

Strategizing national health in the 21st century: a handbook
Chapter 10

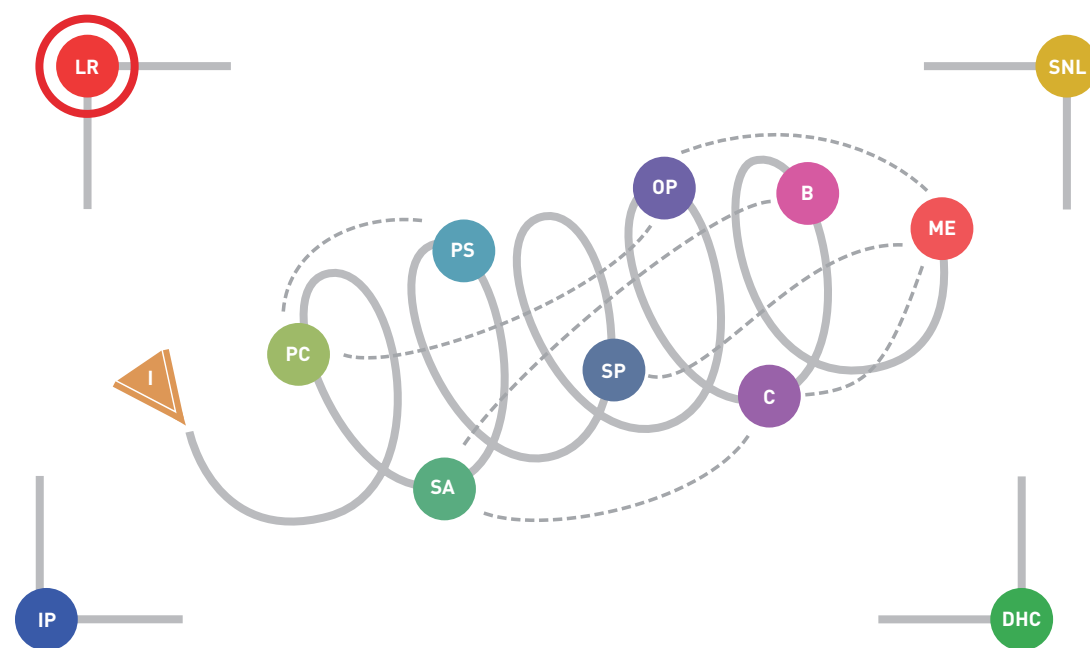
Law, regulation and strategizing for health

David Clarke

A close-up, low-angle shot of a stack of books. The top book is open, showing its yellowed, aged pages. Below it, the spine of another book is visible, featuring the word 'Law' in a large, bold, black sans-serif font. The background is a dark, textured grey.

Law

Legisl



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PC	CHAPTER 2 Population consultation on needs and expectations
SA	CHAPTER 3 Situation analysis of the health sector
PS	CHAPTER 4 Priority-setting for national health policies, strategies and plans
SP	CHAPTER 5 Strategic planning: transforming priorities into plans
OP	CHAPTER 6 Operational planning: transforming plans into action
C	CHAPTER 7 Estimating cost implications of a national health policy, strategy or plan
B	CHAPTER 8 Budgeting for health
ME	CHAPTER 9 Monitoring and evaluation of national health policies, strategies and plans

Cross-cutting topics relevant to national health planning

LR	CHAPTER 10 Law, regulation and strategizing for health
SNL	CHAPTER 11 Strategizing for health at sub-national level
IP	CHAPTER 12 Intersectoral planning for health and health equity
DHC	CHAPTER 13 Strategizing in distressed health contexts

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Overview

For the national health planning process, regulation represents a key means by which a government gives effect to its health policy preferences, especially through the exercise of a government's law-making powers. The last 25 years have seen major changes to the way that governments organize themselves, provide services and make and implement policy. A range of decisions that were once taken by a health minister or a health ministry are now taken by regional and local government, autonomous public sector agencies, private firms, nongovernmental organizations and individuals. As a result, regulation has grown in importance as a key lever for governments to affect the quantity, quality, safety and distribution of services in health systems.



Summary

What is law and regulation?

The term “regulation” is commonly used in two ways.

First, it is used in a narrow sense to describe a category of delegated decision-making involving the use of secondary legislation.

However, in this publication the term is used in a second and broader sense to cover the use of instruments of various types for the implementation of socioeconomic policy objectives and includes laws.

Laws are rules that govern behaviour.

Laws can be made by a legislature, resulting in primary legislation (often called statutes or acts), by executive or local government through the issue of secondary legislation (including decrees, regulations and bylaws), or by judges through the making of binding legal precedent (normally in common law jurisdictions).

Why is law and regulation important?

National health planning process: Law and regulation set the ground rules for the health planning process.

National Health Policy/Strategy/Plan (NHPSP) implementation: Law and regulation are key implementation mechanisms for translating major health policy objectives into action through the setting of standards and requirements and the use of sanctions and incentives to exert leverage over the health system (and its participants).

When should work on law and regulation take place in the national health-planning process?

Thinking about law and regulation should take place at the start of the planning process. It is important for key actors involved to understand any legal rules and requirements that relate to how the process should be carried out.

Specific issues about law and regulation should be taken into account during the various planning activities; for example, regulatory analysis should take place as part of a country’s work on its health-sector situation analysis, and when developing options for legal and regulatory interventions to give effect to the country’s NHPSP.

Who should be involved in work on law and regulation?

The many people involved in work on laws and other forms of regulation, include political decision-makers, lawyers, policy analysts, health planners, health providers, health professionals and members of the public. The roles of the various actors vary, and encompass decision-making, resource mobilization and provision, contribution to the policy/regulatory dialogue, and implementation.

Identify other key people that you need to work with on law and other forms of regulation.

Map out any specific tasks that need to be carried out on law/regulation as part of your work on NHPSP implementation activities, and factor in work on these tasks as part of the process.

As it proceeds, assess at each stage in the process what issues, tasks and inputs you need to consider with regard to law and other forms of regulation.

How do we go about work on law and regulation?

At the beginning of the process make sure that you understand any legal requirements to be met as part of running the planning process, including legal requirements relating to the budget process. Read any relevant laws and guides; get legal advice if necessary.

Meet with the ministry of health's policy and legal team to discuss your respective roles in any work on law and other forms of regulation, and discuss how this work might affect the planning process.

Note: Work on law and other forms of regulation should not be regarded as a separate process, but should be an integral part of a country's health policy dialogue engaging stakeholders from health, finance and other ministries, civil society, nongovernmental organizations, international agencies, academic institutions, professional associations and communities. A similar approach should be taken when implementing law and regulation.

10.1 What do we mean by law and regulation?

10.1.1 Some key concepts

Regulation

Regulation is:

- (a) the promulgation of rules by government accompanied by mechanisms for monitoring and enforcement (usually assumed to be performed through a specialist public agency);
- (b) any form of direct state intervention in the economy, whatever form that intervention might take; or
- (c) all mechanisms of social control or influence affecting all aspects of behaviour, from whatever source.

The first aspect, the promulgation of rules by governments, inevitably involves the exercise of a government's law-making powers, so the first dimension of the definition relates to the use of laws and legal tools to affect behavioural change. For example, a government may put in place mandatory rules requiring the operators of a health facility to obtain an authorization before they provide services, and impose sanctions where the rules are not obeyed.

The second aspect refers to other regulatory tools a government can use to control or influence conduct in the health system. Possible regulatory tools include economic tools and market instruments (such as tobacco taxes, nursing school quotas or drug pricing mechanisms) and disclosure regulation (such as requiring health providers to disclose certain information to consumers to empower them to make better choices).^{1,1}

The third aspect of the definition reflects that increasingly, regulation is carried out by non-government actors as well as by government. This last aspect illustrates that governments have a choice: do they regulate themselves, or do they allow nongovernment actors to self-regulate? A good example is where a government has chosen to allow a health professional group to self-regulate and set the rules of conduct for its members.

While all governments regulate, regulation is also made by non-state actors.

¹ Disclosure regulation is designed to address information asymmetry. Health care organizations are required to provide open and transparent information to consumers and competitors on price, quality and quantity.



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Box 10.1

Examples of the different aspects of regulation

The promulgation of rules by government

Turkey provides a good illustration of how rules made by governments can lead to positive behavioural change (consistent with a government's policy intentions). To implement its policy to reduce smoking related diseases, Turkey introduced laws to impose tobacco taxation, ban tobacco product advertisements and smoking in public places. These interventions have led to a reduction in the proportion of tobacco smokers in the adult population.²



The use of other regulatory tools (e.g. incentive-based regulation)

Demand-side incentives, such as conditional cash transfers or vouchers to encourage the uptake of primary health care, are now being implemented in many Latin American countries and in Asia. These provide direct financial support to families for achieving specific targets, such as attending antenatal care or delivery in a health facility with trained professionals.³

Regulation by nongovernment actors

Many countries regulate their health workers using a self-regulatory model, e.g. the *Indian Medical Council Act*⁴ allows the medical council to regulate professional conduct of medical practitioners by prescribing standards, and a code of ethics for medical practitioners.

