The Content and Uses of Health Laws:

An Overview of Selected International Models and

Lessons Learned for Possible Application in Indonesia

Liza Newby, LL.B, M.A, Grad Dip, F.A.I.M.
Health Law & Policy Consultant

Riitta-Liisa Kolehmainen-Aitken, MD, DrPH
Principal Program Associate, MSH

Chandrawila Supriadi, JD
Senior Lecturer and Secretary of the Masters and Doctoral Law Programs,
Parahiyangan University, Bandung, West Java

Broto Wasisto, MD, MPH
Senior Consultant to the Indonesia Minister of Health and
Senior Consultant to the MSH M&L/Indonesia Program

January 12, 2004

Management Sciences for Health
Management and Leadership Program
Supported by USAID Cooperative Agreement No. HRN-A-00-00-00014-00
with the Ministry of Health, Government of Indonesia

Table of contents

Acknowledgements: The MSH Legal Team would like to express its sincere thanks to a number of individuals without whose guidance and support this report would not have been possible.

The report was commissioned by Professor DR. Dr. Azrul Azwar, MD, MPH, PhD, Director-General for Community Health. It was Prof. Azrul's recognition of the urgent need for an Academic Paper on International experience and possible models in order to guide the Ministry of Health's (MoH) Law Review Team which provided the impetus for this report. Furthermore, it was Prof. Azrul's guidance and support which enabled Management Sciences for Health's Indonesia Management & Leadership (MSH-M&L) Team to apply its USAID-supported resources to carry out the necessary tasks and produce the report. Secondly, Dr. Dini Latief, MD, MSc, the Minister's Expert Advisor on Decentralization and Institutional Capacity-Building, and DR. Faiq Bahfen, PhD, the Head of the MoH Bureau of Law and Organization, exhibited excellence in leadership and managerial concerns while providing the MSH Legal Team technical guidance and inspiration for the Team's work.

The MSH Legal Team obtained essential technical, historical, and legislative input about ongoing efforts to review and update the 1992 Health Law from Dr. Kartono Mohammad, MD, MHA, MA, former Head of the Indonesian Medical Association and Lecturer in Medical Ethics and Health Law at the University of Indonesia, and from Ibu Ermalena, BPharm, Head of the Indonesia Forum of Parliamentarians for Population and Health. Professor Mick Reid, Director of the Policy and Practice Division of the Institute for International Health, University of Sydney, and former Director of Health for the Province of New South Wales, was especially helpful to the MSH Legal Team in providing information about the application of national and sub-national policies and laws in support of the performance of Essential Public Health Functions and Services in Australia.

The MSH Legal Team benefited a great deal from discussions with Technical Advisors associated with other programs. Ms. Sarah Waddell, Law Consultant, and Mr. Joel Friedman, Senior Technical Advisor, respectively, to the USAID-supported PERFORM Project, and Dr. Bernhard May, Program Coordinator for the GTZ-supported Project for Decentralization and Government Reform, helped the MSH Legal Team to identify and understand the nature and reasons for gaps and conflicts in national and regional laws on Basic Health Services and other Obligatory Functions of Local Governments. Discussions with Ms. Helen Watchirs, Law Consultant for the AusAID-supported Indonesia HIV Prevention and Care Project, and Dr. Adrian Hayes, Senior Technical Advisor for the STARH Program, helped the MSH Legal Team identify and understand some of the key decentralization-related policy and legal issues that influence the performance of essential services for Communicable Disease Prevention and Control (e.g., HIV/AIDS) and Family Planning.

Finally, the MSH Legal Team expresses special appreciation for the day-to-day guidance and support of the MSH-M&L Team, especially Dr. Rob Timmons, Team Leader, and Dr. Bob Bernstein, Senior Technical Advisor. Essential support for this special Health Law Review activity was provided by USAID/Indonesia's Health, Population, and Nutrition Team Leader, Ms. Molly Gingerich, and the MSH-M&L Cognizant Technical Officer, Ms. Monica Kerrigan.

Executive Summary

1. Introduction

The Indonesian health law framework, in which legal authority is centrally held, is no longer appropriate for the decentralized health system. A legislative initiative by the Indonesian Parliament in 2001 to revise the present national 'basic health law' (Law 23/1992) did not involve DepKes. Concerned about deficiencies in the draft law, DepKes approached Management Sciences for Health (MSH) for legal technical assistance to support its own development of health law review and reform. DepKes expressed particular interest in obtaining information about international models, lessons learned, and "best practices" in health legislation. It identified the following eight legislative priority areas:

i. Performance of "obligatory functions" and basic health services by sub-national levels of government,
ii. Rights to health,
iii. Social health insurance,
iv. Governance and management of public sector health system facilities, services, and human resources,
v. Private sector health services,
vi. Protection of patients' rights,
vii. Support to population health generally, and
viii. Community empowerment and participation.

In August 2003, the MSH legal team developed a work plan and criteria for choosing the countries for the international review, and obtained the approval of DepKes to both. Australia, Finland, Malaysia, Netherlands, New Zealand, the Philippines, Spain, Thailand, United Kingdom, and USA were selected for the review. In the following months, review material was collected through internet and literature searches and personal contact with knowledgeable individuals in the review countries. The review was completed in November 2003, culminating in this Final Report. The Report:

- Provides comparative information and international examples on health laws and legislative frameworks for national health systems,
- Comments on international experience, and
- Reviews 'best practice' in assessing and developing *national capacities* for effective implementation and maintenance of the legislative and regulatory frameworks that are essential to a good national health system.

Given the extensive subject matter and the time and resource limitations of the consultancy, this Report should be considered a preliminary overview. It is accompanied by extensive appendices, including a bibliography and legislation list, that enable the reader to access more information.

2. Health laws and legislative frameworks for national health systems

When a nation decentralizes, it must systematically re-orient its strategic approach to governance, management and delivery of government functions (including its health system). International experience has shown that failure to do this effectively leads almost inevitably to a

decline in public health and, ultimately, to the health status of the country's population. One essential component of re-orienting a decentralized health system is recasting the *legal* basis for delivery of health services. Effective decentralization requires a health law framework that will:

- Reflect that the health of the nation is a whole of government responsibility,
- Ensure that the responsibilities of the various levels of government in relation to essential public health functions are clearly defined and resourced,
- Define which essential public health functions are clearly a national responsibility, and
- Set national minimum standards for performance of essential public health functions, plus monitoring and action to ensure that health services meet those standards.

Health laws are one of many instruments for implementing health policy. They should be enacted only when there is a clear policy goal that the legislation will achieve, and legislation is the most effective instrument of achieving it. Within a framework aimed at a coordinated approach to achieving national health policy goals / objectives, the health laws that underpin a national health system are generally expected to achieve one or both of the following: (a) Provide authority and governance to run essential public health functions within the public sector, and/or (b) Give government powers and authorities to set standards, regulate, and monitor the private sector. Table 1 of the Report lists essential health function areas, and corresponding areas where legislation is usually needed in order to provide that legal framework or authority.

3. International experience with health sector governance legislation

In devolved countries, where the sub-national levels of government are largely responsible for health service delivery, specific health laws may be useful to spell out which level of government is responsible for what and to what standard. Sometimes (though rarely) such laws can take the form of one overarching statute − 'umbrella legislation' − similar to the now outdated 'Health Law No. 23/92' in Indonesia. Such *'umbrella' legislation on health sector governance* is not common. A few countries, however, have developed a legal framework for the provision of services that allows for different local solutions. Such 'umbrella' legislation refers to the role responsibility of the national government, and then defines what the national body expects the subnational levels of government to do. Three legislative examples, as discussed below, come from Spain, the Philippines and Thailand. The Report also touches briefly on legislation, or proposed legislation, on the roles and responsibilities of the national and local levels in Finland, and New Zealand.

The *Spanish National Health System Cohesion and Quality Act — Law 16/2003*, provides the best example of a national 'umbrella' governance law that the review was able to identify. This fairly short but comprehensive law is the new legal basis for guaranteeing equal access to health care to citizens in the decentralized Spanish National Health System. It defines a list of services which the regional health authorities are obliged to provide. It establishes an Inter-territorial Council as the main coordination body between the health directors of the Autonomous Communities. It determines how the central government finances health treatment of individuals across regions. Finally, it provides for national 'umbrella' organizations for community involvement in health policy decision making.

The Philippines Executive Order 102/1999 (Redirecting the Functions and Operations of the Department of Health) is another short piece of subsidiary legislation that sets out succinctly a

clear rationale, role, and function for a national Department or Ministry of Health in a decentralized health system, where public sector health services are generally provided by subnational levels of government. It provides an interesting example of subordinate legislation that is able, without repealing or changing other health laws, to redefine the role of the national Ministry of Health in a decentralized system as one of leadership, coordination, and responsibility in achieving national policy goals and tasks in health.

The *draft Thai National Health Bill* provides a model for incorporating philosophies and values into national health legislation.

4. International experience with public health model laws

Model laws provide useful examples of 'best practice' in various areas of health law, particularly in terms of the legal framework necessary to underpin 'public' or 'population' health functions. These laws are not actual legislation. They are developed to support capacity building in health legislation through 'modeling' best practice. Significant initiatives include the Turning Point project in the US (managed by the Centers for Disease Control), Australian National Public Health Partnership, and the UK Partnership for the Health of the People (managed by the Nuffield Trust).

All the model law proposals explicitly include as an important objective the provision of a legal framework that:

- Identifies essential public health functions,
- Allocates responsibility for them, and
- Sets standards to ensure their adequate performance.

Model laws also establish the importance of maintaining a healthy community, which requires government to carry out essential public health functions. They set out basic principles that establish the importance of individual liberties and rights, and provide legal frameworks for balancing these two often conflicting objectives. For example, in US, Australia, and New Zealand, model or draft laws use a *risk assessment framework* as the basis for invoking powers and authorities of government to address threats to public health. Finally, all the approaches to developing model laws encourage and legally enable establishment of collaborations and partnerships to achieve common health goals.

5. International experience with legislation on DepKes priority areas

The Report focuses specifically on several of DepKes' key priority areas:

- *Right to health* can be understood as (i) a fundamental human right (e.g. Finland; *European Union draft Constitution 2003*; *Indonesian Constitution 1945*); as (ii) the right to *good quality* health services (e.g. New Zealand, Australian states and the UK), and as (iii) a right for all citizens, regardless of means, to equity and universal access to health care (e.g. through *social health insurance*).
- *Protection of patients and private health sector regulation* happen through legislation on training, licensing and credentialing of health professionals, and licensing of private health facilities. A review of the *Spanish draft Act of Regulating Health Professions* (currently before the Spanish Parliament) is included in the Report appendices as a good example of a broad health professional law.

- Legislative support to *community empowerment and participation* varies depending on the models of community participation chosen. In this area, the Report briefly reviews the legal provisions in *Spanish Law 16/2003*, the proposed New Zealand law, and in the model US and UK laws.

6. Legal and regulatory capacity

The best health laws in the world are ineffective if they are not accompanied by national legislative and regulatory capacity to develop, maintain, and enforce them. The Report discusses, in turn, three aspects of legislative and regulatory capacity − function, process and structure.

- The Public Health in the Americas Initiative of the Pan American Health Organization (PAHO) provides a 'best practice' description of the *functional* capacities required. 'Strengthening of institutional capacity for regulation and enforcement in public health' is one (No. 6) of its eleven essential public health functions (EPHFs). The description of this EPHF includes a definition of four necessary components of this capacity, as well as four indicators of compliance.
- In terms of the law-making *process*, OECD has set a benchmark for 'doing' regulations properly by providing a clear and organized generic approach to regulation making. Its guidelines for good decision-making principles include a checklist of ten criteria.
- *Structural* capacity focuses on legislative policy and regulatory development capacity within Ministries of Health. Indicators of capacity include having a proactive approach, adequate resourcing, effective collaboration, and skilled personnel with a mix of skills, including health law and policy expertise.

7. Future directions of legislative development in Indonesia

Decentralization has created an urgent need for new legislation on health sector governance, and an updated legislative framework for public health functions and service delivery. This Report provides a preliminary overview of the range of legal areas that are generally necessary to run an effective health system and meet a nation's health goals. DepKes might wish to seek resources from other donors and/or lenders to carry out further in-depth analyses of legal frameworks in such priority areas as:

- Essential public health functions and services (their definition, allocation of responsibility, resourcing, setting standards, and monitoring),
- Rights to health and access to health care, including national insurance schemes (e.g. patients' rights and pharmaceuticals),
- Licensing and regulation of public and private health care facilities and practitioners, and
- Preventing and managing communicable diseases.

I. Introduction

Having recently decentralized, Indonesia is moving to review the legal framework of its health system. Old health-related laws, regulations, and other legal instruments need modification, and new ones need developing to accommodate and support decentralization-related changes in health policies, strategies and programs at all levels of government. Existing legal instruments are under review by the Health Commission (VII) of the DPR (national legislature) and by DepKes (Ministry of Health). In this context, it is useful for DepKes to draw on the experience of other countries, regions, and types of government system in the development of the legal frameworks and regulatory environments that are necessary to achieve national health goals. In particular, 'model' laws and programs, already tested in the field, can provide potential examples and signposts in the basic areas where health law is necessary as to what best will legally equip a modern nation to face the health challenges of the 21st Century.

I.A. Background

Several factors led to the commissioning of this report at the current time in Indonesia:

Post decentralization and Law 23/1992 ("Basic Health Law")
The current health law framework within which the Indonesian health system operates is one where legal authority is still held centrally. When Indonesia decentralized responsibility for health, the old health laws were not changed to reflect the altered arrangements. In particular, the present national 'basic health law' (Law 23/1992) is no longer workable for a decentralized health system. In 2001, the Sub-Committee on Health (Commission VII) of the Indonesian Parliament (DPR) took the legislative initiative to revise Law 23/1992. A 'Health Law Academic Paper' was prepared by Dr. Kartono Mohamad. A new Health Law Bill was then drafted and "socialized" in 12 provinces and several districts.

DepKes was not involved either in writing the Academic Paper or in drafting the new Health Law Bill. It became concerned that the draft did not address or was deficient in several essential areas needed in any law replacing Law 23/1992. In March 2003, DepKes approached MSH for legal technical assistance to support its own development of health law review and reform. (See Appendix A for the terms of reference.) DepKes was especially interested in obtaining legal technical assistance on international models, lessons learned, and "best practices", in particular:

- The content and application of national laws and regulations in support of national health policies, and
- Health law frameworks for district/city level health functions and regulations in a decentralized system.

DepKes priorities
The following priority areas were identified by DepKes as being of prime importance:

- Assuring the performance (and quality) of "Obligatory Functions" and basic (especially "minimum/essential") health services in accordance with minimum service standards by sub-national (mainly district/city) levels of government.

- Issues around rights to health and national philosophies of health — why do these rights need to be protected, and how can it be done properly? (Rights to health here are understood in the context of human rights as related to health[1], and also in sense of the right to basic/minimum/essential health services performed in accordance with minimum service standards in terms of quality, accessibility and coverage.)
- Provision of a legal framework for social health insurance to implement whichever model of national health insurance is chosen.
- Governance and management of public sector health system facilities, services, and human resources.
- Regulation of the private sector to maintain minimum standards through legal/regulatory instruments on licensing of private facilities, certification of health professionals, accreditation for quality assurance.
- Protection of patients rights (e.g. in review, in confidentiality of medical records), and in respect to providing remedies and support for patient complaints of preventable adverse events in patient care (e.g. preventable infections or injuries acquired from health care).
- Regulatory framework necessary to support population health ('public health') generally (issues include requirements/duties for reporting of diseases and other events under public health surveillance; regulation of food, drug, and water safety and quality, air pollution, environmental health)
- Community empowerment and participation through e.g. fostering of partnerships, collaborations, and community involvement in public health, support for practice of traditional medicine.

Law 23/1992 is the main national health statute in Indonesia. It is fairly short, and follows the general Indonesian approach to national legislation. It sets policy and the conceptual framework, and identifies areas of regulatory activity. It leaves implementation to the development of further regulations and Ministerial Decrees that are to fill in the detail that makes the law actually workable[2]. DepKes priorities include ensuring that any new Indonesian health law replacing Law 23/1992 must, at least, incorporate those areas of health function that are presently covered by it.[3]

I.B. Objective

The objective of this report is to provide the DepKes Health Law Team (led by Prof. Azrul and Pak Faiq) with evidence and information about international models, lessons learned, and "best practice" regarding:

- Scope and essential components of health law(s), and

[1] In 2000, health and welfare as a human right of all Indonesians was added to the 1945 Constitution as part of a new Chapter (Chap. XA) on human rights. See Article 28 H (1); 2nd Amendment to the 1945 Constitution of the Republic of Indonesia.

[2] It is understood, however, that the regulations for Law 23/1992 were largely undeveloped.

[3] Law 23/1992 covers family health, health personnel, structure of health services, nutrition, food and drink, environmental health, occupational health, mental health, infectious diseases, curative medicine and rehabilitation, organ transplantation, health promotion, pharmaceuticals, drugs, school health, sports health, traditional medicine, health administration and financing, research, offences of abortion, selling body parts, removing organs or human research without consent, unauthorized/unregulated practice in medicine, pharmacy.

- Development, implementation, and applications of such law(s) in a decentralized setting.

To meet this objective, this report will:
1. Provide comparative information and international examples on *health laws and legislative frameworks for national health systems* — focusing on the themes and forms of laws that underpin the operation of health systems, and ensure performance of essential public health functions.
2. Comment on international experience and review *'best practice*' in assessing and developing *national capacities* for effective generation, maintenance and implementation of the legislative and regulatory frameworks that are essential to a good national health system.

The report provides a preliminary overview only. It aims to familiarize the reader with the range of legal areas that are generally seen as necessary to run an effective health system, and meet a nation's health goals. As well, it identifies a range of laws from other countries to illustrate how laws in these areas express the public health goals that they set out to achieve. Materials contained in the bibliography and legislation list in the appendices enable the reader to explore further, and access more information.

I.C. Limitations of the report

The report brings together information about health law frameworks and capacities. Its limitations should, however, also be noted:
- The report is an introductory overview only. Examining in depth all the law related areas that are currently important to health policy in Indonesia is beyond its scope.
- Health law initiatives in other countries (particularly developed countries) may not be relevant or applicable to Indonesia.

No country has identical needs either in its health policy or in the forms of law to implement policy. Countries have different cultural contexts, legal systems, attitudes to law, and levels of resources for public health. Indonesia differs from other countries in the following ways:
- The legal system in Indonesia is based on a combination of traditional laws, European (Roman-Dutch) law inherited from the Netherlands, and post independence Indonesian law. USA, Australia, New Zealand, and the UK have common law legal systems.
- The Indonesian public health system at national and regional levels has different challenges and issues from those in most of the other countries from where examples are drawn.
- Indonesia does not have the same resources or capacity for implementation as developed countries. This can make even good law ineffective.
- Community needs tend to weigh much higher than individual rights in Indonesia, and Indonesian laws are explicitly guided by 'communitarian' values. In contrast, individual autonomy and freedom from interference are highly valued in many of the countries reviewed, particularly in Europe, North America, and Australia.
- Most importantly, none of the model health laws and operating legislation from other countries reviewed is a 'single basic umbrella health law.' They do not comprehensively cover all the areas that health law should cover.

II. Methodology of the legislative review

MSH's team of technical advisers[4] commenced the work in Jakarta in August 2003. The team met with several key agencies and projects working in similar areas, held discussions with DepKes, and prepared a preliminary report.[5] Between August and November 2003, the team conducted the legislative review and wrote the report. Since the team's planned return trip to Jakarta was cancelled, the report was finalized by e-mail.

II.A. Approach to the legislative review

The legislative review approach focused on:

- Accessing health laws in the countries under consideration through Internet Web searches of legal and health data bases
- Literature search
- Review of the legal/regulatory frameworks for essential public health functions, and
- Review of relevant decentralization literature.

Review questions were generated around (a) the role of laws, and the health policy goals and themes that they address, and (b) the government levels at which they are expressed and implemented. Evidence of 'best practice' in using law to achieve public health goals was also examined.

The review focused on health legislation in two contexts:

- Internationally benchmarking public health model laws (or proposed laws), which have emerged from public health partnership activities in various countries. These model laws provide recommendations for 'best practice' legal frameworks for public health in decentralized health services. The model/ proposed laws reviewed are:
  - Centers for Disease Control (CDC) Turning Point initiative in the US
  - National Public Health Partnership (NPHP) in Australia − particularly the 'Legislator's Toolkit'
  - Partnership for the Health of the People project in the UK[6], and
  - Draft Public Health Bill in New Zealand

- Collection of comparative international examples of laws on the main health law themes and areas necessary to an effective health system.

---

[4] The MSH team consisted of Liza Newby (Australian health lawyer), Pak Bruto Wasisto (experienced Indonesian health bureaucrat), Ibu Wila Supriadi (Indonesian academic lawyer), and Riitta-Liisa Kolehmainen-Aitken (Finnish specialist in decentralization and coordinator of the team). The team was supported by the MSH staff in Jakarta, and by Dr. Mick Reid, Director of the Institute for International Health at the University of Sydney in Australia, and his staff.

[5] "Summary and Overview of Themes of Basic Health Laws Internationally − A Comparative Overview: Preliminary Draft Comments," MSH, Aug. 2003.

[6] Monaghan, Stephen, Dyfed Huws, and Marie Navarro. The Case for a New UK 'Health of the People' Act. London, UK: Nuffield Trust, 2003. http://www.nuffieldtrust.org.uk/policy_themes/docs/healthofthepeoplefinal160603.pdf

The countries reviewed were Australia, Finland, Malaysia, Netherlands, New Zealand, the Philippines, Spain, Thailand, United Kingdom, and USA. The review focused on these countries, because they have:

- Health and legal situations comparable to Indonesia in that they have decentralized health systems, and/or
- Developing nation status in the SE Asian region, and/or
- Similar (European based) legal system.

A further essential criterion for inclusion was that legal information was accessible to the review team within the short time available to conduct the review.

II.B. Identifying 'best practice'

Use of the term 'best practice' in relation to health legislation is difficult. Evaluation tools that would enable identification of 'best practice' are lacking. (An exception is a PAHO/CDC instrument to assess legislative and regulatory capacity. See section VII.)

The task of providing comparative international 'best practice' information was approached in two ways:

- By summarizing and reviewing model law initiatives, and
- By reviewing comparable public health laws and laws on health sector governance and standards regulation, particularly functioning examples of health law in the DepKes priority areas.

Model laws reflect 'best practice' because they have been developed proactively as models of reform. Strictly speaking, they are not laws, because they have not been enacted by parliaments. They are examples, which circulate for discussion and adoption with the objective of improving standards of public health legislation.[7] (See Sec. V below).

III. Law and the health sector in a decentralized environment

Functioning, effective legislative frameworks and regulatory environments are the foundations of a national health system. For all countries, on-going systemic and coordinated approaches are essential for continually improving legislative and regulatory frameworks for health. Without such efforts, laws will very quickly become out of date and incomplete. International 'best practice' indicates that establishing and maintaining a legislative framework for the public health system in a decentralized system is clearly a responsibility of the *national* government.

III.A. Role and critical responsibilities of an NHA in a decentralized country

Every country has one institution, usually a Ministry of Health or a National Department of Health, that it considers its highest national health authority (NHA). The main decentralization in the country law sets the parameters within which this NHA operates. Its precise responsibilities, structure and internal organization vary between countries.

[7] Note that in the US several states have adopted parts of the Turning Point model laws through their legislatures. Some of these were presented at the '*'Law and the Public's Health in the 21st Century'* 2002 Conference.

The role of the national health authority changes radically, when the responsibility for health service delivery is transferred to local governments. In its new, vitally important role, the NHA must steer the country's overall health system, and act as the guardian of the whole population's health, without having direct control of most health programs and facilities. To serve in this dual role, the NHA must assume responsibilities in three main areas. The NHA must:

1. Ensure that adequate attention is given to national health priorities when health services are planned and provided.
2. Guide and promote the development of a cohesive, nation-wide health delivery system that is focused on quality, access and equity.
3. Secure the availability, quality and equitable distribution of those human, financial and material resources that are critical for service delivery.

The NHA implements its new responsibilities by undertaking a number of important management functions. The most important of these are shown in Table A (Appendix C), drawn up on the basis of international experience. Where local governments are responsible for health, the NHA must exercise these functions in a spirit of shared leadership with the local level.

Using this kind of approach, 'best practice' in relation to the *legal and regulatory* aspects of these management functions would indicate that a competent National Health Authority in a decentralized health system is capable of a 'stewardship' role, involving:

- Development and implementation of basic health laws and regulations in areas of national priority;
- Use of sectoral health law to define which level of government does what in health, including the obligations and authority limits of regions;
- Development of national regulations which set standards for delivery of essential public health functions at national and regional level; and
- Support and assistance to regional governments to develop regional health regulations in compliance with national health laws.

(See post p. 31.)

The experience with decentralization around the world brings warning examples of what can go wrong, if the functions in Table A are not held as a national level responsibility or if they are not competently executed. Safeguarding and improving a population's health require coherent management systems, adequate funding of priority services, good disease prevention programs, and promotion of healthy behaviors. Regrettably, the cohesion of the national health system has suffered in many countries. For example, the integration of primary care with hospital services and the referral links between them are lost, when primary care and hospital facilities are managed by different local-level governments (as in the Philippines).[8]

Securing the availability, quality and equitable distribution of trained staff, pharmaceuticals and medical technology requires national oversight. Where drug registration is decentralized (e.g. in

[8] In the Philippines, the integration is being restored through "integrated local health zones." These zones link health service delivery provided by a referral hospital with surrounding municipal health services. Their establishment was ratified in an agreement, which was jointly signed by the President of the League of Provinces, the President of the Union of Local Authorities, the Secretary of Health, and the Secretary of Interior and Local Government. This agreement became Philippine national law under an executive order.

India), pharmaceuticals of questionable quality freely cross geographic boundaries. Similar problems occur, if registration of health personnel and accreditation of training institutions are not handled by a competent authority. In most countries, this can only be done at the national level. The rapid growth of private institutions of higher education, some of questionable academic quality, highlights the importance of national oversight of the quality of their educational programs and graduates.

The unwillingness or inability of many local governments to budget sufficient financial resources for health service delivery in general or for national priority programs in particular is another important concern to NHAs in several devolved countries.[9] Preventive programs and health promotion have been particularly vulnerable under local government responsibility for health. Many local governments have shown a strong preference for funding clinical services instead.

Infectious diseases do not respect geographic boundaries, thus threatening the whole population. Surveillance and control of important communicable diseases require national coordination, and special epidemiological and clinical expertise and resources. These are unlikely to be available at the local level.[10] Reliable and up-to-date health information is essential for any NHA, if it is to act competently in its dual steering and guardian role. The transfer of power to local governments has, however, often fractured the national health and management information systems. In some countries, local managers have even questioned the national health authority's right to continue receiving local level data.

The post-decentralization responsibilities of a national health authority are thus crucially important for ensuring the population's health. An NHA can use many different kinds of instruments to implement these responsibilities. Laws and regulations are one such instrument that can ensure the continuation of services and the provision of essential public health functions to a sufficient standard nationally. Thus, providing such legal instruments, and recasting the legal basis for delivery of health services to make it appropriate for a decentralized system are essential components of re-orienting a health system after it has been decentralized. As the UK Nuffield Trust points out, "With the advent of devolution, fundamental legal rationalization is required."[11]

Effective decentralization requires a health law framework that will:

- Reflect that the health of the nation is a whole of government responsibility,

[9] In Uganda, primary care funding dropped by a third within the first three years of decentralization to the district level. Primary health care services were funded through a block grant, giving the district governments the freedom to allocate the money as they wished. Uganda now funds primary health care through a conditional grant. In Papua New Guinea, nurse aide training programs were initially transferred to provincial governments, which did not have sufficient resources to sustain these programs. Within three years, the country's 13 nurse aide schools, producing 135 graduates annually, were reduced to only three schools and thirteen graduates.

[10] Most devolved countries have kept the surveillance and control of their most important diseases as a national level function. In these countries, the NHA supplies vaccines and TB drugs, and carries out the overall coordination of these programs, even if EPI and TB control activities are carried out by local government staff.

[11] Monaghan, Stephen, Dyfed Huws, and Marie Navarro. *The Case for a New UK 'Health of the People' Act*. London, UK: Nuffield Trust, 2003. http://www.nuffieldtrust.org.uk/policy_themes/docs/healthofthepeoplefinal160603.pdf

- Ensure that the responsibilities of the various levels of government in relation to essential public health functions are clearly defined and resourced,
- Define which essential public health functions are clearly a national responsibility, and
- Set national minimum standards for performance of essential public health functions, plus monitoring and action to ensure that health services meet those standards.[12]

III.B. Legal frameworks and laws in defense of health

Public health law can be defined as:

> The legal powers and duties of the State to ensure the conditions for people to be healthy … and limitations on the power of the State to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for the promotion or protection of the community's health. (It) operates as a structural determinant of population health[13].
> *US Conference 'Law and the Public's Health in the 21st Century,' 2002*

> The synergistic intersection of public health practices and the law…… Legal preparedness… is a critical component of public health preparedness… because it offers a framework for public health action'[14]
> *US Conference' Law and the Public's Health in the 21st Century,' 2002*

Public sector health services require legal authority to function. Similarly, all health sector activities, public or private, require some legal definitions of standards and enforcement powers, if they are to be regulated at all. Periodic review and updating of current laws and regulations are a necessary part of discharging 'essential public health functions' at the national level. This was pointed out by the recent initiative by PAHO and the CDC that is discussed further in Section VII of this report. Various other international initiatives have also begun to systematically evaluate existing regulatory environments, and generate review, reform, and capacity improvements where required.[15]

No country, including Indonesia, has only one "health law." International experience shows that decentralized countries (including wealthier ones like Australia and the US) have developed or are developing legislative frameworks and/or laws that will variously specify components of the following:

- How the total health sector is governed (i.e. roles of the NHA and decentralized levels, financing of the sector, minimum service packages, regulation of the private sector), and
- What public health services are delivered by government agencies, to what beneficiaries, and how (i.e. performance of obligatory or essential public health functions, standards).

