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BRIEF

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MÉMOIRE

“Listening to our Patient's Concerns”

Comments on Bill C-54

(Personal Information Protection and Electronic Document Act)

Submission to the House of Commons Standing Committee on Industry

March 18, 1999

Ottawa, Ontario

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The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, CMA's mission is to provide leadership for physicians and to promote the highest standard of health and health care for Canadians.

On behalf of its members and the Canadian public, CMA performs a wide variety of functions, such as advocating health promotion and disease/accident prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 43 affiliated medical organizations.

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Executive Summary

Over the last year, CMA has become increasingly concerned that debate on the issues concerning health information have been framed in terms of access to information with an attendant erosion of privacy and confidentiality. This one-sided approach comes at a time of expansion in our capacity to collect, store, merge, transfer and access information, coupled with trends both in the health care sector and generally related to the use of information. To address these concerns and to ensure that privacy and confidentiality in the medical context are valued, protected and preserved, CMA developed and adopted a Health Information Privacy Code. This Code should form the basis of all legislation governing the collection, use and disclosure of health information.

Health information is special by its nature. Rules relating to health information must be developed in recognition of its special nature. Ensuring protection of privacy and confidentiality of the patient record must take precedence over other considerations. Bill C-54 fails to do this. Bill C-54 is written from the perspective of encouraging commerce. It appears to have access to information as its dominant value. CMA considers the world of health care to be very different from that of commerce and consequently requiring distinct rules.

Health information use must, in all but exceptional and justifiable circumstances, occur *only* under the strict control of the patient. The patient must be able to exercise control through voluntary, informed consent. Bill C-54 permits the collection, use and disclosure of information without knowledge or consent on grounds such as expediency, practicality, public good, research, offence investigation, historic importance and artistic purpose. The evident lack of protection accorded health information based on such ground, is unacceptable. The absence of protection undermines the integrity of the patient-physician relationship and has the potential to erode the trust patients have in their physicians - a trust that is essential to patients' willingness to provide the complete information needed to provide them with care. Moreover, distinctions must be made between a patient's right to know what can or must happen to health information and the right to consent to such use.

Not all purposes for the collection and use of health information are equal. Collection and use beyond the therapeutic context should be subjected to rigorous scrutiny before they are permitted to occur. Bill C-54 fails to make such a distinction and treats all purposes that could be identified for information collection or use as equal. Moreover, the Bill has no mechanism to distinguish legitimate purposes, which should be permitted from illegitimate purposes, which should not.

In light of the clear deficits in Bill C-54 and the inadequate protection of patient privacy and health information confidentiality, CMA makes the following recommendations:

That Bill C-54 be amended to incorporate specific provisions relating to health information and that the provisions of the CMA Code provide the basis of such provisions; and

That the proposed rules for health legislation be subject to the legislative test found in CMA's Code and formulated in light of this process; and

That there be a clear definition of the information being accorded a right of privacy and that this definition, at least in the case of health information, include identifiable information, delinked information, anonymous information and any composite form produced when information is linked to any information about a person from any other source; and

That, at least in connection with health information, the provisions of the Bill apply equally to the public and the private sectors.

I. Introduction

The Canadian Medical Association is the national voice of Canadian physicians. Our mission is to provide leadership for physicians and to promote the highest standard of health and health care for Canadians. The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 43 affiliated medical organizations. On behalf of its 45,000 members and the Canadian public, CMA performs a wide variety of functions, including addressing the emerging issue of electronic health information and confidentiality and privacy. It is in this capacity that we present our position on Bill C-54, *The Personal Information Protection and Electronic Documents Act*.

CMA commends the government for taking the first, important step of beginning the debate on the protection of personal information. The issues are complex and the interests at stake significant. CMA welcomes the opportunity to provide comments on Bill C-54. CMA hopes that its input will strengthen the Bill by ensuring that patient privacy and the confidentiality of medical records are adequately protected. In preparing this brief CMA has had the benefit of the final report of the federal Advisory Council on Health Infostructure, *Canada Health Infoway: Paths to Better Health: Final Report*. ("Advisory Council Report") Where appropriate, CMA cites the findings contained in the report.

CMA wishes to underscore the key themes of its brief:

- A. Health information is special by its nature. Rules relating to health information must be developed in recognition of its special nature. Ensuring protection of privacy and confidentiality of the patient record must take precedence over other considerations. Bill C-54 fails to do this. Bill C-54 is written from the perspective of encouraging commerce. It appears to have access to information as its dominant value. CMA considers the world of health care to be very different from that of commerce and consequently requiring distinct rules.
- B. Health information use must, in all but exceptional and justifiable circumstances, occur *only* under the strict control of the patient. The patient must be able to exercise control through voluntary, informed consent. Bill C-54 permits the collection, use and disclosure of information without knowledge or consent on grounds such as expediency, practicality, public good, research, offence investigation, historic importance and artistic purpose. The evident lack of protection accorded health information based on such ground, is unacceptable. The absence of protection undermines the integrity of the patient-physician relationship and has the potential to erode the trust patients have in their physicians - a trust that is essential to patients' willingness to provide the complete information needed to provide them with care. Moreover, distinctions must be made between a patient's right to know what can or must happen to health information and the right to consent to such use.

