JLN PRIMARY HEALTH CARE INITIATIVE
PRIVATE SECTOR ENGAGEMENT COLLABORATIVE

REGULATION OF PRIVATE PRIMARY HEALTH CARE IN KENYA

A COUNTRY ASSESSMENT REPORT

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This assessment report is part of a series of country regulatory assessment reports that are contributing to the body of evidence and practical knowledge synthesized in Regulation of Private Primary Health Care: Lessons from JLN Country Experiences.

This report was produced by the Joint Learning Network for Universal Health Coverage (JLN), a community of policymakers and practitioners from around the world who jointly create practical guidance to accelerate country progress toward universal health coverage.

For questions or inquiries about this report or other JLN activities, please contact the JLN Coordinator Team at jln-nc@r4d.org.

Contents

ABBREVIATIONS AND ACRONYMS

KePSIE	Kenya Patient Safety Impact Evaluation
KMPDB	Kenya Medical Practitioners and Dentists Board
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
KNDI	Kenya Nutritionists and Dieticians Institute
MOH	Ministry of Health
NCK	Nursing Council of Kenya
NHIF	National Hospital Insurance Fund
OAG	Office of the Auditor General
PHC	primary health care
PPB	Pharmacy and Poisons Board
RPB	Radiation Protection Board

PREFACE

In 2016, the JLN Private Sector Engagement (PSE) Collaborative completed the first two modules of a five-part practical guide on private-sector engagement, titled *Engaging the Private Sector in Primary Health Care to Achieve Universal Health Coverage: Advice from Implementers to Implementers*. These first two modules cover initial communications and partnership around primary health care (PHC) and provider mapping. To inform the third module, and to help fill gaps in guidance on the regulation of private PHC in low- and middle-income countries, six JLN countries—Ghana, Indonesia, Kenya, Malaysia, Mongolia, and Morocco—conducted assessments of their regulation of the private health sector. The assessments addressed the following research questions:

- What types of regulations are in place?
- How are the regulations implemented?
- What outcomes are achieved by those regulations?
- What resources are available for developing and implementing such regulations?

The assessments focused only on regulation of PHC service delivery (the process of providing PHC services and treatments). They did not cover other types of regulation, such as for human resources, training institutions, pharmaceuticals, or medical equipment.

Regulation is broadly defined as the imposition of rules backed by penalties or incentives to ensure compliance with standards—in this case, standards for the safety and quality of health services and providers. Regulations may govern activities such as licensing to open a facility, certification and accreditation, and offering incentives to promote better service quality. In outlining the scope of the assessments, the PSE Collaborative chose to look at regulation of both public and private-sector providers. They also agreed to focus on PHC service delivery, while recognizing that in describing the regulatory system they would inevitably touch on secondary and tertiary care.

The countries each conducted a document review using secondary data sources and collected primary data through in-depth interviews and focus groups involving national and subnational government entities (ministries of health, health financing agencies, regional health directors), regulatory boards and medical councils, professional associations and

representatives of provider groups and unions (for both public and private providers), members of the media, academics, and civil society organizations (representing consumers).

Each country assessment report describes the country's regulatory context, health sector objectives and strategy, and demographic and health indicators; the regulatory mechanisms currently in use; insights on implementation and performance based on primary and secondary data collection; and conclusions and recommendations for improvement.

This report documents Kenya's experience in regulating private PHC.

Methodology

Kenya's assessment team collected primary data through key informant interviews and workshops with various stakeholders—including regulators, representatives of regulated facilities, consumer groups, academics, legislators, and members of the media. The interviews were transcribed, and then key themes were identified and summarized. The authors collated all of the regulatory instruments relevant to PHC and diagnostics service delivery and reviewed their targets, rationale, and implementation status. Regulatory mechanisms were classified as command and control, incentives, or self-regulation. Regulatory instruments reviewed include the constitution of Kenya, acts and bills of national and county parliaments, gazette notices, cabinet decisions, executive orders and decrees, ministerial statements, and standards and guidelines.

REGULATORY CONTEXT

Health Sector Objectives and Strategy

The right of all Kenyans to the highest attainable standard of health is enshrined in the Constitution of Kenya 2010.[1] Under the constitution, delivery of primary health care (PHC) and secondary health care services was decentralized, giving the responsibility to county governments. The national government provides policy direction and oversees tertiary health care services. However, the constitution calls for mutual cooperation between national and county governments in implementing country development plans such as Kenya's Vision 2030 long-term development plan. Vision 2030 recognizes the health sector's role in achieving one pillar of the plan: to maintain a healthy workforce for increased labor production that will transform Kenya into an industrialized middle-income country.

The Kenya Health Policy 2014–2030 focuses on advancing PHC to realize the constitutional right to health in a responsive manner, as well as achieving Vision 2030 goals.[2] The Kenya Health Policy recognizes that realizing the constitutional right to health will require partnerships and stronger collaboration with the private sector (which is broadly defined as all nonstate actors, including private for-profit, nonprofit, and nongovernmental organizations (NGOs); civil society organizations; faith-based organizations, traditional practitioners; the media; and all other people and organizations whose actions have an impact on health but that don't draw their mandate from the state.

The Kenya Health Sector Strategic and Investment Plan (KHSSP III) 2014–2018 defines the service package at each level of care, norms and standards for adequate delivery of the service package, and the partnership framework to improve effectiveness of service delivery.[3] KHSSP III notes the need to "consider the complementarity of the private sector in service provision, for alternative/innovative financing mechanisms (e.g. leasing of equipment) and for the need for concurrent investments in Health Products and Technologies, Human Resources for Health and leadership in order to ensure that capital

[1] Government of Kenya 2010
[2] Ministry of Health 2014
[3] Ministry of Health 2013

investment planning and budget allocations in the public sector are efficient, sustainable and achieve conformity of facilities with the standards of each level of service provision."

Kenya is also committed to achieving regional and global health objectives, including the United Nations Sustainable Development Goals, Every Woman, goals of the Every Child movement, and UNAIDS 90-90-90 targets. Policymakers take these commitments into consideration in their planning and implementation.

Demographic and Health Outcome Indicators

Table 1 shows selected demographic and health outcome indicators for Kenya.

Table 1: Demographic and Health Outcome Indicators

Indicator	Measure	Year	Source(s)
Total population	38,610,097 43,000,000	2010 2015	2009 Kenya Population and Housing Census Volume 1C (Kenya National Bureau of Statistics 2010) Kenya Facts and Figures 2015 (Kenya National Bureau of Statistics 2015)
Population age distribution	Age 0–5: 18.4% Age 6–15: 26.8% Age 16–64: 51.3% Age 65+: 3.5%	2010	2009 Kenya Population and Housing Census Volume 1C (Kenya National Bureau of Statistics 2010)
Urban and rural population	Urban: 32.3% Rural: 67.7%	2010	2009 Kenya Population and Housing Census Volume 1C (Kenya National Bureau of Statistics 2010)
Poverty rate	45.9%	2005	World Bank data bank (World Bank 2017)
Infant mortality rate	39 per 1,000 live births	2015	Kenya Demographic and Health Survey 2014 (Kenya National Bureau of Statistics 2015)
Under-5 mortality rate	52 per 1,000 live births	2015	Kenya Demographic and Health Survey 2014 (Kenya National Bureau of Statistics 2015)

Indicator	Measure	Year	Source(s)
Maternal mortality ratio	362 per 100,000 live births	2015	Kenya Demographic and Health Survey 2014 (Kenya National Bureau of Statistics 2015)
Top three illnesses that create demand for health services	HIV/AIDS Conditions arising during the perinatal period Malaria	2014	Kenya Health Policy 2014–2030 (Ministry of Health 2014)
HIV prevalence	5.6% 5.9%	2014 2016	Kenya AIDS Indicator Survey 2012 (National AIDS and STI Control Programme 2014) Kenya AIDS Progress Report 2016 (National AIDS Control Council 2016)
Diabetes prevalence	3.3% 4.56%	2010 2015	Kenya National Diabetes Strategy 2010–2015 (Ministry of Public Health and Sanitation 2010) Kenya National Strategy for the prevention and control of noncommunicable diseases 2015–2020 (Ministry of Health 2015)
Total fertility rate	3.9 births per woman	2015	Kenya Demographic and Health Survey 2014 (Kenya National Bureau of Statistics 2015)
Proportion of 1-year-olds who have received DTP3	88.3%	2015	Kenya Demographic and Health Survey 2014 (Kenya National Bureau of Statistics 2015)
Prenatal care coverage (4+ visits)	57.6%	2015	Kenya Demographic and Health Survey 2014 (Kenya National Bureau of Statistics 2015)
Use of family planning by married women	58%	2015	Kenya Demographic and Health Survey 2014 (Kenya National Bureau of Statistics 2015)

Indicator	Measure	Year	Source(s)
Tuberculosis incidence	89,000 new infections	2014	National Strategic Plan for Tuberculosis, Leprosy and Lung Health 2015–2018 (Ministry of Health 2015)
Cancer mortality	7% of national mortality	2015	Kenya National Strategy for the prevention and control of non-communicable diseases 2015–2020 (Ministry of Health 2015)
Childhood vaccination coverage	79%	2015	Kenya Demographic and Health Survey 2014 (Kenya National Bureau of Statistics 2015)
Percentage of births assisted by a skilled provider	62%	2015	Kenya Demographic and Health Survey 2014 (Kenya National Bureau of Statistics 2015)

Health System Indicators

Table 2 provides a snapshot of health system indicators, defining the public and private mix of resources used for PHC and diagnostic services.

