Technical Report No. 11

International Comparative Review of Health Care Regulatory Systems

October 1997

Prepared By:

Nihal Hafez, M.D., MBA, M.P.H.

Partnerships for Health Reform

PHR

Abt Associates Inc. # 4800 Montgomery Lane, Suite 600
Bethesda, Maryland 20814 # Tel: 301/913-0500 # Fax: 301/652-3916

In collaboration with:

Development Associates, Inc. # Harvard School of Public Health #
Howard University International Affairs Center # University Research Corporation

Abstract

This review of health care regulatory systems, commissioned by USAID, provides the Government of Egypt with information to support its own internal development of similar functions. The information was compiled using research results from existing documentation and telephone interviews with appropriate personnel.

This report analytically and comparatively reviews international models and experiences in the development and implementation of health care regulations. The study commences with an introduction to the concept of health care regulations, and then describes the most universally common approaches for putting them into practice: licensing, accreditation, and certification. Depending on the country and its economic and political structures, different governmental and voluntary regulations over health services have evolved. Traditionally, in most countries, official licensure of health personnel has been the favored approach. Various other forms of control have, however, been applied to other health resources.

The regulatory systems of four countries -- the United States, Canada, the United Kingdom, and Australia -- were selected for more comprehensive study due to their highly developed regulatory structures as well as their histories as model programs upon which systems in several other countries were based. The U.S. model, for example, directly influenced the systems in Canada and Australia. Several specific functions of these systems are examined, including health care facility regulation; health personnel credentialing; pharmaceuticals; and health care technology.

The report concludes that, based on the experiences of the countries studied, interest in health care regulation is likely to increase worldwide. Without political commitment and feasible institutional capabilities (e.g., ministries of health and regulatory agencies) in place, efforts to regulate any country's health sector will likely fail. Additionally, controlling quality of care requires the integration of providers. Successful implementation of health care regulations often depends upon several specific factors, including a country's ability to recognize and assess market-based changes in the health care structure; the evolution of local medical care standards; and the context of regulation in the country's current political environment.

International Comparative Review of Health Care Regulatory Systems

Technical Report No. 11
Contract No.: HRN-5974-C-00-5024-00
Project No.: 936-5974.13
Submitted to: Policy and Sector Reform Division
Office of Health and Nutrition
Center for Population, Health and Nutrition
Bureau for Global Programs, Field Support and Research
United States Agency for International Development

October 1997

Table of Contents

List of Exhibits . . . . . **iii**

Acronyms . . . . . **v**

Acknowledgments . . . . . **vii**

Preface . . . . . **ix**

Executive Summary . . . . . **xi**

1.0 Introduction to Health Care Regulations **1**

2.0 The International Scene in Health Care Regulation **5**
2.1 Regulation of Health Personnel 5
2.2 Regulation of Health Facilities 8
2.3 Regulation of Health Provider Performance 10

3.0 Health Care Regulation in Selected Countries 15
3.1 Regulation of Health Care Facilities 15
3.1.1 Health Facility Licensure 15
3.1.2 Health Facility Accreditation 18
3.1.2.1 The Evolution of Health Facility Accreditation 18
3.1.2.2 International Models in Health Facility Accreditation 19
3.1.2.3 The United States 19
3.1.2.4 Canada 21
3.1.2.5 Australia 22
3.1.2.6 Britain 22
3.2 Regulation of Health Care Personnel 23
3.2.1 Accreditation of Medical Education Institutions 24
3.2.2 Licensure of Health Personnel 25
3.2.3 Certification of Health Personnel 26
3.2.4 Recertification of Health Personnel 26
3.2.4.1 International Models in Health Personnel Credentialing . . . 27
3.3 Regulation of Pharmaceuticals 30
3.3.1 International Models in Regulation of Pharmaceuticals 33
3.4 Regulation of Medical Technology 36
3.4.1 Regulation of Medical Technology Safety 39

4.0 Conclusions and Recommendations 41

Annex A: The Status of Accreditation Systems Worldwide 49
Annex B: Health Care Systems in the Anglophone 53
Annex C: Regulation of Health Care Providers 55

Bibliography 57

List of Exhibits

Exhibit 1-1 Licensing, Accreditation, & Certification: Major Characteristics 2

Exhibit 2-1 Summary of Measures for Regulation of Health Care Providers 12

Exhibit 3-1 Licensing Principle 15

Exhibit 3-2 Licensing Process 17

Exhibit 3-3 Accreditation Principle 18

Exhibit 4-1 Summary of Health Care Regulatory Policy Options 45

Acronyms

ABIM	American Board of Internal Medicine
ABMS	American Board of Medical Specialties
ACHS	Australian Council on Hospital Standards
AHA	Australian Hospital Association
AHTAC	Australian Health Technology Advisory Committee
AMA	Australian Medical Association
AMC	Australian Medical Council
CFPC	College of Family Physicians of Canada
CME	Continuing medical education
CON	Certificate of need
FDA	Food & Drug Administration
GMC	General Medical Council
GOE	Government of Egypt
GP	General practitioner
HPB	Health Protection Branch
HSA	Health system agency
JCAH	Joint Commission on Accreditation of Hospitals
JCAHO	Joint Commission on Accreditation of Health Care Organizations
KFOA	King's Fund Organizational Audit
MOHP	Ministry of Health and Population
MRI	Magnetic resonance imaging
NHS	National Health Service
NHTAP	Australian National Health Technology Advisory Panel
OTA	Office of Technology Assessment
OTC	Over the counter
PRO	Peer Review Organization
PSRO	Professional Standard Review Organization
RACOG	Royal Australian College of Obstetricians & Gynecologists
RCPSC	Royal College of Physicians & Surgeons of Canada
RN	Registered nurse
SWHAP	Southwestern Hospital Accreditation Program
USAID	United States Agency for International Development
USMLE	The United States Medical Licensing Examination
WHO	World Health Organization

Acknowledgments

I would like to express my appreciation for the valuable technical oversight of Dr. James Knowles of the World Bank and formerly of Abt Associates. I am especially indebted to Greg Becker, also formerly of Abt Associates, who made major contributions to the Facility Accreditation Section. Special thanks to Yale University Department of Public Health for assisting me with the literature review. Last but not least, I am grateful to the superb coordinating efforts of Kathleen Poer, without which this work would not have been possible.

Preface

The Government of Egypt (GOE) Ministry of Health and Population (MOHP) is embarking on a health sector reform endeavor, the need for which has been acknowledged by both local circles and international agencies. In support of these efforts, the United States Agency for International Development (USAID) has developed a Health Sector Program Assistance focusing on five major reform areas: (1) rationalizing curative care; (2) attaining an appropriate balance between the MOHP's various roles as a regulator, financier, and provider of health services; (3) expanding social insurance in a financially viable manner; (4) promoting improvements in the quality of health care; and (5) developing appropriate policies to meet the health sector's manpower needs.

Given the importance of health care regulation in ensuring acceptable quality services to all population groups, especially under limited resource settings, it is anticipated that the systematic expansion of the MOHP's role as a regulator of health care and the overall restructuring of health sector regulation in Egypt would be emphasized under the health policy reform.

Against this background, this regulatory review was commissioned by USAID to draw on international experiences in regulating medical care and provide the GOE with information to support the generation of a menu of regulatory functions feasible and relevant for the Egyptian setting. The status of health care regulation in different countries was researched through an extensive literature search, combined with telephone interviews with international development experts. The review report was constructed in four parts. Section 1 introduces the concept of regulation in health care. In Section 2, we tour regions of the world to show how different countries perform the various regulatory functions and the varying degrees of difference. Section 3 provides a closer look at the regulation of the most important health system factors: facilities, personnel, pharmaceuticals, and technology. Country models included the United States, Canada, the United Kingdom, and Australia, and others. The report ends with lessons learned from the international experience in health care regulation and offers recommendations to ensure successful implementation of regulatory systems (Section 4).

Executive Summary

Health care regulation is defined as any social action exerting an influence, directly or indirectly, on the behavior and functioning of health care personnel and/or organizations. This report reviewed international models and patterns of health care regulation both analytically and comparatively.

In Section 1, the concept of health care regulation is introduced and the methods of licensing, accreditation, and certification are presented as the most common approaches to regulation of the quality of care. Although the terms "licensing," "accreditation," and "certification" are commonly used interchangeably, in a health care context, these quality assurance methodologies refer to very specific programs with sometimes subtle yet very important differences. Licensing serves as a screen to keep facilities or personnel without minimum qualifications or structure from delivering any medical services. Accreditation and certification are public "seals of approval" of the technical practices delivered by health care facilities or personnel, respectively, based on rational criteria or standards.

Section 2 discusses political economy patterns of various world regions and their different impacts on regulatory function performance. In all countries and in a variety of ways, governmental and voluntary regulation over health services exists. While official licensure of health personnel has been the fundamental approach in most countries, various forms of regulation or control have been applied increasingly to other kinds of health resources. Regulation of the day-to-day performance of health services is extended through diverse methods of surveillance or teamwork patterns for organizing health care delivery. Worldwide, where the financing of health care is collectivized (e.g., via social insurance schemes) and a large, underregulated private sector exists, pressures mount for greater regulation to control both the costs and quality of services.

Section 3 takes a closer look at health care regulation in selected countries, including the United States, Canada, the United Kingdom, and Australia. These countries were chosen because they have developed more comprehensive regulatory systems than other countries. Regulatory functions examined include:

1. Health care facility regulation, where country reviews showed that accreditation provides a case study in the international propagation of ideas and models in the health care policy arena. The U.S. model of accreditation directly shaped the systems in Canada and Australia and indirectly influenced developments in Britain. In each case, however, adoption of the model involved adapting it to national circumstances. The result is that, despite common ancestry, there are revealing differences as well as similarities in the systems in the four countries studied. Moreover, there is convergence between them in the way they are revising their approaches and standards: all accreditation systems are devising or considering outcome indicators which more directly measure the quality of care provided than do the traditional review of processes and inputs. The focus is also shifting increasingly towards assessing quality in terms of the experience of those receiving care. Striking differences emerge in other respects, however, particularly when we compare the United States and Britain. In the case of the U.S., the Joint Commission has become a quasi-regulatory body, and accreditation -- though theoretically voluntary -- is the key to unlocking access to public funds and, as such, has become virtually indistinguishable from government regulation. In contrast,

accreditation in Britain is still predominantly an exercise in self-improvement and can be seen as an offspring of the quality movement rather than an instrument of public policy. Canada and Australia are somewhere in between. In neither case has accreditation become a condition for the receipt of public finance; but in both cases, there is -- in contrast to Britain -- a national body using national standards to accredit hospital activities.

2. Health personnel credentialing involves accreditation of educational programs, licensure of personnel by a government agency, and personnel certification and recertification by the profession. Reviews revealed marked variability between countries in both policies and procedures, despite broadly similar goals:

   - Accreditation of medical educational programs in both the U.S. and Canada is a voluntary self-regulation process, conducted by peer groups of educators and members of the profession, in contrast to regulation of educational institutions as a governmental activity through national medical councils in the U.K. and Australia.

   - In the U.K. and Australia, national medical councils control primary certification indirectly through the process of accrediting the medical school curriculum. The medical school is responsible for student assessment and standard setting. In the U.S. and Canada, medical schools have less authority in this regard, with national examinations playing a major role in primary certification. The former approach has potential advantages in terms of flexibility, but disadvantages in terms of the quality of the locally produced assessment procedures.

   - In the area of specialty certification, there is more common ground, yet still more significant differences. Again, it is interesting to contrast the situation in the U.K., Australia, and Canada with that in the United States. In the former, responsibility lies with the nationally based colleges, which are both the certifying body and professional organization for the specialty. In the latter, assessment is undertaken by national boards, and is the sole responsibility of these organizations.

3. Pharmaceuticals is an area where the international experience has shown -- as compared to other factors of health production -- that considerable government involvement occurs in most countries. The extent of involvement, of course, varies with traditions of those governments, their legislative histories, political environments, cultural and religious values, and economic and technological resources, which tend to either enhance or detract from the authority accorded to public regulatory bodies. Even in the U.S. free market economy, the pharmaceutical sector -- through the Food and Drug Administration (FDA) -- is paradoxically rigorously controlled. The FDA model for regulation of the safety and efficacy of drugs provides another example of an international propagation of ideas and models copied by many other countries, including the U.K., Australia, Canada, France, Germany, and the Netherlands. Global trends also show that national drug policies have extended beyond technical and clinical aspects of pharmaceuticals to economic and social aspects, including concepts of social justice in drug distribution and careful allocation of resources for pharmaceutical expenditure. Depending on the country's political economy, regulation is exercised in varying degrees on the production and/or distribution and marketing of drugs. The

overall situation is one of tight regulation of both production and distribution in North America; more control over distribution than production in western Europe; and centralized yet ineffective controls over either production or distribution in Eastern Europe and the developing world.

4. Health care technology has become an increasingly visible issue in many countries, primarily because of the rising costs of health care and the need to weigh costs and benefits of any investment carefully. The international review of patterns of health care technology management shows that an increasing number of industrialized countries have developed active programs during the past two decades. Technology control practices varied widely in the countries studied. For planning purposes, France uses "health maps" that provide overviews of the diffusion and utilization of technologies. The U.K., Canada, and Australia, under their national health care systems, develop policies to manage new and existing technologies in concert with their "global" or "prospective budgeting." Technology control practices in the U.S. are limited to assessments of the merits and costs of new technologies. Health care systems with a limited policy structure for technology management, such as that of the U.S., do little in the way of implementing technology assessment findings, however. In contrast, systems with centralized public management and collectivized financing tend to have greater demonstrable links between technology assessment and technology management. Country experiences showed that national and regional policymaking must be complemented by actions at the operational level of clinical medicine, so as to ensure the efficacy and cost-effectiveness of technology adoption and use. With the exception of the U.S., such actions are just beginning in most of the countries studied.

In Section 4, we conclude that, based on the experiences of the countries examined in this report, emphasis on health care regulation is likely to grow worldwide. Though provider regulation started as an instrument of professional self-education and institutional self-improvement, in most countries, it is becoming a quasi-governmental instrument for holding both professional providers and institutions accountable for product quality and cost. Moreover, growing global trends for separating financing from provision and for encouraging provider multiplicity in the health sector will aggravate the need for regulation. With this realization, the report concludes by presenting the lessons learned from the international experience in health care regulation and offering a menu of regulatory options which can support countries embarking on a reform in their choice of regulatory functions feasible and relevant for their settings.

The experience of many countries in implementing health care regulatory systems shows that, without political commitment and reasonable institutional capacities in ministries of health, public regulatory agencies, and professional associations, efforts to regulate the health sector are not likely to succeed. Additionally, without the integration of providers, government programs to control quality of care tend to fail. State regulation can be wasteful because regulatory programs are traditionally very expensive to implement and sustain. In general, successful implementation of a health care regulatory system tends to be dependent on its ability to:

- Recognize any market-based changes in the structure of health care;
- Consider the evolution of standards of medical care in its setting;
- Be cognizant of the context of regulations in the current political environment;
- Draw upon the best possible scientific research regarding development of tools and methods for measurement and improvement of quality of care; and

- Prioritize and address the key quality problems that may arise in the future.