- C. Not all purposes for the collection and use of health information are equal. Collection and use beyond the therapeutic context should be subjected to rigorous scrutiny before they are permitted to occur. Bill C-54 fails to make such a distinction and treats all purposes that could be identified for information collection or use as equal. Moreover, the Bill has no mechanism to distinguish legitimate purposes, which should be permitted from illegitimate purposes, which should not.

This brief will first look at the apparent rationale of Bill C-54 and its potential application to health information. The brief will next describe why CMA considers health information to be special in nature and worthy of special protection. Finally, the brief reviews the difference in approach between Bill C-54 and CMA's Health Information Privacy Code to illustrate that Bill C-54 provides inadequate protection to patient privacy and health record confidentiality.

II. Rationale and Scope of Bill C-54

A. Rational of Bill C-54

The driving force behind Bill C-54 is the support and promotion of electronic commerce. The second part of the Bill is devoted to permitting electronic versions of documents and signatures to be legitimate or 'originals' if the provisions of the Act are followed. Part two of the Bill is quite distinct from part one and both parts could stand alone as separate pieces of legislation.

Part two simply allows electronic versions of documents and signatures to be recognized as legitimate. On its face, this has little to do with the protection of personal information except to the extent that storage of documents in electronic form provides greater ability to access, link and merge information. Certainly, the Bill appears to draw on this connection by including, in its statement of purpose, the provision of a right of privacy in an era in which technology increasingly facilitates the collection and free flow of information.

Part one concerns all forms of information, electronic and otherwise. It gives some protection to personal information by requiring consent in some instances. In CMA's view, a fundamental difficulty with part one and the Bill in general is that it's goal is to promote commerce and thus all information is implicitly considered as falling within the 'commercial' realm. In the case of health information this is surely not the case or the only consideration.

Moreover, this creates a clash of values when applied to a health care system that is a public system. The Advisory Council Report takes a hard line on this issue and states that legislation respecting the privacy protection of health information, "should also contain a clear prohibition against all secondary commercial use of personal health information."

Because all information is subjected to similar rules, there is no attempt within the Bill to distinguish some purposes for collecting information from other purposes. The Bill takes the approach that the purposes should be known and documented. While not stated explicitly, the assumption is that all purposes identified are legitimate and are permitted. CMA has quite a different view when it comes to health information and will expound its view throughout this brief.

B. Scope - Application to Medical Records

CMA is uncertain whether or to what extent Bill C-54 will apply to health records. The full name of the Act states, in part:

An Act to support and promote electronic commerce by protecting personal information that is collected, used or disclosed in *certain circumstances*....

What are these circumstances?

Section 4(1) states that Part 1 (the part protecting personal information) applies in respect of personal information that:

- (a) the organization collects, uses or discloses in the course of commercial activities;
- (b) the organization collects, uses or discloses interprovincially or internationally; or
- (c) is about an employee of the organization and that the organization collects, uses or discloses in connection with the operation of a federal work, undertaking or business.

It should further be noted that three years after the Act is in force it will apply equally to activities that occur strictly within the province unless there is legislation in the province that is substantially similar to the Bill (see sections 27(2)(d) and section 30).

The first issue is the provision of section 4(1)(a) - collection, use and disclosure in the course of commercial activities. There seems to be an assumption on the part of government that this automatically excludes health records, (although the Act fails to define what is meant by commercial activity). Is this accurate or does the assumption fail to recognize that there is not a clear, unambiguous distinction between what might constitute commercial activity or other activity?

There are two points to be made here. The first concerns clarity around where commercial ends and health care begins. Which health care settings that operate for profit are excluded from the Act? This question speaks to the difficulty of delineating what activity is considered health care and what activity is considered commercial. Moreover it recognizes that the increased encouragement to public/private funding of endeavours within the health care sector may make it increasingly difficult to make this distinction; for example in the area of research.

The second concerns the movement of health information from the health care setting

(recognizing that this is not easily distinguished from the commercial setting) to the commercial setting; for example, health information provided to insurance companies. When health care information is collected in a health care setting and transferred to a commercial setting, which rules apply - Bill C-54 or no rules?

In CMA's view, there is no clear way of distinguishing commercial activity from health care activity in a way that ensures that the health care record is subject to different rules than those pertaining to other records. Moreover, the dilemma for government is that even if such distinction could occur, would it be desirable that health records be subject to no rules? Put in another way, will those organizations that currently collect health care information be entitled to claim that since the information forms part of the health record they are not subject to the provisions of C-54? Under such a regime health care records would be subject to an even lower standard than that provided for information collected in the commercial context.

In terms of the provisions of 4(1)(b) - interprovincial and international transfer of information. This appears to apply to all information. In the existing environment and developments such as the "health information highway," interprovincial transfers of information, the capacity for the central collection and storage of information, mechanisms such as telephone and cable to transfer information and general trends related to population health, it seems likely that interprovincial traffic will grow rather than diminish. The significance of this section, therefore, cannot be underestimated.

Finally, the provisions of 4(1)(c) may well contain health information about the employee.