---

[12] This is so whether services are delivered by national government agencies, NGOs, the private for-profit sector or (most importantly) sub-national levels of government.

[13] Horton, Heather et al. "The Dimensions of Public Health Law Research." *Journal of Law, Medicine and Ethics*. Vol. 30 (3), 2002. http://www.findarticles.com/cf_dls/m0DPE/3_30/95843958/p1/article.jhtml

[14] Conner, McGown and Curran, "Conference Synopsis and Observations," *Journal of Law, Medicine and Ethics*, Vol. 30/3. pp 210, 2002. http://www.findarticles.com/cf_dls/m0DPE/3_30/95843960/p1/article.jhtml

[15] Such initiatives include the Turning Point in the US, the National Public Health Partnership in Australia, and the work of the Nuffield Trust in the UK.

Within this context, health laws underpinning a national health system are generally expected to achieve one or both of the following:

- Provide authority and governance to run essential public health functions within the public sector, and/or
- Give government powers and authorities to set standards, regulate, and monitor the private sector.

The first area, authority and governance for essential public health functions, includes:

- Planning, funding, and maintaining standards of public health care
- Establishing and running health care services
- Managing infectious diseases, emergencies, and food, air, and water quality
- Conducting and/or funding review
- Planning for and training the health workforce
- Promoting active partnerships between public and private sectors, and the community
- Setting standards.

The second area covers regulation of private sector health care services, e.g. licensing and certifying health professionals, licensing hospitals, financing through health insurance. It also encompasses regulation of general private sector industries, whose activities could constitute threats to public health, e.g. through compromising provision of clean air and water, unsafe food and drugs. Some laws cover both public and private sectors. Examples of such laws include standards for patients' rights, and standards for licensing health care facilities. These apply equally to privately run and publicly run health services.

Below is a brief list of the health function areas where legislation is generally needed to provide a legal framework or authority.[16] Table B (Appendix C) indicates the countries where the MSH team identified (and in some cases obtained) examples of laws from the areas listed. These are grouped according to their national origin. Appendix D lists all significant legislation by country that the team identified. These documents, together with Table B, are the resource that allows follow-up and location of legislation from any country relating to a specific area.

[16] Each country organizes its legal 'categories' differently, according to its needs and legislative history. The categories used in this report are based on those used generally (and loosely) in Australia. (See *Australian Health and Medical Reporter*; CCH Sydney)

Table 1: HEALTH FUNCTION AREAS GENERALLY REQUIRING LEGISLATION

1. *Health Services and Facilities*

- Licensing and regulation of private health care facilities
- Establishment, funding, and governance of public health care facilities
- Regulation of special health procedures — transplants, organ donation etc.
- Regulation of private laboratories and establishment and regulation of government laboratories

2. *Public Health*

a) *Individual health and safety related to:*

- Mental health — provision of services, compulsory treatment etc.
- Legal drugs/pharmaceuticals/therapeutic goods
    - Standards — testing, regulation, licensing to provide
    - Distribution — conditions (control of distribution by type of drug and its level of potential harmfulness, contracting, subsidizing)
- Occupational health and safety
- Safety in daily activity and health promotion, e.g. anti-smoking, driving safety (seatbelts etc.), standards of hygiene for food and drink (e.g. testing food quality, regulating commercial food outlets)
- Trade practices and product liability
- Prevention of non-communicable diseases, e.g. fluoridating water, iodization of salt

b) *Communicable diseases*

- Prevention —notification and detection (screening, testing powers, laboratory standards, data protection)
- Management and treatment — quarantine; emergency powers, isolation
- HIV/AIDS epidemic: specific laws that maximize potential for public health interventions to deal with the epidemic and minimize barriers (e.g. authorized needle exchange, condom promotion, accessibility and quality, sex industry health checks, reproductive education for adolescents)

c) *Environmental health*

- Air, water quality[17]
- Pollution control
- Control of hazardous substances and goods — e.g. poisons and dangerous chemicals, radiation
- Building standards for housing, public and commercial buildings
- Sanitation and waste disposal
- Emergency and disaster management powers

[17] E.g. in Indonesia the term 'clean' is applied to characterize the quality of water. Water that is 'clean' is not necessarily potable/drinkable. Health agencies have authority and responsibility for setting criteria for 'clean' water and for measuring its chemical and biological purity. But other agencies have responsibility and authority

Table 1: HEALTH FUNCTION AREAS GENERALLY REQUIRING LEGISLATION

3. *Patients' and Community Rights and Responsibilities*

- Rights and obligations to participate in public health planning and service delivery, e.g. through laws requiring establishment of consumer advisory bodies, community/health sector partnerships, consumer representation on local/State governance/advisory health boards
- Rights of privacy and confidentiality — regulation and control of private information collected and held by government or health care providers
- Rights to complain/get compensation for poor health care services[18]
- Rights to access health care/information/clean safe environment

4. *Health Resourcing*

a) *Technology Support*

- Regulation of new health technology — to establish safety, effectiveness, and quality as a condition of use within the country[19]
- Regulation of traditional medicines and practices
- Review — funding, establishment of public sector review facilities
- Regulation of 'cutting edge' technologies — genetic, reproductive technology

b) Financial Support

- Funding formula for national to regional health sector resourcing
- National health insurance schemes
- Regulation of private health insurance
- Guaranteed levels of health funding

c) Workforce Development

- Training
- Licensing and credentialing − regulation of health professional standards: registration, standards of practice, educational requirements for registration, discipline processes
- Planning, recruitment, placement, career development

for the provision and the 'cleanliness/potability' of water. Multi-sectoral policies, and laws that would integrate these multi-sectoral authorities and responsibilities are needed.

[18] Australia, for example, has a system of 'health ombudsmen,' as well as medical malpractice litigation. The ombudsmen investigate and resolve complaints by consumers about standards of health care.

[19] This is generally achieved through legislation which establishes a Technology Advisory Board of experts and standards against which the Board assesses new technology.

III.C. Moving from policy to law

Laws are just one of many instruments for implementing health policy. Health laws should be enacted only when:

- There is a clear policy goal that the legislation will achieve, and
- Legislation had been identified as the most effective instrument of achieving it.

Developing policy and the legislation to implement it proceeds through several steps. These include assembling a policy team with expertise in the area, collecting information, developing strategy options, consulting with stakeholders, producing a 'white paper'(in Indonesia, an 'Academic Paper'), circulating the white paper widely. The key outcomes/benefits of this process should be:

- Laws that are appropriate to the policy goal, cost effective and implementable
- Strategies and resources to implement the law[20]
- Awareness and ownership by those who are responsible for implementation and also by the stakeholders affected by it. Legislative initiatives should have their sustainability embedded in the process whereby they were developed.

Table 2 below is an example that illustrates the pathways taken by development of anti-smoking policy. These include the necessary legislative components, e.g. regulating sale of tobacco to minors, tax on tobacco sales with the revenue applied to health promotion, restricting advertising.

Table 2. Health law as a instrument of policy /planning/implementation in health

Vision building	–	Improving 'Health for All'?
↓		↓
Data collection	–	Identification of lung disease as a priority health issue
↓		↓
Policy goal	–	Reduction of lung cancer and assoc. costs to health care
↓		↓
Planning	–	Identification of strategies, includes interventions to reduce tobacco smoking
↓		↓
Implementation		• Establishing antismoking campaign • Community education • **LEGISLATION regulating tobacco product promotion and sale**.

[20] Laws should not be passed, for example, regarding sanitation standards for sewage disposal without ensuring that there are trained inspectors with resources to inspect sewage treatment plants and prosecute for non-compliance, or on governance of hospitals through hospital boards without the resources (and if necessary) the capacity building support to set these up.

IV. International experience with health sector governance legislation

Laws develop historically. The 'mass' of health statutes in a country represents incremental evolution as legislatures react to particular health governance requirements and 'events'. Many decentralized countries with a federal form of government (such as the US and Australia) do not legislate directly on national health governance. They rely on general constitutional provisions to make clear who does what and to what standard. In contrast, countries that decentralized through devolution may well require specific health laws to spell this out for the health sector. Their Constitution or general decentralizing laws are often too imprecise in respect to the details in each sector, such as health.

In devolved systems of government, national health authorities may have overall responsibility for 'the health of the nation' but it is the sub-national levels of government that are largely responsible for health service delivery. As discussed earlier, this can be problematic for achieving some national uniformity and minimum standards, as well as for national policy goals and priorities. Laws can help, but in no country does one 'basic health law' cover 'national health governance.'

The model of a *national 'umbrella' law*, as the term is understood in Indonesia, can:

- Set out the philosophical basis and policy priorities for the health of the population
- Define the role and responsibilities of the national government, including setting standards and goals for the health system
- Set out the shape and form of the health system, and define which level of government has responsibility for what
- Identify the health function areas that will need more detailed subsidiary legislation, and responsibility for performance of that function.[21]

This review did not find many such 'umbrella laws' in the jurisdictions examined. They are not common. In a few countries, however, laws were found that could be characterized as national 'umbrella' legislation *on health sector governance*. These 'umbrella' governance laws provide a framework for the provision of services that allows for different local solutions. Typically, they legally specify and define responsibilities as divided up between the various levels of government. This is often embedded in legislation that legally 'creates' a responsibility for population health, and for providing health services. Commonly, these laws refer to the role responsibility of the national government, and then define what the national body expects the sub-national levels of government to do. Regional or local level governments have responsibilities for actual performance of health service delivery. The Acts do not regulate in great detail the range, content and way of organizing the provision of services by local level governments. This is left to local legislatures.

Legislation of this type was identified from Spain, Philippines, Thailand, Finland, and New Zealand. Three examples are described in this report:

- Spain: Law 16/2003 on Cohesion and Quality of the National Health System

[21] E.g. an 'umbrella' law could specify that setting standards of food safety is a role of national or regional level health authorities, but identify that their detailed definition and enforcement is a matter for local regulation.

- Philippines: Presidential Executive Order 102/1999 on the National Department of Health
- Thailand: National Health Bill (draft)

Other, less comprehensive examples from Finland and New Zealand are also discussed below.

IV.A. Spanish National Health System Cohesion and Quality Act — Law 16/2003

The Spanish National Health System Cohesion and Quality Act – Law 16/2003 is the best example of a national 'umbrella' governance law that the review was able to identify. (See Appendix G for the full text.) This law is the new legal basis for guaranteeing equal access to health care to citizens in the decentralized Spanish National Health System. (See Appendix J for a summary of health system governance in Spain.)

Main provisions of Law 16/2003:

The **aim** of this Bill is to "set out a legal framework for the coordination and co-operation of the public health authorities in the exercise of their respective functions in order to guarantee equity, quality and social participation in the National Health System. …… The public health authorities shall ensure the cohesive operation of the National Health System in order to satisfy the right of citizens to health protection"

The main **objectives** of the Law are to (1) coordinate and homogenize the services provided by the public health system across regions in terms of treatments and products offered; (2) improve quality and (3) guarantee equal access to health services across regions. To do so, the Law includes, among others:

- List of services which the regional health authorities will be obliged to provide, and which can be complemented by them
- Establishment of an Inter-territorial council as the main coordination body, in which health directors of the seventeen Autonomous Communities (ACs) are represented.
- Fund financed by the central government to pay for health treatment of individuals across regions.

The Law sets out the **role of the national government** as:

- Basic health legislation and general coordination
- Regulation of the financial aspects of social security (Ministry of Labor and Social Affairs)
- Pharmaceutical policy regulation, including regulation of drug prices
- Standardization of medical and health products
- Regulation of undergraduate and postgraduate training
- Regulation of most aspects of recruitment and employment of health personnel (Ministry of Public Administration), and
- Review and national data collection.

"Best practice" because…?

The breadth and structural approach of the Spanish law are directly relevant to the Indonesia experience. It is a fairly short law that defines the functional areas, and establishes relevant agencies to carry some of them out. It also identifies the subsidiary legal instruments, such as internal regulations, national/regional agreements, and regional laws that are needed to fill in the detail. Law 16/2003 is comprehensive. It covers most governance areas of the health system at

national and regional levels. (Note: It does not cover all areas, however, but only those needed at the time.) The Law also provides for national 'umbrella' organizations that allow for community involvement in health policy decision making.

IV.B. Philippines Presidential Executive Order on the Department of Health

The Philippines Executive Order 102/1999 (Redirecting the Functions and Operations of the Department of Health) legally changed the role of the national Department of Health (DOH) after decentralization of the health system. (See Appendix H for the full text.) It is a very short piece of subsidiary legislation. However, it sets out succinctly a clear rationale, role, and function for a national Department/Ministry of Health in a decentralized health system. Interestingly, it does this under the 'umbrella' authority of the primary *decentralizing* legislation, and not health legislation.

Main Provisions:
The **Preamble** establishes the change of law as necessary because, due to devolution to local governments, the national Department of Health is 'transformed' from being the sole provider of health services to:

- Providing some health services
- Providing technical assistance for health, and
- Operating as the national technical authority on health, to ensure standards of quality health care, health promotion and health protection. These standards apply to local governments units, non-government organizations, private organizations and individual members of society.

Section 1 of the EO mandates the DOH to assist local government units (LGUs), people's organizations (PO) and other members of civic society to implement programs, projects and services that will:

- Promote the health and well-being of every Filipino
- Prevent and control diseases
- Protect individuals, families and communities exposed to hazards and risks that could affect their health, and
- Treat, manage and rehabilitate individuals affected by disease and disability.

Section 2 discusses the various roles of the Department of Health. These fall into a range of categories, such as:

- *Lead agency* in planning, setting strategic objectives, review, and emergency response capacity
- *Direct service provider* for large population wide programs
- *Technical authority and oversight agency* for monitoring and evaluation, and for disease control and prevention
- *Administrator* of selected health facilities at sub-national level (regional referral centers)
- *Advocate* for healthy lifestyles and health promotion
- *Innovator and facilitator* for new strategies and public/private partnerships
- *Capacity builder* for "local government units, the private sector, non-government organizations, people's organizations, national government agencies, in implementing health

programs and services through technical collaborations, logistical support, provision of grant and allocations and other partnership mechanisms
- *Protector of standards* of excellence in training and education, and
- *Implementer* of a national insurance scheme.

Section 3 sets out powers and functions to accomplish these roles, in particular the transition to a decentralized management of health services and functions.

"Best practice" because…?
This legislative instrument provides a good example of supplementing existing health laws by clarifying the new role of a NHA after decentralization. It is a useful model for Indonesia because (a) the types of legal instruments are similar (presidential order/decree), (b) it comes from a developing country in the same region, and (c) it is simple and supplementary. EO102/1999 does not require a major new legislative development process. It simply adds to and supplements existing law.

IV.C. Thai Draft National Health Bill

Thailand is reportedly developing a draft National Health Bill. The MSH team was unable to get access to an English translation to conduct a comprehensive review. Reference to this Bill, however, in another Thai text, translated into English,[22] was considered sufficiently interesting and useful to be included here.

Main Provisions:
The Bill appears to define the underlying values/policy goals which inform the Thai national health system. These are:[23]
- Holistic: Health should be defined as a dynamic state of complete physical, mental, social and spiritual well-being. In this regard, health development and health care should be integrated and designed to respond to all of these dimensions.
- Participatory: To comply with the new constitution, all stakeholders must be regarded as partners in executing the health systems of the country.
- Healthy public policy: Public policy promulgated in the country should be conducive to health development.
- Equity: There should be an equitable distribution of health and health care services, and fairness of financial contribution.
- Efficiency: Health service must be re-oriented from passive to be proactive so that cost-containment of health care may be truly achieved. Health technology and intervention need to be well assessed to optimize the benefits for the people.
- Quality: Quality accreditation should be undertaken by the State so that unqualified health care will not be disguised by distorted advertisement.
- Consumer empowerment: Consumers should be empowered to be capable of safe-guarding themselves from unjust propaganda and delivery of health services and products.

[22] Wibulpolprasert. Suwit (Ed.) "Chapter 11. Health Systems Reform and Decentralization," in the *Thailand Health Profile, 1999-2000*. Ministry of Public Health, Bureau of Policy and Strategy, Thailand, 2002.
[23] The report paraphrases from the text of Dr Wibulpolprasert. (See above.)

- Self-reliant: Thai society should rely more on the country's own health capacity.
- Health technology development and review should be aimed at empowering the community and national authority so that they will not depend only on imported technology and concepts.

"Best Practice" because…?
The Thai legislative initiative is of interest because it provides a model from an Asian developing country for incorporating philosophies and values into national health legislation. It sets out useful and helpful "values" upon which health governance laws could be based.

IV.D. Other Examples

Other useful examples are drawn from legislation on the roles and responsibilities of the national and local levels within a decentralized health system. They come from:
- Finland: Primary Health Care Act 1972
- New Zealand: Public Health and Disability Act 2000, and
- US model state public health law (See section V)

Finland – Primary Health Care Act 1972
In Finland, the main responsibility for arranging health services lies with the *municipalities*. (See Appendix K for a summary of health system governance in Finland.) The 1972 Primary Health Care Act obliges them to provide the following services for their inhabitants:
- Health promotion and disease prevention
- Medical care
- Medical rehabilitation
- Dental care
- School and student health care
- Occupational health care
- Cervical and breast cancer screening
- Family planning services
- Mental health care (when it is appropriate to provide it at a health center)
- Ambulance services.

Below are two examples of text assigning responsibility from the Finnish Primary Health Care Act. The examples are drawn from an English translation of the Act. (The full text is available in English at http://www.finlex.fi/pdf/saadkaan/E9720066.PDF.)

> Section 2:
> 1. "General planning, guidance and supervision concerning primary health care is the responsibility of the Ministry of Social Affairs and Health.
> 2. Guidance and supervision concerning primary health care within each province is the responsibility of the provincial State office"

Section 14:

1. Municipalities shall perform the following primary health care functions…….”

Sec. 14 then goes on to list them in detail. (See above.)

New Zealand − Public Health and Disability Act 2000

This legislation establishes District Health Boards (DHB), and allocates functions to them within New Zealand’s devolved health system. E.g.: “Section 19 (1) This section establishes each of the organizations named in Column 1 of Schedule 1 as a District Health Board in respect of the geographical area specified in that schedule for the organization”.

Objectives and functions of District Health Boards are set out in Secs. 22 and 23.
Sec 23 **(**i): ‘to ensure the provision of services for its resident population and for other people as specified in its Crown funding agreement:

1. to actively investigate, facilitate, sponsor, and develop co-operative and collaborative arrangements with persons in the health and disability sector or in any other sector to improve, promote, and protect the health of people, and to promote the inclusion and participation in society and independence of people with disabilities
2. to issue relevant information to the resident population, persons in the health and disability sector, and persons in any other sector working to improve, promote, and protect the health of people for the purposes of paragraphs (a) and (b): and
3. ……..
4. to monitor and collect statistics on the heath status of the population in the geographical area”.

US Model State Public Health Act[24]

(Note: This Act refers only to ‘essential public health services and functions.’ They are defined as ‘assuring the conditions under which the population can be healthy.’)

> Sec 2-103 a) ‘State (regional level) and local governments are responsible for assuring that the public health system accomplishes the mission of public health….

Sec 2-104 − to carry out the mission of public health, State and local health agencies are authorized to provide or implement essential public health services and functions….”

[24] See also post p. 22, et sequa.

V. International experience with public health model laws

V.A. Efforts to develop public health model laws

Updating public health law
Public health laws/regulations provide one of the implementing arms for 'doing' public health functions which focus on maintaining a healthy population as a whole. Without them, the State has no legal authority to act, for example, to prevent or control infectious disease outbreaks (e.g. compulsory vaccination, notification etc.) or to manage national emergencies. It cannot even require restaurants to handle food in a way that they do not poison their customers! All countries with a public health system have some laws and regulations that provide authority and powers for the implementation of public health activities. However, existing public health laws are often outdated in regard to current public health issues.

Purpose of model health laws
Model or draft laws provide examples of progressive up-to-date legal frameworks for public health. Such frameworks support proactive approaches from government at all levels working in partnership with each other, the private sector, and the community. They are useful examples of 'best practice' in various areas of health law. Similar, useful models can come from legislation review and reform proposals that have been developed for public consultation and discussion.

Model public health laws/draft Bills from four countries
Significant initiatives to develop proposals for public health legislation have recently taken place in several countries. In three of them, this included proposals for comprehensive public health legislation, and in two, the actual drafting.

The initiatives are:
- *Turning Point project in the US*, run by the Centers for Disease Control (CDC). Sponsored by a coalition of government agencies and private funding, it provides model public health laws for the state (sub-national) level in a decentralized (federal) system.
- *Australian National Public Health Partnership (NPHP)* provides models of cooperative legislative and other public health activity in a decentralized (federal) system. This policy approach of non-legislated co-operation has valuable lessons for any decentralized country.
- *UK Partnership for the Health of the People*, run by the Nuffield Trust, has used the partnership model to develop proposals for a comprehensive 'Health of the People' Act in a devolving system. It also tested methods to evaluate the effectiveness of legal instruments as public health intervention tools.

In addition, a number of the countries reviewed have draft public health legislation in development. The New Zealand Public Health Bill Discussion Paper 2002 proposes a national public health Bill for a devolved (unitary) system. It is particularly noteworthy because it adopts an explicit 'risk assessment' approach to public health regulation.

V.B. Limitations of the model approach

Recognizing the limitations of the model approach is important, if the initiatives described are used as legislative models. Firstly, these laws are not yet in force. Although they are sponsored by government at the highest level, they are intended as 'ideal examples' that legislators can draw from in developing their own regulatory framework. Secondly, these laws are not comprehensive. They are intended as a guide in specific areas of public health. They do not address issues of governance or management of health services, nor do they comprehensively cover all the areas that health law should cover. As a result, there are large gaps in the 'modeling' that they can provide for health law development in Indonesia.[25]

V.C. Overview of the key model laws

USA: Turning Point — The Model State Public Health Act[26]
This Act has nine Articles. (See Appendix F.) It sets out the purposes, missions and functions of state and local level public health agencies. The rest of the Act covers:

- Public health infrastructure
- Collaboration and relationships with public and private sector partners (including the community)
- Powers and authorities of public health agencies
- Powers and actions for public health emergencies
- Health information and privacy, and
- Criminal and administrative provisions.

Australia: NPHP — model health legislation priority areas
In Australia, the NPHP has developed a 'Legislator's Toolkit.' This is intended to provide a resource to legislators at all three levels of government (depending on the topic). It covers a number of key public health areas of law, but by no means the whole field. Currently, the Toolkit includes reports on nine subjects:

- Role of local government
- Implementation options for national legislative schemes in public health
- Notifiable diseases and notification mechanisms
- Requiring immunization certification for entry to school and child care
- The application of risk management principles in public health, with a focus on environment law
- Passive smoking
- Public health laws for Aboriginal and Torres Strait Islander communities, and
- Regulating infection control in the body art industry.

[25] Australia's model is particularly restricted. The 'risk assessment' model law focuses on environment law only, and the Legislator's Toolkit covers only a few selective aspects of some basic public health issues. There is no focus on health service provision, health governance or management.
[26] In USA and Australia, 'state' is the level of government equivalent to an Indonesian province.

New Zealand: Proposed Public Health Bill

The Proposed New Zealand Public Health Bill is complementary to the 2000 Public Health and Disability Act, which established the structure for delivery of health services in that country. The Public Health Bill covers:

- Information management
- Promoting public health
- Preventing ill health and promoting child health
- Care, management and compulsory powers for people with communicable conditions
- Contact tracing, and
- Border protection.

UK: Proposed Health of the People Act

The available information on the proposed UK Health of the People Act is not specific about what should go into the legislation. The purpose of the Act is to consolidate into one package the establishment of health rights of the people, duties of government to population health, and specific health powers and authorities. It is also aimed at creating a new national authority, which has responsibility for monitoring the nation's health and the governments' performance of essential public health functions, and for providing advice.[27]

V.D. What topics do model public health laws/draft Bills cover?

This section of the report provides a brief overview of the model public health laws/draft Bills, mentioned in the previous section. It is organized by topic.

V.D.1. Principles and purposes of model laws

The model laws set out basic principles that establish the importance of individual liberties and rights (to health, privacy, respect and dignity, non-discrimination etc.), and the importance of maintaining a healthy community. This requires government to carry out essential public health functions for the sake of community health. Such government action may sometimes conflict with individual rights.[28] (See below under 'risk assessment.')

Statements of principle are intended to provide guidance on how to interpret and apply the content of the laws. Examples of such statements, drawn from the model laws, are set out below. A variety of terms are used — 'principles,' 'mission,' 'values,' 'rights and duties,' etc. — but the import is similar.

[27] On January 8, 2004, the Nuffield Trust, the UK Public Health Association and the Faculty of Public Health jointly organized a national conference, called *Health of the People: The Highest Law?*. The conference considered whether the UK needs a new Health of the People Act, and if so, what brief should be given to the Parliamentary Counsel on drafting such a Bill.

[28] E.g. religious groups may object to immunization and other preventive medical treatments. However, attaining a minimal level of community coverage is necessary to protecting a population's health. On that basis, a government can legally justify requiring that all children be fully immunized.

New Zealand – Proposed Public Health Bill

The New Zealand Ministry of Health Discussion Paper on the draft Bill[29] articulates particularly well the balance that must be struck in health legislation. This balance is between two sets of values that may be in opposition to one another. The draft Bill establishes **principles** for balancing these competing values, using the 'risk assessment' approach. (See below.)

The proposed Bill states:

> In general… societal expectations embody values such as the importance of personal autonomy, freedom, privacy and human dignity. The new Public Health Bill will recognize and give expression to these values. At the same time, the Bill is a vehicle for implementing other rights and values. Such values relate to ideas about justice, equality (and minimizing inequalities), community, wellbeing and interdependence. They concern the protection of health and wellbeing of people and communities…… (They) recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, and that steps to be taken to achieve this right include those necessary for the prevention, treatment and control of epidemic, endemic, occupational and other diseases.
>
> The Public Health Bill will aim to implement both sets of values. …. In (some) instances (however), it may not be possible to give full expression to both sets of values. Several criteria must be borne in mind when deciding whether, and to what extent, one value may be given fuller expression than another. ….. Examples include the:
>
> - Relative importance of the provision
> - Likely effects of the provision or policy in promoting or detracting from various values
> - Impact of any proposal in terms of the kind and degree of harm that may be involved – proportionality
> - Extent to which harms may be imposed on people involuntarily
> - Availability of options and their costs (to people individually, their communities and society as a whole)
> - Availability of means to mitigate the effects of giving less weight to a particular value.

US – Model State Public Health Act

Sec. 2-101 refers to the **mission** of the State to protect and promote the health of the public through the public health system, while respecting individual rights. The state is to do this by:

- Assuring conditions under which people can be healthy
- Providing essential public health services
- Encouraging collaborations with the private sector
- Making available resources adequate to provide for essential public health functions.

[29] Public Health Legislation - Promoting Public Health, Preventing Ill Health, and Managing Communicable Diseases. Discussion Paper. New Zealand Ministry of Health, 2002. http://www.moh.govt.nz/moh.nsf/0/10b6c56858141ed9cc256c7c006f50d5/$FILE/public-health-discussion.pdf

UK – Proposed Health for the People Act

The proposal for the UK Act argues for establishment of a general statutory **right to public health**, and a corresponding statutory duty to care for population health:

> A 21st Century UK Health of the People Act should aim to provide legal rationalization based on general rights and basic principles of public health …… in order to achieve readjustment of the balance between individual rights and the common good.[30]

V.D.2. Risk Assessment

In US, Australia, and New Zealand, model/draft laws use a risk assessment framework as the basis for invoking powers and authorities of government to address threats to public health. 'Risk assessment' provides mechanisms for maintaining the balance between dealing with threats to community public health, and protecting individual rights. Ascending levels of risk have to exist before public health agencies can legally use correspondingly escalating levels of intrusiveness and overriding individual rights to deal with the public health threat. If these criteria are not met, individuals affected by the exercise of powers and authorities can apply in courts to have them declared invalid.[31]

The US Model law sets out criteria to guide government public health agencies to exercise their powers and authorities to maintain public health in the community. This is to be done with the minimum level of interference with individual rights that is necessary to deal with the public health issue. A similar approach is taken in proposals made under the Australian NPHP, and in New Zealand by the Ministry of Health. Under the **'risk assessment'** approach, legal interventions for public health into individual liberty must:

- Have a public health purpose
- Be scientifically sound
- Be well targeted, and
- Be the minimum necessary to achieve the desired result.

V.D.3. Essential public health functions/services

All the model law proposals explicitly include as an important objective the provision of a legal framework that:

- *Identifies* essential public health functions
- Allocates *responsibility* for essential public health functions, and
- Sets *standards* to ensure adequate performance of essential public health functions and services.