Table 2. Health System Indicators

Indicator	Measure	Year	Source(s)
Number of hospital beds per 100,000 population	11,771	2014	Kenya Service Availability and Readiness Mapping Report 2013 (Ministry of Health 2014)
Number of maternity beds and incubators	9,304	2014	Kenya Service Availability and Readiness Mapping Report 2013 (Ministry of Health 2014)
Inpatient admission rate	3.8% Public: 48% of total Private 52% of total	2014	2013 Kenya Household Health Utilization and Expenditure Survey (Ministry of Health 2014)

Indicator	Measure	Year	Source(s)
Outpatient utilization rate (visits per person per year)	3.1 visits Public: 58% Private: 42%	2014	2013 Kenya Household Health Utilization and Expenditure Survey (Ministry of Health 2014)
Number of outpatient facilities by type	7,995 total Public: 49.8% Private: 50.2%	2014	Kenya Service Availability and Readiness Mapping Report 2013 (Ministry of Health 2014)
Number of clinical laboratory facilities	3,672 total Public: 47.5% Private: 52.5%	2014	Kenya Service Availability and Readiness Mapping Report 2013 (Ministry of Health 2014)
Number of specialized laboratory facilities	481 total Public: 38.9% Private: 61.2%	2014	Kenya Service Availability and Readiness Mapping Report 2013 (Ministry of Health 2014)
Number of imaging (X-ray) facilities	404 total Public: 36.9% Private: 63.1%	2014	Kenya Service Availability and Readiness Mapping Report 2013 (Ministry of Health 2014)
Number of pharmacies	3,525 total Public: 58% Private: 42%	2014	Kenya Service Availability and Readiness Mapping Report 2013 (Ministry of Health 2014)
Number of health workers (e.g., doctors, nurses, midwives, technicians, pharmacists, health extension workers)	16.08 per 10,000 population Public: 57% Private: 43%	2014	Human Resources for Health (HRH) Results Policy Brief Issue 2013 (Ministry of Health 2014)
Percentage of population covered by a public health insurance plan	15.1%	2014	2013 Kenya Household Health Utilization and Expenditure Survey (Ministry of Health 2014)

Indicator	Measure	Year	Source(s)
Percentage of population covered by a private health insurance plan	2%	2014	2013 Kenya Household Health Utilization and Expenditure Survey (Ministry of Health 2014)
GDP per capita	US$ 1,376.70 PPP[4]: US$2,901	2015	World Bank data bank (World Bank 2017)
GDP growth rate (past 5 years for which data are available)	2016: 5.8% 2015: 5.7% 2014: 5.4% 2013: 5.9% 2012: 4.5%	2017	Economic Survey 2017 highlights (Kenya National Bureau of Standards 2017)
Total health expenditure (THE) per capita	US$: 66.6 Local currency: KES 5,679.50	2015	Kenya National Health Accounts 2012/2013 (Ministry of Health 2015)
THE as a share of GDP	6.8%	2015	Kenya National Health Accounts 2012/2013 (Ministry of Health 2015)
General government health expenditure (GGHE) per capita and as a share of THE	US$22.3 per capita 33.5% of THE	2015	Kenya National Health Accounts 2012/2013 (Ministry of Health 2015)
Private health expenditure per capita and as a share of THE	US$27.3 per capita 39.8% of THE	2015	Kenya National Health Accounts 2012/2013 (Ministry of Health 2015)
External health expenditure per capita and as a share of THE	US$17.0 per capita 25.6% of THE	2015	Kenya National Health Accounts 2012/2013 (Ministry of Health 2015)

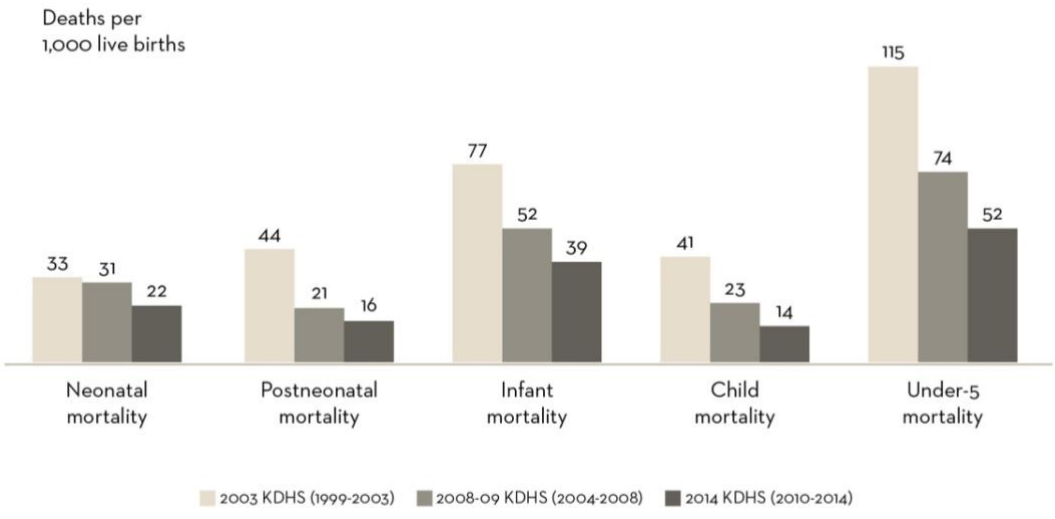
[4] Purchasing price parity

Indicator	Measure	Year	Source(s)
Out-of-pocket expenditure (OOPE) on health per capita and as a share of THE	US$17.7 per capita 26.6% of THE	2015	Kenya National Health Accounts 2012/2013 (Ministry of Health 2015)
Degree of government decentralization	National government is responsible for policy and national referral institutions. The 47 county governments are responsible for public health, including primary and secondary health care service delivery at the county level.	2010	Constitution of Kenya 2010 (Government of Kenya 2010)
Key political stakeholders and the dynamics among them	Cabinet Secretary for Health County Health Executive Committee Members Parliamentary Committee for Health Senate Committee for Health County Committee for Health	The Cabinet Secretary heads the Ministry of Health (MOH) which is charged with health policy development. The 47 County Health Executives head their respective county health departments; they engage with the Cabinet Secretary at annual forums to discuss health strategy and policy. The Parliament develops national-level legislation while the Senate develops legislation related to counties. Their Committees for Health are responsible for health specific concerns including drafting legislation, sponsoring legislation, and raising queries on the conduct of the MOH and the County Governments (Senate). The 47 County Assemblies develop legislation specific to a county. Whereas the Senate's jurisdiction cuts across all counties, the County Assembly and its health committee is limited to the county's physical boundaries.	

Kenya has committed to achieving universal access to health care for high-priority groups. Recent executive declarations have called for free treatment for children under age 5 and free services at all public facilities, in addition to free PHC at public primary-level facilities that target lower-income groups that access care at this level of the health system. The government has also expanded health insurance coverage for indigents at county level, orphaned and vulnerable children, and the elderly through the National Hospital Insurance Fund (NHIF).

These policies have had a positive impact. For example, a review of implementation of the user fee abolition in 2013 showed a 25% increase in PHC use among those under age 5 and an increase of 35% among those above age 5 in the year after implementation.[5] Figure 1 below shows the steady decline in newborn, post-newborn, infant, child, and under-5 mortality over successive demographic health surveys.[6] Maternal mortality has also declined, from 520 per 100,000 live births in 2008–2009 to 362 per 100,000 live births in 2014. Delivery at health facilities increased from 43% to 61% during the same period, while delivery by a skilled attendant increased from 44% to 62%.6 Overall, equity within the health system and health outcomes have improved.

Figure 1. Trends in Mortality



Source: Kenya Demographic and Health Survey 2014

[5] Maina and Kirigia 2015
[6] Kenya National Bureau of Statistics 2015

Despite these gains, challenges remain. Kenya has a double burden of both communicable and noncommunicable diseases. The country has the third-highest population of people living with HIV, at 1.5 million,[7] and is one of the top 20 countries in tuberculosis burden.[8] Morbidity and mortality from cancer, heart disease, and diabetes are on the rise and are among the top 10 causes of morbidity and mortality in Kenya.[9] Challenges in equity also persist. A 2013 survey showed that those in the lowest income quintile were twice as likely to report poor or unsatisfactory health status compared to those in the richest quintiles; they were also more likely to forgo health care.[10] Meanwhile, the richest quintiles had the highest utilization of PHC services; the lowest quintiles had the lowest utilization.[11] Variations exist between counties, with marginalized counties in northern Kenya having less health infrastructure and human resources than urban counties.

To tackle these challenges, smart investments are needed to increase access to services. A strong regulatory framework for both the public and private sectors is also essential to harmonize service delivery and achieve the policy goals of improved health services and improved health outcomes for all Kenyans. Collaboration with the private sector is necessary—the private sector owns 51% of the health infrastructure and provides 42% of PHC. Harnessing the potential of the private sector requires an enabling policy environment to enhance dialogue and increase private-sector participation.

[7] UNAIDS 2017
[8] World Health Organization 2016
[9] Ministry of Health 2013
[10] Ministry of Health 2014
[11] Ministry of Health 2014

REGULATORY LANDSCAPE

This section provides an overview of the regulations related to PHC service delivery and diagnostic services, the regulatory actors involved in developing and implementing regulations, resources available to those actors, and the data available for tracking the performance of regulatory efforts.

Regulatory Efforts to Date

Table 3 summarizes the regulatory mechanisms in place, targets of the regulation, rationale for the regulation, and the status of implementation. Table A-1 in the Annex provides further details.

Regulatory mechanisms are classified in three broad categories:

- **Command and control mechanisms**—legal requirements that are enforceable through sanctions. These include requirements on licensing, registration, adherence to facility norms and standards, and criteria setting for continuous professional development as a requirement for licensing.
- **Incentive mechanisms**—mechanisms that change behaviors in response to financial and nonfinancial rewards and penalties. These include improved rebates for higher accreditation scores, financial penalties for malpractice and misconduct, and nonfinancial incentives for service delivery reporting.
- **Self-regulation mechanisms**—guidelines and norms developed by professionals that govern their practice. These can include codes of conduct and professional ethics as well as voluntary accreditation.