In preparing this brief CMA has assumed that the Bill will provide a scheme that applies to some health information. No doubt the extent of the federal governments ability to legislate in this area generally will be the subject of extensive debate. However, CMA has no comment on this debate and provides its opinion in the interests of ensuring that the rules that relate to health information are compatible with preserving the integrity of the patient-physician relationship and the protection of patient privacy and health information confidentiality. CMA considers that the government has an opportunity to provide Canadians with strong privacy rights in health information. Indeed, CMA believes that it is incumbent upon the government to do so.

C. Scope - Government Excluded

Bill C-54 expressly excludes a large part of government activity from its ambit. While government activity is to some extent governed by the *Privacy Act*, R.S.C. 1985, P-21, the rules of this act provide less protection than those of Bill C-54. Government should subject itself to at least the same rules that it requires of the private sector in so far as it is a collector and user of information. Moreover, CMA is of the view that government's practices relating to the collection, storage, merging, transfer and use of health information must be subject to more stringent rules than those found in either the *Privacy Act* or Bill C-54. The Advisory Council Report also calls for the same rules to apply to the public and private sectors, rules that are more stringent than those found in the *Privacy Act* or Bill C-54.

Therefore, CMA recommends:

That, at least in connection with health information, the provisions of the Bill apply equally to the public and the private sectors.

III. Considerations Regarding Patient Privacy and Confidentiality: Medical Context Versus Commercial Context

A. CMA's Opinion

Over the last year, CMA has become increasingly concerned that debate on the issues concerning health information have been framed in terms of access to information with an attendant erosion of privacy and confidentiality. This one-sided approach comes at a time of expansion in our capacity to collect, store, merge, transfer and access information, coupled with trends both in the health care sector and generally related to the use of information

To address these concerns and to ensure that privacy and confidentiality in the medical context are valued, protected and preserved, CMA developed and adopted a Health Information Privacy Code, which is appended to and forms part of this brief. In commenting on this Code the Advisory Council Report notes:

The code represents an important contribution to the deliberations of Canadians and legislators on how to safeguard privacy across the health domain.

There are a number of principles underpinning the Health Information Privacy Code:

1. The provision of health care to all Canadians irrespective of social circumstances or health status is a highly regarded value in Canadian society. The system is publicly funded and universally accessible.
2. The right of privacy is fundamental to a free and democratic society.
3. Rules relating to health information must recognize its special nature. Health information has a high level of sensitivity, it is confided or collected in circumstances of vulnerability and trust for the primary purpose of benefiting the patient.
4. Physicians now and historically promise that they will keep their patients' information secret; this is a hallmark of the profession.
5. The patient-physician relationship is one of trust and a central feature of this trust is the belief in patients that information confided in or collected by physicians and other health care providers will be kept secret.
6. Patients believe that the information they disclose or that is gathered as a result of their seeking health care will be used to provide them with health care; uses beyond the provision of health care without knowledge or consent go beyond what a patient's reasonable expectations were when information was disclosed or gathered and is a breach of the trust patients place in their physicians.
7. Except in very limited circumstances, consent is required for health information collection, use, disclosure or access for any purpose.
8. Information required to provide patients with the health care sought should be readily available to those who require it to provide an aspect of care.
9. Uses of health information for purposes other than the provision of health care to the person seeking care should be subject to rules that:
 - protect and promote privacy and confidentiality;
 - generally require express consent;
 - can be justified according to specific criteria.
10. Patients should know the uses to which their health information is put prior to their disclosure of it.
11. Patients may be reluctant to disclose information if they are concerned about the uses to which the information is put or the persons entitled to access it.

B. Public Opinion

To determine the public's view on these issues, CMA commissioned Angus Reid to conduct research in two forms, quantitative (survey) and qualitative (focus groups), and has found the following:

1. Patients believe that their health information will be kept confidential and consider this to be important.
2. Patients believe it important to know and control how their health information is shared with others.
3. Patients do not want their health information released to third parties (including governments and researchers) without their knowledge and consent.
4. Patients may have concerns about the release of delinked or anonymous information to third parties without their consent.
5. Patients may be reluctant to confide information as a result of concerns related to its use or disclosure.

These findings are consistent with general findings relating to the public's concerns about privacy and confidentiality.

C. The Advisory Council Report

The Advisory Council Report relates to the electronic health record. However, given the direction towards the greater use of technology and the underlying principles informing the Advisory Council, CMA believes that the recommendations are generalizable to all health information.

A key principle of the Advisory Council is that access by health care professionals should be based on a need-to-know basis under the strict control of the patient. The Council, like CMA calls for scrutiny and justification of secondary uses of health information. The Council is opposed to the use of multipurpose identifiers on the grounds that it becomes too easy for government officials from one department to gain access to a person's health record or combine a number of records to assemble a comprehensive profile. (Anecdotal evidence suggests that this concern may be justified and that there are insufficient safeguards preventing the flow of health information among government departments) The Council recommends that all governments ensure that they have legislation to address privacy protection specifically aimed at protecting personal health information through explicit and transparent mechanisms. Included in these mechanisms are:

- The provision of a precise definition of free and informed consent, as well as a statement of principle that informed consent should be the basis for sharing personal health information;

- Any exemption to the requirement of informed consent should be clearly set out in law. More specifically, legislative guidance should be provided on how to balance the right of privacy with the public good for research purposes to implement a coherent and harmonized pan-Canadian system for independent, ethical review.
- There should be provisions regulating secondary uses of non-identifiable health information. These provisions should address privacy concern surrounding the degree to which data might be linked back to an identifiable individual.
- Legislation should set clear limits on access to and use of health information by third parties outside the health care system. To prevent the serious invasions of privacy that can result from the unrestricted linking of personal health information with other kinds of information on the same individual, the legislation should contain provisions prohibiting the use for any other purpose of unique personal identifiers in health information systems.

