in the Act, particularly with respect to the consequences where a licensee or prospective licensee fails to pay such fees. As a result, certain amendments are required.

a) The Act does not currently contemplate enforcement mechanisms where there has been a failure by the licensee to pay a fee established by the IB. As a result, the only enforcement mechanism available to an IB in respect of unpaid inspection fees would be to commence a Small Claims Court action against the licensee. This is inefficient and consumes resources from the IB that are better spent in its role ensuring patient safety and quality of care.

   The College strongly urges amendments so that the payment of inspection fees is a condition for the issuance, transfer or renewal of a license in every case. The College has proposed amendments to subsections 5(1) (issuance); 9(2) (transfer) and 55(1) (renewal) to provide that licenses may not be issued, transferred or renewed where inspection fees are outstanding.

b) Subsection 23(1) provides that licensees must comply with conditions of their license. Subsection 55(1)(c) provides that the executive officer may suspend, revoke or refuse to renew a license where the executive officer has reasonable grounds to believe that the licensee has failed to comply with a requirement under the Act. The College proposes that it must be a prescribed condition of every license, pursuant to subsection 23(1), that the licensee pay fees established by an IB pursuant to a regulation made under s. 72(3)(g). The government must be prepared to suspend a license under 55(1)(c) upon being provided with notice and evidence by the IB that a licensee or prospective licensee has not paid a fee established by an IB.

c) In order to make it clear that IBs may establish and collect fees for associated administrative and overhead costs associated with the activities and functions that the IB is required to perform, the College strongly urges an amendment to the regulation-making clause set out in the Act to make this explicit (s.72(3)(t)). In addition, the College urges that the language in the Act regarding the IB's responsibility for establishing and collecting fees be made congruent with the language in the regulation-making section (s.36(3)9).

Proposed revisions

Issuance

5 (1) The executive officer may issue a licence to an applicant where the following conditions are met:

1. The applicant has applied in a manner that complies with the requirements under subsection 4 (3).

2. The applicant has paid any fee established in a regulation made by the Minister.

2.1 The applicant has paid any fee prescribed under subsection 72(3)(t).

Transfer of licence

9 (1) A licence in respect of a community health facility is not transferable without the prior written consent of the executive officer.

Criteria

(2) In deciding whether to consent to the transfer of a licence, the executive officer,

(a) shall treat the proposed transferee of the licence as if the proposed transferee were an applicant for a licence, and for that purpose section 5 applies with necessary modifications; and

(b) shall also consider whether the current holder of the licence is complying with the requirements under this Act, and may refuse to consent, or consent subject to conditions on the consent, where either or both of the Minister and executive officer have identified a failure to comply with any requirement under this Act by the current holder of the licence.

Conditions

(3) The executive officer's consent to the transfer of a licence may be made subject to conditions, and in consenting to the transfer of a licence, the executive officer may attach to the licence any conditions that the executive officer considers necessary in the circumstances.

Same

(4) It is a condition of the transfer of a licence that the current holder of the licence has paid any fee prescribed under subsection 72(3)(t).

Suspension, revocation, etc.
Community health facilities

55 (1) With respect to a community health facility, the executive officer may suspend, revoke or refuse to renew a licence or suspend or revoke a licensee's authorization to provide one or more services under a licence where the executive officer has reasonable grounds to believe that,

(a) the requirements under section 5 for the issuance of a licence were not met at the time of issuance, or are no longer being met;

(b) the community health facility does not meet the prescribed safety and quality standards, having regard to any factors the executive officer considers relevant, including, without being limited to,

(i) the nature of risks revealed in the course of inspections, and

(ii) the actions taken by the licensee in response to compliance orders;

(c) the licensee or anyone else operating or working at the community health facility has failed to comply with a requirement under this Act, or with any other relevant Act or law; or

(d) the licensee has not provided services provided for in the licence for a period of at least six months and is not taking reasonable steps to provide the services.

Same – condition for renewal

(2) It is a condition to renew a license or authorization to provide one or more services under a license that the licensee has paid any fee prescribed under subsection 72(3)(t).

Same, community health facilities

72 (3) The Lieutenant Governor in Council may make regulations governing community health facilities and their licensing and, without restricting the generality of the foregoing, may make regulations,

(t) requiring applicants for a licence, prospective licensees and licensees to pay fees established by an inspecting body for any activity, including any administrative or overhead costs related the activity, that the inspecting body is required to carry out under this Act.