1.0 Introduction to Health Care Regulations

In a broad sense, health care regulation can be defined as "any social action exerting an influence, directly or indirectly, on the behavior and functioning of health care personnel and/or organizations." Regulatory systems protect the public by countering market failures, bringing efficiencies to areas in which the market has been retarded, or correcting the market's emphasis on a single dimension, such as cost. Some regulatory roles may have an economic focus to address provider monopolies, combat scarcity of certain necessary services such as primary care, or curb wasteful service utilization in insurance arrangements. A more socially oriented set of regulatory roles can improve equity and access through geographic redistribution and anti-discrimination statutes, or protect the public by controlling the quality of the health services they receive.

Licensing, accreditation, and certification are the most commonly practiced approaches to regulation of the quality of health care. Although these three terms are often used interchangeably, in a health care context, these methodologies refer to very specific regulatory approaches with sometimes subtle yet very important differences. Licensing prevents entities (i.e., facilities or personnel) which lack minimum qualifications or structure from delivering medical services. Accreditation and certification are public "seals of approval" of the technical practices of health care facilities and personnel, respectively, based on rational criteria. As public recognitions, accreditation and certification increase patients' ability to judge the level of technical quality of a provider. In requiring compliance with a well-developed set of quality standards, the processes of accreditation and certification not only judge technical performance, but provide facilities and caregivers with important information on practices that improve the delivered care. Exhibit 1-1 compares the three methods in terms of areas of coverage, targets, results, and implementation. The following definitions further delineate the differences between the three processes:

- *Licensing* is the process by which legal permission is granted by a competent authority, usually public, to an individual or organization to engage in a practice, occupation, or activity otherwise unlawful (e.g., a license to practice medicine and surgery). A license is usually granted on the basis of examination and/or proof of education rather than on measurement of actual performance. A license is usually permanent, but may be conditional on annual payment of a fee, proof of continuing education, or proof of competence. Grounds for revocation of a license include incompetence, commission of a crime (whether or not related to the licensed practice), or moral turpitude.

- *Certification* is the procedure and action by which a duly authorized body evaluates and recognizes (certifies) an individual as meeting predetermined requirements, such as standards. Certification programs are generally non-governmental and do not exclude the uncertified from practice, as do licensure programs. While licensure is meant to establish the minimum competence required to protect the public health, safety, and welfare, certification enables the public to identify those practitioners who have met a standard of training and experience set above the level required for licensure.

Exhibit 1-1

Licensing, Accreditation and Certification: Major Characteristics

	Licensing	Certification	Accreditation
Applied to	Health care facilities Health care personnel	Health care personnel	Health care facilities or educational institutions
Granting body	Government agency	Peer organization, government agency, payor organization, or mix	Peer organization, government agency, payor organization, or mix
Required for	Entry into practice	Professional status and possibly reimbursement	Professional status and possibly reimbursement
Purpose	Restricts entry into field to personnel or facilities meeting minimum standards	Recognized qualification to practice at higher level	Public assurance of desired level of quality of care
Duration	Permanent	Permanent or fixed term	Fixed term
Type of standards	Minimum quality "Structure" Minimum qualifications (education)	Qualifications (education and experience)	Optimal quality: "Structure," "Process," and "Outcome"
Indicates high quality	No	Yes	Yes
Performance based	No	Sometimes	Yes
Administration	Simple	Moderate	Complex
Renewal	Automatic Possible exam	Continuing education Possible exam	Complete reinspection

- *Accreditation* is the formal process by which an authorized body assesses and recognizes an organization, program, or group as complying with requirements, such as standards or criteria. For example, accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in the United States is a determination that an eligible health care organization complies with applicable standards. Certification is essentially synonymous with accreditation, except that certification is often applied to individuals (such as certifying a medical specialist), whereas accreditation is applied to institutions or programs (such as accrediting a hospital or medical education program).

Although most countries have some form of licensing for health care providers and facilities, many of these programs are poorly administered, or even ignored, particularly in the case of government-owned facilities. There are far fewer countries that have programs in accreditation or certification. Fortunately, with advances in quality assurance technologies and the increasing importance of private sector providers around the world, these programs are under serious consideration in many places.

2.0 The International Scene in Health Care Regulation

Political ideologies and economic levels are major determinants of health care systems worldwide. This section examines the influence of political economy on the way health care is regulated in the various regions of the world. Governmental and voluntary regulatory influences on both the training and authorization to practice of health manpower are studied, followed by an examination of health care facilities regulation and performance monitoring under various international health care systems.

2.1 Regulation of Health Personnel

Policies for regulation of health manpower vary among different countries and different types of health personnel. They encompass licensing of practitioners, specialty certification, and accreditation of educational institutions or programs.

In the United States, the health system is characterized by a predominantly private financing of health care through commercial insurance corporations, although public financing of care to the elderly and poor is maintained through federal “Medicare” and “Medicaid” health insurance programs. Though the U.S. system was conceptually envisioned in the free enterprise ideology, as the system matured, insurers increasingly imposed controls and constraints on the performance of providers, thus affecting costs and quality of services. The government, mainly through its Medicare program, has much influence on the way the U.S. health sector functions, however. The result is that the U.S. health system can be described as a predominantly private yet heavily regulated industry.

Regulation of health manpower in the U.S. is characterized by the critical role of non-governmental agencies. Even in areas where a governmental role is observed, state authorities usually transcend federal involvement. This results in significant variation in personnel regulation practices amongst the 50 states.

Until the beginning of the twentieth century, American universities and medical schools were essentially free from any regulation. Later, state authorities started requiring their own medical examinations for licensure, a practice that is relatively uncommon around the world. - Over time, reciprocity grew among the states in recognition of each other’s licensees, thus permitting mobility of doctors among states. As will be further discussed in Section 3.0, the non-governmental National Board of Medical Examiners was later formed as a voluntary body administering the United States Medical Licensing Examination (USMLE), which standardized licensure standards nationwide.

Medical specialties have also been subject to only non-governmental regulation in the United States. More than 24 specialty boards, which establish criteria for training as well as for formal examinations, are currently responsible for certifying specialty and subspecialty competence. Although nationwide in operation and impact, the board certification regulatory program is not affiliated with the government. It is recognized by many government programs,

such as Medicare, for participation and payment purposes, however, and by most hospitals for staff appointments.

Most other health science disciplines followed the model of medicine in their state licensure requirements, with only a few noteworthy variations that further demonstrate the U.S. interstate differences. Dentistry, for example, has a statutory rather than a purely voluntary basis for specialty status in several states. Registration of trained nurses requires a formal examination in every state, but a national federation has established a uniform exam resulting in reciprocity in recognition of registered nurses' (RN) qualifications among the 50 states. Examinations in pharmacy are also required in all states, and in many jurisdictions relicensure is periodically required on the basis of a minimum record of continuing education. Licensure of laboratory technicians is mandatory in some states, where the candidate must pass an examination and have credentials from an approved school. In other states, the laboratory technologist or technician may offer to prospective employers voluntary certification by the American Society of Clinical Pathologists. Hospital administration is a field subject to state licensure in only a few states. But nursing home administration is the first field that, by national law, requires state licensure.

Neither state nor federal governments have a role in approving or accrediting professional training programs in the U.S., accomplished instead by private societies and professional associations. The roles of the American Medical Association and Association of American Medical Colleges in accrediting medical schools will be discussed in Section 3.0. The same approval is carried out by the American Pharmaceutical Association with respect to schools of pharmacy, the National League of Nursing regarding professional nursing schools, and so on. Government intervention appears only in the role of the federal U.S. Office of Education in approving the private associations responsible for accrediting medical education institutions.

In western Europe, financing of health care is mainly governmental, through social insurance schemes that have mostly achieved universal coverage. Yet, as in the U.S., much of the provision of health services remains in private hands, with a variety of measures applied by the government to control quality and costs. Adapted version of these systems appear in Japan, Australia, and New Zealand, where social insurance makes access to care universal or nearly so, but where the private sector still predominates ambulatory care.

Though health manpower regulation in western Europe employs the basic methods of licensing, certification, and educational accreditation, the diversity of patterns of regulation is too great to permit anything but a few examples. In general, greater control is exercised by national governments over educational programs, and as a result, the establishment of qualifications for engaging in various forms of health services is usually much simpler than in the United States. Proof of graduation from a government-approved training program usually grants the legal right to engage in the profession anywhere in the country. For example, in Sweden or Norway, where all the medical schools are approved by the national Ministry of Education, a medical graduate need only present his credentials to the health authorities in the Ministry of Social Affairs for registration. In France and Germany, where basic government controls apply also to the educational institutions, no further examination is required of medical graduates and registration with provincial (not national) health authorities is a matter of formality. Similar policies are followed in Belgium and Holland.

As will be discussed in Section 3.0, Great Britain differs slightly; it requires approval of its medical schools and examinations by the voluntary General Medical Council (GMC), even

though all the educational institutions are also approved and supervised by the Ministry of Education. In addition, there are the voluntary specialized examinations of the Fellowships of the Royal Colleges, which mark additional status and competence.

Specialty certification varies among European countries, although it is mostly the responsibility of professional bodies. Norway's national medical association maintains a committee that regulates specialty training requirements and administers certification examinations. In Belgium, an especially rigorous sequence of training is required and approved in advance by its national medical association. In addition, specialty status must be registered with a government authority if the doctor is to be entitled to payments from the social insurance program at the higher specialist rates. In France, specialists are registered with the Ministry of National Education after completing appropriate training and passing certification examinations given by the several specialty societies.

Generally speaking, procedures for licensure or registration of nurses, pharmacists, and other health personnel follow the model of physicians in each country. There may be slight modifications in certain fields, as in Norway, where the maintenance of nurse registration records is delegated by the government to the voluntary nursing association.

In Eastern Europe and the former Soviet Union, where both financing and delivery of care was available through public institutions, private medical practice gradually declined. Most health service responsibility is in the hands of governments and central ministries of health, with a hierarchy of branches operating at provincial and district levels. The regulatory capability of these ministries, however, remains very limited.

This health system model was pioneered in the former Soviet Union and has been emulated, with various modifications, in China and Eastern Europe, in adaptation to local circumstances. In Poland, for example, a strong private sector still exists in rural areas. In the Czech Republic, university hospitals are independent from the ministry of health. In China, great emphasis is put on community participation.

Most Eastern European countries require no licensing examinations by a government authority beyond completion of specified educational programs. Health education institutions are mostly controlled by the national health rather than educational authorities. Professional societies are active primarily in the field of post-graduate or continuing education.

Most developing countries started by emulating the socialist model of a predominantly governmental health system inefficiently run by ministries of health. They also maintained a rapidly growing "laissez-faire" private medical sector that the government largely failed to regulate. Many countries, however, initiated social insurance schemes and tried to expand coverage, but were severely restrained by their budgets. Most of these social insurance systems, as are those of the Middle East and Latin America, are financed by obligatory payroll contributions (paid by the employer or shared with the employee), with the service delivery system owned and operated by a social insurance organization. These delivery systems have problems similar to those of the government-owned and operated delivery system, but have more assured levels of funding.

As in Eastern Europe, the role of government in developing countries is greater but less efficient, and the role of the professional bodies is weaker than in North America and western Europe. Registration of physicians with the ministry of health follows automatically from completion of prescribed courses of training, and no additional licensing examination is

required. Within the Ministry of Health in Colombia, for example, there is a Council of Professional Practice, which registers all physicians and other health personnel who have completed training from a school recognized by the Ministry of Education. Physicians must also show proof of a one-year internship in a hospital, plus a second year of service in a public health post or rural facility. Many Latin American countries require the latter form of service as an approach to solving the problem of rural doctor shortage. Nurses and allied health personnel are registered in substantially the same way as physicians.

Beyond these proforma registrations, physicians, dentists, and others engaged in individual practice must join a professional society for purposes of ethical control over their behavior. These societies may also engage in bargaining with government agencies on rates of payment for services, or they may establish parallel non-government bodies for such purposes.

2.2 Regulation of Health Facilities

Due to the importance of hospitals in total health service delivery, standards for hospital construction and operation have been emphasized by most all government authorities. The application of these controls varies with the overall political ideology of the countries.

In the United States, there were few public standards for hospital construction until the federal law to subsidize such projects was passed in 1947. As a condition for federal grants, each state was required to enact a hospital licensure law. Under these laws, all hospitals were periodically inspected with respect to physical standards, laboratory facilities, kitchen sanitation, fire safety, radiological hazard protection, and related matters. Enforcement of these laws was weak, however, since the staffing of the state inspection authorities (usually the state Department of Health) was generally meager. Moreover, most state laws stressed standards connected with the hospital's physical features and demanded little in the way of standards for the staff. Compensating for this deficiency, the Joint Commission on Accreditation of Hospitals (JCAH) was established as a non-governmental body representing several professional associations.

Until about 1960, any hospital could be built or enlarged as long as it met state licensure requirements. As bed-population ratios increased, along with expansion of voluntary insurance for hospitalization, New York was the first state to enact a law in 1961 requiring that any construction providing new hospital beds had not only to meet the licensure standards, but also to satisfy the state government that there was a social need for the additional beds. Such "certificate of need" laws were soon passed by many other states. In 1974, a national law was enacted (i.e., the National Health Planning and Resource Development Act), requiring that every state must have such legislation controlling the hospital bed supply as well as quality standards.

Similarly, after the federal-provincial hospital insurance program was enacted in Canada, provinces soon realized that any new beds constructed would quickly become filled with patients whose care was paid for by the entire population under the social insurance system. The provincial governments accordingly started exercising control over all new hospital construction or enlargement, requiring that there be proven a definite need for any additional beds. Moreover, some provinces, faced with spiraling hospital costs, were ordered to close certain small hospitals to limit bed availability.

Hospital construction in western Europe has generally been subject to more government controls, although the levels of public authority differ. Voluntary accreditation bodies play minimal roles. In the British and French systems, standards for both construction and operation of hospitals are promulgated by the ministries of health at the national level, although they are monitored by regional or provincial authorities. In Great Britain, where the majority of hospitals are actually owned and controlled by the central government, exercise of this authority is not difficult. In France, where the government sponsors a large portion of hospital beds, the implementation of standards, although theoretically universal, is not so perfect for the non-governmental minority. The French Ministry of Health was, until a few years ago, using the system of Health Mapping (Carte Sanitaire) to plan the diffusion and geographic distribution of government hospitals and other provider organizations.

Constraints over the number of beds or bed-population ratios of hospitals in western Europe are less than those in North America. With salaried hospital doctors, problems of over-hospitalization and its serious cost burdens have not been strongly felt. As a result, any local community or, in some countries, any voluntary group has been free to build hospitals, as long as they met technical standards of licensing. The high cost of construction necessary to meet such standards acted as an inherent constraint.

In Japan, however, where open staff hospitals and fee remuneration of doctors for inpatient care prevail, the national government exercises control over all new hospital construction or enlargement, requiring that there be proven a definite need for any additional beds.

Hospital construction in the formerly socialist Eastern Europe, being entirely governmental, presents no special problems of regulation. Depending on the degree of centralization of authority, hospitals are simply built according to the plans of the national or local government bodies. In the highly centralized model of the former Soviet Union, the national Ministry of Health in Moscow planned all construction and approved projects for the local level, since the operating costs eventually must be met from the national health budget, a process that eventually led to overbuilding of hospitals.

