Chapter 7: Achieving universal access to quality health services

**SUMMARY POINTS**

- Universal health coverage is the goal of ensuring that all members of the population and their communities have access to promotive, preventive, curative, rehabilitative and palliative health services that are of sufficient quality to be effective, without being exposed to financial hardship.

- To expand health insurance systems towards achievement of universal health coverage, governments need to make progress along three axes: to “expand priority services, include more people and reduce out-of-pocket payments”.

- Making progress towards universal health coverage requires governments to strengthen those building blocks of the health system that make it possible to deliver services of high quality. This includes investing in basic infrastructure, human resources and financing systems; developing an effective health information system; systems for procuring and distributing essential medicines, vaccines and technology, and systems for governance and accountability.

- Different countries will take different pathways towards universal health coverage. Priorities for law reform are likely to emerge incrementally as countries identify particular problems with the performance of their health systems and seek to remedy them. However, many of the regulatory issues that governments will need to consider relate to: (i) defining membership and entitlements under a health insurance scheme; (ii) regulating health service providers; (iii) financing health services; and (iv) establishing governing institutions.

- Governments scaling up health insurance systems may wish to formally recognize the right of members of the population to access a defined set of benefits or services. Governments may strengthen the implementation of this right – as well as the quality of the health services provided – by creating a formal complaints scheme for those who are not treated in accordance with their entitlements under the scheme.

- The right to health imposes an immediate obligation on governments to protect members of the population from discrimination, including discrimination in access to benefits under a health insurance scheme. Governments may consider creating statutory protection for the privacy, confidentiality and security of the health information of members of a health insurance scheme.

- Governments should pursue financing systems for health services that avoid two important risks. The first is the risk of catastrophic expenditure (leading to impoverishment), caused by the need for large out-of-pocket payments for medical services when a person falls ill. The second is the risk that even modest user fees may dampen demand and create barriers to access for the poorest members of the population. Governments can mitigate these risks by raising funds for expanded coverage through compulsory pre-payment mechanisms, such as taxation and/or compulsory insurance contributions, and by providing an exemption from contributions for those who cannot afford to contribute at any level.

- Legal regulation of the financing of health services includes the regulation of revenue collection, legal control of the funding pools that are used to pay for health services, and regulation of the purchasing of health services provided to covered populations.

- WHO has recommended that governments consider new ways of increasing their revenues, including by imposing or increasing excise taxes on tobacco and alcoholic beverages, sugary drinks,
· Depending on the structure of the health insurance system, governments may regulate funding pools to ensure capital adequacy and to impose controls over the investment of funds. They may also impose requirements to report to the central government, and impose governance requirements on the entities (health insurance schemes) that administer insurance schemes based on pooled funds.

· Private health insurance schemes often coexist with the public schemes that are the vehicle used by governments to scale up coverage. In the case of private insurers, governments typically regulate a wide range of matters including registration and prudential requirements, competition, advertising, premiums, adverse selection and reporting requirements.

· In scaling up the health services that are provided from pooled funds, governments have been advised by WHO to place particular emphasis on primary care. Robust primary health care systems are associated with reduced morbidity and premature mortality as well as lower costs.

· The health workforce is a crucial input in strategies to scale up the coverage of health services. In addition to regulating the purchasing of services and the remuneration of health care providers, legislative frameworks perform important gateway functions. These include licensing health care providers to practice their profession in the jurisdiction, and accrediting service providers under the health insurance scheme. Governments may also establish quality agencies to support the improvement of quality standards and governance processes across all facilities.

· Formal recognition of new professional categories and roles may be required as countries scale up the training and education of the health workforce and adapt to the changing burden of disease.

· By imposing licensing requirements on the practice of medicine and other health professions, governments can protect the public from unskilled and poorly skilled individuals who claim the right to provide medical services. Some countries have introduced national councils that oversee registration, continuing professional education and professional conduct across a range of health professions.

· Licensing requirements for health professionals should be sufficiently flexible to permit the delivery of emergency health services by authorized personnel following a natural disaster or other public health emergency. This may include foreign health professionals contracted to international agencies or to accredited nongovernmental organizations.

· Legislation may create a range of offences for inappropriate medical practice; for example, forging documents, using unapproved medicines, carrying out experimental treatment without consent, and soliciting or illegally accepting money and gifts from patients.

· Governments may consider requiring accredited health care providers to contribute to premium-based compensation schemes for individuals who are injured through medical negligence or substandard care, or who are victims of criminal offences committed by health professionals.

· Establishing governing institutions is an important part of the law reform process as countries scale up towards universal health coverage. Two important institutions commonly seen in health insurance systems are a national health insurance authority, and a medicines regulation authority. In some countries, the functions of both agencies may be merged into a single institution.

· The key functions of a national health insurance authority charged with improving population coverage include registering members, collecting health insurance contributions, managing pooled funds, accrediting, contracting and reimbursing health service providers, and complying with government reporting requirements.
The functions of a medicines regulatory authority include assessing and authorizing the entry of medicines into the country (drug registration), monitoring safety and effectiveness, regulating domestic manufacturing, importation and distribution of drugs, and regulating pharmaceutical advertising. In order to perform these functions, regulatory authorities commonly perform a wide range of more specific functions set out in legislation.

