CHAPTER 2

Cultural-Communication, Legal, Ethical, and Organizational Aspects of Medicine

Darren Lau, Brendan Leier, and Sharla Sutherland

All medical care is provided against the backdrop of the pt– physician relationship. This relationship, the duties and entitlements it entails, and the organizational backdrop supporting it comprise the MCCQE's *Considerations of the* C2LEO objectives. C2LEO relates the social aspects of the medical enterprise that are essential to sound clinical practice.

Ethics concerns the values, customs, and notions of right and wrong behavior that underlie clinical relationships. Three approaches to ethics are dominant: **Consequentialist ethics** defines actions as right or wrong by the nature of their consequences. **Virtue ethics** considers the personal characteristics, i.e., virtues or vices, underlying the action.

MCCQE C2LEO Essentials

The Four-Principles Approach

In 1989, Beauchamp and Childress popularized a four-principle approach to medical ethics: r**espect for pt autonomy, benefience, nonmaleficence**, and **justice**.

- **Respect** for pt autonomy means realizing the pt's right to make decisions with regard to their own lives and medical care.
- **Benefience** obliges physicians to provide care, to do good by their pts, and to seek good outcomes.
- **Nonmaleficence** is the duty not to harm.
- **Justice** refers to fair allocations of, and fair processes for allocating medical resources.

These principles command broad acceptance, and have *prima facie* status: they are each meant to be binding unless they conflict with other significant moral values.

MCCQE C2LEO Essentials

Patient-Physician Relationship

The pt – physician relationship is a fiduciary relationship. The physician is bound to:

- Serve the pt's interest with due care and diligence
- Refrain from conflicts of interest
- Resolve all conflicts of interest in the pt's favor

Moreover,

- The fiduciary relationship confers a legal duty of the utmost loyalty.
- Trust is essential to the pt–physician relationship. The pt is entitled to have faith in the relationship's integrity.
- The pt–physician relationship is **pt centered.**
- Physicians must provide continuous and accessible care, and never abandon their pts.

The relationship is terminated when:

- Care has been transferred
- Adequate notice has been given for the pt to make alternative arrangements

Duty-based or deontologic approaches define right or wrong by reference to primary duties that are valuable in and of themselves, regardless of their outcomes. Duties may be derived from professional codes, religious law, or philosophical principles. Elements of all three ethical approaches are incorporated in the well-accepted four-principles approach to medical ethics.

The first principle, **respect for pt autonomy**, refers to the rights of individuals to make decisions with regard to their own lives and medical care. Respect for pt autonomy is a fundamental duty of the physician from both professional and legal perspectives. The principle of beneficence compels physicians to provide care, and to see to the well-being of his or her pt. The pt– physician relationship is therapeutic: its purpose is to promote pt welfare.

Nonmaleficence is the duty not to harm. Medical interventions come with risks, and often result in unintended consequences. Physicians should be aware of their limitations, and of the appropriate applications of medical technology, procedures, and pharmaceuticals.

The principle of **justice** refers to the fair allocation of scarce resources as well as the fair process through which this distribution occurs.

The ethical dimensions of clinical practice vary from situation to situation, and are topics of discussion and controversy. For example, conflict among the four principles may occur in respect of challenging or novel cases. Often, where consensus is achieved regarding right and wrong behavior, ethical principles find their way into Canada's formal system of rules. These are the legal aspects of clinical medicine. Some of these rules are statutes enacted by legislatures. On issues unaddressed in statute, the demands of the law may be created and refined by judicial precedents, which form a coherent body of common law; or by invoking and applying the general principles laid out in a **Civil Code**, as occurs in civil law jurisdictions. Apart from Quebec, where civil law is practiced, Canada is a common-law jurisdiction. Principles of law referred to in this chapter are rooted in common law. In many instances, common law and civil law formulations of physician duties and pt rights will be substantially similar, although subtleties of law and vocabulary will certainly differ.

The law recognizes the pt as a person with human and other legal rights, including the right to security of person and inviolability, and the right to freedom from discrimination. These rights are formulated at a constitutional level, in the Canada **Charter of Rights and Freedoms**. In addition, both common and civil law recognize a fundamental right to self- determination in judicial precedent and in the **Civil Code** of Quebec, respectively. Rights are trumps that can normally be expected to take precedence over other considerations. However, rights may be legitimately limited for a certain social interest. Specific instances under which individual rights must give way are recognized in various statutory and nonstatutory laws.

The physician– pt relationship can be characterized in light of these ethical and legal values. It can be described as a **fiduciary relationship**, in that the physician is an agent acting on behalf of a vulnerable pt to whom he or she must be loyal. The physician must always place the best interests of the pt first. It is also a trust relationship in that the pt should be entitled to have faith in the relationship's integrity. Current physicians, as the stewards of trust inspired by generations of previous professionals, are obliged to honor and nurture this relationship for future generations of physicians.

Physicians must follow through on undertakings made to pts, must not exploit the relationship for personal advantage, and must maintain and respect professional boundaries at all times. Physicians are obliged to provide for continuous and accessible care, and never to abandon their pts. These basic duties arise from ethical and legal understandings of the pt– physician relationship, and are only terminated when care has been transferred, or after adequate notice has been given to allow the pt to make alternative arrangements. The pt– physician relationship, as the central fixture of medical practice, permeates medicine's legal, ethical, and organizational aspects.

CONSENT

Consent is the autonomous authorization of a medical intervention by individual pt. Valid consent– or refusal to consent– requires that a **capable** pt makes a **voluntary** decision regarding a **referable** procedure or treatment, in light of a physician's **disclosure** of information. Physicians are duty-bound to seek consent before any treatment or procedure. The treating physician is ultimately responsible for ensuring consent.

MCCQE C2LEO Essentials

Consent

- Is required, ethically, by respect for pt autonomy, and legally, by the pt's common-law right to self-determination and by statute, where applicable
- Refers to specific interventions performed at particular times and places by certain personnel
- Requires
  - Disclosure
  - Voluntarism
  - Capacity
- Is required whenever treatment or diagnostic options are recommended

The pt has the right to refuse consent, even when this may lead to death. Consent may be withdrawn at any time without prejudice on the level of clinical care provided.

ETHICAL AND LEGAL BASIS

Patient **self-determination** or **autonomy** is a fundamental right. Individuals' abilities to pursue various life-projects, their perceptions, and their relations with the world are contingent on their states of physical well-being. Control over one's body is therefore fundamental in determining the direction of one's own life. This is recognized in common law, under which physicians find themselves liable for battery if they treat a pt without consent, or for negligence, if they treat a pt under inadequately formed consent and pt harm occurs as a result. Certain provinces have taken the further step of legislating consent. Ontario's *HCCA, e.g.*, ''provides rules with respect to consent to treatment that apply consistently in all circumstances''.

Physician colleges also recognize a professional duty to seek consent. Failure to adequately uphold these norms could lead to professional disciplinary action, including suspension or loss of licence.

DISCLOSURE

Meaningful decision making requires that individuals are apprised of information relevant to their circumstances. Only then can the decision be attributed to their authentic preferences.

In *Reibl v. Hughes*, the court decided that adequate disclosure should include **whatever a reasonable person in the pt's circumstances would want to know**. This **modified-objective** standard strikes a balance between objectivity and subjectivity in determining adequate disclosure on a case-by-case basis. An entirely subjective standard might read: **what the pt would have wanted to know**. However, this alternative is difficult to evaluate fairly. In the modified-objective standard, the reference to **a reasonable person**, a hypothetical legal construct, allows courts to infer the content of an adequate disclosure independent of a pt's whims, while remaining responsive to particular circumstances.

MCCQE C2LEO Essentials

Disclosure

- What a reasonable person in the pt's circumstances would want to know
- Usually includes
  - Nature of the intervention
  - Gravity of the pt's situation and of intervention
  - Material risks and benefits, including special or unusual risks
  - Alternatives and consequences of nonconsent
  - Information regarding delegation of care
- Pt questions must be addressed
- The treating physician must ensure pt understanding

Supreme Court Chief Justice Laskin's formulation of the general content of an adequate disclosure in *Hopp v. Lepp* is instructive:

> '' ... a surgeon, generally, should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him *the nature of the proposed operation, its gravity, any material risks and any special or unusual risks ...* However, having said that, it should be added that *the scope of the duty of disclosure and whether or not it has been breached are matters which must be decided in relation to the circumstances of each particular case."* (*Hopp v. Lepp*, italics added by present authors.)

Information should be presented in broad terms and simple language. Translation services should be sought to address linguistic barriers. Information should account for extramedical (e.g., social and financial) circumstances. And the treating physician should check for pt understanding.

VOLUNTARISM

Voluntarism refers to freedom from coercion, so that a pt's authentic sense of what is good, right, and best can guide medical decisions. Is the pt free to act ''in character,'' in accordance with those values and interests formed and congealed throughout the pt's life?

In the clinic, voluntarism can be thought of as freedom from external interference. These include pain, a rushed environment, local resource scarcity, physical restraints, and coercive family dynamics. Medical staff should facilitate a voluntary decision by providing pain control; creating calm and supportive settings for discussing major decisions; ensuring that local resource scarcity does not restrict the pt's range of options, including arranging for pt transfer, prn; using restraints only as necessary, and using the least restrictive modalities; and checking in with the pt regarding the role of the family. A family conference may be appropriate. Hospital ethicists should be consulted for difficult cases.

CAPACITY

Capacity refers to the ability to consent or refuse consent to medical treatment. According to the Ontario *HCCA*, the capable pt is ''able to understand the information that is relevant to making a decision''; and ''able to appreciate the reasonably foreseeable consequences of a decision or lack of decision.''