In the more decentralized model of China, the provincial authorities make their own hospital or health center construction decisions, but they may obtain advice on technical standards, if they wish, from the central health ministries. In general, the need for hospital beds has been so great and the economic resources to build them so limited that controls over quality standards and bed supply have been very limited. Many of the national ministries of health maintain technical offices to prepare architectural plans for hospitals and health centers of various sizes, along with rosters of appropriate equipment. These offices are concerned with any facilities constructed by the ministry itself (or by a ministry of public works) and they may offer advice to private and charitable hospitals.

In most developing countries, a few social security agencies have similar architectural design offices, but disciplinary controls are rarely exercised if a non-government body establishes a private hospital that does not meet central government standards. The concept is that almost any sort of hospital in countries desperately short of beds is usually better than none.

2.3 Regulation of Health Provider Performance

After the licensure of personnel and approval of health facilities, there are many further forms of regulation that can ensure effective performance within a health care system. These are sometimes built into the delivery patterns, such as the discipline implicit in the closed-staff salaried doctor model of hospital organization in Europe, compared with the open-staff model with numerous private visiting doctors in the United States. In addition, regulatory influences are exercised by payment agencies, professional societies, or judicial systems.

The U.S. free market economic approach to medical care has led to a long-term escalation of costs, with the rate of inflation increasing rapidly over the past 30 years. Largely in response to this and also due to concerns about the quality of care, various payment agencies have applied increasing controls over providers. Thus, with fee-for-service payments being used in most government programs of medical care for the poor and elderly (Medicaid and Medicare), many states require prior authorization by a government medical consultant before elective surgical procedures are paid. Other government programs, such as those for rehabilitation of disabled workers, may stipulate that only board-certified specialists may participate and get reimbursed. Within the Medicare program, in which costs have risen very rapidly, the federal government has been compelled to introduce more and more regulatory constraints. Rules for determining "usual and customary" fees have become increasingly restrictive, and legal actions have been taken against doctors suspected of submitting fraudulent claims. In 1973, amendments to the federal law required establishment of Professional Standard Review Organizations (PSROs) to exercise peer review over all Medicare and Medicaid payment claims for hospital services. Voluntary health insurance programs also review payment claims with a focus on potential abuses, such as excessive diagnostic tests or surgical procedures of dubious value. Under the present “managed care” movement, even further controls are being imposed, with managed care organizations imposing utilization review (screening and approval) for hospital admissions, surgical interventions, long hospital stays, and referral to specialists.

Professional societies of physicians, dentists, nurses, and others theoretically promote professional ethics of their members. In the United States, nevertheless, it has been very rare for such societies to discipline any of their members, except for the most egregious behavior, such as that associated with drug addiction, alcoholism, or frankly illegal actions.

Another indirect channel of regulation of provider performance is the right of the patient to take legal action against his doctor or health provider for injuries suffered due to negligence. In the U.S., malpractice lawsuits have become increasingly frequent in recent years. The reasons reflect the sophistication of patients, aggressiveness of lawyers, high costs of medical care (often not covered by insurance), and tendency of insurance companies covering the doctor to settle claims of even dubious merit rather than run the risk of court litigation. In any event, the rate and amounts of malpractice awards and out-of-court financial settlements have risen so much that the personal liability insurance carried by nearly all American physicians has become extremely costly, with premiums especially high for surgeons and anesthesiologists.

Another aspect of provider regulation present in the highly private delivery system in the U.S. is anti-trust or anti-monopoly regulation, whereby the U.S. Justice Department sometimes takes legal action to try to prevent hospitals from merging and creating monopoly power over the availability of certain technologies and fees for services.

Annex C summarizes the various patterns for regulation of health care providers in the United States, whether centralized (i.e., federal-level) or decentralized (i.e., state-level).

Under the predominant social insurance settings in western Europe, cost containment measures and regulations to prevent unnecessary care are somewhat rigorous. The British general practitioner (GP) pattern with its capitation payment, for example, uses a simple approach whereby the government sets a maximum number of patients allowable on any GP list. The German sickness funds conduct computerized reviews of each doctor's practice habits, as measured by such criteria as the number of drug prescriptions, office visits, and laboratory tests per case; or the rates of certain surgical procedures; and so on. These measurements are compared with those of other doctors in the same specialty, and highly deviant individuals are identified. Such identification is a screening step, to be followed by a detailed audit of the individual doctor's work. If this reveals unjustified services, the doctor may be reimbursed for only a fraction of his claims, and. in serious instances, be ruled out of participation in the social insurance program entirely.

Not all European health insurance systems are as rigorous in their regulatory practices. Belgium and Japan are examples of countries where the private medical profession has great political power. Doctors have successfully resisted almost all efforts of the insurance system to control their behavior. In these countries, the social insurance program is regarded essentially as a financing mechanism that cannot challenge the performance of any licensed physician.

Professional societies in most European countries generally fall into two types: the association concerned with technical development and continuing education; and the body concerned with negotiations regarding economic matters with government or social insurance organizations and with monitoring the ethical behavior of its members. In addition, there are also various societies in the medical specialties. In nursing, pharmaceutical, and other health professions, the two roles are sometimes played by committees or divisions of one national association.

For many reasons, legal actions for malpractice against doctors, hospitals, or other health services providers are rare in Europe. Most prominent among the causes is probably the national health insurance legislation, under which any medical costs due to malpractice are covered, along with other health care costs. The more disciplined medical staff organization within hospitals, as compared with that in the United States, may also reduce poor performance. The legal systems concerning torts generally differ: contingency fees for lawyers are either prohibited or considered unethical, and jury trials are not used in civil (non-criminal) actions. Private insurance companies are not commonly used for carrying malpractice liability insurance; instead, medical associations often operate protective organizations to which all their members contribute premiums. Whenever the doctor's behavior has been considered reasonable, he is vigorously defended, rather than having a financial settlement offered to avoid litigation. As a result, malpractice insurance premiums paid by doctors in Great Britain and Australia are a fraction of those in the U.S.

In Eastern European and former Soviet countries, the entire delivery system is the principal regulator of the quality of medical care. Salaries paid to personnel and the responsibilities assigned to them are based on rewards for competence and seniority. Correspondingly, performance regarded as poor by organizational leadership may result in failure to advance, or even demotion. Payment schemes for health personnel influence performance by giving incentives for diligent work; the judgment of merit, however, depends on internal supervision rather than preset standards.

In addition, in many former Soviet countries, a system called “medical-economic standards” is used to regulate provider performance. This system imposes financial penalties on provider personnel for deviation from practice norms set for each diagnosis and subdiagnosis.

Exhibit 2-1

Summary of Measures for Regulation of Health Care Providers

Health System Inputs	Health System Operations
Health Facilities	
Facility licensure	**Health Provider Performance**
Approval of facility construction and/or expansion e.g., Certificate of Need programs, Health System Agencies, Antitrust Law	Facility Accreditation
	Professional Standards Review Organizations
	Peer Review Organizations
Health Personnel	Clinical Practice Guidelines
Personnel licensure	Outcomes Analysis
Specialty Certification and Recertification	Penalties, fines, and sanctions

In Eastern Europe, the role of professional associations outside the sphere of continuing medical education is primarily to mediate grievances of personnel and represent their members in salary negotiations. Medical specialty societies in countries such as Poland play a role in monitoring performance in their respective fields through committees that periodically visit hospitals and polyclinics to monitor the quality of care and provide ratings that influence promotions. In addition, these committees may be consulted on problems at a particular facility where the local medical director needs advice. Judicial redress through the courts plays little part in the regulation of health care performance in socialist settings. A patient with cause for dissatisfaction can bring his complaint to the attention of the program supervisor.

In developing countries, doctors are often salaried rather than paid by fees or capitation, so that the scheme of remuneration as such is not relied on for regulation of performance. Rather, it is the organizational dynamics within the delivery system -- supervision, consultation, meritorious promotion -- that influence the behavior of health care providers. As far as purely private professional practice is concerned, regulation is virtually non-existent after professional licensure or registration. Similarly, the professional societies do little if anything to discipline practitioners in developing countries. The role of the societies is again to continue medical

education and negotiation with government and social insurance bodies on economic issues. In a sense, the diligence of medical and other societies in protecting patients against malpractice of health providers varies with the sophistication of the general population about medicine, which tends to be quite weak in most of the developing world. For the same reason, legal redress for patient grievances is seldom sought in the developing countries. Grievance procedures sometimes operate in social security medical care systems, although these generally concern problems of accessibility (e.g., a long waiting time before seeing the doctor) rather than medical performance.

3.0 Health Care Regulation in Selected Countries

3.1 Regulation of Health Care Facilities

Today, there is a growing global interest in regulation of hospitals and other health care facilities, both by international institutions such as the World Health Organization (WHO), and by an increasing number of industrialized and developing countries. This interest mirrors wider worldwide concern about promoting quality of care and an increased emphasis on accountability to the public, both as consumers and taxpayers.

The regulation of hospital construction in different parts of the world was discussed in Section 2. In Section 3, we focus on the regulation of hospital operation and quality of care through the methods of health facility licensure and accreditation. The development and status of such systems in a number of countries is presented.

3.1.1 Health Facility Licensure

Licensing is the process of judging a health care facility or provider against a set of standards that specify the minimum structure that must be present in order for the facility to operate. Licensing standards specify the equipment, staff, and physical facilities that are absolutely essential for delivering medical care. If the facility meets these minimum standards, it is granted a license, which represents the government's permission for the facility to be open and provide care to patients. A facility that lacks any of these minimum requirements cannot provide safe or effective patient care and is not allowed to remain open.

As opposed to accreditation, which is voluntary and mostly administered by non-governmental bodies, licensing of health care facilities is mandatory and government imposed.

Exhibit 3-1
Licensing Principle

The idea behind licensing is the recognition that there are levels of quality below which patient care should be prohibited. As licensing is defined as the absolute minimum level of quality, licensing standards are written to define the resources that must be present for the hospital to safely and effectively treat patients. The goal of licensing is not to define desirable quality, but to define the minimum level of capability.

Standards for licensing of health care facilities vary from one country to another, according to development status. The following licensing standards were developed for the Republic of Kyrgyzstan to represent the absolute minimum structure that must be present for any hospital in any country to deliver care to patients.

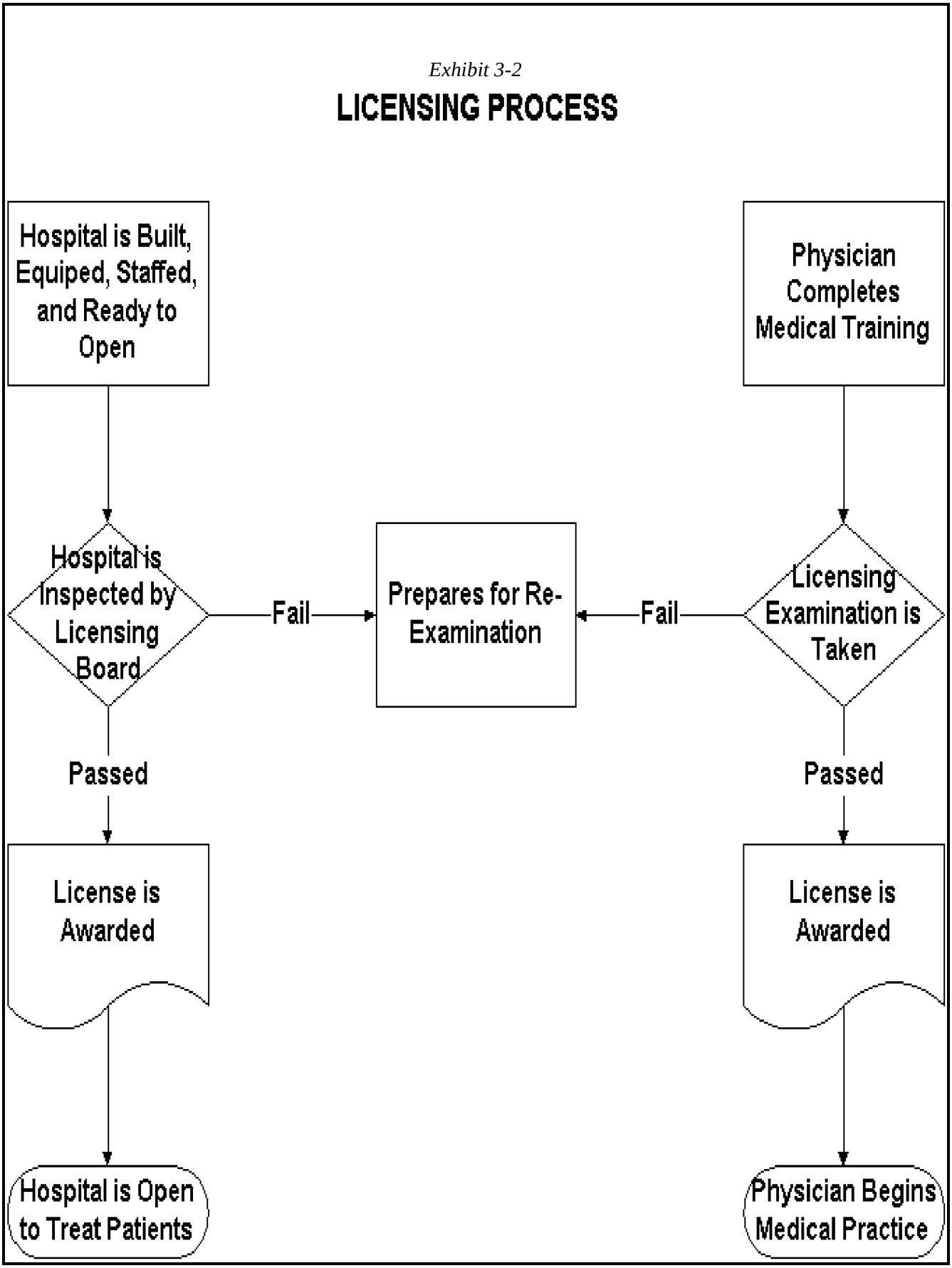
A *hospital* is defined as “a location where persons suffering physical or mental ailments are provided medicine, surgery, or other forms of therapy for a continuous period of 24 hours or longer.” Any hospital must have:

- A licensed physician who is responsible for ensuring that each patient is diagnosed as to the nature of his or her ailment and receives either effective therapy to alleviate the malady, or palliative care in cases where effective therapy is not available;
- Nursing care whenever there are patients at the facility;
- Beds, each occupied by a single individual, except in extreme situations of need where beds may be shared by more than one person, although at no time may more than one person occupy a bed when such sharing would result in an adverse medical outcome for any of the persons;
- Sufficient sanitary facilities to prevent the spread of communicable disease;
- Potable drinking water;
- Food service providing meals appropriate to patient needs, adequate kitchen facilities, or arrangements where food is provided to patients by outside sources or contractors;
- Transport, or regular and reliable access to transport;
- A working telephone line;
- Compliance with public health and environmental standards;
- The minimum set of medical equipment and surgery instruments required by existing norms; and
- Linens, bed supplies, and other "hotel" service necessities, in addition to medical equipment.

The majority of governments worldwide have much more sophisticated measures for licensing of their health care facilities which exceed these minimum standards.

