Submitted by

College of Physicians and Surgeons
of Newfoundland and Labrador

Submission to the Task Force on Adverse Health Events

June 2008

College of Physicians and Surgeons of Newfoundland and Labrador
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I. Introduction

In any human activity, events will occur that adversely affect the desired outcome. These events may occur for a variety of reasons. They may be foreseen or unforeseen. In either case, they must be addressed.

Health care is no different from any other human activity. As with any other complex human activity, health care involves many components, each of which has a role to play in preventing or avoiding adverse events or outcomes, identifying when they occur and setting a course of action to mitigate the impact they may have on the desired outcome.

The following submission provides observations on the role played by the College of Physicians and Surgeons of Newfoundland and Labrador in adverse events or outcomes as they relate to the practice of medicine. The submission includes recommendations which the College believes the Task Force should bear in mind as it fulfills its mandate.

II. Task Force on Adverse Health Events

The Task Force on Adverse Health Events was appointed in May 2007 to examine how the health system In Newfoundland and Labrador identifies, assesses, discloses, takes action, communicates and evaluates with respect to adverse events.

To fulfill its mandate, the Task Force is responsible for assessing current practices within Newfoundland and Labrador, examining best practices across Canada, identifying case studies, interviewing experts, and consulting closely with regional health authorities and stakeholders.

The Task Force is also responsible for proposing a mandate, structure and budget for the establishment of a health quality council in Newfoundland and Labrador.

III. College of Physicians and Surgeons of Newfoundland and Labrador

The College of Physicians and Surgeons of Newfoundland and Labrador regulates the practice of medicine in the province, in the public interest.

It continues the Newfoundland Medical Board which was established, by legislation in 1893. The mandate and powers of the College are established in the *Medical Act, 2005*.

The College fulfills its mandate in several ways:

1. The College assesses qualifications for registering and licensing medical practitioners.
2. The College sets professional standards for the practice of medicine in the province.
3. The College sets practice policies and guidelines for medical practitioners, including on disclosure of adverse outcomes.
4. The College participates jointly with the Colleges of Physicians and Surgeons in Atlantic Canada in a peer assessment to monitor the practice of medical practitioners through peer assessment review.
5. The College investigates allegations made against medical practitioners which raise a question of breach of professional standards. The results of investigations are presented to a Complaints Authorization Committee (CAC) which determines the disposition of the allegation. In certain cases, the Committee may refer a matter to a hearing before an adjudication tribunal. This is in cases where the CAC has reasonable cause to believe that a medical practitioner has engaged in conduct deserving of sanction including professional misconduct, professional incompetence, conduct unbecoming a medical practitioner, incapacity or unfitness to engage in the practice of medicine, and acting in breach of the *Medical Act, 2005* and the regulations and the code of ethics made under the *Medical Act, 2005.*
6. The College is required to maintain registers for medical practitioners, specialists, medical students, and professional medical corporations.

Given its mandate, the College has a significant interest in adverse medical events or outcomes.

The College's approach starts with the ethical considerations. The practice of medicine in Newfoundland and Labrador is based on the principles expressed in the Canadian Medical Association Code of Ethics which have been adopted by the College. The Code establishes the role of a physician and his or her professional obligations in practicing medicine.

The Code is founded on the belief that health care is best provided in a context in which patients are directly involved in making decisions about their own care. Care is founded on a relationship of trust and confidence between the physician and the patient. The well-being of the patient is paramount.

The Code recognizes that patients have a fundamental right to be informed about their care. They have a right to provide informed consent to care, including being advised in advance of any risks associated with a particular course of treatment.

They also have a right to know of any adverse events. As the Code of Ethics provides:

> 14. Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient.

The College, in the fulfillment of several aspects of its mandate identified above, has as one of its aims the identification and correction of practices and conduct which, if left uncorrected, could lead or contribute to adverse medical outcomes. To the extent possible, the College participates in the Atlantic Province's Medical Peer Review program.