---

[30] Monaghan, Stephen, Dyfed Huws, and Marie Navarro. *The Case for a New UK 'Health of the People' Act*. London, UK: Nuffield Trust, 2003. http://www.nuffieldtrust.org.uk/policy_themes/docs/healthofthepeoplefinal160603.pdf

[31] See Reynolds, Chris. *The Application of Risk Management Principles in Public Health Legislation*. National Public Health Partnership Final Report. Australia, June 2000. http://www.dhs.vic.gov.au/nphp/publications/legislation/riskmgtrep.pdf

The US model law takes as its starting point the 'essential public health services,' defined by the Core Public Health Functions Steering Committee in 1994.[32] The Australian NPHP sets out a description of public health as a set of commonly recognized functions or 'core functions.'[33] These are similar to those in the US Model law, but use slightly different terminology. (See Appendix E.) The UK Health for the People Act proposes giving legislative force to an explicit definition of the 'public health function,' and adopts the US definitions of what they are.

V.D.4. Partnerships and collaborations to achieve common health goals

Robust, dynamic partnerships and collaborations, together with a union of purpose between the different government levels, are *essential* for realizing common national public health goals of 'health for all' in a decentralized country. Public/private partnerships acknowledge that the private sector is a key component of the health service delivery system. Strong links and ongoing consultations and alliances between government and the community are vital, if the public health system is to remain responsive to the community it serves. Most collaborations of this nature are voluntarily entered into. Health law and policy has, however, a key role in fostering, and even legally mandating such partnerships.

All the approaches to developing model laws encourage and legally enable establishment of collaborations and partnerships. These are formed between all levels and sectors of governments, public health agencies and the private sector, public health experts, and the community. Other legal devices used include provision for formal contracts or agreements, informal agreements and Memoranda of Understanding (MOUs), and establishment of broader stakeholder input through agencies, such as local and state boards of health. These may have governing authority or advisory functions to local and state health departments.

The *US Model State Public Health Act* quite explicitly provides a legal framework for relationships in planning and delivery of public health. The relationships are between the various levels of public, between public and private, and with community sectors.[34]

The UK *'Health for the People Act'* proposes establishment of an independent national Commission for the Health of the People. This body would provide advice to both national and (devolved) regional governments. Its membership would be drawn from all relevant sectors and expertise. The model uses this device to encourage all elements of a devolved system to take an overall nationally cooperative approach to achieving population health. A national commission can monitor health status and delivery of health services. It can also ensure that all levels of government are accountable for their performance.

---

[32] The Committee was made up of representatives from US Public Health Service agencies and other major public health organizations. See http://www.phppo.cdc.gov/nphpsp/10EssentialPHServices.asp.

[33] Endorsed in 2000 by the Australian Health Ministers Advisory Council (a committee of the heads of all health departments in the country (State, Territory, and National). Available from the NPHP secretariat or on the Website (www.nphp.gov.au).

[34] US Model State Public Health Act Art. 1V.

V.D.5. Other key content areas

The model Acts under discussion cover several other key areas seen as basic to public health legislation in the countries concerned. All model legislation proposals cover at least some of the following areas, but none cover all of them:[35]

- Powers and authorities of public health agencies at all levels.
- Dealing with public health emergencies
- Health information − management, privacy etc.
- Communicable diseases − compulsory powers of surveillance, contact tracing, screening, testing, vaccination, isolation, border health.
- Health promotion, prevention.
- Provision of infrastructure − planning, workforce, standards.

VI. International experience with legislation on DepKes priority areas

VI.A. Rights to health

Many of the countries reviewed provide their citizens with rights to health,[36] and to equality of access to health care.[37] How these are implemented is, however, another matter.

The 'right' to health can be understood in a variety of ways. It is a '**fundamental human right**' protected by the UN Convention on Human Rights and enshrined in the Constitutions of many countries.[38] A handful of countries actually provide for a general 'right to health.' Finland, for example, was one of the first countries to do so in its *1992 Act on Status and Rights of Patients.*[39] In the UK, the Nuffield Trust model law proposals also suggest that legislation should encompass this right, and correspondingly impose a statutory duty of care for population health on public authorities.[40] Right to health is also a fundamental entitlement under the European Union (EU) Conventions. The July 2003 final draft of the EU constitution fully incorporates the EU Charter of Fundamental Rights. This Charter, which was adopted in December 2000, provides for "the right to access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices."[41]

Another concept is the **right to good quality health services**, i.e. to basic and minimum essential health services performed in accordance with minimum service standards. Such laws

---

[35] Based on PAHO essential public health functions – see Section VIII.

[36] Den Exter, André and Bert Hermans. "Constitutional Rights to Health Care: The Consequences of Placing Limits on the Right to Health Care in Several Western and Eastern European Countries." *European Journal of Health Law*. 5 (3): 261-289, 1998.

[37] Spain: Article 43.1 of the Constitution, as in the General Health Act 14/1986; Finland: Constitution.

[38] For example — health and welfare as a human right of all Indonesians was added to the 1945 Constitution as part of a new Chapter (Chap. XA) on human rights. See Article 28 H (1); 2nd Amendment to the 1945 Constitution of the Republic of Indonesia*;* 2000.

[39] Full text of the Act in English is available at http://www.finlex.fi/pdf/saadkaan/E9920785.PDF.

[40] Monahan, Hews et al at p. 30.

[41] Belcher, Paul, Martin McKee and Tamsin Rose. "Is Health in the European Convention?" *Eurohealth*. Vol. 9 (2): 1-4, summer 2003. http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/eurohealth/vol9no2.pdf

require health services and functions to be performed to a set standard. The laws vest in citizens the right to take action if governments or health ministries do not support this right. These laws are unusual, except in some developed countries, where legislation establishes rights to complain of substandard health treatment, and seek remedies. For example, New Zealand, Australian states (regions), and the UK all have 'complaints' legislation that sets up independent Commissioners for Health Complaints.

Finally, there are **rights to equity and universal access** to affordable health care. These rights are generally manifested in some system for provision of free or affordable (financially subsidized) health care. Social health insurance is one such system. (See below.)

VI.B. Social health insurance

'Rights to access' health care can take the form of national legislation that provides for all or some of the population access to health services at low or minimum cost. A common method is to provide for some sort of national insurance scheme. Several Acts, e.g. those in Finland, Spain, and the Philippines, refer to these schemes without defining, what form they should take. Legislation on establishing national insurance schemes was not analyzed in-depth in this report, but a number of countries reviewed have established them.[42] The form that laws take will reflect the nature of the scheme. Policy decisions as to how the schemes will operate determine how the law is rolled out. An interested reader may wish to consult additional reference materials.[43]

VI.C. Protection of patients and private health sector regulation

VI.C.1. Training, licensing and credentialing of health professionals

Robustly independent, non-corrupt, well-trained and clinically competent health professionals are essential to any health system. Legally, the competence of the health workers is generally ensured by requirements of compliance with professional registration Acts, as a condition of the right to practice. Professional Registration Acts are common to all of the countries reviewed. 'Best practice' Acts in the UK, USA, Australia, and New Zealand have a number of key elements:

- They establish a Professional Registration Board, independent of the government and comprising senior members of the profession, community representatives, and legal members.
- They empower the Board to set minimum standards of training and experience for registration with the Board. Without registration, a professional who offers services/practices in the community commits an offence for which s/he will be fined or jailed.
- They create disciplinary offences of unprofessional or substandard conduct, clinically and/or ethically. Health professionals who do not meet these standards can be reported to the

[42] Australia, Finland, Netherlands, New Zealand, UK, US, Spain, and Thailand (draft National Health Bill).

[43] E.g. Hamilton, Geert Jan. "Private Insurance for All in the Dutch Health Care System?" *European Journal of Health Law*. 10 (1): 53-61, 2003. Sinuraya, Timur. "Decentralization of the Health Care System and Territorial Medical Insurance Coverage in Russia: Friend or Foe?" *European Journal of Health Law*. 7 (1): 15-27, Mar. 2000.

Boards. Boards investigate the allegations, and if these are found to be justified, impose a range of penalties, including the loss of the right to practice the profession.

Health professional laws can also go a lot further than this. A good example is the current Bill before the Spanish Parliament to regulate health professions.[44] (See Appendix J for a summary of the draft Act.) The Spanish Act of Regulating Health Professions includes many of the elements above, but it also legislates to cover:

- Organization of pre-graduate and specialty training, and continuing education
- Professional development
- Private practice and employment, and
- Participation by professionals in planning and structuring professions and the health system through a Commission.

VI.C.2. Private health facilities

Private health facilities (hospitals, clinics, nursing homes etc.) are required by law to be licensed in most countries. If they operate without a license, they operate illegally, and can be shut down by the health authorities. Australia, for example, has comprehensive legislation in this area. Australian aged-care facilities are regulated by the national government, and hospitals and clinics by the state governments. In this way, provision of minimum reasonable standards of care can be monitored and policed, and substandard facilities prevented from operating. In developed countries, many private hospitals and other private providers take very seriously this requirement for high standards and quality in the health care they provide. As well as meeting legal standards for licensing, they participate in voluntary accreditation processes where independent bodies assess the standards of care they provide.[45] If they meet rigorous benchmarks, they are accredited/certified, and can advertise that fact, giving them a competitive edge.

VI.D. Community empowerment and participation

VI.D.1. Participation

Partnership with the community and empowering the community is a significant policy priority in modern health systems. The general trend towards decentralization is at least in part fuelled by this goal. Community involvement and input into planning and operation of health systems, and a functioning accountability of health services to the community are greatly facilitated, when those services are run at local levels. The question for health laws is "How can legal requirements/mandates facilitate this process?" How laws will do this again varies widely, depending on the models of community participation chosen.

US: One section (Article IV) in the US model public health law describes a requirement for good working relationships between the community, the private sector, and government health agencies. The law provides for legally mandated partnership agreements between public and

[44] Spanish Act of Regulating Health Professions (Ley de Ordenación de las Profesiones Sanitarias) was approved by the Spanish Senate in October 2003. It is waiting for approval by the House of Representatives.

[45] E.g. the Australian Council for Health Care Standards and the US Joint Commission of Accreditation of Health Care Organizations.

private sector 'partners' to coordinate delivery of health services and functions. ('Private' sector partners in this case include the community.) The model law also establishes a Health Advisory Council.

UK: The Nuffield Trust proposal envisages community involvement in health through creation of Commissions for the Health of the People at national, regional, and local level. These Commissions would perform a range of functions, including supporting community development and monitoring implementation of Community Plans, established by the National Health Service in consultation with community stakeholders

Spain: The Spanish *National Health System Cohesion and Quality Act – Law 16/2003* integrates a requirement to foster 'civil society's participation in the national health system' throughout the statute. Section IX is headed 'Social Participation,' and has an 'umbrella' provision establishing the form of community involvement:

Sec. 65:

1. 'To make effective social involvement in the National Health System, the National Health System's Social Involvement Council is being set up under the aegis of the Ministry of Health and Consumer Affairs. It shall be organized in a Consultative Committee, an Open Health Forum and a Virtual Forum.
2. Its functions, composition and operating regime shall be determined by law."

VI.D.2. Empowerment

Legislation can empower the community by creating rights that can be legally claimed and/or enforced in courts. Consumer protection legislation is a classic example of this.[46] Most countries have some form of health professional regulation. This can be initiated by members of the public who lodge complaints of substandard medical (or other) practice. (See above at p. 30.)

VII.Legal and regulatory capacity

Three questions arise in relation to legislative and regulatory capacity to establish and maintain health law frameworks that are essential to national health systems. These are discussed in turn.

- *Function*: What functional capacities are needed?
- *Process*: What kind of processes must an NHA be able to perform to carry out these functions? and
- *Structure*: What kind of bureau/unit (in terms of skills matrix, location, resources.) within a NHA would be necessary to effectively carry out these functions and processes?

VII.A. Legal and regulatory functional capacity

There are two aspects to regulatory functional 'capacity.' These are:

[46] Generally, the range of health legislation focused on safety. Standards of food, drink, pharmaceuticals, medical devices. fall into this category. See, for example, Philippines Special Law on Counterfeit Drugs, Consumer Act of the Philippines, and Philippine Code of Marketing of Breast Milk Substitutes, also Thailand Drug, Food, Cosmetic, and Medical Device Control Acts.

1. Ongoing monitoring, review and updating of health laws and regulations, and enactment of new laws, when policy identifies this as necessary, and
2. Capacities for implementation and/or enforcement of health laws and regulation.[47]

This report reviews only the *first* aspect of capacity. While the second is a major issue in its own right for Indonesia, it is beyond the scope of this report.

The Public Health in the Americas Initiative of the Pan American Health Organization (PAHO) provides one example of a 'best practice' approach to illustrate the first aspect of capacity.[48] This Initiative and 'best practice' are described below.

The PAHO Public Health in the Americas Initiative

Following an extensive consultation within the Latin American region and PAHO itself, the PAHO Public Health in the Americas Initiative produced a regional definition of 11 Essential Public Health Functions (EPHFs) for the Americas. These functions are considered necessary for any nation that wishes to take care of its population's health. The national health authority (NHA), usually the national Ministry of Health, has the ultimate responsibility for the EPHFs.[49] PAHO, CDC and the Latin American Center for Health Systems Review (CLAISS) jointly defined an instrument to measure the capacity of governments in the Americas to perform these functions.[50] It was then used to assess the capacity of 41 countries and territories in the Americas.[51]

Legal and regulatory capacity is one of the eleven essential public health functions.[52] EPHF #6 refers to '*strengthening of institutional capacity for regulation and enforcement in public health.*'[53] Four necessary components of capacity are identified in this area:

1. Institutional capacity to develop the regulatory and enforcement frameworks that protect public health and monitor compliance within these frameworks.
2. Capacity to generate new laws and regulations aimed at improving public health, as well as promoting healthy environments.
3. Protection of civil society in its use of health services
4. Execution of all of these activities to ensure full, proper, consistent and timely compliance with the regulatory and enforcement frameworks.

---

[47] This can be, for example, through the capacity to routinely discover and prosecute breaches of food handling regulations or to 'contact trace' sources of infection during an outbreak of communicable disease.

[48] "*Public Health in the Americas: Conceptual Renewal, performance assessment and bases for action*," Pan American Health Organization, Washington DC, 2002.

[49] Even though the actual function might be carried out by sub-national levels of government or private agencies.

[50] See *Public Health in the Americas: Instrument for Performance Measurement of Essential Public Health Functions*, PAHO, CDC and CAISS, November 2001. http://www.phppo.cdc.gov/dphsdr/whoccphp/documents/Instrument.doc (Accessed December 23, 2003)

[51] The MSH team understands that a similar, but more limited exercise was undertaken by WHO/SEARO in several South and South Eastern Asian jurisdictions. It was, however, not possible to get sufficient information on this exercise.

[52] Strictly speaking, PAHO refers only to public heath legal and regulatory capacity, but its comments are equally applicable across the whole of health law capacity building.

[53] 'Regulation' in this context is used generically to mean both 'law', and the form of subsidiary legislation called 'regulation.' See *Recommendation of the Council of the OECD on Improving Quality of Government Regulation*. Paris: Organization for Economic Cooperation and Development. 1995.

Four indicators of compliance are set out for a NHA to be regarded as 'capable' in this area. These are followed by a series of standards, and questions to be asked as part of the capacity assessment. (See Appendix I for the full text.) The four indicators are:

1. Periodic monitoring, evaluation and review of the regulatory framework
2. Enforcement of laws and regulations
3. Knowledge, skills, and mechanisms for reviewing, improving and enforcing regulations, and
4. Support and technical assistance to the sub-national levels in developing and enforcing laws and regulations.

VII.B. Capacity in law making process: Developing regulations

The quality of health regulations concerns all who are working to establish improvements in public health and health care. Government agencies at national level, including the NHA, have a critical role in:

- Developing and maintaining national laws/regulations in health, and
- Supporting, mentoring, and training sub-national health authorities to establish and sustain their own regulatory systems through e.g. development of model regulations, training and mentoring programs.

OECD has set one benchmark for 'doing' regulations properly, by developing guidelines for good decision-making principles in the design and review of regulations.[54] These guidelines are not health based. However, they provide a clear and organized generic approach to regulations that is very useful for any government ministry, interested in improving its regulatory capacity. The guidelines set out a *checklist* of ten criteria (in the form of questions) that must be satisfied. They include the following:

- Is the problem correctly defined?
- Is regulation the best form of government action?
- Is the regulation clear, consistent, comprehensible and accessible to users? and
- How is compliance achieved?

The checklist is intended to be used in conjunction with a 'broader regulatory management system which includes elements such as information collection and analysis, consultation processes, and systematic evaluation of existing regulations.'[55]

An example from Malaysia sets out diagrammatically how legislation, regulation and code of practice development, and monitoring / enforcement flow one from the other in relation to laws on food handling standards.[56]

---

[54] See p 28 of *Report on Regulatory Reform: Synthesis*. Paris: Organization for Economic Cooperation and Development. 1997. http://www.oecd.org/dataoecd/17/25/2391768.pdf

[55] Recommendation of the Council of the OECD on Improving Quality of Government Regulation. Paris: Organization for Economic Cooperation and Development. 1995, at pp 9. http://www.olis.oecd.org/olis/1995doc.nsf/LinkTo/OCDE-GD(95)95

[56] See Annex L.

VII.C. Structural capacity: Skills and resources

Successful bureaucratic agencies within NHAs that are responsible for development and maintenance of effective laws and regulations in the health system share a number of factors in common.

- They have an organized, proactive approach to their role, with vision, mission, objectives and strategic plan clearly articulated.
- They are resourced and sufficiently close to the most senior decision making levels within the NHA to enable their proposals and recommendations to be listened to and acted upon.
- They can mobilize resources and collaborate effectively with a range of agencies to achieve outcomes. The collaborative agencies range from stakeholder groups to expert and specialized policy development teams, and lawyers with expertise in legislative drafting.
- They have skilled professional personnel with a mix of skills. Most importantly, they have staff with legal expertise, knowledge of the health sector, and an understanding of how policy is translated into law, and how law can implement and impact on policy.
- They maintain good collaborative relationships with decentralized public sector health agencies at sub-national levels of government. They provide them with assistance, guidance and support (e.g. through model laws and training) for developing effective sub-national regulatory frameworks.

VIII.Possible future directions for legislative development in Indonesia

Several law-related areas are currently important to health policy in Indonesia. There is an urgent need for new legislation on health sector governance, and an updated legislative framework for public health functions and service delivery. There is also a need for clarification and/or resolution of uncertainties and conflicts in the legislative authorities and responsibilities of the executive, legislative and judicial branches of the Government of Indonesia at all levels. It is beyond the scope of this report to examine these in depth. The purpose of the report is to provide a preliminary overview only. It familiarizes readers with the range of legal areas that are generally necessary to run an effective health system and meet a nation's health goals. In addition, it identifies a range of laws from other countries to illustrate, sometimes as 'best practice', how laws in these areas express the health goals they set out to achieve. Materials contained in the bibliography and legislation list enable the reader to explore further and access more information on them. (See Appendices B and D.)

Set out below is a list of areas where DepKes might wish to seek resources from other donors and/or lenders to carry out in-depth analyses of legal frameworks that are useful to support and/or implement Indonesian health policy priorities. (This form of development assistance cannot be supported with the USAID resources that are currently available to MSH.)

- Essential public health functions and services; using law to:
  ==> Define them
  ==> Allocate which level of government has which responsibility for what
  ==> Resource them (including a plan for assessing and building public health law competencies in the health sector at all levels of the Government of Indonesia)

==> Set standards for their performance, including technical quality standards where appropriate
==> Monitor and enforce their performance in accordance with standards

- Rights to health and access to health care/national insurance schemes
  ==> Patients' rights, including the protection of human subjects in research[57]
  ==> Pharmaceuticals: Guidance from international experience in health laws and regulations in quality control, distribution, pricing, and harm classification.[58]

- Licensing and regulation of public and private health care facilities and practitioners
  ==> Focus on laws re. establishment, funding, and governance of public health care facilities

- Preventing and managing communicable diseases, such as HIV/ AIDS (including recording and reporting).[59]

[57] Garay, Alain. "The New French Legislation Relating to Patients' Rights and the Quality of the Health Care System." *European Journal of Health Law*. 9 (4): 361-379, Dec. 2002. Merakou, Koula and Ellie Tragakes. "Development of Patients' Rights Legislation." *European Journal of Health Law*. 6 (1): 71-81, Mar. 1999.
[58] Mossialos, Elias and Monique Mrazek. *The Regulation of Pharmacies in Six Countries*. Report Prepared for the UK Office of Fair Trading. London: Office of Fair Trading. 2003. http://www.gerenciasalud.com/AOPS34.htm
[59] See also DPR initiative reviewing laws relating to HIV/ AIDS.

LIST OF APPENDICES

The Content and Uses of Health Laws: An Overview of Selected International Models and Lessons Learned for Possible Application in Indonesia

---

Appendix A−Terms of reference: MSH assignment

THEMES OF BASIC PUBLIC HEALTH LAW — AN INTERNATIONAL COMPARISON for the INDONESIAN MINISTRY OF HEALTH

TASK OUTLINE and WORK PLAN

MSH 28.8.03

---

1. TOR — SCOPE OF WORK[1]

- **What are the components of basic health law benchmarked internationally starting from zero base;**[2]
- **Based on international experience, what is 'best practice' in developing and implementing basic health laws; and in particular:**
  - **In a decentralized context, how are basic health laws put into effect to maximize effective delivery of good health services, including in terms of divisions of responsibilities and authorities, obligatory functions, and minimum service standards.**
  - **What is needed to roll out follow-on regulations from the basic health law framework in terms of the required:**
    - **process (e.g. OECD law and regulation making principles) and**
    - **skilled personnel, and the structure of the government office which drives implementation (e.g. equivalents of health law unit in DepKes).**

Priority Areas

The international review will fully cover all health areas and issues with a legal component. However, the major emphasis will be on priority areas identified by the Directorate of Community Health in DepKes. These are:

- Philosophy of health — why do we need to protect it, how can we do this properly; concept of human rights as related to health[3];
- Legal framework for social health insurance as part of public social security;
- Human resources[4] — planning; training; recruitment, deployment, management;[5]

---

[1] These represent TOR / SOW as revised from the original, following meeting with Director General Community Health, DepKes, 21st August

[2] Law 23/92 is the basic health law in Indonesia. A new draft health law has been prepared by Commission 7 of the DPR (May 2003). This review recognizes this context; however, it examines issues of what should be in a new basic health law from 'zero base'; that is, from a perspective of what *should* be covered by a new health law, based on international benchmark comparisons.

[3] Health and welfare as a human right of all Indonesians was added to the 1945 Constitution as part of a new Chapter (Chap. XA) on human rights. See Article 28 H (1); 2nd Amendment to the 1945 Constitution of the Republic of Indonesia*;* 2000.

[4] Ref: 2003 Draft Human Resource Law in Spain re health workforce.

[5] E.g. how do other countries use laws and regulations to reach a more equitable distribution of medical public sector staff; until 1992 all doctors were employed by the government under bond for 3 – 5 years. This allowed the central government to address the issue of equitable distribution. Subsequent to

- Protection of patients / patient rights / health professional regulation.
- Privatization and private / commercial health sector regulation. This relates to private sector health services, private health insurance, standards etc. It involves regulation of that sector, and providing the legal framework for their contribution to the overall health of the nation.
- Community Empowerment and Participation

- Outputs

Outputs for the revised task are defined in two stages:

- Final output at the end of the project—Mid November
- Output at the end of the first & second stage of project (team work in Jakarta 18th — 29th August.)

Final Report by Mid November 2003
A Report[6] in English for translation to Bahasa which covers the following areas, as set out in the attached Workplan and Task Definition.

- Philosophical framework for health and health law in Indonesia and internationally;
- International comparison of basic health laws from a range of countries with decentralized health systems — including (probably) USA, Australia, Thailand, Malaysia, a European country (Holland, Germany, Finland), and the Philippines
- Implementing basic health law in a decentralized setting; international best practice;
- A suggested contents outline — a new basic health law for Indonesia based on international experience.
- Elements of effective implementation of basic health law based on international experience.

Outputs — Stage 1 & Stage 2: Project team work in Jakarta 18th — 29th August.

- A detailed plan of work and outline of report content (as in the above headings) and;
- An interim report which gives an overview of main areas generally covered by health legislation:
    - Compared internationally with the two model laws included in the original SOW (NPHP from Australia, and the Turning Point Model State Public Health Law from USA); and
    - In terms of content.

changes to this requirement in 1992, GOI ceased to have direct power to deploy medical graduates to remote areas as a requirement of their license.

[6] Note that the original SOW required the outputs of a) commentary on the DPR drafts of the new health law and accompanying Academic Paper, and b) a new Academic Paper supporting a revised health law based on comparisons internationally of basic health laws. The revised SOW does not include these.

2. OUTLINE OF WORK PLAN AREAS[7]

a) Philosophical framework for health and health law in Indonesia and internationally:

- *Internationally* — Health in UN Conventions, Declarations etc
  - Which ones have implications for health in Indonesia, and what do they say?
  - Current status in Indonesia (signed, ratified, put into national laws, etc.). For example e.g. in the 1948 Declaration of Human Rights, there is a right to good health; this is part of the 2003 Amendment to the Indonesian Constitution

- *Health Philosophy and Values in Indonesia*
  - Health philosophy/values that underpin and inform health policy and law;
    - In general
    - In relation to the philosophy of the nation
  - How this is translated into laws and policy in practice (e.g. Indonesian Law 23/92; 'Healthy Indonesia 2010'; 'National Health System' (draft) 2003)

- The need for an improved health legal framework for Indonesia:
  - To comply with decentralization;
  - To meet the demands of trends towards globalization;
  - To meet the needs of modern, healthy civil society in Indonesia[8]
  - To meet the demands of new medical advances
  - To reflect that the health of the nation is a whole of government responsibility

b) International Comparison of Basic Health Laws

Issues:

i) The analysis framework through which health laws from different countries are compared?

- Criteria for selection:
  - Makes sense in terms of Indonesia's health policy priorities and health system organization
  - Works legally.
- Analysis frameworks in order of importance are:
  - An international comparison of main areas / themes of health law that are generally seen as a necessary framework to delivery of essential public health functions;
  - Emphasizing DepKes priority areas;[9]
  - National Health System identification of national health laws as the basis for development of regional health regulations.
  - Implementing essential public health functions in the context of decentralization; including ensuring sufficient percentage of the

[7] This is also likely to become the order in which the final report will be written. The second section on International review will be the most important and largest part.

[8] See e.g. ADB/WB/WHO Analysis of minimum set of basic health interventions *(CHK REF)*

[9] (see ante p.1)

GDP and of ADPN is allocated to public health and health development.
    - Indonesian health policy priorities; 'Healthy Indonesia 2010' etc.
    - International human rights to health.

ii)International selections for comparison

- Criteria for choosing countries
    - Model laws
    - Developing countries
    - Decentralized health systems
    - Similar legal systems
    - Project team has access to information.
- How many countries/which ones?
    - Australia (federation / model NPHP law)
    - US (federation/model law Turning Point)
    - Malaysia? (federation)
    - Holland?
    - Thailand? (good public health system; not decentralized)
    - Spain? (decentralized state)
    - Finland? (decentralized unitary state)
    - Philippines? (unitary decentralized state)

c) Implementing essential health functions and basic health laws in a decentralized setting

- Based on international experience, what must the national level retain responsibility and authority for, to ensure the delivery and quality of essential public health functions/sub-functions?
- What lessons that could inform decision-making in Indonesia can be drawn from international experience from countries where these essential functions/sub-functions have nevertheless been decentralized to lower levels?
- Among other countries that decentralized through devolution, what examples can be found of the processes they used to maintain essential health sector management links between levels; or to re-establish them where broken by devolution?[10]
- What could an implementing health law framework look like within the context of Indonesian decentralization laws?
- Implementing obligatory responsibilities, authorities, functions, and minimum service standards in the decentralized environment?

[10] For example, devolution in the Philippines transferred hospitals, including district hospitals, to provincial governments but primary care facilities to municipal governments. The integration between primary care and hospital services that was thus lost was restored by establishing local health zones that integrate health service delivery of a referral hospital with surrounding municipal health services. The establishment of such local health zones was through an agreement that was jointly signed by the President of the League of Provinces, the President of the Union of Local Authorities, the Secretary of Health, and the Secretary of Interior and Local Government. The agreement became national law under an executive order.

d) A new basic 'umbrella' health law for Indonesia based on international experience — A suggested contents outline.

A possible umbrella legislative framework could include:

- Provision for essential public health functions that are required to be national;
- Development of standards and model laws for regional health legislation programs and other essential regional public health functions.
- Establishment of legal mechanisms and encouragement for intergovernmental and government /community collaborations and consultative processes in health, including opportunities for community advocacy and accountability.

(This section will be developed from outcomes of sections 1, 2 and 3)

e) Elements of effective implementation of basic ''umbrella' health law based on international experience.