D. The Approach in Bill C-54

Bill C-54 is inadequate in its protection of health information. The Bill makes a meagre attempt at distinguishing among varying types of personal information and gives no additional protection to information that is highly sensitive (such as health information). The Bill permits the collection, use and disclosure of information *without knowledge or consent* on grounds such as expediency, practicality, public good, research, offence investigation, historic importance and artistic purposes. In the context of health information, these grounds should be subject to intense scrutiny to determine their relevance and legitimacy. In CMA's view and according to the tests established in the CMA's Code, some of these grounds would not withstand such scrutiny.

E. Conclusion

CMA's Code offers a template for the protection that should be accorded health information, a template that appears to have some public support and that strives to retain patient confidence in their physicians and the health care system. The Report of the Federal Advisory Council also recognizes that special rules are required for health information. The Council's Report places strong emphasis on the protection of privacy, recognizes that as a general rule the flow of health information should be on a need-to-know basis and under the control of the patient through the exercise of free and informed consent and requires limits on the secondary use of health information. In CMA's view, Bill C-54 should incorporate specific rules relating to health information and CMA's Code should form the basis of these rules. CMA recommends:

That Bill C-54 be amended to incorporate specific provisions relating to health information and that the provisions of the CMA Code provide the basis of such provisions.

In addition, CMA's Code provides a test that legislation addressing health information should be subjected to. This test (found in section 3.6 of the CMA Code) states:

Any proposed or existing legislation or regulation made under legislative authority that permits or requires health information collection, use, disclosure or access shall be subjected to the following legislative test:

- (a) There must be demonstration that:
 - (i) a patient privacy impact assessment has been conducted, the analysis has been made public and has been duly considered prior to the introduction of legislation [section 3.5 of the Code provides guidance with respect to the patient privacy impact assessment];
 - (ii) collection, use, disclosure and access will be limited to the greatest degree possible to ensure that
 - the collection of health information by persons external to the therapeutic context will neither trade on nor compromise the trust of the patient-physician relationship;
 - patients are not likely to be inhibited from confiding information for primary purposes;
 - the ability of physicians to discharge their fiduciary duties to patients will not be compromised; and,
 - patient vulnerability will not be exploited;
 - (iii) collection, use, disclosure and access will be restricted to what is necessary for the identified purpose(s) and will not impede the confiding or collection of information for primary purposes;
 - (iv) provisions exist for ensuring that patients are provided with knowledge about the purpose(s) and that, subject to 3.6(b), patient consent is clearly voluntary;
 - (v) the means used are proportionate and the collection will be limited to purposes consented to or made known to the patient;
 - (vi) the patient's privacy will be intruded upon to the most limited degree possible in light of the purpose(s) consented to or made known to the patient;
 - (vii) linkage of the health information will be limited; and
 - (viii) unless clear and compelling reasons exist:
 - all reasonable steps will be taken to make health information anonymous; and
 - if it has been demonstrated that making health information anonymous would render it inadequate for legitimate uses, the information will be collected and stored in a deidentified-relinkable format.
- (b) When nonconsensual collection, use, disclosure or access is permitted or required by legislation or regulation that meets the requirements of the Code, the following conditions must also be met:
 - (i) the right of privacy has to be violated because the purpose(s) could not be met adequately if patient consent is required; and
 - (ii) the importance of the purpose(s) must be demonstrated to justify the infringement of the patient's right of privacy in a free and democratic society.

- (c) Any legislative provision or regulation that permits or requires health information collection, use, disclosure or access nonconsensually shall not, without compelling reasons, be applied retroactively to existing health information.

In its current form, Bill C-54 would not pass the scrutiny of the test. Consequently, CMA recommends:

That the proposed rules for health legislation be subject to the legislative test found in CMA's Code and formulated in light of this process.

IV. Specific Comments on Bill C-54 From the Perspective of CMA's Health Information Privacy Code

This section highlights some key distinctions between the approach taken by Bill C-54 and CMA's Health Information Privacy Code. The purpose of this section is to illustrate through examples the divergence of approaches taken with the ultimate aim of demonstrating that Bill C-54 is inadequate in the protection it accords health information.

A. General

Bill C-54 and CMA's Health Information Privacy Code are based on the Canadian Standards Association's Model Code for the Protection of Personal Information (CSA Code). Bill C-54 and the CMA Code also augment the CSA Code's provisions where considered necessary. The need to extend the provisions of the CSA Code demonstrates that the CSA Code, being general in nature, provides inadequate protection to information in many instances.