Law

Law is one of the most important types of regulation.

Law is a key type of regulation and is used to encourage or change behaviour.

Laws are rules that govern behaviour, backed by coercive force and made by a legitimately constituted nation state.⁵ Laws can be made by a legislature, resulting in primary legislation (often called statutes or acts), by executive or local government through the issue of secondary legislation (including decrees, regulations and bylaws), or by judges through the making of binding legal precedent (normally in common law jurisdictions).

Legislation

Legislation is a catch-all phrase to cover the different types of laws made by a country's legislature or other law-making body. The term legislation covers two main types of law: primary legislation and secondary legislation.

Primary legislation refers to statutes made by national legislatures (or by state legislatures in federal systems). Primary legislation usually defines broad powers and principles. However, as it is not always appropriate or possible for primary legislation to address all the technical details, systems and structures that are needed for implementation, these details are set out in secondary legislation.

Secondary legislation refers to laws made by executive or local government (examples include decrees, regulations, rules, orders and bylaws). Secondary legislation defines necessary technical details, as well as the systems and structures required to give full effect to primary legislation.

Box 10.2

Some examples to illustrate the differences between primary and secondary legislation

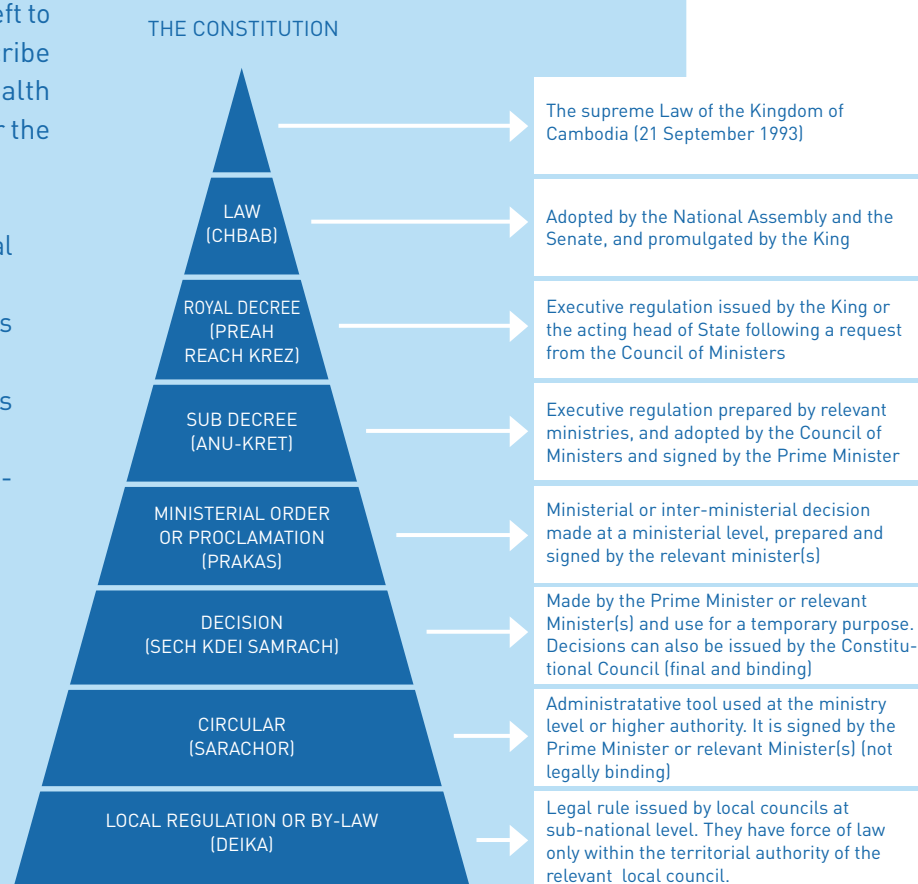
Nigeria

In 2014 Nigeria passed a National Health Act (an example of primary legislation) to provide a legal framework for the provision of health services. The Act ascribes health services roles and responsibilities to different tiers of government and to nongovernmental organizations. The operational details of the Act and its implementation have been left to secondary legislation, policy and administrative arrangements. For example, Part II of the Act provides a framework for regulating health establishments and technologies. The details of the framework are, however, left to secondary legislation, which will prescribe details about the classifications of health establishments and technologies under the Act, based on:

- ▶ their role and function within the national health system;
- ▶ the size and location of the communities they serve;
- ▶ the nature and level of health services they are able to provide;
- ▶ their geographical location and demographic reach;
- ▶ the need to structure the delivery of health services in accordance with national norms and standards within an integrated and coordinated national framework;
- ▶ and in the case of private health establishments, whether the establishment is for-profit or not.

Cambodia

In Cambodia's hierarchy of laws, matters of broad legal principle, key functions and powers and institutional arrangements are set in higher level "laws" and royal decrees, with sub-decrees, ministerial orders, decisions, circulars and local regulation used to clarify meaning and intent and provide for practical implementation (see the diagram below).



10.1.2 Ways in which law and regulation are used in the health sector

The strength of law and regulation comes from its power to:

- ▶ create and recognize rights;
- ▶ impose obligations and penalties;
- ▶ establish permanent institutions and institutional arrangements.^{II}

Governments use laws and other forms of regulations in three broad ways.

Law and regulation help implement national health policy, establish rights, rules, and safeguards and help assure health security.

1. First, countries regulate to establish the legal architecture for the health system to ensure cohesion and efficiency. A health systems law establishes legal responsibility and accountability for the performance of key health-system functions (planning, priority setting, financing, service provision, integrity and supervision, etc.). For example, see Box 10.3 on the United Kingdom's National Health Services Act.
2. Second, governments regulate in order to advance important policy objectives for their health systems, such as providing universal access to health services, establishing social protection floors, encouraging the efficient and equitable use of resources, or ensuring compliance with a country's international obligations - for example, the International Health Regulations.^{III} For examples, see Box 10.4.
3. Third, governments regulate to protect members of the public from harm or from the adverse effects of unconstrained business activities in the health system (and to address market failure and inefficiencies in the health system). For instance, private providers might want to segment markets to concentrate on profitable market niches, such as patients with easy-to-treat conditions, or patients with higher incomes. In those circumstances, laws and other forms of regulation might be required to oblige (or incentivize) private providers to provide a broader range of services and allow service access regardless of patient income. For example, see Box 10.4.

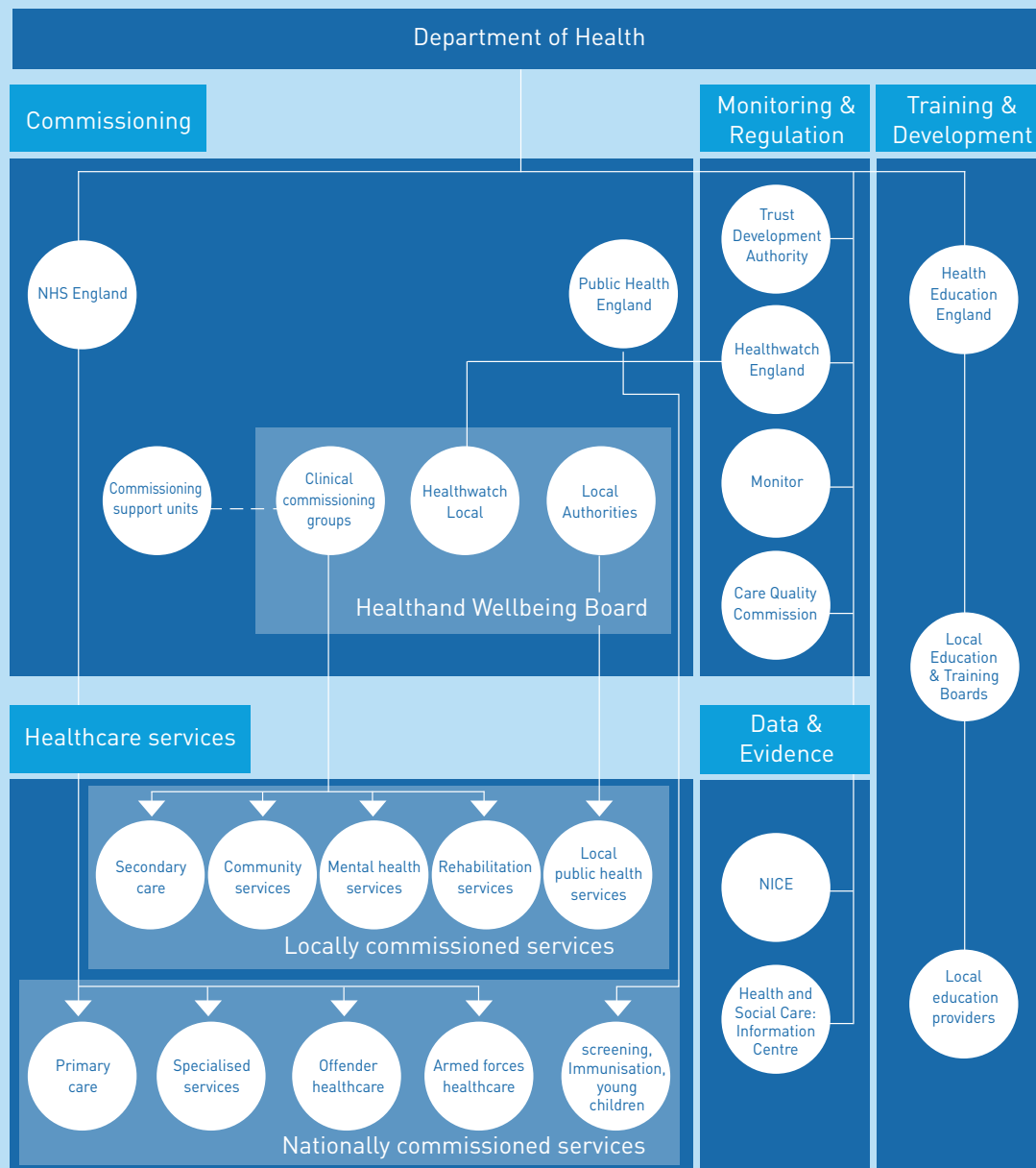
^{II} For example, see the discussion about the use of legislation to sustain and formalize the operation of Thailand's National Health Assembly (Box 10.9).

