Health Protection and a Canadian Public Health Strategy: A Comprehensive Approach To Public Health

Submission to Health Canada

April 2004

ASSOCIATION MÉDICALE CANADIENNE
CANADIAN MEDICAL ASSOCIATION

A healthy population…a vibrant medical profession
Une population en santé…une profession médicale dynamique

The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, CMA's mission is to serve and unite the physicians of Canada and be the national advocate, in partnership with the people of Canada, for the highest standards of health and health care.

On behalf of its more than 57,000 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.

ASSOCIATION MÉDICALE CANADIENNE

CANADIAN MEDICAL ASSOCIATION

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Executive Summary

This submission is the response of the Canadian Medical Association to Health Canada's request for feedback on its detailed "Health Protection Legislative Renewal" legislative proposal released in June 2003. Our submission calls for and is embedded in the broader context of a comprehensive approach to public health.

The Canadian Medical Association is committed to working with others to realize the vision of a comprehensive, robust public health strategy as a vital component of Canada's health care system. This strategy should rest upon three pillars:

- ***Emergency Response*** Empowering rapid and effective response to health emergencies, e.g. communicable disease outbreaks, water contamination, bio-terrorist attacks.
- ***Health Protection:*** Ensuring that Canadians are protected from health risks in their daily environment; for example, risks associated with the use of health or consumer products, or with the potential spread of infectious disease.
- ***Health Promotion and Disease Prevention*** Instituting programs to encourage healthy behaviour and advocating for public policy and fiscal policy that supports health.

Though these three pillars have different foci and different legislative instruments, they must all be part of a strategy to enhance public health and public health service delivery in Canada.

With specific reference to health protection, CMA believes that legislation should rest on the following principles:

a) Commitment to the primacy of health and safety.

b) Commitment to evidence-based decision making.

c) A thorough risk-analysis procedure based on the relative risk of products or services.

d) Support for informed patient decision-making.

e) Accountability vested in the Government of Canada.

f) A comprehensive, effective post-marketing surveillance system.

g) Enforcement through effective, meaningful penalties for noncompliance.

h) Flexibility to quickly and efficiently accommodate new technologies.

i) Openness and transparency.

j) Encouragement of collaboration and co-operation with other stakeholders, while respecting existing jurisdictions and legislative mechanisms.

Recommendations

A Canadian Public Health Strategy

1) That the federal government ensure that legislative and administrative measures related to public health complement one another in function and are connected through communications and co-ordination mechanisms.

The Drug Review Process

2) That the federal government implement a timely and efficient drug review process to reduce review times to the fastest level consistent with ensuring improved health outcomes and the safety of the drug supply.
3) That the federal government consider co-operative agreements for drug review with comparable agencies in Europe, the United States and Australia, while retaining final authority as to whether a new product should be allowed on the Canadian market.
4) That the drug review and approval process be open and transparent, providing updates on review status and the opportunity for stakeholder input.
5) That Health Canada apply a priority review process to “breakthrough” drugs, i.e. those that demonstrate a substantial improvement over products already on the market.

Patient Safety and Post-Marketing Surveillance

6) That Health Canada work in partnership with stakeholders including CMA and other national medical and health professional associations, to develop a rigourous post-marketing surveillance system to monitor the ongoing safety of marketed drugs.
7) That government accelerate activities to establish the Patient Safety Institute using a systems approach to support a culture of safety.
8) That all stakeholders join in supporting and encouraging outcome-based research to ascertain best practices in prescribing.
9) That the federal government invest in measures such as electronic communications networks, to increase physicians' capacity to report medication incidents and to improve the timeliness of adverse event reporting.

Drug Information and Advertising

10) That all stakeholders work to ensure that Canadians have ready access to a source of comprehensive, reliable information on health products and their uses, and that governments fund development and dissemination of validated information to physicians and to the public.

11) That the legislation define “promotion” and “advertising” so as to clearly distinguish them from unbiased health information, and from counselling by health professionals.

12) That the current safeguards against deception be strengthened in order to
    - Forbid fraudulent or misleading health claims in advertisements, on labels or in any other promotional or descriptive material pertaining to the product;
    - ensure pre-clearance and ongoing review of all health claims by an objective agency;
    - provide meaningful penalties for infraction.
13) That Health Canada maintain the current ban on advertising health products for treatment, prevention and cure of conditions or disease states to be identified in a regulatory schedule or administrative list; the inclusion of conditions in this list should be determined through a set of criteria that are written into the Act or regulations.
14) That the existing ban on direct to consumer advertising of prescription drugs be maintained and enforced to the full extent of the law, and that the loophole that currently permits advertising the name, price and quantity of a prescription drug be closed.
15) That all stakeholders, including medical associations and industry groups, work together toward effective regulation of drug promotion to health practitioners.

Safeguarding the Privacy of Health Information

16) That the Health Protection Act respect the provisions of the Charter of Rights and Freedoms, the Federal Privacy Act and the Personal Information Protection and Electronic Documents Act (PIPEDA).
17) That the privacy provisions in the Health Protection Act meet the legislative test outlined in Section 3.6 of CMA's Health Information Privacy Code.

Other Issues

18) That the Health Protection Act give Health Canada a clear mandate to develop guidance documents to address health and safety issues raised by new technologies.
19) That Natural Health Products be regulated on a strict framework that ensures their safety, quality and efficacy as well as the provision of complete and unbiased information to the public.
20) That the Act provide Health Canada with a clear mandate to collaborate with provincial/territorial and local governments across Canada in reviewing legislation governing all aspects of drinking water from source to consumption to ensure that comprehensive programs are in place and being properly implemented.
21) That Health Canada urgently review the Quarantine Act and modernize its provisions.

1. Introduction

This submission is the response of the Canadian Medical Association (CMA) to Health Canada's request for feedback on its detailed "Health Protection Legislative Renewal" legislative proposal released in June 2003. Our submission calls for and is embedded in the broader context of a comprehensive approach to public health. It also includes recommendations dealing with selected specific issues raised in the proposal, particularly those that have a potential major impact on physicians and other health professionals, and on the practice of medicine.

The Canadian Medical Association supports the government's efforts to update and revitalize health protection legislation. Physicians are committed to working with others to realize the vision of a comprehensive, robust public health strategy as a vital component of Canada's health care system, in order to realize Canada's potential as a healthy nation.

Recent headlines illustrate the diversity of public health challenges facing Canadians:

- The spread of avian flu across Asia, and the reappearance of SARS in China;
- Reports linking the use of Selective Serotonin Reutake Inhibitor antidepressants to increased suicide and other behavioural disorders in children and adolescents, which led to a public warning against their use in this population;
- The rapidly rising rates of obesity in Canada and other developed countries.

To deal with these problems and others, a comprehensive public health strategy is required. This strategy should rest upon three pillars: emergency response, health protection and health promotion (Figure 1). Each of these pillars is discussed in greater detail in the following section.

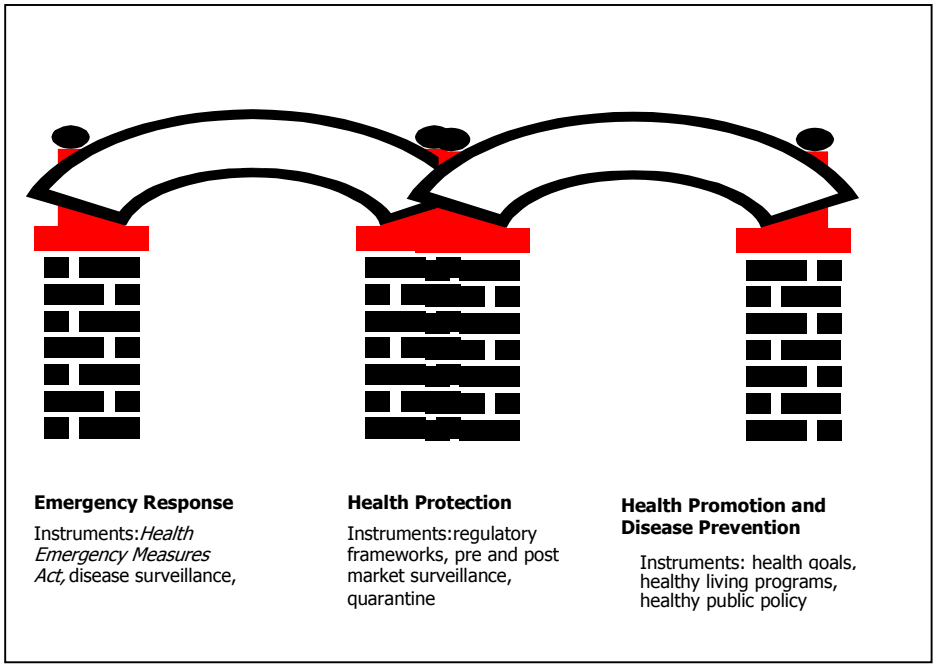
2. Three Pillars of a Canadian Public Health Strategy

a) Pillar #1: Emergency Response

The 2003 SARS outbreak shone a merciless light on the difficulties that Canada's stretched public health system can encounter when it needs to respond to health emergencies. The 21st century has brought a disturbing array of new public health risks (such as avian flu) and old risks revisited (such as contamination of water supplies). A comprehensive public health strategy should be able address these risks by:

- Empowering rapid and effective response to health emergencies, e.g. communicable disease outbreaks, water contamination, bio-terrorist attacks.
- Supporting health surveillance, screening and research, to identify potential health risks.