The Medical Act, 2005 provides for peer review with clearly defined goals:

> **54.** (1) The peer assessment committee shall, subject to the approval of the college, develop and administer a peer assessment program that shall include
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> (a) assessment standards of practice for medical practitioners including
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> (i) standards for the clinical assessment and care of patients, and
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> (ii) standards for the maintenance of records of care administered to patients;
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> (b) procedures and requirements for the selection and education of assessors;
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> (c) standards and methods of communication with physicians to be assessed;
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> (d) budgetary and expense arrangements;
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> (e) requirements and methods respecting the preparation of assessment reports;
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> (f) the development of policies and procedures for the peer assessment committee and the delegation of these to subcommittees, assessors or employees as the peer assessment committee considers appropriate; and
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> (g) the determination of further activities including the establishment of other committees and subcommittees to better administer the peer assessment program.

As well, the College has established a policy on adverse events or outcomes to give guidance to physicians on the appropriate response to an adverse event or outcome. The complete policy is included with this submission as Appendix A.
Under the policy, an adverse outcome is defined as "a non-trivial adverse outcome or consequence of health care treatment, which adverse outcome or consequence is not solely related to the course of the illness or condition being treated but has resulted at least in part from the health care treatment itself or from the manner in which the health care was delivered. Adverse outcome includes a situation where the possibility of the adverse outcome may be a recognised risk of the treatment."

The adverse outcomes policy recognizes explicitly that "patients have a right to know their present medical status, not only as an intrinsic right but also so that they may make informed decisions about their health care. Patients have a right to know when an adverse outcome of health care treatment has affected their present medical status."

In addition, other aspects of the College's legal mandate to regulate the practice of medicine may be related to an adverse event or outcome, depending on the nature of the event. In the investigation of an adverse event, authorities other than the College may become aware of issues that fall under the College's mandate. For example, investigation of an adverse event may properly involve the College's complaints and discipline process.

IV. The Task Force Questions and the College of Physicians and Surgeons

The Task Force has requested that written submissions address three specific questions:

Question 1. How can we improve the current approach used by our health and community services system to manage adverse events?

Question 2. In particular, are there gaps in how the system identifies, assesses, discloses, and takes action on adverse events?

Question 3. Are there gaps in how the system coordinates and communicates when it is managing an adverse event?

Following are general observations which can be made on the role of the College and which may be useful in developing a system for responding to adverse events within the health care system.

The essence of the relationship between a physician and patient as envisaged by the Code of Ethics, and the College's policy on adverse outcomes, is open communication. This has been discussed above.

Given that health care is delivered in the province through a system of agencies, professions and individuals, any policy on adverse events or outcomes should be founded

on a relationship among agencies which includes the same exchange of necessary information as should occur between a physician and patient.

That is, there must be a relationship of trust and confidence which recognizes the roles each agency, profession and individual plays in the health care system. The regional health authorities may have an undoubted and critical role based on their size and the scope of their responsibilities. However, other organizations, including the College have a role to play in preventing adverse events or in responding to them.

Licensing: The College's role in regulating the practice of medicine is intrinsic to the provision of health care, especially through the College's role in assessing the qualifications of physicians for licensure.

Assessments and reporting requirements: As well, assessments of physician competence through peer review either conducted through the Peer Review program of the College or through a review internal to the regional authorities may reveal issues related to the licensing of physicians that should be communicated to the College promptly so that necessary changes can be made.

It is the understanding of the College that, by current law, the College cannot be apprised of the detailed results of peer reviews. However, the College believes it is important that regional health authorities be able to provide sufficient information to permit the College to act upon its mandate, in particular where such reviews give rise to questions of professional misconduct or competence, without compromising the integrity of the peer review process.

Section 36 of the Medical Act, 2005 presently requires medical practitioners to report to the College circumstances where they have knowledge of conduct deserving of sanction by a medical practitioner. The College suggests that consideration should be given to whether other agencies, such as the regional health authorities, should also have a statutory requirement to report such circumstances to the College, and that further consideration be given to whether and how information learned in the course of peer review, peer assessment and other quality assurance processes could be included in such reporting to the College.

Complaints and Discipline: The regional health authorities acknowledge the role of the College in addressing complaints about professional practice, typically, through the medical by-laws under which the authorities operate.

It should be understood that, in many respects, the complaints and discipline process often functions as a form of quality assurance. The investigation of allegations and the discipline process are also integral to quality assurance in the delivery of health care, including by the identification and correction of practices and conduct which cause or contribute to, or have the potential to cause or contribute to, adverse outcomes.