^{III} The International Health Regulations 2005 are an international legal instrument that is binding on over 196 countries, including all of the member states of WHO.

Box 10.3

The structure for the NHS established by the Health and Social Care Act 2012⁶

The Health and Social Care Act 2012 provides for an extensive reorganization of the structure of the National Health Service in England (see the diagram below).



The Secretary of State for Health has overall responsibility for the work of the Department of Health (DH). DH provides strategic leadership for public health, the NHS and social care in England.

The Chief Medical Officer is the UK government's principle medical and scientific adviser, the professional lead for doctors in England, and the professional lead of all directors of public health in local government.

The National Medical Director of NHS England is responsible for clinical policy and strategy, promoting a focus on clinical outcomes, enhancing clinical leadership and promoting innovation.

The Chief Nursing Officer is the professional lead for nurses and midwives in England and oversees quality improvements in patient safety and patient experience.

The Chief Professional Officers (including the Chief Scientific Officer, Chief Dental Officer, Chief Pharmaceutical Officer and Chief Health Professions Officer) are the heads of their respective professions and provide expert clinical advice across the health system.



Box 10.4

Examples of the different aspects of regulation

Health systems laws which establish the basis on which a country's health system is organized, governed and financed.

Laws which protect public health from communicable diseases or other public health risks, providing for public health surveillance and powers to take action to prevent the spread of disease or other public health risk. (These laws should be consistent with a country's obligations under the International Health Regulations 2005).

Laws which regulate the quality of health service provision.

Laws which provide for health system financing, such as social health insurance laws.

Laws which regulate the operation of hospitals, clinics or other health services.

Laws which establish social protection floors (a basic set of social rights derived from human rights treaties, including access to essential services – such as health, education, housing, water and sanitation, and others, as defined nationally – and social transfers, in cash or in kind, to guarantee income security, food security, adequate nutrition and access to essential services).

Laws which control the required training, qualifications and practice standards of health workers.

Laws governing the treatment and care of people with mental disorders.

Laws which regulate the safety and efficacy of medicines and medical devices.

Laws which regulate the manufacture, marketing and sale of food.

Laws which protect patient rights.

Laws which address noncommunicable disease risk factors including:

- ▶ tobacco consumption (where parties to the Framework Convention on Tobacco Control^{IV} should ensure that their tobacco control laws comply with the Convention's requirements);
- ▶ the harmful use of alcohol;
- ▶ diet-related diseases (such as laws which control the marketing to children of foods and beverages which are high in fat, sugar or salt).

Laws which regulate the collection and use of health information (including protecting patient privacy).

^{IV} The Framework Convention on Tobacco Control (FCTC) is an international treaty negotiated under the auspices of WHO to respond to the globalisation of the tobacco epidemic.

10.2 Why do we need law and regulation in the national health planning process?

Law and regulation in national health planning is used to establish a legal roadmap for the process and as a key implementation mechanism to translate policy objectives into action.

Law and regulation in the context of the national health planning process serves two key purposes:

- (a) to establish a legal roadmap for the national health planning process; and
- (b) as a key implementation mechanism, to translate major health policy objectives into action through setting standards and requirements and the use of sanctions and incentives to exert leverage over the health system (and its participants).

Box 10.5

An example of using law to give effect to health policy

As part of its policy of ensuring “health access for all”, Burkina Faso passed a new law on universal health insurance in 2015. The passage of this law represents a major achievement as it enshrines the “right to health” in a legal framework designed to increase access to health services while reducing the risk of financial hardship for paying for them.

The key features of the new law are:

the provision of basic health protection for the whole population via a pooled fund;

mandatory enrollment in the fund based on a person’s ability to pay and with government subsidizing the poor;

benefits paid on the basis of health need rather than on the ability to pay.



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10.2.1 A legal road map for the national health planning process

In some countries there are laws that set out what is in effect a legal road map for the national health planning process. This road map needs to be studied carefully to decide which issues are of most concern and require action with regard to a country's national health planning process.

This road map may consist of:

- (a) law(s) which deal with the establishment of a national health plan or strategy; and/or
- (b) law(s) which establish the rules for establishing and approving a country's health budget.

Potential actionable issues within these two main road map areas are described further below.

Laws about national health policies, strategies and plans

For the national health plan/strategy a country may have a law that:

- ▶ requires the country to have a health strategic plan;
- ▶ tasks an agency or person with the making of the plan (e.g. a health ministry or a health minister);
- ▶ describes the key content that must be included in such a plan;
- ▶ prescribes who must be consulted on a plan and how;
- ▶ requires a certain process to be followed to finalize the plan;
- ▶ requires reporting against the plan to an oversight body (for example, a country's national assembly/legislature).

Laws help formalize and create a sustainable basis for the planning process.

The purpose of this sort of law is twofold.

- ▶ To provide a sustainable mechanism for national health planning (if the requirement to make a plan is a legal duty, it is far more likely to happen than if the requirement is an administrative matter).
- ▶ To provide a legal obligation to adhere to a mechanism that is designed to give national coherence for health policy (especially if a law provides that all sub-plans or activities should be consistent with the national health plan – an especially important issue in decentralized health systems).

Box 10.6

The New Zealand Public Health and Disability Act 2000 (NZPHD) – an example of a legal framework for health strategy formulation and planning

The NZPHD Act establishes the structure underlying public sector funding and the organization of health and disability services in New Zealand. It establishes district health boards (DHBs), and sets out the duties and roles of key participants, including the Minister of Health, Ministerial committees, and health sector provider organizations. DHBs are responsible for providing or funding the provision of health services in their assigned districts (with disability support services and some health services funded and purchased nationally by the Ministry of Health).

Setting a strategic direction

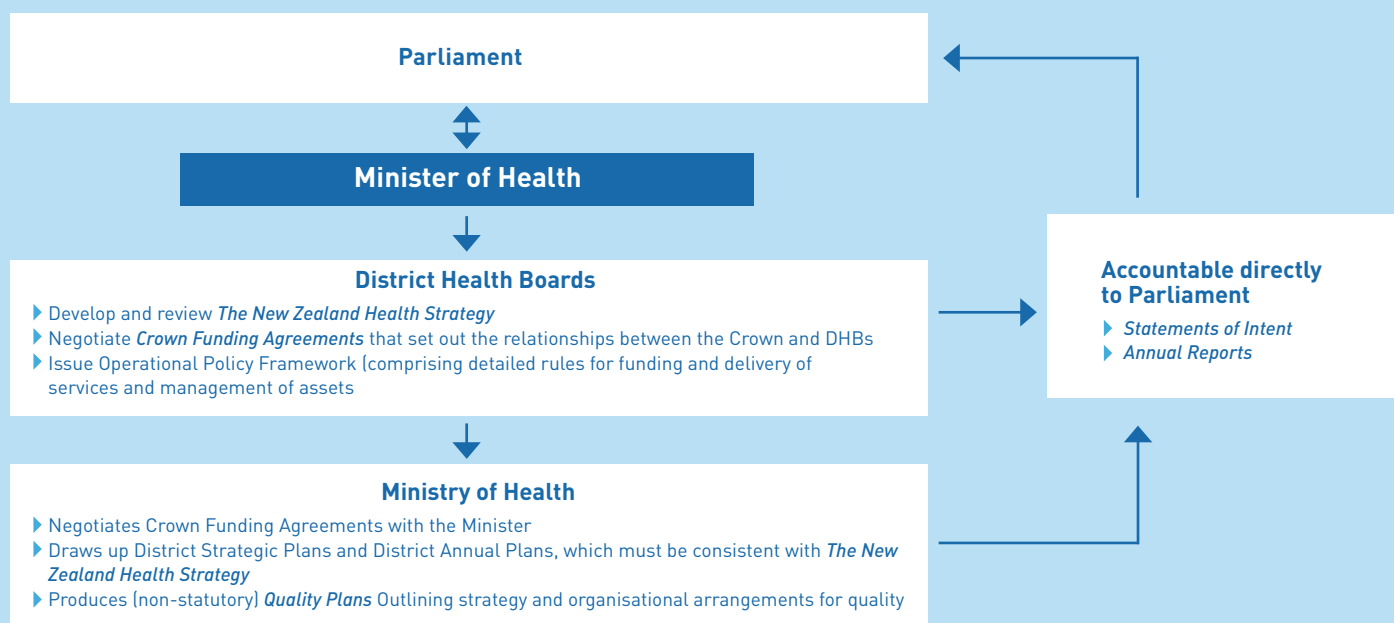
The NZPHD Act also sets the strategic direction and goals for health and disability services.