Figure 1. The Three Pillars of Public Health



CMA Position: CMA's 2003 submission to the National Advisory Committee on SARS and Public Health (the Executive Summary is attached as Appendix I) recommended a number of measures to strengthen Canada's capacity to respond to health emergencies. These included:

- The enactment of a *Canada Emergency Health Measures Act* to allow for a more rapid national response to emergencies that pose an acute and imminent threat to human health and safety in Canada.
- The creation of an independent *Canada Public Health Agency,* headed by a Chief Public Health Officer of Canada who would work with provinces and territories to develop and implement a pan-Canadian public health action plan.
- Enhancements to the current system of disease surveillance and response, so that it remains privacy sensitive and ensures a two-way flow of information between public health experts and front-line clinicians.

In 2004 CMA reiterated these recommendations to the Honourable Carolyn Bennett, Minister of State for Public Health, in response to her request for consultation on a Canada Public Health Agency.

b) Pillar #2: Health Protection

The Health Protection function ensures that Canadians are protected from health risks in their daily environment; for example, risks associated with the use of health or consumer products, or with the potential spread of infectious disease. Specific health protection functions include:

- Ensuring that Canadians have access to the right pharmaceutical drugs, which have been proven safe and efficacious, at the right times, for the right prices. Our policy in this area is further discussed in our 2003 submission to the House Standing Committee on Health's review of prescription drugs, an executive summary of which is attached (Appendix II).
- Monitoring Canada's pharmaceutical drug supply to ensure its safety, effectiveness and continued availability.
- Ensuring the safety of natural health products, medical devices, hazardous products and other consumer products. This should include the regulation of toxic substances, including tobacco.
- Regulating health claims for consumer products.
- Monitoring the advertising and promotion of health products to the public.
- Administering quarantine procedures.
- Developing regulatory frameworks to ensure the safety and effectiveness of new technologies such as gene therapy and genetically modified foods.

CMA Position: The principles that CMA believes should guide review of health protection legislation are discussed in Section 3.

c) Pillar #3: Health Promotion and Disease Prevention

For more than 30 years the federal government has incorporated the promotion of health, as well as the treatment of disease, into its mandate. Activities undertaken in pursuit of this function include:

- Programs to encourage healthy behaviours, e.g. physical activity strategies.
- Advocating for or implementing public policy that supports health e.g. bans on tobacco advertising and sponsorship, and fiscal policies, such as high tobacco taxes.
- Research strategies to increase our understanding of the determinants of health.

CMA Position**:** The CMA has called on the federal government to commit to the goal of establishing Canada as the top country in the world with regard to the health status of its citizens. Canada remains one of the few countries in the industrialized world without a clear statement of national health goals, targets and strategies. All levels of government should enable the Health Council of Canada to monitor and report on defined health goals and priorities.

In addition, the CMA has developed policies and statements urging action on specific health promotion issues including: obesity control; injury prevention; physical activity; tobacco control; mental health; and many others.

Though these three pillars have different foci and different legislative instruments, they must all be part of a comprehensive legislative agenda and strategy to renew and enhance public health and public health service delivery in Canada. Addressing issues under one pillar without reference to the other pillars or to a comprehensive public health framework and strategy fails to address the overall public health needs of Canadians.

Recommendation

1. ***That the federal government ensure that legislative and administrative measures related to public health complement one another in function and are connected through communications and co-ordination mechanisms.***

3. A Policy Framework for Health Protection Legislation

This submission is a response to a legislative proposal regarding health protection; consequently the rest of this document will focus on the second of the three pillars described above, the "health protection" pillar.

This section discusses the overall policy framework that the CMA believes should govern health protection in Canada. The CMA holds that health protection legislation should rest on the following principles:

i) ***Primacy of Health and Safety***. Legislation should commit to protection of public health and safety as its primary objective.

ii) ***Core Values***. Legislation should recognize the core values of Canadians, such as privacy of health and personal information, freedom of choice, and protection of vulnerable citizens, and be sensitive to cultural, gender, socio-economic and other factors where relevant. Where there is a conflict between Principle (i) and other values, this conflict and the grounds on which to resolve it should be explicitly stated.

iii) ***Evidence-based Decision Making.*** Legislation should reflect a commitment to scientific, evidence-based decision making. It should provide for the requisite mechanisms to ensure that reviews of risk are independent and unbiased.

iv) ***The Risk Assessment Process.*** Legislation should reflect a thorough risk-analysis procedure including risk assessment and evaluation. The pre-approval scrutiny to which a product[1] is subjected should be based on its relative risk: regulatory requirements should be greater for products with greater risk and lower for those with less risk. Risk assessment should take into account risk to the community as well as to individuals. While the risk assessment process should be science-based, it should also recognize that public perception might influence the management and communication of risk. In areas of risk uncertainty, application of the precautionary principle could be considered on a case-by-case basis.

[1] Though this submission uses the word "product" in this context, it is understood that services, e.g. therapeutic procedures, may also be covered by the *Health Protection Act.*

v) ***General Safety Requirement.*** The CMA supports the proposal to include in the legislation a General Safety Requirement that would make it illegal for anyone to manufacture, promote or market a product that may present an undue risk to health, under reasonably foreseeable conditions of use. However, this overall requirement should not be used as a substitute for enacting regulations to cover specific products if evidence indicates that such regulations are necessary to protect public health. Nor should it be used as a rationale for relaxing regulatory regimes currently in place.

vi) ***Support for Informed Patient Decision-Making.*** Legislation should ensure that Canadians have access to reliable, evidence-based information to support them in making decisions regarding their own health, and should ensure that the information they receive is not misleading or deceptive.

vii) ***Accountability***. Legislation should ensure that there is clear accountability for decision-making, and that this is vested in the Government of Canada.

viii) ***Surveillance.*** Legislation should ensure comprehensive, effective post-marketing surveillance of drugs and other health products. This should be co-coordinated with surveillance and research programs governed by related public health acts such as the proposed *Canada Emergency Health Measures Act*.

ix) ***Enforcement.*** Legislation should provide and enforce effective, meaningful penalties for noncompliance.

x) ***Flexibility***. Legislation should allow for flexibility in product approval, consistent with Principle i, in order to quickly and efficiently accommodate emerging issues (such as new technologies) developed in Canada and internationally.

xi) ***Openness and Transparency.*** Legislation should operate transparently, incorporating ongoing, two-way communication with stakeholders, including health professionals and the public.

xii) ***Working with Others***. Legislation should encourage collaboration and co-operation with other federal departments, with provinces and territories, and with non-governmental and international organizations. At the same time it should respect existing jurisdictions and existing legislative and administrative mechanisms.

4. Impact of Health Protection Legislation on Medical Practice

Physicians, along with other health professionals, play an important role in maintaining high health standards and communicating appropriate health information to Canadians. Some of the proposals included in the legislative proposal could have a significant positive or negative impact on medical practice. These include:

a) The Drug Review Process

Stakeholders have repeatedly drawn attention to the slowness and secrecy of Canada's drug approval process. Between 1996 and 1998 Canadian approval times (median 518 days) were significantly longer than Sweden (median 371 days), the UK (median 308 days) and the United States (median 369 days). These have not improved significantly even after Health Canada implemented a cost-recovery approach to funding drug reviews. In addition, the review process may not distinguish genuinely new and innovative "breakthrough" drugs from imitations of products already on the market.

The legislative proposal discusses possible means of modernizing the drug review process, including co-operative agreements with comparable drug review agencies in other jurisdictions, and establishment of a mechanism for public comments. The CMA approves both these suggestions.