- The 'Stewardship' role of a national Ministry of Health in a decentralized health system could involve:
  - Developing and implementing basic health laws and regulations in areas of national priority;
  - Using sectoral health law to define which level of government does what in health, including the obligations and authority limits of regions;
  - Developing national regulations which set standards for delivery of essential public health functions at national and regional level;
  - Supporting and assisting regional governments to develop regional health regulations in compliance with national health laws.
- Processes:
  - Law making processes — including 'best practice' policy development processes (consultation, stakeholder input etc.)
  - Development of subsidiary regulations[11];
  - Fostering collaborations in decentralized health systems. (e.g.inter-governmental committees; local community boards of health.)
- Ministry of Health legislation development bureau requirements — what is best practice based on international experience?
  - Vision, mission, objectives, & strategic plan
  - Personnel & structure
    - Skills : Numbers
    - Location: Role

[11] see e.g. OECD 1995 principles of regulation development

Appendix B−Bibliographic references and websites

References in the report:

Belcher, Paul, Martin McKee and Tamsin Rose. "Is Health in the European Convention?" *Eurohealth*. Vol. 9 (2): 1-4, summer 2003.
http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/eurohealth/vol9no2.pdf (Accessed Jan. 12, 2004)

Conner, Jean, Angela McGown and James Curran. "Conference Synopsis and Observations." *Journal of Law, Medicine and Ethics*. Vol. 30 (3), Sept. 22, 2002.
http://www.findarticles.com/cf_dls/m0DPE/3_30/95843960/p1/article.jhtml (Accessed Dec. 29, 2003)

Den Exter, André and Bert Hermans. "Constitutional Rights to Health Care: The Consequences of Placing Limits on the Right to Health Care in Several Western and Eastern European Countries." *European Journal of Health Law*. 5 (3): 261-289, 1998. Abstract available at
http://www.kluwerlawonline.com/toc.php?mode=byjournal&level=4&values=European+Journal+of+Health+Law%7E1998+%26%23150%3B+Volume+++5%7EIssue++3&PHPSESSID=05fa4404eb4006fd85a74113fb670529
(Accessed Dec. 31, 2003)

Garay, Alain. "The New French Legislation Relating to Patients' Rights and the Quality of the Health Care System." *European Journal of Health Law*. 9 (4): 361-379, Dec. 2002. Abstract available at
http://www.kluwerlawonline.com/toc.php?mode=byjournal&level=4&values=European+Journal+of+Health+Law%7E2002+%26%23150%3B+Volume+++9%7EIssue++4 (Accessed Dec. 31, 2003)

Gostin, Lawrence O and James G. Hodge Jr. *Turning Point: Collaborating for a New Century in Public Health — State Public Health Law Assessment Report*. Turning Point National Program Office at the University of Washington. Sponsored by the Turning Point Public Health Statute Modernization National Excellence Collaborative. April 2002.
http://www.turningpointprogram.org/Pages/phsm_state_ph_law_assessment_report.pdf (Accessed Dec. 30, 2003)

Hamilton, Geert Jan. "Private Insurance for All in the Dutch Health Care System?" *European Journal of Health Law*. 10 (1): 53-61, 2003. Abstract available at
http://www.kluwerlawonline.com/toc.php?mode=byjournal&level=4&values=European+Journal+of+Health+Law%7E2003+%26%23150%3B+Volume++10%7EIssue++1 (Accessed Dec. 31, 2003)

Horton, Heather et al. "The Dimensions of Public Health Law Research." *Journal of Law, Medicine and Ethics*. Vol. 30 (3), 2002.
http://www.findarticles.com/cf_dls/m0DPE/3_30/95843958/p1/article.jhtml (Accessed Dec. 29, 2003)

Merakou, Koula and Ellie Tragakes. "Development of Patients' Rights Legislation." *European Journal of Health Law*. 6 (1): 71-81, Mar. 1999. Abstract available at
http://www.kluwerlawonline.com/toc.php?mode=byjournal&level=4&values=European+Journal+of+Health+Law%7E1999+%26%23150%3B+Volume+++6%7EIssue++1 (Accessed Dec. 31, 2003)

Monaghan, Stephen, Dyfed Huws, and Marie Navarro. *The Case for a New UK 'Health of the People' Act*. London, UK: Nuffield Trust, 2003.

http://www.nuffieldtrust.org.uk/policy_themes/docs/healthofthepeoplefinal160603.pdf (Accessed Dec. 29, 2003)

Mossialos, Elias and Monique Mrazek. *The Regulation of Pharmacies in Six Countries*. Report Prepared for the UK Office of Fair Trading. London: Office of Fair Trading. 2003. http://www.gerenciasalud.com/AOPS34.htm (Accessed Dec. 29, 2003)

Newby, Liza. "Summary and Overview of Themes of Basic Health Laws Internationally − A Comparative Overview: Preliminary Draft Comments," Consultant report. Jakarta: Management Sciences for Health. Aug. 2003.

Nordlund, Yvonne Göricke and Lars Edgren: "Patient Complaint Systems in Health Care — a Comparative Study between the Netherlands & Sweden." *European Journal of Health Law*. 6 (2): 133-154, Jun. 1999. Abstract available at http://www.kluwerlawonline.com/toc.php?mode=byjournal&level=4&values=European+Journal+of+Health+Law%7E1999+%26%23150%3B+Volume+++6%7EIssue++2 (Accessed Dec. 31, 2003)

Public Health in the Americas: Conceptual Renewal, Performance Assessment and Bases for Action. Pan American Health Organization, Washington DC, 2002. http://www.americas.health-sector-reform.org/english/publichealth-americas.htm (Accessed Dec. 29, 2003)

Public Health in the Americas: Instrument for Performance Measurement of Essential Public Health Functions. PAHO, CDC and CAISS. November 2001. http://www.phppo.cdc.gov/dphsdr/whoccphp/documents/Instrument.doc (Accessed Dec. 23, 2003)

Public Health Legislation - Promoting Public Health, Preventing Ill Health, and Managing Communicable Diseases. Discussion Paper. New Zealand Ministry of Health, 2002. http://www.moh.govt.nz/moh.nsf/0/10b6c56858141ed9cc256c7c006f50d5/$FILE/public-health-discussion.pdf (Accessed Dec. 30, 2003)

Public Health Practice in Australia Today: A Statement of Core Functions. Australian National Public Health Partnership. http://www.nphp.gov.au/publications/phpractice/phprac.pdf (Accessed Dec. 31, 2003)

Recommendation of the Council of the OECD on Improving Quality of Government Regulation. Paris: Organization for Economic Cooperation and Development. 1995. http://www.olis.oecd.org/olis/1995doc.nsf/LinkTo/OCDE-GD(95)95 (Accessed Dec. 29, 2003)

Report on Regulatory Reform: Synthesis. Paris: Organization for Economic Cooperation and Development. 1997. http://www.oecd.org/dataoecd/17/25/2391768.pdf (Accessed Dec. 31, 2003)

Reynolds, Chris. *The Application of Risk Management Principles in Public Health Legislation*. National Public Health Partnership Final Report. Australia, June 2000. http://www.dhs.vic.gov.au/nphp/publications/legislation/riskmgtrep.pdf (Accessed Dec. 29, 2003)

Sinuraya, Timur. "Decentralization of the Health Care System and Territorial Medical Insurance Coverage in Russia: Friend or Foe?" *European Journal of Health Law*. 7 (1): 15-27, Mar. 2000. Abstract available at

http://www.kluwerlawonline.com/toc.php?mode=byjournal&level=4&values=European+Journal+of+Health+Law%7E2000+%26%23150%3B+Volume+++7%7EIssue++1 (Accessed Dec. 31, 2003)

"The Essential Public Health Services." In "Using Performance Standards to Strengthen Public Health Systems." *National Public Health Performance Standards Program*. Atlanta, USA: Centers for Disease Control. http://www.phppo.cdc.gov/nphpsp/10EssentialPHServices.asp (Accessed Dec. 29, 2003)

Turning Point: Collaborating for a New Century in Public Health. Model State Public Health Act: A Tool for Assessing Public Health Laws. United States: Public Health Statute Modernization National Excellence Collaborative. September 2003. http://www.turningpointprogram.org/Pages/MSPHAfinal.pdf (Accessed Dec. 29, 2003)

Wibulpolprasert. Suwit (Ed.) "Chapter 11. Health Systems Reform and Decentralization," in the *Thailand Health Profile, 1999-2000*. Ministry of Public Health, Bureau of Policy and Strategy, Thailand, 2002.

Relevant references not cited in the report:

Alarcón, RD and SA Aguilar-Gaxiola. "Mental health policy developments in Latin America." *Bulletin of the World Health Organization*. 78 (4): 483-490, 2000. http://www.who.int/docstore/bulletin/pdf/2000/issue4/bu0580.pdf (Accessed Jan. 9, 2004)

Benjamin Georges, Wilfredo Lopez and Angela Zoe Monson. "Partners in Public Health Law: Elected Officials, Health Directors, and Attorneys." *Journal of Law, Medicine and Ethics*. 30, 3, p.17, fall 2002. http://www.findarticles.com/cf_dls/m0DPE/3_30/95843929/p1/article.jhtml (Accessed Dec. 30, 2003)

Bidmeade, Ian and Chris Reynolds. *Public Health Law in Australia − Its Current State and Future Directions*. Canberra, Commonwealth of Australia: Australian Government Publishing Service. June 1997. http://www.health.gov.au/pubhlth/publicat/document/metadata/law.htm (Accessed Dec. 31, 2003)

Bulletin of the World Health Organization. 80 (12), 2002. http://www.who.int/docstore/bulletin/tableofcontents/2002/vol.80no.12.html (Accessed Dec. 30, 2003) Journal issue with a special theme on "Global Public Health and International Law" that includes several articles on health law, such as:

- Aginam, Obijiofor. "International Law and Communicable Diseases." *Bulletin of the World Health Organization*, 80:946, 2002. http://whqlibdoc.who.int/bulletin/2002/Vol80-No12/bulletin_2002_80(12)_946-951.pdf (Accessed Dec. 30, 2003)

- Patterson, David and Leslie London. "International Law, Human Rights and HIV/AIDS." *Bulletin of the World Health Organization*. 80 (12):964-969, 2002. http://whqlibdoc.who.int/bulletin/2002/Vol80-No12/bulletin_2002_80(12)_964-969.pdf (Accessed Dec. 30, 2003)

- Taylor, Allyn L. "Global Governance, International Health Law and WHO: Looking towards the Future." *Bulletin of the World Health Organization*.

80 (12): 975-980, 2002. http://whqlibdoc.who.int/bulletin/2002/Vol80-No12/bulletin_2002_80(12)_975-980.pdf (Accessed Dec. 30, 2003)

Carrin Guy, Martinus Desmet and Robert Basaza. "Social Health Insurance Development in Low-Income Developing Countries: New Roles for Government and Nonprofit Health Insurance Organizations in Africa and Asia." In Scheil-Adlung, Xenia (ed.) *Building Social Security: The Challenge of Privatisation*. Somerset, NJ: Transaction Publishers, 2001.

Fielding, Jonathan E, James S Marks, Bradford W Myers, Patricia A Nolan, Raymond D Rawson, and Kathleen E Toomey. "How Do We Translate Science into Public Health Policy and Law." *Journal of Law, Medicine & Ethics*. 30, 3, p.22, fall 2002. http://www.findarticles.com/cf_dls/m0DPE/3_30/95843930/p1/article.jhtml (Accessed Dec. 30, 2003)

"Health Legislation." In *The Work of WHO in the Western Pacific Region*. Report of the Regional Director, 1 July 2000 - 30 June 2001, Chapter 11 (Health Systems Reform). Manila: WHO/WPRO, 2001. http://www.wpro.who.int/pdf/rcm52/rd/chap11b.pdf (Accessed Dec. 30, 2003)

Implementation Options for National Legislative Schemes in Public Health. Revised final paper. Submitted to Legislation Reform Working Group. Melbourne: Centre for Comparative Constitutional Studies, University of Melbourne. Sept. 7, 1999. http://www.dhs.vic.gov.au/nphp/workprog/lrn/legtools/options.pdf (Accessed Dec. 30, 2003)

Legemaate, J. "The Patient's Right of Complaint – Opinions and Developments in the Netherlands." *European Journal of Health Law*. 3, p. 255, 1996.

Monaghan, Stephen. *The State of Communicable Disease Law*. London: Nuffield Trust. May 2002.

Murray, Christopher J.L. and Julio Frenk. "A framework for assessing the performance of health systems." *Bulletin of the World Health Organization*. 78 (6): 717-731, 2000. http://whqlibdoc.who.int/bulletin/2000/Number%206/78(6)717-731.pdf (Accessed Dec. 30, 2003)

Pathmanathan, Indra. *Malaysia Case Study: Decentralization and performance management in the health sector*. World Bank, DTF and Ministry of Home Affairs International Workshop on Obligatory Functions and Minimum Service Standards, Jakarta, Oct. 22-24, 2002. (See especially PowerPoint presentation Slide 13 - *Devolution: Legislation + management tools – Food Act example*, included as Appendix L.)

Rodriguez, Augusto S; Roehlano Briones and Robert R Teh Jr. *The Regulatory Environment in the Health Care Sector*. Discussion Paper Series No 95-30. Manila: Philippine Institute for Development Studies. November 1995. http://dirp4.pids.gov.ph/ris/dps/pidsdps9530.pdf (Accessed Dec. 31, 2003)

Useful websites:

ASIA

Asian Law Centre of the University of Melbourne, Australia:

(http://www.law.unimelb.edu.au/alc/)

Asian Law Online: http://www.law.unimelb.edu.au/alc/bibliography/

Useful links by country: http://www.law.unimelb.edu.au/db/useful_links/alc/

(Accessed Dec. 31, 2003)

The Asia Law Centre at the University of Melbourne (Australia) provides various links and gateways to accessing Asian laws generally in English and in Bahasa.

AUSTRALIA

National Public Health Partnership, Legislation Reference Network:

The Legislators' Tool Kit www.dhs.vic.gov.au/nphp/workprog/lrn/legtools.htm (Accessed Dec. 30, 2003)

EUROPE

European Journal of Health Law:

http://www.kluwerlawonline.com/toc.php?mode=byjournal&level=2&values=European+Journal+of+Health+Law&PHPSESSID=0a2aef3dec66ee1332e9211c2cc5a9ea

(Accessed Dec. 30, 2003)

Index of articles from 1996 to current. Also provides links to a large number of international law journals.

FINLAND

Finlex:

http://www.finlex.fi/english/laws/index.php (Accessed Dec. 30, 2003)

A database of translations of Finnish acts and decrees into other languages (mostly English), containing approximately 200 full-text translations. Includes reference information on the availability of a translated text, when full-text translation is not available.

LATIN AMERICA AND THE CARIBBEAN

Joint Project CDC/PAHO: Project on Performance Measurement of Essential Public Health Functions in Latin America and the Caribbean:

http://www.americas.health-sector-reform.org/english/publichealth-americas.htm (Accessed Dec. 31, 2003)

A series of Web sites clustered around this project provide access to methodology, performance assessment instruments, and assessment reports on capacity in performance of essential public health functions, including Function 6 – Legal and Regulatory Capacity.

MALAYSIA

Laws of Malaysia:

http://www.lawsofmalaysia.com/shop/store/lomintroduction.asp and

http://www.lawsofmalaysia.com/shop/store/alpha.asp (Accessed Dec. 30, 2003)

A commercial web-site of a venture between Percetakan Nasional Malaysia and Malayan Law Journal aiming to make available a complete reprint of the Laws of Malaysia for purchase.

NEW ZEALAND

New Zealand Health Legislation:

http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes (Accessed Dec. 31, 2003)

A data base of all legislation for New Zealand. Includes all health legislation. Access to NZ health laws is also possible through the Ministry of Health website: http://www.moh.govt.nz (Accessed Dec. 31, 2003)

PHILIPPINES

Philippines Health Legislation:

http://www.doh.gov.ph/health_laws.htm and http://www.doh.gov.ph/executive_orders.htm (Accessed Dec. 31. 2003)

THAILAND

Thai Health Legislation:

http://eng.moph.go.th/PolicyAdvocacy/index.asp (Accessed Jan. 12, 2004)

UNITED KINGDOM

Nuffield Trust for Research and Policy Studies in Health Services, London, UK:

http://www.nuffieldtrust.org.uk/policy_themes/index.php?pt=4 (Accessed Dec. 30, 2003)

The Nuffield Trust acts as an independent commentator on the UK health scene and the National Health Service. It seeks to illuminate current issues through informed debate, meetings and publications. It has also commissioned research and policy studies aimed at the development of policy and the improvement of health services. This is the web site of their "public health" policy theme, whose key objective is to "establish the case for a new Health of the People Bill and for the creation of a mechanism to monitor public health policy."

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

OECD — Committee of the Council on Improving Quality of Government Regulation:

http://www.oecd.org/about/0,2337,en_2649_37421_1_1_1_1_37421,00.html (Accessed Dec. 31, 2003)

Contains the materials from the OECD initiative to set benchmarks for 'doing' regulations properly, by developing guidelines for good decision-making principles in the design and review of regulations. Although the guidelines are not health based, they provide a clear and organized generic approach to regulations that is very useful for any government ministry, interested in improving its regulatory capacity.

UNITED STATES

Turning Point Model Public Health Laws Project: Public Health Statute Modernization National Excellence Collaborative:

http://www.turningpointprogram.org/Pages/MSPHAfinal.pdf (Accessed Dec. 29, 2003)

The Turning Point Public Health Statute Modernization National Collaborative commenced in 2000. It seeks to strengthen the legal framework for public health law by developing a Model State Public Health Act with guidance from a multi-disciplinary panel of experts in public health, law, and ethics. It provides models and support to States in upgrading and reforming the aging system of public health laws in the US. Web sites clustered around this

project provide access to model public health laws in the US, articles reviewing US States which have adopted parts of the laws, and discussion around development of the laws.

The project is based in the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities (http://www.publichealthlaw.net/). The Center for Law and the Public's Health is a primary national resource on public health law, ethics, and policy for public health practitioners, lawyers, legislators, policy-makers, and others. It was founded in 2000 with support from the Centers for Disease Control and Prevention. Guided by a diverse group of affiliated experts and national collaborative partners, the Center seeks to enhance the visibility and effectiveness of law as a tool for the promotion of the public's health. Its Website gives access to a range of public health law development tools, model laws, and training programs on public health law.

WORLD HEALTH ORGANIZATION

International Digest of Health Legislation:

http://www3.who.int/idhlrils/frame.cfm?language=English (Accessed Dec. 30, 2003)

Contains a selection of national and international health legislation. Texts of legislation are summarized in English or mentioned by their title. Where possible, links are provided to other websites that contain full texts of the legislation in question.

Appendix C−

TABLE A
ESSENTIAL PUBLIC HEALTH FUNCTIONS BY CORE SERVICE AREA BY LEGISLATIVE AREA BY HEALTH LAW BY COUNTRY

Note: The health law areas identified below are internationally regarded as the areas where health legislation is necessary for an effective health system. However, whether each piece of legislation is at national, regional or local level, or a mixture, will vary according to the constitutional organization of the country and the division of responsibilities for functions between the different levels.

In a decentralized health system where most services are provided at regional or local level, the NHA may enact health legislation where necessary:

- In areas of national responsibility,
- To define and legally establish the functional responsibilities of different levels of government,
- To establish machinery to enable setting of national policy goals and priorities with which sub-national levels of government must comply,
- To set minimum service standards and monitor compliance,
- To ensure access to health care for citizens through establishing e.g. funding arrangements with sub-national governments; social health insurance.

Achieving national health goals / priorities in areas where regional or local levels are responsible for services may not necessarily require direct national legislation. For example, in Australia, national health priorities are:

- negotiated between all levels of government, and
- imposed through national financing to regional governments (states) being conditional on compliance with the priorities.

Therefore, in Australia, compliance with national health goals by regional health systems is implicit in the legislation authorizing financial arrangements between different levels of government.

National responsibility for the legal and regulatory machinery for a health system falls into two major 'clusters' of activity:

1. Responsibility for enactment and administration of necessary national legislation as per above (See Sec. 4 of the Report), and
2. Capacity guidance and support to sub-national levels of government in developing and administering their necessary legal and regulatory frameworks for health through e.g. development of model laws and regulations; training; monitoring and accountability etc.

Guaranteeing attention to national priorities

MAIN FUNCTIONS of a NHA[1] in a DEVOLVED HEALTH SYSTEM – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	HEALTH LAW AREA	SELECTED EXAMPLES FRM RELEVANT MODEL, DRAFT AND OTHER LAWS ANALYSED /REFERRED TO IN REPORT[2]
1. Defining national health priorities and goals *Generally expressed through identifying the purpose of the legislation. Specific machinery to set out responsibility and task is not so common.*	• Constitutional responsibility of national government. • Definition of health responsibilities by level of government	• *Finland – Primary Health Care Act 1972 e.g. Secs.1, 5, 14.* • *Thai National Health Bill (not sighted in English. Copy of newspaper article undated on M of H Website).* • *Philippines Executive Order 102 Sec. 2; esp. 2 (a)* • *Spanish National Health System Cohesion and Quality Act 2003Arts. 1,2,3,7.* • *US Model State Public Health Act Sec. 2/101 and 2* • *Australia – Legislator's Tool Kit 'The Role of Local Authorities in Public Health Regulation' 2000.*
2. Monitoring key national health indicators, and evaluating achievement of national health goals	• Establishment of legal machinery for statistical collection and analysis of data e.g. mandatory reporting of	• *Finland – Primary Health Care Act 1972 Sec. 4.1 and ref. to 1992 Act establishing Research and Development Centre for Welfare and Health* • *Australia — National Health and Medical Research*

[1] NHA = 'National Health Authority' – a generic term to describe the national governmental body with overall responsibility for population health. It is usually the Ministry or Department of Health.

[2] References here are drawn from the main laws analyzed in the report; model and draft laws; and operational statutes from Australia, NZ, US, UK, Finland, Thailand, Philippines, and Spain. Each country (and others referred to – e.g. France; Netherlands) have other health laws which may be relevant to each of these categories. It was beyond the scope of this report to undertake the legal research necessary to identify these comprehensively. This could be worth doing, as a further research project, however.

MAIN FUNCTIONS of a NHA[1] in a DEVOLVED HEALTH SYSTEM – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	HEALTH LAW AREA	SELECTED EXAMPLES FRM RELEVANT MODEL, DRAFT AND OTHER LAWS ANALYSED /REFERRED TO IN REPORT[2]
	certain health conditions; census; etc. • Legal establishment of research / data collection agencies?	*Council Act 1992* • *US Model State Public Health Act Sec. 2/103 (i) and (l),2/104 (l), 3/101; 3/103, 105 - 107, 5 / 102 and 103. .* • *NZ Public Health and Disability Act 2000. Sec. 17* • *Philippines Executive Order 102 Sec. 3 (m)* • *Spanish National Health System Cohesion and Quality Act 2003 Section 1V on Research; Section XI on Chief Inspectorate (monitoring agency)*
3. Assessing health risks and demands (from epidemiologic changes, new industries, etc.)	• Possibly a legislative framework necessary for reporting and monitoring of private sector etc. • Laws/regulations requiring health impact assessments prior to new • major industrial, mining, etc. projects	• *NZ Discussion Paper on Public Health Legislation 2000 Chap. 5. esp. para. 5.3* • *Australia Legislator's Tool kit: 'Application of Risk Management Principles in Public Health Law' - Report 2000.*
4. Environmental health standards and monitoring	Legislation to establish minimum national standards and *capacity support* to sub national gov. levels to regulate	• *Australia – NPHP: 'Legislator's Tool - Kit' - National Legislation, Standards and Guidelines on Water Quality Management; Drinking Water; Water Quality Monitoring and Reporting; Building*

MAIN FUNCTIONS of a NHA[1] in a DEVOLVED HEALTH SYSTEM – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	HEALTH LAW AREA	SELECTED EXAMPLES FRM RELEVANT MODEL, DRAFT AND OTHER LAWS ANALYSED /REFERRED TO IN REPORT[2]
	and enforce environmental standards on • Air, water quality[3] • Pollution control • Control of hazardous substances and goods — e.g. poisons and dangerous chemicals; radiation; • Building Standards for housing, public and commercial buildings; • Sanitation and Waste Disposal;	*Code of Australia* • *Finland – Decree of Minister of Social Affairs and Health relating to Quality and Monitoring of Water Intended for Human Consumption.* • *Philippines – Air Control Policy.* • *US` Model State Public Health Act Sec. 6/102*
5. Surveillance and control of the most important infectious diseases (e.g. HIV/AIDS, TB, etc.) *Note – all of the countries reviewed in the report have some legislation in this area. The issue is: how up to date and appropriate it is.*	• Infectious diseases legislation – national OR models for sub national levels. Includes powers / functions : - *Prevention* — notification and detection (definition, screening, testing powers etc; laboratory standards; data protection) - *Control, management* and *cure* — quarantine; emergency powers; isolation. etc *HIV/AIDS epidemic*: specific laws which	• *US` Model State Public Health Act Sec. 6/101; 2/104 a)* • *Philippines – Aids Prevention and Control Act 1998; Law on the Reporting of Communicable Diseases 1929(?)* • *Malaysia – Prevention and Control of Dangerous Diseases Act 1988 / Destruction of Disease Bearing Insects Act 1975.* • *NZ Public Health Legislation Discussion Paper 2002 Chaps. 7,8,9.* • *Australia – Legislator's Tool Kit - 'Notifiable*

[3] E.g. in Indonesia the term 'clean' is applied to characterize the quality of water. Water which is 'clean' is not necessarily potable / drinkable. Health agencies have authority and responsibility for setting criteria for 'clean' water and for measuring its chemical and biological purity. But other agencies have responsibility and authority for the provision and the 'cleanliness / potability' of water. Multi-sectoral policies, and laws that would integrate these multi-sectoral authorities and responsibilities, are needed.

MAIN FUNCTIONS of a NHA[1] in a DEVOLVED HEALTH SYSTEM – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	HEALTH LAW AREA	SELECTED EXAMPLES FRM RELEVANT MODEL, DRAFT AND OTHER LAWS ANALYSED /REFERRED TO IN REPORT[2]
	maximize public health interventions to deal with the epidemic, and minimize barriers (e.g. authorize needle exchange; condom promotion, accessibility and quality; sex industry health checks; reproductive education for adolescents etc.)	*Diseases and Notification Mechanisms' Report 2000* • *UK The Case for a New UK 'Health of the People' Act', 2003 – esp. p6 'Public Health Function'; p 27 'Communicable Diseases' and p 31 "Powers, functions and Responsibilities" See also Nuffield publication - Monaghan S. The State of Communicable Disease Law.*
6. Developing and/or fostering interagency and inter-sectoral coordination and cooperation mechanisms in support of national health priorities	Laws to facilitate cooperation by: e.g. • Requiring co-operation • conferring legal status on collaborative activities e.g. MOUs • establishing machinery of cooperation e.g. local level health Councils	• *Spanish National Health System Cohesion and Quality Act 16/2003 Arts 2, 64, 67, 70.* • *US Model State Public Health Act Art. IV, Sec.4/102 – 103; 2/103 b).* • *UK – 'The Case for a New UK 'Health of the People' Act', 2003 – esp. p 31 and App 1 – Health of the People Commission.* • *NZ Public Health and Disability Act 2000 Secs. 24; 34-36*
7. Defining minimum data requirements and data flow for the national health and management information system	Laws are not necessary to *define* the minimum data flow and requirements. However, they are necessary in a decentralized system to ensure all levels of government and (where appropriate) private sector collect and provide the necessary data.	• *US Model State Public Health Act Art. VII.* • *NZ Public Health and Disability Act 2000 Sec. 44* • *Spanish National Health System Cohesion and Quality Act 16/2003 Arts. 1, 2 e), 3. Sec. 5 Arts. 50 - 54* • *NZ Public Health Legislation Discussion Paper 2002 Chap. 4 – 'Information'*

MAIN FUNCTIONS of a NHA[1] in a DEVOLVED HEALTH SYSTEM – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	HEALTH LAW AREA	SELECTED EXAMPLES FRM RELEVANT MODEL, DRAFT AND OTHER LAWS ANALYSED /REFERRED TO IN REPORT[2]
8. Ensuring national emergency preparedness in health	• Emergency and Disaster management powers; • *Capacity support* to sub-national levels of government to do the same	• *US Model State Public Health Act Sec. VI 'Public Health Emergencies'.* • *Philippines Executive Order 102 Sec.2 (m); 3 (j)* • *PAHO project EPHF No. 11 – 'Emergency Preparedness and Disaster Management in Health* • *Malaysia – Emergency (Essential Powers) Act 1979(?)* • *UK – 'The Case for a New UK 'Health of the People' Act', 2003 – see Forward and p 7.*
9. Fostering essential national health research on current national health priorities and future health risks	• Laws to establish and fund national 'peak' research institute / funding agency, e.g. Australia NHMRC; UK MRC	*(See para. 2 ante.)* • *Finland − Primary Health Care Act 1972 Sec. 4.1 and ref. to 1992 Act establishing Research and Development Centre for Welfare and Health* • *Australia — National Health and Medical Research Council Act 1992* • *US Model State Public Health Act Sec.2/101(j); 3/104.* • *Philippines Executive Order 102 Sec. 3 (m)* • *Spanish National Health System Cohesion and Quality Act 16/2003 Section 1V on Research.*

Steering the development of a cohesive national service delivery system, focused on quality, access and equity

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
10. Defining the National Health Service network (e.g. functions of different types of facilities, links between them, etc.)	• Establishment, funding, and governance of nationally run public health care facilities • Legal machinery to allow compulsory treatment of the mentally ill • Functional specification	• *Spanish National Health System Cohesion and Quality Act 16/2003 Art. 1; 3; 6; 9; 10; 11 etc.* • *Finland − Primary Health Care Act 1972 Secs. 2, 5, 14- 16, 27. = Local level health clinics etc.* • *Finland - Specialized Medical Care 1989 = hospital system.* • *Finland – Mental Health Act 1990* • *NZ Public Health and Disability Act 2000 – see esp. Part 3 'District Health Boards'.* • *Philippines Executive Order 102 Sec 2 (j), 3 (g), 4 (b); Administrative Order No 8 National Mental Health Policy 2001* • *Australia – Mental Health Acts in all States.*
11. Developing and/or fostering mechanisms for coordination and cooperation between local health authorities, and between these authorities and the NHA	• *Capacity Building* − guidance, support, models to sub national government levels on legal framework to establish and govern sub national public sector health care facilities	*See ant para: 6;* • *Philippines Executive Order 102 Sec 2 (j);* • *Spanish National Health System Cohesion and Quality Act 16/2003 Art. 64* • *Finland − Primary Health Care Act 1972 Sec. 27* • *US Model State Public Health Act Sec 2/103 (b), Art. IV, Sec.4/101*
12. Defining minimum service packages		• *Spanish National Health System Cohesion and Quality Act 16/2003 Arts. 4 and 5; 17 and 18; 24, 25, and 26.*