The majority of Kenyan health regulations can be classified as command and control mechanisms, which are enforceable by the Ministry of Health, regulatory boards, and county health departments. The Constitution of Kenya defines the main roles for the health sector being service delivery as a mandate of the county governments and developing policy and regulations as a mandate of the national government through the Ministry of Health.

The overarching health law is the Health Act, which received presidential approval in 2017. It replaced the Public Health Act from the colonial era, which had undergone multiple amendments and required an overhaul to reflect the needs of the decentralized health

system. The Health Act establishes a unified health system to coordinate the relationship between the national government and county government health systems and provide for regulation of health care services and health care facilities, health care workers, health products, and health technologies.[12]

Kenya has nine regulatory boards for various cadres of health workers; an act of Parliament established their mandate as registering and licensing health workers and health facilities. Four of these boards have further mandates of registering and licensing health facilities and separately registering diagnostic facilities within a health facility, including the laboratory, pharmacy, and X-ray departments. This results in double registration and additional expenses for facilities because they have to register with multiple regulatory agencies and pay fees to each agency.

County governments also pass laws that govern county health services, but few laws have been passed at this level and those that have are largely related to establishing county health departments or granting health facilities management autonomy. Oversight and tracking by the Ministry of Health are needed to ensure that these county laws align with national policy, further health sector goals, and do not duplicate or conflict with existing laws.

Incentive mechanisms are few and poorly developed in Kenya; opportunities to provide incentives to providers to control costs, improve efficiency, and improve the quality of care and overall health outcomes have not been embraced. For example, accreditation is required only for private facilities, while public facilities are automatically "gazetted"[13] for payment by NHIF. Through the accreditation process, the reimbursement level for private providers is set, so providers have an incentive to invest in upgrading their services and infrastructure to attain a higher reimbursement level. However, there is no clear process for reaccreditation, and the additional time and effort required to gain reaccreditation is significant. Further, the process is not linked to quality assurance and continuous quality improvement because this is not mandated to any agency.

[12] Government of Kenya 2017

[13] The government and its ministries and departments make declarations through the Kenya Gazette. In the health context, NHIF makes declarations in the Kenya Gazette that govern enrollee contributions, which health facilities are accredited to provide services, and which are no longer accredited.

Doctors, dentists, nurses, pharmaceutical manufacturers and distributors, physiotherapists, and radiographers are among the cadres of health care workers that have developed codes of conduct and ethics to guide their professional behavior. Health care workers who do not abide by these codes of conduct can be deregistered by their regulatory board. Voluntary certification from international organizations such as Joint Commission International (JCI) and the International Organization for Standardization (ISO) are expensive; only a few private providers are able to afford it. However, the certification is prestigious and can result in increased revenue for providers because some enrollees prefer to seek care from a provider who has been certified by an internationally recognized institution.

Table 3. Regulatory Mechanisms

Mechanism	Instrument(s)	Target(s)	Rationale	Status of Implementation
Command and control— *legal requirements accompanied by sanctions for noncompliance*	Bill of Rights in the Constitution of Kenya	Citizens, MOH	Every Kenyan has the right to the highest attainable standard of health.	Constitution enacted after promulgation in 2010
	Health Act	MOH, county health departments	Defines structure of service delivery, health products, health financing, and human resource regulation.	Presidential approval granted in May 2017 for immediate implementation
	Nine Regulatory Boards' Acts	Health personnel, health facilities, training institutions, medical device and commodity manufacturers, retailers, and distributors	Training, registration, and licensing of human resources. Registration and licensing of health facilities and facility departments. Registration of medicines.	Multiple laws implemented since 1978
	County health laws	County health departments, county health facilities	Defines county health department functions. Provides for autonomy of health facilities.	Multiple laws enacted by counties since 2014

Mechanism	Instrument(s)	Target(s)	Rationale	Status of Implementation
Incentives *(financial)*— *financial rewards or penalties to influence provider behavior*	NHIF service delivery contracts	Health facilities	Contracts define services and rebates that are linked to accreditation.	NHIF contracting ongoing
Incentives *(nonfinancial)*— *nonfinancial rewards or penalties to influence provider behavior*	Accreditation frameworks	Health facilities	JCI and ISO certification is prestigious and draws clients. Facilities are incentivized to maintain standards to maintain certification.	Ongoing
Self-regulation*—standards set by provider or professional groups for their own members*	Professional associations codes of conduct	Health professionals	Set standards for operational behavior.	Developed by each cadre, implemented since 2009

Regulatory Actors

Regulatory actors are institutions and agencies that are responsible for regulation and regulatory efforts. The Fourth Schedule of the Constitution of Kenya 2010 defines the role of government in health, which consists of policy development through the Ministry of Health and implementation and service delivery through county governments. Health-related legislation is developed by elected parliamentary representatives in consultation with the Senate and county assemblies. Regulators, including the Ministry of Health and health care professional regulatory boards, draw their mandate from acts of Parliament. Through these acts of Parliament, they develop and enforce regulations on regulatory targets, including health care facilities, pharmacies, diagnostic services, health professionals, and health professional training institutions.

Figure 2 depicts the relationships among the various regulatory actors in Kenya's health sector. The arrows indicate the targets of the regulatory actions. For example, the public elects members of the National Assembly, the Senate, and county assemblies as their representatives. The representatives enact legislation that affect the Ministry of Health, health care professional regulatory boards, NHIF, and county health departments, who in turn develop the regulations, policies, and statutes that guide the health care professionals, training institutions, health care facilities, and diagnostic services. (See Table A-2 in the Annex for more details.)

Figure 2. Relationships Among Regulatory Actors

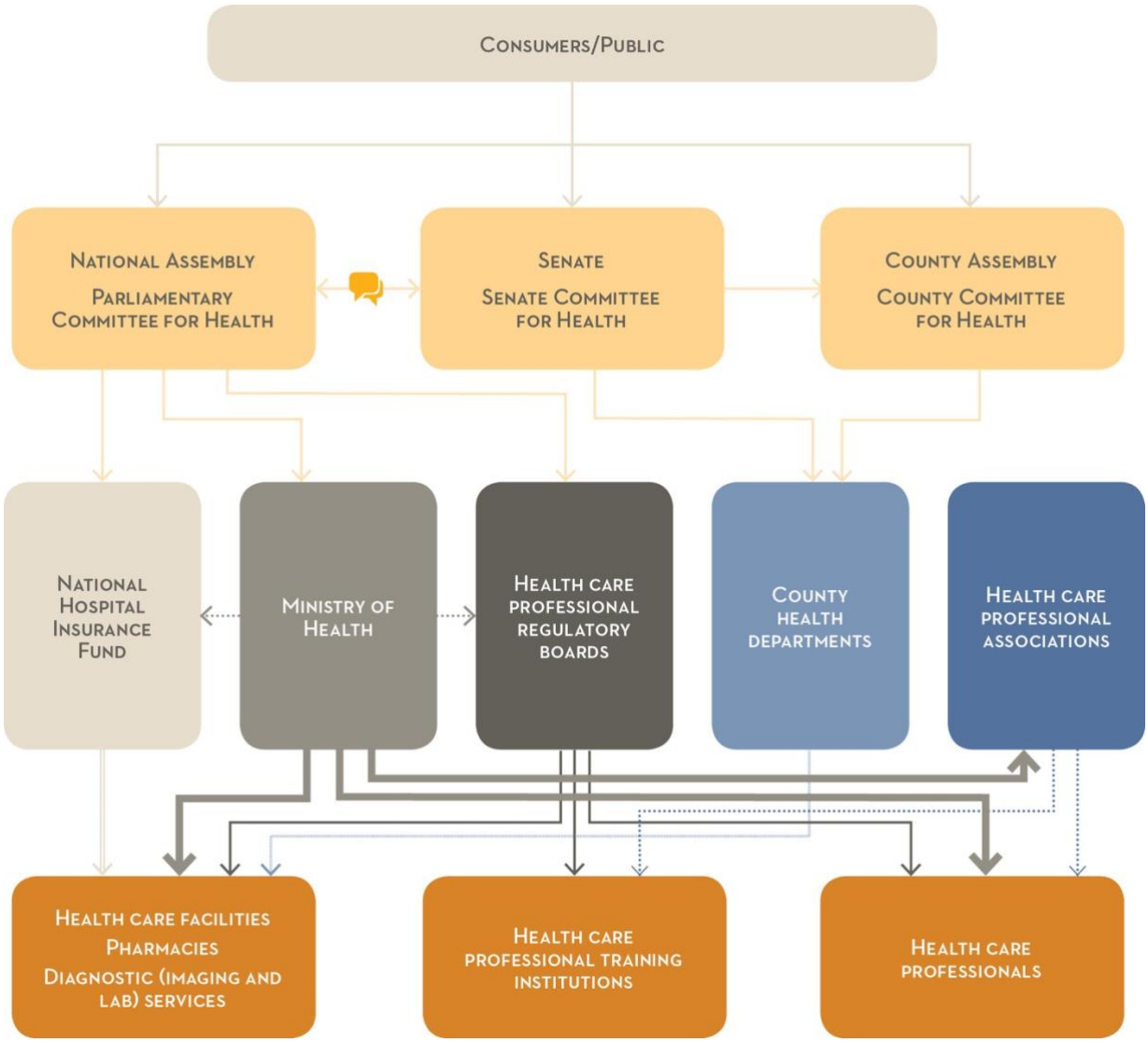


Table 4 further describes the relationships among regulatory actors depicted in Figure 2.