To ensure that Canadians have access to the right drugs for their conditions as quickly as is consistent with safety, the CMA recommends:

Recommendations

2. ***That the federal government implement a timely and efficient drug review process to reduce review times to the fastest level consistent with ensuring improved health outcomes and the safety of the drug supply.***
3. ***That the federal government consider co-operative agreements for drug review with comparable agencies in Europe, the United States and Australia, while retaining final authority as to whether a new product should be allowed on the Canadian market.***
4. ***That the drug review and approval process be open and transparent, providing updates on review status and the opportunity for stakeholder input.***
5. ***That Health Canada apply a priority review process to "breakthrough" drugs, i.e. those that demonstrate a substantial improvement over products already on the market.***

b) Patient Safety and Post-marketing surveillance

Recent reports have drawn public attention to the need for a rigourous, well-resourced post-marketing surveillance system to monitor the ongoing safety of marketed drugs and other health products in Canada.

CMA strongly recommends that Health Canada work in partnership with stakeholders to develop such a system. The system should be non-punitive, supporting a "culture of safety" rather than one of blame, and should respect the privacy of patients and physicians. In this context the CMA supports the establishment of the Patient Safety Institute.

In developing its post-marketing surveillance capacity, Health Canada should ensure that sufficient resources are in place to enable the system to:

- *Facilitate the reporting of adverse reactions by health professionals and others.* The CMA supports activities that encourage the voluntary reporting of adverse reactions by physicians and others. For example, to facilitate timely and comprehensive reporting, forms should be easily accessible and the reporting process should be computerized, simple and transparent.
- *Collect and analyze data* and produce information that health care professionals and policy makers can use in decision-making at the population level. With appropriate privacy safeguards, this information could also be used for a number of research purposes, e.g. monitoring the importation and use of drugs not yet licensed in Canada; ascertaining best practices in prescribing.

- *Communicate this information back to the provider in real time*. The importance of real-time two-way communication with front-line practitioners and institutions cannot be overstated. The CMA has repeatedly called for sustained and substantial investment in a Health Communications and Coordination Initiative to improve the technical capacity of front-line health providers to communicate in real time with one another and with the rest of the health care system. This is a critical endeavour and should be undertaken immediately, using funds established for health surveillance in the March 2004 Federal Budget, and implemented within the next 6 months. This network could form the cornerstone of an adverse drug reaction reporting system.

Recommendations:

6. ***That Health Canada work in partnership with stakeholders including CMA and other national medical and other health professional associations, to develop a rigourous post-marketing surveillance system to monitor the ongoing safety of marketed drugs.***
7. ***That government accelerate activities to establish the Patient Safety Institute using a systems approach to support a culture of safety.***
8. ***That all stakeholders join in supporting and encouraging outcome-based research to ascertain best practices in prescribing.***
9. ***That the federal government invest in measures such as electronic communications networks, to increase physicians' capacity to report medication incidents and improve the timeliness of adverse event reporting.***

c) Drug Information and Advertising

CMA believes that the public has a right to unbiased, accurate information on drugs and other therapeutic products. This information should be provided in accordance with CMA's "Principles for Providing Information about Prescription Drugs to Consumers" (Appendix III). Brand-specific product advertising is a less than optimal way of providing this information, and should be carefully monitored to discourage fraudulent or misleading claims. In particular, direct to consumer advertising of prescription drugs should not be permitted in Canada.

Physicians and their associations are willing to work with Health Canada and other stakeholders in developing and disseminating accurate, unbiased information to the public and to health professionals about drugs and other health products.

Recommendations:

10. ***That all stakeholders work to ensure that Canadians have ready access to a source of comprehensive, reliable information on health products and their uses, and that governments fund development and dissemination of validated information to physicians and to the public.***
11. ***That the legislation define "promotion" and "advertising" so as to clearly distinguish them from unbiased health information, and from counselling by health professionals.***

12. ***That the current safeguards against deception in advertising be strengthened in order to***
    - ***Forbid fraudulent or misleading health claims in advertisements, on labels or in any other promotional or descriptive material pertaining to the product;***
    - ***Ensure pre-clearance and ongoing review of all health claims by an objective agency;***
    - ***Provide meaningful penalties for infraction.***
13. ***That Health Canada maintain the current ban on advertising health products for treatment, prevention and cure of conditions or disease states to be identified in a regulatory schedule or administrative list; the inclusion of conditions in this list should be determined through a set of criteria that are written into the Act or regulations.***
14. ***That the existing ban on direct to consumer advertising of prescription drugs be maintained and enforced to the full extent of the law, and that the loophole that currently permits advertising the name, price and quantity of a prescription drug be closed.***
15. ***That all stakeholders, including medical associations and industry groups, work together toward effective regulation of drug promotion to health practitioners.***

d) Safeguarding the privacy of health information

Patients must be able to feel assured that anything they tell their physicians will remain confidential, imparted to others only to the extent necessary to ensure optimal care. Accordingly, the privacy and confidentiality of patient-specific and physician-specific information should be safeguarded to the fullest extent possible.

New technologies, e.g. electronic health records, have made the transfer of information simpler and more efficient. They have also made it more vulnerable to infringements on a patient's right to privacy. Several important pieces of legislation to safeguard privacy have already been enacted. In addition, the CMA has developed a Privacy Code (Appendix IV) that discusses confidentiality issues specific to health information. Section 3.6 of this Code contains a legislative test to which all proposed legislation, including the *Health Protection Act*, should be submitted.

Recommendations

16. ***That the Health Protection Act respect the provisions of the Charter of Rights and Freedoms, the Federal Privacy Act and the Personal Information Protection and Electronic Documents Act (PIPEDA).***
17. ***That the privacy provisions in the Health Protection Act meet the legislative test outlined in Section 3.6 of CMA's Health Information Privacy Code.***

e) Other Issues

The legislative proposal discusses giving Health Canada the power to develop guidelines or regulatory frameworks for specific circumstances, e.g. for new products and technologies such as genetically modified foods; or for situations in which the health of the public may otherwise be at risk, such as contamination of drinking water. In addition, the proposal discusses the possibility of modernizing existing laws that have become outdated.

The CMA supports the direction of these proposals. The *Quarantine Act,* for example, is a piece of legislation the CMA believe merits urgent updating; new legislation should incorporate quarantine provisions for possible vectors leaving as well as entering Canada, and for inter-provincial as well as international traffic.

With regard to specific issues not addressed elsewhere in this submission, the CMA recommends:

Recommendations

18. That the Health Protection Act give Health Canada a clear mandate to develop guidance documents to address health and safety issues raised by new technologies.

19. That Natural Health Products be regulated on a strict framework that ensures their safety, quality and efficacy as well as the provision of complete and unbiased information to the public.

20. That the Act provide Health Canada with a clear mandate to collaborate with provincial/ territorial and local governments across Canada in reviewing legislation governing all aspects of drinking water from source to consumption to ensure that comprehensive programs are in place and being properly implemented.

21. That Health Canada urgently review the Quarantine Act and modernize its provisions.

5. Conclusion

Health protection is one of three pillars of an effective public health system, along with rapid and effective emergency response, and programs and policies to maintain health and prevent disease. The CMA is pleased to have been able to advise governments on all of these pillars, in order to establish the health of Canadians on a strong foundation.

We look forward to continued consultation with Health Canada on the proposed *Health Protection Act*, both on its overall framework and on specific issues of concern to the medical profession. We trust that the result will be strong legislation, founded on fair and enduring principles, to safeguard the health and security of Canadians.

Answering the Wake-up Call: CMA's Public Health Action Plan
CMA Submission to Naylor Advisory Committee on SARS and Public Health
(Executive Summary)

The public health system in Canada lies at the heart of our community values. It is the quintessential "public good" and is central to the continued good health of our population. When the public health system is working well, few are even aware that it *is* at work! Only when something goes terribly wrong — like the Walkerton tragedy or when we are faced with a new threat like SARS — is the integral, ongoing role of public health really recognized.

The Canadian Medical Association (CMA) has been warning that our public health system is stretched to capacity in dealing with everyday demands, let alone responding to the latest crises. Canada's physicians have repeatedly called for governments to enhance public health capacity and strengthen the public health infrastructure throughout Canada.

Our public health system is the first — and often the only — line of defence against emerging and ongoing infectious and noninfectious threats to the health of Canadians. But we are only as strong as the weakest link in the emergency response chain of survival. As most health threats know no boundaries, our public health armaments must be in a constant state of "battle readiness." In today's climate of SARS, West Nile Virus, mad cow disease and monkey pox, even the thought that the public health system may be stretched beyond capacity strikes fear into the hearts of Canadians.

Physicians have always been an integral part of the public health system serving as medical officers of health, community health specialists and other related roles. Indeed public health cannot successfully fulfill its mandate without the cooperation and commitment of front-line clinicians.

In this submission, we reflect on the lessons to be learned from our recent experience with SARS and reflect on the longer-term needs of the public health system as a whole. The objectives of the pan-Canadian *Public Health Action Plan* proposed by the CMA are, first to realize a clearer alignment of authority and accountability in times of extraordinary health emergencies; and, second, to enhance the system's capacity to respond to public health threats across the country (see recommendations, below).