Exhibit 3-2

LICENSING PROCESS



3.1.2 Health Facility Accreditation

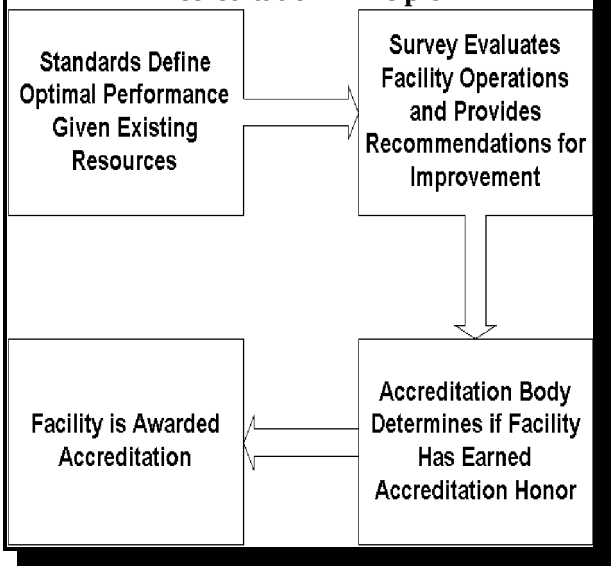
When setting standards for health care facilities, questions of who should define these standards and how they should be monitored must be addressed. In response, two models have been developed. The first could be called regulatory, or public-regulation, where the state takes direct responsibility for setting standards and inspecting health care facilities and certification is a condition for continuing to operate and for receiving public funds. The second is the accreditation, or self-regulation, model, where an independent agency both defines and monitors the standards of those institutions that voluntarily choose to participate in the scheme.

Accreditation is the process of evaluating health facilities according to a set of standards that describe the structures and processes directly contributing to desirable patient outcomes. These standards provide guidance on achieving the highest level of care quality possible, given available resources. When a hospital meets or exceeds the structure, process, and outcome standards of the care delivery system, it earns the honor of accreditation.

3.1.2.1 The Evolution of Health Facility Accreditation

The earliest attempt to set and monitor standards for health care organizations was initiated in the United States in 1917 through the Hospital Standardization Program, which later evolved into the JCAHO. The JCAHO is viewed to be a model of self-regulation by the health care industry, but it assumed a public regulatory role in response to changes brought about by the introduction of Medicare and Medicaid. Today, the majority of health facility accreditation systems worldwide are in large part based on the self-regulation model, with some features of the state regulatory model incorporated to varying degrees.

Exhibit 3-3
Accreditation Principle



The way health facility accreditation is conducted worldwide has also evolved in an attempt to move from “standards monitoring” towards “continuous quality management” or “total quality management.” The notion of standards implies fixed points in the definition of quality -- points which may, from time to time, be revised and upgraded, but nevertheless provide clear-cut criteria and well-defined targets. The notion of quality, as interpreted in the total quality management approach, implies a continual process of self-examination, and a never-ending search for improvement without a fixed destination. Setting standards is seen as an exercise in public accountability to patients and taxpayers for the achievement of a particular level of care. The concept of quality as something in a continual state of evolution is now being incorporated in many accreditation models worldwide.

Over the past few years, accreditation evolved from asking whether the facility has the capability for producing quality care, to asking whether the facility provides quality care. There are two elements in this new approach to facility accreditation. The first is the move from defining quality in terms of inputs (e.g., physical plant, organizational structure) and processes

(e.g., policies and plans for the delivery of care) to outcomes. The second is the increased emphasis on the ways whereby the hospital itself can assess the quality of care it provides.

3.1.2.2 International Models in Health Facility Accreditation

Although successful accreditation programs have been completely established in only a few countries (U.S., Canada, Australia, and New Zealand), recent experience suggests that hospital standards can be produced in developing countries if the standards reflect the actual conditions found in local hospitals. Presently, there are efforts under way to develop and implement hospital accreditation programs in approximately 15 additional countries worldwide. The approach taken in these countries has been to make a realistic appraisal of local conditions, especially of available resources, and develop hospital standards that reflect a level of care that can be achieved, given environmental realities.

For Annex A, the current stage of development of all accreditation systems worldwide was researched through interviews with experts in international development and an extensive literature search. Evident from this list is the fact that many systems are in the developmental stage. Implicit in the list is the driving force of private medical practice on the development of accreditation systems. As private practices and private hospitals begin to account for larger shares of a country's health care delivery system, concerns over maintaining or establishing quality monitoring mechanisms increase.

The developmental stage is often prolonged in nascent accreditation systems because of the necessity to establish a body charged with carrying out the survey and accreditation process. At the same time, standards must be created that are appropriate to local conditions. In the early spread of accreditation systems, standards were created from scratch, as the only model readily available was that of the JCAHO in the U.S. Although providing a good overall model for the design of standards, U.S. standards were not appropriate for countries with fewer economic resources. As world experience with accreditation increases, available models for standards and lessons learned from accreditation structure development made the process less difficult for moderate income countries.

The accreditation model as it has developed in the Anglophone countries -- the U.S., Canada, Australia, and the U.K. -- was chosen for a more detailed review for two reasons. First, these models are all derived from the U.S. model, and therefore form a family group. Second, no other country has developed a whole hospital accreditation system to the same extent as the Anglophone group. Further information on the structure of the health systems in these four countries is presented in Annex B.

3.1.2.3 The United States

Accreditation in the United States is the product of an initiative taken by the medical profession. In 1917, the American College of Surgeons established the Hospital Standardization Program. The intent was to ensure "that those institutions having the highest ideals may have proper recognition before the profession and the public, and that those of inferior standards should be stimulated to raise the quality of their care."

The Hospital Standardization Program, as originally conceived, was one of the means by which the U.S. medical elite asserted its claim to control the system. The five original standards indicate that the program represented an assertion of medical autonomy against the trustees and administrators who had dominated the hospital scene in the past. Three of the

standards were concerned with the organization of the medical staff, and were intended to ensure that the medical staff should collectively determine the rules, regulations, and policies affecting the "professional work of the hospital." These standards also enforced staff power to exclude physicians who were not considered to be adequately qualified or competent. A fourth standard dealt with medical records, while the fifth sought to ensure that the technical resources required for the practice of medicine -- i.e., the appropriate diagnostic and therapeutic facilities -- were available.

Over time, the number of hospitals submitting themselves to the accreditation process increased. By 1950, more than half the hospitals in the U.S. were involved. The program became too expensive for the American College of Surgeons to carry on its own. As a result, the JCAH -- re-named the JCAHO in 1988 -- was born. As before, the medical profession dominated the JCAH, although the American Hospital Association also secured representation. Until 1993, the Board of Commissioners was composed of 24 members nominated by the American Medical Association, American College of Surgeons, American Dental Association, American Hospitals Association, and one consumer representative. In 1993, the JCAHO added four more seats to its member board, three for public members and one for nursing.

In essence, the JCAHO was initiated as a model of self-regulation by the health care industry. It has been forced, however, to adapt to the changes brought about in the 1960s by the introduction of Medicare and Medicaid, which made hospitals dependent on revenue from tax-financed patients. Reimbursement for the treatment of Medicare patients became dependent on whether hospitals met federal standards, enforced by the states. The JCAH headed off the development of a federal inspectorate whereby accredited hospitals were given what was termed "deemed status," i.e., they were deemed to have met the conditions necessary for reimbursement from Medicare and Medicaid. States could allow hospitals exemption from their own regulatory processes if they received the imprimatur of the JCAH.

In principle, then, the JCAH maintained the twin-defining characteristics of a self-regulation system. The processes of defining and monitoring standards remain independent, and participation by health service organizations is voluntary. The use of JCAH accreditation in government decision making, however, caused it to become part of the public system. Federal and state regulations were drafted to follow many JCAH standards. Some of the standards regarding safety issues have been tightened up in response to pressure from the federal bureaucracy. In practice, the principles of government and self-regulation have been blurred.

Until the mid-80s, JCAH efforts defined standards more precisely and in greater detail. The result was a proliferation of standards -- some 2,200 in all -- and ever-increasing complexity in the process of scoring and assessing them in an attempt to increase objectivity. But starting with the 1986 Agenda for Change, the JCAH started re-envisioning its role from facility standards monitoring to the broader promotion of continual facility self-advancement, thus embracing the paradigm of continuous quality improvement. Accordingly, the JCAHO embarked on an ambitious and expensive program for developing clinical outcome indicators, while concurrently reducing and simplifying input and process standards. The 1994 Accreditation Manual marks a significant step in this direction, reversing the trend towards ever-increasing complexity of previous decades. The manual also signals a move away from defining standards in terms of specific services or departments and adopting a more cross-cutting, thematic approach, testing the functioning of the hospital as a whole.

Although hospitals are not compelled to seek JCAHO accreditation, they now have a very strong incentive to do so, and 80 percent participate (the main exceptions are small rural

hospitals). Even though there are a number of small accreditation systems developing in the wake of the JCAHO, it has remained the market leader in health care organization accreditation in the U.S.

Nevertheless, the JCAHO is criticized inside and outside the U.S. on two major issues. The first is their reluctance to refuse accreditation to a hospital because of the damaging financial consequences that may result from such a decision, especially when such a decision may force the closure of a community's only hospital. It is also criticized for being too bureaucratic and imposing an excessive burden of paperwork on those being accredited.

3.1.2.4 Canada

The Canadian system is the most direct offspring of the U.S. system, and was actually part of it. Canadian members sat on the board of the JCAH, but with the advent of the Canadian Health Service, it was believed that Canada required a purely Canadian system of accreditation. In 1958, the Canadian Council on Hospital Accreditation (renamed the Canadian Council on Health Facilities Accreditation in 1988) was founded. Like the JCAHO, it is an autonomous, independent body, although its composition is significantly different: the nominees of the medical profession account for less than half the membership of the board and there is more representation for the nursing profession. Unlike the JCAHO, it had official recognition from the start, receiving its letter patent from the Secretary of State. It is the sole authority to accredit hospitals in Canada, including not only general hospitals, but also long-term, mental health, and rehabilitation facilities.

The Canadian Council's history, like that of the JCAHO, is one of steady expansion. By the end of the 1980s, it was accrediting around 1,300 facilities. It also graded the results of its accreditation visits, although it used a different approach, ranging from non-accreditation to a four-year accreditation, with four intermediate awards. It also engages in a continual process of standards revision. In 1990, a marked shift in the standards occurred, which reduced the number of questions and indicated a move towards outcomes rather than inputs and processes.

Since there is no Canadian equivalent to the financial incentives to meet Medicare standards, the Council’s emphasis is on organizational education and self-development. The client for accreditation in Canada is the individual health care provider. The accreditation process is designed to act as a yardstick by which health care organizations can measure their own performance against national standards. The Canadian Council has permitted some moves towards regulation, however, at least for training purposes, in that it is a requirement for hospitals wishing to train medical interns and other health professionals.

As compared to the American model, the Canadian system is less bureaucratic and legalistic. The accreditation documentation is much less complex. There is much less emphasis on trying to reduce the discretion of surveyors by elaborate scoring systems. The Canadian system is also much nearer to a professional peer review model than the American original.

3.1.2.5 Australia

The Australian Council on Hospitals Standards (subsequently renamed the Australian Council on Health Care Standards) was launched in 1974 in Victoria, subsequently extending its services to other states.

The Australian Council was the product of a long campaign by the Australian Medical Association (AMA) and the Australian Hospital Association (AHA). The influence of the U.S. JCAHO model in shaping this initiative was widely acknowledged. As in the United States, the medical profession dominates the membership, although nurses, allied health professionals, and consumers are also represented, albeit sparsely. Like its North American counterparts, the Australian Council has adapted its accreditation processes over the years. Two developments, in particular, are significant. First, the Australian Council puts much emphasis on reviewing the quality assurance activities of the facilities being accredited, as part of its emphasis on promoting continuing improvement in the quality of care delivered. Second, like the JCAHO, the Australian Council, in cooperation with the medical colleges, has been developing a set of clinical outcome indicators, the first of which were used in accreditation reviews during 1993.

3.1.2.6 Britain

Britain's system for regulating the private sector of health care is one whereby hospitals and nursing homes must be registered with and quality inspected by the health authorities. Within the National Health Service (NHS), however, there was remarkably little interest in quality and standards until the 1980s. The general assumption seemed to be that the NHS's system of hierarchic control over the nation's hospitals made concern about quality and standards redundant.

As a result of the separation between purchasers and providers introduced by the 1991 NHS reforms, the interest in standards began to develop before the dismantling of the system of hierarchic control. In contrast to the experience of the other countries reviewed, the changes were not driven by the medical profession, which has remained very much on the sidelines. Changes have not led to the creation of a single dominant accreditation body. Instead, there has been a stumbling, halting progress towards accreditation, in which a number of competing actors have taken part.

The only true whole hospital accreditation system in the U.K. at present operates within one Regional Health Authority (southwestern) and is directed only at small and community hospitals. This was derived from the Canadian model, has explicit standards, uses health service practitioners as surveyors, and awards a pass or fail. The standards focus only on organizational processes and make no attempt to incorporate clinical standards.

A partial accreditation system was developed by the King Edward's Hospital Fund for London, an independent foundation whose mission is to improve the quality of management in the NHS. This scheme evolved from an interest in the experience of other countries with accreditation in the early 1980s, when it sent a multi-disciplinary team to study the JCAHO. JCAHO standards were implemented in two pilot hospitals. Later, the Fund established what is now known as the King's Fund Organizational Audit Scheme, whose design was based upon that of Australia. Although the scheme incorporates advice from the medical profession and colleges, is not dominated by them. As in Canada and Australia, but only more so, the original emphasis was on self-improvement, and on professional peers learning from each other during the surveying process. This was reflected in the fact that the King's Fund audit did not award a graded outcome following the visits of its surveying teams, but simply reported its findings and recommendations to the hospital concerned. This will soon change, however, as the Fund moves toward graded outcomes and becomes a fully fledged accreditation system. As the name of the scheme suggests, organizational process is the main focus of the standards and surveys. Unlike the U.S., Canada, and Australia, there has been no attempt to integrate a clinical audit into the

standard setting process. Clinical audits, although much stressed in the 1991 reforms, remain an entirely separate activity. There has been no attempt, as yet, to introduce outcome indicators.

Some NHS health authorities, both at the district and regional levels, are developing their own standards and accreditation systems, either for institutions as a whole or for particular services like nursing. Professional services, such as pathology, are also developing accreditation systems. In addition, some hospitals are accrediting themselves, using a national system designed for all service industries which surveys the effectiveness with which participating institutions maintain the standards they set for themselves. The private sector of health care is also pushing for an accreditation system, which it sees as an advantage in the competition for contracts in the NHS's internal market, as well as a potentially superior alternative to public regulation.

The future of accreditation in Britain is, therefore, not clear. The Department of Health has so far adopted a neutral stance. Conceivably, the King's Fund organizational audit scheme may evolve into the kind of dominating accreditation body that characterizes the other Anglophone countries. Alternatively, Britain may develop a rather different, more pluralistic model of accreditation, with a variety of organizations defining and monitoring standards and a national body responsible for accrediting the accreditors. The direction of change will, however, largely depend on the view taken by the Department of Health and others regarding the purposes of accreditation and the balance struck between seeing accreditation as the instrument of self-improvement and a tool for ensuring the achievement of national standards.

