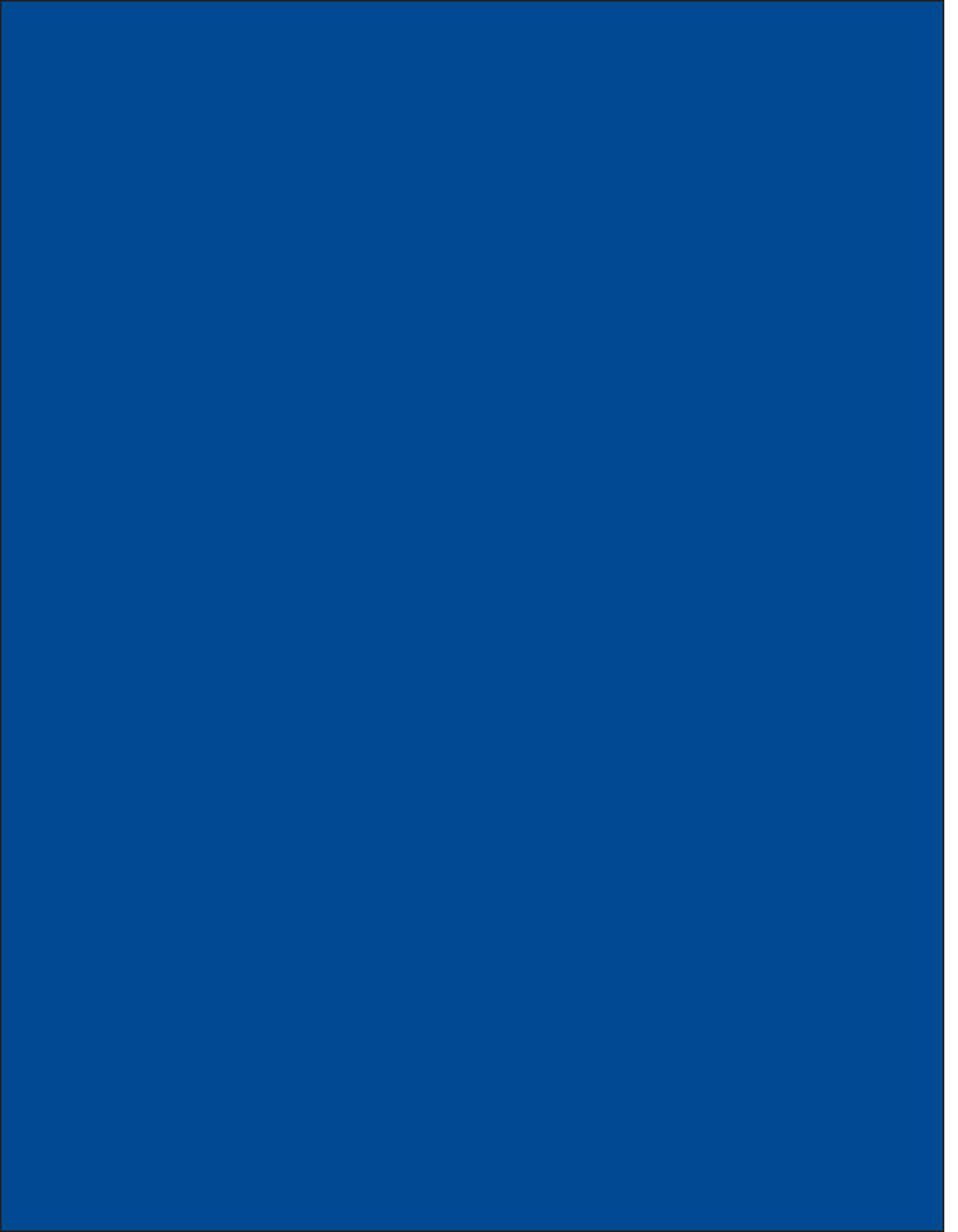


Medical Regulatory Authorities and the Quality of Medical Services in Canada and the United States



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Federation of Medical Regulatory
Authorities of Canada

Federation of State
Medical Boards

Milbank Memorial Fund

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territories, including fourteen state boards of
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FOREWORD

In this report leading regulators of the medical profession in Canada and the United States assess the relationship between quality improvement and the current responsibilities of authorities that license and discipline physicians. The participants in this project are strongly committed to medical regulatory authorities taking a more expansive role in maintaining and improving the quality and safety of physicians' services. They make provocative and, to us, compelling recommendations to their colleagues and to the medical profession more generally, on the basis of their analysis of the historical and current status of regulation and of a survey of authorities in both countries, which they had planned and analyzed in order to inform their discussions.

