



**MANITOBA INSTITUTE  
FOR PATIENT SAFETY**

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## **A Submission on Bill 17**

# **THE REGIONAL HEALTH AUTHORITIES AMENDMENT AND MANITOBA EVIDENCE AMENDMENT ACT**

**Presented to the Standing Committee  
on Social and Economic Development  
Manitoba Legislature**

**May 31, 2005**

## **I. INTRODUCTION**

The Manitoba Institute for Patient Safety (MIPS) is pleased to provide the following commentary and indicate its support for Bill 17 as one important initiative in support of a safer, higher quality health care system serving all Manitobans.

This submission will be divided into three parts. First, we will provide a brief description of MIPS which was only created in June 2004 and may not be all that well known to Manitobans. Secondly, we will provide a brief discussion of patient safety issues and initiatives in this country which represent the context for the introduction of Bill 17. Thirdly, we will analyze the contents of the Bill in terms of the balance achieved among the public interest goals of reporting critical incidents causing harm to patients, the promotion of learning to prevent a recurrence of such incidents, the protection of the privacy of the individuals involved and the upholding of accountability for the performance of individual care providers and institutions.

## **II. MANITOBA INSTITUTE FOR PATIENT SAFETY**

The Manitoba Institute for Patient Safety was recommended in 2003 by a representative committee of key stakeholders in the health field chaired by Dr. John Wade, former Dean of Medicine at the University of Manitoba. In May 2004 the Minister of Health announced that the government had agreed to the creation of the Institute and announced the composition of the first board of directors. MIPS was incorporated under the Companies Act in June 2004.

The Institute is a not-for-profit corporation with a mandate to undertake activities, to stimulate and coordinate the efforts of others and to provide independent and objective advice to all parts of the health care system in support of minimizing preventable injuries to patients. MIPS is currently governed by a twelve member board of directors appointed either by the Minister of Health or by Manitoba Health. The majority of board members have backgrounds in the health field, but there are also several citizen representatives on the board. Individual directors do not represent the institutions with which they are affiliated; all members provide independent advice based upon their expertise and experience with the health care system. By 2007, the majority of directors will be elected.

It is important to note what MIPS is not authorized to do. It does not operate any programs or deliver any health services. It is not a regulatory body, so it will not displace in any way the licensing, monitoring and disciplinary processes of the self-regulation bodies for the various health professions. MIPS is not a complaints and investigatory body; it does not perform an ombudsman – like role in the health field; although an important part of its mandate is to strengthen the voice of patients in debates over the safety and quality health care. Health is an increasingly technologically sophisticated field, but MIPS is not involved with the review and approval of new technologies which might enhance or represent risks to patient safety. In summary, MIPS will have influence within the patient safety

field through the development of good ideas in a credible and objective manner and through the promotion and mobilization of support for those ideas in a timely manner with key stakeholders. Collaboration and partnership with others will be the predominant style of operation.

A collaborative approach is based upon the recognition that there is great depth of expertise in relation to patient safety in all parts and at all levels of the multi-tiered health care system and many initiatives are already underway. Part of our role is to serve as a clearinghouse of best practices and to promote the transfer of knowledge. A further reason for working through and with others is the small size of MIPS. With a core operating grant from Manitoba Health of just over \$500,000.00 for fiscal year 2005-2006, and with a full time staff of an Executive Director and Administrative Support person, there are definitely limits to what MIPS can do on its own. It was part of the original design of MIPS that it would diversify its revenue beyond the annual government grant. Even though the Institute has only been existence for less than a year, we have already been quite successful in following a collaborative approach. Appendix A contains a synopsis of MIPS activity to date and we would be pleased to answer any questions you might have in relation to those initiatives.

### **III. BILL 17 AND THE BROADER PATIENT SAFETY AGENDA**

Issues related to patient safety have recently gained prominence on the agendas of governments across the world. Medicine and other health disciplines have always involved a strong concern for the well being of the people they serve. However, in the past there has been an assumption of scientific certainty and a culture of perfection associated with the provision of health services. These attributes made it difficult to acknowledge and learn from mistakes or slips which contributed to adverse events causing injury, temporary disability, prolonged hospital stays and other unfortunate outcomes.