The experience of Ghana illustrates the role of legislation in establishing and expanding a national health insurance scheme.

Universal health coverage (UHC) has emerged as a unifying concept and goal for governments as they seek to strengthen their health systems and to discharge their obligations under the right to health.\(^2\) UHC is the goal of ensuring that all members of the population have access to promotive, preventive, curative, rehabilitative and palliative health services that are of sufficient quality to be effective, without being exposed to financial hardship.\(^3\) In 2015, the United Nations General Assembly adopted a global target for UHC as part of the Sustainable Development Goals. This target states: “Achieve UHC, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all” (Target 3.8).\(^4\) The right to health, as recognized in international human rights law, directs attention to a wide-ranging set of features that may assist governments to strengthen their health systems and to accelerate their progress towards UHC.\(^5\)

7.1 The concept and scope of universal health coverage

The quality services that governments are obliged to make universally accessible include health services delivered to individuals in hospitals, in primary care facilities and in other community settings. These include diagnostic services, medical procedures, the provision of essential medicines, palliative care and preventive services such as immunizations and perinatal health assessments. In addition, UHC encompasses the delivery of services to the population as a whole, or targeted segments of it, through information campaigns, vector control, the performance of public health regulatory functions, and other public policies addressing the determinants of health.

Making progress on the overarching goal of UHC requires governments to strengthen those building blocks of the health system that make it possible to deliver services of high quality (see Table 1.1). Health financing is a critical component, since all functions of the health system depend upon adequate and sustainable financing. Other vital components of the delivery of quality health services include the training, development and retention of the health workforce; strategies for achieving universal access to essential medicines, vaccines and technology; the development of an effective health information system; management of infrastructure and capital investments; mechanisms for governance and accountability, and effective leadership at senior levels.\(^6\) Health systems are complex: making progress with each of the building blocks is necessary to make progress towards the overall goal of UHC. For example, it will not be feasible to expand the range of health services available under a health insurance system, or to extend the coverage of services to more people, unless countries simultaneously invest in the development of their health workforce. Countries that
have made strong progress towards UHC have prioritized their health workforce needs, investing in workforce planning, training, improving remuneration systems and in governance frameworks.\(^7\)

In addition to investing in the health system itself, the goal of UHC requires governments to implement public policies to address the broader determinants of health, many of which lie outside the health sector.\(^8\) This is partly why the goal of UHC requires a government-wide commitment, supported by governance mechanisms and other practical ways of achieving cooperation between government sectors (see further, Chapter 6).

This report provides examples of the law’s role in both strengthening health systems and addressing the broader determinants of health that lie outside the health sector, as governments seek to move towards UHC (see Table 7.1). Progress towards UHC will be reflected in efforts to:

- expand the range of health services that are accessible by individuals and populations (a generous benefits package);
- expand the proportion of the population who are covered by those services (by scaling up the capacity of service providers to deliver a sufficient volume of services to meet the needs of the covered population);
- increase the quality of health services; and
- improve the affordability of health services (financial protection).

Table 7.1: Important ways that law can support progress towards universal health coverage

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7.2 Legislative frameworks supporting the provision of health services

Legal frameworks are an essential part of the fabric or structure of an effective health system. Seen from outside, the function and purpose of legal and regulatory structures may not always be visible, but without them, roles, powers and responsibilities may be unclear, accountability absent, institutions may be missing, and vital functions may be performed haphazardly, or not at all. However, laws are neither self-executing, nor sufficient by themselves. Laws must be enforced, and legislative frameworks function as parts of broader, integrated systems for the financing, administration and delivery of health services.

This section adopts a very simple framework for presenting some examples of legal and regulatory issues that may arise as governments move towards expanding national health insurance systems. Building on the UHC cube discussed in Section 1.2, governments may use legislation and regulatory processes to:

- define membership and coverage under a health insurance scheme (the population axis);
- introduce funding mechanisms and regulate for greater affordability (cost axis);
- regulate health service providers and service provision (the service axis); and
- establish governing institutions and processes.

(a) Memberships, coverage and entitlements

Recognizing the legal entitlement of all members of the population to have access to essential health services, vaccinations, essential medicines and technologies – without discrimination based on inability to pay – provides a foundation for planning and resource allocation as governments move towards UHC. Recognition of such a right does not require the government to become the sole provider of all health services. However, it does commit the government to pursuing those intermediate objectives that will help to achieve the broader goal of UHC.

The process for expanding coverage under a health insurance scheme will usually involve formally defining the parameters of programme entitlements, including any means-tested exemptions, co-payments, safety nets and rights of access for those who cannot afford to pay. Registration systems for government-subsidized health insurance schemes may involve systems for ensuring proof of identity and membership (e.g. identity cards or other identifiers), in order to enable the monitoring of claims submitted by health providers and utilization of the scheme by enrolled members.