Although Bill C-54 and the CMA Code are based on the CSA Code, each takes a different approach to the ultimate protection accorded information. This divergence demonstrates that there are many ways to resolve issues left unresolved by the CSA Code. In other words, it is not a foregone conclusion that basing provisions on the CSA Code will result in appropriate or adequate protection of information. Rather, resolution of issues requires thought and deliberation and will depend in some measure on the primacy given to certain values. Bill C-54 appears to have given access primacy in the pursuit of commerce, whereas CMA gives privacy protection primacy in the pursuit of the provision of health care in accordance with physicians fiduciary obligations to patients and the integrity of the patient-physical relationship.

CMA did not develop its approach in a vacuum. It reviewed and was inspired by the report of the House of Commons Standing Committee on Human Rights and the Status of Persons with Disabilities, entitled *Privacy: Where Do We Draw the Line?* This report articulates and makes explicit many of the issues that should be informing the current debate on Bill C-54. In addition, the Report of the Advisory Council takes a very different approach to Bill C-54. The Report recognizes the need to pay more than lip service to

protecting privacy and confidentiality and recommends specific measures aimed at doing this.

B. Information Protected

Bill C-54

The Bill covers “personal information” which is defined to mean “information about an identifiable individual that is recorded in any form.” This definition raises a host of questions:

1. Does the Bill cover or not information that has been delinked to an identifiable individual but that could be relinked to identify them?
2. Does the Bill only exclude anonymous information - that is, information that could never be relinked to an identifiable individual? And if so, is there an unjustified assumption that information can, in all cases, be rendered truly anonymous?
3. In the case of delinked and anonymous information, who decides that information about an identifiable individual can be rendered delinked or anonymous? The holder of the information or the person to whom the information pertains?
4. Is it accurate or reasonable to assume that people have no interest in information emanating from them once it has been rendered delinked or anonymous?

CMA Health Information Privacy Code

The CMA Code provides a broad definition of health information:

Health information means any information about a patient that is confided or collected in the therapeutic context, including information created or generated from this information and information that is not directly or indirectly linked to the provision of health care. It includes all information formats.

In addition, the CMA Code covers identifiable information, delinked information, anonymous information and any composite form that is produced when health information is linked to other information about the patient.

CMA's research indicates that patients may have an interest in their information when it is in delinked and anonymous formats.

Advisory Council Report

The Advisory Council Report addresses this issue in a number of ways. In making recommendations concerning the definition of health information the Report calls for legislation that embodies:

a clear definition of health information, broad enough to incorporate health information collected in public and private systems and to ensure that equal obligations and penalties apply to both public and private sectors.

The report recognizes a spectrum of data formats: completely anonymous, linked to pseudo-identities, code linked and reidentifiable, completely identifiable. In terms of sensitivity, the Report notes that information that can be re-identified is somewhat more sensitive than completely anonymous data or anonymous data linked to pseudo-identities and that completely identifiable health information is the most sensitive type of health information. The Report also notes that there can be some degree of risk of re-identification of what was believed to be anonymous data through such processes as data matching and the results of analysis using small cells. In this light, the Report recommends:

A definition of personal health information, which takes into account the spectrum of potential identifiability in the case of health information.

Furthermore, in the case of secondary uses of health information, the Report notes that provisions regulating secondary uses of non-identifiable health information must form part of the legislation. Such provisions should address privacy concerns surrounding the degree to which data might be linked back to an identifiable individual.

The Report raises further issues relating to the use of delinked and anonymous data. The Report notes that there may be group interests and concerns regarding data collected and states:

Privacy can also be a concern for groups such as Aboriginal and immigrant communities. These communities worry that research on their members could be released to the media without notice and used in a negative way. This emerging issue is growing in importance and, in the Council's view, should be a serious consideration in the context of ethical reviews of proposed research projects.

It is important to note that in these instances it is not the fact that data is linked to an identifiable individual that is of concern. Rather, it is the ability to accumulate, process and dissect information that has ramifications for an individual because they are part of a group segregated and identified by the research.

Finally, the Report considers the use of person-based data but not people's names, for statistical purposes and notes that this too raises concerns about privacy. The Report notes

that:

“These concerns have traditionally been seen as a tradeoff against data access for research and analysis in the public interest.”

The Report restates this to provide a more positive view of privacy and states: “the best way for analysts to maintain the public’s consent to use sensitive (but anonymous) health data is to show the public that privacy, confidentiality and security are being taken seriously.”

Recommendation

That there be a clear definition of the information being accorded a right of privacy and that this definition, at least in the case of health information, include identifiable information, delinked information, anonymous information and any composite form produced when information is linked to any information about a person from any other source.

C. Knowledge of Purpose Prior to Collection

Bill C-54

Bill C-54 is ambiguous in its provisions relating to whether or not a person should know the purposes for which information will be used prior to disclosure. This is due in part to the use of the term “knowledge and consent” as one concept rather than distinguishing the knowledge requirement from the consent requirement. What a person should know in relation to the purposes information might be used or disclosed for, prior to its being given is distinct conceptually from whether the person must consent before information can be used or disclosed for a particular purpose.

