



DATA STEWARDSHIP PRINCIPLES
INFORMATION SHARING AGREEMENTS

Version 1.3
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1.0 DOCUMENT HISTORY

1.1.1 Revision History

Version	Description	Author	Date
1	Initial Draft	Doug Campbell John Swiniarski	December 31 st 2008
1.1	Feedback from MIC, CPSBC, AMA, BCMA	Doug Campbell	February 10 th 2009
1.2	Feedback from CMPA	Doug Campbell	February 24 th 2009
1.3	Status Change following Council Approval on March 13 th 2009		March 17 th 2009

1.1.2 Document Purpose

The purpose of this document is to establish and support the CPSA position on provincial data sharing agreements.

1.1.3 Intended Audience

This document is intended for use by:

- Medical Informatics Committee
- Persons or organizations with an interest in understanding the College position regarding Information Sharing Agreements

1.1.4 Status

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2.0 INFORMATION SHARING AGREEMENTS & DATA STEWARDSHIP

2.1 ISA Context & Importance

An Information Sharing Agreement (ISA) is the legal contract that defines the data stewardship rules and processes that the parties have agreed to. It establishes the roles, expectations and accountabilities of each of the parties in their stewardship of the medical information in their custody.

Key elements of an ISA include:

- Identification of the needs and objectives of the key stakeholders
- Principles that guide the development and maintenance of the agreement
- Details of the information uses and disclosures
- Details of the products and services available
- Transition services (entering and exiting the agreement)
- Record retention and access
- Definition of the service levels
- Roles and responsibilities of each party to the agreement
- Financial and legal terms
- Governance and administration processes (including the makeup of the governing body and the dispute resolution process)

The ISA represents the operational application of health policy by physicians, and is a major determinant in the structure and processes in Electronic Medical Record (EMR) deployments and other medical record initiatives.

2.2 Current Status of IMA Agreements & Provincial Information Systems

Currently there is no standard for IMAs in the province which creates an environment of uncertainty and risk for physicians. There are also a variety of medical record initiatives in process which are hindered by the lack of a standardized IMA.

2.3 Challenges & Opportunities

The IMA will be a challenge to develop because it articulates and implements new information management concepts and by its nature is a comprehensive and complex document. . Inherent in the development of the agreement will be the establishment of the governance process, as the governance of change will be critical and a major concern for participating physicians.

There are also some opportunities that arise:

- Establish the principles that will guide the development of the agreement
- Engage the key stakeholders to build consensus on the principles and framework for the agreement
- Establish an overarching medical record strategy supported by a plan which details high level structures and timelines.
- Define the governance process which will guide the ongoing process for change and resolve disputes
- Develop guidelines and education materials for physicians.

3.0 CPSA POSITION & ACTIONS ON DATA STEWARDSHIP

The primary purpose of the College is to ensure that the public receives safe, quality care from ethical and competent physicians. The College continually monitors trends and issues to identify factors affecting competent medical care as well as changes that enable improvements in medical practice. The past 10 years has seen dramatic changes in medical record processes and the information that is available to and disclosed by physicians. The impact of these changes, and the potential to affect both the quality and continuity of care, the relationship between the physician and the patient, and the security and confidentiality of patient information has led the College to focus on appropriate principles for data stewardship.

Data stewardship is the management of health information by a health professional including the collection, use, disclosure, management and security of that information. For many physicians there is a new paradigm of clinical practice management which requires a creation and/or re-design of practice processes, potentially modified relationships both within the practice and also with other health system resources, and the implementation of information and communication technology which potentially changes security and confidentiality of patient information.

In addition to these practice specific changes, on an on-going basis there are technologies and processes that are being implemented within the health system that require integration with physician processes and technology. These processes need to facilitate health systems processes as well as the support of physician practices.

It is critical that there is a structure to ensure the strategies are developed which support an enduring management data stewardship framework.

3.1 Data Stewardship Principles

Inherent in the discussion of data stewardship is a natural tension between conflicting objectives and principles. Given the wide spectrum of practice situations these Data Stewardship Principles offer general guidance. It is recognized that no principles are absolute and can often be in conflict with each other in specific situations. Examples of these types of tension include:

- Information needs of the health system (e.g. research, public health, patient populations, etc.) versus the wants and desires of the individual patient and physician
- Patient wishes and physician obligations/duties
- Public safety versus the privacy of the patient as well as physicians and other providers
- Legal, ethical and best practices versus practical demands of time
- Physician autonomy and integrated health system care models
- Advanced medical record solutions and data stewardship practices versus manual processes
- Technology advancements versus historical standards of practice.

Autonomy

- Patient autonomy
Patients have the right to self-determination of their health care, and to the extent possible, to control the management of their information.
- Physician autonomy

Physicians have the ethical and professional responsibility to direct the care of their patients, which includes their information management protocols. Physicians have the right to control the management of information regarding their provision of care.

- Health system management
Physicians have a responsibility to support the planning, management and quality improvement in the health system in which they practice, recognizing the scope of their professional practice and the increasing nature of the multi-disciplinary and cross-organizational nature of the system.