In order to facilitate access to the scheme by those it is intended to benefit, governments may consider building a right of access into the design of the scheme, such as through a patient charter of rights, coupled with a complaints system for the investigation and conciliation of complaints by those who are not treated in accordance with their entitlements. The right to health imposes an immediate obligation on governments to prevent discrimination in access to services on a range of prohibited grounds. These grounds include race, colour, sex, language, religion, political opinion, national or social origin, property, physical or mental disability, health status and sexual orientation. Protection from unlawful discrimination implies that individuals will have adequate access to a
mechanism for making complaints about discrimination, such as an ombudsman or discrimination commissioner. Discrimination may occur not only by excluding an individual from coverage or by refusing to provide services covered by the scheme on grounds prohibited by law, but by failing to treat an individual with dignity, through inferior levels of service, or by imposing unjustified additional requirements. The regulation of membership and coverage under a health insurance system extends to statutory protection for the security, privacy and confidentiality of health information about enrolled members.

(b) Financing of health services

There are vast discrepancies between countries in the amount of total spending on health per person, in total government spending on health per person, and in the share of private expenditure on health as a percentage of total expenditure. For example, in 2012, Norway, a high-income country with a well-developed social security net spent US$ 9312 on health, although US$ 7919 of this total was made up of government spending, meaning that private spending was about 15%. By contrast, in a number of low-income countries around the world, total health spending per capita is only a few tens of dollars, and a high percentage of this is private spending (exceeding 70% in some countries).

Access to a set of priority health care services for all members of the population requires a financing system that avoids two important risks. The first is catastrophic expenditure (leading to improverishment), caused by the need for large out-of-pocket payments when a person falls ill. The second is the risk that even modest user fees, and other bureaucratic requirements (eg the need for annual re-enrolment) will dampen demand and create barriers to access for the poorest households in low-income countries.

Countries that have come closest to achieving UHC raise funds to pay for health and medical services through compulsory pre-payment mechanisms, such as taxation, compulsory insurance contributions or, frequently, a combination of both. At the same time, universal access to priority health services cannot be achieved unless governments cover the cost of services for those who cannot afford to contribute at any level. There is strong evidence that both community-based health insurance schemes, and social health insurance schemes (typically based on mandatory, salary-based contributions), can improve financial protection as well as the use of health care services by insured persons.

For example, Rwanda first introduced community-based health insurance schemes (known as mutuelles) in 1999, with participation and annual premiums organized on a household basis. Enrolled households are affiliated with a local health care centre, which provides referral for hospital services covered by their mutuelle. In 2012–2013, 86% of the population was covered under this scheme. The government pays premiums for 25% of the population, consisting of people who are classified as vulnerable, subsidizing the provision of services through payment of block grants to administrative districts.

In nearly all OECD countries, public sector financing accounts for the majority of health care financing. The World Health Assembly has urged Member States to develop their health financing systems in order to reduce out-of-pocket payments at the time of service delivery and to pool risks...
among the population in order to avoid catastrophic health care expenditure by those in need of care. 19

Legal regulation of the financing of health services includes the regulation of revenue collection, legal control of the funding pools that are used to pay for health services, and regulation of the purchasing of health services provided to covered populations. 20 WHO has recommended that governments increase the public funds that are available for health financing by improving revenue collection, and by giving greater priority to health within national budgets. 21 WHO has also encouraged governments to consider innovative ways of increasing revenue, such as imposing or increasing excise taxes on tobacco and alcohol products, sugary drinks, airline tickets or currency transactions. 22

The regulation of revenue collection is conceptually distinct from the regulation of fund pooling. Revenue collection includes the mobilization of funds through general taxes, voluntary or compulsory insurance premiums paid by employers or households, and donations from development partners. Fund pooling refers to the control of those monies for the benefit of the beneficiaries of the health insurance system, and includes the governance of institutions that control fund pools. 23 Fund pooling permits governments to reduce duplication and to create economies of scale, and to require that revenues from higher income contributors are used to cross-subsidize the provision of services to those on lower incomes.

Depending on the structure of the health insurance system, the government may regulate funding pools to ensure capital adequacy and to impose controls over the investment of funds. It may also impose requirements to report to the central government, and impose governance requirements on the health insurance entities that administer insurance schemes based on pooled funds. 24 Governments may also make scheme membership mandatory for eligible households, prohibit medical underwriting (risk-adjusted premiums based on medical history), and link premiums to household income. In many countries, private health insurance schemes pre-date social health insurance schemes, community-based health insurance schemes and other vehicles used to pursue the goal of UHC. 25 In the case of private insurers, governments may need to address a wide range of issues, including prudential requirements, consumer protection, competition, advertising, adverse selection, premiums and mechanisms for government oversight. 26

The regulation of purchasing refers to the regulation of the financial relationship between providers of health services and government agencies, health insurance schemes or other entities purchasing health services on behalf of enrolled populations. 27 For example, providers may be employed on salary, or remunerated on the basis of fee-for-service, but strong demand, cost escalation and/or the risks of over-servicing often require governments to trial other approaches, such as capitation or use of fixed rate reimbursement based on diagnosis-related groups. 28 A number of countries have considered performance-based financing as a way of expanding child immunization and coverage of other health services (Box 7.1).