There is no one-size-fits-all or easy way of assessing capacity. Capacity does not refer to global cognitive or affective status, as assessed, e.g., by the Folstein MMSE, although bad

MCCQE C2LEO Essentials

Disclosure

- Voluntarism
- Minimize coercive influences, or influences that interfere with decision making, e.g., provide adequate pain control.
- Capacity
- A process standard of capacity applies: Is the pt able to understand and appreciate information? The consequences and alternatives to action or nonaction?
- Capacity is specific for each decision
- Capacity (/=) global cognitive status
- Capacity my fluctuate
- The pt should be allowed to direct treatment as much as possible
- Refusal to consent (/=) incapacity
- Minors and mentally disabled pts raise special issues for capacity
- If the pt is not competent, consent may be obtained from a court, parent, or SDM according to provincial law and specific circumstances
- At least two justifications for proxy or substitute decisions should be recognized: **what the pt would have wanted** and the **best interests** standards; the acceptability of the justification will depend on the circumstances

MMSE performance may lead a physician to suspect the pt's capacity. Capacity is specific. It refers to a pt's ability to make a particular decision. A pt incapable of making one decision is not necessarily incapable with respect to another. Capacity is also dynamic. It *.6*s with time and circumstance. Therefore, capacity should be assessed and reassessed regularly, and for different sorts of decisions. Out of respect for autonomy, pts should direct their own care to the extent that they are capable. Where the stakes resting on a capacity determination are substantial, a formal assessment by a psychiatrist and/or an ethicist consultation should be sought.

Capacity can be affected by many factors, including dz, drug-use, and depression. Reversible factors should be addressed, and important decisions delayed until capacity is restored, if possible.

Capacity goes beyond simple understanding: to **appreciate** one's circumstances, the pt must **be able** to recognize that he or she has a condition to which the treatment and its consequences might apply. This is not to say that the pt must characterize his or her condition as pathological or as necessitating treatment. To presume this would be tantamount to saying that a pt is capable if he or she agrees with the medical opinion. **Nonconsent does not constitute evidence of incapacity** and medical staff must be open to idiosyncratic perceptions of health and wellness.

EXCEPTIONS TO CONSENT

When a pt presents in an urgent care setting, efforts should be undertaken to facilitate consent (e.g., find a translator for a capable non-English speaker, or locate a SDM for an incapable pt). This might not be feasible in emergencies, where delay could lead to significant bodily harm. In such situations, it would be better to err on the side of bodily integrity: treatment should occur without delay.

However, the emergency exception does not apply where there is reason to believe that the pt would refuse treatment if he or she were capable. In *Malette v. Shulman*, an emergency physician was held liable for initiating a life-saving transfusion on an incapable car accident

victim, despite his awareness that a card declaring refusal of blood products for religious reasons had been found in the victim's purse.

Provincial public health statutes require compulsory diagnostic testing or treatment in suspected cases of certain infections. Mental health statutes may also provide for admission to hospital without consent. These vary from province to province. Legislation may also require that an SDM consent to diagnostic or therapeutic interventions, after admission.

THE INCAPABLE PATIENT

A pt may be unable to understand the medical problem, the proposed treatment, alterna- tives, or consequences of consent/nonconsent. The pt may be unable to appreciate his or her situation, i.e., unable to recognize that he or she has a condition to which this information applies. He or she may be unable to make a decision that is not substantially based on delusion or depression. This pt is incapable.

ETHICAL AND LEGAL CONSIDERATIONS

When pts are incapable, their decision making– or lack thereof–may subject them to undue harm. Moreover, decisions made in these states cannot meaningfully be said to be rooted in the values and beliefs that comprise a consistent self-identity. That is to say, decision making is no longer autonomous.

We protect incapable pts by making decisions on their behalf– but according to whose guiding values? Pts' illnesses should not deprive them of the right to live a full and complete life according to their own values. To ensure that their preferences continue to guide their care during illness, physicians rely on personal directives, and on SDMs **duty-bound to consider what the pt would have wanted if he or she were capable**. The right to control one's own body continues, even during a period of incapacity, even during a life-threatening emergency.

For some incapable pts, such as young children or pts who have had lifelong and severe mental handicap, it may be difficult to speak of a coherent set of care-guiding principles that reflect the authentic preferences of a core self. Respect for pt autonomy must be balanced against beneficence. Such a pt should be involved in decision making to the extent that maturity or disability permits, out of respect for nascent capacity and/or a burgeoning sense of selfhood. However, consent should be sought from the pt's guardian or an appropriate SDM, **who is obliged to act in the pt's best interests**. Here, the pt's circumstances privilege considerations of beneficence. Young children, lifelong severe mental handicap, and genuine uncertainty about a pt's preferences are examples of when the best interests standard should apply.

Clinical Box

Valid Personal Directive

A valid personal directive written by or on behalf of a previously capable individual must be obeyed.

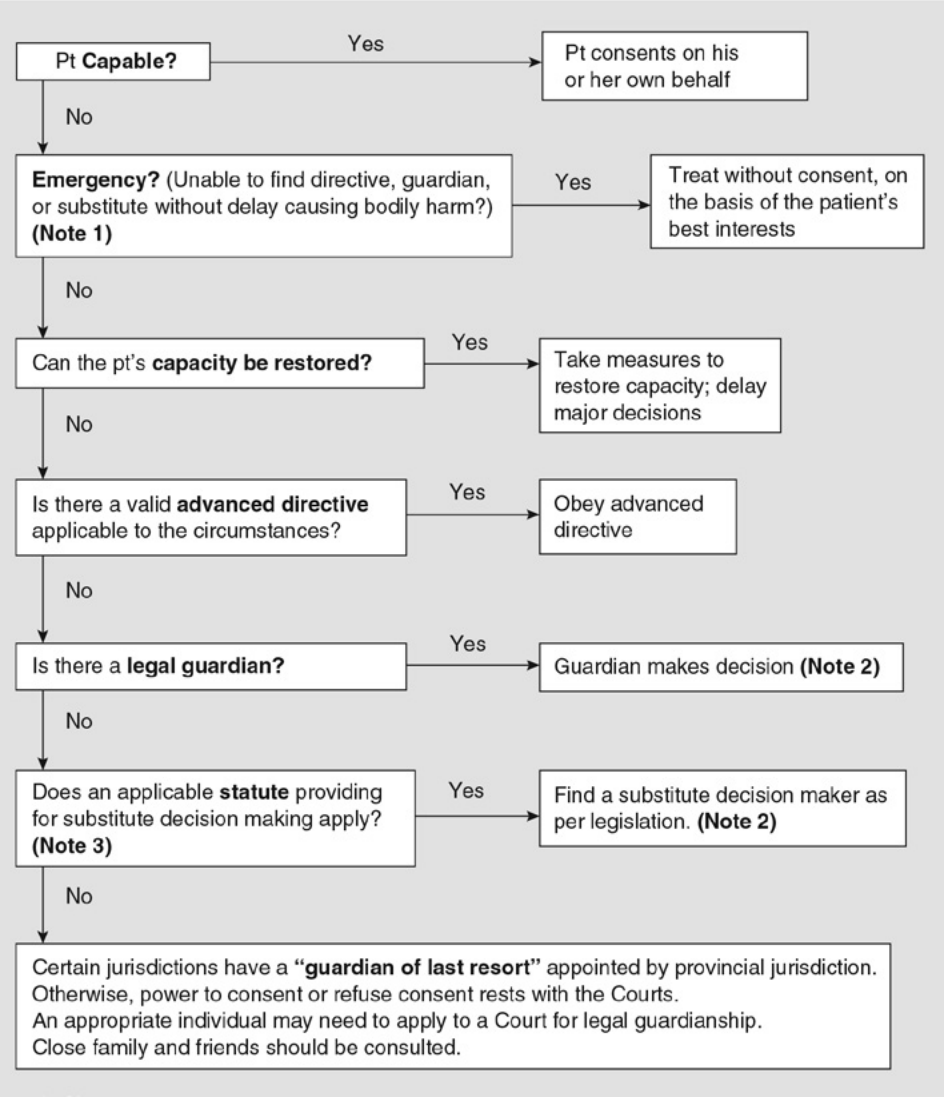

Figure 2.1 Consent algorithm for incapable pt.

Note 1: Evidence of a pt preference, even in the event of a life-threatening emergency, must nonetheless guide decision making (see, for e.g., Malette v. Shulman).
Note 2: SDMs are duty-bound to act on what the pt would have wanted, if he or she were capable. If the pt was never previously capable to make health care decisions, is a minor, or if the pt's wishes are unknown, substitutes should apply the best interests standard.
Note 3: Applicable statutes include child welfare statutes (e.g., Alberta's *Child, Youth, and Family Protection and Enhancement Act*), mental health statutes, and statutes concerning dependent adults.

AGE AND CAPACITY

Age does not necessarily correlate with capacity. Under the common law doctrine of the mature minor, minors, like adults, are presumed capable, unless a specific assessment reveals incapacity. Extending the notion of capacity to encompass minors privileges their autonomy: The preferences of a capable minor must be respected.

For most minors, decision making will integrate medical opinion, the pt's preferences, and the family's preferences in varying degrees depending on the family's dynamics. It is therefore preferable to facilitate a therapeutic alliance inclusive of both the pt and his or her family. However, in the event that this is not feasible, the doctrine of the mature minor privileges the autonomy of a capable pt, age notwith- standing.

Statutory law may supercede common law. British Columbia's *Child Family and Community Services Act* allows the Director of Child Family and Community Services to appeal to the court, and for the court to order treatment, where a child– any individual <19 years of age– or his or her guardians refuse to consent for treatment necessary to ''preserve the child's life or to prevent serious or permanent impairment of the child's health'' (B.[*S.J.*] v. *British Columbia* [*Director of Child, Family and Community Services*]). Therefore, a minor in BC is legally prevented from refusing life-saving care. This is not to say that a minor is incapable of providing consent, or of refusing treatment that is not necessary to preserve life or to prevent serious injury.