Fiduciary Duties of the Physician

- Doctor-Patient relationship
Physicians have a duty to act in good faith vis-à-vis their patients and to protect the confidentiality of the information in their trust. This includes informational privacy (information about the patient) as well as associative privacy (the potential impacts on the patient of the use of the information). This duty requires that physicians limit disclosures (or allowable uses) of identifiable patient information to those with a need to know. And unless the physician is authorized or required by law to disclose the information without consent, requires the informed consent of the patient if the use or disclosure of the identifiable patient's information extends beyond the clinical use for which it was obtained.
- Beneficence
A physician has a duty to advance the good of patients in their care, which includes the management of the personal information they hold in trust.
- Non-maleficence
A physician has a duty to do no harm to the patient, including through the handling of the patient's information.
- Maintain a medical record
A physician has a legal and professional duty to maintain a medical record including the creation, retention and destruction of those records. The physician must retain access to those records consistent with medical record retention requirements and be able to satisfy medical-legal standards for confidentiality, access, document integrity and records management processes.
- Care delivery
A physician has a duty to utilize sound data stewardship principles to optimize the quality and continuity of care of patients.

Balance

- Legitimate infringement
There is a balance between the individual's control and the needs of society including legal, regulatory and ethical obligations to disclose information.
 - Pragmatism
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There is a balance between the time required to access/research all information sources and the benefits and risks associated with improved access.

Fiduciary Duty of an Custodian / Information Manager

- Custodian-Information Manager Relationship

Custodial responsibility extends to the physical and/or virtual data stored in shared medical records under the contracted control of an Information Manager, such as an EHR or a Shared EMR. The Information Manager must act in good faith and trust to maintain the security and confidentiality on behalf of the custodian who collected the information.

All information sharing relationships should be formalized either as or within a contract, a memorandum of agreement or as an Information Sharing Agreement. The agreement must enable physicians to comply with all medical record obligations, quality assurance processes, and to ensure ongoing access for professional or patient needs. The agreement should address indemnifications, limitation of liabilities and appropriate representations and warranties.

- Information integrity

A physician, as well as the information manager has a duty to ensure patient information is accurate and complete. The collection of information including the procedures, rules and edits applied to the medical record should be considered to ensure that the stored data is made in the context of both the local medical record requirements supporting the delivery of care as well as any known prospective uses (i.e. EHR posting). Considerations should include:

- Accuracy
- Consistency
- Granularity
- Precision
- Comprehensiveness
- Relevance
- Currency/timeliness

Subsequent changes to collected information must be duly noted and propagated to EHRs to preserve an audit trail of changes to documentation.

- Information privacy

A patient is the owner of information pertaining to them maintained in all types of medical records, and has the rights pertaining to:

- confidentiality
- controlled access (enabled by express wishes for masking, limiting disclosures, uses, etc.)
- accuracy of the information, including the right to request corrections
- access to, and obtaining copies of their own information
- access to a record of all accesses to, or disclosures of their information
- basic and controlling interest in the record.

- Defined Uses

Physicians may use and disclose information (with appropriate consent where required) for defined, legal and ethical purposes:

- Information relevant to the care and treatment of patients in a process of health care
- Facilitating good patient management practices
- Data analysis for the betterment of patient populations
- Quality assurance programs
- Research (with appropriate consent and ethics approvals)

Managing Change

- Governance
An effective governance process must be in place to ensure ongoing adherence to data stewardship principles and effective change management. The process must be inclusive of key stakeholders (i.e. professions, Ministry, service delivery organizations, the public) and have effective dispute resolution mechanisms and sanctions.
- Continuous Improvement
Physicians have an obligation to evaluate and where possible to enhance the stewardship of patient information where there is opportunity to enhance the quality or continuity of care.

3.2 Influence the Evolution of the Data Stewardship Governance Process

The College will take an active leadership role to influence the creation and ongoing operations of the governance organization which will guide the data stewardship of medical information.

- Ensure that there is appropriate representation and decision making in the makeup of the group and the processes that occur
- Ensure that there is an effective and transparent dispute resolution process in place
- Ensure that the College data stewardship principles are reflected in the decisions

3.3 Influence the Development of a Strategic Plan for Medical Records

The College recognizes the tight correlation of medical record initiatives and the day to day application of data stewardship principles and rules. The indecision and uncertainty that currently exists need to be addressed with a comprehensive plan for medical records in the province (including EMRs, the provincial EHR, Shared EMRs, etc.). The College will take an active leadership role in the creation of an over-arching medical record strategy (i.e. products, data sharing agreements, governance, EMR/EHR integration, decision support tools, etc.) and the updating of data stewardship rules and guidelines.

3.4 Communicate with Physicians

The College will provide guidance to physicians with targeted communications:

- College actions regarding data stewardship governance and medical record strategies
- College expectations regarding current data stewardship practices and standards of practice
- Specific guidelines on relevant topics (e.g. disclosures in a shared-EMR, EHR utilization, agreements, etc.)