The acknowledgement that the health care system and individual care providers do not always achieve the desired outcomes must be put in the context of its safe and effective operation for the vast majority of patients. If societies have recently recognized a dark side to the provision of health care, it is partly because of the contrast to the bright side which involves safe, quality, compassionate and at times miraculous care which saves lives and improves the quality of lives of millions. The public's expectations regarding health care are high and therefore recent reports highlighting problems are all that more disturbing.

There is a strong consensus in reports on patient safety from a number of countries that incompetent or callous health care providers are rarely the cause of unwanted events. Instead, most errors are made by capable, well motivated but fallible professionals who are working in complicated, increasingly high-tech health care systems built on cultures which treat errors as moral failures. We need to develop professional health cultures that prize safety and are open to discuss

errors and learn from them. Minimization rather than absolute avoidance of mistakes is a realistic goal because we cannot anticipate everything that can go wrong in the delivery of a service as complex as healthcare.

The aim of the patient safety movement is to move away from a culture of naming, blaming and shaming and toward a culture of prevention and learning. This does not mean removing the legal and moral responsibility and accountability of health care providers and institutions for the provision of safe, quality care. Rather, what is needed is less emphasis on trying to pinpoint blame when something goes wrong and more emphasis on a culture of mutual, collective responsibility and accountability for meeting the needs of patients. Achieving fundamental changes to well-established professional health cultures like medicine, nursing and pharmacy will be a slow and uncertain process. It will require action on a number of fronts: legal changes, changes to the educational curricula of the health professions, changes to the structures and processes of health institutions, financial support for research on patient safety, coordination of activities across a dispersed health care system and committed leadership. The following discussion focuses mainly on legal reforms which can make a significant contribution to the enhancement of patient safety.

A legal issue which has come to the forefront in patient safety debates involves mandatory reporting of critical incidents and disclosure of information about adverse events to the public. Over 20 states in the United States have some kind of legislated mandatory reporting systems. Previously reporting was done on a voluntary basis. Hospitals are the usual targets of the new mandatory reporting programs. The types of adverse events that must be reported vary widely, from specific occurrences, such as brain damage in Florida, to general events, such as those incidents that “seriously compromise quality assurance or patient safety” in Pennsylvania. The only reportable event common to all states is unanticipated death. Reporting can be internal to the health institutions or external to a department of health or separate patient safety body. There has been resistance in the United States to the adoption of such laws from both physician groups and hospitals because of fears of damage to their reputations, malpractice claims and the extra work involved with recording and reviewing adverse events.

The primary purpose of reporting requirements is to learn from experience. There are other methods which could be used to identify threats to safety, but a good reporting system contributes awareness of major hazards. Reporting is also important for monitoring progress in the prevention of mistakes and adverse events. It can also lead to the identification and sharing of best practices. These benefits presume reports are analyzed and used as a basis for improvement. In fact, most state departments of health lack the experts to analyze more than a small fraction of the reports they receive.

Most states make some information on adverse events available to the public, but usually in an aggregated format. Detailed information about particular cases is

generally protected against legal discovery. For example, the 2003 Adverse Events Reporting Act passed by the Minnesota Legislature requires reporting on 27 serious adverse events and the Minnesota Department of Health publishes an annual report on the occurrence of adverse events by facility together with an aggregate analysis of corrective action taken throughout the system. A recent review of the Minnesota law reported that the public generally favoured reporting on “near misses,” involving potential but not actual harm to patients, and also supported full disclosure on a facility basis.

The debates over mandatory reporting and disclosure involve a tension between the public policy goals of encouraging honest dialogue about mistakes in order to improve patient safety versus the right of patients to know the reasons for outcomes and the requirement that individual care providers and institutions be held accountable for their actions or inactions. Participation by physicians is less than desirable for several reasons. First, physicians and other health professionals are reluctant to speak out because of the fear of litigation - being held legally liable for adverse events. Second, prevailing approaches to accountability in the health care system focus on mistakes and on blaming, often accompanied by intense media coverage. Third, the prevailing cultures in medicine and to a lesser extent the other health professionals expect perfection and personalize error, making it difficult psychologically for health professionals to talk openly about mistakes. If health care safety and quality programs are impeded by lack of participation by health professionals, there is a public interest in removing barriers to participation. This is the basis for providing confidentiality for the information generated through such peer-review processes as mortality and morbidity rounds (M & M rounds), standards committees and the complaints/investigation processes operated by the professional regulatory bodies. However, these considerations must be balanced against the public interest in access to information in order to allow patients to obtain satisfactory explanations of adverse events and to pursue various avenues of redress. The legal mechanism used to strike the appropriate balance is often referred to as qualified privilege, which amounts to sheltering information related to individual cases involving patient safety and quality improvement to be exempt from discovery in the course of legal proceedings.