In such instances, it is likely that the doctrine of the mature minor still applies. Other jurisdictions may have their own, unique, legislative frameworks. In general, a mature minor should be presumed capable. If the question of a mature minor's capacity to consent or to refuse consent becomes problematic, perhaps in light of life-threatening circumstances, the advice of child welfare authorities, hospital counsel, or the hospital ethicist should be sought.

In any case, physicians **must** report a parent's failure or refusal to seek necessary medical therapy to child protection authorities.

Clinical Box

Child Protection

Failure to meet a child's medical needs must be reported to child protection agencies.

PERSONAL DIRECTIVES AND SDMs

Personal directives are mechanisms enabling a competent person to maintain control over clinical care in the event of future incapacity. Directives may be instructional, proxy, or combinations of the two. Instructional directives specify clinical interventions that should or should not be undertaken in the event of certain illnesses, such as the use of a feeding tube under conditions of complete paralysis or severe dementia. Instructional directives have pitfalls, in that they are unable to anticipate all possible situations that may arise, and in that instructions may be too vague to be practicable. Proxy directives appoint a competent individual to act as a decision maker on the pt's behalf. The proxy is normally bound to act on the basis of what the pt would have wanted. This approach overcomes the pitfalls of the instructional approach but requires that the proxy be well informed in advance. Notably, the proxy's powers are not absolute. Physicians cannot legally comply if the proxy's decisions are unjustifiable either by the pt's wishes or values, or by the pt's best interests.

Provincial legislation provides an enabling framework for health care directives. Where legislation does not exist, case law suggests that written directives must nonetheless be respected because they express the pt's autonomous preferences.

If no personal directive can be discovered, or if no legal guardian with powers of agency over health care decisions can be found, consent can be obtained, where statutes permit, from an SDM. The Ontario HCCA, for example, provides a prioritized list of individuals empowered to give or refuse consent on behalf of an incapable pt. Depending on the circumstances, the SDM may be obliged either to consider what the pt would have wanted or to consider the pt's best interests. Where statutes do not provide for substitute decision making, power to consent or refuse consent on a pt's behalf rests with the Courts or with Court-appointed guardians. However, medical staff regularly consult and consider the views of close family members.

CONFIDENTIALITY

Confidentiality refers to the physician's duty to safeguard information disclosed by pts, i.e., never to divulge it in ways inconsistent with the understanding of the original disclosure, except as the pt directs or permits. Privacy refers to the pt's control over knowledge of his or her personal affairs. Confidentiality protects pts' privacy.

CONFIDENTIALITY–ETHICAL AND LEGAL CONSIDERATIONS

Confidentiality is essential to the pt– physician relationship. We perceive our bodies as intimate, private domains. Information about our bodies should be intimately kept. Health information can also affect social relations, self-perceptions, and the range of life-projects that are accessible to the pt. The knowledge that a pt has HIV/AIDS, for example, may subject the pt to stereotyping and discrimination if revealed unwittingly. Given its importance, health information should fall under the ambit of self-determination. Physicians are obliged to maximize a pt's autonomy, as well as defend the pt from potential harm, by observing confidentiality. Health information should go only where the pt would wish it. The pt– physician relationship is built on pt' trust that physicians will apply these moral standards in their activities.

MCCQE C2LEO Essentials

Confidentiality

- Underpinned ethically by autonomy and beneficence, and legally by fiduciary duty
- Facilitates trust in the pt-physician relationship
- Health information **must** be disclosed to a third party when
  - The law requires reporting
  - To prevent serious harm from befalling a third party, **i.e., duty to warn**
  - To prevent serious harm from befalling the pt
  - Where the pt requests or authorizes that health information be transferred
- The pt should be notified of a required disclosure
- Common mandatory disclosures with which physicians should be familiar vary from province to province, and may include:
  - Certain communicable dzs
  - Suspected child abuse or abandonment
  - Fitness to operate a motor vehicle
- Decision-capable minors are entitled to confidentiality anonomized or deidentified information is generally not considered private, but should be created or used carefully nonetheless
- Confidentiality rules and exceptions are complicated–guidance should be sought from the professional college

Certain provinces have enacted statutes with the primary aim of regulating the treat- ment of health information (e.g., Alberta's *Health Information Act*). These statutes outline the responsibilities of health information custodians and pts' rights in respect of their information. At common law, the pt– physician relation can be modeled as a trust relationship, in which the physician is a fiduciary agent acting for his or her principal, the pt. Physicians are typically in positions of power relative to their pts. A fiduciary (from Latin, *fides*, meaning ''faith'') is bound to further the interests of the beneficiary with the utmost loyalty. Fiduciaries are prohibited from allowing personal interests to supersede their duties to a principal, from being in a position where duties to multiple principals clash, and from profiting from their position of trust without their beneficiary's consent. Fiduciary duty is therefore a legal guarantee that the physician's position of power is never used for personal gain, third-party gain, or in a manner that harms the pt.

A pt has a continuing interest in his or her health information. Serving this interest means safeguarding the pt's information and disclosing it as directed. In practice, this means taking reasonable precautions to maintain confidentiality by:

- Limiting information disclosed over phone
- Avoiding the transmission of health information by fax or E-mail
- Securing charts and maintaining computer network security
- Deidentifying pt data for presentations or educational and research purposes

In general, anonomized, or deidentified, data is not considered private. Personal information may also be used or disclosed without the subject's knowledge or consent for statistical or scholarly purposes, where such ends cannot be achieved without pt information, and where it is impractical to obtain consent, subject to ethical research review. There are instances in which, regardless of pt preferences, health information must be disclosed to a third party. For example, maintaining confidentiality may pose significant risk of substantial harm to the public. Disclosure of health information to the appropriate authorities may be necessary. Disclosure is also mandatory where statute requires it. In many cases, these laws (e.g., public health legislation) express a broader public interest that legitimately limits the exercise of individual rights. Confidentiality is not absolute, and it is important that physicians know the exceptions.

Clinical Box

Danger to Others

"...the confidential character of pt-psychotherapist communications must yield to the extent that disclosure is essential to avert danger to others. The protective privilege ends where the public peril beings" (*Tarasoff v. Regents*).

Clinical Box

Recent Disclosure Legislation - Two Examples of Emerging Issues

- In 2007, Saskatchewan became the second province to enact mandatory disclosure of gunshot and stabbing wounds. Medical staff must report, to local police, that such a wound has been treated, the name of the pt, and the location of the medical facility. Reporters are immune for liability for disclosure. Ontario has had similar legislation since 2005.
- In 2007, Alberta passed a legislation requiring a "source individual" to submit to testing upon the request of an emergency services personnel who was exposed to the source individual's bodily fluids in the course of their work.

(Source: Rossall, Jonathan. "Mandating Disclosure – Where Art Thou?")

Table 2.1 Disclosures of Health Information

Keywords	Scenario	Mandatory
Nonstatutory		
Court order	Upon request of a court order	X
Executor of estate	To the executor of the estate, for a deceased pt; the executor represents the deceased legally, not the next-of-kin	X
Pt consents	With pt consent, any use or disclosure is permissible	
Parents, minor pt incapable	Upon request of a pt's parents, **but not** where the pt is a mature minor	X
Pt directs	Must disclose information to a third party as directed or authorized by the pt	X
Federal Jurisdiction		
Aviation safety[a]	Medical conditions of flight crews, air traffic controllers, and others where the conditions is a threat to aviation safety	X
Mental illness, violent[b]	Patients treated for mental illness associated with violence or threatened violence	X
Railway safety[c]	Medical conditions of railroad workers in safety critical positions, where the condition is a threat to public safety	X
Provincial Jurisdiction		
Animal bites	Animal bites in which rabies is suspected	X
Board, statutory	Upon request of a Board or Tribunal, empowered by statute to issue subpoena (e.g., Attendance Board, *School Act*)	X
CA	Pathological reports indicating malignancy	X
Care-giver	To a person responsible for providing continuing care and treatment to the pt	
Child abuse	Suspected child abuse	X
Deaths, suspicious	Deaths under certain conditions (e.g., unexplained deaths, or deaths consequent to negligent care)	X
Discipline, professional	To the College of Physicians and Surgeons of Alberta pursuant to an Ix	X
Dzs, communicable	Certain communicable dzs	X
Dzs, notifiable under OH & S	Specific notifiable dzs (e.g., lead poisoning, asbestosis, and noise-induced HL)	X
Family members	To family members or individuals close to the pt, or for purposes of contacting such individuals, **if** the information is in general terms and **not contrary to the pt's express wishes**	
Legal guardian	Upon request of pt's legal guardian, with documentation of appointment	X
Motor vehicles	Persons medically unfit to drive	
Persons in care	Suspected abuse of a "person in care"	X
WCB	Upon the request of the WCB, only information relevant to work–related injuries likely to disable the pt from work for >1d	X
Danger to others[d]	Pts who present a clear and substantial danger to society	?

This table is based on Alberta disclosures as of 2005. Disclosures not marked "mandatory" are meant to be considered "permissible" or "discretionary."
Where the table references a federal statute, the disclosure applies uniformly across Canada. Otherwise, disclosure obligations are developed in provincial statute or case law, and vary from province to province. Practitioners must be familiar with regulations in their own jurisdictions.
[a]Aeronautics Act (Federal Statute)
[b]Firearms Act (Federal Statute)
[c]Railway Safety Act (Federal Statute)
[d]The case-precedent suggesting a duty to disclose in this situation is an American case, *Tarasoff v. Regents*. This duty has not been tested in Canadian jurisprudence.
(College of Physicians and Surgeons of Alberta, *Release of Medical Information: A Guide for Alberta Physicians*.)