This report deserves to be discussed widely among regulators and leaders of the organizations that educate, examine, certify, license, and represent physicians. Many of the points the collective authors make could also be usefully discussed with policymakers in the provinces and the states, and jointly with regulators of other health care professions.

The report began as a conversation between a regulator and a colleague at the Milbank Memorial Fund (MMF), an endowed philanthropic foundation established in 1905 to help decision makers bring the best available evidence and experience to bear on policy for health care and population health. The conversation expanded to include leaders of the Federation of State Medical Boards (FSMB) of the United States and the Federation of Medical Regulatory Authorities of Canada (FMRAC). The federations selected participants in the meetings that led to this final report.

We thank everyone who participated in this project and in particular the six volunteers who wrote the report. Their names are listed in the Acknowledgments.

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EXECUTIVE SUMMARY

The Federation of State Medical Boards (FSMB) in the United States, the Federation of Medical Regulatory Authorities of Canada (FMRAC), and the Milbank Memorial Fund (MMF) convened thirty medical regulators from both countries in 2006 in order to explore innovative ways for regulatory bodies to increase their capacity to protect the public and improve health care quality and safety. After sharing pertinent experiences, participants recommended that the FSMB and FMRAC survey all member boards and colleges about their work to protect the public, initiatives currently operated by medical regulatory authorities (MRAs), and their opinions about how MRAs could be more effective in the future. Members of the group met again in mid-2007 to assess the results of the survey and their implications for regulatory policy.

Fifty-six respondents completed the survey: forty-three respondents representing forty-three of the seventy FSMB authorities, and thirteen respondents representing twelve of the thirteen FMRAC member authorities. The survey identified considerable variance in the scope and intensity of current efforts of state and provincial regulators to improve health care quality. Moreover, the regulatory authorities that completed the survey expressed their willingness to explore innovative ways to enhance the effectiveness of regulation as a method for improving the quality of medical practice. Many respondents said, however, that resource constraints and statutory limitations within their jurisdictions impeded their ability to expand their activities.

This report presents the results of the survey in the context of the history of medical regulation. Then its collective authors propose a “value proposition” for physician-led medical regulation. They describe the implications for policy arising from the survey and close with questions for their colleagues in medical regulation to ponder and then discuss with their professional colleagues and policymakers in their jurisdictions.

**THE HISTORICAL AND CONTEMPORARY CONTEXT
OF THE REPORT**

The practice of medicine has for millennia offered the hope and promise of benefit as people struggle with disease and suffering. Medicine’s potential for benefit has, however, always been tempered by potential for harm.

Advances in the sciences and their applications have in recent centuries increased the capacity of physicians to intervene to reduce the incidence and alter the course of disease. The proliferation of potentially useful medical interventions has, however, also resulted in greater risk of harm.

As medicine evolved from a craft into a learned profession, practitioners took responsibility to mitigate the risk of harm associated with medical practice. Codes of ethics and conduct and discipline by peers became accepted methods of reducing harm. Medicine, once a guild of interested parties with few or no rules or regulations, is now an increasingly regulated, peer-reviewed, evidence-based profession.

According to historians of medicine, government and civil society eventually recognized that voluntary physician compliance with codes of ethics written by leaders of the profession did not sufficiently protect citizens from risk. Various models for statutory regulation of medical practice therefore emerged.

Authority to regulate professionals in Canada and the United States is vested in the governments of states, provinces, and territories. Each of these jurisdictions has established a legislative mechanism to regulate access to the privilege of practicing medicine. The governing bodies of these medical regulatory authorities are populated with both physicians and non-physicians. This arrangement is often described as “physician-led regulation” in acknowledgment of the fact that physicians enjoy a majority position at the governing tables of these statutory medical regulatory authorities. While the degree of involvement by public members in day-to-day oversight of the operations and decision making varies among jurisdictions, in most medical regulatory authorities there is board-level oversight of organizational operations. There is almost always public member representation on those bodies whose job it is to consider allegations against physicians.

Through voluntary participation in the Federation of State Medical Boards (FSMB) and the Federation of Medical Regulatory Authorities of Canada (FMRAC) the state medical boards and Canadian Colleges of Physicians and Surgeons strive to ensure uniformly rigorous and effective regulation across the United States and Canada. While there are significant differences between models of regulation in the United States and Canada, the FSMB and the FMRAC continually endeavor to gain new insights with respect to the effectiveness of regulatory practices and to share these insights with their members.

Statutory medical regulatory authorities (MRAs) in Canada and the United States have, since their inception, sought to protect the public from harm associated with medical care. However, recent research on patient safety and on the quality of health care has yielded a new understanding of the risks associated with health services. This research emphasizes a systems approach to understanding and addressing adverse medical events rather than acknowledging only individual accountability. The findings of this research reinforce the need for effective physician-led regulation in medicine.