Table 4. Relationships Among Regulatory Actors

→	The public elects representatives to the Parliament, Senate, and county assemblies during elections every 5 years. These representatives develop legislation and have a mandate to represent the will of those who elected them. The constitution also requires public participation in the development of legislation.

	Health is decentralized in Kenya, so health regulations developed by Parliament must also be reviewed and approved by the Senate. This may result in delays in passing legislation, given that the constitution requires consultation with the public, followed by consultations within both the Parliament and the Senate. Any disagreements between the two bodies are mediated through a joint process. The mediated version of the legislation must undergo three readings in both bodies for final voting by elected representatives. Passed legislation is forwarded for presidential assent or veto. A veto leads to a repeat of the processes described above to develop a mutually agreeable bill that can receive presidential assent.
	Both the Parliament and county assemblies generate health-related legislation. The Senate can also develop legislation that affects counties, and it approves budget appropriations to counties, which affects the amount of resources available for health service delivery. County legislation is binding within the county; Parliament develops national-level legislation. Legislation at the county level is expected to align with national-level legislation, priorities, and strategies. However, as autonomous units, counties can enact legislation that is in their own interest. For example, some counties have proposed legislation to set up their own health insurance funds despite the existence of NHIF, which serves as Kenya's social health insurer. This would fragment the national pool.
	These regulators produce various regulatory instruments, including policies, strategies, treatment protocols, codes of conduct, accreditation guidelines, and purchasing contracts for regulatory targets. The Ministry of Health, regulatory boards, and NHIF derive their mandate from an act of Parliament.
	The mandates of the nine regulatory boards are each derived from an act of Parliament. All nine boards regulate training of the health professionals within their purview. For example, training institutions that train multiple cadres of professionals must register with each relevant board, pay registration fees, and coordinate with the regulatory boards in registering students, indexing and examinations.

	These regulated actors, which include health professionals, facilities, and training institutions, are regulated by multiple regulatory actors, which results in duplicate efforts and resources. For example, they pay multiple fees to various agencies, which increases their cost of doing business and requires them to keep abreast of multiple pieces of legislation. Each regulatory board must raise revenue to meet its core responsibilities, which raises administration costs. These functions could be consolidated into fewer agencies, reducing transaction and administration costs for both the regulators and the regulated institutions.

Resources for Regulation

To carry out their responsibilities effectively, regulatory actors require adequate resources—including human resources, financing, equipment, infrastructure, grants, and in-kind resources. Table A-3 in the Annex summarizes the resources available to regulatory actors.

The Office of the Auditor General (OAG) audits regulatory boards and publishes the results on the OAG website, where the public can access them. However, the most recent OAG report is for the 2014–2015 fiscal year; more recent data are not publicly available. In addition, not all regulatory boards have been audited, and the quality and quantity of information reported has been inconsistent. For example, the Kenya Medical Practitioners and Dentists Board (KMPDB) is the only board that also reported performance on activities in their audited reports. Audit reports for the national and county governments, including the Ministry of Health and the county health departments, did not include sufficient detail on regulation activities. This presented limitations for secondary data collection for this country assessment.

A review of the few available audits found that regulatory boards are expected to raise sufficient revenue from member fees to meet their operational expenses. This revenue is rarely supplemented by government grants, although some boards had additional revenue from donor-funded projects. Resource limitations limit the ability of these boards to carry out all their responsibilities, particularly supervising health professionals and facilities.

The Office of the Controller of Budget conducts annual and quarterly budget implementation reviews for the national and county governments, which it posts on its website. These reviews do not include expenditure on regulatory functions. However, the 2016–2017 financial year national budget implementation review included expenditure for the regulation and standards department of the Ministry of Health for the first time. Expenditure on regulatory functions at the national and county levels may be included in the future.

Tracking Regulatory Performance

Information on health sector regulation is publicly available from the Ministry of Health (including on its website); acts of national and county assemblies are published by the Kenya Gazette and are available online in the Laws of Kenya database. Professional associations disseminate regulations, laws, and codes of conduct to their members at their annual meetings.

Tracking and reporting regulatory performance is important to providing transparency and maintaining accountability to constituents, members, and representatives. Regulatory actors use a variety of systems to track performance. Regulatory agencies develop annual work plans and budgets at the beginning of the fiscal year to plan for activities, as stipulated in their mandates. The Ministry of Health, NHIF, and regulatory boards are audited annually by the OAG, and results are published on the OAG website. Regulatory boards provide quarterly reports on inspections by the Ministry of Health. Professional associations are also audited, and financial and activity accounts are presented to members.

Table 5 summarizes the reported performance of one regulatory board, the KMPDB, between July 2014 and June 2015.

Table 5. Regulatory Activities and Performance

Regulatory Activity	Performance Indicators	Performance Period	Source
Applications to open a new facility processed	No publicly available data		
Accreditation inspections conducted	11 new and 12 existing internship training centers 2,037 health facilities accredited by NHIF	July 2014–June 2015	KMPDB Audited reports July 2014–June 2015 (Government of Kenya 2016)
Health facilities inspected	858 joint inspections	July 2014–June 2015	KMPDB Audited reports July 2014–June 2015 (Government of Kenya 2016)
Health personnel registered and licensed	1,178 doctors and dentists registered 2,891 part-time and full-time private practices licensed	July 2014–June 2015	KMPDB Audited reports July 2014–June 2015 (Government of Kenya 2016)
Health facilities registered	3,627	2017	KMPDB website (KMPDB 2017)
Sanctions imposed on facilities for failed inspections	130 health facilities closed	July 2014–June 2015	KMPDB Audited reports July 2014–June 2015 (Government of Kenya 2016)
Complaints received	No publicly available data		
Complaints reviewed	No publicly available data		
Sanctions imposed on facilities due to complaints	No publicly available data		

Regulatory Activity	Performance Indicators	Performance Period	Source
Sanctions imposed on provider personnel due to complaints	40 personnel arrested and charged in court for offenses related to the practice of medicine and dentistry	July 2014–June 2015	KMPDB Audited reports July 2014–June 2015 (Government of Kenya 2016)
Incentive payments made for achieving quality or other targets	No publicly available data		

Not all audited regulatory boards report their performance, and data related to consumer protection, such as complaints received and sanctions imposed on health facilities, are not available in the OAG audit reports. Some professional boards report regularly to the Ministry of Health, but this information is not available to citizens and civil society organizations.

Summary of Regulatory Efforts

Kenya has an elaborate regulatory framework to support its health sector goals. The regulations have evolved since pre-colonial times, with frequent amendments and subsidiary legislation. The Health Act 2017 aimed to consolidate these changes into a coherent framework for the decentralized health system.

Existing regulations address most aspects of the health system, including infrastructure and staffing, service delivery levels, types of services to be delivered at each level, the supply chain for medical commodities and pharmaceuticals, and information technology and e-health. However, the regulations focus more on inputs than on outputs and outcomes.

Existing regulations rely heavily on command and control mechanisms with sanctions for noncompliance. Regulations that incorporate financial and nonfinancial incentives are few and largely focus on public facilities. Self-regulation happens mainly through codes of conduct. These instruments are relatively new, so it is difficult to gauge their effectiveness.

Nine regulatory boards license and register various health care professionals and regulate their training and training institutions. Their mandates overlap in places, as shown earlier in Figure 2. Training institutions and health facilities may be overseen by two or more regulatory actors. Another overlap is in registration of health facilities, where the KMPDB licenses health facilities but the radiology, laboratory, and pharmacy units within the health facility must also be registered by those respective boards. This is required only of private facilities, resulting in an uneven playing field. The multiple licensing fees also impose a heavy burden on private facilities. In addition, each regulatory board plans its own inspections and relies on the KMPDB and the police to close down facilities as necessary.

The Ministry of Health is working to improve coordination in this area by developing a Joint Health Inspections Checklist and organizing joint inspections by regulatory boards, which would be more comprehensive. Box 1 describes this innovation, which is funded by the World Bank. The Health Act calls for improved coordination of regulatory boards through the Kenya Health Professions Oversight Authority, which addresses overlaps in mandates, improves coordination among regulatory boards, and facilitates joint inspections.

An analysis of available audit reports from regulatory boards shows that these organizations are heavily dependent on licensing and registration fees collected from health professionals and health facilities. The regulatory boards generally do not receive additional funding or grants from the government, though the boards that do receive government funding receive limited resources that account for less than 20% of their operational budget. Human resources support is limited to a Nairobi-based secretariat that is largely engaged in registration and licensing activities. Most of the boards' income is used to pay for salaries, rent, and committee meetings, with little funding for supervisory activities.

The regulatory boards are expected to report to the Ministry of Health on their regulatory activities, but they do not publish this information on their websites; the only publicly available information is outdated audited reports on the OAG website. Therefore, it is difficult to assess performance of regulatory agencies and boards.

Box 1. Streamlining Regulatory Oversight

Kenya began exploring health regulatory reforms in 2008 by initiating dialogue between the public and private health sectors. The Ministry of Health, in collaboration with the World Bank Group and USAID, subsequently engaged the private health sector in mapping its operations within the overall health sector and exploring ways for private providers to help advance national health goals. Public and private stakeholders then collaborated on a set of reforms to the health regulatory framework, including making health inspections more efficient and effective. From 2010 to 2012, the Ministry of Health, health professional regulatory boards, and the private health sector engaged in a participatory process to develop a Joint Health Inspections framework. The regulatory bodies agreed to jointly carry out inspections of health facilities, and the Joint Health Inspections Checklist (JHIC) was published in 2012.

The JHIC was piloted, and an improved version focusing on patient safety launched in 2015 along with a JHIC toolkit with clear implementation guidelines, a scoring system for facilities, a risk framework for categorizing facilities, and warnings and sanctions to accompany each risk category.