CONFIDENTIALITY–DISCLOSURES TO THIRD PARTIES

Infectious dz reporting to public health officials often constitutes mandatory disclosures of health information. Notifiable dzs commonly include sexually transmitted infections such as HIV/AIDS, gonococcal infections, C. trachomatis infections, mucopurulent cervicitis, LGV, syphilis, and chancroid; and other infections such as hepatitis, TB, enteric pathogens, foodborne illnesses, epidemic gastroenteritides, small pox, anthrax, viral hemorrhagic fevers, etc. Practitioners should be familiar with local regulations. Additionally, it is usually desirable to notify the pt about the required disclosure. This practice may enlist the pt. At the least, it helps maintain the bond of trust and transparency underlying the pt– physician relationship.

In the absence of legislation requiring otherwise, medical staff need not report gunshot wounds, stabbings, admitted use of illegal drugs, or injuries suffered during the commission of a crime. Such information may be obtained by a police officer with a valid court order.

PATIENT ACCESS TO HEALTH INFORMATION AND THE MEDICAL RECORD

The medical record is subject to physician control and responsibility. Medical staff have professional duties to document clinical activities, observations, and interactions on a medical record; to maintain the integrity of the record, and keep it up-to-date; to ensure for its secure storage; and to facilitate continuity of care by transmitting copies of the record as appropriate. The physician-clinic maintains ownership over, control of, and responsibility for the medical record.

MCCQE C2LEO Essentials

Pt Access and the Medical Record

- Physicians have a duty to maintain adequate records for each pt they treat.
- The law specifies minimum time frames for the preservation of medical records (10 yr in most jurisdictions.)
- Pts have a right of access to health information, including the contents of the medical record.

Pts should be allowed access and control over their health information. For example, a pt request that a medical record– or, rather, a copy thereof–be transferred to a new clinic must be respected. A pt should also be able to review his or her medical record on request. It is reasonable to recover costs incurred providing access to the medical record, perhaps with a small access fee.

TRUTH TELLING

ETHICAL AND LEGAL CONSIDERATIONS

Health information, and control thereof, is important in determining the direction of one's life. A pt's autonomy is furthered when health information is made available so that the pt can make an informed decision based on authentic preferences. Withholding or falsely representing health information has previously been justified under the physician's duty of beneficence. By this account, the doctrine of therapeutic privilege, the health information is said to be too complex, or too tragic for the pt to deal with. It may concern a terminal Dx, to which the pt might respond with despondency or cynicism. This might in turn lead the pt to self-harm, or to forgo further treatment. It is for the pt's well-being that the physician withholds information.

Therapeutic privilege presumes that the physician knows the pt's best interests better than the pt does. In a plural society of individuals, each pursuing unique ends, this presumption is untenable at best, paternalistic at worst. Therapeutic privilege serves a narrow set of interests determined by physicians, and may fail to account for complex circumstances or conceptions of wellness. This failure may do the pt harm. It certainly infringes on self-determination, by preventing the full range of pt preferences from expressing themselves.

Therapeutic privilege may usefully be invoked where a significant risk of substantial harm accompanies honest disclosure. However, means of mitigating the risk of harm should be explored first, including emotional support and counselling. The situations that remain will be extraordinary. Therapeutic privilege is, properly, a last resort.

There are consequential grounds for truth telling. Pts or their families will inevitably come to know information that was withheld or misrepresented. The consequent feelings of betrayal may jeopardize the pt– physician relationship. The importance of honesty should not be

underestimated.

Of course, none of the foregoing should dismiss the psychological coping value of shunning information. A pt's way of dealing with illness will be affected by personal and cultural context. A decision to waive disclosure, if made voluntarily, is a valid decision, and should be respected.

Legally, pts have rights of access and control over their health information– these rights and the corresponding obligations they place on health information custodians can be found in health information statutes and in the fiduciary nature of the pt–physician relationship (see Confidentiality). Additionally, failure to disclose health information that leads to pt harm may be construed as negligence.

Medicine is best practiced within the pt's own conception of best interests– this requires honesty, frank discussion, and attentiveness to pt preferences.

MCCQE C2LEO Essentials

Truth Telling

- Truth telling is based on the respect for pt autonomy, and is important for the maintenance of faith in the pt–physician relationship
- Physicians must speak truthfully, and refrain from falsehood
- Provide pts with opportunities to know important health information, including
  - Purpose and implications of investigations
  - Dx and prognosis
  - Risks and benefits of treatment
  - Risks to which the pt may have been exposed (e.g., by medical error)
- Respect the pt's right to know, seek consent for disclosure, and ascertain pt preferences
- The doctrine of therapeutic privilege has been discredited except in extraordinary circumstances

A Pt-CENTERED PROTOCOL FOR BREAKING BAD NEWS

Pts should be provided with opportunities to know their health information. Admittedly, health information may be difficult to handle, and should be disclosed sensitively. Permis- sion to disclose information should be sought first. The SPIKES protocol published by Baile et al. is useful.

Clinical Box

SPIKES Protocol for Breaking Bad News

S - Setting up the interview

P - Assessing pt's Perceptions

I - Obtaining the pt's Invitation (i.e., to disclose information)

K - Giving Knowledge and information to the pt

E - Addressing the pt's Emotions

S - Strategy and Summary

NEGLIGENCE

Negligence is a tort: a private, as opposed to a public, wrong actionable through legal means, involving an injury to person or property. The usual remedy imposed by courts for physicians found liable for negligence is monetary compensation for damages and costs.

Professional colleges may also suspend or revoke license to practice. This occurs separately from the negligence suit.

At common law, the physician is liable for negligence when the plaintiff is able to prove the existence of a duty of care, a breach of that duty, causation, and consequent harm.

MCCQE C2LEO Essentials

Negligence

Negligence requires that the plaintiff prove the existence of a duty of care, a breach of duty, causation, and consequent pt harm.

- Duty of care
  - Arises from the doctor–pt relationship
  - Duty is also owed to third parties in certain instances
  - The duty of care ends at the termination of the pt–physician relationship
- Standard of care
  - **The quality of care can be expected of a reasonable practitioner of similar training and experience**
  - Specific to the time of alleged negligence
  - Different for specialists and generalists
  - Standard of care is the same for similar practitioners **regardless of location**
- Breach of Duty
  - Breach of duty (does not equal) error of judgment
  - Key question: Could a reasonable practitioner with appropriate training commit this error or omission? If no, then breach of duty has likely occurred.
- Causation
- Pt harm

Actions for negligence must be launched within certain time periods after treatment, with limits varying from province to province according to statute.

DUTY OF CARE

A duty of care arises from the pt–physician relationship. Physicians also owe duties of care to individuals outside established pt– physician relationships. For example, there exists, in the United States, a duty to disclose health information when maintenance of confidentiality would result in significant risk of substantial harm to others (see Confidentiality). This responsibility is essentially a duty of care owed to third parties threatened with substantial harm. The legal precedent establishing this duty is the US case, *Tarasoff v. Regents.* Case-law precedent has yet to be established in Canada, but it is likely that similar duties will be found to exist.

In the event of an emergency, a physician may be called upon to care for an individual with whom he or she has no pt– physician relationship. Whether or not Canadian law recognizes a duty of rescue, under which a physician-as-bystander would be obliged to act, is controversial. Nonetheless, if emergency care is provided, the provider may be obliged to exercise due diligence

and to meet professional standards, to the extent that emergent circumstances make this possible. The physician may therefore owe a duty of care to the injured individual.

To those to whom a duty of care is owed, the medical practitioner is bound to provide adequate care, and to exercise **the degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing**. This standard of care differs according to training; however, it should be noted that generalists performing procedures typically performed by specialists will be held to the specialist standard of care. Recognizing that medical knowledge *.6s* quickly, the standard of care is also dynamic. In medical malpractice suits, the relevant standard is the set of expectations that existed at the time of the alleged negligence. Additionally, the standard of care is common to all equivalent practitioners, regardless of locality. Therefore, a rural emergency physician is held to the same standard as an urban emergency physician. And although physicians cannot be expected to provide services that are not locally available, there is a duty to disclose such services and how they might be accessed to the pt, and to arrange for appropriate referral or transfer.

In an era of health care reform, physicians may feel pressured to minimize referrals or transfers, or to reduce the utilization of expensive services. This pressure often relates to institutional cost-containment efforts. However, where medically appropriate services are available, physicians are required to disclose this fact, to discuss access with the pt, and to arrange access as appropriate, regardless of cost. Cost-containment is not a defence to negligence.

The specific content of the standard of care is usually based on the approved practices that exist at the time of care. These are to be determined at court by reference to, among other things, expert testimony, clinical practice guidelines, and hospital policies. However, there is some latitude for the courts to deviate from approved practice, in effect, substituting judicial opinion for the expert medical opinion. This may occur when approved practices are fraught with obvious risk, or when the matter under consideration is of a nontechnical nature, such that an individual without clinical expertise may determine a minimum standard of care. These circumstances are limited, but they highlight the point that physicians should not accept approved practices unquestioningly.

BREACH OF DUTY

A breach of care occurs when a medical provider makes an error or omission that no reasonable physician of similar training and experience would make under the circumstances. Not all errors are breaches of duty. Physicians are not infallible, and circumstances can militate against diagnostic or therapeutic success. Errors in Dx and treatment, **i.e., errors of judgment**, will occur. These errors may lead to significant harm, but do not constitute negligence if the standard of the reasonable practitioner is met.

Notably, an error of judgment in the initial instance may become a breach of duty if, e.g., medical staff fail to revaluate a (mis-)Dx in light of nonresponse to treatment.

CAUSATION AND INJURY

A negligence suit requires that there be pt harm, and that the harm occurred as a result of the breach of duty. If injury or causation cannot be established, damages will not be awarded. Recently, certain claims have made thorny issues of causation and injury. A suit alleging wrongful life is brought by parents, **on behalf of a disabled child**, who is born, e.g., as a result of a physician's failure to recommend genetic screening. If the physician had fulfilled the standard of care and recommended genetic screening, the disability may have been detected, the parents would have terminated the pregnancy, and the child would have been saved from the harm of a

life of disability. Wrongful life suits have not been well received by Canadian courts: establishing injury on behalf of the child would require comparing the child's life to nonexistence!