Section 8 of the Act requires the Minister of Health to determine a strategy for health services, called the New Zealand health strategy, to provide the framework for the Government's overall direction of the health

sector in improving the health of people and communities. Section 8 also requires the Minister who is responsible for disability issues to determine a strategy for disability support services, called the New Zealand disability strategy, providing the framework for the Government's overall direction of the disability sector in improving disability support services.

Planning frameworks and requirements

Section 38 of the NZPHD⁷ provides for the formulation of annual plans by DHBs. This section requires that every plan must address local, regional, and national needs for health services; how health services can be properly coordinated to meet those needs; the optimum arrangement for the most effective and efficient delivery of health services; and must reflect the overall direction set out in, and not be inconsistent with, the New Zealand health strategy and the New Zealand disability strategy.



Laws governing the budget process

Another important category of laws which impact on the national health planning process are budget laws.

Most countries have norms governing the operation of their national budget process. In an increasing number of countries, the norms governing the national budget process (for historical reasons or because of budget reforms) have been made into legally binding rules (incorporated into a country's budget laws).⁸

There are a number of key reasons why countries establish the rules around their budget processes in their laws. For example, to:

- ▶ enhance the transparency of the budget system and its accountability for expenditure;
- ▶ clearly specify the financial powers of the legislature and the executive;
- ▶ provide clear operational rules for the budget system;
- ▶ ensure that budget rules have sufficient authority;
- ▶ elaborate on constitutional requirements for the budget system;
- ▶ reform the budget system;
- ▶ contribute to macroeconomic stability.

In countries where rules about the national budget process and budget system have been incorporated into the law, the legal approaches they have taken can vary widely though usually involve a hierarchy of laws made up of a country's constitution, an organic budget law and financial regulations.

The level of detail and specifications vary greatly

The constitutions of many countries specify the general roles of the legislature and executive, including a few essentials for budget processes; other countries' constitutions contain an entire chapter devoted to the budget and to public finance.

The details can be found in overarching laws as well as lower-level regulations

In some countries, the content of budget laws designed to support the annual budgeting processes is confined to setting out key principles concern to the legislature. The details of budget processes are then set out in lower-level regulations. In other countries, laws contain very specific provisions about all of the main stages of the budget process.

Budget laws can sometimes hold a special status

A few countries have given special status to budget-system laws. In these cases, constitutions require that a law specifies the schedule and procedures by which the budget should be prepared, approved, executed, accounted for, and final accounts submitted for approval (sometimes referred to as an organic budget law).

A legal framework for the health budget enhances good governance for the health sector, transparency and accountability.

Box 10.7

An example of a legal framework for budget laws

Rwanda has a legal framework for public finance management established by the Rwandan Constitution 2003 and the Organic Budget Law 2006.

The Constitution and the Organic law provide that the main institutions responsible for the budget are Parliament, Cabinet, the Ministry of Finance and Economic Planning and the Office of the Auditor General. Under the Constitution, the Chamber of Deputies is responsible for receiving and debating the annual finance bill before it becomes finance law with the concurrence of the Senate. The Cabinet, as the Executive, is responsible for the formulation, preparation and submission of finance bill to the Chamber of Deputies. The Executive is also responsible for budget execution, once the bill has become finance law. The Constitution also establishes the Office of the Auditor General. This Office provides independent assurance that governmental activities are carried out, and accounted for, consistent with Parliament's intentions. The Auditor General is required to submit an annual audited financial report to Parliament. The audit report indicates the manner in which the budget was utilized, unnecessary expenses that were incurred or expenses which were contrary to the law, and whether there was misappropriation or general misuse of public funds.

The Organic Budget Law and the accompanying Financial Regulations set out detailed procedures for the control and use of public funds.

10.2.2 Law and regulation as a key implementation mechanism for health policies and plans

Law and other forms of regulation are key tools for implementing health policy and plans.

Specifically law and regulation can support work on:

- ▶ achieving desired policy outcomes; and
- ▶ the management of specific inputs and processes which impact on health system performance (see Table 10.1 for examples of how law and regulation contribute to elements of health system performance relevant to Universal Health Coverage [UHC]).

Laws and regulations are key tools for implementing health policy and plans.



Table 10.1 Law and regulation and health system performance

HEALTH SYSTEM OBJECTIVES	EXAMPLES OF REGULATORY STRATEGIES	EXAMPLES OF POSSIBLE REGULATORY TOOLS AND APPROACHES
Extend access to services relative to people's health needs.	<ul style="list-style-type: none"> ▶ Minimize barriers to service access ▶ Prevent discrimination (age, gender and disability) ▶ Focus on reducing inefficiency in the health system ▶ Develop equitable and transparent criteria for distributing health resources ▶ Empower service users to claim access rights 	<ul style="list-style-type: none"> ▶ Establish a list of essential health services and clear access criteria ▶ Establish mechanisms for ensuring access based on the criteria (e.g. through a law or through a contractual mechanism) ▶ Require the provision of information about health services and access criteria ▶ Legislate to prohibit specific activities which interfere with access rights ▶ Legislate to prohibit discrimination ▶ Establish patient-rights laws and charters ▶ Provide dispute resolution mechanisms to ensure access rights ▶ Use tax policy and subsidy ▶ Establish gatekeeping requirements
Financial risk protection	<ul style="list-style-type: none"> ▶ Minimize inefficiency ▶ Develop mechanisms for pooling funds ▶ Promote the development of sustainable funding mechanisms ▶ Ensure transparency and accountability in the health financing system 	<ul style="list-style-type: none"> ▶ Provision of universal services funded through tax revenues ▶ Tax policy and subsidies ▶ Price controls ▶ Contracting and tendering processes ▶ Regulation of the health insurance market (for example licensing of insurers, prudential supervision, information provision, requirements to maintain reserves) ▶ Mandatory information disclosure (for example, freedom-of-information laws) ▶ Auditing and reporting mechanisms ▶ Mechanisms for addressing corruption and unauthorized charges for services

HEALTH SYSTEM OBJECTIVES	EXAMPLES OF REGULATORY STRATEGIES	EXAMPLES OF POSSIBLE REGULATORY TOOLS AND APPROACHES
<p>Increase service coverage and quality and effectiveness relative to population need.</p>	<ul style="list-style-type: none"> ▶ Ensure access to essential medicines ▶ Assure the quality, safety and effectiveness of services ▶ Focus on reducing inefficiency in the health system ▶ Promote the development of sustainable funding mechanisms ▶ Incentivize the private sector to align its goals with the government's desired social outcomes ▶ Improve clinical outcomes and effectiveness 	<ul style="list-style-type: none"> ▶ Generic substitution ▶ Price controls ▶ Maintenance of essential medicine lists and access criteria ▶ Control of prescribing practices ▶ Taxes and subsidies ▶ Contracting mechanisms ▶ Establishment of agreed priorities and outcomes for private sector service provision linked to incentives and sanctions for non-performance ▶ Control of noncommunicable disease (NCD) risk factors ▶ Use of clinical guidelines ▶ Regulation of services (e.g. licensing, certification, accreditation) ▶ Regulation of health professionals (entry criteria, competence and fitness to practice) ▶ Prohibition of anticompetitive behaviours ▶ Provision of incentives to work with at-risk or underserved groups ▶ Laws and mechanisms for controlling corruption

10.3 When should legislation be used?

10.2.3 Law and constraints on government powers

Governments are limited and held accountable by the law.

As well as enabling government action, the law also provides the means, both constitutional and institutional, by which the powers of the government and its officials and agents are limited and held accountable under the law. Checks on government's powers take many forms. For example in some countries there is a formal separation of powers between the three branches of government: legislature, the executive government and the courts, where each branch is given powers to check and balance the other branches.

There may also be institutional checks and balances on the operation of executive government; examples include checks on government power by the legislature, the judiciary, and independent auditing and review agencies. In addition to these checks and balances, a country may also have controls which hold government officials accountable for misconduct.

What is important is that key actors involved in the planning process should understand any legal rules and requirements that relate to how the policy and planning process should be carried out. They should also ensure that in carrying out their work they act in accordance with any policies, procedures and rules that apply to their organization or to them individually.