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
		• *NZ Public Health and Disability Act 2000 Sec. 33* • *Philippines Executive Order 102 Sec 3 (g)*
13. Fostering of equity, community and individual rights and empowerment; patients rights etc.	Laws which provide for: • Rights and obligations to participate in public health planning and service delivery e.g. laws requiring consumer advisory bodies; community / health sector partnerships; consumer representation on local / State governance / advisory health boards etc. • Rights of privacy and confidentiality — regulation and control of private information collected and held by government or health care providers • Rights to complain / get compensation for poor health care services (e.g. Australia has, as well as medical malpractice litigation, a system of 'health ombudsmen' who investigate and resolve complaints by consumers about standards of health care.)	• *Spanish National Health System Cohesion and Quality Act 16/2003 Art. 1, Art. 4, Art. 20 – 26, Art. 41 and 44, Art. 50; Sec. IX on Social Participation. See also Spanish Constitution Article 43.1, as laid down in the General Health Act 14/1986.* • *Netherlands − Clients right of Complaint (Care Sector) Act 1995* • *US Model State Public Health Act Art. VII – Public Health Information Privacy* • *Australia –State based legislation establishing health complaints ombudsman statutory commissioners e.g. Victoria - Health Services (Conciliation and Review) Act 1987* • *New Zealand Health and Disability Commissioner Act 1994.* • *NZ Public Health Legislation Discussion Paper 2002 Sec. 3.2 and 3.4 (Values of Rights and Equality); Chap 4 (Information).* • *UK – 'The Case for a New UK 'Health of the People' Act', 2003 − esp. pp 29 / 30* • *European Union draft Constitution 2003 – adopted EU Charter of Fundamental Rights of*

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
	• Rights to access health care / information /	*Dec. 2000, provides "the right to access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices."*
14. Defining and disseminating clinical standards for preventive and curative health services (e.g. immunization schedules, clinical protocols, etc.)	(*Clinical standards / protocols / guidelines are not usually legislated for, although they may be given more force through reference to them in subsidiary legislation).* • Legislation may provide for only approved procedures to be offered in the public sector (Spain) or subsidized by health insurance (Australia) • Special clinical issues may require legislation. (Finland, Malaysia).	• *Spanish National Health System Cohesion and Quality Act 16/2003: Arts 17 – 19 and 24 on portfolio of medical services provided in Spain to be approved by Minister. See also Art. 66 (2) c.* • *Australia − Health Insurance Act 1973; Health Insurance Commission Act 1973.* • *Finland – Act on the Medical Use of Human Organs and Tissues 2001* • *Malaysia – Human Tissues Act 1974.*
15. Regulating private sector health care	• Legislation to provide for licensing and regulation of private health care facilities. Standards and Enforcement powers for public and private sector.	• *Philippines − Hospital Licensure Act 1965* • *Spanish National Health System Cohesion and Quality Act 16/2003 Art. 3.* • *Malaysia − Private Healthcare and Facilities and services Act 1998;* • *NZ Public Health and Disability Act 2000 Sec. 9.*

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
		• *Australia – hospitals are licensed under various State Acts. Aged Care facilities are regulated by the national government – see Aged Care Act 1997.*
16. Defining and disseminating standards for protection of individual consumer health and safety (e.g. food, therapeutic goods, building standards etc; micro environment hazards such as swimming pool, work places etc.)	National legislation will set standards and establish systems in relation to: • Providing legal basis to restrict import / manufacture and supply of therapeutic goods to those approved by national body through e.g. quality testing / licensing / prevention of sale of non approved TGs etc. • Provide *capacity support* to sub national gov. levels through model laws about safety in daily activity – health promotion e.g. anti smoking; driving safety (seatbelts etc.); food and drink standards of hygiene etc. (e.g. testing food quality; regulating commercial food outlets etc.) • Trade practices and product liability • Prevention of non communicable diseases e.g. fluoridating water;	*(Selected examples only. All jurisdictions have a wide range of laws and regs at all levels on these topics)* • *Philippines 'Special Law on Counterfeit Drugs'; 'Consumer Act of the Philippines'; Food, Drug and Cosmetic Act; and 'Code of Marketing of Breast Milk Substitutes';* • *Thailand Drug, Food, Cosmetic, and Medical Device Control Acts.(see M of H, and Law Asia Websites)* • *Australia – Legislator's Tool Kit – "National Response to Passive Smoking in Enclosed Public Places and Workplaces"* • *US Model State Public Health Act* • *Malaysia — See Report Appendix L for case study of national / local interaction in developing and enforcing food standards.* • *Australia — Trade Practices Act 1974.* • *Malaysia – Occupational Safety and Health Act 1994;* • *Finland — Occupational Health Care Act 1383/2001; Occupational Safety and Health Act 299/1958; Occupational Safety and Health Act*

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
	iodization of salt etc. • Occupational health and safety laws	*738/2002.*

Ensuring availability, quality and equitable distribution of critical resources for service delivery

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
Financing **17.** Defining national health financing policy		*All countries have a range of laws for funding public health care / ensuring equality of access through subsidies for medical expenses etc. Below are examples:* • *Philippines Executive Order 102 Sec 3 (d), (f), and (l); Sec. 4 (d); and Sec 6 – Funding.* • *Australia – Health Insurance Act 1973; Medicare Levy Act 1986; Private Health Insurance Incentives Act 1997; Social Security Act 1991.* • *NZ Public Health and Disability Act 2000 Secs 10, and 41- 44*
18. Designing health financing mechanisms (possibly including a national health insurance system)	• Financial laws • Law necessary to establish a national health insurance scheme	
19. Assessing the adequacy and equity of health funding in the nation and	• Legal basis for funding formula for national to regional health	

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
at the decentralized levels	sector resourcing	• *Thailand – National Health Insurance Bill (not sighted in English; reference to newspaper article on M of H website only))* • *Finland – Primary Health Care Act 1972 Sec 21; see also Act on Client Fees in Social Welfare and Health Care 1992. Sec 26 and 28 (on inter area reimbursement)* • *Finland - Specialized Medical Care 1989 Secs 41 – 44 (compensation between health areas);* • *US Model State Public Health Act Sec. 3/105* • *Philippines National Health Insurance Act 1995 – see also An Act Prohibiting the Demand of Deposits or Advance Payments for the Confinement or Treatment of Patients in Hospitals and Medical Clinics in Certain Cases 1996* • *Spanish National Health System Cohesion and Quality Act 16/2003 Art 7 (funding) Art 42 (5) research funding; Art 74 (k) and (l).*
20. Advocating with local and national authorities for appropriate funding for national health priorities	• Laws imposing guaranteed levels of health funding.	
21. Soliciting and/or coordinating donor assistance in support of national health priorities	• Laws to authorize such arrangements	• *Philippines – Administrative Order No 179 : Policies and Guidelines in the Conduct of Local and Foreign Medical and Surgical Missions. 2000*
Human Resources: Trained health profs. **22.** Defining and disseminating national		• *Netherlands – Medical Treatments Contracts Act 1995;*

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
human resource policy		• *Australia – Various State and national laws regulating work conditions generally; and State level anti discrimination / equal opportunity legislation.* • *Spanish National Health System Cohesion and Quality Act 16/2003 Sec. III – Professional Staff Arts 31 – 40. See also General Health Act 1986 Art.84* • *Philippines Executive Order 102 Sec 2 (n),3 (k), 4 (c), 5, and 7.* • *US Model State Public Health Act Sec 3/102 and 105.* • *Philippines - Magna Carta of Public Health Workers 1992; and Magna Carta of Public Health Workers (Revised Implementing Rules and Regulations) : 1999. Administrative Order No 172.*
23. Undertaking strategic human resource planning / training etc.		
22. Developing minimum staffing standards for facilities	Part of legislation setting general standards for licensing and regulation of health care facilities.	
23. Incentive systems or special programs to promote adequate staffing, particularly in underserved areas		
24. Guaranteeing legal protection for staff: Systems for fair hiring and firing practice, protection of pension rights, malpractice insurance, etc	Anti discrimination laws General industrial relations and workforce conditions laws	
25. Harmonizing salary and incentive systems (in collaboration with Civil Service)		
26. Registration of health professionals (may be done by an agency outside the NHA)	National legislation establishing standards to regulate private health professional practice. It will provide	• *Netherlands – Individual Health Care Professions Act 1996* • *Australia and US – various State level Acts*

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
	for: • registration as a condition of practice, • standards of practice; • educational requirements for registration, discipline processes etc • Independent body to undertake:- - Licensing and credentialing - Enforcement of health professional standards. •Regulation of traditional medicines and practices.	*regulating different health professional groups – doctors; nurses; dentists; psychologists etc* • *UK − various Acts regulating different health professional groups – doctors; nurses; dentists; psychologists etc. e.g. Medical Act .* • *New Zealand − Health Practitioners Competence Assurance Act 2003.* • *Finland – Health Care Professionals Act and Decree 1994* • *Malaysia − Medical Act 1971; Medical Assistants (Registration) Act 1977* • *Spain − Regulation of Health Professionals Bill (draft) 2003 − generally.*
27. Accreditation of training programs and institutions (may be done by an agency outside the NHA)	Laws to establish the agency and define its role and function	• *Spain − Regulation of Health Professionals Bill (draft) 2003 − Title II "Training Health Professionals - Chaps II, III, and IV on undergraduate, graduate specialty, and continuing education / training − Arts 13 – 40.*
Health Care Facilities **28.** Defining and disseminating a national policy on health facility development	Legislation supporting role of government in developing or commissioning development of public infra-structure	• *Finland − Primary Health Care Act 1972 Secs 15 – 18, 22 and 23.* • *Finland - Specialized Medical Care 1989 generally – see especially Chap 9 on inter district compensation*
29. Developing and disseminating	Laws to establish machinery to create	

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
minimum facility standards	and enforce standards.	• *Philippines Executive Order 102 Sec 2 (g) and (l), Sec 3 (d), (g), and (i), Sec 4 (b).* • *Spanish National Health System Cohesion and Quality Act 16/2003 – focus on services, governance and monitoring rather than facilities.* • *NZ Public Health and Disability Act 2000 − Part III Role of District Health Boards – focus on function/services rather than facilities. See also New Zealand Hospitals Act 1957.*
30. Devising mechanisms for equal access by all decentralized areas to facilities with essential specialized services and costly technology (such as intensive care unit for adults and neonates, MRIs, cobalt units, etc.) that are unavailable locally		
31. Managing nationally important institutions that require special skills and technology, e.g. a national public health reference laboratory.	Legislation to establish and regulate national public sector government laboratories.	
32. Accreditation of private health care and diagnostic facilities	Legislation to set standards to regulate private laboratories and national enforcement or *capacity support* to sub national gov. levels	
Drugs / Pharmaceuticals **33.** Defining and disseminating a national drug policy		• *Spanish National Health System Cohesion and Quality Act 16/2003 Art. 2 (b), Art 4, Art. 13, Sec.*

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
34. Defining an Essential Drug List **35.** Registration of pharmaceuticals (may be done by an agency outside NHA)	National legislation to establish a drug classification register based on quality of drug and degree of dangerousness etc.	*II Arts 27 – 30, Art. 50 (2), Art. 60 (e), Art. 70 . See also Drugs Act 1990.* • *Malaysia − Sale of Drugs Act 1952; Dangerous Drugs Act 1952, Medicines (Advertisement and Sale) Act 1956.* • *Thailand − Drug Act 1967* • *Philippines − Traditional and Alternative Medicine Act 1997; Philippines Executive Order 102 Sec 2 (l); Generics Act 1988; see also various Administrative Orders – Nos 29,1,56, 85, 65, 55.* • *NZ Public Health and Disability Act 2000 − Part 4 – Pharmaceutical Management Agency Secs. 46 – 53.* • *Australia − Therapeutic Goods Act 1989.* • *Netherlands − Prescription Drugs Provision Act; Medicines Pricing Act;* • *USA − State level legislation licenses pharmacies.*
36. Developing and disseminating standard treatment guidelines	National legislation / regulation on supply and use of legal drugs / pharmaceuticals: It should • Establish standards • Provide for mandatory quality testing • Control import / manufacture etc. • Establish distribution conditions (control of distribution by drug / harm potential classification etc.); • License to supply etc. • Provide for public sector distribution and supply through authority to contract • Provide for access equity through subsidies	
37. Defining and ensuring a national buffer stock of pharmaceuticals		
38. Quality control of imported and locally manufactured pharmaceuticals and vaccines (may be done by an agency outside NHA)		
Health Technology	• Regulation of special health procedures — transplants, organ donation etc.	• *Spanish National Health System Cohesion and Quality Act 16/2003 Art. 18 (2) – (5)*

MAIN FUNCTIONS of a NHA in a DEVOLVED COUNTRY – OVERSIGHT of CORE SERVICES/PRACTICES OF GOVERNMENT	POSSIBLE HEALTH LAW AREA	INTERNATIONAL EXAMPLES of HEALTH LAWS AND REGULATIONS in THESE AREAS
39. Developing standards for adopting new health technology	• Provide legal basis to restrict import / manufacture and supply of new therapeutic goods /technology to those approved by national body •Regulation of new health technology — to establish safety, effectiveness, and quality as a condition of use within the country: generally achieved through legislation which establishes a Technology Advisory Board of experts, and standards against which they assess new technology. E.g. technologies — genetic, reproductive technology etc.	• *Australia − Therapeutic Goods Act 1989; various State Reproductive Technology Acts* • *Philippines − Organ Donation Act 1991; National Blood Services Act 1994.* • *Finland − Medical Use of Human Organs and Tissues Act 2001.*
40. Develop and disseminate equipment and maintenance standards		

TABLE B - HEALTH LAW AREAS BY COUNTRY

- Australia = A/a: Finland = F/nd: Netherlands = Nthlnds: Malaysia = M/a: New Zealand = NZ: Philippines = Ph/s: Spain = Spn: Thailand = Thlnd:
- United Kingdom = UK: United States = US: (France = Frnc: Greece = Grc: Russia = Rsa?)

NOTE: As research effort was limited by language barriers and lack of time & resources, the .legislation review from each country was not comprehensive. Below is a table of all legislation selected/discovered by country by health law area. Note that for US, Australia, UK & NZ − there is health legislation in relation to all of the areas listed below. The report does not examine these – it focuses only on selected model laws development and key Acts. For a complete list of health legislation referred to in report see Appendix D.

✓ = Act listed / known of but not read

✓✓ = Act available & read for report

*= excellent models

	A/a	F/lnd	Nthlnds	M/a	NZ	Ph/s	Spn	Thlnd[1]	UK	US
In decentralized/dvlvd system - define health responsibilities by level of gov.		✓	✓		✓✓	✓✓*	✓✓*[2]	✓*	✓✓ Model law	✓
Health Services & Facilities- provision[3]	✓	✓✓			✓✓		✓	✓	✓	✓
Health Services & Facilities - standards[4]	✓			✓ Prvt Hosp.	✓✓	✓ Priv. Hosp.	✓	✓	✓	✓

[1] Most of the elements included here are contained in the draft National Health Act − close to a comprehensive 'basic health law' for Thailand in terms of what it covers.

[2] Law 16-2003: 'Cohesion & Quality of the National Health System – is also close to a 'basic health law'.

[3] = Establishment, funding, and governance of public health care facilities; Allocation of responsibility between different levels of government; health planning.

[4] = Licensing and regulation of private health care facilities; regulation of private health insurance; regulation of special health procedures — transplants, organ donation etc; regulation of private laboratories and establishment and regulation of government laboratories.

	A/a	F/Ind	Nthlnds	M/a	NZ	Ph/s	Spn	Thlnd[1]	UK	US
Public Health – Individual health and safety related[5]	✓ MHA; OHSA Tobacco TGA	✓ MHA; OHSA Tobacco	✓ all	✓ OHSA Food Pharm.	✓ all	✓ Pharm. Trad. Med. Food/water	✓ Tobacco OHSA	✓ OHSA Tobacco Food/Pharm. Cosmetics Hlth Prmtn	✓ all	✓ all
Public health – Infectious Diseases[6]	✓	✓	✓	✓	✓	✓ Gen HIV/Aids		✓	✓	✓
Public Health – Environment[7]	✓	✓	✓		✓	✓ Air		✓	✓	✓
Patient / Community rights to:										
• Access health care	✓	✓			✓		✓		✓	
• Participate • Information access	✓	✓			✓		✓	✓	✓	✓
• Privacy	✓	✓			✓		✓		✓	✓
• Ptnt Compensation	✓	✓			✓		✓		✓	✓
	✓	✓	✓		✓	✓			✓	✓
				✓						

[5] = Mental health:- compulsory treatment etc; Pharmaceuticals / therapeutic goods - standards:- testing, regulation, licensing to provide etc. – distribution – classification – contracting etc; Occupational health and safety; health promotion e.g. anti smoking; driving safety (seatbelts etc.); food and drink standards of hygiene etc. (e.g. testing food quality; regulating commercial food outlets etc.); Trade practices and product liability; Prevention of non communicable diseases e.g. fluoride in water; salt iodization.

[6] Prevention:- notification and detection (screening, testing powers etc; laboratory standards; data protection;)/ Management and cure — quarantine; emergency powers; isolation. HIV/AIDS laws to maximize public health interventions & minimize barriers e.g. needle exchange; condom accessibility and quality; sex industry health checks; contact tracing etc.

[7] Air, water quality; Pollution control; Control of hazardous substances and goods:- e.g. poisons & chemicals; radiation; Building Standards; Sanitation and Waste Disposal; Emergency and Disaster management powers.

	A/a	F/Ind	Nthlnds	M/a	NZ	Ph/s	Spn	Thlnd[1]	UK	US
Health Resources − Technology regulat/n[8]	✓	✓ Research	✓	Human tissue	✓	✓ Organ don	✓	✓	✓	✓
Health Resources − Financial:										
• Funding services	✓	✓	✓		✓		✓	✓	✓	✓
• Ntnl Health Insrnce	✓	✓	✓		✓	✓	✓	✓	✓	
• Funding level guarantees	5 yrly agrmnts Nat & State govs.	✓					✓	✓?		
Health Resources − Workforce:										
• Licensing / Crdntlng[9]	✓	✓	✓	✓	✓		✓	✓	✓	✓
• Planning & Mngmgnt		✓					✓	✓	✓	✓
• Training		✓					✓	✓		

[8] Standards regulation; regulation of use, testing, approval of new technology (reproductive, genetic etc); research; organ donation.

[9] Regulation of health professional standards — registration, standards of practice; educational requirements for registration, discipline processes etc.

Appendix D −Selected legislation list

(Note: Acts cited in bold type are those referred to in the report, or are particularly relevant to Indonesian priorities. Normal type legislation is other useful examples of health laws.)

Countries where legislation is drawn from:

- Australia
- Finland
- Malaysia
- The Netherlands
- New Zealand
- Philippines
- Spain
- Thailand
- United Kingdom
- United States

The reference list (Appendix B) also refers to material from:

- France
- Greece
- Russia

1. List of Model Health Legislation

- **Australian NPHP Legislator's Tool Kit: —** (various — access via www.dhs.vic.gov.au/nphp/workprog/lrn/legtools.htm)
- **UK — The Case for a New UK 'Health of the People Act' 2003**
- **US Model State Public Health Act 2002.**

(See also legislation and draft legislation from New Zealand, Spain, and Thailand:- below)

2.List of Health Acts / Bills by Country

AUSTRALIA

(Australia is a federation with 8 jurisdictions, each of which has a comprehensive list of health laws. It is not practical or useful to reproduce them here. For access to lists of Australian health laws see Bidmeade & Reynolds 1997; *'Australian Health & Medical Law Reporter* — CCH – Sydney[1]; and legislation Websites for each State and the federal government.)

FINLAND

Acts

- Medical Use of Human Organs and Tissues Act 101/2001
- **Health Care Professionals Act 559/1994**
- Experiments with Seamless Service Chains in Social Welfare and Health Care Services and with a Social Security Card Act 811/2000
- Finnish Constitution 731/1999
- Medical Research Act 488 & 986/1999
- Mental Health Act 1116/1990
- Occupational Health Care Act 1383/2001
- Occupational Safety and Health Act 299/1958
- Occupational Safety and Health Act 738/2002
- Occupational Safety and Health Supervision and Appeal in Occupational Safety and Health Matters Act 131/1973
- **Primary Health Care Act 66/1972**
- Specialized Medical Care Act 1062/1989
- **Status and Rights of Patients Act 785/1992**

Decrees

- Health Care Professionals Decree 564/1994

[1] No date— CCH is a continually updated reference service.

- Labeling — Decree of the Ministry of Social Affairs and Health on Labeling the Unit Packets of Tobacco Products, on Maximum Yields of and Methods for Measuring Harmful Substances, and on Testing Laboratories 641/2002
- Mental Health Decree 1247/1990
- National Advisory Board on Health Care Ethics Decree494/1998
- Occupational Safety and Health Supervision Decree 954/1973
- Tobacco Smoking — Decree on Measures to Reduce: 225/1977
- Water quality — Decree of the Ministry of Social Affairs and Health Relating to the Quality and Monitoring of Water Intended for Human Consumption 461/2000

INDONESIA

- **Constitution 1945.** (See especially — Chapter (Chap. XA) on human rights; & Article 28 H (1) on rights to health. (2nd Amendment)
- **Health Law. Law 23/92**
- **Population Development & Development of Prosperous Families. Law No 10 / 1992. &**
- **Draft Bill amending Law No 10 / 1992 on Population Development & Development of Prosperous Families — Preamble & Elucidations 2003.**

MALAYSIA[2]

- Dangerous Drugs Act 1952
- Destruction Of Disease-Bearing Insects Act 1975
- Emergency (Essential Powers) Act 1979
- Estate Hospital Assistants (Registration) Act 1965
- Food Act 1983
- Human Tissues Act 1974
- Medical Act 1971
- Medical Assistants (Registration) Act 1977
- Medicines (Advertisement And Sale) Act 1956
- Occupational Safety And Health Act 1994

[2] Note: this project was unable to access /research the content of Malaysian Health laws because the only accessible data base is commercial and the project was not able to purchase them.

- Optical Act 1991
- Prevention And Control Of Infectious Diseases Act 1988
- Private Healthcare Facilities And Services Act 1998
- Sale Of Drugs Act 1952
- Tobacco Product Control (Amendment) Regulations 1993 + amendments of 1995; 1997.

THE NETHERLANDS

- **Care Institutions Quality Act 1996**
- **Clients Right of Complaint (Care Sector) Act 1995**
- **Individual Health Care Professions Act 1996**
- Medical Treatment Contracts Act 1995
- Right of Decision Making in Health Care — Law concerning: 1996

(Note that a total of 164 health laws & decrees in the Netherlands are listed on the WHO International Digest of Health Laws (IDHL) http://www3.who.int/idhl-rils/frame.cfm?language=English)

NEW ZEALAND

- **Health Practitioners Competence Assurance Act 2003,**
- **Public Health & Disability Act 2000**
- **Public Health Bill 2002.** (draft only — see Discussion Paper; Reference List Appendix B)

(Note: New Zealand has multiple health laws. For access to them follow links from MOH Website http://www.moh.govt.nz. The WHO IDHL site lists 55.)

PHILIPPINES

Acts

- Air Pollution Control Policy and for other Purposes 8749/1998
- Comprehensive Dangerous Drugs Acts 2002
- Consumer Act 7394/1991
- **Communicable Diseases Reporting Law. 3573/1929**
- Dangerous Drugs Act 1972
- Food, Drug, and Cosmetic Act 3720/1963
- Generics Act 1988

- **Hospital Licensure Act: 4226/1965**
- Magna Carta of Public Health Workers: 7305/1992; & Magna Carta of Public Health Workers (Revised Implementing Rules and Regulations) : 7305/1999
- National Blood Services Act 1994
- **National Health Insurance Act 1995**
- Organ Donation Act of 1991
- Pharmacy Practice & Standards Settings for Pharmaceutical Education Regulation Act 5921/1969
- Philippine AIDS Prevention and Control Act 1998
- Philippine Food Fortification Program Act 8976/2000
- Prohibition on Demand of Deposits or Advance Payments for the Confinement or Treatment of Patients in Hospitals and Medical Clinics in Certain Cases Act 8344/1996
- Special Law on Counterfeit Drugs: 8203/1996
- Tobacco Regulation Act 2003
- Traditional and Alternative Medicine Act 1997

Executive Orders

- Executive Order No 51 — Philippine Code of Marketing of Breast milk Substitutes 1986
- **Presidential Executive Order No 102 – Redirecting the Functions & Operations of the Department of Health 1999**
- Presidential Decree No 881: Regulation by the Secretary of Health on Labeling, Sale and Distribution of Household Hazardous Substances 881/1976

Administrative Orders

- Manufacturing Practice Guidelines for Cosmetic Products 2002
- Creation of DOH National Infectious Disease Advisory Council (NIDAC) 2002
- Implementation Guidelines for the Unified GTZ Support to the Philippines Health Sector 2002
- Guidelines for Implementing the Polio-Free Maintenance Immunization Campaign 2002
- Revised Rules & Regulations Governing the Registration, Licensure & Operation of Hospitals & Other Health Facilities in the Philippines 2002
- A.O. 14: Regulations for the Licensing of Salt Manufacturers. 1999

- A.O. 18-A: Standards of Quality Requirements for the Processing, Packaging and Labeling of Bottled Drinking Water. 1993
- A.O. 39: DOH-Administrative Order No. 18: Standards of Quality Requirements for the Processing, Packaging and Labeling of Bottled Drinking Water. 1996
- A.O. 42: Regulation Part C-10: Drugs -- Registration of Health and / or Traditional Drugs, Local and Imported. 1982
- A.O. 4-B: Consumer complaints -- Supplementary Procedure in the Conduct of Conciliation and Arbitration of as applicable to cases under DOH Jurisdiction. 1998
- A.O. 55: Labeling Materials of Pharmaceutical Product -- Requirements. 1988
- A.O. 56: Licensing of Drug Establishments and Outlets -- Revised Regulations. 1989
- A.O. 65: Guidelines on Advertisement and Promotions to implement the Generics Act of 1988. 1989
- A.O. 85; & A.O. 99 : Requirements for labeling Materials Pharmaceutical Products containing four or more active ingredients. 1990
- A.O. 88-A: Food Additives -- Regulatory Guidelines. 1984
- A.O. No. 1: Provisional accreditation to pharmaceutical suppliers that renewed/applied for accreditation on or before 31/12/2000. 2001
- A.O. No. 150: Regulation Part D-4 -- Registration of Cosmetic Specialties. 1971
- A.O. No. 172: Policies and Guidelines on the Private Practice of Medical and Paramedical Professionals in Government Health Facilities. 2000
- A.O. No. 179: Policies and Guidelines in the Conduct of Local and Foreign Medical and Surgical Missions. 2000
- A.O. No. 181: Reforms for government hospitals to complement other reform strategies in the areas of local health system, public health, health financing and regulation, and to provide equitable quality health services. 2000
- A.O. No. 23: Policies and Guidelines on Over the Counter OTC Drug Products. 2000
- A.O. No. 29: Regulation Part D-5 Cosmetic: Listing of Cosmetics Specialties. 1994
- A.O. No. 8: National Mental Health Policy. 2001
- A.O. No. 85: Registration, Requirements for a Government Agency Importing a Pharmaceutical Product with a Registered Counterpart Brand in the Philippines. 2000
- A.O.10: Rules and Regulations on Labeling and Advertisement of Cigarettes. 1993

SPAIN

- **Constitution** (see especially Article 149.1.16.ª assigns the State exclusive powers as regards the bases and overall coordination of heath care.)

- **General Health Act 14/1986**
- **National Health System Cohesion and Quality Act 2003**
- **Regulating Health Professions Bill 2003**

(Note: WHO IDHL site references 14 other laws in English.)

Thailand

- **Communicable Disease Act B.E. 2523 / 1980.**
- **Constitution 1997**. (See especially rights to equality and freedom from discrimination in health — Sec 30; rights to health services (free if poor) — Secs. 52 & 82; freedom from environmental hazard — Secs 56 & 79; government decentralization — Secs 78 & 234).
- **Drug, Food, Cosmetic, & Medical Device Control Acts** (various — see Website http://eng.moph.go.th/PolicyAdvocacy/index.asp)
- **National Health Draft Bill** (referred to in Thailand Health Profile, 1999-2000 — Ed. Dr.Suwit Wibulpolprasert 2002. Chap 11 Health Systems Reform & Decentralization. Not seen in English by authors) (WHO IDHL site references 12 Acts, regulations, and decrees for Thailand)

NOTE: The European Union also has multiple health conventions, laws and regulations applicable to member States. It was beyond the scope of this report to review them. However, access to most of them can be obtained via the WEB.

Appendix E−List of essential public health functions − Australia and US model laws.

Essential Public Health Functions and Services

1. U.S. Model Law Sec. 2-102

'For the purposes of this Act', "essential public health services and functions" means services and functions to

- Monitor health status to identify and solve community health problems;
- Diagnose and investigate health problems and health hazards in the community;
- Inform, educate, and empower people about health issues;
- Mobilize community partnerships and action to identify and solve health problems;
- Develop policies and plans that support individual and community health efforts;
- Enforce laws and regulations that protect health and ensure safety;
- Link people to needed personal health services and assure the provision of health care when otherwise unavailable;
- Assure a competent public and personal health care workforce;
- Evaluate effectiveness, accessibility, and quality of personal and population-based health services; and
- Research for new insights and innovative solutions to health problems.