The findings also challenge medical regulators to develop new strategies that continue to reduce harm and that also enhance quality and safety.

A primary purpose of statutory medical regulation has always been to identify persons qualified to practice the profession so that the public can differentiate them from those who are not qualified. The task of identifying the professionally qualified practitioner has changed immensely over the past century. Medical education reforms initiated by the profession and then accelerated by Abraham Flexner's landmark report to the Carnegie Foundation for the Advancement of Teaching in 1910 initiated the implementation of uniform standards of medical education in all U.S. and Canadian medical schools. Undergraduate medical education in both countries became subject to joint accreditation by the Liaison Committee on Medical Education (LCME) and the Committee on Accreditation of Canadian Medical Schools (CACMS). The accreditation of postgraduate medical education, while not jointly conducted, adheres to substantially similar standards in both countries. In addition to these rigorous accreditation organizations, independent evaluating authorities, such as the National Board of Medical Examiners and the Medical Council of Canada, subject all U.S. and Canadian graduates to standardized testing of medical knowledge and clinical skills required for the practice of medicine.

Although eligibility for medical licensure in many jurisdictions in Canada and the United States is not statutorily linked to specialty certification, achievement and maintenance of such certification have become a professional norm for most physicians in both countries. As a result, after completing accredited residency programs, most physicians educated in Canada and the United States are evaluated and, if successful, certified to have satisfactorily completed the requirements of their specialty associations—the Royal College of Physicians and Surgeons and/or the College of Family Physicians of Canada and specialty boards in the United States (for example, the American Board of Medical Specialties and the American Osteopathic Association's Bureau of Medical Specialists).

Assessing the qualifications for practice of physicians educated outside Canada and the United States is a considerably more complex task. The Educational Commission for Foreign Medical Graduates (ECFMG) in the United States and the Medical Council of Canada assure that international medical graduates have knowledge and skills comparable to those of graduates of Canadian and U.S. medical schools before they enter postgraduate education in either country. The assessments by these bodies focus on the testing of knowledge of medicine and, to the extent possible, testing of other attributes, such as communication skills and legal, ethical, and professional aspects of medicine. However, the application of that knowledge in the clinical arena—what physicians actually do in practice—is beyond the capabilities of such tools.

In their early history most regulatory authorities believed they had discharged their duty to protect the public once they had determined an applicant to be eligible for licensure. While mechanisms for investigating complaints against physicians by members of the public or by their colleagues evolved over time, once licensed, only a small percentage of physicians were suspended or removed from practice for cause. The number of medical errors that do occur and the variation in

risk-adjusted outcomes that is otherwise unexplained, however, have suggested that a change in the regulatory paradigm is needed from a primarily reactive one to one that is more proactive and systems-based.

Medical regulatory bodies currently confront complex challenges that include:

- The accelerating pace of scientific research and technological advancement creates the need both to ensure that physicians' knowledge and skills remain current and to assure the public of that currency.
- Understanding is increasing but still insufficient about ways to reduce risks to patient safety from physicians who are impaired as a result of chemical dependency and other illnesses.
- As the number of regulated health care professions and their degree of specialization increase, so does substantial overlap in the competencies of their practitioners.
- As health care becomes more complex, effective practice requires collaboration with persons in different specialties and professions.
- A consequence of team-based health care is that outcomes are more significantly influenced by the performance of team members and the institutions they reside in than by the efforts of individuals.
- The growth of team care makes it increasingly necessary for bodies that regulate different professions to collaborate with one another as well as with other authorities of government and of the health sector.
- In the environment of health care teams, reliable and effective communication between members is a major determinant of patient safety.
- Systemic sources of risk significantly eclipse professional incompetence as the dominant cause of harm to patients.
- Medical regulatory authorities are expected to remove or otherwise correct incompetent or unethical doctors, while striving to avoid a "name and blame" approach to their work in recognition of the systemic factors underlying most adverse events and in fairness to physicians and other health care workers who have been found at the "sharp end" of such events yet not found to have been individually responsible. Stigmatizing health care professionals by blaming them for inadvertent errors often impedes the search for root causes of such errors and limits our capacity to mitigate systemic risk.
- Most of the resources of medical regulatory authorities have historically been allocated to essential reactive strategies, such as investigating complaints, conducting disciplinary hearings, and imposing sanctions. This commitment of scarce resources to a disproportionate focus on these strategies limits the capacity of regulators to participate in proactive systemic strategies to enhance safety and improve quality.
- A major constraint on innovation by medical regulators is variation in the funds available to them as a result of differences in the annual fees physicians pay to maintain licensure.