To achieve these twin objectives, three broad strategies are presented for immediate attention. They are legislative reform; capacity enhancement; and research, surveillance and communications.

Legislative reform (see recommendations 1–3)

The country's response to SARS has brought into stark relief the urgent need for national leadership and coordination of public health activity across the country, especially during a health crisis.

The apparent reluctance to act quickly to institute screening at airports, the delay in unifying the practice community for a concerted response and the appalling communications confusion worked against optimum handling of the outbreak — despite the best efforts of health care professionals.

This is a wake-up call that highlights the need for comprehensive legislative reform to clarify the roles of governments with respect to the management of public health threats. A renewed and enhanced national commitment to public health should be anchored in new federal legislation to be negotiated with the provinces and territories.

Specifically, the CMA recommends an *Emergency Health Measures Act*, to deal with emergent situations in tandem with the creation of a Canadian public health agency headed by a *Chief Public Health Officer of Canada*.

Capacity enhancement (see recommendations 4–7)

The SARS crisis has demonstrated the diminished capacity within the public health system. The Greater Toronto Area (GTA), with one of Canada's most sophisticated public and acute health systems, has not been able to manage the SARS crisis adequately and carry on other health programs. The acute care system virtually ground to a halt in dealing with SARS. There was little or no surge capacity in Canada's largest city. We should be grateful that SARS did not first strike a smaller centre in a far less-advantaged region of Canada.

A critical element of the public health system is its workforce and the health professionals within the acute care system, such as hospital-based infectious disease specialists and emergency physicians who are the front-line interface. Let there be no doubt that the ongoing efforts of the GTA front-line providers are nothing short of heroic. However, the lack of coordinated contingency planning of hospital and community-based disease control efforts was striking. The overall shortage of critical care professionals and the inability of governments to quickly deploy the required professionals to areas of need contributed to the enormous strain on the public and health care system.

Considering the importance of the public health system and its clearly limited capacity to protect and promote the health of Canadians, it is incomprehensible that we do not know how much is actually spent on the system. It is imperative that public health expenditures and capacity, in terms of both physical and human resources, be tracked and reported publicly.

The CMA recommends a $1-billion, 5-year capacity-enhancement program to be coordinated with and through the new Canadian public health agency.

Research, surveillance and communications (see recommendations 8–10)

Canada's ability to respond to public health threats and acute events, such as SARS, and to maintain its effective public health planning and program development depends on sound research, surveillance and rapid, real-time communications.

A concerted pan-Canadian effort is required to take full advantage of our capacity for interdisciplinary research on public health, including infectious disease prevention and control measures. New-millennium challenges require moving beyond old-millennium responses. Enhanced surveillance is an overdue and integral part of public health, performing an essential function in early detection and response to threats of infectious diseases. Mandatory national reporting of identified diseases by all provinces and territories is critical for national and international surveillance.

During times of crisis, rapid communication to the public, public health staff and front-line clinicians is of critical importance, but in many jurisdictions impossible. We tested our systems during the SARS outbreak and they came up short.

The CMA recommends a one-time federal investment to enhance technical capacity to allow for real-time communication.

Conclusion

The CMA believes that its proposed three-pronged strategy, as set out in the attached recommendations, will go a long way toward addressing shortfalls of the Canadian public health system. Action now will help to ensure that Canadians can once again be confident that they are protected from any future threat of new infectious diseases. Action now will help Canada regain its position as a leader in public health.

We wish the advisory committee well in its deliberations and offer the CMA's assistance at any time in clarifying the strategies set out in our submission.

Recommendations to the National Advisory Committee on SARS and Public Health

Legislative reform ($20 million / 5 years*)

1. The enactment of a *Canada Emergency Health Measures Act* that would consolidate and enhance existing legislation, allowing for a more rapid national response, in cooperation with the provinces and territories, based on a graduated, systematic approach, to health emergencies that pose an acute and imminent threat to human health and safety across Canada.

2. The creation of a *Canadian Office for Disease Surveillance and Control* (CODSC) as the lead Canadian agency in public health, operating at arm's length from government.

3. The appointment of a Chief Public Health Officer of Canada to act as the lead scientific voice for public health in Canada; to head the Canadian Office for Disease Surveillance and Control; and to work with provinces and territories to develop and implement a pan-Canadian public health action plan.

Capacity enhancement ($1.2 billion / 5 years*)

4. The creation of a *Canadian Centre of Excellence for Public Health,* under the auspices of the CODSC, to invest in multidisciplinary training programs in public health, establish and disseminate best practices among public health professionals.

5. The establishment of a Canadian Public Health Emergency Response Service, under the auspices of the CODSC, to provide for the rapid deployment of human resources (e.g., emergency pan-Canadian locum programs) during health emergencies.

6. Tracking and public reporting of public health expenditures and capacity (both physical and human resources) by the Canadian Institute for Health Information and Statistics Canada, on behalf of the proposed Canadian Office for Disease Surveillance and Control.

7. Federal government funding in the amount of $1 Billion over 5 years to build adequate and consistent surge capacity across Canada and improve coordination among federal, provincial/territorial and municipal authorities to fulfill essential public health functions.

Research, surveillance and communications ($310 million / 5 years*)

8. An immediate, sequestered grant of $200 million over 5 years to the Canadian Institutes of Health Research to initiate an enhanced conjoint program of research with the Institute of Population and Public Health and the Institute of Infection and Immunity that will expand capacity for interdisciplinary research on public health, including infectious disease prevention and control measures.

9. The mandatory reporting by provinces and territories of identified infectious diseases to the newly established Chief Public Health Officer of Canada to enable appropriate communications, analyses and intervention.

10. The one-time infusion of $100 million, with an additional $2 million a year, for a "REAL" (rapid, effective, accessible and linked) Health Communication and Coordination Initiative to improve technical capacity to communicate with front line public health providers in real time during health emergencies.

APPENDIX II

The Right Drugs, at the Right Times, for the Right Prices: Toward a Prescription Drug Policy for Canada

CMA Submission to House of Commons Standing Committee on Health

Every year, three hundred million prescriptions – about 10 for every man, woman and child – are filled in Canada. Prescription drugs have benefited both the health of Canadians, and the health care system itself; they have meant dramatically improved quality of life for many Canadians, and have saved the country a great deal in hospitalization, social benefits and other expenses. However, it could be questioned whether all of Canada's prescription drug use is appropriate; patients may be receiving too few medications, too many medications or suboptimal medications for their conditions. In addition, prescription drugs carry a price tag of their own. Since 1975, expenditures on prescription medication have risen faster than any other category in the health sector in Canada, and more is now spent on prescription drugs than on physician services.

Governments, health care providers, drug manufacturers and the public must constantly strive to ensure that Canadians receive optimal and appropriate prescription drug therapy: the right drugs, at the right times, for the right prices.

A considered, coherent, comprehensive, "made in Canada" approach to prescription drug policy should:

- Put the health of the patient first;
- Promote and enhance quality prescribing;
- Respect, sustain and enhance the therapeutic relationship between patients and health professionals;
- Promote patient compliance with drug therapy;
- Respect the principles of patient confidentiality and the privacy of patient and prescriber information.

Prescription drug policy in Canada should address:

Access: to

- efficacious new drugs within an appropriate time;
- coverage for medically necessary drugs for catastrophic care;
- generic drugs at reasonable prices;
- a patient/physician consultation as part of the prescribing process;
- continued research and development capacity in Canada.

Information for health care providers and the public that is balanced and accurate.

Safety: through mechanisms for the systematic monitoring of prescription drugs and their effects.

Canada's doctors are committed to working with others to ensure that Canadians receive the right drugs, at the right times, for the right prices.

Summary of CMA Recommendations:

1. That the federal government implement a timely and efficient drug review process to reduce review times to a level at or better than that in other OECD countries.
2. That the pharmaceutical industry give priority to research and development on drugs and delivery mechanisms that demonstrate a substantial improvement over products already on the market.
3. That Health Canada apply a priority review process to all drugs that demonstrate a substantial improvement over products already on the market.
4. That governments and insurance providers conduct research to identify the current gaps in prescription drug coverage for all Canadians, and develop policy options for providing this coverage, including consideration of the roles of public and private payers.
5. That the federal government monitor and, if necessary, regulate the export of prescription medications to ensure their continued availability to Canadians.
6. That prescribing of medication be done within the context of the therapeutic relationship which exists between the patient and the physician.
7. That brand-specific direct to consumer prescription drug advertising (DTCA) not be permitted in Canada,
8. That the federal government enforce the existing restrictions on DTCA found in the Food and Drug Act to the full extent of the law.
9. That the federal government develop and fund a comprehensive program to provide accurate, unbiased prescription drug information to patients.
10. That all stakeholders join in supporting and encouraging outcome-based research to ascertain best practices in prescribing.
11. That government accelerate activities to establish the Patient Safety Institute using a systems approach to support a culture of safety.
12. That a post-marketing surveillance system be implemented to monitor the ongoing safety of marketed drugs.