With support from the World Bank Group, Kenya used the JHIC toolkit to conduct the Kenya Patient Safety Impact Evaluation (KePSIE), which tested the effectiveness of two ways of conducting quality and patient safety inspections in three counties: 1) conducting a single intensified inspection of every facility and 2) conducting an initial inspection with a peer-support mechanism and a follow-up inspection.

Findings from KePSIE have led to a marked improvement in adherence to infection prevention practices and other patient safety standards.

The Ministry of Health intends to scale up KePSIE to the other 44 counties, with support from the World Bank. The KePSIE project has also led to the development of procedures that have been included in electronic versions of the JHIC and a web-based inspection monitoring system.

KePSIE has reduced the burden of inspections by multiple agencies. One individual conducts each inspection and shares the results with the regulatory agencies and health providers. Providers receive regular supervisory visits and continuous feedback on areas for improvement.

KePSIE is a donor-funded project and will need significant investment by the Ministry of Health to expand nationally.

IMPLEMENTATION AND PERFORMANCE OF REGULATORY ACTIVITIES

This section documents the actual implementation of regulatory efforts and summarizes the views of both regulators and regulatory targets. Table A-44 in the Annex documents details from interviews and describes the status of health sector regulation and regulatory performance.

Implementation Successes

Interviewees noted the following regulatory successes:

- **A robust regulatory framework.** There was consensus that the regulatory framework is good and meets most needs of the health system. A culture of developing and using regulation has taken hold, with the Ministry of Health regularly developing standards and policies as needed and also updating and reviewing outdated regulations and policies. The Kenya Health Policy Framework guides the development of health sector strategies, planning, and priorities.
- **Strong regulatory institutions.** Regulatory actors have well-defined mandates through acts of Parliament, which define their roles and responsibilities and grant them the authority they need to carry them out. These regulatory actors are well-established independent institutions and are given the resources to carry out their core mandates.
- **A rights-based approach to regulation.** The constitution lays out a rights-based approach to health care that empowers citizens to demand the highest attainable standard of health care, including reproductive health care. The constitution also guarantees citizens access to emergency treatment from any provider and requires all public and private health facilities to provide emergency treatment regardless of the patient's ability to pay.
- **Stakeholder engagement in policy formulation.** Stakeholder engagement has improved over the years, with stakeholders being actively informed and engaged in the process of developing regulation and legislation. Some forums to engage both state and non-state actors in the process of developing policies.
- **Effective licensing and registration functions.** Interviewees rated regulatory actors and boards highly in the areas licensing and registration of medical commodities and devices, registration and licensing of health professionals, and regulation of training and training institutions.

Implementation Challenges

Interviewees noted the following challenges in implementing regulations:

- **Insufficient focus on supervision and monitoring of health facilities and professionals.** Interviewees noted that regulatory boards focus more on licensing and registration than on supervision and monitoring of the practice of health care. This has resulted in a proliferation of unregistered health businesses, including businesses that provide herbal remedies that are not properly regulated, unlicensed health facilities and health professionals, and health professionals who falsely claim higher levels of expertise and perform procedures and offer treatment that they are not licensed to provide. This has led to adverse outcomes at some health facilities that have been highlighted in the media.
- **Regulators who are reactive rather than proactive.** Interviewees said that regulators focus too much on urban areas and limit their activities to cities and towns, and that regulatory efforts increase as a reaction to media attention on medical incidents.
- **Insufficient financial and human resources.** Regulators have insufficient resources to fulfill their mandate, particularly in regard to monitoring and supervision. Some boards struggle to raise enough funds to undertake all of the activities in their mandate. Interviewees also indicated that the Ministry of Health does not have a provision for a direct budget line to support regulatory activities and relies on external sources to help it achieve its mandate.
- **Overlapping and conflicting mandates among regulatory boards.** Regulatory boards have conflicts and overlaps in their mandates, resulting in gray areas or gaps in regulation. Providers also have a double burden of registering with multiple regulatory agencies, which is costly and time-consuming.
- **Lack of an accreditation framework.** Interviewees noted the lack of an adequate accreditation framework and that current accreditation is used partially for private facilities only. They also noted that quality was not well recognized in accreditation frameworks. Further, accreditation and licensing requirements are not differentiated enough to allow innovative service delivery models within the private sector (for example, to provide niche services that are currently underprovided).
- **Barriers to private-sector investment and growth.** The multiplicity of regulators and the regulatory requirements increases the cost of starting up a health business. In addition, registration of facilities under the names of health professionals limits the scope of investors to health professionals or makes partnership with a health professional mandatory. This discourages the private sector from investing in health.

Suggestions for Improvement

Interviewees offered suggestions for strengthening regulatory implementation:

- **Harmonize existing regulations.** Interviewees identified a need to review existing regulations to address overlapping mandates and meet the decentralized service delivery at the county level. The Health Act seeks to improve coordination between the national government and county governments through biannual forums and spells out roles at each level. It also recommends establishing an institution— the Kenya Health Profession Authority—with oversight over all regulatory boards. However, subsidiary legislation will be required to address these issues in detail.
- **Increase resources for regulation.** All of the interviewees mentioned a need to increase financial and human resources for regulatory actors. Some also recommended increasing the presence of regulatory boards in non-urban areas through regional offices. This could also improve supervision and monitoring of health professionals and facilities across the country.
- **Develop an accreditation framework that rewards investments in quality improvement.** Interviewees called for a common accreditation framework to provide regulatory actors with standards for assessing both public and private health facilities; these would be linked to quality assessments and contracting requirements to ensure that facilities are rewarded for investments in improving quality. The framework would also allow for various provider models, not the limited classification of only four tiers of health facilities. Some interviewees suggested forming an accreditation authority whose sole mandate would be accreditation and quality assurance for both public and private health facilities.

CONCLUSIONS

Kenya has a well-articulated policy and regulatory framework that ensures alignment of policies with overall health sector goals. Private providers have defined processes for registering health facilities, norms for infrastructure and staffing, service guidelines for each level of care, and protocols to ensure quality. However, gaps remain. This assessment identified a number of strengths and weaknesses of existing regulations, as summarized in Table 6.

Table 6. Strengths and Weaknesses of Existing Regulations

Strengths	Weaknesses
• Regulations are designed to advance the goal of upholding the constitutional right to health in a responsive manner. • Reputable regulatory agencies have a well-defined mandate established by an act of Parliament. • Requirements and processes for registration and licensing of health professionals, health care training institutions, and health facilities are clear. • Licensing and registering of health professionals is well done.	• Regulations largely focus on command and control, and few regulations provide incentives to providers to improve their behavior. • Agencies have overlapping mandates, which increases the cost of doing business for private providers. • Regulations are focused on private providers, while public providers are automatically gazetted and registered, which creates an unequal regulatory environment. • Regulatory gaps include lack of regulation for accreditation of both public and private providers. • The performance monitoring and reporting framework for regulatory agencies is inadequate. • Enforcement of regulations in regard to quality assurance, supervision, and monitoring is lacking.

Policymakers need to sustain the gains made so far, such as by setting up a strong regulatory framework with a rights-based foundation, establishing institutions with clear mandates, and coordinating supervision of health facilities by regulatory actors to reduce duplication of resources.

Gaps that require additional attention include developing a performance monitoring and reporting system for regulatory agencies that includes targets monitored by the Ministry of Health and/or the Kenya Health Professions Oversight Authority. Kenya also needs an accreditation agency that can carry out the quality assurance, supervision, and monitoring responsibilities that are not currently well implemented by regulatory actors. The agency should provide the same regulatory environment for both public and private providers. There is a need to harmonize the mandates of regulatory boards to reduce overlaps and thereby reduce the regulatory and financial burden on private providers.

Finally, decentralization of health service delivery has necessitated review of legislation to support delivery of services at county level. The Health Act 2017 is a first step in reshaping health sector governance, but subsidiary legislation is required in areas such as regulation of health products, health workers, and health care financing. These will the responsibility of the Ministry of Health, whose main post-decentralization role is health policy development. Further recommendations are provided in Table 7.

Table 7. Recommendations for Improvement

Recommendation	Rationale	Impact on Private Health Sector	Priority Level
Provide a line in the MOH annual budget to support development of regulations and enforcement-related activities and improve performance monitoring	To avoid capture of regulation development by interest groups and to support enforcement. MOH and other regulatory agencies must have the resources to develop regulations that benefit the entire health sector. Performance benchmarks should be set for these agencies to improve accountability.	Private-sector providers will benefit from fairer and more objective regulations and enforcement.	1
Revise all legislation governing health regulators to ensure harmony and eliminate the overlaps	To revise outdated health-related regulations and laws and reduce overlaps and conflicts.	This will help eliminate barriers that stifle private-sector investment and growth.	2
Establish the Kenya Health Professions Oversight Authority, as provided for in the Health Act 2017.	To ensure smooth coordination among the nine regulatory boards. To eliminate duplication, conflict, and multiple registration fees.	Having one clear set of requirements, one licensing fee, and one inspection agency would reduce setup costs and requirements for private providers.	3

Recommendation	Rationale	Impact on Private Health Sector	Priority Level
Establish a Health Facility Accreditation Authority as an independent body to ensure fairness in health facility accreditation	To make it easier for purchasers to objectively determine service delivery standards at all levels of care, as well as fair reimbursement for each level of care.	This would ensure a fair environment and encourage improvement in the quality of health care delivered. This body would also help to weed out underqualified and/or dangerous health care providers.	4
Develop a health sector registration act to regulate registration of health provider institutions as enterprises, not as a private practices registered under the name of an individual health worker.	To change the practice of requiring health facilities owned by companies, faith-based organizations, or NGOs to register under the name of an individual doctor and register the pharmacy, laboratory, and radiology departments independently.	This would remove a barrier to private investment.	5
Develop an incentive system to encourage health providers to provide high-quality health services.	To institute reward systems for improvements in performance and quality of care.	A reward mechanism can be a powerful motivator for the private sector. Incentive systems could be initiated first as small-scale pilots.	6

The priority given to these recommendations may depend on available resources. For example, setting up new institutions to support accreditation and oversight functions may be a high priority, but the effort and resources required would be significant. Items that do not require as much structural change may thus move higher in the list of priorities.