THE VALUE PROPOSITION FOR PHYSICIAN-LED REGULATION

After agreeing about the scope and significance of the historical and contemporary issues described in the previous section, the regulators who wrote this report discussed a value proposition for the field. This value proposition offers answers to three questions:

- What value does physician-led regulation offer to society?
- Does that value justify the continuation of physician-led regulation?
- What difference would it make if policymakers created a new regulatory model?

Government and the medical profession have for centuries regarded physician-led regulation (now conducted through public authorities) as the optimal mechanism to protect the public. Physicians have viewed such regulation as necessary to insure proper professional governance, and especially maintenance of clinical autonomy. In exchange for controlling regulation, physicians and their professional organizations accepted accountability for their professional acts. Society has granted confidence and trust to the medical profession, which the profession must validate through public accountability. Central to this accountability has been the obligation of physicians to place the interests of their patients above their own.

Many members of the public and their representatives in government are, however, no longer willing to accept on faith professional assertions of accountability and the priority of patients' interests. In Great Britain, for example, failures of medical regulation have resulted in severe restrictions on professional governance. Where, historically, trust in professional probity justified the autonomy of practice and regulation, actual evidence of accountability is now being demanded. Freedom of professional action, including regulatory action, appears to be at stake.

Physicians who are the leaders of the medical regulatory authorities have traditionally seen themselves as bringing unique capabilities to work in which they serve the public interest. These capabilities begin with recognizing that the public benefits from a physician workforce that is professional in all domains of professional action, not solely in the "technical" application of scientific information and methodology. Professionalism also requires physicians and their regulators to be accountable for their legal, ethical, and fiduciary obligations to their patients and the public. Moreover, the public benefits when the regulatory process maximizes physicians' sense of fulfillment and self-efficacy.

The value proposition this report sets forth is that proper regulation of the medical profession should demonstrate the following characteristics:

- Physicians, as individuals and through organizations of the profession, should make clear that they recognize their ethical obligation to set high standards. Standards that are established collectively by a profession for the conduct of its members should be *higher* than those others would set
 - because of concern for the care of patients and a sense of duty
 - because of the recognition that the privileged role of the medical profession and of individuals within it is best justified by the setting and maintenance of high standards

- because standards of action within the domain of the profession can only be properly understood and set by practitioners themselves, who are the validated experts in the field
- Physicians and organizations of the profession should make clear that beyond the theoretical obligation to set high standards, the very fact of direct involvement in the practice of medicine creates an objective expertise that is *required* to regulate effectively and fairly. Given this obligation and involvement, they have a responsibility to participate actively in the regulatory process, indeed to provide the leadership for such processes as members of regulatory bodies.
- The profession, collectively, is uniquely positioned to understand the exigencies of actual practice, including
 - the importance and use of clinical judgment based on context, experience, and knowledge and hence the inadequacy of black and white, rules-based thinking
 - the need to act prudently and compassionately in the face of uncertainty and fraught circumstance
- Physician-led regulation should continuously incorporate the use of scientific evidence and experience in decisions about physicians and their practices.
- The profession should recognize and accommodate patients' and public perceptions into regulatory decision making. This important progressive shift in regulatory attitude is reflected in the change in language from the former terminology of "self" or "autonomous" regulation to physician-led regulation.
- Only under a regime of physician-led regulation do regulators have the capability and confidence to exercise appropriate clinical judgment about the risk to patients by physicians who are impaired by illness of various kinds (e.g., mental illness, substance abuse, chronic disease) and to determine the capacity to return to practice of physicians who have demonstrated problems in clinical care (e.g., faulty reasoning, inadequate knowledge and skill, poor judgment).
- Physician-led regulation, by virtue of its dedication to the application of medical knowledge and skill in the public interest, should be free of fiscal and political exigencies that can constrain government-led regulation in other areas of policy. The traditional rationale for physician-led regulation (i.e., the willingness and ability to set high standards in the public interest) is now challenged by the public expectation of accountability for the actual achievement of standards. Medical regulators must go beyond the simple "assertion" of capability to provide evidence of the maintenance of accepted standards in both the processes and outcomes within their regulatory domain.

FINDINGS FROM THE SURVEY

The fifty-six respondents (representing twelve Canadian authorities and forty-three U.S. authorities) who returned the survey provided evidence, in summary, that:

- Although each authority examines competency at initial licensure, there is substantial variation in what authorities do to monitor competence at re-licensure.
- Although each authority accords high priority to investigating complaints about physicians' behavior, and each imposes sanctions, the scope and methods of programs of remediation vary significantly.
- Many authorities have programs to improve quality and many others report that they would like to begin such programs. But a considerable number of authorities report that they are not interested in or lack the capacity to offer new programs to improve quality or do not have the statutory authority to do so.