This may be most apparent in those cases which proceed to a hearing before an adjudication tribunal. The hearings are presumptively public. Where there is a finding of serious misconduct, the tribunal decision must be published, and thereby serves an educational function for the whole of the profession. Even where there is not a finding which requires publication, the issues arising from the hearing may form the basis for a notice to the profession on professional conduct and practice.

Even where there may not be reasonable grounds to proceed to a hearing, as determined under the Medical Act, 2005, the Complaints Authorization Committee, comprising a minimum of two medical practitioners and one lay person, follows a practice (a continuation of one developed by the Newfoundland Medical Board) of providing detailed reasons for the Committee's decision and where appropriate issuing advice, caution or counsel to the medical practitioner. Receiving such advice, caution and or counsel may carry considerable weight in the mind of the practitioner and there may be occasions when this is more valuable than a peer review as most would understand that term.

While many observers may view the allegation investigation and discipline process of the College as being solely punitive, in practice, it is most often positive and corrective in the fashion akin to that of a peer review. Regional health authorities and others should bear this in mind as they develop procedures to deal with adverse health events.

Further Initiatives: The College is also pursuing other initiatives which are aimed at assuring professional standards, and by extension serve to identify and correct practices and conduct which could cause or contribute adverse outcomes. One of these initiatives is the recent making of a Code of Ethics By-Law of the College. Another is the College's participation in the development of a Provider Registry as part of an electronic Pharmacy Network. The College has also corresponded with the Department on the subject of quality assurance, and in particular revalidation of the credentialing of practicing physicians. A copy of the College's correspondence to the Department on this issue is attached as Appendix B.

Conclusion: In responding to an adverse health event, regional health authorities and other authorities should be mindful of the full spectrum of response. There are aspects which are entirely within the mandate of the authority. However, other aspects may fall to the College as a result of responsibilities set out in law. The College also has explicit or implicit obligations to others, including its counterpart Colleges across the country.

It is with those ideas in mind, that the College makes the following observations.

While immediate action may be taken to address an adverse event, in the overall process, certain issues can and should be referred to the College for assessment of the medical component of any incident. The College can provide professional advice to physicians and administrators individually or collectively on the medical regulatory (ethical and policy) aspects of any issue. These sorts of consultations currently take place, however, it

is timely to remind those who are not physicians that the College is available to provide this assistance.

Where adverse events trigger an investigation or review within a regional health authority, College should be advised of results of investigation so that it may take its own action, if needed, based on its own legal responsibilities to public.

In many instances, the result may not involve the College's complaint and discipline process even though this may sometimes be the one aspect of the College's role which comes foremost to some minds.

There may be regulatory or policy direction to be given as a result of adverse events that would be beneficial to all physicians. The College may wish to review and amend some aspect of its credentialing process, in some instances. There is no way of anticipating all the possible ramifications of every event, however, as a general principle, the College can only take action to fulfill its mandate if it is properly informed.

Appendix A: Disclosure of an Adverse Outcome

The purpose of this guideline is to affirm the College's position that patients are entitled to be informed of all aspects of their health care. This right to be informed includes the right of a patient to disclosure of an adverse outcome in the course of receiving health care.

The disclosure of an adverse outcome, in accordance with this guideline, is not about attributing or admitting any fault or blame. In the view of the College, an adverse outcome will not necessarily be the result of negligence or incompetence.

Scope

This guideline applies to all medical practitioners, and all medical students and residents whose names are entered on the Educational Register, who become aware, while treating a patient, that the patient has suffered an adverse outcome in the course of receiving health care.

Meaning of "adverse outcome"

Of course, medical practitioners have always been expected, and should continue, to disclose adverse outcomes which can be said to be one of the possible consequences of an illness.

However, for the purpose of this guideline, adverse outcome means a non-trivial adverse outcome or consequence of health care treatment, which adverse outcome or consequence is not solely related to the course of the illness or condition being treated but has resulted at least in part from the health care treatment itself or from the manner in which the health care was delivered. Adverse outcome includes a situation where the possibility of the adverse outcome may be a recognised risk of the treatment.