**Box 7.1: Improving health systems through performance-based financing**

While performance-based financing can take many forms, the common theme is to formalize the relationship between a central government or funder of health services and the different
organizational units of the health system. Payment is then based on organizational units meeting the performance criteria set out in a contract or agreement with the funder, rather than being based on inputs, such as salaries and pharmaceuticals. Well-designed performance-based financing systems can attract a high level of commitment from health professionals, through incentives or additional funding for those organizational units that exceed basic performance standards.

Health service providers that are subject to performance-based funding may be more likely to demand performance and accountability from other parts of the health system that they depend upon (for example, for data collection, the supply of pharmaceuticals, or the roll-out of national programmes) and to respond to the populations they serve in more flexible ways (e.g. with home visits, community outreach programmes, subcontracting to community organizations and more flexible working hours). Performance-based financing may be useful not only for the funding of child immunization, and the provision of antenatal and postnatal health care, but for improving diabetes management, smoking cessation and other risk factors for noncommunicable diseases.

(c) Health services and health service providers

UHC requires governments not only to expand the range of services provided in the benefits package, but also to expand the capacity or volume of the services provided in order to achieve greater population coverage. The service axis therefore requires a focus both on the services themselves, and on the production and regulation of service providers and on other inputs that are needed in order to expand service provision.

WHO has advised governments that are moving towards UHC to place particular emphasis on primary care, taking account of the health inequalities that exist within countries based on disparities in income, education, employment status, geographical location and membership of different ethnic, racial or religious groups. Some key features of primary health care, as this term is used by WHO, are set out in Box 7.2. Providing a minimum package of integrated services, based upon population health needs, that ensures continuity of care and affordable access to all members of the population, including those in rural and remote areas, should be the overriding goal.

Box 7.2: Distinctive features of people-centred, primary health care systems

A responsive, people-centred primary health care system:

- focuses on the health needs of the population and aims to provide a comprehensive package of health services for all ages, rather than targeting particular groups, or a limited set of priority diseases;
- provides continuity of care, through well-articulated referral systems, rather than fragmented and episodic relationships, or disease or programme-specific interventions;
- makes health care available to all, irrespective of ability to pay;
- resists all forms of discrimination that create obstacles to access and equity;
- places the emphasis on “close-to-client” care provided locally, rather than on hospitals or specialist practitioners;
• uses the primary care team as a coordinating centre for referral to specialist health care services when required;
• is responsive to the population it serves, providing both curative and palliative care, as well as preventive services and health promotion;
• works in partnership with people to improve their health and the health of the wider community, builds bridges to the wider community, and addresses the social determinants of ill-health.

The health workforce is a crucial input – but all too often a limiting factor – in strategies to scale up the coverage of health services. In addition to regulating purchasing and remuneration, legislative frameworks perform important gateway functions: licensing health care providers to practice their profession in the jurisdiction and accrediting health clinics and health service providers under a health insurance scheme. Licensing and accreditation play an important role in safeguarding quality of care and in improving accountability for the delivery of health services. In addition, they may enable countries to innovate and to adapt their health workforce to meet new challenges. For example, in 2014, Tonga graduated its first cohort of nurses specializing in the prevention, detection and management of noncommunicable diseases. Tonga’s noncommunicable disease nurses illustrate the fact that new professional categories and designations may be required as countries both expand the production of health care workers and adapt to the changing burden of disease.

Licensing requirements allow authorities to impose prerequisites for those who wish to practise medicine, the allied health professions and other technical roles. For example, medical practitioners are typically required to complete a medical training course or degree at a recognized medical school, to successfully pass State medical exams, to complete a period of practical training in a medical facility (a medical internship), to fulfil ethical and character requirements and to maintain their knowledge of their field. Additional requirements apply to medical specialists. In some countries, a national council oversees and supports the operations of professional boards representing the different professions (Box 7.3). By imposing licensing requirements on the practice of medicine, or by formally recognizing the entry requirements imposed by respected professional bodies, governments can protect the public from unskilled and poorly skilled individuals who claim the right to provide medical services. Licensing requirements may be imposed upon medical practitioners, nurses, and other allied health professionals at national or state level.