Responsibilities of inspecting bodies

36 (3) Subject to the regulations, an inspecting body has the following powers and responsibilities with respect to the community health facilities provided for in the regulations:

9. Establishing and collecting fees ~~from the operators of community health facilities in respect of the administration of quality assurance programs, the administration of inspection systems and the performance of inspections~~ from applicants for a license, prospective licensees and licensees, for any activity, including any administrative or overhead costs related the activity, that the inspecting body is required to carry out under this Act.

3. Immunity and Non-Compellability of IB staff and agents

The College, as an IB, requires that its staff, agents and members of its governance structures including Council and Committees, be able to perform their duties without the threat of being compelled to provide evidence in civil proceedings, and that these persons be afforded immunity with respect to their activities.

The College's activities are governed and overseen by Council. Physician Council members are elected by members of the College and while public Council members are appointed by the LGIC. It is anticipated that the activities of the College as an IB will be overseen by Council and by Committees at the College. Committee members are appointed by Council.

Currently, the *OHFDA* contemplates only non-compellability with respect to an inspector or a person accompanying an inspector and provides immunity only to inspectors, employees and agents of the IB. This language does not capture Committee members or Council members. Accordingly, amendments are required so that employees, agents, committee members, and Council members are not compellable in civil suits or any proceeding (section 42) and to provide immunity to the IB and such persons against causes of action or proceedings for damages arising from the performance of their duties (section 62).

Proposed Revisions

Not compellable witness

42 ~~An inspector or person who, at the request of an inspector, accompanies an inspector doing anything authorized under this Act~~ A person employed, retained or appointed by an

inspecting body for the purposes of the administration of this Act and a member of Council or a committee of an inspecting body is not a compellable witness in a civil suit or any proceeding respecting any information or material furnished, obtained, made or received by them under this Act while acting within the scope of their duties ~~employment~~.

Protection from liability

62 (1) No action or other proceeding, other than an application for judicial review under the *Judicial Review Procedure Act* or any right of appeal or review that is permitted under this Act, shall be commenced against the Crown, the Minister, the executive officer or any employee or agent of the Crown, including a local health integration network, or any officer, director or employee of a local health integration network or an inspector appointed by the executive officer or an inspecting body or any employee or agent of an inspecting body or person appointed by an inspecting body or a member of Council or a committee of an inspecting body, for anything done or omitted to be done in good faith in the execution or intended execution of a power or duty under this Act.

4. Role of the quality advisor

The *OHFDA* will require community health facilities to have a quality advisor. This quality advisor must be a regulated health professional and must be approved by the executive officer. Pursuant to the Act, the quality advisor is responsible for advising the licensee on the quality and standards of services provided in the CHF. The details regarding the quality advisor's role and responsibilities will be set out in regulation.

Most fundamentally, the College has significant concerns with the ownership structure contemplated by the *OHFDA.* As currently drafted, there is no obligation for the licensee of a CHF to be a physician or a member of a regulatory College. The College's experience with facility regulation in the IHF and OHP context has underscored the challenges of overseeing facilities with non-physician owners. Owners who are not regulated health professionals do not have professional obligations regarding their conduct and practice, which greatly limits their accountability in these areas and the enforcement tools available. The *OHFDA* does not contemplate requiring that licensees be regulated health professionals. The College urges the government to consider the consequences and limitations of allowing non-health professional licensees of CHFs.

The College has a number of specific concerns with regards to the quality advisor role. Those are set out below along with proposed amendments to strengthen the responsibilities of this role:

a) The role of the quality advisor will be a very important one to patient safety and quality care at CHFs, particularly in light of the proposed structure that contemplates licensees who are not regulated health professionals. The Act provides that the quality advisor must be a regulated health professional and is responsible for "advising the licensee on the quality and standards of services at the facility".

There will often be circumstances where the IB has information about a proposed quality advisor because the proposed quality advisor is a member of the IB and/or based on prior inspections or experience with that quality advisor at other facilities. This information may not be public information but may nevertheless be relevant to the appropriateness of the proposed person acting as a quality advisor (e.g. where a member is under investigation by the College). In order to address this potential information gap, the College has proposed an amendment to subsection 28(2)(b) to ensure that both the IB responsible for inspecting the CHF in question and the executive officer must approve the appointment of the quality advisor.

b) Given the importance of the role of the quality advisor, again particularly in light of the proposed structure that contemplates licensees who are not regulated health professionals, the quality advisor must be responsible for providing advice to the licensee not only about the "quality and standards of services" but also about the **safety** of services provided in a CHF. The College has proposed an amendment to subsection 28(3)(a) to this effect.

c) The Act provides that it is the responsibility of the quality advisor to "advise the licensee on the quality and standards of services provided in the community health facility" and that the quality advisor is responsible for "any other functions provided for in the regulations". The College believes that framing the quality advisor's primary responsibility as providing "advice" to the licensee poses two challenges.