In summary, the U.S. model of accreditation has directly shaped the systems in Canada and Australia and indirectly influenced developments in Britain. But, in each case, adoption of the model involved adapting it to national circumstances, so that, despite the common ancestry, each system in the countries studied revealed differences as well as similarities.

3.2 Regulation of Health Care Personnel

Regulation or credentialing of health manpower takes three forms -- accreditation of educational programs, certification of personnel by the profession, and licensure by a government agency.

Accreditation, licensure, and certification of health personnel have developed independently of one another to meet pragmatic functional and social needs. Based upon this historic pattern of evolution, the structure of these evaluative systems today interlock with each other. Licensure and certification are both dependent upon graduation from accredited programs. Governmental practice acts that establish licensing procedures usually contain educational requirements. Professional associations, too, usually require that the applicant satisfy certain educational qualifications to be certified. Key members of the profession often serve simultaneously on both accrediting teams and licensure boards.

In this section, we introduce the various methods of health personnel credentialing and examine the experience of the Anglophone countries (i.e., U.S., Canada, U.K., and Australia) in this respect.

3.2.1 Accreditation of Medical Education Institutions

Accreditation is the regulatory process whereby an external association or agency grants public recognition to a school, institute, college, university, or specialized program of study having met certain preset criteria or standards as determined through initial and periodic evaluations.

The purposes of accrediting educational institutions are many and varied, some of which include:

- Establishing criteria for professional certification and licensure;
- Assisting prospective students in identifying acceptable programs;
- Creating goals for self-improvement and stimulating higher standards among institutions; and
- Helping to identify institutions and programs for the investment of public and private funds and providing bases for determining eligibility for governmental assistance.

In general, there are two types of accreditation applicable to medical education institutions: institutional and specialized. Institutional accreditation applies to the total institution and indicates that the institution as a whole is achieving its own validated and specified objectives in a satisfactory manner. Specialized program accreditation protects the public against professional incompetence resulting from failure of medical education and training to meet accreditation criteria. Due to the differing emphases of the two types, accreditation of the institution as a whole by the institutional accrediting associations should not be interpreted as being equivalent to specialized accreditation of each of the several parts or programs of an institution. Institutional accreditation does not validate a specialized program in the same manner and to the same extent as specialized accreditation. For example, institutional accreditation of a college or university does not imply that each specific curriculum and/or department, such as dental hygiene or physical therapy, is accredited. Specialized accreditation, however, usually requires that the program be housed in an institution that has been accredited.

The accrediting procedure usually follows five basic steps:

a. The accrediting agency, in collaboration with professional groups and educational institutions, establishes standards.
b. The institution or program desiring accreditation prepares a self-evaluation study that provides a framework for measuring its performance against the standards established by the accrediting agency.
c. A team selected by the accrediting agency visits the institution program to determine first-hand if the applicant meets the established standards.
d. Upon being satisfied through the information obtained from the self-evaluation and the site visit that the applicant meets its standards, the accrediting agency lists the institution or program in an official publication with other similarly accredited institutions or programs.
e. The accrediting agency periodically reevaluates the institutions or programs that it lists to ascertain that the standards are still being met.

3.2.2 Licensure of Health Personnel

Licensure is the process by which a government agency grants permission to medical practitioners to engage in a given profession or occupation by certifying that those licensed have attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably protected.

The nature of licensing statutes can be classified as compulsory, where only persons holding a license are permitted to practice medicine (unlicensed persons are prohibited from working in the field); or voluntary, where only persons holding a license are authorized to use a particular title or official designation (unlicensed persons are not prohibited from working in the field, but they may not use the protected title).

Over the past years, the tendency in licensing has been to move towards a mandatory licensing act away from voluntary statutes. Medical practice legislation is typical of the compulsory licensing statute. Most countries have enacted such restrictive legislation, embodying the principle that no person may practice the profession of medicine unless he has complied with certain conditions and then applied for and received a license. Typical of the voluntary statutes are the laws providing for the optional licensing of practical nurses who are then awarded the title “registered” or “licensed” nurse. The desire to protect the public through higher standards for nursing care has led the nursing associations to strive for a compulsory licensing system in many countries. Licensure involves such activities as:

- Examination of applicants' credentials to determine whether their education, experience, and moral fitness meet statutory or administrative requirements;
- Inspection of schools to determine whether training programs meet requisite standards;
- Administration of examinations to test the academic and practical qualifications of medical graduates against preset standards;
- Granting of licenses on the basis of reciprocity or endorsement to applicants from other states or foreign countries;
- Issuance of regulations establishing professional standards of practice; and
- Investigation of charges of violation of standards established by statute and regulation; suspension or revocation of violators' licenses; and restoration of licenses after a period of suspension or further investigation.

3.2.3 Certification of Health Personnel

Certification or registration is the process whereby a non-governmental agency or professional association grants recognition to a medical practitioner who has met certain predetermined qualifications specified by that agency or association. Such qualifications may include graduation from an accredited or approved program; acceptable performance on a qualifying examination or series of examinations; and/or completion of a given amount of work experience.

Associations set minimum certification requirements for beginning workers that, in effect, attempt to prevent employment of uncertified persons. The certification process is helpful to the potential employer, as it eliminates the necessity of having to judge the educational and experience background of each worker subjectively. In addition, the prestige attached to certification makes the worker feel he is the best qualified to do the work in his field, which should result in a professional attitude and efforts to improve his competence.

Whether the professional association can control the quality of performance of its members once certified is open to question. It would seem desirable to have renewal of registration or recertification contingent upon the demonstration of maintained competency.

3.2.4 Recertification of Health Personnel

Recertification is the process by which a professional body testifies intermittently to the competence of its members, either with or without a period of formal retraining. Since a certificate issued to a practitioner cannot be easily withdrawn, recertification requires instituting a time-limited certification practice in the system from the beginning. Relicensure, however, is the means by which a government or employing agency grants permission to the practitioner whose original license to practice has lapsed or was suspended to continue or recommence practice.

Recertification can be contingent on meeting certain requirements, some of which may include:

- Continuing professional experience, e.g., documenting a certain number of hours of professional practice per year;
- Assessment of competence, e.g., undergoing periodic tests of clinical knowledge, clinical judgement, or surgical skill;
- Assessment of performance, e.g., assessment of a doctor's authenticated medical records of cases seen over a certain period to evaluate his mode of practice; or
- Assessment of clinical outcomes.

The body that issued the original certificate is responsible for recertification. The structure of the body varies across countries, and, to a lesser extent, across specialties within a country. The body responsible for recertification should also assume responsibility for organizing activities that assist its members in maintaining competency for recertification.

Maintenance of professional competence can be through positive strategies that focus on maintenance of competence or negative strategies that focus on identification of incompetence, or on both. These approaches are also referred to as the “Theory of Bad Apples” and “Theory of Continuous Improvement.” Positive maintenance strategies focus on encouraging continuous improvement by the average practitioner, rather than identifying and dealing with outliers, e.g., promulgation of practice guidelines, provision of continuing education activities, and support of quality assurance activities. Negative maintenance strategies involve withdrawing certification because of major deficiencies in professional performance or withholding recertification because of failure to pass a recertification examination. Most credentialing agencies worldwide have the power to use such negative strategies, even if they exercise it infrequently.

Approaches to recertification vary in the extent to which these two purposes are served among different countries, and among certifying bodies within a given country. Evidence from country experiences shows that adopting either of the two extremes exclusively has not been effective. An effective strategy for recertification should focus primarily on maintaining the competence of all practitioners, yet incorporate a system of identifying the minority who were not maintaining competence.

International experience also shows that a participant-centered approach to recertification, one that values the intrinsic motivation of the practitioner to maintain competence over the external motivation provided by reward or threat, is most successful.

3.2.4.1 International Models in Health Personnel Credentialing

The United States and Canada

Physician credentialing in both the U.S. and Canada consists of three components: accreditation, licensure, and specialty certification.

a. *Accreditation.* Accreditation of undergraduate medical educational programs in both the U.S. and Canada follows identical guidelines, thus establishing one standard for medical education in North America. In contrast to other countries where regulation of educational institutions is a government activity, accreditation of medical education programs in these countries is a voluntary self-regulation process conducted by peer groups of educators and members of the profession as represented by a joint accreditation committee of the national medical college association and national medical association. Graduate education in the U.S. is overseen by residency review committees and councils of the American Medical Association. In Canada, it is the responsibility of two organizations, the Royal College of Physicians and Surgeons of Canada and the College of Family Physicians of Canada.

Unlike most other countries, there is no ministry of education or other centralized authority to control educational institutions. The states, and in many cases counties and cities, assume varying degrees of control but permit institutions of higher education to operate with considerable autonomy. As a consequence, institutions vary widely in the character and quality of their programs. Private educational associations of regional or national scope have established criteria to evaluate institutions or programs, with the intent of determining whether they are operating at basic levels of quality. The U.S. Office of Education, as the party responsible for determining eligibility of federal aid to educational institutions, establishes a list of nationally recognized accrediting agencies that are considered a reliable authority in determining the quality of training offered by educational institutions. Only accredited or pre-accredited institutions (institutions showing evidence of working towards accredited status) are eligible to receive federal aid in the U.S.

b. *Licensing.* To practice, a physician in North America must obtain a license. The license itself is unrestricted, i.e., a doctor may practice in any field and use the title of “specialist” upon merely holding a valid license. Individual states or provinces have the legal authority to license practitioners (and other health care professionals), and generally coordinate their activities through voluntary membership of national associations (the Federation of State Medical Boards in the U.S. and Federation of Provincial Medical Licensing Associations in Canada). Requirements for licensure typically include:

- Graduation from an accredited U.S. or Canadian medical school, or a special certification process for graduates from medical schools not in North America (administered by the Educational Commission on Foreign Medical Graduates in the U.S. and by the Medical Council of Canada in Canada);

- A period of supervised graduate education in an approved internship or residency program, often lasting one year; and

- Passing a national examination: in the U.S., the USMLE and in Canada, the Medical Council of Canada Licensure Examination.

Generally, there is reciprocity of licensure among states within the U.S. and the provinces of Canada. Reciprocity between the two countries is more complicated and depends on the state and province involved. At the present time, the license is awarded for life so long as the practitioner performs according to certain codes of conduct. Periodic recredentialing, however, is still being debated in both countries.

c. *Certification*. The desire on the part of some practitioners to establish their credentials as specialists prompted them to develop a voluntary certification process based on meeting well-defined standards. Unlike licensure, certification is not required by law. Specialty board certification is sought by most current medical school graduates in both the U.S. and Canada, although there is no professional or legal requirement for a medical practitioner to obtain it. Hospitals, however, may require specialty board certification as a prerequisite for obtaining certain privileges.

As practitioners began to voluntarily limit their practice to a specific area of medicine, they formed specialty societies and boards and developed formal training programs. In the U.S. in 1991, there were 23 specialty boards that certified doctors in various specialties and subspecialties. They coordinate their activities through the American Board of Medical Specialties (ABMS), which also oversees the establishment of additional specialties and/or subspecialties.

In Canada, licensure is under the auspices of the provincial councils. Specialty certification functions are under those of the two national certifying bodies: the Royal College of Physicians and Surgeons of Canada and the College of Family Physicians of Canada. The former certifies 43 specialties and subspecialties and recognizes another 9 subspecialties by way of accreditation without certification.

d. *Recertification***.** In the U.S., voluntary recertification and time-limited certification has been established by members of the maturing specialty boards. When established in 1969, the American Board of Family Practice instituted time-limited certification requiring subsequent, time-limited recertification. The American Board of Internal Medicine (ABIM) gave its first recertification examination in 1974 on a voluntary basis. By 1991, 16 of the 24 specialty boards had either instituted or had plans to institute time-limited certification and recertification. More than 23 states in the U.S. currently require the completion of specific amounts of continuing medical education (CME) for recertification.

Although the issue of recertification has long been the subject of discussion in Canadian professional circles, compulsory recertification is not currently required. The two national certifying bodies -- the College of Family Physicians of Canada (CFPC) and the Royal College of Physicians and Surgeons of Canada (RCPSC) -- have, in collaboration with nine national specialty societies, established a pilot competence maintenance program in 1990. The program features voluntary enrollment, documentation of CME activities, and confidential summaries of aggregate clinical outcomes. The CFPC also has a maintenance of certification program, in which all certificants are required to participate every five years. Members are also required to meet the College's CME credit requirements on an annual basis. This maintenance of certification program is not an examination, but a self-learning program to assist the certificant in reviewing current knowledge of the primary care literature. Participation in the program, rather than achieving a minimum score, is required to maintain status as a certificant.

Standards for initial certification and recertification are often different in both the U.S. and Canada. Boards are generally reluctant to fail large numbers of the older candidates, and consequently lower test standards.

The U.K. and Australia

a. *Accreditation.* The British system of medical education was transported to Australia in colonial days, and close similarities exist between the two. In the early nineteenth century, increasing concerns in the U.K. about the unregulated system of medical practice led the British government to pass the Medical Act of 1859 establishing the GMC, which regulated entry to the profession by forming a medical register including only physicians with approved qualifications. To do this, the GMC determined what the doctor needed to know and what training was necessary. It set guidelines for the curriculum of the medical schools, whether they were university-based or hospital-based (then the common pattern in London). In addition, the GMC was given the right to inspect examinations. Thus, a process developed whereby standards and external supervision were imposed for all aspects of education. This same process is in operation today in the U.K. and almost identical processes have evolved in Australia. It is only recently that the Australian Medical Council (AMC) has been established to take over the role of the GMC.

b. *Licensing.* Registration (licensure) in the U.K. is still a GMC function, available only to those who have graduated from an accredited institution. In Australia, registration is the function of state (or territory) medical boards, which make decisions about the qualifications of applicants seeking licensing. Those whose credentials are not accepted must pass an examination, now conducted by the AMC.

c. *Certification*. There are two main categories of strategies used by Royal Colleges of Physicians in the U.K. and Australia to maintain professional standards for medical specialists: entry strategies and maintenance strategies.

Entry strategies ensure the competence of new members of a medical specialty. In addition to being involved in accreditation of hospital training programs and provision of postgraduate courses, Royal Colleges are involved in certification of medical graduates, first as members (an interim qualification) and then as Fellows of the college.

In addition, most colleges employ maintenance strategies to maintain high standards of service by those already admitted to the professional group, including:

- Setting and promulgating ethical and technical standards of professional practice;
- Informing Fellows of continuing education and other professional development activities (such as quality assurance programs);
- Providing professional development activities;
- Accrediting professional development activities offered by other providers; and
- Withdrawing Fellowship or certification from Fellows who fail to meet standards.

d. *Recertification.* In Australia, the issue of recertification of medical practitioners has surfaced several times, but no uniformity exists in the practices of the various bodies responsible for continuing medical education. Only one of the specialist colleges, the Royal Australian College of Obstetricians and Gynecologists (RACOG) incorporated in its constitution a system of mandatory recertification since it was founded in 1978. The system is dependent on the accumulation of a minimum number of 'cognate points' for participation in CME activities. The Royal Australian College of General Practitioners, while not insisting on mandatory recertification, expects its members to participate in professional development activities and indirectly contributes to a re-registration scheme of the federal government. Several other colleges are in the process of actively developing their recertification schemes. All are to be based on participation in CME, but also include elements of audit and peer review.