Box 7.3: Gateway requirements for the practice of medicine: an example from South Africa

The Health Professions Council of South Africa (HPCSA), a national body established by the Health Professions Act 1974, regulates the medical and allied health professions in matters including registration to practice, education and training and professional conduct. The South African Nursing Council, established by the Nursing Act 2005, performs a similar function for the nursing profession. Registration by the HPCSA is a prerequisite for practising as a medical practitioner or in one of the other professional categories recognized by each of the 14 professional boards. The HPCSA accredits medical programmes and aspiring doctors are required to attend an accredited university and participate in an internship at an accredited facility. The Medical and Dental Board...
registers practitioners who meet specified criteria under a range of professional categories. Each of the boards that operate within the framework of the HPCSA may enquire into allegations of unprofessional practice by health practitioners and impose penalties in appropriate cases, including fines, suspension from practice or removal of registration.\(^{37}\)

Under China’s law on medical practitioners, adopted in 1998, health administration departments at the county level and above are responsible for regulating medical practitioners within their respective regions, overseen by the health administration department under the State Council.\(^{38}\) Those with bachelor degrees in medicine who have completed a one year internship may sit the state exam; those who pass may apply to their local health administration department for registration, and following registration, may practice at medical institutions in accordance with the location, category and scope of their registration.\(^{39}\) Doctors with five years’ experience at medical institutions may apply for approval for private practice. Local health administration departments have a variety of responsibilities, including maintaining a list of registered and deregistered doctors, assessing the continuing professional performance of practising doctors, and providing continuing medical education.\(^{40}\) The law specifies a number of legal responsibilities of practicing doctors and provides for warnings, suspension or revocation of registration for those who fail to meet these requirements. Grounds for prosecution (including criminal prosecution) include malpractice, forging documents, using unapproved medicines, carrying out experimental treatment without consent, soliciting or illegally accepting money and gifts from patients, and making improper use of one’s position.\(^{41}\) The law authorizes local health administration departments to close unapproved medical treatment facilities and to confiscate illegally-obtained income, medicines and equipment.\(^{42}\)

When framing licensing requirements, governments should be aware of the need for flexible arrangements for authorizing the delivery of emergency health services by authorized personnel following a natural disaster, pandemic or other public health emergency. Creating a process to expedite approval by executive order during an emergency ensures that communities will not be deprived of medical care at the time they most require it. Where appropriate, medical and health care services may be delivered by health professionals contracted to international agencies, accredited nongovernmental organizations, or attached to the security forces of a friendly government that is performing disaster relief functions in partnership with national authorities.

Governments may also consider requiring accredited health care providers to contribute to premium-based compensation schemes for individuals who are injured through medical negligence or substandard care, or who are victims of criminal offences committed by health professionals. Although individuals can seek legal remedies through court actions, governments in some countries have established health care complaints agencies as alternative dispute resolution systems to investigate and conciliate complaints about medical care and to uphold compliance with codes of conduct adopted by the profession. Legislation may also support health care complaints schemes by defining what constitutes inappropriate care or medical misconduct.

In addition to licensing health professionals, governments may also impose licensing requirements and accreditation criteria upon hospitals, nursing homes and other health care establishments, not only to improve accountability and to identify the best-performing institutions, but to support the improvement of quality standards across all facilities.\(^{43}\) In some countries, government agencies or
an independent agency perform accreditation functions. In Argentina, the Technical Institute for Accreditation of Health Care Organizations – a nongovernmental non-profit organization – provides voluntary accreditation to both public and private hospitals according to Pan American Health Organization standards. In performing these functions, regulatory agencies must avoid any conflict of interest with businesses that own or run health care establishments for profit.

(d) Governing institutions

The capacity of governments to expand the range, coverage, affordability and quality of health services will depend on their capacity to manage, coordinate and expand the underlying resources (inputs) needed to deliver those services. Underlying resources include physical infrastructure, human resources, health information, medicines, vaccines, health technology, funding streams and payment systems. Expanding towards UHC requires simultaneous investments in each of these areas, as well as governing institutions to coordinate and integrate their functions. In some countries, this coordinating role may be performed by a single national health insurance commission or authority; in others, a large number of community or employment-based health insurance schemes may share governance functions. Key functions include registering members, collecting health insurance contributions, managing pooled funds, accrediting, contracting and reimbursing health service providers, and complying with government reporting and other legislative requirements.

However the system is organized, governments nevertheless retain an overarching stewardship role, which may be partly delegated to purpose-built institutions. Stewardship functions include the overall design of the health insurance system, assessment of its performance, advocacy for the policies and coverage goals of the system within the political structures of government, the performance of regulatory functions, and accountability for progress towards the realization of the right to health for all members of the population.

Improving the performance of institutions is an important part of the law reform process as countries move towards UHC. In turn, institutions will themselves be subject to administrative and financial requirements. For example, governing legislation may include requirements relating to: the appointment, tenure and removal of senior executives, the establishment of principal committees, units and directorates, and provisions relating to meetings and conflicts of interest. Governing legislation may also specify a level of direct government control over the organization (e.g. through ministerial directives), and include provisions relating to accounts, auditing requirements and annual reports.

Two important institutions commonly seen in health insurance systems include a national health insurance authority (discussed in the following section), and a drugs and medicines regulation authority. A drug regulation agency performs three important roles. The first is drug registration, including assessing and authorizing the entry of medicines into the market, and monitoring their safety and effectiveness. The second is regulation of manufacturing, importation and distribution of drugs. The third is regulation of pharmaceutical advertising and the provision of information. In order to fulfil these roles, regulatory authorities may perform a range of more specific functions (see Box 7.4). In order to fulfil all of these roles effectively, and to negotiate contracts for the bulk
purchasing of essential medicines, drug regulatory authorities should be centralized at the national level.