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CMA POLICY

Principles for Providing Information about Prescription Drugs to Consumers

Approved by the CMA Board of Directors, March 2003

Since the late 1990's expenditures on direct to consumer advertising (DTCA) of prescription drugs in the United States have increased many-fold. Though U.S.-style DTCA is not legal in Canada[2], it-reaches Canadians through cross-border transmission of print and broadcast media, and through the Internet. It is believed to have affected drug sales and patient behaviour in Canada. Other therapeutic products, such as vaccines and diagnostic tests, are also being marketed directly to the public.

Proponents of DTCA argue that they are providing consumers with much-needed information on drugs and the conditions they treat. Others argue that the underlying intent of such advertising is to increase revenue or market share, and that it therefore cannot be interpreted as unbiased information.

The CMA believes that consumers have a right to accurate information on prescription medications and other therapeutic interventions, to enable them to make informed decisions about their own health. This information is especially necessary as more and more Canadians live with chronic conditions, and as we anticipate the availability of new products that may accompany the "biological revolution", e.g. gene therapies.

The CMA recommends a review of current mechanisms, including mass media communications, for providing this information to the public. CMA believes that consumer information on prescription drugs should be provided according to the following principles. [3]

Principle #1: The Goal is Good Health
The ultimate measure of the effectiveness of consumer drug information should be its impact on the health and well-being of Canadians and the quality of health care.

Principle #2: Ready Access
Canadians should have ready access to credible, high-quality information about prescription drugs. The primary purpose of this information should be education; sales of drugs must not be a concern to the originator.

Principle #3: Patient Involvement
Consumer drug information should help Canadians make informed decisions regarding management of their health, and facilitate informed discussion with their physicians and other health professionals. CMA encourages Canadians to become educated about their own health and health care, and to appraise health information critically.

[2] DTCA is not legal in Canada, except for notification of price, quantity and the name of the drug. However, "information-seeking" advertisements for prescription drugs, which may provide the name of the drug without mentioning its indications, or announce that treatments are available for specific indications without mentioning drugs by name, have appeared in Canadian mass media.

[3] Though the paper applies primarily to prescription drug information, its principles are also applicable to health information in general.

Principle #4: Evidence-Based Content
Consumer drug information should be evidence based, using generally accepted prescribing guidelines as a source where available.

Principle #5: Appropriate Information
Consumer drug information should be based as much as possible on drug classes and use of generic names; if discussing brand-name drugs the discussion should not be limited to a single specific brand, and brand names should always be preceded by generic names. It should provide information on the following:

- indications for use of the drug
- contraindications
- side effects
- relative cost.

In addition, consumer drug information should discuss the drug in the context of overall management of the condition for which it is indicated (for example, information about other therapies, lifestyle management and coping strategies).

Principle #6: Objectivity of Information Sources
Consumer drug information should be provided in such a way as to minimize the impact of vested commercial interests on the information content. Possible sources include health care providers, or independent research agencies. Pharmaceutical manufacturers and patient or consumer groups can be valuable partners in this process but must not be the sole providers of information. Federal and provincial/territorial governments should provide appropriate sustaining support for the development and maintenance of up-to-date consumer drug information.

Principle #7: Endorsement/ Accreditation
Consumer drug information should be endorsed or accredited by a reputable and unbiased body. Information that is provided to the public through mass media channels should be pre-cleared by an independent board.

Principle #8: Monitoring and Revision
Consumer drug information should be continually monitored to ensure that it correctly reflects current evidence, and updated when research findings dictate.

Principle #9: Physicians as Partners
Consumer drug information should support and encourage open patient-physician communication, so that the resulting plan of care, including drug therapy, is mutually satisfactory.

Physicians play a vital role in working with patients and other health-care providers to achieve optimal drug therapy, not only through writing prescriptions but through discussing proposed drugs and their use in the context of the overall management of the patient's condition. In addition, physicians and other health care providers, and their associations, can play a valuable part in disseminating drug and other health information to the public.

Principle #10: Research and Evaluation
Ongoing research should be conducted into the impact of drug information and DTCA on the health care system, with particular emphasis on its effect on appropriateness of prescribing, and on health outcomes.

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CMA POLICY

HEALTH INFORMATION PRIVACY CODE

This Code articulates principles for protecting the privacy of patients, the confidentiality and security of their health information and the trust and integrity of the therapeutic relationship. Its provisions are more exacting than those currently in place in the Canadian health care system. Although a patchwork of laws across Canada permit or require health information collection, use, disclosure and access without patient consent, or even knowledge, this Code would require that all of these laws and any proposed laws be reviewed for consistency with its provisions. Moreover, existing practices and initiatives concerning health information collection, use, disclosure and access, including health information systems or networks, may be contrary to patient expectations and the physician's duty of confidentiality. These practices and initiatives must also be reviewed for consistency with this Code. Many laws, practices and initiatives may not withstand the kind of scrutiny deemed necessary and reasonable for the protection of privacy and the trust and integrity of the therapeutic relationship.

CMA issues this Code in recognition that its implementation raises numerous issues and challenges, and that the changes it envisions will require time and the expenditure of resources. CMA appreciates that, given the complexity of the health care system, agreement and cooperation among a wide range of users and collectors of health information will be essential to the successful implementation of this Code. In view of these challenges, CMA issues this Code to the Canadian health care community at this time as an ideal to strive for, to guide and coordinate the efforts that need to be made to protect the privacy of patients, the confidentiality and security of their health information and the trust and integrity of the therapeutic relationship. Moreover, this Code is issued in the understanding that those to whom it applies will not be able to achieve full compliance with its provisions until such time as numerous implementation issues have been clarified and resolved through cooperation and the coordinated efforts of many different stakeholders. Consequently, companion implementation documents are being developed that provide for a gradual implementation of the Code's provisions over a five–year span and outline work that needs to be done to achieve the ideal it envisions.

Section A: Scope

This Health Information Privacy Code ("Code") has been produced by physicians to protect the privacy of their patients, the confidentiality and security of their health information and the trust and integrity of the therapeutic relationship. This Code is based on the Canadian Standards Association's Model Code for the Protection of Personal Information ("CSA Code") as a sectoral code of the CSA Code. This Code provides instruction and guidance respecting health information collection, use, disclosure and access.

1. This Code describes the minimum requirements to protect the privacy of patients and the security and confidentiality of their health information.

2. This Code has been developed by physicians in their capacity as clinicians and in recognition of their principal obligation to patients.

3. This Code recognizes the potential benefits of the use of health information for secondary purposes, including teaching, research and system planning, and contains provisions to permit such use under clearly defined terms and conditions.

4. This Code has been developed as a sectoral code of the Canadian Standards Association's Model Code for the Protection of Personal Information and consequently adopts the minimum standards contained in the CSA Code and augments them to meet the special circumstances of health information.

5. The development of this Code has been 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?*

6. The Code applies to all health information and to all individuals, groups or organizations that collect, use, disclose or access such information. Its objective is to instruct in the development and implementation of policies, practices, health information systems or networks and legislation.

7. The principles that make up this Code are interrelated. Health information custodians adopting this Code shall adhere to these principles as a whole.

8. Health information custodians must subscribe to the principles contained in this Code and agree to uphold them, but may tailor this Code by modifying or adding principles provided the changes afford no less protection to the privacy of patients and the confidentiality and security of their health information.

9. Statements containing "shall" or "must" indicate requirements that must be met by any health information custodian who wishes to adopt this Code and be recognized for having done so. The use of "should" indicates a recommendation or aspiration.

Section B: Definitions

The following definitions apply in this Code:

“Access” means the ability to acquire or possess health information in any information format.

“Accountability” means having clearly defined and understood responsibilities in connection with health information, agreeing to accept those responsibilities and being subject to appropriate sanctions for failing to fulfil accepted responsibilities.

“Authorized” means that which occurs with patient consent or within the provisions of this Code and applies to purposes, collection, use and disclosure of, or access to, health information.

“Authorized user” is someone permitted to collect, use, disclose or access health information under the provisions of this Code, who is properly instructed on his or her limits and responsibilities, and who can be held accountable for his or her compliance.

”Collection” means 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.

“Confide” and “confided” mean the revelation of information by a patient within the therapeutic context.

“Confidentiality” and “confidential” mean that health information that is confided by a patient is to be kept secret and not disclosed or made accessible to others unless authorized by patient consent. A breach of confidentiality occurs whenever a health professional discloses or makes health information available to others without or inconsistent with the patient's consent.