More details of what respondents reported follow, arrayed according to the questions in the survey, which are listed in the Appendix.

INITIAL LICENSURE / REGISTRATION

Authorities in both countries report taking similar actions to evaluate competency at the time of initial licensure or registration. The entry-level competency of physicians is assessed at such time in a relatively uniform manner, using both objective and subjective parameters. Requirements for graduates of Canadian and U.S. medical schools include graduation from an accredited medical school, successful completion of one or more years of an accredited residency program, and passage of an obligatory exam (the United States Medical Licensing Examination [USMLE] or the Medical Council of Canada Qualifying Examination [MCCQE]) within a specified time frame (and generally with a limited number of attempts at successful completion). It is expected that in answering any required personal history questions the physician will be honest and provide complete information.

Proof of good standing is also required of applicants for licensure, for example, by asking residency directors, employers, and hospital staff as well as regulatory authorities where the candidate was previously licensed to provide verification of competency and performance.

RENEWAL OF LICENSURE/REGISTRATION

While all the survey respondents reported that their authorities examine and attempt to ensure competency at the time of initial licensure, there is substantial variation in what medical regulatory authorities do to monitor competence at renewal of licensure. Of the fifty-six respondents, only twenty-two reported that they examine competency at the time of renewal.

Currently, the primary method of providing any assurance of ongoing competency in both countries is through attestation or an audit of the licensee's continuing education hours and review of

the physician's response to questions about personal history. Thirty-seven of the fifty-six respondents mandate continuing education. The underlying assumption is that participation in continuing education courses is required for maintenance of competence. States that require continuing education as a condition of ongoing licensure vary in the number of hours needed. In Canada, regulatory authorities are in the process of implementing revalidation requirements that will include, but not necessarily be limited to, mandated continuing education. The number of hours needed generally coincides with those required for ongoing membership/fellowship in the two certifying medical organizations, namely the College of Family Physicians of Canada and the Royal College of Physicians and Surgeons of Canada.

Generally the license is renewed and a subsequent audit of a certain percentage of the licensees is performed by the medical authority. Failure to substantiate compliance with the continuing education requirement may result in sanction of the noncompliant physician.

Most jurisdictions specify a period of absence from active practice after which the physician may not reenter practice without further scrutiny. If at the time of license renewal a physician reports in the personal history questions that he or she has been out of practice for an amount of time exceeding the limit for a given jurisdiction (usually two to three years), the regulatory authority could require a peer assessment to ensure the physician's ability to practice medicine competently and safely. If a physician fails to report his or her absence from practice, most, if not all, regulatory authorities would not find out unless notified by another source. There is a significant reliance on the physician's honest and complete declaration of relevant information.

Just one state responding to the survey requires recertification through specialty boards. Of the fifty-six respondents, thirteen expressed a desire or were currently thinking of assessing competency at the time a license is renewed. Only five of the respondents undertake multi-source evaluations, such as a 360-degree process (a formal process to elicit information about a person being evaluated from a group that is representative of those with whom that person routinely interacts).

ASSESSMENT OF PHYSICIANS IN PRACTICE

Twenty-two respondents reported that they use peer review to assess licensed physicians' practices. The question was not specific enough to determine when such peer review takes place (e.g., randomly, when an application for licensure is pending, at the time of renewal of licensure, in response to an investigation calling into question a physician's competency, or a combination thereof). In both countries, peer review of a particular physician's practice may also be done as part of a disciplinary penalty, either by order of the medical regulatory authority or as part of a formal agreement with the physician.

A possible outcome of a disciplinary case is periodic review of the physician's practice by a peer in the same specialty. In a few states there are independent, private programs that address practice deficiencies through hands-on remediation. In Canada, university continuing medical education programs do most of this work.

RESPONDING TO COMPLAINTS

There was significant concordance among all the respondents in both countries about assessing competence in reaction to a formal complaint. Fifty-five of the fifty-six respondents reported that they negotiate settlements with physicians as part of the disciplinary process. All of the respondents may sanction a physician by limiting, suspending, or revoking a license. All may require remediation and all but three may require a fine. Those that cannot impose fines wish they could. Interestingly, seventeen of the respondents noted that they may negotiate community service as part of a settlement.

If the impetus for discipline arises from reasons related to competency to practice medicine, whether or not related to behavioral issues such as substance abuse, the usual remedy is a reprimand or probation with conditions and/or restrictions on the license, such as practice in a supervised setting (e.g., for boundary violations), regular meetings with a board or staff member of the regulatory authority, monitored practice, and remedial education. Several authorities have the ability to seek payment of costs for the prosecution from the licensed physician.