Box 7.4: Some regulatory functions of a national medicines administration authority

- Establishing a national list of essential medicines that responds to country-specific needs and disease burden, with a focus on primary care;
- Licensing drug manufacturers, wholesalers and other drug dispensers, and monitoring good manufacturing practices;
- Establishing evidence-based clinical guidelines for rational use of prescription medicines;
- Monitoring demand for essential medicines and monitoring prices in the public and private sectors;
- Educating prescribers and establishing financial incentives for prescribers to substitute generic brands;
- Preferential registration and quality assurance of generic medicines;
- Working with donors to reduce duplication of distribution systems;
- Investigating counterfeit medicines and referring cases to law enforcement authorities;
- Negotiating prices and licences on behalf of government-funded or subsidized health insurance schemes;
- Monitoring safety and quality of medicines and investigating safety issues – using legal powers to inspect premises, to remove, test and recall products, and to restrain misleading and fraudulent practices;
- Negotiating prices on behalf of government-funded and subsidized schemes;
- Advising the government on use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

7.3 The role of legislation in defining a national health insurance scheme: case study from Ghana

Ghana’s National Health Insurance Scheme provides a helpful case study of the role of legislation in creating the governing institutions and formalizing the funding mechanisms for UHC. Ghana’s experience may be relevant to other countries where responsibility for the provision of health services is decentralized, where a large proportion of the uninsured population works in the informal sector, and where many of those covered by the scheme cannot afford to contribute through premiums or user fees. The national health insurance model Ghana introduced in 2003 was based on service provision through a network of semi-autonomous, district-based mutual health organizations, strengthened by national governance and financing mechanisms. A decade later,
however, Ghana passed legislation that created a single agency (the National Health Insurance Authority) with district offices. 49

(a) Legislative regulation of Ghana’s National Health Insurance Scheme

Governing institutions

Ghana’s National Health Insurance Act 2003 established the National Health Insurance Authority (NHIA), with the goal of replacing a user pays policy with a national health insurance scheme providing basic health care services to all residents. 50 The Act required each district to establish a mutual health insurance scheme for residents of that district, which was registered as a company limited by guarantee under Ghana’s Companies Act. 51 The Act authorized three kinds of health insurance schemes: district mutual health insurance schemes, private mutual health insurance schemes, and private commercial health insurance schemes. 52 However, it was the district schemes that provided the basis for a system of national coverage. The NHIA’s functions included registering, licensing and regulating health insurance schemes, granting accreditation to health care providers, monitoring their performance and ensuring the quality of services delivered to beneficiaries of schemes. The NHIA maintained a register of licensed health insurance schemes and accredited health care providers 53 and was authorized to inspect and investigate schemes and issue enforceable directives. 54 The NHIA also managed the National Health Insurance Fund, which subsidized the provision of health services by district mutual health insurance schemes. 55

Membership and coverage

The 2003 Act made district schemes responsible for enrolling residents of each district as members, obtaining membership contributions, issuing health insurance identity cards, and administering a means test for indigent persons. 56 The legislation prohibited schemes from discriminating against a person with respect to their admission as a member of a scheme on the basis of “race, sex, disability, marital status, ethnicity, social origin, nationality, religion or creed”. 57 The Act also stipulated that the subsidy that mutual health insurance schemes received from the National Health Insurance Fund would not be paid unless the Council (the governing body of the NHIA) was satisfied that persons had not been excluded from membership based on their physical disability, social, economic or health status. 58

Regulation of health services and health service providers

The 2003 Act required health insurance schemes to use the services of health facilities and health care providers that had been accredited by the NHIA. 59 The Regulations set out the accreditation requirements for defined classes of health care facilities and for health professionals. 60

The 2003 Act also required all licensed schemes to provide the minimum health care benefits set out in the Regulations, thus ensuring a nationally applicable set of priority services. 61 These included outpatient services (including laboratory, X-ray and ultrasound services), inpatient services, oral
health and eye care services, maternity care (antenatal and postnatal care, deliveries – including caesarean sections), and all emergencies. Minimum benefits also include the prescription medications included in the National Health Insurance Scheme Medicines List. The Regulations set out a list of public health services that were to be paid for by the government and were to be free to all members of the population, including immunization, family planning, treatment of mental illness, HIV testing, and treatment of tuberculosis, onchocerciasis, Buruli ulcer and trachoma. Health care services excluded from the scheme were also defined.

Except in emergencies, the Regulations required primary health care facilities to act as gatekeepers, referring patients to secondary and tertiary care services as appropriate. All health care facilities were required to adopt the referral protocols, practice guidelines and health resource sharing arrangements approved by the Council as a requirement for accreditation. Accredited facilities were required to submit quarterly reports containing specified data to enable the Council to monitor the performance of health care facilities and pharmaceutical service providers. The Regulations also set out the circumstances in which health insurance schemes were authorized to refuse payment for services provided by health care facilities.