2. Australian NPHP Core Functions

- Assess, analyze and communicate population health needs and community expectations;
- Prevent and control communicable and non – communicable diseases and injuries though risk factor reduction, education, screening, immunization and other interventions;
- Promote and support healthy lifestyles and behaviors through action with individuals, families, communities and wider society;
- Promote, develop and support healthy public policy, including legislation, regulation and fiscal measures;
- Plan, fund, manage and evaluate health gain and capacity building programs designed for achieve measurable improvements in health status, and to strengthen skills, competencies, systems and infrastructure;
- Strengthen communities and build social capital through consultation, participation and empowerment;
- Promote, develop, support and initiate actions which ensure safe and healthy environments; Promote, develop, and support healthy growth and development through all life stages;
- Promote, develop, and support actions to improve the health status of Aboriginal and Torres Strait Islander people and other vulnerable groups.

Appendix F−US Turning Point Model State Public Health Act

The complete text of the Act, published September 16, 2003, is available from two web sites. The URL references are:

http://www.turningpointprogram.org/Pages/phsm_TP_model_state_ph_act.pdf

and

http://www.hss.state.ak.us/dph/improving/turningpoint/PDFs/MSPHAweb.pdf

Appendix G −Law 16 – 2003: National Health System Cohesion and Quality Act − Spain

NATIONAL HEALTH SYSTEM COHESION AND QUALITY ACT

PRELIMINARY SECTION

GENERAL PROVISIONS

Article 1. Aim and General Principles

The aim of this Bill is to set out a legal framework for the coordination and co-operation of the public health authorities in the exercise of their respective functions in order to guarantee equity, quality and social participation in the National Health System.

The public health authorities shall ensure the cohesive operation of the National Health System in order to satisfy the right of citizens to health protection as recognised in Article 43.1 of the Constitution in the terms laid down in General Health Act 14/1986 of 25 April.

They are also principles set out in Section of Heading I of the General Health Act also inform this Act.

Article 2. Scope

The actions referred to in the previous Article shall cover:

a) Health services
b) Pharmacy services
c) Professionals
d) Research
e) Information systems
f) Health system quality
g) Comprehensive plans
h) Public health
i) Participation of citizens and professionals

The Interterritorial Council and Chief Inspectorate shall monitor these actions.

Article 3. Actions with respect to health bodies that are not part of the National Health System.

In pursuance of Article 43.2 of the Constitution, the Ministry of Health and Consumer Affairs and the relevant bodies of the Autonomous Regions, in the remit of the powers falling to them, shall monitor the health bodies that are not part of the National Health System as regards their activities; they shall also

require them to provide the necessary information on their structure and operation. Similarly, they shall collaborate with said bodies in training programmes for health professionals and in health research.

SECTION I

SERVICES

Subsection 1. Service Inventory

Article 4. List of Services

1. The list of National Health System health services aims to ensure comprehensive ongoing health care at the appropriate care level.

Preventive, diagnostic, therapeutic, rehabilitation and health promotion services, either individually or as a group for citizens, are deemed to be covered by National Health System health care provision.

The list shall include services provided by public health, primary care, specialised care, social health care, emergency care, pharmaceutical services, orthoprostheses, dietary products and health care transport.

2. People who receive such services will be entitled to health care information and documentation in accordance with Act 41/2002 of 14 November, an essential piece of legislation governing patient autonomy and patient rights and obligations with respect to information and clinical documentation.

Article 5. Portfolio of Services

Health care provision shall be made effective by means of the portfolio of services defined and regulated in Subsection 2 of this section.

Article 6. Staff and Authorised Centres

The services included on the list will only be provided by legally qualified staff in centres and by means of services that are either part of the National Health Service or have been approved, except in life-threatening situations when it is proven that NHS means could not be used, without detriment to the stipulations of international agreements to which Spain is a signatory.

Article 7. Funding

1. The services are the financial responsibility of the Autonomous Regions without detriment to the existence of a third party that is obliged to meet costs. Likewise, financial responsibility for the guarantee systems laid down in this Act falls to the Autonomous Regions.

2. Adequacy with respect to financing the services and guarantees set out in this Act is determined by the resources allocated to the Autonomous Regions in accordance with the provisions in Act 21/2001 of 27 December.

3. The Autonomous Regions shall allocate the minimal amounts laid down in Act 21/2001 of 27 December to finance the services set out in this Act.

Article 8. Public Health Services

1. Public health is the series of nation's health. It is a combination of sciences, skills and attitudes aimed at maintaining and improving the health of the whole population by means of collective or social actions.

2. The services in this ambit shall include the following actions:
a) Epidemiological information and surveillance
b) Health protection
c) Health promotion
d) Preventing disease
e) Surveillance and monitoring of possible risks to health from the import, export or transit of merchandise and international travel.
f) Assessment, prevention and control of the effects of environmental factors on human health.
g) Promotion and protection of occupational health
h) Fostering food safety

Article 9. Primary Health Care Provision

1. Primary health care is the initial and most basic level of care, which ensures the continuity of care throughout a patient's lifetime. It shall include activities to promote health, health education, disease prevention, health care and recovery, as well as physical rehabilitation and social work.

2. Primary health care shall include:
a) Health care in the doctor's surgery or consultation and in the patient's home.
b) Indicating or prescribing and carrying out, where necessary, diagnostic and therapeutic procedures.
c) Preventive measures, health promotion and community care.
d) Information and surveillance with respect to health protection.
e) Basic rehabilitation.
f) Specific care and services for women, infants, adults, senior citizens, risk groups and the chronically sick.
g) Palliative care for terminal patients.
h) Mental health care.
i) Dental health care.

Article 10. Specialised Care Provision

1. Specialised care includes assistance, diagnosis, therapy and rehabilitation, as well as health promotion, health education and disease prevention, the

nature of which makes it advisable for them to be administered at this level. Specialised care shall ensure the continuity of the patient's overall care, once the possibilities for primary care have been exceeded and until such time as the patient can revert to the latter level of care.

2. Specialised health care shall include:
a) Specialised care in doctors' surgeries.
b) Specialised care in medical and surgical day hospitals.
c) Hospital treatment as an inpatient.
d) Hospital treatment at home.
e) Recommendation or prescription and carrying out, where necessary, of diagnostic and therapeutic procedures.
f) Palliative care for the terminally ill.
g) Mental health care.

3. Specialised care shall be provided in external surgeries/consultations and day hospitals as long as the patient's conditions allow.

Article 11. Social health care services.

1. Social health care includes the range of care for patients, generally suffering from chronic illness, who due to their special characteristics, may benefit from simultaneous and synergetic actions by the health and social services in order to increase patient autonomy, mitigate patient limitations or palliate suffering and facilitate social reintegration.

2. Within the health ambit, social health care shall cover:

a) Long-term health care.
b) Health care in convalescence.
c) Rehabilitation in patients with recoverable functional deficit.

3. The continuity of the service shall be guaranteed by the health and social services by means of the appropriate coordination between the corresponding public administrations.

Article 12. Emergency Health Care

Emergency care shall be provided to patients when their clinical situation requires immediate health care. It shall be provided within and outside health centres, including in the patient's residence twenty-four hours a day through medical care and nursing.

Article 13. Pharmaceutical Services

Pharmaceutical service covers the drugs and health products and the whole series of actions aimed at patients receiving them appropriately to meet their clinical needs in the precise doses according to their individual requirements for the appropriate time and at the least possible cost to them and to the community.

This service shall be governed by the stipulations set out in the Drugs Act 25/1990 of 20 December and by the regulations governing health products, as well as other applicable provisions.

Article 14. Orthoprotheses Provision

Orthoprostheses provision consist in using health products, whether implantable or not, whose purpose is to wholly or partially replace a bodily structure or modify, correct or facilitate its function.

This service shall be provided by the health services or shall give rise to financial aid in cases in accordance with the prescribed legislation and provisions.

Article 15. Provision of Dietary Products.

The provision of dietary products includes dietary therapeutic treatment for people suffering from specific congenital metabolic disorders, home nutrition for patients whose nutritional needs cannot be covered with normal foodstuffs due to their clinical situation.

This service shall be provided by the health services or shall give rise to financial aid in cases and in accordance with the prescribed legislation and provisions.

Article 16. Health Transport Provision

Health transport provision consists in transporting patients for exclusively clinical reasons.

Subsection 2. Implementation and Updating of the Portfolio of Services

Article 17. Implementation of the Portfolio of Services

1. The portfolio of services is the series of techniques, technologies or procedures, taking these to mean each of the methods, activities and resources based on knowledge and scientific experimentation, by means of which health services come into effect.

2.The portfolio of services corresponding to the package of services referred to in the abovementioned articles shall be approved by means of a Royal Decree following consultation with the National Health System's Interterritorial Council; this process shall take into account the services' therapeutic efficacy, efficiency, effectiveness, safety and utility, as well as the advantages and alternatives in terms of care, care of less protected groups, at-risk groups and the social needs, and their economic and organisational impact.

3. It shall, however, not include techniques, technologies and procedures whose effective contribution to prevention, diagnosis, treatment, rehabilitation

and cure of disease, conservation or improvement of life expectancy, autonomy and elimination or reduction in pain and suffering has not been sufficiently proven.

Article 18. Updating the Portfolio of Services

1. The National Health System's portfolio of services shall be updated by means of an Order from the Ministry of Health and Consumer Affairs, following consultation with the NHS Interterritorial Council. The procedure for updating it shall be implemented in accordance with the prescribed legislation and provisions.

2. New techniques, technologies or procedures shall be subject to assessment by the Ministry of Health and Consumer Affairs via the Health Technologies Assessment Agency of the Instituto de Salud Carlos III, in conjunction with other assessment bodies.

3. The assessment shall aim to verify that the services meet the following requirements:
a) Contribute effectively to prevention, diagnosis or treatment of disease, to conservation or improvement of life expectancy, self-sufficiency or elimination or reduction of pain and suffering.
b) Contribute to an improvement, in terms proven safety, efficacy, effectiveness, efficiency or usefulness in relation to alternatives currently available.
c) Meet the demands established by the legislation currently in effect where they include the use of drugs or health products.

4. Only techniques, technologies or procedures that meet the requirements indicated can be included in the portfolio of services for public funding

5. A technique, technology or procedure currently included on the portfolio of services shall be excluded when it falls within one or more of the following situations:

a) Its lack of efficacy, effectiveness or efficiency is evident, or there is a significantly unfavourable balance between benefit and risk.
b) It becomes less interesting as a result of technological and scientific advances.
c) It fails to meet the requirements established by the legislation in force.

Article 19. Supervised Use

1. The Ministry of Health and Consumer Affairs, on its own initiative, or at the behest of the corresponding public health authorities and following consultation with the Interterritorial Council of the National Health System, will be able to authorise the supervised use of specific techniques, technologies or procedures.

2. Supervised use shall aim to establish the degree of safety, efficacy, effectiveness and efficiency of the technique, technology or procedure before deciding on the advisability or need to include it in the portfolio of National Health System services.

It will be carried out in accordance with a research format, for limited periods of time, in centres expressly authorised for that end purpose and in accordance with specific protocols aimed at guaranteeing safety, respect for bioethics and achieving important outcomes that further knowledge. It will be essential to have the informed consent of the patients to whom such techniques, techniques or procedures are going to be applied.

3. Supervised use shall be financed out of the Cohesion Funds outlined in Article 4 of the Act of 21/2001 of 27 December in accordance with the regulations governing said Fund.

Subsection 3. Provision Guarantees

Article 20. Guarantee of accessibility

All users of the National Health Service shall have access to health services recognised in this Act under conditions of effective equality. In implementing the portfolio of services, the isochrones recommended in each case shall be defined.

Article 21. Guarantees of Mobility

1. Access to the health services set out in this Act shall be ensured regardless of location on national territory wherever National Health Services users find themselves at any given time.

2. Similarly, all users shall be guaranteed access to those services that may be regarded as benchmark services in accordance with Article 25 of this Act.

Article 22. Guarantees of Time

1. The framework to guarantee a maximum access time to National Health Service services shall be established by means of Royal Decree, following consultation with the National Health System's Interterritorial Council. The Autonomous Regions shall define the maximum access times for access to their portfolio of services within said framework.

2. Surgical operations for organ transplants, which depend on organ availability, and health care in disasters are excluded from the guarantee referred to in the previous section.

Article 23. Guarantees of Information

1. The health services shall inform all citizens of their rights and duties, of the services and portfolio of services of the National Health System, of the

necessary requirements for access to the latter and the other rights set out in the basic Act governing patient autonomy and patient rights and obligations with respect to information and clinical documentation. Likewise they shall adopt the necessary measures so that health centres in their respective ambits may draw up charters for the services each one of them provides.

2. The General Register of Centres, Establishments and Health Centres of the Ministry of Health and Consumer Affairs, which is public, shall enable users to find out about all the kinds of centres, establishments and services authorised by the Autonomous Regions (*Comunidades Autónomos*).

Article 24. Safety Guarantees

1. In the case of techniques, technologies or procedures for whose correct utilisation it is advisable to concentrate the cases to be treated, Benchmark Services shall be designated in accordance with the provisions in the following article.

2. In techniques, technologies or procedures for which not enough information exists to determine their safety, the Ministry of Health and Consumer Affairs shall authorise, where necessary, the supervised use set out in Article19.

3. By means of Royal Decree, minimum requirements shall be determined as a basis for the authorisation by the Autonomous Regions of the opening and operation of all public and private health centres, services and establishments as a guarantee of safety and quality in service provision.

Said requirements shall aim to ensure that the centre, establishment or health service has the means necessary to carry out the activities for which it is designed.

The minimum requirements can be complemented by the Autonomous Regions for all the centres, establishments and health services within its territorial ambit.

Article 25. Guarantees of Quality and Benchmark Services

1. The Autonomous Regions shall guarantee the quality of the services as set out in Section VI of this Act. They shall carry out external audits for this purpose.

Health care bodies shall ensure that their organisation is equipped to facilitate the free choice of doctor and a second opinion in the terms laid down in the legislation and provisions.

Similarly, they shall address actions to humanise care and improve administrative accessibility and level of comfort. National Health System hospitals shall strive to achieve the progressive inclusion of individual rooms.

2. Benchmark services shall be designated within the National Health System to attend to those pathologies that require diagnostic and therapeutic resources to be concentrated at a small number of points in order to ensure the quality, safety and efficiency of care.

The Ministry of Health and Consumer Affairs, after consultation with the Interterritorial Council of the National Health Service, decide which services are deemed to fall within this category, the number of the latter required and their strategic location within the National Health System, with a joint planning approach for the National Health System.

The Ministry of Health and Consumer Affairs shall accredit the Benchmark Services, bearing in mind the quality criteria laid down for each service, and shall regularly reassess them.

The care provided in a benchmark service shall be funded out of the Health Cohesion Fund established in Article 4 of Act 21/2001 of 27 December in accordance with the provisions that regulate it.

Article26. Scope of the Safety and Quality Guarantees

Guarantees of safety and quality are applicable to all public and private centres regardless of the funding of the services that they are offering at any given time, it being the responsibility of the public health authorities to ensure compliance with such guarantees at the centres in their remit.

SECTION II

PHARMACEUTICAL PROVISION

Subsection 1. Organisation and exercise of the powers of the State with respect to pharmaceutical provision

Article27. State Responsibilities With Respect to Pharmaceutical Provision

Exercise of State powers as regards assessment, registry, authorisation, surveillance and monitoring of medicaments for human and animal use and health products is the responsibility of the Ministry of Health and Consumer Affairs, as are decisions on public financing and price fixing in such matters in the terms laid down in the Drugs Act 25/1990 of 20 December.

Article28. Exercise of State Powers with Respect to Pharmaceutical Provision

1.Exercising State powers with respect to pharmaceutical provision falls to the Ministry of Health and Consumer Affairs via the Directorate General for Pharmacy and Health Products and the Spanish Agency for Drugs and Health Products, an autonomous body.

2. Responsibility for management, implementation and execution of the Department's pharmaceutical policy as well as the exercise of the functions

that fall to the State with respect to public financing and price setting for medicaments and health products come within the remit of the Directorate General for Pharmacy and Health Products.

3. The Spanish Agency for Medicines and Health Products, as a specialist technical body, is responsible for assessment, registry, authorisation, inspection, surveillance and monitoring of medicaments for human and animal use and health, and health care, animal health, cosmetics and personal hygiene products, and for carrying out the necessary economic analyses to assess these products.

Article 29. Management, control and technical and scientific advisory bodies of the Spanish Agency for Medicines and Health Products.

1. The managerial bodies of managerial organs of the Spanish Medicines and Health Products Agency are the Governing Council and the Agency's Director.

The Governing Council shall be presided over by the Under-secretary for Health and Consumer Affairs. Its functions, composition and operational regime shall be established by prescribed by law. Representatives of the ministries of Health and Consumer Affairs, Agriculture, Fisheries and Food and Science and Technology, as well as from the Autonomous Regions shall form part of the Governing Council.

Management and legal representation of the Spanish Medicines and Health Products Agency are the responsibility of the Agency's Director. Its functions shall be prescribed by law.

2. The Spanish Medicines and Health Products Agency shall have an Advisory Committee consisting of experts. Its composition, functions and operational regime shall be established by law.

3. The Spanish Medicines and Health Products Agency shall have be provided with technical and scientific advisory bodies for assessment of medicines and health products which are regulated in its Statute.

Subsection 2. Collaboration of Pharmaceutical Offices

Article30. Collaboration of Pharmaceutical Offices

1. The pharmaceutical offices shall collaborate with the National Health System in the exercise of pharmaceutical services. To that end, they shall co-operate with doctors and other health professionals. Likewise, electronic prescribing and personalised dispensing will have to be introduced.

2. Establishment of general and common criteria that would foster the collaboration of pharmaceutical offices by means of the agreements set out in the Medicines Act is the responsibility of the Ministry of Health and Consumer

Affairs, following consultation from the Interterritorial Council of the National Health System.

3. Among the criteria in the previous section, basic pharmaceutical data shall be defined for managing, via computerised means, the information needed to carry out the abovementioned activities and for collaboration with the National Health System's care structures. They shall be adjusted to the provisions of Organic Act 15/1999 of 13 December concerning Personal Data Protection, and to the specifications laid down by the health services of the Autonomous Regions.

SECTION III

PROFESSIONAL STAFF

Subsection 1. Planning and Training of Human Resources in the National Health System

Article31. General Principles

The training and development of technical competence of professionals must be oriented to improving the quality of the National Health System. This requires:

a) Ongoing collaboration between the bodies of the relevant public administrations in education and health, universities, scientific societies and professional organisations.
b) Arranging the entire health care structure of the health system to be utilised for teaching professionals at pregraduate and postgraduate levels and ongoing occupational training.
c) Ongoing review of teaching and educational methodology in the health field to adapt professionals' knowledge to developments in scientific and technical fields and to the health needs of the population.
d) Ongoing updating of knowledge aimed at improving the process of care provision.

Article 32. Human Resources Commission

1. The Human Resources Commission, part of the Ministry of Health and Consumer Affairs, shall carry out planning, the design of programmes for the training and modernisation of human resources in the National Health System.

2. The analysis of training needs shall take into account qualitative and quantitative aspects in order to fit the offers of training to future demands in health care. They are necessary instruments in planning training:

a) Co-ordination between health and education systems.
b) Co-operation with the Autonomous Regions.
c) Technical advisors of scientific societies and professional organisations.

d) A human resource information system, reflected in the Health Information System of the National Health System governed by Article 50.

3. The Human Resources Commission shall be presided over by the Minister of Health and Consumer Affairs. Its composition shall be established by law, and all the Autonomous Regions must be represented.

4. By means of Royal Decree a Professional Consultation Committee shall be regulated, which shall be composed of the national commissions of the health specialties and representatives from the health professions. It shall be set up as their highest participatory body to act as an advisory body in all the ambits of professional organisation, as well as a support body for the Human Resources Commission.

The Continuing Training Commission of the National Health System's Interterritorial Council is also a support body for the Human Resources Commission.

Article33. Pre-graduate Training

The Human Resources Commission, taking into consideration the needs of the health system, motivated by social and health developments, shall convey to the Ministry of Education, Culture and Sport criteria to adapt study plans leading to various university degrees in health sciences.

Article34. Postgraduate Training

The Human Resources Commission shall supervise specialised postgraduate training programmes, proposed by the corresponding national commissions, as well as the number of professionals needed in each in-take.

The Quality Agency governed by Article 58 shall co-ordinate the accreditation of the services for postgraduate teaching and those referred to in the previous section.

Article35. Continuing Professional Development

The public administrations shall establish common criteria in order to establish order in ongoing professional development, with the aim of guaranteeing quality throughout the National Health System. Common criteria shall be adopted within the Interterritorial Council of the National Health System.

Article36. Professional Training

The Human Resources Commission shall collaborate with the Ministry of Education, Culture and Sport in adapting professional training in the field of health sciences to health system requirements.

Subsection 2. Professional Development and Modernisation of the National Health System

Article37. Professional Development

Professional development is a basic aspect of the modernisation of the National Health System and will have to respond to common criteria agreed within the NHS's Interterritorial Council with respect to the following fields:

a) Continuing professional development
b) Professional careers
c) Competence assessment

Article38. Professional Development

1. A professional career is a professional's right to progress, in an individualised way, in recognition of professional development regarding knowledge, experience in care, research and in meeting the aims of the organisation where he or she works.

2. The framework statute set forth in Article 84 of the General Health Act 14/1986 of 25 April, shall contain the basic regulations applicable to National Health System personnel, which shall be implemented by the Autonomous Regions.

Article39. Competence Assessment

1. Under this Act, professional competence is the process by which a person utilises the knowledge, skills and attitudes associated with his or her profession in order to resolve the problems he/she faces.

The Human Resources Commission shall define the basic criteria for assessing the competence of health professionals.

2. The Ministry of Health and Consumer Affairs, following consultation with the Interterritorial Council of the National Health System, shall accredit the bodies authorised to assess the competence of professionals within the framework of the National Health System.

Article40. Professional Mobility

Guaranteeing staff mobility throughout the National Health System is an essential aspect of its cohesion, for which reason the calls for applications for job transfer made by the various Health Services must be carried out harmoniously.

By means of Royal Decree and following consultation with the Interterritorial Council of the National Health System, the basic criteria and conditions of the calls for applications for professional posts shall be established in order to

ensure professional mobility throughout the State without detriment to the powers legally attributed to the health administrations.

SECTION IV

RESEARCH

Subsection 1. Research into Health

Article 41. Principles

It is the State's responsibility with respect to research into health:

a) To establish measures so that scientific research and innovation contribute to improving significantly and sustainably the preventive, diagnostic, therapeutic and rehabilitation interventions and procedures.

b) To guarantee that research and transfer of results to clinical practice is carried out on a basis that is scientifically demonstrable.

c) To ensure that rights, health protection and guarantees as to the safety of society, patients and professionals involved in research are observed and ensured.

d) Include scientific activities in the health field in the European Research Space.

Article 42. Sector initiative in health research in the framework of the National Plan for Scientific Research, Development and Technological Innovation.

1. Following consultation with the Interterritorial Council of the National Health System, the Ministry of Health and Consumer Affairs shall draw up a sector health research initiative, which shall be proposed via the Ministry of Science and Technology for discussion at the Interministerial Science and Technology Commission for inclusion in the National Plan for Scientific Research, Development and Technological Innovation within the procedure that is agreed upon for drawing it up.

2. The proposals contained in the sector initiative for health research must be co-ordinated with those that come from other ministerial departments with powers in scientific research and technological development with the aim of ensuring close interaction with other actions in biomedicine, biotechnology and other areas of action related with the health field.

3. In drawing up the sector initiative, the following needs and aims shall be taken into account:

a) The nation's health needs and the drive for innovation in health care and the modernisation of the biomedical R+D strategy in health services and public health.

b) The participation of all the social agents involved.
c) The transfer of duly verified research results to clinical practice.
d) Taking into consideration, where necessary, scientific results in decision-making by the responsible bodies of the National Health System.
e) Improving the quality of management in research by introducing effective systems of information exchange, assessment and economic-financial administration.
f) Promotion, via the Instituto de Salud Carlos III, of the Scientific Research Council (Consejo Superior de Investigaciones Científicas), of other public research bodies and universities, modernisation of National Health System centres and research networks.
g) The increase in collaboration with private research centres as well as with foreign centres, favouring the pooling of resources for common aims.
h) having research abide by the regulations in effect and by the ethical principles accepted by the institutions and by the scientific community.

4. Execution of actions derived from the proposals contained in the sector initiative for health research that would be included in the National Plan for Scientific Research, Development and Technological Innovation by the Interministerial Commission for Science and Technology, whose management is the responsibility of the Ministry of Health and Consumer Affairs, shall be carried out in accordance with the participation modalities set out therein and shall be subject to a system of assessment with the participation of national and foreign experts based on the practices of the National Assessment and Prospection Agency.

5. Financing the actions outlined in Section 4 and managed by the Ministry of Health and Consumer Affairs must make use of the financial instruments set out in the National Plan for Scientific Research, Development and Technological Innovation and drawing on budgetary sections from that ministry without detriment to joint financing agreements with public and private bodies.

6. With respect to human resources linked to health research, mobility and exchange of researchers from different public and private centres, both national and foreign, will be fostered, as well as the setting up of research groups, of suitable dimensions, that favours broad critical masses, and their ongoing training shall be fostered.

7. The bodies dependent on or linked to the Ministry of Health and Consumer Affairs responsible for managing the measures of the National Plan for Scientific Research, Development and Technological Innovation shall be co-ordinated with the Ministry for Science and Technology in the overall assessment of such measures and their possible updating during the execution of the abovementioned Plan.

Article 43. Co-operation between public and private sectors

1. The Health Research Advisory Commission (*Comisión Asesora de Investigación en Salud*) has been set up as an advisory body on co-operation between the public and private sectors in the field of health.

2. Its functions, composition and operational regime shall be established by law.

Article 44. Patient Rights, Health and Safety in Research

The Ministry of Health and Consumer Affairs, in conjunction with the Advisory Commission on Health Research ,shall ensure that health research is carried out in accordance with the norms of good scientific and bioethical practice.

Subsection 2. Instituto de Salud Carlos III

Article 45. Functions of the Instituto de Salud Carlos III

The Instituto de Salud Carlos III shall foster health research:

a) In the organisational aspects of research by means of :

1.º Planning and prioritisation of research with the aim of adjusting its annual work plans to the aims of the sector initiative in health research.
2.º Joining up the resources devoted to research of the National Health System by forging links among National Health System research centres and by accreditation of institutes and networks.
3.º Promoting research, with advisory services, dissemination of results, back-up for researchers and records.

b) By Developing Own Research Programmes.

2. The Autonomous Regions *(Comunidades Autónomos)* shall participate in the organs of government of the Instituto de Salud Carlos III and of the foundations allied to the latter.

3. To help link up research efforts in the National Health System, the Instituto de Salud Carlos III:

a) Shall be associated with the National Health System research centres.
b) Shall accredit institutes and networks for co-operative research so that research is concentrated on the aims set out in the Plan and high standard research is fostered.
c) Shall provide its own research resources.

Article 46. National Health System Research Centres

Under this Act, National Health System research centres shall be deemed to be those designated by the Ministry of Health and Consumer Affairs in accordance with the priorities of the sector initiative for research into health,

among the Instituto de Salud Carlos III's own centres and its associated centres. The latter shall be associated with the Instituto de Salud Carlos III.

Article 47. Research Institutes

The National Health System shall collaborate with other institutions and organisations involved in research for joint use of scientific infrastructures. To this effect, arranging health research institutes by associating research centres that will be accredited by the Instituto de Salud Carlos III shall be promoted by according to the procedure laid down by prescribed legislation/provisions.

Article 48. Co-operative Research Networks

The Instituto de Salud Carlos III shall promote the establishment of multidisciplinary and inter-institutional co-operative research networks comprising accredited research centres or groups.

These networks shall act as research and scientific consultation structures and as such shall present joint projects, access specific funding and take part in European research programmes.

The integration of networks with national centres and institutes to facilitate the transfer of research to clinical practice, and for scientific advances to be introduced faster and better into the prevention, diagnosis and treatment of disease shall be promoted.

Article 49. Support for Research

The Instituto de Salud Carlos III shall support research via the following lines of action:

a) Methodological support, which shall cover:
1.ª Advice on designing, conducting, quality control and data analysis, and advice on ethical and legal aspects of projects and information technologies.
2.ª Information and management back-up needed to take part in European Union programmes.
3.ª Support infrastructures for health research, such as tissue banks, serum banks, bio-IT databases and large scientific installations, inter alia.

b) Dissemination of the resources and results for joint use in computer networks, which shall include:
1.ª Mapping of public and private research centres serving health research.
2.ª Register of National Health System researchers.
3.ª Own documentary resources and those from the centres and other existing health organisations in the Autonomous Regions.
4.ª Results of own research and of the centres and other existing organisations in the Autonomous Regions.

SECTION V

THE HEALTH INFORMATION SYSTEM

Subsection. Health Information System

Article 50. Health Information System of the National Health System.

1. The Ministry of Health and Consumer Affairs shall establish a health information system of the National Health System that guarantees the availability of reciprocal information and communication between State health administration and those of the Autonomous Regions *(Comunidades Autónomos).* For that reason it shall define the aims and contents of the information as well as the technological means to provide it.