MISCELLANEOUS ISSUES

- Most medical boards in the United States are not involved in accrediting public and private hospitals or other health care facilities (e.g., diagnostic imaging and laboratory facilities) and are not interested in doing so. In Canada many medical regulatory authorities are engaged in the accreditation of diagnostic, laboratory, and private surgical facilities.
- Most Canadian medical regulatory authorities also monitor methadone treatment programs.
- In the absence of a disciplinary action, most state boards do not routinely monitor billing practices or surgery centers. Other state entities often provide that oversight.
- Twenty-two respondents are monitoring prescribing practices, related for the most part to prescribing narcotics and other drugs of potential abuse.
- A majority of respondents (thirty-six out of fifty-six) also promulgate rules and policies regarding acceptable practice. Another five respondents would be willing to do so or are considering the option.

MEDICAL REGULATORS' WISH LIST

Most of the respondents indicated a willingness to consider or a desire to take measures to improve the quality of medical care and ensure patient safety, such as to require recertification by specialty board for renewal of licensure, to establish more comprehensive physician assessment processes, and to set and disseminate practice policies and guidelines.

The barriers identified to fulfilling the wish list of the medical regulatory authorities fall into two main categories. The first is lack of resources (financial and human). For example, peer review

of physicians' practices is a very expensive and time-consuming enterprise, particularly for the larger jurisdictions. The second barrier is legislative impediments, such as privacy legislation that can limit the flow of relevant information from one jurisdiction to another, and indeed even within a jurisdiction.

**HOW MEDICAL REGULATORY AUTHORITIES IN
CANADA AND THE UNITED STATES COULD RESPOND
TO THIS REPORT**

The central question raised by the contextual information and survey findings in this report is whether medical regulatory bodies in Canada and the United States ought to significantly shift their focus from reactive strategies to promoting proactive systemic patient safety and health care quality improvement strategies. Medical regulators could have one of four responses to this report:

1. A strong sense of comfort with the status quo, no perception of external threats to the status quo, and no internal motivation to change.
2. A moderate sense of comfort with the status quo, a perception of some external threats to the status quo, some internal interest in change, but no sense of urgent need for change and considerable uncertainty about how to pursue change.
3. A sense that the status quo is insufficient and potentially unsustainable, a perception of significant external threats to the status quo, a genuine willingness to embrace change, but a lack of capacity to support change.
4. A strong internal conviction of the need for change of the status quo, a clear vision of future goals, and some early experience with change management in pursuit of those goals, limited by constrained resources.

The members of the group recognized wide variation in perceptions of external threats to historical professional regulatory policies and practices in Canada and the United States. This may be attributable, in part, to varying awareness of events in other countries that have precipitated profound change in public policy regarding medical regulation. Even where there is awareness of these events in other countries, there are variable perceptions about the susceptibility or immunity of the medical regulatory authorities in Canada and the United States to comparable forces of change.

In the United Kingdom, for example, the General Medical Council came very near to being replaced because of a loss of public trust. It has survived only as a consequence of massive reform that has resulted in much more extensive public control over medical regulatory processes. In Australia, state-based medical regulation is under siege as the federal government seeks to centrally consolidate some regulatory functions, such as setting standards for licensure eligibility.

At one extreme, there is a belief that the changes under way in the United Kingdom, Australia, and elsewhere are of academic interest but of little relevance to Canada and the United States. At the other extreme, there is a belief that the changes occurring in these countries are inevitable in Canada and the United States, and the only choice is to be swept along by the tsunami of change or try to “get ahead of the wave.”

The group also identified another noteworthy view in its discussion. Within the medical regulatory community, there is growing awareness of the research literature on patient safety and health care quality improvement, which identifies a relationship between structure, process, and expected outcomes. Leaders in the U.S. and Canadian medical regulatory communities who have reflected on that literature are becoming convinced that medical regulation in the two countries needs to shift to strategies that are more systemic in nature “because it is the right thing to do” rather

than because change may be forced upon the community. When the motivation for organizational change is grounded in that belief, regulatory bodies appear to be more advanced in their adoption of systematic approaches to patient safety and quality improvement.

This cross-border dialogue highlighted the wide variation in resources available to support medical regulatory activities in the states, provinces, and territories of the United States and Canada. While there is considerable variation within each of the two nations, the contrast between them is starker. Since effective authority programming relies upon adequate resources, capacity for innovation may be compromised by resource constraints even when there is a strong desire for innovation. If medical regulatory organizations aspire to become more effective contributors to the patient safety and health care quality improvement agenda, they need to explore different funding models.