“Consent” means a patient's informed and voluntary agreement to confide or permit access to or the collection, use or disclosure of his or her health information for specific purposes. Express consent is given explicitly, either orally or in writing. Express consent is unequivocal and does not require any inference on the part of the provider seeking consent. Implied consent arises where agreement may reasonably be inferred from the action or inaction of the individual and there is good reason to believe that the patient has knowledge relevant to this agreement and would give express consent were it sought.

“Disclosure” means the provision of health information to a third party for any reason, or making health information available for a third party to collect. It includes any transfer or migration of health information from one provider or user to another.

“Duty of confidentiality” means the duty of physicians and other health professionals in a fiduciary relationship with patients to ensure that health information is kept secret and not disclosed or made accessible to others unless authorized by patient consent.

“Emergency situations” mean those instances when health care must be provided to preserve life or prevent severe harm to a patient who is unable, owing to the circumstances, to be cognizant of the context and whose surrogate is not immediately available to make decisions on the patient's behalf.

“Fiduciary duty” means the obligation to act with the utmost good faith for the benefit of another.

“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.

“Health information custodian” means any organization or institution that has custody, care or control of health information, and includes hospitals, regional boards, governments, corporations and solo or group medical practices.

“Information format” means any form containing or recording health information, including:

(a) a form that identifies or could identify a specific patient, either directly or indirectly;

(b) a form that removes the link between the patient and information about him or her and which could, either directly or indirectly, be manipulated to reconnect the link between the patient and information about him or her ("deidentified-relinkable");

(c) a form that removes the link between the patient and information about him or her with the intent of preventing any reconnection of the link between the patient and information about him or her in accordance with recognized standards ("anonymous"); or

(d) the composite form produced when health information is linked to any information about the patient from any other source, whether or not it is also health information.

“Integrity of health information” means the preservation of its content throughout storage, use, transfer and retrieval so that there is confidence that the information has not been tampered with or modified other than as authorized.

“Health professional” is any person having a fiduciary duty to patients who is registered and entitled by provincial or territorial law to practise or provide health care in that province or territory.

“Knowledge” means the patient's awareness of what can or must happen with the health information he or she confides or permits to be collected.

"Linkage" is the joining together of health information with information from any other source or database, in whatever form. When health information is linked to any other information, the composite is also health information.

"Nonconsensual" collection, use, disclosure or access, whether justified or not, occurs without a patient's consent and contravenes the patient's right of privacy.

"Patient" means the person about whom health information is collected and, for the purposes of this Code, may also mean a surrogate or guardian acting on behalf of this person.

"Physician" means a person who is registered and entitled under the laws of a province or territory to practise medicine in that province or territory.

"Primary" means that which occurs for the therapeutic benefit of a particular patient. Secondary means not directly related to the therapeutic benefit of the particular patient from whom the information has originated.

"Purpose" means an end or aim for which health information is collected, used, disclosed or accessed. A description of purpose can be general enough to incorporate a range of like information uses provided that the generic description is sufficiently narrow and limited so as to communicate to the ordinary person a clear understanding of the potential information uses that could reasonably be expected to be relevant to their consent. The primary therapeutic purpose is the delivery of health care to a particular patient with respect to a particular and immediate health need or problem. It encompasses consultation with and referral to other providers on a need-to-know basis. A primary longitudinal purpose concerns developing composite health information about a particular patient, such as a detailed medical history, beyond direct application to any particular and immediate health need or problem, in order to enhance ongoing care to that person. Secondary legislated purposes have been subjected to the legislative test specified in this Code and have subsequently been written in law. Secondary nonlegislated purposes are any other purposes, such as education or research not governed by legislation, that meet the provisions of this Code and the secondary nonlegislative test provided by this Code.

"Provider" means a health professional or institution that delivers health care services or products in the therapeutic context.

"Right of privacy" includes a patient's right to determine with whom he or she will share information and to know of and exercise control over use, disclosure and access concerning any information collected about him or her; it entails the right of consent. Nonconsensual collection, use, disclosure or access violates the right of privacy, even if it is justified.

"Security" means reasonable precautions, including physical and technical protocols, to protect health information from unauthorized collection, use, disclosure and access, and to ensure that the integrity of the information is properly safeguarded. A breach of security occurs whenever health information is collected, used, disclosed or accessed other than as authorized, or its integrity compromised.

"Sensitivity" of health information refers 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.

"Therapeutic context" means a setting in which information is confided by or collected from, about or on behalf of a patient who:

(a) is in a therapeutic relationship with or under the care of a physician or health professional;
(b) is resident in or seeking health care within a facility or institution whose principal purpose is the provision of health care, including physicians' offices, hospitals and other health care facilities;

(c) confides information within a fiduciary relationship to a health care professional and with the belief that the health care professional will maintain its confidentiality, subject to very limited exceptions; or
(d) confides information in the belief that it is necessary for the safe, timely and effective delivery of health care.

"Transparency and openness" are the characteristics of policies, procedures and practices that seek to ensure that patients know what can or must happen with the health information they confide or permit to be collected, used, accessed or disclosed.

"Use of health information" means any processing of health information including storage, retention, retrieval, manipulation, connection or linkage to other sources of information in any format.

Section C: Principles

Principle 1: The Right of Privacy

The right of privacy is fundamental in a free and democratic society. It includes a patient's right to determine with whom he or she will share information and to know of and exercise control over use, disclosure and access concerning any information collected about him or her. The right of privacy and consent are essential to the trust and integrity of the patient-physician relationship. Nonconsensual collection, use, access or disclosure violates the patient's right of privacy. The right of privacy is important and worthy of protection, not just for the good of individuals in society but also for the good of society as a whole.

1.1 Canadians are entitled to expect and enjoy fundamental privacy rights and guarantees, which include:
(a) physical, bodily and psychological integrity and privacy;
(b) privacy of personal information;
(c) freedom from surveillance;
(d) privacy of personal communications; and
(e) privacy of personal space.

1.2 The basic duties owed to others to ensure that their privacy rights are adequately respected include:
(a) the duty to ensure consent;
(b) the duty to take all the steps necessary to respect adequately others' privacy rights or, if their rights must be infringed, to interfere with privacy as little as possible;
(c) the duty to be accountable;
(d) the duty to be transparent; and
(e) the duty to build privacy protection features into technological systems and designs.

1.3 The specific duties related to the protection of the patient's right of privacy in health information include:
(a) the duty to hold health care information in trust;
(b) the duty to limit information collection to what is necessary and justifiable for the benefit of the patient;
(c) the duty to ensure that patients are informed by reasonable means about purposes for collection, use, disclosure or access at or before the time of collection, including the potential for such to occur nonconsensually;
(d) the duty to ensure that the information is accurately recorded;
(e) the duty to ensure consent by reasonable means, except in limited circumstances where the right of privacy and of consent are justifiably infringed by some compelling right, good or duty;
(f) the duty to ensure that the right of privacy and the right to consent are infringed no more than is necessary by the compelling right, good or duty;
(g) the duty to use and disclose health information only as consistent with the purposes identified at or before the time it was collected;
(h) the duty to keep health information only for as long as necessary to fulfil identified purposes;
(i) the duty not to disadvantage people because they elect to exercise their right of privacy; and

(j) the duty of physicians and other health professionals to hold information in confidence.

1.4 Although the patient's interests and concerns about health information may vary depending on the sensitivity of the information, the right of privacy extends to all health information in whatever format.

Principle 2: Special Nature of Health Information

Governing principles and rules for health information must recognize the patient's right of privacy in health information, its highly sensitive nature, the circumstances of vulnerability and trust under which it is confided or collected, and the fiduciary duties of health professionals in relation to this information. The patient-physician relationship as defined by trust and a professional promise of confidentiality is a societal good worthy of protection.

2.1 Principles and rules governing health information must recognize:

(a) its high level of sensitivity and protect the patient's right of privacy accordingly;
(b) that the principal purpose for confiding and collecting this information is to benefit the patient;
(c) that in the therapeutic context patients may be vulnerable and under duress, and must not be subjected to manipulation, coercion or exploitation;
(d) that patients confide information to physicians and other health professionals under a very special trust, and that physicians and other health professionals have fiduciary duties to patients, including a duty to hold information in confidence.

2.2 Principles and rules governing health information must ensure that physicians and other health professionals can discharge their fiduciary duties and therefore shall take into account that:

(a) patients may be in a situation of vulnerability owing to infirmity or incapacity, urgent need, lack of knowledge and power, or simply because they have needs and have to rely or depend upon providers to meet those needs;
(b) patients confide information that is ordinarily considered by them to be private because they have certain needs that require the care of a provider and believe the information is required by the provider to help meet those needs;
(c) were it not for those needs, and the expectation that the provider can help patients meet them, the occasion for the collection of the health information would not exist and the information would remain private;
(d) were it not for the reputation of health professionals for trustworthiness and the expectation that information disclosed to them will be held in confidence, patients would be less willing to confide health information fully and truthfully in the therapeutic context; and
(e) to the extent that provisions for health information inhibit patients from confiding health information fully and truthfully, their health care will be adversely affected.