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ANNEX

Table A-1. Summary of Regulations

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Command and control—legal requirements accompanied by sanctions for noncompliance					
Bill of Rights	The constitution states that all citizens have a right to the highest attainable standard of health care, a right to reproductive health, and a right to emergency treatment, and it calls for equality and freedom from discrimination.	• Public • MOH • County governments • Health care professionals • Health facilities	• To give Kenyans redress in the courts if their rights are not upheld • To prevent health professionals from denying treatment and/or discriminating by race, tribe, gender, age, sex, or social status	The constitution was promulgated August 2010 and came into effect immediately after.	The Constitution of Kenya 2010 (Government of Kenya 2010)

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Public Health Act	Provides for public and private provision of health care.	• MOH • County governments • Health care professionals • Health facilities	• To require municipal councils to provide adequate public facilities for their residents • To provide a management structure for public health services. • To require registration of private health facilities	The Act was passed in September 1921 and has had multiple revisions. See www.kenyalaw.org for details. The health sector, led by the MOH, is developing the Health Bill to replace the Public Health Act.	Public Health Act Chapter 242 of Laws of Kenya Revised Edition 2012 (1986)
Health laws	Define the structure of service delivery, health products, health financing, and human resource regulation.	• MOH • County government • Regulatory boards • Health care professionals • Health facilities	• Resulted from a review of the outdated Public Health Act to meet the needs of the decentralized system of government	Received presidential approval in May 2017 for immediate implementation, but subsidiary legislation has yet to be developed.	Health Act 2017

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
County health laws	Established the county health department of Marsabit. Defined county health services provided by both private and public providers.	• All public and private health facilities in the county • Health care professionals in the county	• To serve the health needs of all residents in Marsabit County. • To define county health management. • To define the rights and duties of health care workers in the county	Enacted 27 May 2015	Marsabit County Health Services Act, 2015
County health laws	Established the Machakos County HIV and AIDS Management Committee and the HIV and AIDS Units. Provides a framework for mobilizing resources for HIV and AIDS management.	• County health department • All public and private health facilities in the county • Health care professionals in the county	• To establish an efficient framework for managing HIV and AIDS and cooperation among agencies • To uphold the rights and freedoms of people living with HIV • To support resource mobilization for HIV	Enacted June 2015 for implementation by the county health department.	Machakos County HIV and AIDS Management Bill 2015

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Registration and licensing of health professionals, health facilities, and training institutions.	Law establishing the Kenya Medical Dentists and Practitioners Board (KMPDB). Law requiring registration and licensing of medical doctors and dentists, regulation of the medical and dentistry profession, registration and licensing of private health facilities, and registration of institutions training medical doctors and dentists.	• All medical doctors and dentists • Universities or other institutions in Kenya offering courses in medicine or dentistry • Health institutions	• To require registration and licensing of doctors and dentists • To regulate the practice of medicine and dentistry • To require supervision of medical and dental education • To require supervision of internship training • To enforce continuous professional development • To require inspection, registration, and licensing of health institutions. • To institute disciplinary measures for medical and dental malpractice	The Act was passesd in November 1977 and went into effect in January 1978. Subsequent amendments include: • Act No. 20 of 1977 • L.N. 308/1977 • Act No. 13 of 1978 • Act No. 19 of 1984 • Act No. 7 of 1990 • Act No. 11 of 1992 • Act No. 11 of 1993 • Act No. 9 of 2000 • Act No. 12 of 2012	Kenya Medical and Dentists Practitioners Act Chapter 253 of Laws of Kenya

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Registration and licensing of health professionals and training institutions.	• Law establishing the Nursing Council of Kenya (NCK). • Law requiring indexing, training, examination, registration, and licensing of all nursing professionals, registration of all training institutions, and regulation of the nursing profession.	• Nurses • Nurse training institutions	• To require indexing, registration, training, and licensing of nurses • To regulate nurses' conduct • To implement supervision of nursing education	The Act was passed in May 1983 and went into effect in June 1983. Subsequent amendments include: • Act No. 2 of 2002 • Act No. 27 of 2011 • Revised Edition 2012 [1985]	Nurses Act Chapter 257 of Laws of Kenya
Registration and licensing of health professionals and training institutions.	• Law establishing the Clinical Officers Council of Kenya. • Law requiring registration and licensing of clinical officers, registration of clinical officer training institutions, and regulation of their practice.	• Clinical officers • Clinical officer training institutions	• To require registration, training, and licensing of clinical officers • To regulate the practice of clinical officers and their conduct • To implement supervision of clinical officer education and internship training	The Act was passed in August 1988 and went into effect in July 1989. Subsequent amendments include: • LN 241/1989 • Act No. 9 of 1989 • Act No. 14 of 1990 • Revised Edition 2012 [1990]	Clinical Officers (Training, Registration and Licensing) Act, Chapter 260 of Laws of Kenya

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Registration and licensing of health professionals.	Law establishing the Counsellors and Psychologists Board and the Counsellors and Psychologists Society of Kenya. Law requiring registration and licensing of counsellors and psychologists and regulating their practice.	• Counsellors and psychologists	• To require registration, training, and licensing of counsellors and psychologists • To regulate the practice of counsellors and psychologists	The Act was passed in July 2014 and went into effect in August 2014. It has had no amendments.	The Counsellors and Psychologists Act No. 14 of 2014 of Laws of Kenya
Registration and licensing of health professionals, pharmacies, drugs, and training institutions.	Law establishing the Pharmacy and Poisons Board (PPB). Law requiring the registration and regulation of the practice of pharmacy, regulation of the training of pharmacy professionals, and registration of manufacturers, importers, distributors, and retailers of pharmaceutical commodities and drugs.	• Pharmacy personnel • Pharmaceutical manufacturers, importers, distributors, and retailers • Pharmacies	• To require registration of pharmacy personnel • To regulate training institutions for pharmacy personnel • To require registration of manufacturers, importers, distributors, and retailers of pharmaceutical commodities and drugs. • To implement drug surveillance • To require inspection of pharmacies and manufacturing plants • To require licensing of pharmacies • To require import and export licenses and regulate the pharmaceutical trade	The Act was passed in May 1956 and went into effect in May 1957. It has undergone revision: Revised Edition 2012 [1989]	Pharmacy and Poisons Act Chapter 244 of Laws of Kenya

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Registration and licensing of health professionals, laboratories, and training institutions.	Law establishing the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB). Law requiring registration and licensing of laboratory technicians and technologists, regulation of training institutions, regulation of the business and practice of laboratory diagnostic facilities.	• Medical lab technicians and technologists • Institutions that train lab technicians and technologists • Business practices of registered laboratory technicians and technologists	• To require registration of medical lab professionals • To require registration and examination of students in medical lab courses. • To require registration of medical lab training institutions • To regulate the design and review of medical lab training curricula. • To require inspection and registration of medical labs • To require validation of medical lab reagents, equipment, and in-vitro diagnostic devices	The Act was passed in January 2000 and went into effect in December 2000. The Act has undergone revision: Revision 2012 [1999]	Medical Laboratory Technicians and Technologists Act, chapter 253A of Laws of Kenya
Registration and licensing of health professionals and training institutions.	Law establishing the Kenya Nutritionists and Dieticians Institute (KNDI). Law requiring registration and licensing of nutritionists and dieticians and requiring approval of institutions that train nutritionists and dieticians.	• Nutritionists and dieticians	• To require registration and licensing of nutritionists and dieticians • To require approval of institutions that train nutritionists and dieticians • To regulate the standards and practice of the profession	The Act was approved in October 2007 and went into effect in October 2008. The Act has had the following amendments: • LN 130/2008 • Revised Edition 2012 [2007]	Nutritionists and Dieticians Act No. 18 of 2007 (Chapter 253B) of Laws of Kenya

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Registration and licensing of health professionals and radiology diagnostic services.	Law establishing the Radiation Protection Board (RPB). Law provides for the protection of the public and radiation workers from dangers arising from the use of devices or materials capable of producing ionizing radiation. The law requires registration and licensing of radiology professionals; regulation of irradiating devices and radioactive materials; regulation of the importation and manufacture of irradiative devices; and proper disposal of radioactive waste.	• Radiology professionals • Owners and premises with irradiating devices, radioactive materials, or other sources of ionizing radiation	• To maintain a registry of owners of irradiating devices, radioactive materials, and other sources of ionizing radiation imported into or manufactured in Kenya. • To require inspection, registration, and licensing of medical radiology services • To require registration of premises licensed to dispose of radioactive waste	The Act was passed in December 1982 and went into effect in November 1984. The Act has had the following amendments: • Act No. 20 of 1982 • L.N. 171/1984 • Act No. 19 of 2014	Radiation Protection Act Chapter 243 of Laws of Kenya

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Registration and licensing of health professionals and training institutions.	Law establishing the Public Health Officers and Technicians Council. Law calls for training, registration, and licensing of public health officers and public health technicians, regulates their practice, and governs the establishment, powers, and functions of the Public Health Officers and Technicians Council.	• Public health officers and public health technicians • Training institutions for public health officers and technicians	• To require registration and licensing of public health officers and public health technicians. • To require accreditation of institutions that train public health officers and public health technicians. • To regulate the conduct of public health officers and public health technicians	The Act was passed in January 2013 and is to commence by notice. The Act has not undergone any revisions.	Public Health Officers (Training, Registration, and Licensing) Act No. 12 Chapter No. 12 2013 of Laws of Kenya
Fee schedule	Subsidiary legislation that provides a fee schedule for services provided by doctors and dentists.	• Doctors • Dentists • Health facilities	• To set fees for outpatient, inpatient, lab, imaging, and ultrasound diagnostic services • To establish that noncompliance is deemed an act of professional misconduct punishable by the board	The legislation was passed in July 2016.	Legal Notice 131 The Medical Practitioners and Dentists (Professional Fees) Rules, 2016.