A wrongful birth suit, in contrast, is brought on behalf of the parents, and seeks compensation for costs and damages incurred in caring for the disabled child. Damages for the cost of raising the child have been awarded in such cases.

RESOURCE ALLOCATION

Resource allocation decisions concern questions of justice: How are resources fairly dis- tributed among health needs? On what basis is it acceptable to make these decisions? The basis, whether intentional or unintentional, for differential access to health care goods and services among pts should meet ethical and legal standards for fairness.

Responsibilities for health care resource allocations occur, at three levels: macrolevel, mesolevel, and microlevel. Broadly speaking, global budgets are determined at the macrolevel. Services and access conditions are determined by mesolevel policy. Finally, clinical decision making occurs at the microlevel.

MCCQE C2LEO Essentials

Resource Allocation and Clinical Decision Making

- The physician owes a primary duty to th ept.
- Clinical care (i.e., **micro**level decision making) must not be compromised by cost constraints.
- Resources should be allocated fairly: on the basis of morally relevant criteria, i.e., need and potential benefit, using fair and publicly defensible procedures.
- The impact of **meso**level and **macro**level rationing decisions should be discussed with the pt in a supportive way.
- Resources should be deployed prudently.

While macrolevel and mesolevel decision makers must make decisions that incorporate considerations of costs and competing interests, the microlevel decision maker (e.g., the physician) must remain loyal to the pt's interests. The physician may– and should– advocate for the pt interests in macrolevel and mesolevel decisions. Ultimately, though, the physician's clinical work occurs **within** the resource frameworks and constraints determined at the upper levels. This division of responsibilities removes global cost considerations from the microlevel, freeing clinicians to focus on pt welfare. Clinical decisions should be driven entirely by pt need and potential benefit.

This section addresses clinical resource allocation, and focuses on three issues: fair access to health care, the obligation to seek the pt's best interests, and prudent use of health care resources.

Table 2.2 Levels of Health Care Resource Allocation

Macro	Meso	Micro
Government policy–federal and provincial (e.g., health insurance policy, taxation, federal transfer payments, physician fee-for-service regulations)	Health region/institutional policy (e.g., decision to add ICU beds, ICU admissions policy)	Physician–Patient clinical interaction (e.g., prescription decisions, aggressive vs. conservative approaches)

FAIR ACCESS TO HEALTH CARE

Individuals are morally equal, and equally worthy of respect. In practice, this means that the interests of all who are affected by a particular decision should be considered equally in the decision-making calculus. This is not to say that equality of outcomes must follow: not all individuals who show up in hospital should receive equal quantities of morphine, for example. In medical decision making, the fundamental equality of individuals is observed when cases that are similar in morally relevant ways are treated similarly, and dissimilar cases dissimilarly.

The ‘‘morally relevant ways’’ usually boil down to need and potential benefit. Differential treatment on the basis of such properties as age, sex, and religion are tolerated **only insofar** as these properties can be demonstrably linked to need and potential benefit. Otherwise, these properties are irrelevant. All other things being equal, granting a white differential access to reproductive health over a of aboriginal descent– perhaps by providing better counselling or by providing access to services such as abortion more readily– represents a devaluation of the aboriginal ’s interests on the grounds of race. This sort of discrimination fails to recognize the pt as a morally significant being worthy of equal respect.

Legally, equality rights are recognized in Section 15 of the Canadian *Charter of Rights and Freedoms*. Constitutional case law has conceptualized equality obligations into two sorts: nondiscrimination requires that individuals be treated alike; substantive equality requires that positive measures be undertaken to provide equal access for those whose special characteristics disadvantage them on the basis of race, religion, sex, disability, and so on. The *Charter of Rights and Freedoms* has been found to apply to hospitals. Physicians may also be bound by professional codes of ethics, and by provincial human rights statutes that impose similar duties.

In clinical care, this means that discrimination is unacceptable. Resources should be allocated on the basis of morally relevant criteria, using fair and publicly defensible procedures. Positive measures (e.g., sign language or TTD services for the deaf, access to female physicians for female pts whose cultural beliefs prohibit care from a male physician, etc.) should be taken to ensure that the interests of all pts are equally served.

PRUDENT USE OF CLINICAL RESOURCES AND THE OBLIGATION TO SEEK THE PATIENT’S BEST INTERESTS

In the late 1980s and 1990s, governments, perceiving budget deficits and rising health care costs, embarked on a series of health care reform initiatives. As a side effect, physicians have felt pressure to contain costs, e.g., by minimizing the use of expensive modalities. In the negligence case, *Law Estate v. Simice et al*., physicians accused of negligence in failing to provide a pt with a medically necessary CT scan mentioned cost constraints. In response, British Columbia Supreme Court Justice Spencer writes:

> ‘‘If it comes to a choice between a physician’s responsibility to his or her individual patient and his or her responsibility to the Medicare system overall, the former must take precedence in a case such as this. The severity of the harm that may occur to the patient who is permitted to go undiagnosed is far greater than the financial harm that will occur to the medicare system if one more CT scan procedure only shows the patient is not suffering from a serious medical condition.’’ (*Law Estate v. Simice*)

Cost constraints should not interfere with clinical care. First, physicians, owing a duty of care to their pts, must meet the standard of care that can be expected from a reasonable practitioner of similar training and experience. Cost constraints are no defence against negligence. Second, physicians are fiduciaries in a trust relationship with their relatively vulnerable pts. They

are duty-bound to look after the interests of their pts with the utmost loyalty. Because the cost of physicians' services in Canada is borne by the Medicare system, allowing cost considerations into clinical reasoning amounts to the entry of a third-party interest. Physicians are duty-bound to resist this intrusion, and to maintain the independence of their clinical judgment. Where cost constraints do affect clinical decisions, perhaps because of limitations imposed at the mesolevel and macrolevel, physicians need to discuss, in a sensitive manner that avoids laying blame, the effects of cost constraints, available treatment alternatives, and the means of accessing them.

This does not mean, of course, that physicians should not use resources prudently. Physicians may need to mediate a common understanding of fair and prudent care with pts. Excessive treatment, or treatments of marginal benefit, may subject pts to more harm than good. Physicians, having many pts, are also fiduciaries to many beneficiaries. Moe Litman suggests that physicians might apply the legal concept of ''keeping an even hand amongst beneficiaries'' as a lens. Not to be applied literally, this principle is satisfied if ''allocation decisions are made on a nonpersonalized, relatively objective basis, in accordance with appropriate principles intended to maximize the health care of pts''. In the clinic, this means:

- Choosing interventions known to be beneficial on the basis of evidence
- Minimizing the use of marginally beneficial tests or interventions
- Seeking the tests or treatments that will accomplish the diagnostic or therapeutic goal for the least cost
- Advocating for one's own pts, but not manipulating the system to gain unfair advantage to them.

Physicians are not obliged to provide interventions that are harmful or futile, though the notion of futility needs to be approached with respect for alternative conceptions of ''meaningfulness'' in health care. The duty to seek consent, i.e., a duty not to treat pts against their will does not imply a positive duty to treat. Physicians are bound by professional ethics and by the law of negligence to provide a professional level of care, but not to pursue pts' every whim.

RESEARCH ETHICS

Research involves the use of formal methods, in a purposeful way, for the generation of generalizable knowledge. Ideally, medical research contributes to social welfare by increasing our capacity to detect, treat, and predict the course of dz. However, research that involves human subjects poses special considerations, given, among other things, the risk of doing harm to research subjects.

Physicians are often involved in human research. That physicians are also clinicians, expected to form treatment relationships with their pts, admits for some confusion. Whereas the goal of research is to develop generalizable knowledge, the purpose of a therapeutic relationship is to promote pt well-being and autonomy. Often, the two aims do not coincide. For instance, a clinical trial may require randomization of pt to treatment or treatment control groups. In a therapeutic relationship, treatments are matched to pts on the basis of need and potential benefit. Can a physician, in good conscience, permit randomized treatment?

Another example: A chart review may require health information to be accessed, in a way that confers no direct benefit to the pt whatsoever. The chart review would appear to contravene the physician's duty to further the pt's welfare, which normally rules against noneffective interventions, i.e., those known to provide no benefits to the pt. Conflicts such as these are ubiquitous– they stem from a fundamental tension between the research and clinical roles physicians inhabit. The task of physician-researchers and regulators is to negotiate these tensions:

first, by maintaining respect for autonomy as a touchstone; second, by negotiating a balance between them.

MCCQE C2LEO Essentials

Research Ethics

- Ethical research involves a balance between pt welfare interests and the social benefits of research
- Pt autonomy and the right of self-determination are privileged.
- Fully informed and voluntary consent is the default norm, but consent and disclosure standards very for different sorts of research, and for research with different populations.
- Pts cannot consent to otherwise unethical research.
- Sound and ethical research meets a high standard of scholarly merit and minimizes the risk to which pts are exposed.
- Conflicts of interests must be disclosed.
- Human research should be approved by and accountable to an independent REB.

CANADA'S RESEARCH REGULATORY FRAMEWORK AND REBS

Canada lacks comprehensive human research legislation. Instead, there are a number of statutes that relate to various aspects of research, in patchwork fashion (e.g., provincial con- sent and health information laws). But the most comprehensive statements of researchers' duties and subjects' rights are quasi-legal guidelines and recommendations, which fall into two categories. First, ethical codes and conduct guidelines developed by professional organizations form a body of professional norms, adopted by members themselves, that professionals are obliged to uphold. These include the **CMA Code of Ethics** and the World Medical Association's **Helsinki Declaration**. Although they do not carry the force of statute, they have power nonetheless. Courts may invoke them to determine the standard of care in negligence suits, and professional colleges may discipline breaches as professional misconduct. Second, funding may be contingent on guidelines developed by research funders, the most notable of which is the tricouncil (i.e., joint CIHR, NSERC, and SSHRC) policy statement, **Ethical Conduct for Research Involving Humans**. Researchers who fail to observe these guidelines may be ineligible for public funding, or may have their funding revoked. This gives the tricouncil policy great clout for publicly funded research.