Principle 3: Constraints on Purposes and Limitation on Collection, Use, Disclosure and Access

The principal purpose for the collection of health information is to benefit the patient who confides or permits information to be collected for a therapeutic purpose. Secondary purposes for the use of the information shall not be pursued if they inhibit patients from confiding information for the primary purpose, exploit patients' vulnerability, compromise the ability of physicians to discharge their fiduciary duties to patients or borrow on the trust patients invest in physicians for the primary therapeutic purpose. Collection, use, disclosure or access for secondary purposes shall be restricted to what is necessary for those purposes and shall not impede the confiding or collection of information for primary purposes. Nonconsensual access to and collection, use or disclosure of health information is a violation of

a patient's right of privacy, compromises the physician's duty of confidentiality and is potentially disruptive of the trust and integrity of the therapeutic relationship. Therefore, it must only occur in very limited circumstances — namely emergency situations, in accordance with legislation that meets the requirements of this Code, or in response to a court decision or order. Even consensual collection, use, disclosure or access may erode the right of privacy and the trust and integrity of the therapeutic relationship. Therefore, it must only occur with due consideration of possible negative impacts and with measures designed to maximize privacy protection.

3.1 Provided that the principles contained in this Code are adhered to, and in particular that the principles related to patient consent are rigorously applied, health information may be collected, used, disclosed or accessed for the following purposes:

(a) Primary purposes:

(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.

(b) Secondary purposes:

(i) Secondary legislated purpose refers to health information collection, use, disclosure or access required or permitted by legislation or regulation that meets the provisions of this Code and the legislative test provided by this Code.

(ii) Secondary nonlegislated purpose is any other purpose, such as education or research not governed by legislation, that meets the provisions of this Code and the secondary nonlegislative test provided by this Code.

3.2 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.

3.3 Health information collection, use, disclosure or access for any secondary purposes shall be as minimal as necessary in recognition of the need to protect the patient's right of privacy in the therapeutic context.

3.4 Health information collection, use, disclosure or access without patient consent shall only occur in the limited circumstances provided by this clause. Nonconsensual health information collection, use, disclosure or access, including the conversion of health information from one information format to another, is a violation of a patient's right of privacy, may compromise the physician's duty of confidentiality, and is potentially disruptive of the trust and integrity of the therapeutic relationship. Therefore, it must only occur under strict conditions and in these very limited circumstances:

(a) when permitted or required by legislation or regulation that meets the requirements of this Code; or

(b) when ordered or decided by a court of law.

3.5 Any existing or proposed secondary purpose for health information collection, use, disclosure or access, including health information systems or networks, shall be subjected to a patient privacy impact analysis that shall include an evaluation of:

(a) the likely impact of the proposed measures on the right of privacy of patients;

(b) the likely impact of the proposed measures on the relationship between patients and their physicians, and in particular on the duty of confidentiality and the trust within this relationship;

(c) the likely impact of the proposed measures on the willingness of patients to disclose health information;

(d) the likely impact of the proposed measures on the ability of patients to receive health care; and

(e) compelling evidence to demonstrate broad public support for the proposed measures.

3.6 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;

(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 this 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.

3.7 Any proposed or existing secondary nonlegislated purpose shall be subjected to the following nonlegislative test:

(a) Before a health information custodian uses health information in its custody for secondary nonlegislated purposes, or before it releases or makes health information accessible to an external third party for secondary nonlegislated purposes, it must demonstrate or require the third party to demonstrate that:

(i) a patient privacy impact assessment has been conducted, the analysis has been made public, the results have been duly considered and uses for that purpose will not be pursued if there is an adverse effect on privacy;

(ii) collection of health information by persons beyond the therapeutic context will not exploit or compromise the trust of the patient-physician relationship;

(iii) patients are not likely to be inhibited from confiding information for primary purposes;

(iv) the ability of physicians to discharge their fiduciary duties to patients will not be compromised;

(v) patient vulnerability will not be exploited;

(vi) collection will be restricted to what is necessary for the identified purpose(s) and will not intrude upon primary purposes;

(vii) patients will be fully informed of the purpose(s) and patient consent will be clearly voluntary;

(viii) patient privacy will be intruded upon to the most limited degree possible in light of the purpose(s) consented to;

(ix) linkage of health information will be restricted and consented to by the patient;

(x) unless clear and compelling reasons exist,
- all reasonable steps will be taken to make health information anonymous;
- if it has been demonstrated that making health information anonymous will render it inadequate for legitimate uses, then the information will be collected and stored in a deidentified-relinkable format;

(xi) any third party to whom health information is released has adopted this Code or has equivalent provisions in place; and

(xii) the purpose(s) will not be applied retroactively to existing health information unless patient consent is given.

3.8 Health information shall not be collected by means that are unlawful, unfair or exploit the patient's vulnerability, nor shall any of the patient's beliefs or potentially false expectations about subsequent collection, use, disclosure or access be exploited.

3.9 Courts of law should respect the provisions of this Code when issuing orders or decisions.

3.10 Health information shall be retained only as long as it is necessary to fulfil authorized purposes. Once the authorized purposes are fulfilled it shall be securely destroyed, unless some issue or decision related to the patient and pertinent to the patient's health information is pending.

Principle 4: Knowledge and Specification of Purpose, Collection, Use, Disclosure and Access

In the therapeutic context, health information is confided by or collected from patients under the patient's presumption that it is necessary to meet his or her therapeutic needs. 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 known to the patient by reasonable means before it is confided or collected for primary purposes. It is not acceptable to withhold such knowledge from patients deliberately out of concern that knowledge could inhibit them from confiding important information fully and truthfully.

4.1 A health information custodian must have documentation that lists all purposes for which it uses or discloses the health information it collects, including to whom it permits access to what information, in what format and whether consent is required.

4.2 Within the therapeutic context health information is confided or provided by patients in the knowledge or with the belief that it is necessary to achieve therapeutic purposes. Patients must be explicitly informed about any other purposes.

4.3 Health information must not be used for purposes not identified to the patient at or before the time it is confided or collected, unless patient consent is subsequently sought and obtained.

4.4 Patients must either have or be provided by reasonable means with knowledge about what can or must happen with their health information. The degree of detail or specificity of this knowledge is what could be presumed germane to the decision of a reasonable person in the circumstances of the patient.

4.5. Unless a particular patient has given indication to the contrary, the conveyance of generic information is a reasonable means of providing knowledge. When the preferences of a particular patient for being informed are known or can be reasonably inferred given his or her circumstances, the provision of knowledge should as much as possible be tailored to these known preferences.

4.6 The goal of providing knowledge to patients is to ensure that before they confide information or permit information to be collected they actually understand what can or

must subsequently happen with their information, particularly without their consent.

Principle 5: Consent

The patient's ability to decide with whom he or she will share information is crucial for the protection of the right of privacy and for the preservation of trust in the therapeutic context. Only the patient's consent to health information collection, use, disclosure and access for the primary therapeutic purpose can be inferred. Except for the very limited nonconsensual purposes addressed in this Code, any other collection, use, disclosure or access requires express consent. Nonconsensual collection, use, disclosure or access infringes the right of privacy and compromises the trust of the fiduciary relationship. To satisfy the requirement that consent be informed, the patient must have, or by reasonable means be provided with, knowledge about the potential for subsequent nonconsensual collection, use, disclosure or access before he or she confides any information.

5.1 Except for the very limited conditions set out in 3.4 concerning nonconsensual collection, use, disclosure or access, consent is required for health information collection, use, disclosure or access for any purpose.

5.2 For the purposes of this Code, consent for health information collection, use, disclosure or access in emergency situations is deemed to have been given to the extent necessary to allay the emergency as consistent with legal principles governing emergency medical care. The protection accorded this information shall be consistent with the provisions of this Code.

5.3 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.

5.4 Interpretation of "need-to-know" shall be guided by consideration of what the reasonable person in similar circumstances would expect, or otherwise authorize by his or her consent. If expectations are unclear or ambiguous, care should be taken to ascertain those expectations and to make the flow of information among providers in the therapeutic context consistent with those expectations.

5.5 Consent to collection, use, disclosure and access for longitudinal primary purposes must be express unless the provider has good reason to infer consent.

5.6 For the purposes of this Code, disclosure of health information to the patient's relatives or significant others is recognized as assisting in primary purposes. Consent to this disclosure must be express unless the provider has good reason to imply patient consent.