   First, the requirement to provide "advice" is not sufficiently strong or concrete to enable the quality advisor's health regulatory college to take action against the quality advisor. The College urges the government to clearly define the quality advisor's specific responsibilities in regulation as contemplated by subsection 28(3)(b).

   The College's OHP Standards regarding the responsibilities of Medical Directors (an analogous role to the quality advisor role in CHFs) provide a potential framework for the specific responsibilities of a quality advisor that should be set out in regulation. At a minimum, these specific responsibilities should include:

   - developing and updating policies and procedures to ensure the safety, quality and standards of services delivered at the facility;
   - ensuring staff are properly qualified and that their training and qualifications are up to date;
   - developing and updating staff job descriptions; and
   - attending and chairing Quality Committee meetings at the Facility a minimum of two times per year.

   The second challenge with the Act, in relation to the role of the quality advisor, as currently drafted is that it leaves open the possibility that the licensee could choose to ignore the advice of the quality advisor and the Act is silent on the responsibilities of a quality advisor in such circumstances. The College has proposed an addition at subsection 28(4) to provide that, where a quality advisor has reasonable grounds to believe that a licensee has not

followed the advice of the quality advisor with respect to the safety, quality and standards of services provided in the CHF, the quality advisor must advise the executive officer and IB.

We urge the government to strengthen and more clearly define the quality advisor's responsibilities and to specify the quality advisor's precise responsibility if he or she has reasonable grounds to believe that the licensee has ignored the quality advisor's advice.

d) The College notes that the quality advisor is likely to be an employee of the licensee. This gives rise to an inherent conflict of interest. A quality advisor may be reluctant to take certain steps or provide certain advice if it would jeopardize his or her employment with the licensee. The College urges the government to consider safeguards regarding this conflict of interest. Again, it would be helpful in this regard to clarify in the Act the quality advisor's responsibility if the licensee does not follow the advice of the quality advisor, as set out at c) above.

e) More generally, there is a lack of clarity regarding the respective accountabilities and relationship between the quality advisor, the quality committee, and the licensee. The quality committee will provide advice to the quality advisor regarding the quality and standards of services provided in the CHF; and the quality advisor in turn advises the licensee. As it currently stands, the reporting structure appears problematic and susceptible to confusion and break-downs in communication and accountability. The College urges the government to clarify the roles, responsibilities, and relationship between the quality advisor, quality committee, and licensee.

Proposed Revisions

Quality Advisor

28 (1) Every licensee and prospective licensee in respect of a community health facility shall, in accordance with the requirements provided for in the regulations, if any, ensure that there is a quality advisor for the community health facility.

Requirements

(2) The quality advisor,

(a) must be a member of a regulated health College;

(b) must be approved by the executive officer and the inspecting body responsible for conducting inspections of the community health facility;

(c) must not be a licensee or prospective licensee, except with the prior written approval of the executive officer; and

(d) must meet any other requirements provided for in the regulations.

Responsibilities

(3) The quality advisor is responsible for,

(a) advising the licensee on the safety, quality and standards of services provided in the community health facility; and

(b) any other functions provided for in the regulations.

Reporting obligation

(4) Where the quality advisor has reasonable grounds to believe that the licensee has not followed the quality advisor's advice to the licensee on the safety, quality and standards of services provided in the community health facility, the quality advisor must immediately report this information to the executive officer and the inspecting body.

5. Adverse Event Reporting

Section 33 of the *OHFDA* contains provisions regarding the establishment of an internal incident review process at CHFs. There is, however, no requirement that licensees report adverse events to the IB.

Adverse events are different from critical incidents. Currently, physicians practicing at OHPs are required, pursuant to a College By-law (Tier 1 events) and to OHP standards (Tier 2 events), to report adverse events to the College within specific time frames. In particular, physicians must report "Tier 1" adverse events (the death of a patient at the facility, death within 10 days of a procedure performed at the facility, any procedure performed on the wrong patient, site or side, or the transfer of a patient from the facility directly to the hospital for care) to the College within 24 hours of learning of the event. Facilities and Medical Directors must report "Tier 2" adverse events (including but not limited to, unscheduled treatment of a patient in a hospital within 10 days of a procedure performed at the facility, complications such as infection, bleeding or injury to other body structures, cardiac or respiratory problems during the patient's stay at the facility, allergic reactions, medication-related adverse events) to the College on an annual basis.