Additionally, protocols for clinical trials intended to demonstrate a drug, medical device, and biologic or natural product's safety and efficacy for regulatory purposes must undergo review and approval by various directorates of Health Canada before initiation. Health Canada's powers and mandates over these matters are provided by the federal *Food and Drug Act* and related federal regulation. These regulations also impose other ethics requirements. The culmination of these legal, and quasi-legal instruments is a decentralized and somewhat patchwork research ethics framework.

Prominent in this system of regulation is the requirement for independent review. A Hx of ethical disasters in human research– the Nazi doctors and Tuskegee, to name two examples– suggests that research should be reviewed before projects are undertaken. Aspects of research proposals– e.g., research design and purpose – require scientific expertise to assess. Yet the researcher cannot be the final arbiter of his or her own proposal. The research imperative and potential conflicts of interest may militate too strongly against a balanced ethical assessment, esp when positive undertakings may be required to safeguard pt interests. Generally, research must be independently reviewed by an institutional REB. REBs integrate scientific, clinical, ethical, legal, and community representation in light of relevant circumstances to review a research proposal's

scholarly and ethical value. They may authorize lower standards for consent or disclosure, where higher standards would preclude socially beneficial research and where the risk of research is low or effectively mitigated. Alternatively, REBs may compel researchers to institute stronger measures to safeguard pt well-being. REBs are a check and balance on human research, and represent an institutional commitment to scholarship that balances research's social importance with the rights of research subjects.

CLINICAL EQUIPOISE AND SCHOLARLY MERIT

If a physician should feel that a certain treatment is in a subject's best interests, is a randomized treatment protocol acceptable? The notion of clinical equipoise helps navigate this tension between the aims of research and the aims of therapy. Clinical equipoise occurs when there is genuine uncertainty regarding appropriate therapy for a dz. In clinical trials, researchers experience clinical equipoise when they perceive an even chance that the treatment regime will be as effective as the control regime. For many dzs, a control regime that meets this criterion will be the current standard of care, **not** placebo. To sketch the point simply, when clinical equipoise exists, randomization is compatible with the duty of beneficence because there is no certain knowledge to suggest that the pt would benefit more from one regime than another.

Clinical equipoise relates to the concept of scholarly merit. When clinical equipoise is not the case, i.e., if there is already reasonable certainty in the professional community regarding the research question or hypothesis, the utility of the research is questionable. All research that involves human subjects, whether the project is a chart review or a trial of an invasive intervention, involves some risk to the subjects. If the research will not produce new knowledge, then subjects are exposed to risk for no good reason. Other factors impacting the utility of the research effort include the research question, which should be nontrivial; the design of the study, which must be adequate to address the question posed; and the inclusion criteria, which must isolate pts for whom the test and control treatments are equally appropriate and screen out confounding elements. These factors are issues of scholarly merit. Because their evaluation requires expertise in the field and its methodologies, REB review may require independent peer or expert input. To be ethical, research must meet a standard of scholarship.

CONSENT AND DISCLOSURE

Is clinical consent required? If so, to what standard? The first article of the Nuremberg Code, a set of principles developed at the Nuremberg ''Doctors' Trial,'' in the aftermath of inhumane experiments on humans performed by the Nazis, articulates an absolute requirement for consent that is informed, voluntary, and capable. This standard applies to clinical trials, where there may be substantial risk to pts undertaking novel interventions. In clinical trials (and other sorts of research, e.g., population surveys) the dual role of clinician-researchers may give rise to a perception that research will benefit the pt, even if it does not; or that clinical care may be affected if the pt refuses participation. Pts must be free to decline participation at any time without prejudice to the care they can expect from their care providers. Care providers and research staff may need to operate at some distance from each other to prevent coercion. And continuing opportunities to withdraw should be provided and respected.

But what about chart reviews, or epidemiologic studies in which obtaining consent from all pts involved would be excessively onerous? In such studies, the major risk to pts is that their health information may be exposed. Identifiable health information is sensitive information, in which subjects have a continuing interest. In certain jurisdictions, the conditions under which health information, identifiable or deidentified, can be accessed for research purposes without

consent may be outlined in legislation. Generally, REBs are reasonable: where the risk is minimal and well managed, and the social benefits substantial, and otherwise unattainable, consent and disclosure may be waived.

Notably, the Nuremberg Code leaves no room for research involving incompetent pts, whether they are children or incompetent adults. These individuals may yet benefit from participation in research, e.g., in a clinical trial that gives them access to new treatments. The group to which these individuals belong, for instance, the subset of children to whom the research applies, may benefit from the new knowledge generated. Newer formulations of consent requirements allow the participation of incompetent individuals through consent by SDM. However, parents of potential child-subjects are generally obliged to seek their children's best interests: If a child does not stand to benefit directly from research, the legal ability of a parent to consent to participation is questionable. The law around this issue is unclear in Canada, except in Quebec. In general, research should not pose a serious risk to the subject; if children are sought as subjects, their participation must be necessary to the project; and a child's refusal to participate should be respected, whatever the child's capacity.

As with consent, the requirement of disclosure may vary with the research project. For a chart review involving hundreds of charts, with proper safeguards for pt information, it seems prohibitive that researchers should be required to contact each and every pt for disclosure. Consent and health information statutes and the guidance of the institutional REB will determine the extent of investigators' obligations. Of course, riskier undertakings, like clinical trials, will require disclosure. In court cases that have addressed the issue, the standard of disclosure has been determined to extend beyond the usual clinical standard. It has been characterized as ''the most exacting duty possible, requiring full and frank disclosure of all risks, no matter how rare or remote, as well as other material information about the research.'' The experimental nature of any novel treatments offered should be emphasized to distinguish them from routine clinical care. Developments that alter the material risks and benefits of participation may need to be disclosed as they occur. Investigators are responsible for ensuring pt understanding.

Importantly, informed consent is a necessary, but not a sufficient, requirement for participation in research. REB reviewers and investigators must also consider factors such as scholarly merit, conflicts of interest, and the risk/benefit profile. Potential research participants cannot consent to otherwise unethical research, even if their consent is fully autonomous.

CONFLICTS OF INTEREST IN RESEARCH

Many entities influence and have a stake in the research enterprise. Of these interests, the commercial link between industry and the research community has attracted much attention. Industry contributes significantly to health research, undoubtedly facilitating research that otherwise would not be possible. Where the scientific and ethical standards of research are upheld, the commercial incentive may be socially beneficial. However, numerous commentators and high-profile cases of commercial conflicts of interest have brought public attention to bear on commercial involvement in research. For example, in 1996, Dr. Nancy Olivieri identified adverse effects of the drug deferiprone during a clinical trial. The pharmaceutical company and research sponsor, Apotex, insisted that she abide by confidentiality clauses attached to her research funding, jeopardizing the safety of her research participants.

The fiduciary responsibility of a physician to his or her pts is a duty of utmost loyalty. It requires that the fiduciary refrain from conflicts of interest and, where this is not possible, that the fiduciary resolve conflicts of interest in the pts' favor. Applied to the research setting, this means that physicians are obliged to disclose conflicts of interest to regulators, and to pts when performing disclosure for consent. Physicians should maintain their scientific and clinical

independence, and must resolve conflicts of interests in favor of research participant welfare.

PROFESSIONALISM AND THE REGULATION OF HEALTH CARE PROFESSIONALS

Professionalism refers to the practice of medicine according to a common set of norms and standards, characterized by ethical conduct, clinical independence, and self-regulation. These norms and standards are developed and enforced by physicians themselves, through physician organizations that control practitioners' entry to the health care market.

Health care is an imperfect market. Pts are unable to know when or if they will be sick. The Dx, Tx, and prevention of illness require years of training. Health care decisions can impact third parties, and stricken pts may not be in a position to make autonomous decisions. The public is exposed to substantial harm in a ''free'' (i.e., unregulated) health care market. To protect their citizens, governments intervene in the supply and provision of health services to produce a uniform standard of care.

Provincial governments accomplish this purpose by restricting the supply of medical practitioners to specially certified and licensed individuals, governed by physician-run colleges. However, allowing physicians to determine their own standards of professional entry and practice creates an occupational monopoly through which physicians have acquired extraordinary power and privilege. This arrangement is justifiable only insofar as it continues to serve the public interest. Physicians are therefore charged by statute, and obliged by social contract, to set and uphold common standards of conduct, collectively, and as individuals. Additionally, standards of professional conduct translate principles of pt autonomy, beneficence, nonmaleficence, justice, and pt-centred care into clinical practice. Adhering to professional norms ensures sound care, helps guarantee fidelity to the core principles of medicine, and maintains the public's trust in the profession.

Challenges to professionalism interfere with the ethical and clinically independent practice of medicine according to commonly accepted norms and standards. Personal factors, such as alcoholism, overwork, marital strife, loneliness, and financial distress, may affect an individual's ability to practice medicine. The line between the professional and the personal can be indistinct. Personal problems may affect pt care. Equally, professional responsibilities may weigh down personal life. Professionalism therefore requires achieving balance and equanimity in both clinical **and** personal matters.

Impairment occurs when personal factors interfere with the professional practice of medicine. Physicians have a duty to prevent practice-under-the-influence.