The overall aim of the health information system of the National Health System shall be to respond to the needs of the following collectives, indicating the following in each case:

a) Health authorities: the information shall favour policy development of decision-making, providing updated comparative information on the situation and developments in the National Health System.

b) Professionals: the information shall aim to improve their knowledge and clinical skills. It shall included directories, study outcomes, assessments of medicines, health products and technologies, analysis of good practice, clinical guides, recommendations and suggestions made.

c) Citizens: shall contain information on their rights and duties and health risks, shall facilitate decision-making on lifestyle, self-care practices and utilisation of health services and shall offer the possibility of making suggestions on the abovementioned aspects.

d) Organisations and associations in the health field: the Ministry of Health and Consumer Affairs shall draw up a list of associations of patients and relatives, of non-governmental organisations that are active in the health field as well as scientific societies, with the aim of fostering civil society's participation in the National Health System.

2. The health information system shall contain information on provision and the portfolio of public and private health care services, and shall include, as basic data, those relating to the population with health cover, human and material resources, activities carried out, pharmaceutical and health products, funding and outcomes obtained, and citizens' expectations and opinions, all from a comprehensive health care approach.

3. With the aim of achieving maximum reliability of the information that is produced, the Ministry of Health and Consumer Affairs following consultation with the Interterritorial Council of the National Health System, shall establish

the definition and standardisation of data and flows, the selection of indicators and technical requirements necessary for information to be integrated.

4. The health information system shall be available to users, which will be public health administrations, health managers and professionals and citizens, in the terms of access and dissemination laid down in the National Health System's Interterritorial Council.

5. The Autonomous Regions must provide this health information system with the data necessary to maintain and develop it.

6. The provision of data, including those of a personal nature required by the health information system, shall be subject to the legislation covering personal data protection and to the conditions agreed in the Interterritorial Council of the National Health System.

Article 51. Knowledge Networks

The Ministry of Health and Consumer Affairs shall attend to the information and knowledge needs of health professionals, teachers, students, consumers and users by means of specific documentation strategies that incorporate information and communication technologies.

Article 52. National Health System Communications Network

The Ministry of Health and Consumer Affairs, via preferential utilisation of the common communications and telematic service infrastructures of the public administrations, shall put at the disposal of the National Health System a secure communications network that facilitates and provides guarantees regarding the protection and exchange of exclusively health information among its component parts.

The transmission of information in this network shall be based on the requirements of electronic certification, electronic signature and ciphering in accordance with the legislation currently in effect.

Said network shall relay information relating to future conduct in the proceedings leading to a unique personal identification code, the warning and health emergency networks, exchange of clinical information and health records, electronic prescriptions and the information necessary to manage the Health Cohesion Fund, as well as other information deriving from health information needs in the National Health System.

Article 53. Statistics of General Supracommunity Interest

1. The health information system shall specifically cover the formulation of statistics for state purposes in health matters, as well as statistics of general supracommunity interest and those deriving from commitments with supranational and international organisations, which shall be carried out in accordance with the methodological and technical specifications laid down by

the Ministry of Health and Consumer Affairs following consultation with the Interterritorial Council of the National Health System.

2. The information needed to produce statistics on health care shall be gathered from both the public and private sectors.

Article 54. Exchange of Health Information Among Bodies, Centres and Services of the National Health System

In order that citizens may receive the best possible health care in any National Health System centre or service, the Ministry of Health and Consumer Affairs shall co-ordinate the mechanisms of electronic exchange of clinical information and information on individual health in order to enable interested parties and the professionals involved in health care to access clinical histories in the terms strictly necessary to guarantee the quality of said care and the confidentiality and integrity of the information, whichever Administration should provide it.

The Ministry of Health and Consumer Affairs shall establish a procedure that renders possible the telematic exchange of information that is legally exigible for the exercise of its powers by the public administrations.

The exchange of information to which the previous paragraphs refer shall be conducted in accordance with the provisions of Organic Act 15/1999 of 13 December and Act 41/2001 of 14 November.

Subsection 2. Individual Personalised Health Card

Article 55. Individual Health Card

1. Citizens' access to the health service provision of the National Health System shall be by means of individual health cards as an administrative document that accredits specific data relating to the holder. The following section deals with these data.

2. Without detriment to its management in the respective territorial ambit of each Autonomous Region *(Comunidad Autónoma),* the cards shall include, in a standardised way, basic identifying data on the cardholders, on their right to pharmaceutical provision and on the health service or body responsible for health care. The mechanisms incorporated in the cards to store basic information and the applications that process that information must make it technically possible for the data to be read and verified throughout the territory of the State. For this purpose, the Ministry of Health and Consumer Affairs, in conjunction with the Autonomous Regions, shall establish the necessary requirements and standards.

3. In order to be able to generate the unique personal identification code, the Ministry of Health and Consumer Affairs shall create a database which gathers basic information on National Health System users so that the health services shall have at their disposal a service of information exchange on the

population with health cover, maintained and updated by the system's component parts.

4. As electronic data processing systems for clinical information become available, the individual health card must make it possible for duly authorised professionals to access that information so as to help to improve the quality and continuity of care.

5. Individual health cards must be adapted, where necessary, to the standardisation that may be established for the entire series of public administrations and within the European Union.

Subsection 3. Health Information Institute

Article 56. Health Information Institute

1. The Health Information Institute shall be created. This body shall depend on the Ministry of Health and Consumer Affairs, which shall carry out the activities necessary for the operation of the health information system set out in Article 43.

It shall be created in accordance with the procedure set out in Article 67.1 of Act 6/1997 of 14 April on Organisation and Operation of the General State Administration.

2. The Health Information Institute shall be responsible for gathering, processing and distributing the information that responds to the needs of the National Health System, with criteria of transparency and objectivity of the information generated, in accordance with the directives for its use laid down by the Interterritorial Council of the National Health System.

3. It shall also be a function of the Institute to gather data from other national and international sources in order to complement the information intrinsic to the National Health System, to make it possible to establish correlations and to facilitate comparability with other fields.

4. The Institute shall ensure the integrity and security of the data entrusted to it, guaranteeing the confidentiality of that data in accordance with the provisions of the Organic Act of 15/1999.

5. The Institute may recognise as valid for the National Health System health information records in various professional and scientific fields.

SECTION VI

QUALITY

Subsection 1. Actions Relating to Quality

Article 57. The Infrastructure of Quality

1. Improving quality in the health system must take precedence among the measures taken by public and private health bodies.

2. The infrastructure to improve the quality of the National Health System shall comprise the following features:

a) Quality and security norms to provide care safely.
b) Indicators, which are statistical elements that will make it possible to compare the quality of diverse health centres and services in an approved fashion that is adapted to risk and reliable.
c) Guides to clinical practice, which are descriptions of processes by which a health problem is diagnosed or treated.
d) The good practice guide, which shall gather information on practices that offer innovation or a way of providing a service that is better than the current one.
e) The register of adverse events, which shall cover information on practices that have resulted in a potential safety problem for patients.

This infrastructure shall be at the disposal of the Autonomous Regions and of public and private health centres and services in order to improve the quality of the services that they provide to patients.

Article 58. National Health System's Quality Agency

1. The Quality Agency of the National Health System, depending on the Ministry of Health and Consumer Affairs, shall be set up to take responsibility for drawing up and maintaining the elements of the quality infrastructure.

It shall be created in accordance with the procedure laid out in Article 67.1 of Act 6/1997 of 14 of April concerning the Organisation and Operation of the General State Administration.

2. The Agency shall draw up or adopt the elements of the infrastructure with advice from scientific societies and sector experts, on the basis of national and international experience. It will also be able to promote agreements with scientific institutions to draw up or manage the elements of the infrastructure. Likewise, it shall disseminate the elements of the infrastructure so they are known and used by the Autonomous Regions and National Health System centres and services.

Article 59. National Health System's Quality Plans

1. The Ministry of Health and Consumer Affairs and the relevant bodies of the Autonomous Regions shall regularly draw up in the Interterritorial Council of the National Health System quality plans for the National Health System. These plans shall contain the priority aims in terms of quality for the corresponding period.

2. The Minister of Health and Consumer Affairs shall be accountable to the Senate for meeting the provisions of the National Health System's quality plans.

Article 60. External Assessment

1. The Ministry of Health and Consumer Affairs shall foster regular external assessment of the quality and security of the health centres and services by means of audits by public institutions or private companies, totally independent of the management of the centres and services.

2. The National Health System's Quality Agency shall accredit the public institutions and private companies competent to carry out the audits. The certificates issued by these auditors shall be valid the entire National Health System. The Agency will be able to accept certificates issued by other assessors, which will thus be valid for the entire National Health System.

Subsection 2. National Health System Observatory

Article 61. National Health System Observatory

The National Health System Observatory shall be set up under the aegis of the Ministry of Health and Consumer Affairs. It shall provide ongoing analysis of the National Health System as a whole by means of comparative studies of the health services of the Autonomous Regions in the fields of organisation, service provision, health management and outcomes.

Its shall be created in accordance with the procedure set out in Article 67.1 of Act 6/1997 of 14 April concerning the Organisation and Operation of the General State Administration.

The Observatory shall produce an annual report on the state of the National Health System, which the Ministry of Health and Consumer Affairs shall present to the Interterritorial Council of the National Health System.

SECTION VII

COMPREHENSIVE PLANS

Article 62. Comprehensive Health Plans

1. The Ministry of Health and Consumer Affairs and the relevant bodies of the Autonomous Regions shall draw up comprehensive health plans concerning prevalent or important pathologies, ensuring comprehensive health care that covers prevention, diagnosis, treatment and rehabilitation.

2. Comprehensive Health Plans

a) Shall establish criteria governing the way to organise the services in order to deal with pathologies in a comprehensive and similar way throughout the National Health System.

b) They shall determine the minimum standards and basic care models for prevention, early detection, diagnosis, treatment and rehabilitation of groups of diseases.

c) They shall specify actions of acknowledged effectiveness, shall identify care models for these interventions, develop assessment tools and activity indicators, indicate goals and objectives to assess progress and shall identify shortcomings in knowledge in order to guide research priorities.

2. Once the general standards, bases and criteria have been established, the Autonomous Regions shall organise their services in accordance with the model that is best adapted to their peculiar features and needs.

SECTION VIII

PUBLIC HEALTH

Article 63. Co-ordinated Actions in Public Health and Food Safety

1. Declaring co-ordinated actions in public health matters shall correspond to the Ministry of Health and Consumer Affairs, after consultation with the Interterritorial Council of the National Health System, except in situations of urgent need, in which case the measures that are strictly necessary shall be taken and information on the measures adopted shall be provided.

2. Declaring co-ordinated actions is compulsory for all parties involved, and the actions must come within one of the following scenarios:

a) Respond to situations of special risk or alarm concerning public health.
b) Comply with international agreements, as well as programmes deriving from the demands of regulations passed by the European Union, when it is necessary to ensure co-ordinated action within the National Health System.

To carry out co-ordinated actions, the following mechanisms inter alia could be applied:

a) Joint use of technical instruments.
b) Setting up of a Network of Public Health Laboratories.
c) Definition of minimum standards in analysing and intervening in health problems.
d) Coordination of epidemiological information systems and programs for promotion, health protection, prevention and control of the most prevalent diseases, when their effects go beyond the regional ambit .

3. The declaration of co-ordinated actions in food safety shall correspond to the Spanish Food Safety Agency in accordance with the provisions of Act 11/2001 of 5 July.

Article 64. Co-operation in Public Health

The State and Autonomous Regions via the National Health System's Interterritorial Council shall establish a co-operation and harmonisation action plan for public health aimed at fostering activities that complement those carried out by the regional and local administrations. Said plan shall:

a) set out the basic functions in public health to be carried out throughout the State based on an analysis of the health situation and on the strategies and commitments acquired in the international ambit in accordance with the available scientific evidence.
b) define the portfolio of services and guarantees corresponding to said services.
c) establish the means and systems of relations among the public administrations to facilitate reciprocal information and monitoring of the plan.
d) facilitate the promulgation of health legislation and the application of European Union directives and regulations affecting public health.
e) foster the collaboration and participation on which professional practice is based.

SECTION IX

SOCIAL PARTICIPATION

Article 65. National Health System's Social Involvement

1. To make effective social involvement in the National Health System, the National Health System's Social Involvement Council is being set up under the aegis of the Ministry of Health and Consumer Affairs. It shall be organised in a Consultative Committee, an Open Health Forum and a Virtual Forum.

2. Its functions, composition and operating regime shall be determined by law.

Article 66. Knowledge Networks

1. The Ministry of Health and Consumer Affairs shall create networks that generate and convey scientific knowledge and encourage social participation in matters within its remit. These networks shall serve as a platform to disseminate information, exchange experiences and as support for decision-making at all levels of the National Health System.

2. The Ministry of Health and Consumer Affairs shall create a communications infrastructure that would allow the exchange of information and promote the complementary nature of actions in the following matters, inter alia:
a) Health information, promotion and education
b) International co-operation.
c) Assessment of health technologies
d) Training in public health and health management

3. The public health administrations shall support participation in these networks of international, national, regional, local or third sector bodies.

SECTION X

THE INTERTERRITORIAL COUNCIL

Article 67. Aim

The Interterritorial Council of the National Health System oversees co-operation between the State and the Autonomous Regions and aims to promote the cohesion of the National Health System.

Article 68. Composition

The Interterritorial Council of the National Health System will be composed of the Minister of Health and Consumer Affairs, who shall preside over it, the relevant counsellors competent in health matters from the Autonomous Regions *a*nd a representative of the Ministry of Health and Consumer Affairs, who shall act as Secretary. When the subject matter of the issues to be dealt with thus requires, representatives from other departments of the General State Administration or from the Autonomous Regions involved shall be included on the Council.

Article 69. Functions

The Interterritorial Council of the National Health System shall inform on whichever subjects within the remit of the various public health administrations may affect the cohesive functioning of the National Health System, above all:

a) The preliminary drafts and bills for general provisions in health matters drawn up by the various public administrations that are particularly important.

b) The general provisions on State actions relating to the European Union and international agreements concerning health.
c) Bills concerning scheduling and planning involving international co-operation drawn up by the various public administrations in the exercise of their remit in health matters.
d) Projects of programming or planning in health matters and intersector actions drafted by the various public administrations in the exercise of their powers.
e) Overall analysis of the quality and financing of pharmaceutical provision.
f) Annual report on the state of the National Health System.
g) Controversies concerning powers and responsibilities among the various public administrations, which the State or the Autonomous Regions submit for consideration in order to facilitate an extrajudicial solution without recourse to the law.
h) The remaining functions covered in this Act and in other legal provisions.

Article 70. Joint Health Actions

The State and the Autonomous Regions by means of the Interterritorial Council of the National Health System will be able to establish co-operation agreements to carry out joint health actions in matters of health protection, health care, pharmaceutical delivery and health products, human resources and international relations, among others. They shall be formalised through the Interterritorial Council of the National Health System.

Article 71. Operation

Operation of the National Health System's Interterritorial Council shall be governed by the provisions laid down in its internal regulations.

Article 72. Support Bodies

1. The Management Commission of the Interterritorial Council of the National Health System is created, consisting of the General Secretary for Health, who shall preside it, health service directors and a representative from the Ministry of Health and Consumer Affairs, who will act as Secretary.

This commission shall exercise the functions and adopt the decisions that the Interterritorial Council of the National Health System delegate to it and, shall act as:
a) A support and discussion body on any matters that have to be submitted to the Council.
b) Technical and administrative co-ordination body in matters that affect operation of the health services.

2. The Commission can create the subcommissions and working groups needed for the National Health System's Interterritorial Council to carry out its functions.

SECTION XI

CHIEF INSPECTORATE

Article 73. Functions

The State shall exercise the Chief Inspectorate as a function that guarantees and checks state and Autonomous Region functions are fulfilled in health matters and National Health System health care in accordance with the provisions of the Constitution, the Statutes of Autonomy and the legislation.

Article 74. The Role of the Chief Inspectorate

The Chief Inspectorate shall:
a) check the guarantees of National Health System services in the ambit of the Autonomous Regions in accordance with the provisions of the current Act.
b) Check that no discrimination exists in the administration systems or the provision regimes of the health services.
c) Oversee the implementation and use of the individual health card in the National Health System.
d) Supervise the implementation and adaptation of the comprehensive plans in the Autonomous Regions.
e) Check that the exercise of responsibilities in health matters is adjusted to criteria of the democratic participation of all stakeholders; to this end, it shall follow the provisions of Article 5.2 the General Health Act.
f) Verify that no discrimination exists in the provision and selection systems and procedures for National Health System posts.
g) Oversee the sound application of state regulations in the Autonomous Regions.
h) Study the effects arising from the application of state legislation in order to, where necessary, propose appropriate modifications.
i) Monitor and analyse the acts and provisions of the Autonomous Regions.
j) Follow-up the implementation of agreements adopted in the Interterritorial Council of the National Health System, as well as the agreements signed by the Ministry of Health and Consumer Affairs with other public administrations and public and private bodies.
k) Monitor health care funding in the National Health System, checking that resources are assigned for that purpose.
l) Oversee the destination and utilisation of State funds and grants assigned to the Autonomous Regions that they have a specific destination and aim.

Article 75. Procedural Action

1. The functions of the Chief Inspectorate shall be exercised by the relevant State bodies with responsibility for health. The civil servants of the General State Administration that form part of the Chief Inspectorate shall be given the status of public authority to all effects and purposes, and in the exercise of their duties they shall receive from the State authorities and the bodies of the

Autonomous Regions and other public administrations the collaboration required to carry out the functions legally entrusted to them.

2. the Chief Inspectorate shall carry out its functions of analysis and assessment of the operation of the system by monitoring the regulations, from the information provided by the management centres and the Department's bodies arising from the exercise of their substantive functions or from the collection of data for planning, from data obtained by means of participation in the Interterritorial Council of the National Health System or on the initiative of the latter and from information that which other public or private bodies or institutions may suggest.

3. The Chief Inspectorate shall contrast the information and analyses produced as a result of its monitoring tasks with the Autonomous Regions in order to check or convey the issues that may be dealt with subsequently.

When as a result of the exercise of the functions of the Chief Inspectorate it is confirmed that there has been a failure to comply on the part of an Autonomous Region, the State health authorities shall alert the fact known to the former and urge it to rectify the situation.

If, once such a warning has been issued, failure to comply should persist, the Government shall formally require the relevant body of the Autonomous Region to adopt the requisite measures, it being possible, at all events, to contest the provisions and resolutions adopted by the bodies of the Autonomous Region.

The decisions that the General State Administration adopts in the exercise of its powers as regards the Chief Inspectorate shall always be made known to the highest body responsible for the health service in each Autonomous Region, without detriment to previous actions involving the exchange and contrasting of information already referred to above.

Article 76. Coordination and Co-operation of the Chief Inspectorate in the National Health System

The State's Chief Inspectorate shall establish coordination and co-operation mechanisms with the inspection services of the Autonomous Regions, particularly with respect to co-ordinating actions aimed at preventing or pursuing all manner of fraud, abuse, corruption and diversion of health care provision or services in the public sector, when motives of general interest make it advisable.

For this purpose, the Chief Inspectorate shall carry out the following activities:

a) The creation and maintenance of a database shared with National Health System inspection services.
b) The fostering of collaboration between the different inspection services of the National Health System in joint action programmes relating to monitoring the assessment of services and delivery.

c) Monitoring, from health sectors, the fight against fraud in the National Health System, as regards temporary disability and programmes that may be promoted in fields considered to be liable to give rise to fraud in health care provision or which involve diversions with a markedly financial impact.

First additional provision. State powers in Ceuta and Melilla.

References in the current Act to the responsibilities of the Autonomous Regions shall be understood to be powers belonging to the State in the cases of the cities of Ceuta and Melilla.

Second additional provision. Health care provision abroad.

The stipulations in this Act shall be understood without detriment to the provisions of specific regulations governing the right to health care provision of Spanish people working abroad for Spanish companies and staff on public service abroad.

Third additional provision. Responsibilities of other pubic administrations relating to health bodies that do not form part of the National Health System.

The exercise of actions referred to in Article3 of this Act are understood without detriment to those corresponding to the other relevant public administrations in accordance with the agreements made under cover of their specific legislation for the provision of health services with outside means.

Only transitory provision. Portfolio of services.

Until the Royal Decree by means of which the portfolio of services can be implemented is passed, Royal Decree 63/1995 of 20 January concerning arrangements for health provision in the National Health System shall continue in force.

Single provision on waivers. Legislation waiver

Articles 43 and 47 of General Health Act 14/1986 of 25 April are waived, as are any other regulations of the same of lesser rank whose stipulations are contrary to the provisions of this Act.

First Final Provision. Assignment of Powers

1. This Act has been adopted under Article149.1.16.ª of the Constitution, which assigns the State exclusive powers as regards the bases and overall coordination of heath care.

2. The following precepts are exempted from the stipulations in the previous point:

a) Articles 7, 19.3 and the last paragraph of Article25.2, adopted under cover of Article 149.1.14. of the Constitution, which attributes exclusive responsibility for general finance to the State.

b) Section IV, which comes under Article149.1.15.ª of the Constitution, which attributes to the State exclusive responsibility for promotion and overall coordination of scientific and technical research.

c) Subsection 1 of Section II, Articles 51, 52, 56, 58 and 61 and the first additional provision, which are only applicable to the General State Administration.

Second final provision. The National Health System's Financial Equilibrium.

The Government, within the three months of the entry into force of this Act, shall adopt the necessary provisions to create a collegiate interministerial body that will mandatorily inform on matters of importance affecting the budget for the financial equilibrium of the National Health System or matters that have significant economic implications.

Third final provision. Adapting the organic structure of the Ministry of Health and Consumer Affairs.

The Government, within one month following the entry into force of this Act, shall modify the organic structure of the Ministry of Health and Consumer Affairs in order to create the Health Care Information Institute, the National Health System Quality Agency and the National Health System Observatory, dismantling the corresponding General Subdirectorates in accordance with the stipulations of Article 67.1 a) of Act 6/1997 of 14 April on the Organisation and Operation of the General State Administration.

Fourth final provision. Implementing legislation

The Government is empowered to adopt, within the scope of its remit, as many provisions as are necessary to implement this Act.

Fifth final provision. Entry into force.

This Act shall enter into force on the day following its publication in the "Official State Gazette" (*Boletín Oficial del Estado*).

BROUGHT BEFORE THE COUNCIL OF MINISTERS

Madrid

MINISTER OF HEALTH AND CONSUMER AFFAIRS

Ana María Pastor Julián

Appendix H – Philippines Presidential Executive Order No 102 1999: Redirecting the Functions & Operations of the Department of Health

MALACAÑANG
MANILA

BY THE PRESIDENT OF THE PHILIPPINES
EXECUTIVE ORDER NO. 102

REDIRECTING THE FUNCTIONS AND OPERATIONS OF THE DEPARTMENT OF HEALTH

WHEREAS, the Department of Health, hereafter referred to as DOH, has been transformed from being the sole provider of health services, to being a provider of specific health services and technical assistance provider for health, as a result of the devolution of basic services to local government units;

WHEREAS, the DOH seeks to serve as the national technical authority on health, one that will ensure the highest achievable standards of quality health care, health promotion and health protection, from which local governments units, non-government organizations, other private organizations and individual members of civil society will anchor their health programs and strategies;

WHEREAS, to effectively fulfill its refocused mandate, the DOH is required to undergo changes in roles,: functions, organizational processes, corporate values, skills technology and structures;

WHEREAS, Section 20, Chapter 7, Title I Book III of Executive Order No. 292 series of 1987, otherwise known as the Administrative Code of 1987, empowers the President of the Philippines to exercise such powers and functions as are vested in him under the law:

WHEREAS, Section 78 of the General Provisions of RA 8522, otherwise known as the General Appropriations Act of 1998, empowers the President to direct changes in organization and key positions of any department, bureau or agency;

WHEREAS, Section 80 of the same General Provisions directs heads of departments, bureaus and agencies to scale down, phase out or abolish activities no longer essential in the delivery of health services;

NOW, THEREFORE, I, JOSEPH EJERCITO ESTRADA, President of the Republic of the Philippines, by virtue of the powers vested in me by law, do hereby order the following:

SECTION 1. **Mandate**. Consistent with the provisions of the Administrative Code of 1987 and RA 7160 (the Local Government Code), the DOH is hereby mandated to provide assistance to local government units (LGUs), people's organization (PO) and other members of civic society in effectively implementing programs, projects and services that will:

a) promote the health and well-being of every Filipino;

b) prevent and control diseases among populations at risks;

c) protect individuals, families and communities exposed to hazards and risks that could affect their health; and

d) treat, manage and rehabilitate individuals affected by disease and disability.

SECTION 2. **Roles**. To fulfill its responsibilities under this mandate, the DOH shall serve as the:

a) lead agency in articulating national objectives for health to guide the development of local health systems, programs and services;

b) direct service provider for specific programs that affect large segments of the population, such as tuberculosis, malaria, schistosomiasis, HIV-AIDS and other emerging infections, and micronutrient deficiencies;

c) lead agency in health emergency response services, including referral and networking systems for traull1a, injuries and catastrophic events;

d) technical authority in disease control and prevention;

e) lead agency in ensuring equity, access and quality of health care services through policy formulation, standards development and regulations;

f) technical oversight agency in charge of monitoring and evaluating the implementation of health programs, projects, research, training and services;

g) administrator of selected health facilities at sub national levels that act as referral centers for local health systems i.e. tertiary and special hospitals, reference laboratories, training centers, centers for health promotion; centers for disease control and prevention, regulatory offices among others;

h) innovator of new strategies for responding to emerging health needs;

i) advocate for health promotion and healthy life styles for the general population;

j) capacity-builder of local government units, the private sector, non-government organizations, people's organizations, national government agencies, in implementing health programs and services through technical collaborations, logistical support, provision of grant and allocations and other partnership mechanisms;

k) lead agency in health and medical research;

l) facilitator of the development of health industrial complex in partnership with the private sector to ensure self-sufficiency in the production of biologicals, vaccines and drugs and medicines;

m) lead agency in health emergency preparedness and response;

n) protector of standards of excellence in the training and education of health care providers at all levels of the health

care system; and

o) implementor of the National Health Insurance Law; providing administrative and technical leadership in health care financing.

SECTION 3. **Powers and Functions**. To accomplish its mandate and roles the Department shall:

a) Formulate national policies and standards for health;

b) Prevent and control leading causes of health and disability;

c) Develop disease surveillance and health information systems;

d) Maintain national health facilities and hospitals with modern and advanced capabilities to support local services;

e) Promote health and well-being through public information and to provide the public with timely and relevant information on health risks and hazards;

d) the resource allocation shift, specifying the effects of the streamlined set-up on the agency budgetary allocation and indicating where possible savings have been generated;

f) Develop and implement strategies to achieve appropriate expenditure patterns in health as recommended by international agencies;

g) Development of sub-national centers and facilities for health promotion. disease control and prevention, standards. regulations and technical assistance;

h) Promote and maintain international linkages for technical collaboration;

i) Create the environment for development of a health industrial complex;

j) Assume leadership in health in times of emergencies, calamities and disasters; system fails;

k) Ensure quality of training and health human resource development at all levels or the health care system;

l) Oversee financing or the health sector and ensure equity and accessibility to health services; and

m) Articulate the national hea1th research agenda and ensure the provision of sufficient resources and logistics to attain excellence in evidenced-based interventions for health.

SECTION 4. **Preparation of a Rationalization and Streamlining Plan** In view of the functional and operational redirection in the DOH and to effect efficiency and effectiveness in its activities, the Department shall prepare a Rationalization and Streamlining Plan (RSP) which shall be the basis of the intended changes. The RSP Plan shall contain the following:

a) the specific shift in policy directions. functions, programs and

activities/ strategies;

b) the structural and organizational shift stating the specific functions and activities by organizational unit and the relationship of each units;

c) the staffing shift, highlighting and itemizing the existing filled and unfilled positions; and

d) the resource allocation shift, specifying the effects of the streamlined set-up on the agency budgetary allocation and indicating where possible, savings have been generated.

The RSP shall submitted to the, Department of Budget and Management for approval before the corresponding shifts shall be affected by the DOH Secretary.

SECTION 5. **Redeployment of Personnel**. The redeployment of officials and other personnel on the basis of the approved RSP shall not result in diminution in rank and compensation of existing personnel. It shall take into account all pertinent Civil Service laws and rules.

SECTION 6. **Funding**. The financial resources needed to implement the Rationalization and Streamlining Plan shall be taken from funds available in the DOH, provided that the total requirements for the implementation of the revised staffing pattern shall not exceed available funds for Personnel Services.

SECTION 7. **Separation Benefits**. Personnel who opt to be separated from the service as a consequence of the implementation of this Executive Order shall be entitled to the benefits under existing laws. In the case of those who are not covered by existing laws, they shall be entitled to separation benefits equivalent to one month basic salary for every year of service or proportionate share thereof in addition to the terminal fee benefits to which he/she is entitled under existing laws,

SECTION 8. **Implementing Authority**. Following the approved RSP, the DOH Secretary, in addition to his authority to implement the RSP is hereby authorized to determine the type of agencies and facilities necessary to carry out the Department's mandate and roles, including the pilot testing of programs and such-pre corporization of hospitals following strictly the principles of efficiency and effectiveness.

SECTION 9. **Effectivity**. This Executive Order shall take effect immediately

DONE in the City of Manila this 24th day of May in the year of Our Lord, Nineteen Hundred and Ninety-Nine.