Legislation is a means to an end, one of a number of regulatory tools that can be used to achieve a particular policy outcome.

For example, a country may wish to establish a strategic health plan that binds government and nongovernment organizations to follow a particular approach. One way to meet this objective might be to pass a law to bind all these actors to act in accordance with the desired approach. However, this might not be necessary where these actors have incentives to follow the approach. For example, there may be a broad consensus about it or financial incentives which encourage the actors to follow it. In that situation passing legislation might not be necessary.

It follows that when deciding between the use of law, a regulatory approach or a non-regulatory approach to achieve a particular policy objective, careful consideration should be given to the advantages and disadvantages and the practicalities of implementing the different options. Here, Regulatory Impact Analysis (RIA) provides a systemic approach to critically assessing the positive and negative effects of the various alternative approaches (see Box 10.10).

10.4 Who should be involved in work on law and regulation? What are their roles and responsibilities?

Work on law and other forms of regulation covers technical health issues, policy dialogue, consideration of legal issues, political processes, planning and resource mobilization. It follows that many different actors are likely to be involved, including political decision-makers, lawyers, policy analysts, health planners, health providers, health professionals and members of the public.

To help health planners (and others) identify people with whom they may need to work on laws and other forms of regulations, a summary of the key actors and their roles is set out in Table 10.2.

Work on law and regulation should be well integrated into policy and planning processes.

Table 10.2 Key actors and their roles in health law and regulation

ACTOR	ROLE
Political decision-makers (e.g. ministers of health, other members of executive government)	<ul style="list-style-type: none"> ▶ Advocate for the need for law or other forms of regulation ▶ Mobilize resources ▶ Make the ultimate decision on approach ▶ Provide political leadership and support for regulatory approach (whether laws or some other regulatory approach)
The health policy-maker	<ul style="list-style-type: none"> ▶ Establish the policy objectives ▶ Coordinate the process ▶ Undertake analysis ▶ Provide advice to the ultimate decision-maker on how to proceed ▶ Evaluate the ultimate success of the chosen regulatory tool
The health planner	<ul style="list-style-type: none"> ▶ Confirm that the objectives of the work are aligned with national plans for the health sector ▶ Ensure there is sufficient space within the health work programme to devote to a proposed law or other form of regulation ▶ Contribute data for the situation analysis ▶ Provide information about the costs and benefits of various alternative regulatory approaches (including the use of law) ▶ Help with planning for implementation



ACTOR	ROLE
The regulator	<ul style="list-style-type: none"> ▶ Provide input during the situation analysis ▶ Help generate regulatory solutions (laws and others) that will work in practice ▶ Supervise and enforce the new regulatory approach
Other government agencies (for example the ministries of justice and finance)	<ul style="list-style-type: none"> ▶ Ministry of justice to provide input on legal principles and legal policy It may also be involved in the drafting and making of any necessary laws ▶ Finance ministry will be involved in discussions about the economic impact of any new law or other form of regulation and its cost to government and the regulated sector
State, regional or local governments (in countries with decentralized health systems, national governments work with state, regional and local government on health sector regulation)	<ul style="list-style-type: none"> ▶ Have input into the process of establishing policy objectives ▶ Provide input during the situation analysis. ▶ Help generate regulatory solutions (laws and others) that will work in practice ▶ Be part of the process of approving the preferred option ▶ Act as regulator, supervising and enforcing the new regulatory approach
The public	<ul style="list-style-type: none"> ▶ Provide input for the situation analysis, for example: how does the current situation in a country affect the public in practice ▶ Help generate solutions
The subject of the proposed regulation	<ul style="list-style-type: none"> ▶ Provide information for situation analysis, information about the impact of the chosen type of regulation (laws or otherwise) on the subject group (including costs) ▶ Help generate solutions ▶ Help to explain any new regulatory mechanism to staff and partners
Civil society organizations	<ul style="list-style-type: none"> ▶ Representing public and community interests in the process ▶ Promoting equity, and the interests of disadvantaged groups ▶ Negotiating public health standards and approaches ▶ Building policy consensus, disseminating information about laws or other forms of regulation ▶ Enhancing public support for a proposed approach

ACTOR	ROLE
Professional associations	<ul style="list-style-type: none"> ▶ Provide information for the situation analysis ▶ Provide input on behalf of their members ▶ Help with the generation of solutions ▶ Help build consensus with their memberships about the use of law or other forms of regulation ▶ Help explain the requirement of new laws or other forms of regulation to their members
Donors	<ul style="list-style-type: none"> ▶ Provide resources for the law-making/regulatory process ▶ Provide information for the situation analysis ▶ Contribute to work on the development of regulatory options
International partner agencies	<ul style="list-style-type: none"> ▶ Provide independent guidance and advice about the use of laws and other regulatory approaches and solutions ▶ Provide technical assistance to support the process ▶ Act as a facilitator or coordinator in the process
The law-making body (e.g. legislature or executive government)	<ul style="list-style-type: none"> ▶ Provide a forum for political debate on a proposed new law ▶ Provide a forum for stakeholder comment on a draft law ▶ Create a new law or changes to an existing law
The courts	<ul style="list-style-type: none"> ▶ Provide guidance on the requirements of regulatory tools (especially laws) ▶ Make binding rulings on disputes ▶ Provide a means for people to enforce their legal rights ▶ Ensure that regulators follow due process when applying the regulatory approach ▶ Impose and enforce sanctions for breaches of new regulatory requirements
The media	<ul style="list-style-type: none"> ▶ Provide information about the process to encourage participation by a range of the actors described above ▶ Help people understand the requirements of the new regulatory approach

A health planner should ensure consideration of the following issues: a checklist

- ✓ Health planners should understand any legal rules and requirements, both in relation to the preparation of a country's National Health Plan/Strategy and in relation to the country's budget process.
- ✓ Copies of relevant laws and guidelines should be reviewed (for example those about the process of making health strategies or plans and relevant laws about the budget cycle), and legal advice taken where necessary on how to meet any related obligations, to ensure that any legal requirements about making plans are complied with (such as specific consultation requirements).
- ✓ Planning processes and procedures should be designed and implemented so as to meet relevant legal requirements.
- ✓ Health planners should work closely with finance ministry officials to ensure that the requirements of a country's budget laws are understood and complied with.





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10.5 How do we go about work on law and regulation in the context of national health planning?

10.5.1 Specific law and regulation issues to consider during each stage in the national health planning process

Issues about legal/regulatory matters should be considered during these various stages:

Population consultation

There are two main ways that law and regulation are relevant to the population consultation stage of the national health planning process.

First, there may be legal rules and requirements about consultation. For example, there may be rules about consultation in a law or established legal conventions, or duties about consultation that are enforced by the courts. The rules might apply to:

- ▶ who is to be consulted;
- ▶ how they are to be consulted;
- ▶ how long they have to respond;
- ▶ what should be done with any feedback from those consulted.

The second way that law or other forms of regulation relate to the consultation process is where they are proposed for use to give effect to a government's policy preferences or to help solve health system problems.

Here it might be necessary to consult the population on the details of the legal/regulatory proposals or issues under consideration. This is done to:

- ▶ inform people about the issue or problem and the government's objectives;
- ▶ gather required information to permit analysis of legal/regulatory options and to feed into work on the design of the law/regulation;
- ▶ facilitate collaboration and solution generation;
- ▶ gather information for a regulatory impact assessment (see the discussion below about stages 4 and 5 of the national health planning process);
- ▶ attempt to generate a consensus position/support for the legal/regulatory proposal.

Some countries have legal rules about consultation.

Box 10.8

A Danish example of a law about consultation on health plans

The Danish Health Act 2005 provides for cooperation between municipalities and regions established in the form of mandatory regional health care agreements covering issues such as coordination of treatment, prevention, discharge and rehabilitation. The health care agreements are anchored in regional consultative committees consisting of representatives from the region, the municipalities within the region and private practitioners. The regional consultative committees are used to resolve disputes (e.g. about the service level, professional indications and referral criteria in the area of training) and to create the basis for a continuous dialogue about planning.