The 2005 CMA Policy, **Medical Professionalism,** identifies other challenges to professionalism, including resource restraints, commercialism (e.g., the market mentality and commercial interests), and consumerism (e.g., pt demand for unnecessary or inappropriate interventions). These challenges are environmental and systemic. They express identifiable social trends that impact the professionalism of physicians not only at the level of individual practitioners but collectively as well. Of these challenges, physician relations with industry have received particular attention.

Drugs consume more and more health care spending every year– spending that remunerates pharmaceutical companies. Because physicians direct and control consumer access to the prescription drug market, the pharmaceutical industry has a commercial interest in influencing physician-prescribing practices. Commercial interests further the public good when pharmaceuticals encourage the adoption of safer, more effective, or more cost- effective treatments. They set the public back when, for example, expensive drugs with no benefit over

cheaper alternatives are aggressively marketed, or when physicians experience pressure to suppress negative clinical outcomes. With respect to drugs, physicians need to assess industry claims independently, on the basis of sound evidence, to maximize the social benefit of the commercial incentive. More generally, physicians should maintain their professional distance and clinical independence.

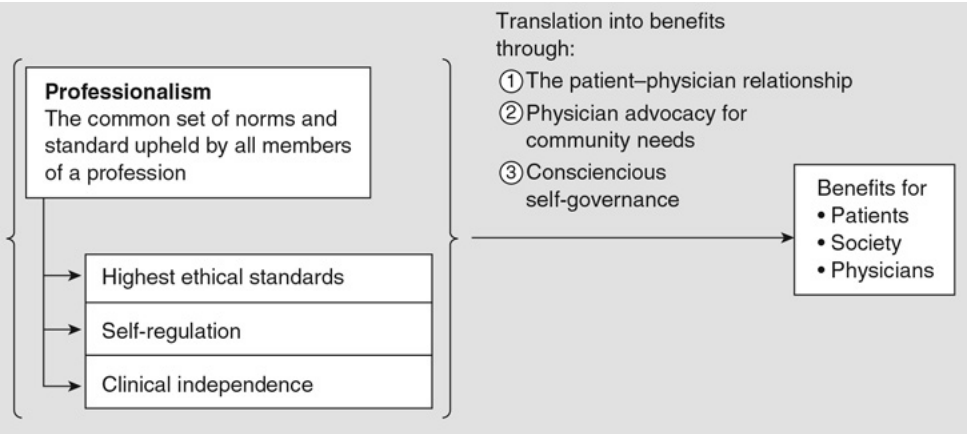

Figure 2.2 Professionalism. With abstractions from the CMA policy, **Medical Professionalism**

MCCQE C2LEO Essentials

Professionalism

Physicians should conduct themselves according to the common norms and values of the profession.

- Practice should be characterized by clinical independence and the highest ethical standards. Dignity, respect, integrity, and honesty are essential.
- Possess and maintain medical expertise.
- Practice without impairment by substances, ill health, or other incapacity.

As a self-regulating profession, physicians have responsibilities of loyalty to pt welfare and to the public interest.

MCCQE C2LEO Essentials

Physicians and Industry

Relationships with pharmaceuticals

- Are regulated by an ethical code
- Must not affect independent clinical judgment
- Must not impinge on duty to one's pts

Table 2.3 Professional Expectations of Physician–Pharmaceutical Interactions

Situation	Expectation
Drug samples	Should not result in material gain for the physician or practice
CME	Physician-organizers must control organization, content, and choice of activities Funds from commercial sources should not be directed to individual attendees (e.g., no industry funding of individual travel bursaries) Allocation of promotional displays should not be influenced by sponsorship
Industry-sponsored research	Sponsors should guarantee that results will be made public within a reasonable period Remuneration for enrolling pts is unacceptable, except to recover costs Physicians should disclose relevant relationships to industry to research subjects and to academic journals
Investment in pharmaceuticals	Should be avoided if it might inappropriately affect clinical practice
Personal gifts	Should not be accepted
Teaching aids	Are acceptable only if they do not refer to specific agents, services, or products

Selected and abridged from the CMA Policy, *Physicians and the Pharmaceutical Industry*.

REGULATION OF MEDICAL PRACTICE

MCCQE C2LEO Essentials

Regulation of Medical Practice

- Health care is an imperfect market. Unregulated, it would subject consumers to unacceptable risk.
- Physicians' competence and conduct is legally (and ethically) regulated to protect pts and society in general.
- The objectives of regulation are performed by self-regulating physician licensing and certification bodies.
- Certification indicates that a practitioner has met certain requirements of education, knowledge, and competency. Certification bodies include the MCC, CFPC, and the RCPSC.
- Licensure from a provincial board or college is a legal requirement for medical practice.
- Licensure is nontransferable between provinces.
- Physician representation and advocacy are carried out by distinct medical associations (i.e., the CMA and its provincial chapters) separate from the regulatory functions of licensing and certification.
- The CMPA is a medical defence association.

CERTIFICATION AND LICENSING

Medical practice is regulated at the level of input and output. Input regulation throws up barriers to entry into the health care market, and might in turn be conceptualized as consisting of two sorts of schemes: certification and licensure. In a certification regime, certain agencies are granted exclusive powers to certify individuals as having met particular performance or educational standards. Certification provides a ''quality signal'' to pts, hos- pitals, and other organizations interested in acquiring or accessing physician services; and certified practitioners gain an advantage in the health care market. Canada's physician certification bodies include the CFPC, the RCPSC, and the MCC. These three organizations set national standards for family practice, specialty practice, and independent medical practice, respectively. The national character of these organizations means that the medical degree and certification are portable from province to province.

Under a licensing regime, unlicensed individuals are legally prohibited from providing certain services. Licensing represents an d level of state intervention in the health care market beyond certification because unlicensed practitioners are excluded from the market altogether. Physician-run colleges or boards, established in each province by statute, govern licensing. Licensure is nontransferable from province to province, and must be sought and awarded by the college or board responsible for medical licensing in each province of practice. Additionally, provincial colleges typically require certification from the MCC, as well as certification from one of the CFPC or RCPSC. In practice, then, uncertified physicians are excluded from medical practice, although certifying bodies bear no responsibility for licensing.

SELF-REGULATION

Physician certification and licensing bodies are self-regulating. Their operations, the stan- dards they set and enforce, and the policies for which they advocate are determined by physicians themselves. The responsibilities of certification and licensure require considerable medical expertise and organizational resources, which would need to be acquired or contracted by nonphysician regulators. Physicians fulfill these duties more effectively and efficiently by self-regulation. Self-regulation also makes use of collegiality and peer pressure to compliance with medical standards. However, the interests of the profession may occasionally clash with the interests of the public. To prevent certification and licensing functions from, **in extremis**, being held hostage by professional interests, professional advocacy is carried out separately by distinct medical associations– the CMA and its provincial chapters. Medical associations neither certify nor license, and membership is voluntary. Medical student and resident associations perform analogous functions for medical students and residents, respectively.

Finally, the CMPA, a legal defence fund, looks after the legal interests of individual practitioners. In return for annual membership fees, the CMPA provides members with legal representation in the event of a malpractice suit, and foots the bill for settlements or damages awarded to plaintiffs.

OUTPUT REGULATION

Output regulation concerns actual performance, after the fact. Penalties assessed against deficient care or conduct provide an incentive to maintain professional standards. Disciplinary proceedings, whereby provincial colleges leverage their powers to grant, revoke, or suspend medical licensure to penalize breaches of professional standards, are an important form of output regulation. Legal liability is another form of output regulation.

GENERAL ORGANIZATION OF HEALTH CARE IN CANADA

In the Canadian constitutional framework, the provinces have primary responsibilities for health care, executed through a range of statutes that vary from province to province. The federal government nevertheless performs an important and varied role in health care that goes beyond merely funding provincial efforts.

CONSTITUTIONAL UNDERPINNINGS

Except for marine hospitals and quarantine, which are matters of federal jurisdiction, the 1867 Constitution Act apportions responsibility for much of what we recognize as health care to the provinces. The federal government therefore has no power to mandate or interfere directly with a province's arrangements for the provision of health care to its citizens. However, the constitution grants the federal government powers which affect health care, including responsibility for patents, and for the criminal code. These powers are listed in Table 2.5.

Particularly important is the federal spending power. The national CHA framework leverages this power, through the use of conditional federal-provincial transfer payments, to achieve specific aims among and within the provinces.

Table 2.4 Overview of Physician Organizations

Major fxn(s) (Simplified)	Organization	Licensure/Certification/ Membership Required for Practice?	Comments
Licensing	Provincial College of Physicians and Surgeons	Yes	Provincial colleges determine licensing, scope of practice, standards of practice, and codes of conduct
Certification	MCC	Yes	Evaluate medical graduates according to national standards for independent medical practice
Certification and PGME	CFPC	One of certification with the CFPC or RCPSC	Certify family physicians, set criteria for family medicine residency programs, advocate for family medicine as a specialty
Certification and PGME	RCPSC		Certify specialists, set criteria for specialty residency programs
Advocacy	CMA	No	Support provincial medical associations, represent physicians nationally, develop clinical practice policies
Advocacy	Provincial Medical Association	No	Advocate for physicians, negotiate terms of work with provincial ministries of health
Advocacy and professional development	Specialty organizations	No	Publish clinical practice guidelines, provide continuing education, advocate for specialities
Legal representation, malpractice suits	CMPA	No	Provide legal representation in the event of malpractice suits, provide financial support against settlements or damages awarded to plaintiffs