Debates over the content and processes related to qualified privilege have recently taken place in several countries. A report on the issue released in 2003 by the Australian Council for Safety and Quality in Health Care identified the following six principles as important to the effective administration of qualified privilege legislation in all jurisdictions:

1. Qualified privilege protection should be available only to the extent necessary to ensure that quality assurance activities are not hindered by health care professionals' reasonable fear of unreasonable adverse professional consequences of disclosure of information. In addition, it should only be available if there is no paramount

countervailing public interest that requires information to be accessible.

2. Confidence in the integrity of the protection should be strong.
3. Protection should be provided only in relation to activities that are well designed and effective.
4. Governments and health care organizations have important leadership and educational roles.
5. The public should regularly be informed about the rationale underpinning qualified privilege and its application in each jurisdiction, within the scope of the protection.
6. Administration of qualified privilege schemes should be efficient.

These are useful principles to be applied in evaluating Canadian approaches to the sensitive issues involved.

In September, 2004, Saskatchewan became the first jurisdiction in Canada to require all health care districts to report all adverse events to the provincial department of health. Reporting is mandatory, but anonymous. The department will analyze the details of each reported event and issue province-wide alerts in cases where similar incidents could be prevented. Six types of critical incidents must be reported. For the previous two years, health districts had reported on a voluntary basis, which eased the transition to the new system. There was no reluctance to adopt the new system and it was supported by the College of Physicians and Surgeons of Saskatchewan. The Saskatchewan legislation on mandatory reporting served as a model for Bill 17 in Manitoba.

#### **IV. Bill 17: A Reasonable Balance**

MIPS believes that Bill 17 represents a reasonable accommodation of the various values and interests involved with the discovery and response to mistakes and adverse events. It seeks to remove the fears of health professionals that the information they supply for the purpose of safety and quality reviews will not be used to their detriment. Under the proposed bill, six types of critical incidents must be reported – the same six categories covered by the Saskatchewan legislation. There is the requirement that critical incidents be investigated by Critical Incidents Review Committees and that written reports be provided to the responsible health agency. Retaliation against individuals providing information to the Critical Incident Review Committees is prohibited. There is also the requirement for health care organizations to ensure that persons affected by critical incidents will be fully informed as soon as possible about the facts involved, the consequences for the person and the actions taken to deal with those consequences. The information

generated through the investigation process is protected from legal discovery and is not accessible through the Personal Health Information Act, the Privacy Act or the Access to Information Act. Mandatory reporting, combined with disclosure to affected individuals and the requirement for investigations and follow up reports on actions taken to prevent a recurrence, represents a compromise among a number of values and interests that need to be protected. Care providers and hospitals cannot legitimately expect an entirely consequence free process if the rights of individuals and the requirements for accountability are to be upheld. Patients and the public may not receive complete disclosure, but this is done in the interest of promoting information sharing and learning among care givers. In summary, the proposed bill creates a legislative framework which compels reporting, offers protection against punitive consequences for care givers who report critical incidents in order to improve learning, and requires disclosure of the consequences of critical incidents to affected parties – all of which represents a reasonable balancing of interests and values.

The one feature not found in Bill 17, which exists in the Saskatchewan framework and many state models in the U.S.A., is provision for aggregated reports on critical incidents to be made public as a way to share experiences and to strengthen accountability to the public. In Saskatchewan, data on the number and type (surgical event, product or device failure, medication error, etc.) of incidents reported are compiled by Saskatchewan Health and shared with regional health authorities. This information is also made public. Saskatchewan Health does not collect identifying information on specific patients and care providers and does not comment on specific cases. It is not clear at this point how the practice of releasing aggregate information at the RHA level and/or the provincial level will be addressed. MIPS believes that such a practice would permit the identification of regional, provincial and national trends and add to levels of accountability within the health care system.