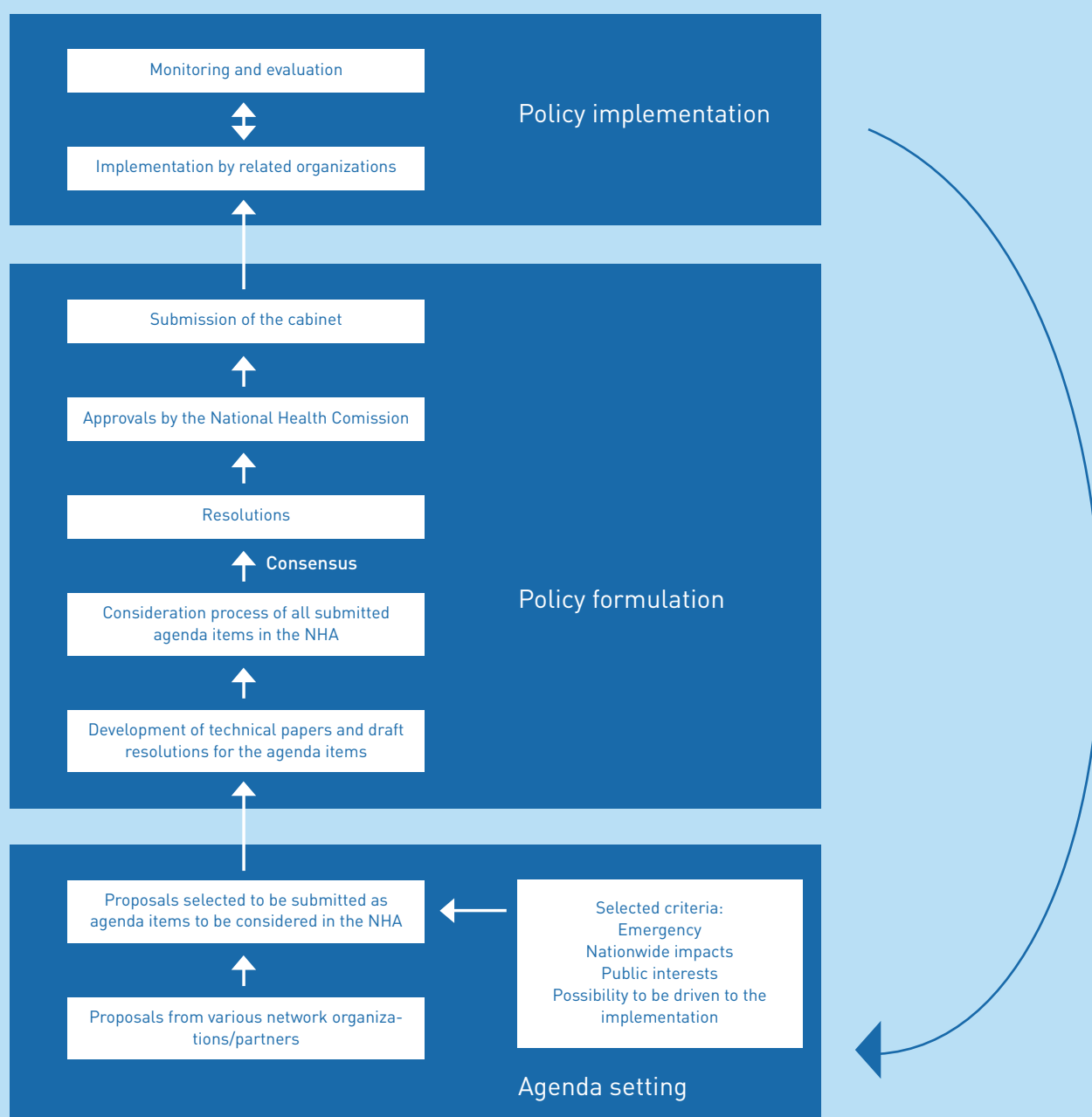
Box 10.9

An example of a legal framework for population consultation – Thailand's National Health Assembly

In 2007 Thailand enacted the National Health Act mandating the establishment of the National Health Commission and Office and the convening of an annual National Health Assembly. The Commission, chaired by the Prime Minister, has 39 members, evenly divided between and

nominated from government, academia and health professionals, and civil society organizations.

The following diagram summarizes the process used by the National Health Assembly.



Legal issues to consider when preparing a population consultation

It is important to understand what the legal rules are about consultation in a particular country. The rules can be understood by examining relevant laws and guidance documents and by asking for advice from a specialist who understands the rules.

In the context of developing laws for the health sector, a population consultation can be carried out on a proposal for a new law, just as on any other topic.

When a population consultation is carried out on any health topic, possible

related legal issues should be identified beforehand, and the population consultation methodology and questions adapted accordingly.

Decision-making on these issues is guided by the aim of the consultation process. For example, very different approaches may be required if you are consulting to simply inform people about a new law or consulting to encourage stakeholders to collaborate with government on finding feasible legal/regulatory solutions to particular health system problems.



Situation analysis

Regulatory analysis should form part of a country's broader situation analysis. Regulatory analysis involves assessing a country's:

Regulatory analysis helps expose legal problems and constraints and supports regulatory reform efforts.

- ▶ existing laws and other regulatory mechanisms;
- ▶ regulatory actors, institutions and their capacities;
- ▶ binding international obligations that impact on the operation of the health system; and
- ▶ existing legal/regulatory systems; process and tools used in the country.

Why undertake regulatory analysis?

The purpose of looking at legal and regulatory issues as part of a country's situation analysis is twofold.

First, to look for legal constraints that might impact on a government's plans. This is likely to involve analysing the country's laws (especially the health laws) and constitution to get a picture of any possible areas where existing laws may constrain the government's health plans.

Second, to inform any work on using legal/regulatory approaches to give effect to policy intentions or solve health system problems.

Legal issues to consider when preparing a situation analysis

- ▶ The legal system (and how it works).
- ▶ Types of regulatory tools that are in use (laws and other tools).
- ▶ The overall legal framework (constitution, laws, organic laws, traditional laws, administrative regulations, rules).
- ▶ Any binding treaty obligations (for example, the International Health Regulations).
- ▶ Effectiveness of current regulation tools in use (what has worked and what has not).
- ▶ The process for creating regulation (for example the legislation-making process and requirements).
- ▶ Any legal constraints on regulation (for example, does the constitution affect or constrain regulation in any way).
- ▶ The rule-of-law situation (issues of order and security, whether the legal system has legitimacy, whether there are checks and balances, whether it is applied fairly, the overall effective application of law).
- ▶ Regulatory institutions, their role, capacity and funding (courts, law enforcement agencies, law schools, lawyers associations, public interest law groups, legal advocacy groups, legal NGOs).
- ▶ The government's technical capacity to perform regulatory functions (set standards, monitor, evaluate and enforce);
- ▶ Availability of trained regulatory personnel.
- ▶ Regulatory funding.

Priority-setting

The results of a regulatory situation analysis should feed into a country's work on priority setting.

The assessment can clarify a number of issues for the priority-setting process.

- ▶ Some approaches might not be legally possible (e.g. because they are prohibited by the country's constitution, another law or by its international obligations).
- ▶ Other approaches might be legally possible but might not be legally practicable.
- ▶ The assessment can identify legal/regulatory approaches that are possible and promising and require further consideration during the identification of effective strategies phase.

Regulatory space

Regulatory space refers to the capacity of government to make and effectively implement regulation, and make choices between different regulatory tools. The regulatory space essentially sets the available parameters for work on regulation, including whether regulatory reform is actually possible. This involves looking at the acceptance (or degree of opposition to) the proposed reforms in a country, whether there is actual authority to proceed with reform (especially authority from key political decision-makers) as well as the practical ability to proceed with the planned reforms (e.g. the country has the resources to effectively implement the proposed law/regulation).⁹

Regulatory impact

An important analytical tool for the priority-setting stage (and also for the identification of effective strategies) is regulatory impact analysis (or RIA). RIA involves an assessment of the likely effects of any proposed new law or other regulatory change. It is a formal process that helps government officials to undertake regulation-making based on sound information and analysis.

RIA aims to give clarity on whether a proposed law or other form of regulation will have the desired impact. It helps to reveal possible side-effects and hidden costs as well as possible alternatives. RIA quantifies the likely costs to citizens, businesses and government of new regulation. Typically, the outcome of a RIA will be a report summarizing the problem the regulation aims to address, the preferred options and the main impacts.

RIA is also an important tool in highlighting situations in which regulation is not appropriate or necessary.

RIA are commonly used in OECD countries.¹⁰ There are, however, a number of challenges in using RIA in developing countries.¹¹