3.3 Regulation of Pharmaceuticals

Over the past three decades, there has been considerable progress in regulating the pharmaceutical field, and a trend towards broader public roles with regard to marketed drugs. Until the 1950s, governments were mainly concerned with the quality control of drugs and their compliance with specifications, and with methods for the analysis of the active components. Controlled clinical trials for measuring the efficacy of drugs were developed and regulatory authorities were involved in clinical pharmacological evaluation of drugs. In the early 1970s, the socioeconomic aspects of pharmaceuticals gained importance because of the growing pharmaceutical expenditure in many countries. Governments became involved in issues such as the overprescribing and overconsumption of drugs and reasonable costs for pharmaceutical products. At the international level, there was a search for ways and means of making the most necessary drugs accessible to larger segments of the world population, whose purchasing power was low. Thus, national drug policies moved from technical and clinical aspects of pharmaceuticals to economic and social aspects, including concepts of social justice in drug distribution and careful allocation of resources for pharmaceutical expenditure.

The regulatory arrangements instituted by national governments vary in form and substance in relation to the traditions of those governments, their legislative histories, political traditions, and economic and technological resources. Cultural factors, including local traditions, the degree of acceptance of folk remedies, religious beliefs, and marketing practice, enhance or detract from the authority accorded to public regulatory bodies. In addition, a variety of local political issues affect the public regulation of pharmaceuticals.

Depending on their individual circumstances, different countries have chosen regulatory models and structures that incorporate different functions. Most countries established some kind of drug control administration or agency for the purposes of enforcing their regulatory policy. In some countries, the functions of such an administration or regulatory authority are financed through the imposition of fees for registration or licensing of pharmaceutical products and the licensing of premises. As compared to other elements of the health care system, pharmaceuticals is usually an area of heavy government involvement. Regulation can be exercised at every stage, from research and development to manufacturing, marketing, distribution, and consumption. Regulatory bodies can:

- Determine which drugs are to be manufactured or imported, especially by the public sector, through adopting essential drug policies and import restrictions;

- Decide whether or not a proposed medication meets safety, quality, and efficacy standards based on data from laboratory studies and clinical tests on animals and humans;

- Exercise surveillance over production processes;

- Limit distribution systems by licensing pharmacies, determining which health personnel are authorized to handle drugs, and specifying their qualifications;

- Control how patients obtain medications by enforcing prescription requirements for dispensing of medications, and restricting the use of particular medications to selected medical conditions (thus limiting discretion of prescribing professionals);

- Establish standards for advertising as well as for printed inserts in packages so as to prevent false claims or drugs of unproven efficacy or safety;

- Require monitoring processes for reporting instances of adverse effects, and require producers to take drugs off the market;

- Specify prices, insurance coverage, and reimbursement methods, especially in relation to systems that cover all or some of the cost of drugs either through government subsidy or reimbursement; and

- Impose sanctions in the event of failure to conform with any provisions of a regulatory act.

Due to particular significance to developing countries, some of these regulatory functions are further discussed here:

- *Approval of pharmaceutical products*. Safety, quality, and efficacy are the internationally accepted prerequisites for the approval for sale of a pharmaceutical product. As for the number of drugs to be marketed, regulatory agencies, prepaid insurance systems, and hospitals in many developing and developed countries have argued for limiting the number of drugs and pharmaceutical products that can be prescribed, mainly for cost-containment purposes. The decision to limit the number of pharmaceutical products requires a balance between several sometimes conflicting objectives, the most important of which is to establish a drug supply system that both satisfies the health needs of the community and responds to the health needs of the individual.

  The overwhelming increase in pharmaceutical products available internationally led many countries, especially those with resource limitations, to screen those products in view of their specific health needs and national priorities. Optimal use of limited financial resources dictated that priority should be given to the availability of drugs that are of proven efficacy and acceptable safety, and satisfy the health needs of the majority of the population. Thus, the concept of essential drugs lists, linking drug priorities with health priorities, was adopted by many countries so as to achieve the widest possible coverage of the population with the most suitable drugs for prevention and treatment of the most prevalent health conditions. The adoption of an essential drug list does not preclude the provision to supply any approved pharmaceutical product excluded from the list to meet exceptional medical needs. Selection of essential drugs also implies a

continuing process, taking into account financial resources and changing priorities for public health action and epidemiological conditions as well as progress in pharmacological and pharmaceutical knowledge.

- *Drug registration and licensing*. The process for approval of pharmaceutical products, known as registration or licensing, involves a series of different but complementary procedures. In a comprehensive drug registration system, adequate data on pharmaceutical, pharmacological, toxicological, therapeutic, and clinical investigations is provided to the regulatory agency for evaluation by its technically qualified staff. Countries that do not have the professional staff to evaluate and handle such documentation frequently seek technical advice from WHO and/or other countries with more advanced regulatory agencies. Authorities in some countries publish summary assessments of specific drugs and brief explanations of their reasons for rejecting applications for pharmaceutical product approval.

- *Price Controls*. Control of drug prices is practiced in some countries with varying success. One approach is to develop regulations setting maximum drug prices. Another is to place drugs within the framework of general price regulation. A third is to make the price of a drug part of the registration requirement, taking into account, for example, the therapeutic importance of the drug, price of equivalent preparations in the country, and price of the same preparation in other countries. In some countries, sale prices are controlled by regulations governing social welfare reimbursement. An important factor in considering controlling the price of drug is the social and political orientation of the country; this also influences the decision as to whether control should apply to the public sector only or also include the private sector. In some cases, control might be exercised only over essential drugs. Prices vary from one country to another for reasons that sometimes make realistic comparisons difficult. A better appreciation of the circumstances in which drugs are supplied and improved data on cost factors related to, for example, the costs of raw materials, research and development, manufacturing, and promotion, would make realistic comparisons more feasible.

Regulations on Prescribing and Dispensing. As part of a national drug policy and to meet the objective of health for all, it is necessary to formulate and/or review legislation, rules, regulations, and professional codes that relate to the prescribing and dispensing of drugs. The development of primary health care in many countries requires that special attention be given to the role of village health workers. In some countries, the gap between manpower needs and availability made it necessary to allow for some degree of flexibility in legislation and codes which may or may not have compromised the objective of safe and rational drug use.

One possible instrument for regulation of pharmaceuticals is the decision by regulatory agencies to make a particular drug available to consumers over the counter (OTC) or require a prescription from a licensed professional for its dispensing. The choice is usually one of balancing two competing risks. Allowing self-prescription by consumers who do not have medical training risks gross errors of diagnosis and possibly endangering health consequences, in addition to the cost consequences of overprescription and overconsumption. Requiring the intervention of a skilled professional, however, risks that the patient does not receive the appropriate, potentially life-saving, drug at all. In addition, with medical personnel in very short supply in many parts of the developing world, the real cost (including travel time and expense) of visiting licensed medical facilities can be prohibitively high. The trade-offs between

these competing risks need to be carefully evaluated in relation to each country situation.

3.3.1 International Models in Regulation of Pharmaceuticals

Manufacture and distribution of pharmaceutical products are probably more dependent on the country's overall economic system than any other aspect of the health services. Thus, in an essentially capitalist economy, even when the delivery of all health care has largely come under the control of government, as in the British NHS, the production and sale of drugs remain mainly a responsibility of private commerce.

In the U.S., pharmaceuticals are manufactured by private corporations that are widely advertised to both physicians and the general population, and they are sold by private pharmacists (small merchants or corporate chains of drug stores). To guard against drugs of unproven safety or efficacy or false claims in labeling or advertising, Congress and many state legislatures have enacted increasingly restrictive legislation. As a result, today the U.S., through the federal FDA, paradoxically has more rigorous controls over drug marketing than many other countries in which the general health care system is more government controlled. A manufacturer must present the FDA with rigorous proof of a new product's safety as well as its efficacy before it may be distributed. There is also careful surveillance of advertising claims. Nevertheless, the freedom of hundreds of manufacturers to produce and sell their products, usually under patented brand names, results in a bewildering array of tens of thousands of drugs. To cope with the confusion caused by this plethora of products and discourage the prescription of high-cost pharmaceuticals by their subscribing providers, many organized health care programs (e.g., managed care organizations) issued formularies or defined lists of drugs, often under the generic rather than the brand name, to be financed by them. Other products may be used only at the patient's personal expense. In addition, many (if not all) states require pharmacies to offer cheaper generic equivalent drugs to consumers when physicians prescribe branded products.

Social insurance programs in western Europe, which usually cover prescribed drugs, have led to more controls over the distribution of pharmaceutical products, yet few controls over manufacturing. In countries where few drugs are domestically manufactured, such as Norway, the legal controls over production are relatively limited. Even in Germany, where many drugs are manufactured domestically, the tests mandated for drug safety are only slightly more strict. The marketing of drugs in the western European countries, however, is subject to many constraints. Ministries of health, usually with the advice of expert committees of medical practitioners and pharmacologists, often issue a periodically updated list of compounds that may be legally imported or sold. In Great Britain, the number of marketable drugs is controlled by a recommended list of products covered under the NHS; drugs not on this list and prescribed by the doctor must be paid for by the patient personally, unless the doctor can specifically justify its use in a particular case. The Belgian social insurance program requires some cost-sharing by the patient for all prescriptions.

Pharmacies come under greater control in several western European systems than in the U.S. There are also controls over the establishment of new pharmacies. In Norway, pharmacies are inspected periodically by the central government to ensure their compliance with defined standards. In Belgium, an unusual law places responsibility on the dispensing pharmacist for ill effects from any prescription. As a result, to protect both their members and the general population, the Belgian Association of Pharmacists has long operated its own elaborate drug-

testing program, over and above the controls imposed on manufacturers by the Belgian Ministry of Health.

In Eastern Europe and former Soviet countries, the number of drugs readily available is generally limited and controls are built into the planning of pharmaceutical production by ministries of health. In recent years, Russia has temporarily accepted the U.S. FDA approvals for drugs imported from the West until it could set up its own system for evaluating the safety and efficacy of pharmaceuticals.

In the People's Republic of China, although the manufacture of allopathic drugs is planned and carried out by the Ministry of Health, herbal drugs of traditional Chinese medicine are freely produced in every local area.

In most developing countries, drug controls are relatively weak. A large percentage of modern drugs is imported. Even if assembly or packaging is done in the country, the required raw chemical compounds are mostly imported. Once a company has been authorized to open a pharmaceutical plant, there is little government surveillance over its operation. Likewise, most drugs are readily dispensed by a pharmacy with or without a prescription. There may be limitations on the sale of certain narcotics, but even these are seldom enforced. Moreover, in many developing countries, many drugs escape the regular pharmacy system and are sold informally in market stalls by itinerant peddlers or street hawkers. The ability to regulate these sellers often is weak. In Bangladesh in 1984, there were estimated to be 15,000 pharmacies and less than 50 pharmaceutical inspectors.

In organized programs, such as the health centers of a ministry of health or polyclinics of a social security program, the drugs dispensed usually come from central depots, and their distribution is therefore more controlled. With respect to the remedies sold or administered by traditional healers in developing countries, there are virtually no attempts at government controls.

3.4 Regulation of Medical Technology

Adoption and utilization of health care technology in different countries is influenced by many factors, including the perception and experience of health and disease, cultural responses to technology, the nature of the medical profession, industrial information and promotion, financial resources, and regulatory policies.

Despite patent protection and multinational conglomeration in production, demand for technological advances has been sufficient to sustain a very rapid pace of introduction of new products in the medical industry. Furthermore, rapid communication and the globalization of markets has meant that the range of technologies available in a given country is likely to be similar to that in another country, at least within the developed world. Incentives for adoption of a new technology include the benefits accruing to patients (decreased mortality or morbidity, increased quality of life); providers (market advantage to given physicians or facility, more efficient provision of services); and societies (economic development and national pride focused on goods perceived to be high-tech).

Today, most countries are confronting increasing demand from an aging population for increasingly costly technologies, and grappling with inappropriate use of technology,

unnecessary care, and rising costs. The pressure for reform has been increasing around the globe, and regulation of medical technology has become increasingly relevant in addressing issues of resource allocation and cost/benefit analysis.

Attempts to regulate technology can be made at national or regional levels, or both. As discussed later, these may include control of the acquisition and/or utilization of technology, and, in some cases, an assessment of its merits.

Regulation of Technology Acquisition. In countries such as Canada and the U.K., where some form of central or system-level budgeting (i.e., global budget) and expenditure management exist, incentives for technology acquisition are managed within the overall policy framework designed to optimize health care spending. To date, the greatest success in regulation of technology acquisition occurred in countries with single-payer or linked multiple-payer financing and involved the shaping of policy decisions on the adoption and diffusion of resource-intensive technologies. Less costly technologies and those requiring minimal infrastructure investment have generally diffused unimpeded by regulation.

Regulation of Technology Utilization. Mechanisms for regulating technology utilization vary widely. The evidence supports the theoretical expectation that fee-for-service reimbursement of providers creates incentives for technology use. For example, in France, magnetic resonance imaging (MRI) equipment diffused more rapidly in private hospitals than in public ones, apparently encouraged by opportunities for fee-for-service reimbursement in the private sector. Similar experiences in other countries have fostered attempts to shift the basis of reimbursement from fee-for-service remuneration of practitioners and facilities to various forms of capitation, global budgets, and salaries for practitioners.

Technology Assessment: In some developed countries, health care technology assessment has developed primarily to aid policymaking. In cases such as the U.S., however, outcomes rarely translated into regulations and policies. In other countries as the U.K., France, and Sweden, where fixed and prospective budgets have led to limitations on rises in health care expenditures and forced choices between competing alternatives, one of the main emphases of the assessment programs is to aid such choices and support the policy process.

The overall international situation of technology regulation shows that the practice is only seen in developed countries, and even there, it is still starting out. Government-funded health systems in Canada, Australia, and Europe are increasingly attempting to investigate the return on their expenditures in terms of improved health outcomes and, in some cases, cost savings. Both national and regional programs have been established. The first was the Australian National Health Technology Advisory Panel (NHTAP), established in 1982. Countries that have established or designated national programs to become involved in health care technology include Sweden (1987), France (1990), the United Kingdom (1990), and Canada (1990). Regional or provincial programs also have been established in Quebec (1988). A description of the system in some of these countries follows.

The United States

The U.S. health care system reflects the free market of its economy -- there is no fixed budget and no limit on expenditures in the loosely structured matrix of largely private sector health industry components. Mainly because of the inaccessibility of adequate health care for a segment of the population, and because the enormous cost of care threatens financial ruin for many more people, the first major reform of the system was debated in Congress for most of

1994, though in the end, no legislation was passed. One focus of the debate on spending has been the problem of excessive use of expensive medical technology and the need for some control, which generally is lacking in the existing system.