These requirements will no longer be in force with the repeal of the regulation establishing OHPs and accordingly must be independently established in the *OHFDA*.

It is critical that the government include strong and clear language in the Act and regulation about what incidents must be reported to the IB, by whom, accompanied by what information, and within what time frame. The College strongly urges amendments to section 33 to address this issue. Section 36(5), providing that the IB has the power to request certain information from licensees is not an adequate or effective substitute for mandated adverse event reporting.

Proposed Revisions

Incident review process

33 (1) Every licensee and prospective licensee shall, in accordance with the requirements provided for in the regulations, ~~if any,~~ establish and maintain a process for the review of prescribed incidents and the disclosure of information, which may include personal information, if necessary, related to such incidents.

Reporting

(2) Every licensee and prospective licensee shall report prescribed incidents at a community

health facility to the inspecting body responsible for conducting inspections of the community health facility in accordance with the requirements provided for in the regulations.

Schedule 1, *Ambulance Act*

Looking next at Schedule 1, which contains proposed amendments to the *Ambulance Act*, the College supports the underlying objective to enhance efficiencies of the health care system, and to decrease burdens on hospital Emergency Departments. We do however, have some concern and questions with some of the specific provisions through which the objective is achieved. These questions relate to sections 7.0.1 and 8(3) of the Schedule.

1) Section 7.0.1: Expanded Scope of Practice
Section 7.0.1 appears to grant paramedics an expanded scope of practice. Specifically, section 7.0.1(3) seems to contemplate that paramedics will be able to redirect patients to locations other than hospital Emergency Departments, and will be able to treat patients on-scene in accordance with Ministerial directives.

The College recognizes the value of paramedics as providers in the health care system. Paramedics do, however, currently operate within a highly regulated framework in accordance with specific medical directives developed by base hospital physicians. It is unclear whether the Ministerial Directives contemplated in section 7.0.1(3) will be comparable to those developed by base hospital physicians or whether under section 7.0.1(3), paramedics will act with a higher degree of independence and autonomy.

The College notes that in order to make clinically appropriate and safe decisions contemplated in section 7.0.1(3) it is essential that a clinical diagnosis be made. Communicating a diagnosis is however a controlled act under the *Regulated Health Professions Act,* and as such is not something that paramedics are currently authorized to do. The College is concerned that if paramedics are making the decisions contemplated in section 7.0.1(3) in the absence of a diagnosis, patient safety will be compromised.

It is the College's understanding that paramedics are not educated and experienced in performing the tasks contemplated by section 7.0.1(3). Rather, their education is suited to the current regulatory framework, where paramedics act in accordance with specific medical directives and with direction from base hospital physicians. Similarly, the experience gained by paramedics to date is that which they've gained in the current regulatory framework. That framework does not involve paramedics making the types of decisions contemplated by section 7.0.1(3). There is no indication in the Schedule or in government materials that the education requirements for paramedics will be altered in light of this Schedule. The College believes that it is essential that paramedical education be augmented and that all paramedics undergo this extended education before performing the actions set out in section 7.0.1 (3). This is necessary to ensure that quality care can be provided and patient safety assured.

Finally, in relation to the Ministerial Directives referenced in the Schedule, the College is uncertain of the process that will be undertaken to develop these Directives. The College recommends that in order to ensure quality care is provided and patient safety assured, clinical input from physicians with training and experience in Emergency Medicine be sought and incorporated into any resulting directive.

2) Section 8(3): Exemption powers

Section 8(3) of the Schedule allows the Minister to make regulations to exempt persons, services, conveyances, vehicles or equipment from the *Ambulance Act*. This is a very broad exemption power. It alludes to pilot projects, but it is clear that the regulation-making authority is not limited to pilot projects. The College believes that it is essential that any parties, vehicles, equipment and pilot projects that are involved in the provision of patient care must be subject to regulation, and indeed to the same high standards that currently apply in the provision of paramedical care through the base hospital programs.

Schedule 4, *Health Sector Payment Transparency Act, 2017*

The College welcomes this Schedule of the Bill and its requirements for the reporting of 'transfers of value' from payors to prescribed recipients, which we understand will include physicians and other health care professionals. While a detailed review of this Schedule was not undertaken, the College is very supportive of the increased transparency and public reporting and would note that that the requirements contained in this Act are complementary to the expectations set in the College policy, *Physicians' Relationships with Industry*.