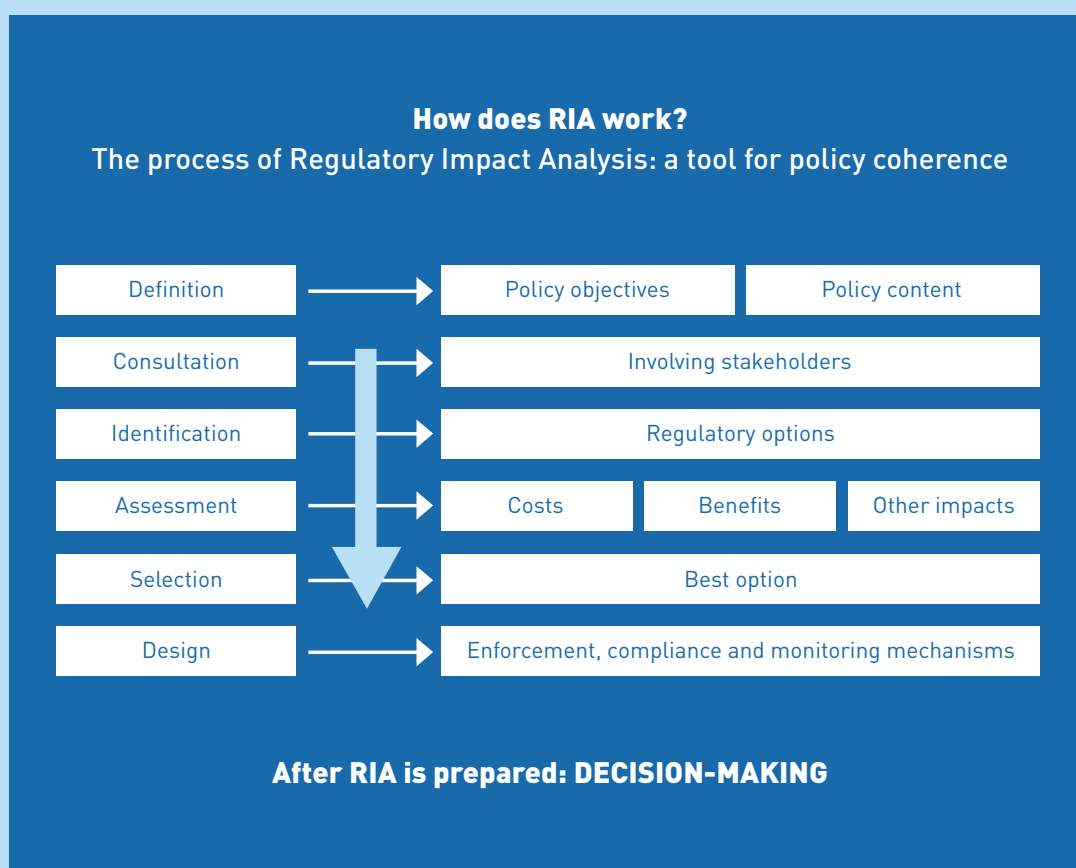
Regulatory impact analysis (RIA) is a formal process for improving the quality of regulatory decision-making.

Judicial intervention in health priority-setting

The other major way that legal issues might affect the priority-setting stage, involves countries whose constitutions, or other laws, confer a right to receive health services or products which can be enforced by a court.

Box 10.10

An example of an RIA process



Box 10.11

An example of courts intervening to enforce a right to health

In recent years, several middle-income Latin American countries have seen a steep increase in the number of court cases litigating access to curative services and inputs. The basis for these claims is legal rights established by the country's constitution or other health laws. The claims are often about the right to access certain treatments or medicines. Some argue that these lawsuits are a mechanism for remedying widespread government failures in the delivery of health care in the affected countries.

On the other hand, public health administrators contend that lawsuits disrupt national and regional pharmaceutical distribution efforts, increase inequality in access, and encourage irrational drug use within the public health care system.¹²

Legal issues to consider during a priority setting-process

Understanding whether there are any legal/regulatory constraints that affect the process of prioritization. Information to make this assessment should have been generated during the situation analysis stage.

Understanding “the regulatory space” for any legal/regulatory work that might be required for a particular priority area.

For countries where priority-setting decisions can be challenged in court, ensure that the process followed and decision reached are objectively fair and evidence-based.

If there is a risk of court action about priority setting, take legal advice to ensure that legal requirements are complied with.

Transforming priorities into a national health plan

Work on laws and other forms of regulation started during stage 3 will continue during stage 4 to support the formulation of a country's national health plan.

During this stage it will be important to ensure compliance with any specific legal requirements that might apply to the process of constructing and finalizing the national health plan (for those countries with specific laws and requirements about national health plans).

Work may also continue on RIA where legal/regulatory approaches are needed to operationalize the plan.

Operational planning

During stage 5, the main focus of work on law and other forms of regulation depends heavily on what strategic direction is given by the NHPSP. If developing a new law or regulation is required to give effect to the national health plan, then implementation of these new laws need to be carefully planned.

There are two distinct phases to implementation of any new law or regulation:

- ▶ the initial phase when a new regulation is introduced; and
- ▶ the ongoing administration and review of the regulation.

The initial phase has distinct characteristics as it is at this point that historical behaviours are required to change in line with the expectations underlying the regulation. Behaviours are a function of both attitudes and capabilities. In addition, often, behaviours of more than one group need to change.

Behaviours that must change to achieve the objectives of the law are often path-dependent and can be deeply embedded, and it is important not to underestimate the effort required to effect change. Therefore, one needs to allow sufficient time for implementation, to adopt appropriate strategies to facilitate and manage the change process, and undertake sufficient ongoing monitoring and evaluation.

Legal issues to consider when transforming priorities into a national health plan

Ensuring full compliance with any legal requirements related to the process of preparing and finalizing the national health plan.

Continuing work on RIA (as required) with a country's policy and legal advisors.

If a new law or regulation is needed, it will need to be implemented, maintained and reviewed.

The questions below should be asked at the outset.

- ▶ What groups will be affected by this regulatory tool (key groups include providers, consumers, regulators, standards bodies, etc.)?
- ▶ What behaviours would we expect these groups to demonstrate if regulation is to achieve its intended objectives?
- ▶ What might act as barriers to behavioural change?
- ▶ What concrete activities are likely to work best to reduce these barriers?
- ▶ What incentives are in place to influence the behaviours of affected parties?
- ▶ What monitoring and evaluation strategy is required to identify and address emerging issues that are affecting the effective implementation of regulation?
- ▶ When considering the factors that influence the implementation of the regulation on an ongoing basis, it is important to note that interventions that do not deliver on their intended objectives may reflect poor strategy choice by the regulator rather than the rules themselves.

Issues to consider during the NHPSP operational planning

Making law and regulation to implement policy is not the end of the process – it is also important to plan for implementation.

Specific regulatory implementation considerations include:

Administration issues, such as which agency will implement and administer the regulation and how it will function.

Timing and transitional arrangements, for instance delayed or gradual introduction of new requirements and provision of interim assistance to affected parties, such as education about the new requirements.

Compliance costs minimization strategies, including what implementation strategies will be required, such as an education campaign, advisory services and testing with stakeholders, and if there exists regulation that can be reduced or removed to prevent overlap.

Implementation risks and their potential impact on the effectiveness of an option. Strategies for mitigating these risks should be explored.

Information that regulated parties will require in order to comply with the regulation, and how this will be provided (Information that regulated parties will require in order to comply with the regulation, and how this will be provided (e.g. whether there is opportunity to rationalize or take advantage of existing information sources or methods of communication)).

Enforcement strategy and how and who will enforce compliance.

Budgeting and costing

The key legal/regulatory issues for stage 6 involve the costing of any legal/regulatory interventions, their implementation, supervision and enforcement.

Specific costing may be required in a number of categories.

Appropriate costing of regulation informs its feasibility.

- ▶ The human resource costs and costs of specific technical inputs (e.g. from legal and regulatory experts) for a law/regulatory reform process. These processes may range in complexity and scale from minor legislative changes to large-scale reform processes that may take several years and significant resources to complete.
- ▶ Ongoing administration costs of any new legal/regulatory scheme.
- ▶ In some cases a country may decide to establish a new regulatory agency to implement and supervise a new law or regulatory scheme. In such cases, the cost of establishing and operating such an agency will need to be determined.
- ▶ The costs of providing information to regulated parties about the new law or regulatory scheme to facilitate compliance.
- ▶ Costs associated with supervision and enforcement of the new law or regulatory requirements (for example the costs of maintaining an inspectorate to monitor compliance).

Box 10.12

An example from Thailand of the costs associated with establishing a regulatory agency

The National Health Security Act B.E. 2545 (2002) is the legal basis for the Universal Coverage Scheme (UCS) in Thailand. The Act stipulates the establishment of the National Health Security Office (NHSO) and the National Health Security Fund. The NHSO is an autonomous body with 13 regional offices which would govern the UCS. The establishment of the NHSO necessitated ongoing expenditure to meet its annual administrative cost. In 2013, the administrative cost of NHSO was 0.85% of the UCS.

This example demonstrates the importance of assessing and factoring in the cost of implementation when considering the feasibility of a new law.

Legal issues to consider during NHPSP costing

Ensuring full compliance with any legal requirements about the process of preparing and finalizing the national health plan.

Ensuring that work on law and other forms of regulation supports and is informed by the country's policy dialogue and is well aligned with the content and intent of the national health plan.

Continuing work on RIA (as required) with a country's policy and legal advisors.

Monitoring and evaluation

Any planned work to monitor and evaluate the impact of the NHPSP should (where legal/regulatory reform forms a key component or enabler of the NHPSP) include evaluation of the legal and regulatory reform itself. Legal and other types of regulation reform should be evaluated to do the following:

- ▶ Provide accountability to funders and stakeholders as to the value of the intervention.
- ▶ Increase knowledge and understanding about the intervention and its objectives, including knowledge of needs of potential beneficiaries and of effective practices.
- ▶ Contribute to the general body of knowledge on effective regulatory strategies and interventions.
- ▶ Measure the actual impact of regulation on the government's desired outcome(s).
- ▶ Governments need to establish indicators for measuring the impact of laws and other forms of regulation with respect to outcomes of concern. Through such measurements, conclusions can be reached about the extent to which law/regulation has actually brought about desired changes.¹³

It is important to monitor the impact of regulation to ensure that it continues to deliver desired outcomes.