There are a number of requirements to ensure the success of the new reporting system. It must be explained to the public that their existing common law rights to information about their medical condition and consequences arising from mistakes does not change under the proposed law. The complaints, investigation and disciplinary procedures operated by the health profession regulatory bodies will not be modified or displaced in any way. The proposed bill also seeks to uphold the privacy rights of individuals. Despite these features, the legal protection against disclosure to the information generated through various peer-review processes might be seen as favouring health care providers at the expense of the public's right to know. Therefore, the need for balance and the nature of the accommodation of different values found in Bill 17 must be explained.

Communication and educational activities will also be needed to ensure that health care providers and the leadership of health care agencies have a clear understanding of the aims of mandatory reporting, the role that Critical Incident Review Committees are intended to play and the nature of the protection against

legal discovery afforded to generate through the critical incident review process. Care providers will need to be educated about the relationship between the Critical Incident Review and existing standards, quality and risk processes. With the addition of a new mechanism for review of occurrences, there may be confusion amongst care providers as to what type of occurrence needs to be reviewed by which process.

Bill 17 makes Regional Health Authorities (RHAs) responsible for ensuring that devolved health agencies operate reporting, investigation processes and critical incident review committees based upon guidelines approved by the Minister of Health. Ideally, a consistent approach should be followed across the province. However, the eleven RHAs and the health agencies within each vary in size and organizational capability. It will be necessary to ensure the smaller entities have enough staff, which is appropriately trained, together with adequate information systems to comply with the new requirements.

The new reporting system must be operated in an efficient and effective manner if it is to receive sustained commitment and involvement from health care providers and the administrative leaders of health care agencies. Participation by physicians is key to the success of the new reporting system. Historically, physicians have operated on an individual basis and the fee-for-service remuneration model means that time dedicated for collective patient safety processes potentially represents lost income. Time spent on the preparation of reports and attendance at Critical Incident Review Committees take physicians and other health professionals away from what they see as their primary role of meeting the needs of patients. Therefore, the new procedures must be as effective as possible and lead to meaningful action to improve patient safety in order to encourage sustained involvement.

Passage of this legislation will contribute to the necessary transformation of the cultures of the health care system by requiring professionals to report critical incidents and to discuss them honestly through a non-blaming, collective process of learning. For this reason, MIPS supports the bill. The Institute also recognizes that other changes will be needed to support patient safety goals: new content in professional health education programs, committed leadership throughout the health care systems, structural and procedural changes in health care institutions, financial investments in safety technologies and training, coordination of safety initiatives, the adoption of more constructive approaches to accountability which emphasizes prevention and learning more than retrospective blaming for mistakes.

The long-term challenge behind all such reforms is to create health care cultures that prize safety, focus on it as a core professional value and is open to discussing mistakes in order to learn from them. MIPS intends to play an important role in achieving this goal for the benefit of Manitobans.

## Appendix A

### Manitoba Institute for Patient Safety Highlights of Activity to date

- 1) Hired an Executive Director and staff, developed a budget for the 2005/2006 and 2006/2007 fiscal years, approved a logo, and found a permanent home;
- 2) Coordinating a two pronged consultation process, one in all Regional Health Authorities with a group of providers and a group of public members, and the second with professional regulatory associations, health care provider educational programs, unions, and consumer groups. The purpose is to seek opinions and input on the strategic directions of the Institute, priorities, challenges, potential solutions, and current activities related to patient safety, and to introduce the Institute to future partners. Funding Partners: Health Canada, Canadian Patient Safety Institute;
- 3) Steering Committee established to coordinate Safer Healthcare Now! in Manitoba, a pan-Canadian campaign parallel to the Institute for Healthcare Improvement (U.S.) 100K Lives Campaign which aims to reduce preventable mortality through instituting 6 interventions known to reduce risk of adverse events;
- 4) Initiating a Culture of Safety Survey in Manitoba, initially in four Regional Health Authorities (RHA) which will assist RHAs in identifying areas for further improvement in their organizational patient safety culture, which is key to improving patient safety in the health system;
- 5) Assessing the feasibility of introducing an Interdisciplinary Safety Internship Program;
- 6) Co-Chairing the Manitoba Patient Safety Conference, Fall 2005;
- 7) Launched the MIPS website, [www.mbips.ca](http://www.mbips.ca);
- 8) Conducted an orientation session across Manitoba via telehealth, which focused on MIPS and patient safety in general, available through the MIPS office or on our website.