"Adverse outcome" should be understood to mean not only a non-trivial adverse outcome or consequence of health care treatment which manifests itself in the course of or following health care treatment, but also an incident in the course of health care treatment which results in a recognized potential risk of a non-trivial adverse outcome or consequence at some future time. Such potential future adverse outcome may require the arrangement for appropriate follow-up surveillance, and perhaps other departures from the usual care plan. An example of such a potential adverse outcome would be the disclosure to a patient that an earlier test had detected a carcinoma, but that the information had apparently not been acted upon. Another example would be where damage is accidentally caused to tissues in the course of surgery, which damage is repaired in the course of surgery, but where even with such repair there is a recognized potential risk of future complications from the damage and/or repair.

Patients' right to disclosure

Patients have a right to know their present medical status, not only as an intrinsic right but also so that they may make informed decisions about their health care.

Patients have a right to know when an adverse outcome of health care treatment has affected their present medical status.

Leaving it to a patient, a substitute decision maker or another health care provider to discover or act upon an adverse outcome is not consistent with the rights of patients outlined above, and in some circumstances the resultant delay may do harm to the patient.

The responsibility to disclose

The medical practitioner who was the most responsible physician for the health care treatment during the course of which the adverse outcome occurred, should disclose the adverse outcome to the patient.

In some circumstances, it may be that more than one medical practitioner was responsible for the health care treatment, which resulted in the adverse outcome. In such circumstances, each responsible medical practitioner has an individual responsibility to ensure that disclosure is made to the patient of the adverse outcome. In such circumstances, the responsible medical practitioners should consult as to who among them will make the disclosure to the patient.

Where another medical practitioner believes there has been an adverse outcome from health care treatment for which that practitioner was not responsible, that practitioner should advise the most responsible physician in relation to that treatment of the practitioner's belief that there may have been an adverse outcome and that this guideline may apply to the situation.

A medical student or resident should disclose an adverse outcome to his or her clinical teacher or supervisor. If the clinical teacher or supervisor is not the most responsible physician for the affected patient, then the clinical teacher or supervisor should ensure that the most responsible physician is informed of the adverse outcome. Upon becoming aware of the adverse outcome, the most responsible physician should disclose the adverse outcome to the patient.

In addition to this guideline, hospitals and health care facilities may have their own procedures for disclosure of adverse outcomes or similar situations to patients, which procedures should also be followed. Where it appears that this guideline may conflict with procedures established by a hospital or health care facility, medical practitioners are encouraged to contact the College to discuss how such apparent conflict may be resolved.

Persons to whom disclosure should be made

Whenever possible, disclosure of an adverse outcome should be made directly to the affected patient.

Where the patient is not competent or where meaningful disclosure of the adverse outcome directly to the patient may not be possible due to the medical condition of the patient, disclosure of the adverse outcome should be made to the patient's authorized substitute decision maker.

The time for disclosure

Where harm or deterioration of condition may result unless there is immediate disclosure of the adverse outcome, the medical practitioner should disclose the adverse outcome with the according urgency, to either the patient or an authorized substitute decision maker.

Where the disclosure of an adverse outcome is not as urgent, the medical practitioner may consider whether it is appropriate to wait until a patient's condition has stabilized sufficiently so that he or she can be expected to reasonably understand the information, provided any delay is in the best interests of the patient.

A medical practitioner may wish to seek the advice of colleagues, of the College or of the medical malpractice protection provider before disclosing an adverse outcome to the patient. Such advice should be sought promptly and should not result in undue delay in disclosing the adverse outcome to the patient.

The manner of disclosure

Disclosure to the patient directly should first be considered. The setting for the disclosure should afford the patient privacy. The patient should be offered the opportunity to be accompanied by a support person. The medical practitioner himself or herself may want to have a support person present.

The adverse outcome should be factually described, with care taken to explain medical terminology so that it is understandable by the patient. Speculation or conjecture should be avoided, and the practitioner may respectfully decline to respond to questions or comments from the patient which invite speculation or conjecture.

Options for treatment to address the adverse outcome should be raised. The patient should be told when such treatment or a second opinion may be able to be provided, or should be provided, by another practitioner.

If upon commencing disclosure, it becomes evident that the patient is unable or unwilling to continue the discussion, the medical practitioner should offer to continue or resume the discussion at another time. In some circumstances, the patient may want to have the

disclosure made to an authorized substitute decision maker or in writing, and the practitioner should give due consideration to such requests.