**Financing**

The 2003 Act required members of district mutual health insurance funds to make membership contributions. However, several classes of people were exempt, including dependent children under 18, pensioners, persons aged 70 years or older, and (subject to a means test) indigent persons with no fixed place of residence or source of income. Unlike private schemes, district mutual health insurance schemes were paid a subsidy from the National Health Insurance Fund, at a level determined by the Council and approved by Parliament. The Fund was financed from a number of sources. These included:

- membership contributions (subject to exemptions including those mentioned above);
- a health insurance levy of 2.5% on selected goods and services (with exemptions on medical services, pharmaceuticals, water, education, and mosquito nets);
- a 2.5% deduction from formal sector contributions to Ghana’s Social Security and Pensions Scheme Fund;
- parliamentary allocations, and investment income.

No co-payments or up-front fees were required at point of service for services covered by the scheme. Under the 2003 Act, the Council, as the governing board of the NHIA, determined the tariffs or levels of reimbursement for health services, in consultation with health care facilities and schemes. The Act authorized payment on the basis of fee-for-service, capitation payments or on any other basis that the Council determined.

**Evolution of the scheme under the 2012 Act**

Community-based, mutual health insurance schemes have the advantage of being flexible, responsive to their members and based on the values of solidarity and mutual assistance.
Community-based schemes may therefore have greater capacity to generate trust and to enrol members from among those who were previously excluded from health coverage for financial or administrative reasons. However, in order to harmonize National Health Insurance Scheme operations, improve service delivery, and address a number of problems (including inefficiencies, difficulties in achieving portability, and irregular billing practices), Ghana repealed its 2003 Act and introduced a centralized health insurance scheme through the National Health Insurance Act 2012.76

The 2012 Act created a single-payer system, overseen by the NHIA, with the stated goal of universal health insurance coverage and access to health care services for all residents of and visitors to Ghana.77 The Act established a multidisciplinary governing board for the NHIA,78 and three specialist committees with specific oversight functions. These included the Finance and Investment Committee, overseeing the management of the National Health Insurance Fund, and the National Health Insurance Oversight Committee. This last committee advises the Board with respect to systems for registration of members in the national scheme, the benefits package available under the scheme, the credentialing of health service providers, tariffs payable to health care providers, and mechanisms for submission and adjudication of claims by service providers.79 The Act provides for the appointment of executives of the Authority, and members of the board, and authorizes the board to establish directorates for the performance of functions of the Authority. The key functions of the Authority under the 2012 Act are set out in Box 7.5.

**Box 7.5: Key functions of Ghana’s National Health Insurance Authority**

In order to achieve its objective of attaining universal health insurance coverage for all residents, the National Health Insurance Act 2012 (Act 852) authorizes the Authority to:

(a) implement, operate and manage the National Health Insurance Scheme;

(b) determine in consultation with the Minister contributions that should be made by members of the National Health Insurance Scheme;

(c) register members of the National Health Insurance Scheme;

(d) register and supervise private health insurance schemes;

(e) issue identity cards to members of the National Health Insurance Scheme;

(f) ensure

   (i) equity in health care coverage;

   (ii) access by the poor to health care services;

   (iii) protection of the poor and vulnerable against financial risk;

(g) grant credentials to health care providers and facilities that provide health care services to members of the National Health Insurance Scheme;

(h) manage the National Health Insurance Fund;

(i) provide a decentralized system to receive and resolve complaints by members of the National Health Insurance Scheme and health care providers;

(j) receive, process and pay claims for services rendered by health care providers;

(k) undertake public education on health insurance on its own or in collaboration with other bodies;
(l) make proposals to the Minister for the formulation of policies on health insurance;
(m) undertake programmes that further the sustainability of the National Health Insurance Scheme;
(n) develop guidelines, processes and manuals for the effective implementation and management of the National Health Insurance Scheme;
(o) ensure the efficiency and quality of services under the national and private health insurance schemes,
(p) protect the interest of members of private health insurance schemes;
(q) identify and enrol persons exempt from payment of contributions to National Health Insurance into the National Health Insurance Scheme;
(r) monitor and ensure compliance with this Act and any Regulations, guidelines, policies, processes and manuals made under this Act; and
(s) perform any other function conferred on it by this Act or that are ancillary to the object of the Authority.

Under the 2012 Act, membership of the scheme is mandatory for all residents, although residents must still apply for registration to the Authority, which issues membership cards. The Act requires the Minister to prescribe the health care benefits package provided under the National Health Insurance Scheme, and the Authority must assess the continued suitability of the benefits package every six months. The Authority must also develop a list of the medicines that may be prescribed under the scheme and the prices that can be charged for these medicines, and review these annually. Similarly, the Authority must review the list of health services and service tariffs that may be charged by health care providers, and may add or remove diagnoses, procedures and examinations and review prices. The 2012 Act also sets out a variety of offences that apply to officers of the Authority, to members of the National Health Insurance Scheme, and health care providers who provide services under the scheme.