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Kenya Quality Model for Health	Quality standards for all health facilities	• Health facilities	• To establish a checklist for inspection of health facilities by accreditation and supervisory agents.	Standards were disseminated in 2009 for use by regulatory actors and institutions.	Kenya Quality Model for Health: Quality Standards for Kenya Essential Package for Health Level 2–6
Guidelines for advertisement and promotion of medicines and medical devices	Guidelines to regularize advertisements, promotional material, and information on medicines available in Kenya and to articulate ethical criteria for medicinal drug promotion in order to support and encourage the improvement of pharmaceutical care and promote rational use of medicines.	• Pharmaceutical and medical device manufacturers • Pharmaceutical and medical device wholesalers	• To ensure that information communicated to health professionals and the general public is accurate and current • To provide a mechanism for complaints and penalties for noncompliance in line with the Pharmacy and Poisons Act.	First edition published and implemented in April 2012. There have been no revisions.	Guidelines for Advertisement and Promotion of Medicines and Medical Devices in Kenya (Government of Kenya 2012)

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Regulatory agency code of conduct	Code of conduct for doctors, dentists, and health facilities developed by the KMPDB.	• Doctors • Dentists • Health faclities	• To require registration and licensing with the KMPDB • To define types of conduct that raise disciplinary issues • To establish a process for registering complaints and initiating disciplinary proceedings • To define professional ethics and ethical conduct that must be upheld by registered practitioners and health facilities	Sixth edition of the code of conduct. Effective 27 January, 2012.	The Code of Professional Conduct and Discipline–6th Edition (Government of Kenya 2012)
Continuing professional development (CPD) guidelines	Guidelines developed by regulatory boards for awarding CPD points.	The following health care professionals have published CPD guidelines: • Doctors • Dentists • Nurses • Nutritionists and dieticians • Public health officers and technicians	• To establish the number of hours of CPD required for relicensing. • To ensure that health professionals keep abreast with new developments in health care	Guidelines published and implemented between 2012 and 2014.	See footnote.[14]

[14] Continuing Professional Development Framework for Nurses in Kenya (Government of Kenya 2012); Guidelines for Implementation of Continuing Professional Development for Pharmacy Practitioners (Government of Kenya 2013); Medical and Dentists Practitioners Board Continuing Professional Development

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Treatment guidelines	Treatment protocols set by the MOH or its departments.	• Health professionals • Health facilities	• To provide protocols for treatment of various medical conditions in order to improve treatment outcomes, promote patient safety, promote rational drug use, and control drug resistance	Guidelines are disseminated to clinicians for implementation.	See footnote.[15]
Prescription list	Kenya Essential Medicines List (KEML) is published in conjunction with the clinical and referral guidelines and supports the provision of the Kenya Essential Package for Health.	• Health professionals • Health facilities • MOH • County health management teams	• To provide a basis for stocking medical commodities at health facilities • To help guide planning by health management teams • To guide the prescribing habits of clinicians	Published in 2010 and disseminated for implementation.	Kenya Essential Medicines List (Government of Kenya 2010)

Guidelines (Government of Kenya 2015); Continuing Professional Development Guidelines for Nutritionists and Dieticians in Kenya (Government of Kenya 2014); Continuing Professional Development Guidelines (Government of Kenya 2015)

[15] Clinical Guidelines for Management and Referral of Common Conditions at Levels 2-3: Primary care (Government of Kenya 2009); National Clinical Guidelines for Management of Diabetes Mellitus (Government of Kenya 2010); Guidelines for Management of Tuberculosis and Leprosy in Kenya (Government of Kenya 2013); National Guidelines for Essential Newborn Care (Government of Kenya 2015); Basic pediatric protocols for ages up to five years (Government of Kenya 2016)

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Human resource staffing norms and standards	Staffing requirements at each level of health care service delivery.	• Health facilities • County health management teams	• To set staffing requirements based on need, population ratios, and fixed staff requirements for each level of care, in line with the Kenya Health Strategic and Investment plan 2014–2018.	Implementation is ongoing.	Human Resources for Health Norms and Standards Guidelines for the health sector
Incentives (financial)—actors change their behavior in response to financial rewards or penalties					
Accreditation linked to insurance rebate	Law to establish NHIF, provide for contributions to and payments from the fund, and establish the NHIF Management Board.	• Public and private accredited health facilities	• To provide health insurance to all contributing members and their declared dependents • To require accreditation of facilities in the NHIF provider panel • To require publication of accredited providers in the gazette.	The Act was passed in December 1998 and went into effect in February 1999. It has had the following amendments: • Act No. 9 of 1998 • L.N. 23/1999 • Act No. 18 of 2014	National Hospital Insurance Fund Act Chapter No. 9 of 1998 Laws of Kenya
Contracts for service delivery	NHIF contracts with private providers to provide services to members.	• Private health facilities	• To stipulate services, diagnostic procedures, and pharmaceutical commodities to make available to members.	Contracts are updated when new services are added to the benefit package.	NHIF contracts for private facilities

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
NHIF rebates	NHIF publishes reviewed rebates to health providers in gazette notices and national newspapers.	• Public and private accredited health facilities	• To publish new and reviewed rebates to health facilities for benefits provided to NHIF members	Done periodically as rates are reviewed.	NHIF gazette and newspaper notices
Performance-based financing	Implementing performance-based financing to encourage meeting maternal, neonatal, and child health targets.	• Health professionals • Public health facilities	• To improve health outcomes through direct financial incentives to health professionals	Currently being implemented as a World Bank project in 20 counties.	World Bank (World Bank 2014)
Replacing lost revenue from user fees	The Health Sector Services Fund (HSSF) recognizes public dispensaries and health centers as autonomous financial units, allowing them to receive funds to replace lost user fee revenue after the 10/20 policy that reduced user fees at dispensaries to KES 10 and at health centers to KES 20.	• Public health facilities • District health management teams • MOH	• To empower communities to take charge of health facility improvements through participation in health facility management committees • To decentralize management, increase autonomy, and support capacity building in health facilities • To replace lost user fee revenue after implementation of the 10/20 policy • To improve the quality of services delivered at health facilities	Implementation began in October 2010. After decentralization, HSSF funds were consolidated with block grants to counties; the funds are managed at the county level.	Legal Notice No. 9 of 5 June 2009

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Incentives (nonfinancial)—actors change their behavior in response to nonfinancial rewards or penalties					
Patient Charter	A charter that defines patients' rights and responsibilities and options for dispute resolution.	• The public • Health professionals • Health facilities	• To ensure patients' rights and responsibilities and to provide options for dispute resolution • To allow patients to seek redress in court, as provided by the Public Health Act and regulatory boards' acts	Published in October 2013.	The Kenya National Patients' Rights Charter 2013 1st Edition (Government of Kenya 2013)
Joint Health Inspections Checklist (JHIC)	A checklist developed collaboratively by the MOH, regulatory agencies, and the private sector for inspection of health facilities before registration.	• Health facilities • MOH • Regulatory agencies	• To harmonize inspection tools used by various regulatory agencies in order to reduce duplication and inefficiencies	The checklist is in use by the MOH and regulatory agencies.	Joint Health Inspections Checklist (Government of Kenya 2014)
SafeCare accreditation	SafeCare is an internationally recognized program to improve the quality of care in resource-poor settings.	• Health facilities	• To assess facilities and assign scores and identify areas for improvement. Facilities can make improvements and be reevaluated to achieve a higher score.	Implementation is ongoing. SafeCare is working with NHIF to link SafeCare scoring to rebates.	SafeCare Basic Health Standards (PharmAccess 2017)

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Joint Commission International (JCI) accreditation	JCI identifies, measures, and shares best practices in quality and patient safety internationally. JCI accreditation is considered the gold standard of quality health care.	• Health facilities	• To draw patients to high-quality health facilities and thereby help them increase their revenue	Ongoing; individual health facilities apply for accreditation.	Joint Commission International (Joint commission International 2017)
Self-regulation—provider and professional groups set their own standards of member behavior					
Code of Practice for the Kenya Pharmaceutical and Medical Devices Industry	A code of practice that is intended to limit the promotion of medicinal products and technologies and limit industry interactions with health professionals in a way that is detrimental to fair competition. The code aims to foster an environment in which the public can be confident that choices regarding their treatment are made in their best interest and are not influenced by interactions between pharmaceutical companies and health professionals.	• Local and multinational pharmaceutical companies • Medical device companies	• To ensure that member companies promote their products and interact with health professionals in a truthful manner, avoiding deceptive practices and potential conflicts of interest and in compliance with applicable laws and regulations • To ban members from providing financial or other inducements to health professionals to influence patient prescriptions • To impose penalties for noncompliance	First edition published in March 2016 and implemented in May 2016	Code of Practice for the Kenya Association of Pharmaceutical and Medical Devices Industry (Kenya Association of Pharmaceutical Industry 2017)