Details of the adverse outcome and of its disclosure to the patient should be documented in the patient's record. Where necessary for the observation or treatment of the patient, the patient's family doctor or other treating physicians should also be informed of an adverse outcome.

Disclosure of an adverse outcome is not an admission of fault or liability

Findings of fault and liability are subject to legal principles of proof and causation. These issues cannot be resolved in a discussion between doctor and patient.

While a medical practitioner should be factually candid in describing the adverse outcome, the practitioner should also be prepared to be equally candid with the patient that the disclosure should not be considered an admission of fault. Should the patient raise questions of fault or liability in the course of the disclosure of an adverse outcome, the patient should be advised that such questions should be discussed with the patient's own legal advisor.

Comments to a patient which may be taken as attributing blame to other health professionals should be avoided.

In circumstances where questions of fault or negligence may give rise to a claim for damages or litigation, a medical practitioner may wish to first seek the advice of the medical malpractice protection provider as to how disclosure of an adverse outcome may be made without it being taken to be an admission of fault or liability.

Within the foregoing context, an expression of regret for the adverse outcome may be appropriate, and should not be taken as an admission of fault or liability.

A patient to whom an adverse outcome has been promptly, candidly and sensitively disclosed may be less likely to pursue litigation or other means of redress.

Summary

- Consider who is the "most responsible physician" for the health care treatment during the course of which the adverse outcome resulted.
- Where more than one medical practitioner is a responsible physician for such care, consultation amongst those practitioners should take place.
- Disclosure should be made promptly.
- The advice of colleagues, of the College, and/or of the medical malpractice protection provider may be sought prior to disclosure, provided this does not result in undue delay.
- The adverse outcome should be factually described; speculation should be avoided.

- Options for treatment to address the adverse outcome should be raised with the patient, including the possibility of obtaining a second opinion from another medical practitioner
- Details of the adverse outcome and of its disclosure should be documented in the patient's record.
- Be prepared for a patient being unable or unwilling to continue with a discussion of adverse outcome, and offer the option of resuming the discussion at another time.
- Be prepared to be frank that disclosure of the adverse outcome is not an admission or attribution of fault or liability.

THE COLLEGE OF PHYSICIANS AND SURGEONS
OF
NEWFOUNDLAND AND LABRADOR
Continuance of the Newfoundland Medical Board - 1893

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October 26, 2007

Dr. Edgar Wilson Hunt
Dept. of Health & Community Services
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Dear Dr. Hunt:

Re: Quality Assurance Initiatives: Non-Hospital Surgical Practice and Physician Revalidation

With reference to the undersigned's recent meeting with yourself, Dr. Cathi Bradbury and Dr. Blair Fleming of your Department, the College is writing at this time in furtherance of two quality assurance initiatives that are being considered by the College. The quality assurance initiatives under consideration are the regulation of non-hospital surgical practice (including, but not limited to, plastic surgery and cosmetic surgery performed outside of the hospital setting) and physician revalidation (the maintenance and demonstration of ongoing competence to practice).

The College's review to date indicates that, at minimum, regulations, requiring the Minister's approval, will be necessary to implement these quality assurance initiatives. It may also be necessary or desirable to amend the *Medical Act, 2005*, to more clearly delineate the College's authority to regulate on matters of quality assurance. Therefore, the College believes it to be important to consult with your Department, at this early stage in the development of these initiatives.

We discuss below the proposed quality assurance initiatives.

Non-Hospital Surgical Practice

Other Canadian Colleges of Physicians and Surgeons are regulating, or are considering regulating, non-hospital surgical practice. The recent death of a patient who underwent cosmetic surgery in a non-hospital setting in Ontario received national media attention, and has led to calls for greater regulation in this area of practice.

The College is aware that the College of Physicians and Surgeons of Alberta (CPSA) is already extensively involved in accrediting non-hospital surgical facilities. In Alberta, all non-hospital diagnostic and treatment facilities, in which medical and surgical procedures are deemed by the CPSA as having a sufficient risk of potential harm to a patient, must register and maintain accreditation by the CPSA as a non-hospital surgical facility.