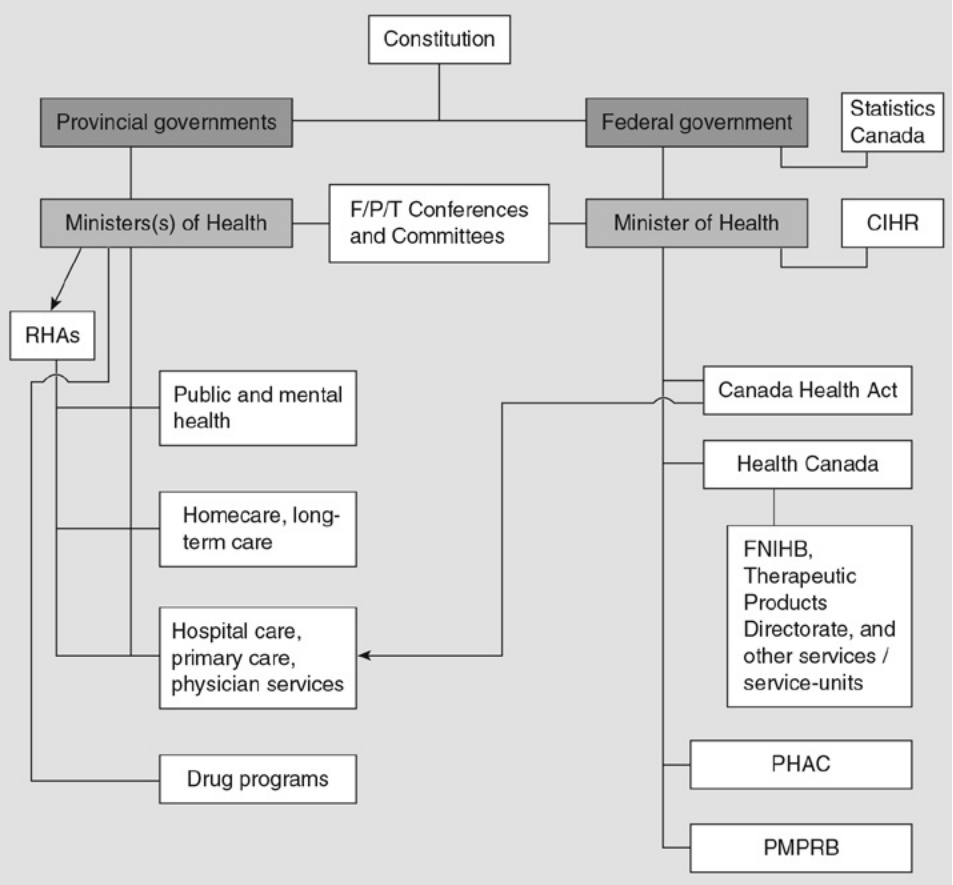

Figure 2.3 General Organization of Health Care in Canada. Organizational scheme, simplified. (Figure modified with permission from Marchildon G. *Healthcare systems in transition: Canada*. Toronto: University of Toronto Press; 2006)

Table 2.5 Additional Federal Powers Related to Health

Constitutional Responsibility for	Application to Health
Criminal law	Laws governing narcotics, food and drugs, and tobacco
Indians and reserves; the militia and military; and penitentiaries	Health care for status Indians, military personnel, veterans, RCMP members, and inmates falls under federal jurisdiction
Taxation and spending	Federal funding for the CIHR, Genome Canada, the Canada Health Services Research Foundation, and other programs that impact health care knowledge and delivery Federal-provincial transfer payments that help fund provincial health care systems
Patents of invention and discovery	The regulation of the prices of patented drugs through the PMPRB
POGG	The POGG power is invoked in situations of crisis or to address issues of "national concern" The POGG power has never been tested in respect of health care; its applications remain theoretic

THE CANADA HEALTH ACT– A "NARROW BUT DEEP" SYSTEM OF HEALTH CARE INSURANCE

The CHA was passed in 1984, consolidating and building on two previous acts, the 1957 federal HIDS Act and the 1966 federal *Medical Care Act*. The CHA establishes criteria and conditions that must be met before provinces qualify for a full federal cash contribution for health care. Provinces must establish a **publicly administered** health care insurance program that provides **universal, comprehensive, portable, and accessible** coverage.

In addition to these five conditions, Section 20 of the CHA prohibits user charges and extra billing. Whereas the CHA **permits** the federal government to withhold portions of the cash transfer if its five conditions are breached, it **requires** the federal government to deduct at least the amount of the user fee or extra billing from federal-provincial cash contributions until user fees and extra billing are eliminated.

Table 2.6 Conditions of the Canada Health Act

Condition	Each Provincial Health Care Insurance Plan Must
Accessibility	Not impede or preclude reasonable access to insured health services (**Note 1**)
Comprehensiveness	Cover all medically necessary hospital, physician, and surgical-dental (i.e., those that require a hospital setting) services
Portability	Cover new residents to the province within a waiting period of not more than 3 mo; cover residents leaving the province during a waiting period for new coverage; pay for insured services for residents temporarily out-of-province or out-of-country (**Note 2**)
Public administration	Be operated on a nonprofit basis by a public authority designated by the province
Universality	Insure all insurees at uniform terms and conditions

Note 1: This condition is an addition to principles outlined in previous health care legislation. It targets such practices as user charges, which impede access for those with lower incomes.
Note 2: The rates of pay for out-of-province services are defined according to rates for similar services in the province of delivery. Those for out-of-country services are defined according to rates in the home province.
Quebec's health insurance plan does not meet portability requirements. The federal government has not pursued this breech.

Despite the lack of federal jurisdiction in health care, the **CHA** framework has fostered the establishment of provincial health care plans along national principles. The public health care system established by the CHA has been characterized as "narrow, but deep": within the narrow range of services that fall under the notion of "comprehensiveness" (i.e., medically necessary physician, hospital, and surgical-dental services), Canadians are very well provided for. The CHA framework represents an understanding that health care is a social good best provided for by the

public weal, and that all citizens deserve adequate care regardless of their circumstances. The CHA act has been criticized for defining services that fall under its ambit by provider and setting (i.e., physician and hospital services). Health care has .6d much since the days of the HIDS and *Medical Care* Acts. Take-home drugs, home care, long-term care, and the services of allied health professionals have become common, and increasingly important to pt-centeredness. For example, home care, not only reduces the cost of unnecessary hospitalization but also maintains pt autonomy by allowing the pt to remain independent in the setting of his or her choice for as long as possible. And take-home drugs impose a rapidly escalating cost on ps. Yet the CHA confers no obligation that provincial insurance plans should provide for these services. For the most part, provinces have voluntarily taken it upon themselves to establish public financing for prescription drugs, long-term care, home care, and certain other services. As a side effect, public financing for these services varies widely across Canada, and may be subject to user fees and other barriers to accessibility.

MCCQE C2LEO Essentials

User Fees and Extra Billing

- **User fees** and **extra billing** refer to fees charged to insured pts for the provision of goods or services convered by the universal provincial health insurance plan.
- User fees typically refer to fees charged by hospitals or health care facilities.
- Extra billing refers to fees charged by physicians.
- User fees and extra billing are prohibited by the CHA. The costs of insured medical or hospital services should be borne by taxpayers through the publicly administered provincial health insurance program, not by the individual pts.

The CHA does not outlaw private funding for health care. However, six provinces have statutes that outlaw private health insurance for medically necessary services covered by the public insurance scheme. The other provinces discourage private health care insurance by preventing clinicians from operating in both private and public sectors. In effect, then, private financing– i.e., private insurance and out-of-pocket payments– plays little role in health care that falls under the CHA framework. However, private sources of funding coexist with public funding for home care, long-term care, and prescription drugs. Additionally, private sources provide most coverage for dental services, vision care, and CAM, services for which public insurance funding is minor.

The balance of private funding in health care has implications for accessibility. Public insurers in Canada community-rate their premiums, providing a single, flat fee for all individuals. Private insurers, on the other hand, may obey the commercial incentive to limit liability for risky or expensive pts. They may risk-rate, i.e., charge higher premiums for higher-risk individuals, or exclude certain pts from coverage. Because higher health risk often coincides with lower socioeconomic status, a regressive effect may arise in sectors dominated by private financing. Those least able to afford care may need to pay proportionally more to finance their health needs. The role of private financing in health care is a topic of hot debate, especially in light of *Chaoulli v. Quebec*, a 2005 legal case in which the Supreme Court of Canada found Quebec's prohibition against private health insurance contrary to the Quebec Charter of Rights and Freedoms.

MORE DETAILS– WHO DOES WHAT?

The provinces and territories regulate health professionals, hospitals, and other aspects of health care provision. Provinces and territories administer hospital and medical services through a universal single-payer system, remunerate physicians through FFS schedules negotiated with the provincial medical association, and run some specialized mental health and public health services. Provinces, to varying degrees, also provide or fund a variety of home care and long-term care services. All provinces also administer provincial drug plans. In the last two decades, health care reform efforts have led provinces to adopt geographic health regions that bear responsibility for hospitals, long-term care, home care, and public health (e.g., illness prevention, population health assessment, emergency planning and preparedness, among other things). These RHAs receive global budgets and distribute health resources in light of local circumstances.

The federal roles in health care stem from the powers outlined in Table 2.4. Notably, the federal department of health, Health Canada, is responsible for administering the CHA; and for regulating drugs, medical devices, natural health products, and biologics. The FNIHB of Health Canada is responsible for the health needs of Canada's aboriginal peoples.

The PMPRB is a quasi-judicial watchdog that reviews and regulates wholesale drug prices for patented drugs. The PHAC, established in 2004, is a federal agency that performs a wide range of public health functions, and has responsibility for national dz centers and laboratories. Statistics Canada helps meet Canada's health information needs. The CIHR is Canada's national health research funding agency.

At the intergovernmental level, the Conference of F/P/T Ministers of Health is the premier policy-making instrument. A range of organizations can be considered intergov- ernmental, being created by F/P/T agreement, with various arrangements for funding and governance. Examples include the Canadian Institute for Health Information, Canadian Blood Services, and the Health Council of Canada.

Source: *Essentials for the Canadian Medical Licensing Exam: Review and Prep for MCCQE Part 1, by Jeeshan Chowdhury BSc MSc (Author), Shaheed Merani (Editor); April 16 2009*