Health care technology assessment is a relatively new field in the United States. Its beginning may be traced to the establishment of a health program in the Congressional Office of Technology Assessment (OTA) in 1975. The first report to describe assessments of specific technologies was published by the U.S. National Research Council in 1975. Subsequent OTA reports described methods of technology assessment and illustrated how they might be applied to a variety of technologies. The U.S. does not have a dedicated national agency for health care technology assessment. Without a national focus, health care technology assessment activities are conducted by numerous public and private organizations. It is also practiced by the government, insurers, medical societies, hospitals, and other groups for their own purposes, mostly in the form of "cost-effectiveness analyses" to help them decide which technologies to pursue. At the national policy level, however, few opportunities for health care technology assessment exist.

In the absence of a framework for national or regional technology regulation, attention has been paid more to the operational level of administration and clinical practice, through attempts to control utilization, rather than to the adoption of the technology. In the U.S., insurers have invested heavily in systems to review technology utilization and set various guidelines and procedures to regulate the use of technology by providers. Many of these guidelines focus on reimbursement, such as insurers declining to cover experimental therapies. Again, the U.S. has not supported these efforts with national or regional policymaking. In this environment, incentives for the use of certain technologies seem likely to overwhelm the mechanisms for use management, leading to overuse in some cases and underuse in others. In the long term, effective technology management requires attention to both system and practice levels.

Canada

In Canada, all citizens are insured for health services. Health care is a provincial responsibility. The federal role is limited to health care financing, health protection including regulation of pharmaceuticals, and environmental health. The health care system represents a balance among government direction, consumer choice, and provider autonomy. Canada has largely controlled the costs of health care by funding and management mechanisms, the most important of which is the "global budget formula" used to fund hospitals. In 1988, the provincial government of Quebec established the first Canadian body dedicated to technology assessment. Since then, a national coordinating office and several other provincial bodies have developed. The work of these and other evaluation efforts has had a growing influence on technology management decisions, particularly those dealing with procurement of capital-intensive technologies. Expanding this influence into the realm of technology use, especially for low-cost, high-volume technologies, remains a challenge.

The United Kingdom

The U.K. NHS is based on the principle that everyone is entitled to any kind of medical treatment for any condition, free of charge. The NHS is funded primarily from general tax revenues. The health service is presently in the middle of a profound change in philosophy and practice. Health authorities have been given specific responsibility for identifying their population's health needs and using public money to buy services under a specific contract so as to meet those needs. Resources are allocated for hospital services as part of a global budget to

purchasers, who then contract with hospitals. A global budget or expenditure limit ties limits on premiums and, indirectly, ties provider payment rates to a national health care budget, controlling costs. These limited NHS budgets have controlled expenditures for health care, through a variety of mechanisms, including regulation of technology acquisition.

Health care technology assessment has recently developed in the U.K. During the past decade, policymakers have focused on the concepts of appropriateness, effectiveness, and cost-benefit analysis. A new R&D strategy in the NHS is emphasizing technology assessment as an aid to choice and management of technology. The increased necessity for making choices and increasing availability of results from health care technology assessment seem to indicate that such research will have a growing impact on health care and its management.

Australia

The health care system in Australia is pluralistic, complex, and only loosely organized. The Commonwealth government is primarily concerned with funding programs and the development of broad policies. The introduction and diffusion of health care technologies in Australia is determined by a complex interaction of market forces, public funding, and regulation. Again, as in Canada and the U.K., the use of global budgets is the main mechanism whereby acquisition of health technology is controlled in Australia.

Australia became involved in health care technology assessment in 1982. In 1990, activities were reorganized and the Australian Health Technology Advisory Committee (AHTAC) was formed at the national level. Despite limited funding, Australia has had some significant successes in informing policymakers through appropriately targeted, well-timed technology assessments.

France

The French health care system combines freedom of medical practice with nationwide social security. The system is centrally regulated with specific attention to technology. Prices and budgets are also regulated. Despite these controls, concerns about quality of care began to appear in France in the 1970s. At the same time, increasing costs became an issue. Health care technology regulation has been under discussion as part of the solution to these problems since the early 1980s, but little was done until 1989, when a national Agency for Health Technology Assessment was established to develop and coordinate health care technology regulation.

The rapid evolution of the introduction and diffusion of health technologies required updated information regarding the real state of its diffusion and utilization. The information allowed policymakers to reshape health care policies regarding the provision of both resources and management. With this purpose, the Agency for Health Technology Assessment was established as part of the national health maps, a register of health technology equipment placed in hospitals and other medical facilities. This register is an information system to support health technology assessment. Variables collected include brand, model, year of purchase, year of functioning, and data of the center in which it is placed. To collect and update the information, a questionnaire is mailed to the health care centers. With this updated database, trends and changes in the purchase of new technologies is available, as well as elaborate maps of the geographic distribution of this equipment. Moreover, the register indicates the diffusion of the equipment according to its coverage (public or private) and type of the health care center (hospital or ambulatory).

In all countries studied, increasing health expenditures was the main incentive for attempts at regulation of technology acquisition and utilization. In most countries that have established formal programs for health care technology regulation, however, regulation was found to strongly affect some technologies, but not others. For the most part, physicians and hospitals retain considerable autonomy despite formal national or regional policies. Most decisions concerning diffusion are made in the purchasing departments of hospitals and in the clinics and practices of physicians.

3.4.1 Regulation of Medical Technology Safety

In the United States, regulation of medical technology safety has always been enforced by the federal FDA. In 1990, a Safe Medical Devices Act and subsequent FDA regulations provided a new dimension in the regulation of health care technology safety. The FDA now has the power to require many health care facilities to investigate, document, and report serious events related to all medical devices, from ventricular assist devices to catheters and sutures. The FDA also has the power to require facilities to track certain devices from receipt, through patient use to disposal. Lack of compliance can carry civil and criminal penalties, affect liability and risk management, and influence accreditation.

In Canada, equipment safety is also ensured by government regulation. Medical device problems are detected by the Health Protection Branch (HPB) of Health and Welfare Canada, which studies the frequency and safety priority of problems in medical devices. The Medical Devices Notification Database contains all notifications for newly marketed medical devices in Canada, and the Reporting System keeps record of all submitted problem reports and manufacturer recalls along with their designated safety priority status. When an important safety hazard is associated with a medical device as determined from information submitted to HPB, an Alert-Medical Devices may be issued to inform hospitals and health care professionals of the problem.

4.0 Conclusions and Recommendations

The international experience in health care regulation provides models and ideas that can assist any country embarking on the development of a regulatory system, and support its decision regarding the menu of regulatory options that is appropriate and relevant to its conditions.

Through our comparative review of international health care regulatory models, we learned that in all types of countries and in a variety of ways, governmental and voluntary regulation over health services exists. While official licensure of health personnel has been the fundamental approach, various forms of regulation or control have been applied increasingly to other kinds of health resources, such as facilities, equipment, and drugs. Regulation of the day-to-day performance of health services is extended through diverse methods of surveillance or teamwork patterns for organizing health care delivery. As the financing of health care by the whole population becomes more collectivized worldwide and the role of the private sector expands, pressure mounts for greater regulation to control both costs and quality of services.

A study of international trends in health care facility regulation revealed that accreditation provides a case study in the international propagation of ideas and models in the health care policy arena. The U.S. model of accreditation directly shaped the systems in Canada and Australia and indirectly influenced developments in Britain. In each case, however, adoption of the model involved adapting it to national circumstances. Moreover, the strong contrast between the U.S. and Britain has significant implications for the design of accreditation systems. In the case of the U.S., the medical profession not only played the leading role in creating the JCAHO, but continued to be highly influential in its subsequent evolution. The same is true of Canada and Australia. The British medical profession, though consulted, has always been peripheral to the development of hospital accreditation, resulting in a lack of clinical measures in this system. Countries embarking on hospital accreditation system development must weigh the pros and cons of medical dominance carefully. Because accreditation systems are seeking to incorporate indicators of clinical quality, the collaboration of the medical profession in ensuring the credibility and acceptance of such measures is essential. This certainly has been the assumption of the various initiatives in the U.S., Canada, and Australia. Accreditation achieves its full potential when it is designed and implemented as an interactive process and the accrediting organization works with the provider seeking accreditation to identify needs and methods to improve performance.

The study of issues of health personnel credentialing from an international perspective illustrated marked variability between countries in both policies and procedures, despite broadly similar goals. Much of what occurs in practice is determined more by traditionally and historically based practices than by the rational use of approaches and methods chosen for their proven value. Similar reasons have determined the nature and function of the official bodies responsible for certification. The overall picture is one where entry requirements into the profession (primary certification) and subsequently into a specialty (secondary certification) are strong and rigorous. The same cannot be said of recertification, where policies and procedures are less well developed in most countries. There is an ambivalence about the purpose of recertification, with the profession concerned more with personal development and maintenance of standards, and the government and community, from whom the stimulus for recertification may be arising, concerned more about decertifying those who are incompetent.

Worldwide, primary certification is either through a process of medical school curricula accreditation by national medical councils (as in the U.K.) or through national licensing examinations (as in the U.S.). The former approach has potential advantages in terms of flexibility, but disadvantages in terms of the quality of the locally produced assessment procedures. In addition, the lack of common procedures in the case of regionally based certification, causes difficulties in the acceptance of qualifications between states or provinces of one country.

Differences in specialty certification and recertification practices reflect not only historical precedents, but also cultural, political, and social differences, both past and present. Medical educators and measurement specialists may agree on desirable approaches to assessment, but these may not be acceptable in a particular country or institution for a variety of reasons. Good examples of this variation are seen in the area of recertification. In the U.K., Australia, and Canada, the approach to recertification is predominantly through maintenance of competence, using participation in CME and other professional development activities as the criteria of achievement. In the U.S., the trend is strongly in the direction of recertification by demonstration of competence based on formal examinations and audit of practice and patient outcomes.

Compared to other health sector resources, pharmaceuticals is an area of heavy government involvement in most countries. Depending on the country's political economy, regulation is exercised on the production and/or the distribution and marketing of drugs to varying degrees. Even in the U.S. free market, extensive regulation of the safety and efficacy of drugs is exercised through the FDA, a model that was copied by other countries, including the U.K., Australia, Canada, France, Germany and the Netherlands. Globally, effective national drug policies had to extend beyond technical and clinical aspects of pharmaceuticals to economic and social aspects, including concepts of social justice in drug distribution and careful allocation of resources for pharmaceutical expenditure.

Countries with national systems of health care (e.g., Canada, Australia and the U.K.) have attempted to develop policies to manage new and existing technologies in concert with global or prospective budgeting. One element of these policies is the development of technology assessment and its linkage to policy decisions. The potential of technology assessment is realized only with effective links to technology policy and management. National and regional policymaking must be complemented by actions at the operational level of clinical medicine to ensure the efficacy and cost-effectiveness of technology adoption and use. With the exception of the U.S., such actions are only beginning in most of the countries studied.

The experience of the countries examined in this report demonstrates that emphasis on health care regulation is likely to grow worldwide. Although it started as an instrument of professional self-education and institutional self-improvement, it now is becoming a quasi-regulatory instrument for holding both professional providers and institutions to account for the quality of their products. In a world where consumers are becoming more educated, where information is needed to make choices about the purchase of health care, and where public agencies are expected to guarantee public safety and the best use of public funds, regulation both from within the profession and by external agencies is likely to flourish. Factors identified as prerequisites for successful implementation of a health care regulatory system include:

- The choice of a regulatory model should be in harmony with the overall political economy of the country. Country experiences show that the appropriateness of a

regulatory practice to a particular country setting is a major determinant of its successful implementation.

- Learning and copying the experiences of other countries and then adapting to local circumstances proved to be a useful approach for countries embarking on health care regulatory reforms. For example, the U.S. model of accreditation directly shaped the systems in Canada and Australia and indirectly influenced developments in Britain. But in each case, adoption of the model involved adapting it to national circumstances. The same could be said about the FDA model for regulation of the safety and efficacy of pharmaceuticals and medical devices.

- The benefits of regulation must outweigh its costs. Unless effective in accomplishing its objectives, state regulation can be a wasteful intervention, not only because it represents needless interference, but also because regulatory programs are often very expensive to implement and sustain. The U.S. provides an illustrative example in this respect where compliance costs for safety, environmental and health regulations have reached $1,000 per household.

- Regulation should be designed to operate at both policy and operational levels. National and regional policymaking is critical in controlling national health care expenditures. Actions at the operational level of clinical medicine are necessary to control quality of care.

- Both positive and negative regulatory measures are needed. A balanced blend of positive strategies, focusing on ensuring compliance and encouraging improvement, and negative strategies, focusing on identification and punishment of non-compliance, is necessary for enforcement of regulation.

- It is clear that political commitment is a primary requirement for reforming the health care regulatory policy. If this commitment is lacking, a national policy cannot be formulated or, above all, implemented. This review, however, has also shown that in many countries, even when commitment was present, there were many other obstacles: internal political pressures, lack of resources, lack of infrastructure, and lack of institutional capacity.

- Involvement of members of the medical profession is crucial. Some country experiences show that the non-responsiveness of regulation in medical care was due, at least in part, to its being viewed as external, and resulted in hostility between regulators and those regulated.

- Regulatory agencies at the central and provincial levels should seek public input in addressing health care regulatory reforms. Public input has frequently lessened legal challenges to the reform by industry and individuals.

- Cooperation and coordination between various regulatory agencies should be encouraged. Failure of government agencies to coordinate with each other in implementing regulatory policies can result in redundancy, conflicts, excessive costs, and regulatory failures.

- Finally, for a health care regulatory system to achieve its goals, it should:

- Recognize market-based changes in the structure of health care;
- Take into account the evolution in standards of medical care in its setting;
- Be cognizant of the context of regulation in the present political environment;
- Draw upon the best scientific research on development of tools and methods for measurement and improvement of quality of care and containment of costs; and
- Prioritize and address the key health sector problems that may arise in the future.