(b) Ghana’s National Health Insurance Scheme and the dimensions of universal health coverage

Ghana’s experience illustrates the central role of legislation in implementing a national health insurance scheme. This includes creating governing institutions and providing for their administration and financial accountability. It also includes formalizing the roles and responsibilities of the government and of health service providers, and the entitlements of members of the scheme. This section briefly reviews how Ghana’s legislation addressed each of the three axes or dimensions of UHC, as discussed in Section 1.2. WHO’s UHC model directs attention to ways of:

- expanding the population covered by the scheme;
- expanding the services provided under the scheme; and
- improving affordability, by reducing out-of-pocket payments and moving towards pre-payment.

The key institutions created by or under the 2003 Act included the NHIA itself, and the district-based, mutual health insurance schemes. Other significant governance mechanisms included the
establishment of the National Health Insurance Fund and the National Health Insurance Levy. Under the 2012 Act, the network of mutual health insurance schemes became branch offices of the NHIA.

Population axis

Under the 2003 Act, district schemes were responsible for expanding the covered population by enrolling new members. This was supported by legislation prohibiting discrimination on a number of grounds. Under the 2012 Act, the NHIA assumed responsibility for registering members, and its functions included educating the population about the benefits of the scheme. Employers were also required to ensure that employees are registered under the scheme.

Expanding membership includes registering new members and verifying identities, in order to reduce the risks of over-servicing and inappropriate billing. There is also a human dimension to expanding population coverage: members must be treated with dignity and respect at point of care, regardless of their economic or social circumstances. Ghana is moving towards biometric registration and on-the-spot issuance of identity cards to new members. Other challenges include identifying and enrolling those who, although not exempt from paying premiums, exist on low and precarious incomes in the informal sector.

Services axis

Under the 2003 Act, the range of covered health services was defined in the Regulations, and the licensing of schemes and the accreditation of health facilities and health care providers was stipulated as a central function of the NHIA. The inspection and accreditation of health care providers and health facilities continued under the 2012 Act. The NHIA reviews the benefits package regularly, and conducts an annual review of the medicines that providers are entitled to prescribe under the scheme, and of the services and supplies for which providers are entitled to charge.

The provision of health services and the administration of the health insurance system both depend on human resources. The scaling up of Ghana’s national health insurance scheme therefore depended on parallel strategies to increase the production of health workers.

Cost axis

The 2003 Act sought to eliminate out-of-pocket payments by switching from fee-for-service to prepaid membership contributions paid by enrolled members with defined exemptions, including for indigent persons. Mutual health insurance organizations were subsidized by the National Health Insurance Fund, which was financed from a variety of sources. Arrangements for the regulation of the Fund, and the administration of the National Health Insurance Levy that partly funds it, were continued under the 2012 Act. Like its predecessor, the 2012 Act provides for oversight of private commercial and private mutual health insurance schemes that operate independently of the national health insurance scheme. Private schemes are not permitted to be subsidized from the National Health Insurance Fund.
As population coverage increases, the cost of paying for cover under the scheme is also likely to increase. Revenue sources to support financial sustainability could include higher excise taxes on tobacco and alcoholic beverages, a tax on sugary drinks or electronic communications services, a levy on extractive industries, or an increase in the National Health Insurance Levy.\(^9\) Raising membership contributions and reviewing exemptions is also possible, but carries the risk of further excluding those on low incomes and in precarious employment.

A single-payer health insurance scheme also creates risks of over-servicing. Administering authorities need the capacity to monitor claims, strong clinical and internal audit capabilities, and the capacity to investigate inappropriate billing practices and to refer appropriate cases for prosecution. No insurance scheme can remain financially sustainable if a culture of inappropriate billing practices takes root among health service providers, or if additional fees are gouged from members in ways that drive indigent and low-income persons away from the scheme. In response to cost pressures, Ghana’s NHIA has trialled capitation payment systems, strengthened its clinical and internal audit divisions, introduced a centralized, consolidated account for collecting premiums, centralized its claims processing and payment functions, strengthened the enforcement of the Ministry’s gatekeeper policy, improved the rational prescribing of medicines by linking diagnosis to treatment, and introduced electronic claims submission. Like several other African countries, Ghana is also moving towards innovative, mobile systems for registering members and collecting premiums.\(^9\)

**Quality**

The 2003 Act sought to address service quality in a number of ways; for example, by requiring health care facilities to adopt quality assurance standards,\(^9\) by requiring schemes to pay accounts submitted by service providers within four weeks, and by requiring licensed schemes to provide a procedure for settling complaints.\(^9\) The 2012 Act requires the Minister to appoint an Adjudication Committee, with membership from a range of professional associations, to hear complaints made by a member of the scheme or by a health care provider accredited to the scheme, or complaints referred to it by the Board.\(^9\) Members of the National Health Insurance Scheme must also be informed about complaint and dispute resolution mechanisms at the time of registration.\(^9\) The Authority is also required to ensure that health care providers “implement policies that guarantee quality health care to members ... and carry out clinical audits”.\(^9\)

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95 National Health Insurance Act 2003 (No. 650) s. 67; National Health Insurance Regulations 2004 ss. 38, 43–7.
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