Box 10.13

Learning practical lessons from evaluating regulation in low- and middle-income countries: an example

'Health system stewardship and regulation in Viet Nam, India and China' (HESVIC) was a multidisciplinary and multi-partner project implemented over a three year period (July 2009 to December 2012). Using maternal health as a critical case study, the project investigated regulation as it relates to wider governance in policy and practice of health systems in maternal health for Viet Nam, India and China. The study:

- ▶ examined the application of international standards in governance and regulation of maternal health activities - to the extent that such standards existed;
- ▶ outlined national standards for governance and regulation of maternal health activities in the three study countries; and
- ▶ explored the effects of governance and regulation of maternal health-care services and systems on equitable access to quality maternal health care, within and across each study country.

One of the key results of the project was the development of an integrated approach for the assessment of regulation. Applying this methodology, the project found that regulatory control is constrained under current conditions in low- and middle-income countries (LMIC) settings, with the possible exception of services that are centrally planned. The study also found that regulation-hampering mechanisms are related to historical, socio-political and administrative conditions in LMIC.

The study concluded that regulation should be nested in larger health policies for a number of reasons.

- ▶ Regulation is not very effective on its own, certainly under LMIC conditions.
- ▶ Regulations can yield undesirable effects. For instance, in Viet Nam, combined with the common perception that the quality of services is better at the provincial level than at district level, the emergency obstetric care regulation resulted in the overburdening of provincial hospitals.
- ▶ Health professionals cannot be motivated merely by material incentives and deterred by punishments, but also need non-financial incentives.
- ▶ Governments commonly are reluctant to ensure regulation for the private sector, but the private sector should be more involved in regulatory processes.
- ▶ Designing regulation in China, India, Viet Nam was carried out in a closed way by bureaucrats, politicians and government external advisers. Granting a voice to non-state actors – like health facility users and various socioeconomic groups – may help ensure that regulations better reflect the needs of these groups.¹⁴

Legal issues to consider during the monitoring and evaluation of an NHPSP

The key question is: how will the effectiveness of the regulatory changes be measured?

Plans should be made for monitoring, evaluating, and reviewing the performance of laws and other forms of regulation over time.

It is also important that any new law/regulation is monitored and periodically reviewed to evaluate whether the option is the preferred solution to the particular issue or problem over time. Such monitoring and evaluation helps to ensure that new laws/regulations are working as expected (delivering the anticipated benefits at expected costs), that there have been no unforeseen consequences and they continue to be necessary as circumstances change and evolve.

When new law or other regulatory options are being proposed, it is important to have a clear understanding of the channels through which the intervention is expected to generate the intended benefits. Analysis needs to consider how effectiveness will be measured: what indicators will be used; what data will be required; how this information will be collected, and by whom.

On-going or periodic consultation with stakeholders may be appropriate, in which case the arrangements for this should be agreed upon. It may be appropriate to establish a feedback mechanism (e.g. a way for stakeholders to ask questions or lodge complaints). Regular, public reporting on the effectiveness of the law/regulation may also be considered.

Plans should also be made for how and when the law/regulation will be reviewed. Agencies should consider committing to a periodic review of particular regulatory interventions. Reviews should be reported and consulted on with a view to ensuring that a law/regulation remains fit for its purpose. Reviews should consider the following issues:

- ▶ Is there still a problem (and is it the one originally identified)?
- ▶ Are the objectives being met?
- ▶ Are the impacts as expected? Are there any unforeseen problems? Are there any indirect effects that were not anticipated?
- ▶ Is intervention still required? Is the current intervention still the most appropriate, or would another measure be more suitable?

10.5.2 Legal impediments and constraints to consider in national health planning

Existing laws can support or block new policies and plans. It is thus important to identify relevant existing laws and their impact on what is being planned.

On occasion, a country's pre-existing legal/regulatory framework might act as a constraint or impediment on a government's policy intentions. A health planner should be aware of and think through such constraints, and potentially seek legal advice or broach the subject at higher-level government meetings if it greatly impacts on a national health plan or any policy change to implement the plan.

There are three main legal impediments a country may face in the health planning process.

1. First, there may be requirements in a country's constitution, laws or international obligations (e.g. binding legal commitments such as treaty obligations), which may either prohibit a particular policy or approach from proceeding or influence the way it is designed or implemented (and where it might not be possible or practical to change the constitution, amend the relevant law or treaty to make it consistent with the planned policy or approach). For example, a country with a decentralized health system may have a constitution which impacts on, or controls, how health services are funded/purchased at the national level. This would mean that the design of any national funding or purchasing system would need to be modified to comply with the constitution.
2. Second, where an existing legal/regulatory framework is not "fit for purpose", that is, it does not enable the proposed policy or approach because the legal/regulatory framework is out of date, out of step with the planned policy approach, or has gaps (and where it is possible to amend the law regulatory tool in question to make it consistent or to enable the planned policy or approach). For example, a country might want to require its health workers to comply with

new requirements about how they provide services (for instance, to improve quality of care), but its existing law might not allow these standards to be imposed. This would mean that the law would need to be amended to address this gap.

3. Third, where the current legal/regulatory framework is consistent with the planned policy or approach, but the legal system is unable to support the planned policy or approach (because of problems with the capacity and/or capabilities of the regulatory actors, institutions or processes required to give effect to the planned policy or approach). For example, a country might want to set up a new scheme for contracting out the provision of health services to the private sector. It may have passed a law to allow this new policy to occur, but might lack the expertise or capacity to prepare and negotiate effective commercial contracts to give effect to its health objectives or to properly monitor the performance of contracted providers against the requirements of a contract.

However, even where a country lacks the capacity to make a commercial contract, it may be possible to adopt the use of what are known as relational contracts. In contracting terms "pure" commercial contracts and "relational" contracts are both categories of contract in the legal sense. The difference is that the first category, the detailed commercial contract, the detailed terms of the contract are important for its operation and the parties may go to court to enforce it in the event of a dispute. Contracts of this nature may, however, be difficult to establish in a context where monitoring the performance of, and enforcing the terms of, such contracts is difficult (because of the general lack of legal institutions).

A relational contract, on the other hand, is based on the parties' confidence that each will act in their mutual interest. Consequently, there is no need for the contract to be exhaustive and detailed; agreement on the main objectives of the relationship, the methods of work, and the means to be used to carry out the actions will suffice. The flexibility and cooperation characteristic of this type of contract are intended to secure not only its permanence, but also contractual efficiency.¹⁵

Box 10.14

An example from Cambodia of the use of relational contracts

A good example of the use of relational contracts is the health reforms in Cambodia. Prior to 1999, the health system was considered extremely weak and ineffective: mortality rates remained high, out-of-pocket payments dominated the total health expenditure of the country, despite the population being one of the poorest in the region, and shortages of drugs and medical supplies led patients to seek traditional care rather than that provided by the health system. Lack of regular salary payments was a major contributor to Cambodia's poor health system performance; health workers often provided informal and extra-legal^V activities for more income, making health policies difficult to implement through existing regulatory channels. While some system weaknesses were addressed by instituting a new health coverage plan and establishing a minimum

package of services, the guarantee of quality services had yet to be achieved. Legal and financial reforms were required to improve access to primary health services and create an effective and cost-efficient public health system.

In order to improve health system performance, a district contracting system was adopted, an approach largely favoured as a way to improve access to care for poor and underserved areas. Cambodian policy-makers experimented with different types of contracting for different districts, relying primarily on four-year relational contracts with NGOs. Some used contracting-out to private contractors, where the contractor would have complete control over staff and budget, while others used contracting-in of district management, where the private sector provided management services in a largely public health sector. The former method was considered more of a political commitment to district contracting, as full responsibility was placed on the contractor for service provision. By using the contracting-in method, the district governments had greater control over budgeting and regulation, including the start of a financial incentive programme for health workers to improve motivation to provide higher quality care.¹⁶

^V Extra-legal activities are activities that are not authorized by government legislation; however, government authorities do not intervene to stop those activities for whatever reason. In this case it refers to government health workers opening their own private practices, laboratories etc. These are informal activities used to generate extra income because of the instability of government payments. Stakeholders accept this fact and understand that the government health workers need more money to live on, so any sort of legal action is not taken to prevent private informal business. In fact, health workers openly publicize and provide information about their activities to their employers.

10.6 Conclusion

This chapter explains the role and the importance of law and regulation for the national health planning process. It explains how law and regulation can:

- ▶ provide the structure and the rules for a country's national health planning process; and
- ▶ act as an important policy tool and lever for improving health system performance.

The key message from this chapter is that work on law and other forms of regulation should not be regarded as a separate process, but should form an integral part of a country's health policy dialogue engaging stakeholders from health, finance and other ministries, civil society, nongovernmental organizations,

international agencies, academic institutions, professional associations, and communities. A similar approach should be taken when implementing law and regulation.

For planners and policy-makers, it is therefore essential to:

- ▶ understand any legal requirements that affect the national health planning process; and
- ▶ ensure that the task and inputs required for developing and implementing law and regulation are fully integrated into the national health planning process.



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