Schedule 1 of the Bill contains a number of principles. For the purposes of this brief the schedule will be referred to in terms of the principles (and their subparagraphs). Principle 2 addresses the identification of purposes that information will be used or disclosed for. Provided a purpose is identified it becomes a legitimate purpose under the Bill. Subparagraph 3 states that the identified purposes *should* be specified at or before the time of collection. Section 5(2) of the Bill states that the use of ‘should’ in schedule 1 indicates a recommendation and does not impose an obligation. Therefore, according to subparagraph 3, it is recommended but is not obligatory that disclosure occur.

On the other hand, principle 3 addresses consent and appears to impose an obligation by stating that the knowledge and consent of the individual *are required* for the collection, use, or disclosure of personal information, except where inappropriate. Similarly subparagraph 2 appears to create something of an obligation by stating, “organizations shall make a reasonable effort to ensure that the individual is advised of the purposes for which the information will be used.”

The relationship between these sections should be clarified and made consistent.

CMA is pleased to note that principle 3 has been modified to define when, and only when, organizations may collect information without knowledge or consent. Section 7(1)(a) permits the collection of information without knowledge and consent when collection is clearly in the interests of the individual and consent cannot be obtained. The intent of this section could be made clearer, particularly in terms of who determines the “interests of the individual.” Otherwise this exception could give undesirable license to collect without knowledge or consent.

The provision in section 7(1)(b) is more problematic. This section appears to favour withholding knowledge from an individual if such knowledge would compromise accuracy, defeat the purpose for collection or prejudice the use. In some instances it may well be that if an individual is provided with knowledge of the purposes for which information is collected and the uses to which it will be put, they may choose to withhold information rather than disclose it, and in doing so would clearly compromise accuracy, defeat the purpose for collection or prejudice the use the information will be put to. This is contrary to the principle found in principle 4.1 which recognizes that information should not be collected by misleading or deceiving individuals.

The intent of this section should be far clearer and circumscribed in such a way as to make it clear that it is not permissible to withhold knowledge or not seek consent simply on the basis that if a person had knowledge they would not wish to disclose information.

Section 7(1)(c) allows collection without knowledge or consent for journalistic, artistic or literary purposes. This provision is totally inappropriate in the case of health information.

CMA Health Information Privacy Code

The CMA Code is considerably more restrictive than Bill C-54. It recognizes that in the therapeutic context, health information is confided by or collected from patients under the patient presumption that it is necessary to meet his or her therapeutic needs. CMA also believes that the potential that health information may be subsequently collected, used, disclosed or accessed for other purposes without patient consent should be made known to patients before information is confided or collected for the primary therapeutic purpose. CMA further notes that it is not acceptable to withhold knowledge from patients deliberately out of concern that knowledge could inhibit them from confiding important information fully and truthfully.

CMA limits the circumstances the nonconsensual collection of health information to those:

1. Permitted or required by legislation;
2. When ordered or decided by a court of law.

Moreover, the CMA gives explicit direction to legislators with respect to the conditions under which legislation should permit or require health information collection (see section 3.6 of CMA Code). In the case of nonconsensual collection, the following conditions are stipulated:

1. The right of privacy has to be violated because the purposes could not be met adequately if patient consent is required; and
2. The importance of the purposes must be demonstrated to justify the infringement of the patient's right of privacy in a free and democratic society.

While Bill C-54 is clearly enabling the collection of information, it does not, in CMA's opinion put sufficient emphasis on or provide protections that preserve privacy and confidentiality, especially in the medical context.

D. Use Without Knowledge Or Consent

Bill C-54

Once information has been collected and despite the, albeit inadequate, limits placed on collection without knowledge or consent, it can be put to even greater use than the purposes it has been collected for with or without knowledge or consent. Section 7(2) opens up dramatically the uses to which collected information may be put without either knowledge or consent. At a minimum and without little additional administrative effort, the enumerated grounds of section 7(2) (and 7(3)) should be made known to an individual prior to their disclosure of information, which would be in keeping with the principle of openness and explicitness.

Section 7(2)(a) allows use in connection with the investigation of an offence. In the medical context this might be problematic particularly if it is interpreted to impose an obligation. Generally, there is no obligation to assist in the investigation of an offence and indeed the fiduciary duty between patient and physician and the duty of confidentiality owed to the patient by the physician would suggest that physicians not offer information despite its usefulness.

Section 7(2)(b) recognizes emergency situations. However, as worded, section 7(2)(b) would allow access to anyone's information if it is for the purpose of acting in respect of an emergency threatening the life, health or security of *an* individual. The implications of this section should be carefully thought through. Do we really intend to give such a broad licence to access anyone's information on the basis of an emergency. In CMA's view there should be some limiting principle that takes into account the prevailing view that people generally are not *required* to go to the assistance of others (emergency or otherwise) and that information about oneself is considered worthy of protection against use or disclosure despite its potential benefit to others for example, genetic information or HIV, Hepatitis C status.

Section 7(2)(c) is very problematic as it permits the use of "identifiable" information for a host of purposes, including statistical and research, when it is impractical to seek consent. Even though the Commissioner must be informed of the use before the information is used the Commissioner has no power to approve or reject the use, and since the use is legitimate under the Bill provided the Commissioner has been notified there would be no grounds open to the Commissioner to cause an audit to occur. This section gives significant scope

to use information that has been collected without knowledge or consent and certainly in the case of health information is problematic.