5.7 Consent can only be inferred in the case of primary purposes, and for primary purposes alone; collection, use, disclosure or access thus authorized must be limited either to the known expectations of a particular patient or to what the reasonable person in similar circumstances would likely believe necessary to receive health care.

5.8 Implied consent does not deprive the patient of the right to refuse consent or the right to challenge the provider's finding of implied consent.

5.9 Patient consent for secondary nonlegislated purposes shall be express, voluntary and fully informed.

5.10 Where express consent is required, patients must be informed of their right to refuse consent. It is not acceptable to compromise care deliberately as a consequence of the patient's refusal to provide express consent or to exploit any fear the patient might have that this could occur.

5.11 Consent shall not be obtained by coercion, deception or manipulation. Failure to inform the patient by reasonable means of relevant information pertinent to consent invalidates this consent.

5.12 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.

Principle 6: Individual Access

Patients have the right of access to their health information. In rare and limited circumstances, health information may be withheld from a patient 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 a denial of access.

6.1 The patient is entitled to know about, and subject to 6.5 to have access to, any information about himself or herself under the custody of the health information custodian.

6.2 Patients should be informed that they have the right to access their health information, to read it and to have copies of it.

6.3 Patients who wish to access their information should be given the opportunity to do so with explanation from a health professional who is knowledgeable about this information and capable of interpreting it for the patient.

6.4 Patients must be able to receive copies of their health information at a reasonable cost that does not exceed the cost of providing the information.

6.5 Providers may, in rare and limited circumstances, withhold health information from a patient 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 is on the provider to justify a denial of access.

6.6 Patients are entitled to know who has gained access to their health information and for what purposes.

Principle 7: Accurate Recording of Information

Accurate recording is important to protect the patient's right of privacy and to meet the purposes for its collection, use, disclosure or access.

7.1 Health information shall be recorded as accurately as possible, and shall be as complete and current as necessary for authorized purposes.

7.2. 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.

7.3 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.

7.4 Whenever possible, health information should be recorded in a form that allows for authorized secondary purposes consented to by the patient. Any standardization of recording requirements relevant to subsequent secondary purposes shall not impede recording of information for primary purposes.

Principle 8: Security

Security safeguards must be in place to ensure that only authorized collection, use, disclosure or access occurs. Such safeguards must also assure the integrity of the available information.

8.1 Health information, regardless of the information format, shall be protected by security safeguards to ensure compliance with the provisions of this Code.

8.2 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.

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

8.4 A health information custodian shall ensure that persons are able to collect, use, disclose or access health information in its control only as authorized. Persons thus authorized must have a clear understanding of the authority, parameters, purposes and responsibilities of their access, and of the consequences of failing to fulfil their responsibilities.

8.5 An authorized person's access to health information, including persons or groups external to the health information custodian,

shall be limited to only the information needed for the authorized purpose(s), in the least intrusive format.

8.6 Security safeguards shall include both physical and human resource safeguards to prevent unauthorized health information collection, use, disclosure and access. Physical security measures include such safeguards as locked filing cabinets, restricted access to certain offices or areas, and the use of passwords, encryption and lock-boxes. Human resource security measures include security clearances, sanctions, training and contracts.

8.7. Health information custodians must protect health information in their custody so as to ensure its integrity and have assurance that the integrity of information received from other health information custodians has been similarly safeguarded.

8.8 Security safeguards should incorporate identification, authentication, information integrity/availability and non-repudiation, as appropriate.

Principle 9: Accountability

Accountability is owed first and foremost to the patient. Health information custodians must have in place policies and procedures that recognize this principal accountability and health professionals' duty of confidentiality to the patient. Anyone a health information custodian authorizes to have access to health information must be capable of being held accountable for his or her actions. In addition, health information custodians must designate a qualified person responsible and accountable for monitoring and ensuring internal compliance with this Code.

9.1 Health information custodians are responsible for the security of health information they collect, use, disclose or permit access to.

9.2 Health information custodians must ensure that persons, including administrative and technical support staff, receive authorization to access health information only as necessary to fulfil authorized purposes.

9.3 A health information custodian must ensure that anyone permitted to have access to health information has clearly defined and understood responsibilities in connection with health information, agrees to accept those responsibilities, and is subject to appropriate sanctions for failing to fulfil the accepted responsibilities.

9.4 Health information custodians must designate a qualified person responsible and accountable for monitoring and ensuring internal compliance with this Code. The designated accountable person shall have the autonomy, authority, and resources necessary to ensure the health information custodian's adherence to the Code. In the case of small private practices, practitioners may designate themselves.

9.5 Policies and procedures to ensure compliance with this Code must consider the special, direct accountability of health professionals to their patients. The high level of trust vested in health professionals is crucial to the initial confiding of health information for the therapeutic purpose.

9.6 Health information custodians must ensure that third parties privy to health information have adopted this Code or are bound by equivalent provisions. Provided that this has been determined before health information is disclosed or made accessible, health information custodians are not accountable for the actions of third parties or for what subsequently happens to the information.

9.7 Although it is the responsibility of the health information custodian to ensure that patients are appropriately informed, secondary users whose information requirements impose a burden upon the health information custodian are responsible for covering their share of any related costs or resource requirements (e.g., preparation of brochures). Health information custodians may reasonably require secondary users to cover their own costs as a condition of making health information available to them as authorized.

Principle 10: Transparency and Openness

Policies, procedures and practices relating to health information must be transparent so that patients can clearly understand the extent and circumstances of health information collection, use, disclosure and access. They must be explicit enough that patients are adequately informed

and able to acquire knowledge germane to their confiding of information, and must be open to scrutiny and challenge.

10.1 Health information custodians must have transparent, explicit and open policies, procedures and practices, tailored to their practice setting, that seek to ensure that patients are provided with information about what can or must happen with their health information without their consent.

10.2 Policies, procedures and practices shall be as explicit as necessary to ensure that patients are aware of any considerations that could be relevant to deciding what information they elect to freely confide or consent to be collected, used, disclosed or accessed. Nothing must be left implicit that, if made explicit, could reasonably be expected to alter a patient's decision to freely confide information. Information about nonconsensual collection, use, disclosure and access must be made explicit.

10.3 Patients should be able to discuss the health information custodian's policies, procedures and practices concerning health information with a knowledgeable person and have specific questions about their own health information answered in a timely fashion.

10.4 A health information custodian's policies, procedures and practices shall ensure that patients can understand what might, can or must happen to their health information, that consent is sought as required by this Code and that nothing is left implicit or unknown to patients that if known or made explicit could reasonably be expected to alter a patient's decision to freely confide information.

10.5 Patients shall be able to challenge the health information custodian's compliance with the provisions of this Code by addressing their concerns to the designated accountable person.

10.6 Procedures shall be in place to receive and respond to complaints or inquiries about policies, procedures and practices relating to health information collection, use, disclosure and access. The complaint process must be easily accessible and simple to use.

10.7 Patients who make inquiries or lodge complaints shall be informed of the existence of relevant complaint mechanisms.

10.8 All complaints shall be investigated. If a complaint is found to be justified, appropriate remedial measures shall be taken such as amending policies, procedures or practices.

Section D: Health Information Policies

Health information custodians must have in place and implement policies, procedures and practices that give effect to the principles of this Code.

1.1 Health information policies, procedures and practices should be tailored to the specific health care setting of the custodian and shall address and provide for:

(a) complying with and giving effect to the principles of this Code;
(b) protecting the security of health information;
(c) ensuring the accurate recording and integrity of health information;
(d) documentation of all purposes for which the health information custodian uses or discloses the health information it collects, including to whom it permits access to what information, in what format and whether consent is required;
(e) documentation of what health information may be linked to other pieces of information;
(f) documentation of what health information is made available to third parties;
(g) allowing access only to authorized users in the appropriate format and for the limited purposes for which they are authorized;
(h) identification of the person who is accountable for the policies, procedures and practices and to whom complaints or inquiries can be made;
(i) receiving and responding to complaints and inquiries;
(j) ensuring that persons who collect, use, disclose or access health information can be held accountable and are under an enforceable duty to keep information secure;
(k) ensuring that persons who work for or in the health institution know and receive

sufficient training about this Code and related institutional policies, procedures and practices to ensure accountability;

(l) the means of gaining access to one's own health information held by the health institution;

(m) making available information that a particular patient specifically requests or reasonably can be presumed to wish to know;

(n) ensuring that patients have, or by reasonable means are provided with, knowledge about their health information and that consent is sought and obtained as appropriate; and

(o) specification of minimum and maximum retention periods and rules for the succession, transfer and destruction of health information.

1.2 The health information custodian's policies must be readily available to patients and should include information about practices and procedures.