By the President:

RONALDO B. ZAMORA
Executive Secretary

Appendix I − 'Function 6 − Legal and Regulatory Capacity' PAHO 'Public Health in the Americas' Project 2001

***Taken from**:*

PUBLIC HEALTH IN THE AMERICAS: Instrument for Performance Measurement of Essential Public Health Functions
Pan American Health Organization/ World Health Organization /Centers for Disease Control and Prevention, November 2001.

LEGAL & REGULATORY CAPACITY

Essential Function 6: Strengthening of Institutional Capacity for Regulation and Enforcement in Public Health

Definition:

This function includes:

- The institutional capacity to develop the regulatory and enforcement frameworks that protect public health and monitor compliance within these frameworks.
- The capacity to generate new laws and regulations aimed at improving public health, as well as promoting healthy environments.
- The protection of civil society in its use of health services.
- The execution of all of these activities to ensure full, proper, consistent and timely compliance with the regulatory and enforcement frameworks.

Indicators:

6.1 Periodic Monitoring, Evaluation and Revision of the Regulatory Framework

Standard:

The NHA:

- Periodically reviews the current laws and regulations that protect public health and ensure healthy environments, based on the best national and international information available.
- Prepares and reviews laws and regulations proposed for future use.
- Proposes updates to the wording and content to ensure laws and regulations reflect current scientific knowledge in public health and correct any undesirable effects of the legislation.
- Requests information from lawmakers, legal experts and civil society, particularly subject to regulation or directly affected by the legislation under review.
- Monitors legislative proposals under discussion and advises lawmakers on them.

6.1.1 Does the NHA have expertise in the drafting of laws and regulations designed to protect public health?

Does this expertise include:

6.1.1.1 Its own legal counsel?
6.1.1.2 Legal counsel contracted externally for specific reviews?
6.1.1.3 Personnel familiar with legislative and regulatory procedures for the passage, amendment and rejection of laws and regulations in public health?

6.1.2 Does the NHA review the laws and regulations designed to protect the health and safety of the population?

Does the NHA:

6.1.2.1 Include draft legislation in the above review?
6.1.2.2 Consider whether the legislation is consistent with current scientific knowledge in public health?
6.1.2.3 Consider the positive and negative impact of these laws and regulations?
6.1.2.4 Complete the review in a timely manner?
6.1.2.5 Conduct this review periodically?
6.1.2.6 Involve other regulatory mechanisms in the above review?

6.1.3 Does the NHA seek input in evaluating health laws and regulations?

Is this input sought from:

6.1.3.1 Key lawmakers who support the development of public health?
6.1.3.2 Legal advisors?
6.1.3.3 Other government agencies?
6.1.3.4 Civil society?
6.1.3.5 Representatives of community organizations?
6.1.3.6 Users' associations, interest groups, and other associations?
6.1.3.7 Individuals and organizations directly affected by these laws and regulations?
6.1.3.8 Interested international organizations?

6.1.4 Does the NHA spearhead efforts to revise laws and regulations based on the results of the review?

Does the NHA:

6.1.4.1 Offer advisory services and assistance to lawmakers for the drafting of the necessary legal revisions based on the results of the review?
6.1.4.2 Actively engage in advocacy to facilitate the necessary legal revisions that protect the health and safety of the population?

6.2 Enforcement of Laws and Regulations

Standard:

The NHA:

- Exercises oversight of public health activities within its jurisdiction to ensure the adherence to clearly written guidelines.
- Coordinates with other sectors to oversee activities that have impact on public health.
- Monitors oversight activities and procedures that correct abuses of authority or the failure to exercise authority if pressured by influential groups.
- Adopts a regulatory stance not only centered on education about public health law and the prevention of infractions, but also on the punishment of violators after the fact.
- Promotes the compliance of health regulations through educating and informing consumers and integrating enforcement activities at all levels of the health system.
- Implements a clear policy formulated to prevent corruption as a practice that can permeate enforcement and ensures its periodic monitoring by independent entities to correct irregularities.

6.2.1 Does the NHA have systematic processes in place to enforce existing laws and regulations?

Does the NHA:

6.2.1.1 Have clear, written guidelines that support enforcement in public health?

6.2.1.2 Identify the personnel responsible for enforcement procedures?

6.2.1.3 Supervise the enforcement procedures that are utilized?

If so, does the NHA:

6.2.1.3.1 Seek to identify the abuse or misuse of its enforcement authority?

6.2.1.3.2 Monitor compliance with the enforcement guidelines?

6.2.1.4 Does the NHA act in a timely manner to correct the abuse or misuse of its authority?

6.2.1.5 Does the NHA have an incentive system in place for enforcement personnel to help ensure that they exercise their authority in an appropriate manner?

6.2.1.6 Does the NHA monitor the timeliness and efficiency of its enforcement procedures?

6.2.2 Does the NHA educate civil society about public health regulations and encourage compliance?

Does the NHA:

6.2.2.1 Widely inform the public about the importance of compliance with health laws and regulations and the applicable procedures for doing so?

6.2.2.2 Have established procedures that inform those individuals and organizations affected by health laws and regulations?

6.2.2.3 Have an incentive system to foster compliance with laws and regulations?

If so,

6.2.2.3.1 Does this incentive system include recognition and certification of quality and certification with respect to compliance with laws and regulations?

6.2.3 Does the NHA develop and implement policies and plans aimed at preventing corruption in the public health system?

Are these policies and plans:

6.2.3.1 Periodically evaluated by independent entities and adjusted when needed in accordance with the results of the evaluation?

6.2.3.2 Consistent with national priorities on the subject of corruption?

6.2.3.3 Considering measures needed to prevent the influence of external pressure groups on the NHA?

6.2.3.4 Capable of responding to corruption in the public health system by utilizing a penalty mechanism?

If so,

6.2.3.4.1 Is the existence of these penalty mechanisms made known to NHA personnel at all levels?

6.3 Knowledge, Skills, and Mechanisms for Reviewing, Improving and Enforcing Regulations

Standard

The NHA:

- Has a competent team of advisors who have thorough knowledge (both national and international) of regulatory procedures that govern the adoption, amendment, and rescinding of public health laws.
- Ensures that mechanisms and resources are available to enforce laws.
- Periodically evaluates national knowledge and competencies, as well as oversight and enforcement capacities in regards to public health laws and regulations.

6.3.1 Does the NHA have institutional capacity to exercise its regulatory and enforcement functions?

Does the NHA:

6.3.1.1 Have a competent team of advisors to develop the regulatory framework and draft regulations?

6.3.1.2 Have the knowledge, skills and resources to exercise the regulatory function in public health?

If so, does the NHA:

6.3.1.2.1 Have sufficient human resources to exercise the regulatory function?

6.3.1.2.2 Have the institutional resources to draft the regulations?

6.3.1.2.3 Have adequate financial resources to exercise its regulatory and enforcement functions?

6.3.2 Does the NHA have procedures and resources to enforce regulations?

Does the NHA:

6.3.2.1 Have an entity that exercises its enforcement function?

6.3.2.2 Have sufficient human resources for enforcement?

6.3.2.3 Have sufficient institutional resources to enforce regulations?

6.3.2.4 Have financial resources to carry out enforcement?

6.3.2.5 Provide orientation to enforcement personnel with regard to procedures they should follow?

If so,

6.3.2.5.1 Is orientation on the regulatory framework provided?

6.3.2.5.2 Does this orientation include setting priorities for enforcement in specific situations?

6.3.3 Does the NHA ensure the availability of training courses for enforcement personnel?

Does the NHA:

6.3.3.1 Train/orient new staff on enforcement?

6.3.3.2 Ensure the availability of training courses on enforcement?

6.3.3.3 Include in these courses content on best practices in enforcement?

6.3.3.4 Ensure that continuing education for enforcement personnel is offered on a regular basis?

6.3.3.5 Help its enforcement personnel develop interpersonal communication and personal safety skills (e.g., handling difficult situations and people)?

6.3.4 Does the NHA evaluate its capacity for reviewing and drafting laws and regulations in public health?

6.3.4.1 Has the NHA made progress toward improving its capacity for reviewing and drafting laws and regulations based on the findings of the most recent evaluation?

6.3.4.2 Can you cite an example of such improvement in capacity for reviewing and drafting laws and regulations?

6.4 Support and Technical Assistance to the Subnational Levels of Public Health in Developing and Enforcing Laws and Regulations

Standard:

The NHA:

- Orientate and supports the subnational levels in how to best comply with current laws and regulations within their jurisdiction.
- Prepares protocols, answers questions and provides technical assistance and training to the subnational levels in best practices for enforcement procedures.
- Assists the subnational levels in difficult and complex enforcement activities.
- Periodically evaluates the technical assistance and support it provides to the subnational levels in regulation and enforcement.
- Introduces improvements based on the results of the above evaluations.

6.4.1 Does the NHA provide assistance to the subnational levels in developing laws and regulations that protect public health?

Does the NHA:

6.4.1.1 Provide protocols to the subnational levels for the decentralized drafting of laws and regulations?
6.4.1.2 Offer advisory services to the subnational levels on the drafting of laws and regulations?
6.4.1.3 Provide training to the subnational levels in decentralized regulation?
6.4.1.4 Offer technical assistance to specialized personnel at the subnational levels for the drafting of complex laws and regulations?

6.4.2 Does the NHA provide orientation and support to the subnational levels on enforcement of public health laws and regulations in their jurisdiction?

Does the NHA:

6.4.2.1 Furnish protocols to the subnational levels that describe best practices in enforcement?
6.4.2.2 Advise the subnational levels on implementing enforcement procedures?
6.4.2.3 Assist the subnational levels with training in enforcement procedures?
6.4.2.4 Assist specialized personnel at the subnational levels who handle complex enforcement activities?

6.4.2.5 Periodically evaluate the technical assistance it provides to the subnational levels on the enforcement of public health laws and regulations?

If so,

6.4.2.5.1 Does it use the findings of these evaluations to improve the quality of its technical assistance?

INDEX of rest of Report / Instrument

Instrument for Measuring the Essential Public Health Functions

Appendix J – Main features of health system governance in Spain, and Draft Spanish Act of Regulating Health Professions

Main features of health system governance in Spain[1]

Riitta-Liisa Kolehmainen-Aitken, MD, DrPH

- Spanish constitution guarantees a right to "health protection" to all citizens. The General Health Law/1986 created the National Health System, which is made up of all public health structures and services in the country, and financed through central tax revenue.

- Between 1981 and 1994, the management of health care was decentralized to the seven special regions, but the other ten regions remained under central control. On 1 January 2002, all seventeen Autonomous Communities (ACs) were made responsible for the management of health care "under the direction and supervision of the State". Each AC has its own Health Service (Servicio de Salud), comprised of all the health facilities and programs in the Community. Each AC prepares its own Health Plan, and determines how to structure health service delivery within its territory.

- A new agreement on regional financing (approved in July 2001) governs health transfers from the State to the ACs. The sustainability and equity of health care financing is clearly guaranteed prior to the transfers. (The agreement was reached after long negotiations between the central government and each AC.)

- Majority of medical staff have a status similar to civil servants. Working conditions are negotiated centrally, but there is a limited local capacity to negotiate salary incentives.

- The 1986 General Health Law established several mechanisms to maintain unity of the National Health System. Two of them, the Integrated Health Care Plan and the High Inspectorate, were not successful.

- The Law 16-2003 on Cohesion and Quality of the National Health System is the new legal basis for guaranteeing equal health care access to citizens in the decentralized Spanish National Health System. The main coordination body is the Inter-territorial council, in which health directors of the ACs are represented. Law 16-2003:
    - sets up a guaranteed minimum benefits package
    - defines standards for quantity and quality of services to be provided by regions

[1] Summarized from (1) Garcia-Milà, Teresa and Puig-Junoy, Jaume. *Spanish Health Care Decentralization*, December 12, 2001; http://www.econ.upf.es/~puig/publicacions/paper22.pdf; (2) *Spain: The basic principles of the health care system*. http://europa.eu.int/comm/employment_social/missoc/2002/03/spain_en.pdf; and (3) *Decentralization process about to be completed: Devolution of the health care network to the 10 remaining regions.* European Observatory on Health Care Systems. http://www.who.dk/eprise/main/who/progs/obs/hits/20020527_1.

  - establishes a unified information system, and
  - defines the post-decentralization roles of the Health Ministry and the Inter-territorial Council.

- The central government, through its various ministries, is responsible for the following legal/regulatory matters:
  - Basic health legislation and general coordination
  - Regulation of the financial aspects of social security (Ministry of Labor and Social Affairs)
  - Pharmaceutical policy regulation, including regulation of drug prices
  - Standardization of medical and health products
  - Regulation of undergraduate and postgraduate training, and
  - Regulation of most aspects of recruitment and employment of health personnel (Ministry of Public Administration)

- A critical remaining priority for the Ministry of Health is to establish a new Framework Statute on the Health Care Professions. The Act on Regulating Health Professions (see the following pages) is one of the steps in establishing the Framework.

- (According to the web page of the European Observatory on Health Care System, there is also an Act on Health Care Personnel, approved by the Parliament in November 2001.)

Summary of the Draft Spanish Act of Regulating Health Professions

Riitta-Liisa Kolehmainen-Aitken, MD, DrPH

- Approved by the Spanish Senate in October 2003; not yet approved by the House of Representatives

- Governs:
    - practice of health professions
    - pre-graduate and specialty training, and continuing education
    - professional development
    - private practice, and
    - participation of professionals in planning and structuring professions

- The main headings of the Act are shown below. Key points under each heading are in square brackets.

>>>

PREAMBLE

[Gives a brief history of laws on health professions in Spain. States that only those occupations that are regulated by State are recognized as professions. Explains that the Act consists of a preliminary chapter and five chapters.]

PRELIMINARY TITLE (TÍTULO): GENERAL NORMS

Article 1: Object and scope of application

[Explains that the Act governs the practice of all health professions that require a university degree or a diploma. It applies both to employees and the self-employed. The act also governs the general structure of training health professionals; their professional development; and their participation in planning and structuring health professions.]

Article 2: Health Professions who hold a qualification

[Health professions are those that are so trained and organized in professional associations, officially recognized by public authorities. The professions are structured in two groups: (1) Those with a licentiate, i.e. doctors, pharmacists, dentists and veterinarians plus Specialists in Health Sciences; (2) Those with a diploma, i.e. nurses, physiotherapists, etc.]

Article 3: Professionally trained professionals of the health area

[Structured in two groups: (1) Upper level, i.e. "Téchnico Superior" (?technologist) in pathology and cytology, in dental hygiene, etc. and (2) Medium level, i.e. Technician in Nursing Care Assistance and in Pharmacy)]

TITLE I: OF PRACTICE OF HEALTH PROFESSIONS

Article 4: General Principles

[Establishes the right to free practice of health professions within legal requirements. Such practice requires possession of the corresponding degree or certification. All health professionals have the duty to participate in projects that benefit health and welfare of individuals, such as prevention, health education, research, and exchange of information with other professionals and with health authorities. Technical and scientific autonomy in the practice of health profession is guaranteed within the following principles: clinical histories have to documented in writing, scientifically based practice guidelines and protocols must be followed, continuity of care for patients guaranteed, etc.]

Article 5: General principles of the relation between health professionals and patients

[States that professionals have the duty to provide technically and professionally adequate care, make rational use of diagnostic and therapeutic resources, and respect personality, dignity and privacy of their patients and their participation in care decisions. Patients have the right to freely choose their doctor, be informed of the name, qualification and specialty of health workers who care for them, and receive information about their care. Professional Colleges and Autonomous and General Councils must establish public registries of professionals that are accessible to the public and at the disposal of the Health Administrations (of the Autonomous Communities)]

Article 6: Licensed health workers [i.e. doctors, pharmacists, dentists and veterinarians]

[Explains what they are and what they do.]

Article 7: Diploma-level health workers

[Ditto]

Article 8: Professional practice in health organizations

[States that health centers have to check every three years that the health professionals they employ meet the required standards for professional practice; have to maintain a registry of staff, etc.]

Article 9: Inter-professional relations and team work

[Defines a health care team as the basic unit of work. Delegation of work within a team can be done, provided there is back-up. Centers and institutions are responsible for the capacity of their professionals to take correct action in tasks that have been allocated to them within a team.]

Article 10: Clinical management in health organizations

[Defines that procedures and systems of clinical management are established by Health Administrations (of the Autonomous Communities), Health Services and the "government organs" in health establishments, as relevant, with the participation of the appropriate professionals. Clinical management is evaluated by assessing performance and results. Each Health Administration can decide the means by which good performance can be recognized by health centers, Health Services and the whole health system.]

Article 11: [Suppressed]

Article 12: Research and teaching

[States that the whole health system is to be available for research and professional training. Health Administrations, together with Education Administrations, promote these activities in all health centers as an essential element in health system development.]

TITLE II: OF THE TRAINING OF HEALTH PROFESSIONALS

CHAPTER I (CAPITULO): GENERAL NORMS

Article 13: Governing principles

[Defines these as permanent collaboration between all Public Administration Organizations responsible for education and health; collaboration between universities and other training institutions and health facilities, etc. etc.]

CHAPTER II: PRE-GRADUATE TRAINING

Article 14: Of university-level training

[States that when necessary, and with previous agreement of Human Resource Commission of the National Health System, Ministry of Health and Consumer Affairs (MOH) can urge Ministry of Education and Sport to initiate new degrees or incorporate new areas in training plans.]

Article 15: Agreements between universities and Health Services, institutions and health centers

[States that State establishes general basis for these agreements in which the "competent organ" of the Autonomous Community has to be a participant.]

CHAPTER III: SPECIALTY TRAINING IN HEALTH SCIENCES

Section 1ª: Object and definitions

Article 16: Character and goal of specialty training

Article 17: Title as specialists in Health Sciences

[States that State establishes the titles. Possession of such a title is necessary for calling yourself a specialist, for practicing as a specialist and for occupying a specialist post.]

Article 18: Awarding of the qualification as a specialist

[States that this is awarded by the Ministry of Education, Culture and Sports. Sets requirements for being awarded the title.]

Article 19: Professional recognition of specialty qualifications, obtained in foreign countries

Section 2ª: Of the structure and training in health science specialties

Article 20: General structure of specialties

Article 21: Specialty training system

[Defines that both theoretical and practical training is required. Speciality training can only take place in accredited centers. Establishes criteria for residency training.]

Article 22: Training programs

[Defines that training programs are elaborated by the National Specialty Commission. National Council of Health Science Specialties ratifies them. Human Resource

Commission of the National Health System and the Ministry of Education, Culture and Sports are informed. MOH approves.]

Article 23: Access to specialty training
[States that this is through an annual national "call" in which theoretical and practical knowledge, clinical and communication skills, and academic merits of applicants are assessed. The system of awarding places is established through regulation. The number of places offered is decided by the Human Resource Commission of the National Health System, following proposals from Autonomous Communities, and in accordance with specialist needs of the National Health System and available budgetary resources.]

Article 24: Training for a new specialty
[States that this can be done only after five years of professional practice in the previous specialty.]

Article 25: Areas of a sub-specialty
[States that the sub-specialty diploma is official and valid in the whole country. It is awarded by the Ministry of Health and Consumer Affairs.]

Article 26: Sub-specialty training
[States that requirements for entry and training are to be established through regulation.]

Section 3[a]: Support structure for training
Article 27: Educational accreditation of centers and units
[States that MOH establishes accreditation requirements, and the Quality Agency of the National Health System assesses them. Accreditation specifies the number of accredited training posts.]

Article 28: Teaching Commissions
[States that every accredited training center or training unit has to have a Training Commission that is responsible for organizing the training, supervising practical work, and meeting training objectives. Autonomous Communities determine the reporting relationship, composition and functions of the Teaching Commissions, within the general criteria established by the Human Resource Commission of the National Health System.]

Article 29: National Specialty Commissions
[States that MOH designates a National Commission for each Health Science Specialty Area to assist the Health and Education Ministries. Defines the composition of a commission. Outlines its main functions which are set through regulation (e.g. elaboration of training plan, establishment of evaluation criteria for trainees and training facilities, etc.)]

Article 30: Committees of Sub-specialty Areas
[Establishes that it consists of six specialists in the appropriate area. Defines training program, evaluation criteria, etc.]

Article 31: National Council of Specialties in Health Sciences

[Sets the composition of the Council and its working mechanisms, e.g. Permanent Commission, working groups, etc.]

Article 32: Technical support and Secretariat of the Commissions
[States that each accredited health center has to support its Training Commission. MOH has to support national commissions and council. Secretariat from the Directing Unit of the centers and the Ministry has voice but no vote.]

Article 33: Registries
[Establishes the different registries of specialists and accredited centers and who is responsible for maintaining them. These registries are public.]

CHAPTER IV: CONTINUING EDUCATION

Article 34: General Principles
[Defines the objectives of continuing education.]

Article 35: Commission of Continuing Education
[States that such Commissions have to be established, and that the Public Administrations of the Inter-territorial Council of the National Health System participate in them. Establishes the functions of these Commissions, e.g. assessing continuing education needs, proposing priority programs, establishing accreditation criteria, etc.]

Article 36: Accreditation of centers, activities and professionals
[States that the MOH and the "competent organs" of the Autonomous Communities can accredit continuing education activities and provide continuing education credits to professionals. Such accreditation/awarding of credits is valid in the whole country, regardless of which Public Administration issued it.]

Article 37: Diplomas of Accreditation and Diplomas of Advanced Accreditation
[States that Public Health Administrations can issue diplomas of credit or diplomas of advanced credit to recognize professional training through continuing education. These diplomas must be issued according to criteria established under Article 35. They are valid in the whole country.]

TITLE III: OF PROFESSIONAL DEVELOPMENT AND ITS RECOGNITION

Article 38: General Norms
[Explains that this is a recognition system that provides for public, express and individual recognition either for advanced skill and experience or for meeting objectives.

Article 39: Professional development
[States that Health Administrations regulate the recognition of professional development for their health facilities. Establishes the general principals for such recognition.]

Article 40: Harmonization of the recognition of professional development

[States that the Inter-territorial Council of the National Health System establishes the principles and general criteria for harmonizing such recognition in the whole National Health System.]

TITLE IV: OF PRIVATE PRACTICE OF HEALTH PROFESSIONS

Article 41: Modalities and general principles of the private practice

[States that health professionals in the private sector can work as employees or as self-employed. Establishes the principles of such private practice, e.g. right to practice in accordance with qualifications and type of profession, respect for technical and scientific autonomy, stable contracting framework, etc.]

Article 42: Provision of services by employed private practitioners

[States that these practitioners have the right to be informed of their tasks, unit's objectives and evaluation criteria; have the responsibility to practice according to technical, scientific and ethical guidelines, to keep their skills up-to-date, etc. Performance assessment in these centers is as established in Chapter III of this Law.]

Article 43: Provision of services by self-employed private practitioners

[States that all service contracts have to be in writing, and that self-employed staff can voluntarily participate in professional development, as per Chapter III of this Law.]

Article 44: Registries of professionals

[States that all centers that have service contracts have to maintain a public personnel registry, according to criteria and requirements that Autonomous Communities establish in accordance with national principles. These registries have to be compatible with the National Health Information System.]

Article 45: Publicity of private professional practice

[States that publicity has to respect the scientific basis of activities and prescriptions, be objective, prudent, and true, etc.]

Article 46: Security and quality in private professional practice

[States that private practices have to meet all the accreditation requirements that are determined by the "competent organs" of the Autonomous Communities.]

Article 47: Malpractice cover

[States that private practitioners have to have malpractice cover. Autonomous Communities determine the essential conditions for such insurance with the participation of the professionals, etc.]

TITLE V: OF PARTICIPATION OF PROFESSIONALS

Article 48: Professional Consultative Commission

[States that this Commission is the organism through which health professionals participate in the health system and in the development, planning, etc. of health professions.]

Article 49: Composition and assignment

Appendix K − Main features of health system governance in Finland[1]

Riitta-Liisa Kolehmainen-Aitken, MD, DrPH

- Finland is a republic with a President (elected every six years by direct popular vote) and a 200 member single chamber parliament (elected every four years). The country is divided into five administrative provinces and the autonomous Ahvenanmaa (Åland in Swedish) islands. Finland became a member of the EU in 1995.

- The governance structure is devolved. The constitution guarantees self-governance of municipalities in executing the responsibilities that they have been given by law. According to the Law on Municipalities 1995, they can be given new responsibilities and duties only through legislation. The same is true about removing their present responsibilities or rights.

- There are 448 municipalities with an average population of 11,000. The main decision-making power is the municipal council, which is elected every four years. A municipal executive board is accountable to the council. The council appoints members to the various municipal committees, including the health committee.

- The constitution of Finland states that public authorities shall guarantee for everyone, as provided in more detail by an Act of Parliament, adequate social, health and medical services and promotion of the health of the population. Central government and municipalities are the main administrative levels in the health sector. An administrative level of the province also exists.

- **Legislation provides a framework for the provision of services that allows for different local solutions. It does not regulate in great detail the range, content and way of organizing the provision of services.** The quality of services is not defined in detail by legislation, but the quality of services and health care facilities are of a high standard.

- The most important health laws are:
    - 1972 Primary Health Care Act
    - 1979 Occupational Health Care Act
    - 1987 Patient's Injury Law, amended in 1999
    - 1991 Specialized Health Care Act
    - 1991 Mental Health Act
    - 1992 Law on social and health care planning and state subsidies
    - 1993 Law on Patients' Status and Rights (the first such law in Europe)
    - Private Health Care Act (modified in 1990)

- At the *central government* level, the Ministry of Social Affairs and Health directs and guides social and health services. It defines policy, prepares major reforms and proposals for legislation, monitors their implementation, and assists the

[1] Summarized from Järvelin J. *Finland: Health Care Systems in Transition, Vol. 4 No. 1 2002.* European Observatory on Health Care Systems.

government in decision making. The government decides on general national priorities and proposes bills to be discussed by the parliament. The Basic Security Council, attached to the Ministry of Social Affairs and Health, may investigate any deficiencies observed in the provision of municipal health services. The five *provincial state offices*, through their social and health departments, are responsible for promoting national and regional objectives of the central administration. They guide and supervise both publicly and privately funded health care, assess basic services and approve the municipalities' medium size capital investment plans

- Other agencies and institutions, attached to the Ministry of Social Affairs and Health and relevant from the legal standpoint, include:
    - The *National Research and Development Centre for Welfare and Health (Stakes)*, which monitors, evaluates and carries out research and development.
    - The *National Authority for Medico-legal Affairs*, which is responsible for the licensing and registration of health professionals, and and the legal protection of patients. It also handles disciplinary matters concerning health professionals.
    - The *National Agency for Medicines*, which licenses pharmacies (all of which are privately owned), grants permissions for the sale of pharmaceutical products, and supervises the manufacture, import and distribution of medicines.
    - The *Radiation and Nuclear Safety Authority*, whic regulates the use of radiation, according to legislation.

- The Social Insurance Institution (with its app. 400 local offices) runs the statutory National Health Insurance scheme that finances part of the total cost of health care. The Institution falls under the authority of the Parliament, and is separate from the Ministry of Social and Health Affairs. The Ministry, however, prepares health insurance legislation.

- **The main responsibility for arranging health services lies with the *municipalities*.** The 1972 Primary Health Care Act obliges them to provide the following services for their inhabitants:
    - Health promotion and disease prevention
    - Medical care
    - Medical rehabilitation
    - Dental care
    - School and student health care
    - Occupational health care
    - Cervical and breast cancer screening
    - Family planning services
    - Mental health care (when it is appropriate to provide it at a health center), and
    - Ambulance services.

- The statutory services are to be provided in health centers, either the municipalities' own or in conjunction with other municipalities. Municipalities can also buy services from the private sector.

- Hospitals are owned by federations of municipalities which form hospital districts. Each municipality must be a member of a hospital district. Publicly owned hospitals do not aim to make a profit.

- Municipalities are also obliged by law to arrange specialized medical care for their inhabitants. These are regulated through the 1991 Specialized Health Care Act and the 1991 Mental Health Act. There is separate legislation concerning some vulnerable groups of the population, such as the disabled.

- State regulation on health service provision was rather detailed until 1993. A major state subsidy reform in that year reduced regulation by the state, and **by 2000, regulation by norms was almost nonexistent. Steering through information became increasingly important for the government as a means of monitoring the health care system.** Steering through information is understood to encompass policy recommendations based on research and evaluation, evidence-based medicine and protocols, education and training, performance indicators and other activities based on information development.

- The health care system is mainly tax-financed. (In 2001, municipalities financed 43% of total health care costs; the state 17%; National Health Insurance 16%; and households 20%, with the remainder coming from other private sources.) Of the running costs of municipal health services, municipalities pay app. 65% of the costs, the state 25%, and clients 10%.

- Municipal health services are financed through state subsidies, municipal tax revenue and out-of-pocket. The law on social and health care planning and state subsidies regulates the state subsidies on social and health services. A state subsidy, on average, covers 28% of a municipality's operating budget and 42% of its capital investments.

- Municipal services that are free of charge are defined by law. Maximum out-of-pocket payments for those services where a fee is allowed are defined by statute. Legislation defines maximum payments that hospitals can charge from patients, but does not regulate payments to hospitals. Municipalities negotiate an annual agreement on the provision and prices of services with their hospital district.

- The control and follow-up of communicable diseases is also defined through legislation and regulations of the Ministry of Social Affairs and Health.

Appendix L – **Devolution: Legislation + management tools – [Food Act] example**
PowerPoint presentation slide from *Malaysia Case Study: Decentralization and performance management in the health* by Indra Pathmanathan in the World Bank, DTF and Ministry of Home Affairs International Workshop on Obligatory Functions and Minimum Service Standards, Jakarta, Oct. 22-24, 2002.

Devolution: Legislation + management tools - example