CMA Health Information Privacy Code

The CMA Code makes a clear distinction between the primary purpose for the collection and use of health information and secondary purposes for its use. The key distinction between these two categories is that primary purposes relates to the provision of the health care benefit sought whereas secondary purposes are ends or aims that are not directly related to the provision of care. The CMA Code divides secondary purposes into two categories:

1. Secondary legislated purposes, those purposes that have been subjected to the legislative test specified in the Code and have subsequently been written into law;
2. Secondary nonlegislated purposes are any other purposes, such as education or research not governed by legislation, that meet the provisions of the CMA Code and the secondary nonlegislative test provided by the Code.

The tests that CMA requires both to go through relate to:

1. Impact on privacy.
2. Impact on the patient-physician relationship, especially confidentiality and trust.
3. Impact on the willingness of patients to disclose information.
4. Impact on patients' ability to receive care.
5. Evidence of broad public support for the measure.
6. The use will not exploit or compromise the trust of the patient-physician relationship.
7. Patient vulnerability will not be exploited.
8. Under most circumstances patients will be fully informed of the purpose and patient consent will be clearly voluntary.
9. Patient privacy will be intruded upon to the most limited degree possible.
10. Linkage of health information will be restricted and consented to by patients.

In other words, CMA is not satisfied that any and all secondary purposes for the use of health information should be permitted. Rather, CMA seeks justification for the secondary use and assurance that the secondary use will neither impede nor undermine the patient-physician relationship and the provision of health care to the patient. Moreover, the CMA Code only permits use without consent if it is permitted or required by legislation or when ordered or decided by a court of law.

The Advisory Council Report

Like CMA, the Advisory Council Report makes distinctions among various types of uses. The report calls for legislation to clearly prohibit all secondary commercial use of personal health information. In addition, the Report recommends that there be provisions regulating secondary uses of non-identifiable health information and that such provisions should address privacy concerns surrounding the degree to which such data might be linked back to an identifiable individual. In this context, the Report recommends that legislation set clear limits on access to and use of health information by third parties outside the health care system.

In addition the Report reviews the uses of health information for statistical and research purposes. The Report's findings with respect to statistical use have already been discussed. In connection with research, the Report calls for a number of safeguards and restrictions:

1. Where the data sets used have a higher level of potential identifiability, "the general rule should be informed consent and stringent assurances about privacy protection and security arrangements are necessary before a researcher can have access to personally identifiable information."
2. The Report recognizes that in some instances it may be impractical to obtain consent from patients. Whether in anonymous or identifiable form the Report requires that notice be given about the use of the information in either form. In the case of the use of identifiable information, the Report states that the research should be subject to independent ethics review with the onus on the person seeking to use the information without consent to demonstrate that:
 - (a) a tangible public good of significant benefit will result;
 - (b) consent is impossible to secure at a reasonable cost;
 - (c) less identifiable data will not serve the same purpose; and
 - (d) no harm can occur to any person directly or indirectly [note the above discussion on group privacy] as a result of this use of his or her personal information.

E. Disclosure Without Knowledge Or Consent

Bill C-54

The comments found under C. and D. above apply equally here. Section 7(3) adds further instances when collected information can be disclosed to others without knowledge or consent.

CMA Code

In the case of health information CMA takes a far more restrictive approach. In the case of use, disclosure or access the CMA Code states:

The potential that health information, in whole or in part, may be subsequently collected, used, disclosed or accessed for other purposes without their consent, and what those purposes might be, must be made know to the patient by reasonable means before it is confided or collected for primary purposes.

Moreover, the CMA Code recognizes that information disclosed by one organization is *collected* by another. The Code defines collection to mean:

the act of accessing, receiving, compiling, gathering, acquiring or obtaining health information from any source, including third parties, and by any means. It includes information collected from the patient, as well as secondary collection of this information in whole or in part by another provider or user.

The collecting organization should be bound by the provisions of the CMA Code, which generally requires consent for use for any purpose and always requires knowledge of the potential purposes that information will or must be put to prior to the information being disclosed. CMA's Code states:

Health information custodians must ensure that third parties privy to health information have adopted this Code or are bound by equivalent provisions.

Finally, the CMA Code explicitly recognizes that information can be retrieved from a variety of sources to formulate records. Any and all such practices and the composite form developed are given the same degree of protection as that accorded the original data collected by or through the patient.

F. Information Flow Within Organizations

Bill C-54

Bill C-54 defines use to include, "the transfer of personal information within an organization." Therefore, to the extent that Bill C-54 restricts the free flow of information it restricts in within an organization. In the health care context this is not a reasonable or

desirable outcome.

CMA Code

The CMA Code recognizes that the free flow of health information is desirable to the extent that it furthers the provision of the health care benefit sought and that it occurs with patient consent. The CMA Code defines the primary purpose to mean:

- (i) Primary therapeutic purpose is the initial reason for a patient seeking or receiving care in the therapeutic context, and pertains to the delivery of health care to a particular patient with respect to the presenting health need or problem. It encompasses consultation with and referral to other providers on a need-to-know basis.
- (ii) Primary longitudinal purpose concerns developing composite health information about a particular patient, such as a detailed medical history, beyond direct application to the presenting health need or problem, in order to enhance ongoing care to that person.