The College at this time has no effective means of regulating the practice of fully licensed physicians who offer non-hospital surgical services, short of being able to consider egregious breaches of standards of practice as professional misconduct. In the view of the College, the discipline process is neither appropriate nor sufficient to address quality assurance issues in relation to non-hospital surgical services which may fall below the threshold of conduct deserving a sanction, but nonetheless deserve regulatory attention for the better protection of the public. In the view of the College, quality assurance should be a matter of being proactive in identifying problems and potential problems, before they rise to the level of conduct deserving of sanction.

Effective regulation of non-hospital surgical practice would require that the College be provided with the means to accredit and audit non-surgical hospital practices. As the accreditation and auditing of non-hospital surgical practices engages areas of public policy including not only regulation of the profession, but also regulation of commercial activity (many of the non-hospital surgical services offered are non-insured), access of the public to non-hospital surgical services, and the confidentiality of patient information, the College believes that it is necessary that amendment to the *Medical Act, 2005* be considered, to provide the College with clear authority to regulate in this area.

The issues arising out of regulation of non-hospital surgical practice are many, and we will not attempt to summarize them all here. However, the College does propose that a working group be established, with representation from the College, your Department, and possibly other stakeholders as may be identified, to be tasked with developing a regulatory regime for non-hospital surgical practice.

Physician Revalidation

The College has previously made reference to this quality assurance initiative, in the College's 2006-2007 Annual Report to the Minister.

Professional revalidation of physicians is an issue which has been reviewed by the Federation of Medical Regulatory Authorities of Canada (FMRAC), culminating in FMRAC's Position Paper of July 4, 2007. The Position Paper defines revalidation as a quality assurance process in which physicians are required to provide satisfactory evidence of their commitment to continued competence in their practice.

The FMRAC Position Paper identifies the issues in relation to physician revalidation as follows:

> *The public places its trust in the medical regulatory authorities to license physicians who, in turn, are expected to remain competent throughout their practice lifetimes.*
>
> *The practice of medicine, including the treatment and prevention of illness, is in constant evolution. Therefore, physicians must be committed to participating in lifelong practice reflection and continuing professional development.*

The demonstration of ongoing competence and performance of physicians is a pillar of professional self-regulation.

The FMRAC Position Statement on physician revalidation is as follows:

All licensed physicians in Canada must participate in a recognized revalidation process in which they demonstrate their commitment to continued competent performance in a framework that is fair, relevant, inclusive, transferable and formative.

While the FMRAC Position Statement is not binding on FMRAC's members (which include all of the Canadian Colleges of Physicians and Surgeons), this College does support the Position Statement, and we believe that it is also supported by most, if not all, of the other Canadian Colleges of Physicians and Surgeons.

As identified in the 2006-2007 Annual Report to the Minister, work remains to be completed to build a consensus around the concept of revalidation. To that end, it is the intention of the College to release its own Position Statement on revalidation in early 2008, for the information and comment of the profession and other stakeholders. As part of that Position Statement, the College would intend to give notice of its intention to develop, in consultation with your Department, regulations regarding revalidation. Naturally, however, we do not wish to embark on such a process without preliminary consultation with your Department to confirm that there is a consensus between the College and your Department on this quality assurance initiative.

While it might be ambitious, it is the College's goal to seek to have in force the necessary regulations, and any necessary amendments to the *Medical Act, 2005*, by the end of 2008, so that the revalidation process will begin to be applicable to new licensures and renewal of licensures in 2009.

Final Comments

As has been adverted to above, the College believes it will be necessary or desirable to make amendments to the *Medical Act, 2005*, to be able to effectively carry out these quality assurance initiatives. We note that the amendments to the *Act* in 2005 focused almost exclusively on the discipline process, and were made with the understanding that further amendments with respect to licensing and other regulatory matters still remained to be considered.

While the final form and shape of these quality assurance initiatives may take some time to develop, the College also recognizes that amendments to legislation can be a protracted process. Therefore, the College believes that the process of identifying necessary or desirable amendments to the *Medical Act, 2005* should be started as soon as possible, so that the necessary drafting and introduction of the appropriate Bill or Bills in the House can be reasonably expected to coincide with the proposed timeframe for implementation of these initiatives by the end of 2008. The College, therefore, hopes to hear from your Department in the near future regarding the above-proposed

initiatives. As always, we would be pleased to meet with you or other Department representatives, at your convenience.

Sincerely yours,

Robert W. Young, MD, FRCPC
Registrar

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