A fundamental principle of physician-led regulation is that the members of the profession underwrite the cost of regulation through annual licensure fees. In an ideal world this implies that the governing board of a medical regulatory authority should define the scope and rigor of regulation essential for effective public protection and then set professional licensure fees to support that work. In the real world, licensure fees are more often set at a level that the board perceives members will tolerate and, in the United States, that state legislatures will authorize. The regulatory authority must then tailor the range and nature of its work to an inadequate resource base. In some cases, fees may be too low to foster extensive programming. The reasons for the variation in fees are not clear.

In general, physicians in Canada pay much higher annual licensure fees than do U.S. physicians. For example, the annual fees for physicians in Canada for 2007 ranged from \$390 to \$1,375, with all but three provinces charging at least \$1,000. The range in the United States was \$25 to \$752. Half the states charged at least \$180. In both countries these fees are a small percentage of physicians' incomes. There may therefore be compelling arguments in favor of raising licensing fees in order to support programs that improve the quality of physicians' services.

However, there may also be good reasons for medical regulatory authorities to explore other sources of funding. It may be appropriate for medical regulatory authorities to review and potentially renegotiate the "social contract" with legislators and, in the United States, governors as well, based upon society's need for rigorous regulation. If society wants and expects more effective mitigation of risk associated with medical practice, perhaps society has a duty to finance the cost of more rigorous regulatory activity.

Because health care is increasingly a team endeavor, professional regulatory authorities that aspire to optimize the safety of health care will have to collaborate to achieve optimal team performance. The effective collaboration with authorities that regulate other health professions may also trigger a need for sharing costs and more innovative funding models.

Another principle of effective professional regulation is that the rigor of regulation ought to be proportional to the risk of harm associated with the activity of persons being regulated. Most people within and outside the profession would agree that the risk of harm associated with medical practice is likely greater than that associated with any other profession in the health sector. The rigor of medical regulation therefore ought to be extremely high.

WHAT NEXT? QUESTIONS FOR MEDICAL REGULATORS

The choice confronting medical regulatory authorities in Canada and the United States is whether they wish to redefine their future roles or have those roles defined for them by external forces beyond their control.

We may choose to deny our risk of having such changes thrust upon us. We may recognize the probability that the status quo is insufficient but fail to act effectively to achieve change. Or, we can choose to follow Eleanor Roosevelt's exhortation, "You must do the thing you think you cannot do."

In the United States and Canada the state, provincial, and territorial medical regulatory organizations are autonomous. The relative weakness of state and provincial regulators is due in part to this arrangement. However, the linkages and facilitation sustained by the FSMB in the United States and the FMRAC in Canada offer opportunities to learn from one another and to adopt leading practices developed by other regulatory authorities.

Through this cross-border dialogue we have identified a number of practices that all medical regulatory authorities would do well to emulate. The challenge for us collectively is to make these practices the norm in our respective organizations. Such leading practices include requiring regular demonstration of maintenance of competence and programs that help impaired physicians return to practice safely.

Another practice that has attracted both support and skepticism from medical regulators is peer review of physicians' work. Because evidence from several Canadian jurisdictions suggests that practice review by peers is the most accurate assessment of physicians' clinical performance, such review could become essential to maintaining the rigor of regulation. Practice monitoring may help physicians to improve before problems arise. Such an approach represents active as opposed to reactive regulation (responding only to complaints) and could meet public expectations and better serve the public interest. Some regulators, however, doubt that their authorities should or could be responsible for peer assessment.

There is evidence that smaller organizations can more readily achieve change than can large national organizations. The decentralized regulatory model in Canada and the United States creates an opportunity for innovation.

However, a decentralized regulatory model also carries some significant risk for unexplained variation in policies, practices, and operational rigor. In the language of quality improvement, needless variation in clinical practice is regarded as "the enemy of excellence."

In a decentralized regulatory system public trust is also at risk because our public credibility is only as strong as our weakest link. A spectacular and highly publicized failure of regulation of any aspect of the health sector in any jurisdiction diminishes the credibility of regulators in other jurisdictions.

To mitigate the risks inherent in unexplained variation in regulatory policies and practices, some have suggested that the FSMB and the FMRAC establish standardized performance objectives or even an accreditation system to foster uniformly high standards of regulation among all of their member

authorities. Most boards are, however, already subject to multiple levels of accountability as public entities. Moreover, boards that fail to achieve accreditation or are placed on probation might have uncertain legal status.