Exhibit 4-1

Summary of Health Care Regulatory Policy Options

Area	Method of Regulation	Application	Target	Description	Country
Health Care Facilities	Facility licensing	Operation of a new facility	Minimum facility structure	Allows only facilities meeting minimum quality and safety standards to operate	Universal
	Certificate of need (CON) programs	New facility construction or expansion	Community need for the service; resource allocation	Ensures that any new facility construction is based on a local social need	U.S.
	Health Maps (Carte Sanitaire)	Health planning and distribution of health facilities	Efficient distribution of health facilities	Plans the diffusion and geographic distribution of government hospitals and other provider organizations	France
	Health system agencies (HSAs)	New facility construction or expansion	Rationalization of capital investment	Reviews hospital expansion and modernization plans to determine their eligibility for capital reimbursement from the federal government	U.S.
	Anti-trust regulation	Relationship between providers (e.g., mergers, acquisitions)	Price and quality of services	Safeguards against provider monopolies and enhances competition	U.S.
	Facility accreditation	Facility structure and performance	Quality of services	Evaluates health facilities according to "standards" for optimal structures and processes	U.S., Canada, Australia, and New Zealand
Health Care Personnel	Licensing	Minimum qualifications	Quality of services	Restricts entry into medical practice to personnel meeting minimum qualifications	Universal
	Primary and specialty certification	Specialized competence	Quality of services	Recognizes higher or more specialized levels of professional competence	Most countries
	Recertification	Maintained competence	Quality of services	Ensures maintained professional competence	U.S. and Canada

Area	Method of Regulation	Application	Target	Description	Country
	Practice guidelines & outcomes research	Clinical practice	Quality of services	Assists physicians in decisions about appropriate health care for specific clinical circumstances	U.S.
	Professional Standard Review Organizations (PSROs)	Utilization review	Quality of services; cost of care	Establishes norms for various procedures and applies them to individual cases of hospital use (e.g., length of stay) so as to identify deterring practitioners	U.S.
	Peer Review Organizations (PROs)	Utilization review	Quality of services; cost of care	As PSROs, but nationwide and centralized in nature	U.S.
	Fines, penalties, and sanctions	Provider compliance with regulation	Varied	Punishes provider personnel and organizations for faulty behavior or non-compliance to regulations	Universal
Health Care Technology	Technology assessment	Technology investment decisions	Cost of care; resource allocation	Weighs costs and benefits of a proposed new technology	U.S. and West Europe
	Health Maps	Technology adoption	Cost of care; resource allocation	Provides updated information regarding the diffusion and utilization of technology	France and Spain
	National health technology agencies/advisory panels	Technology adoption	Cost of care; resource allocation	Acts as a specialized body for new technology review and approval	Australia and others
	Inclusion in global budgets	Technology adoption	Cost of care; resource allocation	Sets an expenditure limit that ties premiums and provider payment rates to national health budget, and therefore controls costs	Canada, U.K., Australia, and others
	Medical technology/ equipment safety acts	Technology monitoring	Safety and efficacy of equipment	Requires health facilities to investigate, document, and report serious events related to all medical devices	U.S., Canada, and others

Area	Method of Regulation	Application	Target	Description	Country
Pharmaceuticals	Control of advertising and labeling	Drug information dissemination	Consumer safety	Protects consumers against false claims and against drugs of unproven efficacy or safety	Many countries
	Drug testing/quality controls	Production of drugs	Consumer safety	Ensures safety and efficacy of new drugs	Most countries
	Requirement of a prescription	Distribution of drugs	Consumer safety; consumption of drugs	Prohibits dispensing of medications without the orders of a qualified professional, therefore prevents self-medication	U.S. and West Europe
	Basic or essential drug lists	Approval of drugs; distribution of drugs	Consumption of drugs; costs of care	Limits distribution of drugs by government providers, or reimbursement for drugs by insurers to only those with proven efficacy and safety and addressing national health priorities	Many developing & developed countries
	Price controls	Price of drugs	Economic access	Ensures affordability of drugs by low-income groups	Many developing countries
	Import restrictions	Production of drugs	Protection of domestic pharmaceutical industries	Prohibits importation of certain pharmaceutical products that are manufactured domestically	Developing and centrally controlled economies

Annex A: The Status of Accreditation Systems Worldwide

Country	Accred. Body	Status	Standards	Primary Uses
USA	*JCAHO* Peer Organizations *NCQA* Peer org and payors	Fully functioning Voluntary (but required for many reimbursements)	Structure, process, and outcomes; -- moving away from reliance on structure and process and towards increased use of outcomes	Reimbursement under federal Medicare and most insurance; used in making purchasing decisions by employers when considering health plans
Canada	*Canadian Counsel on Health Services Accreditation* Peer organizations with federal and provincial observers	Fully functioning Voluntary	Process Outcomes system based on Clinical Care Groups. Moving towards increased use of final outcome indicator monitoring -- in process of developing national set of indicators	Accreditation required by Royal College of Physicians and Surgeons for teaching institutions; increasing peer and consumer demand for accreditation
Australia	*Australian Council on Hospital Standards (ACHS)* Peer organization	Fully functioning Voluntary	Structure and process; developing clinical indicators in a move towards outcomes monitoring	Not formally required by govt or payers; University of New South Wales study demonstrated numerous tangible benefits in the form of improved operations
New Zealand	*Pilot Study Coordinating Committee*	Functioning Voluntary	Structure and process	Not formally required
Russia	Oblast (region) Health Departments Government	Fully Functioning in Some Oblasts (particularly in Siberia); not yet national in scope; several different versions of system are used by various Oblasts	Various, but all based on Medical Economic Standards, a multi-layered retrospective review of all patient records according to fixed treatment protocols	Participation in health insurance and other reimbursement schemes; dual system used for both quality assurance and financial reimbursement and performance incentives

Country	Accred. Body	Status	Standards	Primary Uses
Latin America	N/A	Regional effort with the Pan-American Health Organization to develop hospital standards	Compact set of structure and process standards for acute care hospitals	Not formally required
Egypt	Cost Recovery for Health Project (not actual accreditation system)	Hospital standards developed for the use of hospitals converted to a cost-recovery basis	Comprehensive structure and process standards following 1980 JCAHO model	Adherence to standards was to be required for participation in Cost Recovery for Health Project; excellent potential for Egypt to institute national accreditation system with minimal additional effort
Poland	Government peer hybrid	In the process of pilot testing standards; accreditation system not yet functional	Structure and process standards (pre-1994 JCAHO model)	Not formally required
Czech Republic	Government peer hybrid	Pilot testing standards	Structure and process standards (pre-1994 JCAHO model)	May be required for higher reimbursement level under health financing reform
Romania	Government peer hybrid	Pilot testing standards	Structure and process standards (pre-1994 JCAHO model)	Not required
Hungary	Government organization	Currently developing standards	Structure and process standards (pre-1994 JCAHO model)	Not required
Saudi Arabia	Peer organization	Pilot testing standards	Structure and process standards (pre-1994 JCAHO model)	Not required
Ukraine	National Ministry of Health Regional health authorities	Standards and accreditation system being pilot-tested on a regional basis	Modification of Kyrgyzstan standards of structure, process, and outcomes	Accreditation being considered as requirement for reimbursement under new insurance plans

Country	Accred. Body	Status	Standards	Primary Uses
Pakistan	Peer-Government Hybrid Accreditation organization	Accreditation system development on hold due to government change	Minimalist structural standards based on Latin American model --not yet developed	Accreditation system intended to bring government and private facilities to same level of quality
Kyrgyzstan	National Ministry of Health	Standards and accreditation system being tested on a regional basis as part of health financing reform	Locally developed structure, process, and outcomes monitoring standards	Required for reimbursement for health care delivered under national health financing reform Targeted outcomes review will result in significant cost savings over Medical Economic Standards
Spain	Catalonia State Government	Not yet national in scope	Structure and process	Accreditation required in order to contract with Social Security System for insurance reimbursement
Korea	*Korean Hospital Standardization Program* Peer Organization (Korean Hospital Association)	200 out of 600 acute hospitals participate Voluntary	Primarily limited to structural improvements	Accreditation required for facility to participate in intern and resident program Present program is leading to the development of a more comprehensive accreditation system
United Kingdom	*Kings Fund Organizational Audit (KFOA)* Health Services Research Institution *Southwestern Hospital Accreditation Program (SWHAP)*	47 Hospitals (*KFOA*) 24 Hospitals (*SWHAP*) Voluntary	Borrowed standards from other national systems	Not presently formally required May be required by national health service and/or other purchasers in the near future
Netherlands	Government	Unknown	Structure and process	Required for reimbursement under Sickness Fund Act

Annex B: Health Care Systems in the Anglophone Countries

	United States	Canada	United Kingdom	Australia
Health Care Financing	Multiple private payors (>1,500 commercial insurance company) Medicare/Medicaid public financing	Public financing by federal & provincial governments, with provincial administration Universal insurance coverage Legal prohibition of parallel private sector activity	The NHS funds health care through regional and district authorities Recent purchaser-provider reforms Some parallel private sector insurance and private practice	Multiple payers with mix of private and public insurers Shared state-federal jurisdiction
Physician Reimbursement	Fee-for-service practice Increased amount of managed care	Generally fee-for-service practice Incentives for non-urban practice	Capitation payments to GPs Fund-holding GPs purchase care from trusts and other health services	Fee-for-service, although "national" fee schedule appears to cover most physicians
Drug Regulation	FDA Formularies for managed care programs	FDA Model Formularies for publicly funded programs Price regulation through Patent Medicines Review Board	FDA Model	FDA Model
Equipment and Technology Regulation	CON programs	Global budgets Device registration	Global budgets	Global budgets National centers for highly specialized technologies CON programs

Annex C: Regulation of Health Care Provider Performance in the United States

The evolution of health care regulation in the United States illustrates a rich variety of approaches that were utilized to influence and regulate providers and control costs of care. It began in the 1970s, with decentralized programs to regulate provider behavior through Health Systems Agencies and CON programs. Health care regulation grew more centralized in the 1980s, as federal policymakers expanded their influence on service quality through PROs and medical practice guidelines. Quality regulation increased the heavy micromanagement that providers face in the United States, while budgetary regulation still falls short of the fiscal macromanagement that other Western nations use. The various regulatory tools are defined as follows:

Decentralized Regulatory Functions	Centralized Regulatory Functions
PSROs	PROs
HSAs	Practice guidelines & outcomes research
CON programs	
Anti-trust regulation	

- PSROs establish norms and standards for various diagnostic procedures and apply them to individual cases of hospital use (mainly lengths of stay under Medicare and Medicaid) in hopes of identifying and deterring outlying physicians. This process is what is usually referred to as utilization reviews.

- PROs are the nationwide and centralized replacement of PSROs.

- The HSAs are regional planning bodies subject to federal rules and regulations but governed by large multi-interest boards of consumers whose duty is to review hospital expansion and modernization plans to determine their eligibility for capital reimbursement from Medicaid and Medicare.

- CON programs review hospital plans to expand, modernize, and buy equipment; and issues approvals based on the merits of each case, inquiring whether each proposed project was required by the community.

- Anti-trust regulation is intended to prevent monopolies and modify relationships between providers to increase competition. It does so by inhibiting collaborative efforts between institutions in the health care market that might be considered competitors. A number of statues form the basis of the antitrust law, the most important of which focus on prohibiting contracts or conspiracies between providers that restrain free trade, preventing of monopolies, and regulating mergers between large providers.

- Practice guidelines are systematically developed statements to assist practitioners in decisions about appropriate health care for specific clinical circumstances. They are intended to improve the quality, appropriateness, and effectiveness of care. While particular guidelines may be challenged on the grounds that they are not

comprehensive, there is evidence that they can influence clinical decision-making in a way that has improved outcomes and, in some cases, reduced costs.

Bibliography

Banta, H.D. 1994. “Health Care Technology As a Policy Issue.” *Health Policy* 30 (1-3): 1-21, Oct-Dec.

Battista, R.N, R. Jacob, M.J. Hodge. 1994. “Health Care Technology in Canada (With Special Reference to Quebec).” *Health Policy* 30 (1-3):73-122, Oct-Dec.

Battista, R.N, H.D. Banta, E. Jonnson, M. Hodge, H. Gelband. 1994. “Lessons from the Eight Countries.” *Health Policy* 30 (1-3): 397-421, Oct-Dec.

Becker, G.C., B. Ente, Standards Development Committee, Republic of Kyrgyzstan. 1995. *Licensing and Accreditation Manual for Hospitals*. Ministry of Health, Republic of Kyrgyzstan, and the Zdrav Reform Project, Bethesda, Maryland.

Becker, G.C. 1995. “An Assessment of Quality Assurance Options.” Zdrav Reform Project, Bethesda, Maryland and Kiev, Ukraine.

Becker, G.C. 1995. “A Model Accreditation System for Pakistan.” *World Hospitals* 31 (1).

Bos, M. 1994. “Health Care Technology in the Netherlands.” *Health Policy* 30 (1-3): 207-55, Oct-Dec.

Brennan, T.A. and D.M. Berwick. 1996. *New Rules: Regulation, Markets and the Quality of American Health Care.* San Francisco: Jossey-Bass Publications.

Brown, L.D. 1992. “Political Evolution of Federal Health Care Regulation.” *Health Affairs* 11 (4): 17-37.

Davis, P. 1993. “Pharmaceuticals and Public Policy: Learning from the New Zealand Experience.” Health Policy. 24 (3): 259-72, Aug.

Heideman, Elma, Director, Canadian Council on Health Services Accreditation, Telephone Interview, January 24, 1997.

Hailey, D. 1994. “Health Care Technology in Australia.” *Health Policy* 30 (1-3): 23-72, Oct-Dec.

Hammer, J.S. 1992. “To Prescribe or Not to Prescribe: On the Regulation of Pharmaceuticals in Less Developed Countries.” *Social Science and Medicine* 34 (9): 959-64.

Hopkins, T. 1996. “Cost-benefit Paralysis: Government Regulation of Business.” *National Review* 48 (16): 69.

Janeski, J., Director of the Joint Commission International (Subsidiary of the JCAHO), Telephone Interview, January 28, 1997.

Latin American Federation of Hospitals. 1995. *Quality Assessment: Hospital Accreditation for Latin America and the Caribbean.* Pan American Health Organization.

Light, D. and M. Annabelle. 1993. *Britain's Health System: From Welfare State to Managed Markets*. New York: Faulkner and Gray Inc.

McMahon, B.J., J. Winters. 1993. "Models of Accreditation in Health Care." *Health Bulletin (Edinburgh)* 51 (1): 3-6.

Newble, D., B. Jolly, R. Wakeford, eds. 1994. *The Certification and Recertification of Doctors: Issues in the Assessment of Clinical Competence.* Cambridge: Cambridge University Press.

O'Leary, M., et. al. 1994. *Lexicon: Dictionary of Health Care Terms, Organizations, and Acronyms for the Era of Reform.* Joint Commission on Accreditation of Healthcare Organizations, Oakbrook, Illinois.

Okimoto, D., A. YoshiKawa. 1993. *Japan's Health System: Efficiency and Effectiveness in Universal Care.* New York: Faulkner and Gray Inc.

Pickering, E. 1995. "Evaluating the Benefits and Limitations of an Accreditation System." *World Hospitals* 31 (1).

Roemer, M. 1977. *Comparative National Policies on Health Care.* New York: Marcel Dekker, Inc.

Scrivens, E.E, R. Klein, A. Steiner. 1995. "Accreditation: What Can We Learn from the Anglophone Model?" *Health Policy* 34 (3): 193-204, Dec.

Shaw, C.D., C.D. Collins 1995. "Health Service Accreditation: Report of a Pilot Programme for Community Hospitals." *British Medical Journal* 310:6982, 781-4, Mar.

Shin, Y.S. 1995. "Hospital Accreditation -- A Universal Perspective." *World Hospitals* 31 (1).

Torrens, P. University of California in Los Angeles. Telephone Interview, August 28, 1997.

Tunis S.R., H. Gelband. 1994. "Health Care Technology in the United States." *Health Policy* 30 (1-3): 335-96, Oct-Dec.

U.S. Department of Health, Education and Welfare. 1977. *Report on Licensure and Related Health Personnel Credentialing*. Washington, D.C.: DHEW Publication.

Weill, C. 1994. "Health Care Technology in France." *Health Policy* 30 (1-3):123-62, Oct-Dec.

World Health Organization: Regional Office for Europe. 1980. *The Planning of Health Services: Studies in Eight European Countries*. Copenhagen: WHO Publications.

World Health Organization: Regional Office for Europe. 1979. *Public Health in Europe: National Drug Policies.* Copenhagen: WHO Publications.

World Health Organization: Geneva. 1988. *The World Drug Situation*. Geneva: WHO Publications.

World Health Organization: Geneva. 1988. *Guidelines for National Drug Policies*. Geneva: WHO Publications.