The Code goes on to state that:

Health information collection, use, disclosure or access for the primary therapeutic and longitudinal purposes may be as extensive as necessary to fulfil these purposes and reflect the high level of trustworthiness and accountability of health professionals in the therapeutic context.

And further states that:

Security safeguards shall impede as little as possible health information collection, use, access and disclosure for primary purposes.

Finally, in addressing consent the Code states:

Consent to health information collection, use, disclosure and access for the primary therapeutic purpose may be inferred. Consent to subsequent collection, use, disclosure and access on a need-to-know basis by or to other physicians or health providers for this purpose, and for this purpose alone, may be inferred, as long as there is no evidence that the patient would not give express consent to share the information.

G. Individual Access

Bill C-54

Bill C-54 restricts the right of individual access to personal information. The grounds for denying access to information are inappropriate in the health care context.

CMA Code

The CMA Code follows the prevailing case law as it relates to medical records. Primarily this gives the patients a right of access to their record in all but very limited circumstances. These circumstances are, if there is a significant likelihood of a substantial adverse effect on the physical, mental or emotional health of the patient or substantial harm to a third party. The onus lies on the provider to justify denial of access.

H. Accuracy and Amendment

Bill C-54

Bill C-54 requires that information be as accurate, complete and up-to-date as possible and that it shall not be routinely updated unless this is necessary to fulfil the purpose for its collection. In so far as amendment is concerned, Bill C-54 permits amendment to the record in specified circumstances.

CMA Code

The CMA Code takes a different approach in light of the nature and purpose of health information. The Code recognizes that the “recording of statements of fact, clinical judgements and determinations or assessments should reflect as nearly as possible what has been confided by the patient and what has been ascertained, hypothesized or determined to be true using professional judgement.” In terms of amending the record in light of a patient’s request, the CMA Code seeks to preserve the original record but also note the patient’s concerns. To accommodate both requirements the CMA Code states:

Patients who have reviewed their information and believe it to be inaccurately recorded or false have the right to suggest amendments and to have their amendments appended to the health information.

I. Sensitivity

Bill C-54

In a number of instances Bill C-54 and in particular schedule 1 recognize that medical records have a high level of sensitivity attached. Which in turns warrants special attention concerning consent, reasonable expectations, individual access and implicity, the degree of security that is appropriate.

CMA Code

The CMA Code seeks to recognize that while all health information is sensitive (when considered against other forms of information about individuals) there are also variations in the level of sensitivity in various aspects of the health record. The CMA Code defines the “sensitivity of health information” to refer to:

the patient’s interest in keeping the information secret. It varies according to the nature of the information, its form, and the potential negative repercussions of its collection, use or disclosure on the patient’s interests.

Under the Code’s consent provisions it is stated that:

Although all health information is sensitive and should be treated as such, the more sensitive the health information is likely to be, given what is known about the circumstances or preferences of the patient, the more important it is to ensure that consent is voluntary and informed.

With respect to security the Code states:

The development of security safeguards with respect to levels of access for various users shall recognize the differences in the sensitivity of health information and permit access accordingly.

V. Conclusions

The increased capacity to collect, store, transfer, merge and access information coupled with trends that support increased use of and access to information have the potential to erode our traditional understanding and protection of privacy and confidentiality. The issues are complex and the choices we must make are difficult. Nevertheless, these issues should be squarely on the table and the choices that we make must be clear, transparent and defensible. Of paramount importance is that the public is not misled into believing that their information is being protected or kept confidential when in fact it is not. Therefore, even to refer to Bill C-54 as the “Personal Information Protection and Electronic Documents Act” should be the subject of debate. Is the Bill truly about information protection or is it actually about permitting access to information?

Bill C-54 presents one approach, an approach that values commerce and access. In CMA’s view the approach is totally inadequate when applied to health information. CMA also believes that the public would also find Bill C-54 inadequate.

CMA presents a different approach, an approach that values privacy and the preservation of the trust and integrity of the patient-physician relationship. CMA believes that its approach would receive broad public support. Moreover, CMA believes that to the extent the CMA Code presents tests rather than conclusions, these tests should be administered in good faith prior to legislative initiatives related to health information or in the case of secondary usage of health information in general.

CMA believes that its approach draws support from the Federal Advisory Council Report, which also recognizes the importance of preserving patient privacy and the confidentiality of the health record in an era of increased use of technology. Implicitly, the Report recognizes that the benefits of such technology cannot be realized if public support, based on assurance of privacy protection, cannot be secured.

CMA urges this committee to implement CMA's recommendations and in doing so provide the type of protection that health information deserves and that Canadians desire.

VI. Summary of Recommendations

That Bill C-54 be amended to incorporate specific provisions relating to health information and that the provisions of the CMA Code provide the basis of such provisions; and

That the proposed rules for health legislation be subject to the legislative test found in CMA's Code and formulated in light of this process; and

That there be a clear definition of the information being accorded a right of privacy and that this definition, at least in the case of health information, include identifiable information, delinked information, anonymous information and any composite form produced when information is linked to any information about a person from any other source; and

That, at least in connection with health information, the provisions of the Bill apply equally to the public and the private sectors.