Whether or not standardized performance objectives or accreditation of medical regulatory authorities in Canada and the United States becomes a reality, individual authorities should reflect critically about their effectiveness and their potential to improve it. As a quality improvement tool for individual medical regulatory authorities, we recommend that authorities ponder the following questions with respect to their current operations:

1. From your experience, and from research findings, what do you understand to be the leading causes of harm to patients who receive health care in the United States and Canada?
2. How could medical regulators contribute to reducing these causes of patient harm?
3. How do your current policies, practices, and programs seek to mitigate these causes of harm, and how effective are these efforts?
4. What proportion of your organization's resources is currently focused on interventions related to physician incompetence, impairment, and/or unethical performance/conduct?
5. Does your authority currently have any capacity to modify systemic risks of patient harm as opposed to risks associated with individual physician performance or conduct?
6. If you have such capacity, is it adequate or would you prefer to enhance it in order to mitigate systemic risk of patient harm?
7. What are the principal barriers to achieving enhanced capacity for systemic risk mitigation?
8. How could these barriers be overcome?
9. To what extent has your organization been successful in adopting and sustaining innovative policies and programs pioneered by other medical regulatory authorities?
10. To what extent has your organization been successful in adopting and sustaining program changes based upon research on patient safety?
11. What do you think the FSMB or the FMRAC could do to:
 - a. foster and support the spread and uptake of leading regulatory practices among their member authorities?
 - b. foster the uptake and application of the findings of research relevant to medical regulatory authorities?
12. Do you see merit in the FSMB or the FMRAC developing a system of standardized performance objectives or accreditation for member authorities that would involve external evaluation and recommendations for organizational improvement?
13. If such objectives or an accreditation system were established, would your authority:
 - a. be willing to undergo external evaluation with the goal of acquiring accreditation status?
 - b. be willing to have your authority personnel serve as members of accreditation teams?

We look forward to hearing your answers to these questions, to discussing them with you, and to collaborating with you and with our colleagues in the profession, in private organizations, and in government to enhance the quality and safety of health care by improving the competence of physicians.

**APPENDIX: SURVEY SENT TO
MEDICAL REGULATORY AUTHORITIES IN CANADA
AND THE UNITED STATES IN MARCH 2007**

Respondents to the questions below could choose one of five answers: currently doing, have done but are no longer doing, thinking of doing, willing to consider doing, or wish this were possible. They could also add comments or indicate that the question was not applicable.

ACTIVITIES OF MEDICAL REGULATORY AUTHORITIES TO ADVANCE HEALTH CARE QUALITY AND PATIENT SAFETY

A Complaint Review and Potential Disciplinary Action

- A1 Suspension or revocation of license
 - A2 Limited licensure
 - A3 Negotiated settlement undertaken by physician and regulatory authority
 - A4 Required remedial education
 - A5 Community service
 - A6 Fines levied
 - A7 Other (please describe): _____
-

B Physician Assessment

- B1 At time of initial licensure / registration
 - B1a Competence
 - B1b Behavior
 - B1c Health
 - B2 At time of renewal of licensure / registration
 - B2a Competence
 - B2b Behavior
 - B2c Health
 - B3 Peer review of an individual's practice
 - B3a Competence
 - B3b Behavior
 - B3c Health
 - B4 Multi-source feedback of individual (for example: 360°)
 - B4a Competence
 - B4b Behavior
 - B4c Health
 - B5 Other (please describe): _____
 - B5a Competence
 - B5b Behavior
 - B5c Health
-

C Accreditation of Hospitals or Health Care Facilities

(for example: laboratories, diagnostic imaging)

- C1 Public
 - C2 Private
-

D Monitoring of Physician Practices

(for example: triplicate prescription program, state / provincial prescribing database)

- D1 Prescribing
 - D2 Billing
 - D3 Methadone programs
 - D4 In-office surgery setting inspections
 - D5 Other (please describe): _____
-

E Physician Revalidation / Validation of Continued Competence

- E1 Mandatory CME / CPD requirements
 - E2 Practice-based self-reflection (for example: reading up or consulting colleagues in response to the specific needs of a patient or set of patients)
 - E3 Practice enhancement (for example: instituting a breast cancer screening program for all eligible women)
-

F Recertification

- F1 ABMS
 - F2 AAPS
-

G Require Remediation

(for example: educational prescription / behavior modification)

H Promote Best Practices

If yes, please describe:

I Institute Ethical Review Boards / Panels

(for example: for physician-led research)

J Educational Programs

(development / participation)

- J1 Undergraduate
 - J2 Graduate (U.S.) / Postgraduate (Canada)
 - J3 CME / CPD
-

K Promulgate Advice / Guidelines / Direction / Policies / Standards of Practice and Behavior

L Physician Health and Wellness

(for example: state / provincial physician health / wellness / addiction programs)

- L1 Run by the medical regulatory authority
 - L2 Independent of the medical regulatory authority
 - L3 Partnership between the medical regulatory authority and other stakeholders
-

M Actively Influence Legislative / Regulatory Public Policy

N Mandate Specific Actions

(for example: reporting for and of physicians with blood-borne pathogens)

O Other (please describe): _____

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