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Code of Conduct for Dentists	A code that sets benchmarks for assessing the professional conduct of Kenyan dentists and defines their ethical and moral rights and responsibilities.	• Dentists who are members of the Kenya Dentists Association	• To establish principles that dentists should follow • To define a code of conduct for members to follow • To defines the penalties for breach of the code of conduct.	Published in 2012 and in use by members.	Kenya Dental Principles of Ethics and Code of Professional Conduct (Kenya Dental Association 2012)
Code of Conduct and Ethics for Nurses	A code that sets standards of operational behavior and practice	• Members of the National Nurses Association of Kenya	• To set guiding principles for the nursing profession • To establish disciplinary actions for noncompliance	Launched in July 2009.	National Nurses of Kenya Code of Conduct and Ethics (National Nurses Association of Kenya 2009)
Code of Conduct and Ethics for Physiotherapists	A code that sets standards for physiotherapy practice	• Members of the Kenya Society of Physiotherapists	• To define the conduct expected of members and their rights and obligations • To define enforcement of the standards and the penalties for noncompliance	Launched in July 2009.	Kenya Society of Physiotherapists Code of Conduct and Ethics (Kenya Society of Physiotherapists 2009)

Mechanism	Instrument(s)	Target(s)	Rationale	Implementation Status	Source(s)
Code of Conduct and Ethics for Radiographers	A code that sets standards for radiography practice	Members of the Society of Radiography in Kenya	• To define a code of conduct and professional ethics • To define enforcement of the code and the penalties for noncompliance	Launched in April 2012.	Society of Radiography in Kenya Code of Conduct and Ethics (Society of Radiography in Kenya 2012)

Table A-2. Roles of Regulatory Actors

Regulatory Actor(s)	Regulatory Role		Interaction with Other Actors (Collaborations or Conflicts)
	Development	Implementation	
National Government			
National Assembly Parliamentary Committee for Health	Develop legislation for the health sector. Ensure public participation in development of health legislation.	Investigate underperformance, misconduct, and fraud at the MOH and NHIF.	Collaborate with the MOH, regulatory boards and councils, civil society organizations, county health departments, professional associations, the Council of Governors, Office of the Attorney General, and legislators in national and county parliaments and the Senate.
Senate Parliamentary Committee for Health	Develop county-specific legislation for the health sector. Ensure public participation in development of health legislation. Determine allocation of national revenue to counties.	Investigate underperformance, misconduct, and fraud related to the health sector at the county level.	Collaborate with the MOH, regulatory boards and councils, civil society organizations, county health departments, professional associations, the Council of Governors, Office of the Attorney General, and legislators in national and county parliaments and the Senate.

Regulatory Actor(s)	Regulatory Role		Interaction with Other Actors (Collaborations or Conflicts)
	Development	Implementation	
MOH, Department of Health Standards, Quality Assurance, and Regulations (through the Division of Legislation and Regulation)	Provide leadership and coordinate the development and review of health-related legislation and regulations. Provide leadership and coordination of pre-service and in-service training standards and continuing professional development (CPD) for the health sector. Represented on all health care professional regulatory boards and the NHIF Board.	Monitor the implementation of continuing professional development programs in collaboration with the boards and councils. Coordinate joint inspection of health institutions with relevant regulatory bodies.	Collaborate with regulatory boards and Councils, civil society organizations, county health departments, professional associations, the Council of Governors, Office of the Attorney General, and legislators in national and county parliaments and the Senate.
National Hospital Insurance Fund (NHIF)	Participates in health care financing policy development. Participates in working groups on quality and accreditation of health facilities. Sets rebates to be paid to the provider panel and regularly reviews them.	Categorizes, accredits, and gazettes health facilities for the purpose of setting rebates through the NHIF Act.	Collaborates with regulatory boards and councils, civil society organizations, county health departments, professional associations, and legislators in national and county parliaments and the Senate. NHIF does not have a regulator; the MOH provides oversight.

Regulatory Actor(s)	Regulatory Role		Interaction with Other Actors (Collaborations or Conflicts)
	Development	Implementation	
Regulatory boards: • KMPDB • NCK • PPB • RPB • KMLTTB • KNDI	Develop standards for clinical practice and training. Develop standards for health care and diagnostic facilities. Set codes of conduct and practice. Set continuing professional development guidelines. See Table A-1 for details.	Inspect health care and diagnostic facilities. License and register health professionals and facilities. Register training institutions and students and oversee examinations.	Collaborate with other regulatory boards and councils, MOH, county health departments, professional associations, the public, and legislators in national and county parliaments and the Senate. Oversight roles of regulatory boards overlap. For example, KMPDB registers and oversees health institutions, and the Radiation, Pharmacy, and Laboratory Boards have oversight over units within the health facilities.
County health departments	Implement health system activities (and/or policy and financing as needed) within the decentralized system.	Oversee management and administration of primary and secondary health care service delivery at the county level. Inspect health facilities.	Collaborate with the governor, county executive for health, MOH, and the public.
Accreditation Organizations			
Accreditation organizations	Attend MOH-led stakeholder meetings to give feedback on accreditation and development of quality frameworks.	Implement approved accreditation and quality assurance models.	Collaborate with the MOH, county health departments, and health facilities.

Regulatory Actor(s)	Regulatory Role		Interaction with Other Actors (Collaborations or Conflicts)
	Development	Implementation	
Professional Organizations			
Kenya Medical Association National Nurses Association of Kenya Kenya Association of Pharmaceutical Industry Society of Radiography in Kenya Society of Counsellors and Psychologists	Attend MOH-led stakeholder meetings to give feedback on development of regulations. Represented on health care professional regulatory boards. Set codes of conduct and ethics for professionals.	Provide feedback to members on changes in regulations.	Collaborate with the MOH and NHIF. Some organizations may not have the capacity to ensure their representation on all policy development forums because they do not have fully staffed secretariats and rely on member volunteers at the forums.
Consumers / Civil Society Organizations			
Consumers / civil society organizations	The public is invited to give input on health-related legislation before the National Assembly and Senate. Union representatives represent their constituents on the NHIF Board. Consumer groups are represented in policy development (e.g., development of the Patients' Rights Charter).	Consumers can seek redress in court for lack of access to the highest standard of health care, reproductive health, and emergency treatment.	Collaborate with the National Assembly, Senate, MOH, regulatory boards, NHIF, and the judiciary. Consumer protection groups in health are not well developed to ensure adequate representation at health policy forums.

Table A-3. Resources for Regulation

Regulatory Actor	Technical and Support Staff	Budget[16]	Other Resources
National Government			
Department of Health Standards, Quality Assurance and Regulations	24 technical staff 10 support staff	No specific line item for regulation. Departmental budget supports staff salaries and other operational expenses under the larger MOH budget. Expenditure in fiscal year 2016–2017: KES 5,900,000,000 US$57,843,137 (Government of Kenya 2017)	Grants from donors such as the World Bank. State counsel seconded from the attorney general's office.
Regulatory Boards			
Kenya Medical Practitioners and Dentists Board	7 senior managers	KES 160,006,104 US$1,640,365 (Government of Kenya 2016)	No other income and no government grants.
Nursing Council of Kenya	7 senior managers 33 technical staff 5 support staff	KES 111,635,531 US$1,144,475 (Government of Kenya 2016)	Government grant: KES 11,850,780 US$121,493

[16] Average exchange rate (Central Bank of Kenya 2017): July 1, 2014, to June 30, 2015: US$1 = KES 97.543; July 1, 2013 to June 30, 2014: US$1 = KES 85.131; January 1, 2016, to December 31, 2016: US$1 = KES 102.09

Regulatory Actor	Technical and Support Staff	Budget[16]	Other Resources
Pharmacy and Poisons Board	6 senior managers	KES 813,690,371 US$8,341,863 (Government of Kenya 2016)	No other income and no government grants.
Kenya Medical Laboratory Technicians and Technologists Board		KES 62,929,259 US$739,205 (Government of Kenya 2015)	No other income and no government grants.
Kenya Nutritionists and Dieticians Institute		KES 31,431,705 US$322,234 (Kenya Nutritionists and Dieticians Institute 2016)	No other income and no government grants.
Professional Organizations			
Society of Radiography in Kenya		KES 4,745,370 US$46,482 (Society of Radiographers in Kenya 2017)	No other income and no government grants.

Table A-44. Implementation and Performance of Regulatory Activities

Stakeholder	Are Regulators Fulfilling Their Mandate in Regard to PHC?	Implementation and Performance Strengths	Implementation and Performance Weaknesses	Suggested Changes
Regulators: Division of Legislation and Regulation under the Department of Health Standards, Quality Assurance and Regulation	Neutral	The department is generally able to coordinate meetings and draft and review regulations. Regulators conduct joint inspections to root out illegal providers. The regulation provides acceptable guidance on the education, training, registration, and practice of health delivery in Kenya.	Inadequate capacity and resources to enforce regulations due to shortage in staff, especially on the legal team, and lack of a dedicated line item in the budget delays implementation activities. Local political interference affects closure of illegal providers. The court delays concluding matters on providers who are taken to court. Lack of pricing guidelines for consultations, treatment procedures, and medicines. Lack of regulations that standardize medical records management and storage.	Provision a direct budget line item in the MOH annual budget to support development of regulations and enforcement activities. Add staff, especially legal officers. Fast-track judicial conclusion of health-related matters.

Regulatory boards: Clinical Officers Council of Kenya, Nursing Council of Kenya, Pharmacy and Poisons Board	Neutral	The regulatory boards are empowered by law to collect fees and impose penalties to advance the regulation of their professionals. The law provides for registration of medical commodities and registration and inspection of all providers of medical commodities (manufacturers, distributors, and retailers). The regulatory boards do the following well: • Inspect and approve training at colleges and universities • Index and/or register students • Regulate development of training curricula and exams • License and register health workers	Lack of pricing guidelines for consultations, treatment procedures, and medicines. Lack of regulations that standardize medical records management and storage. Lack of a funded authority to coordinate the nine health regulatory boards. Lack of a clear accreditation framework or nomenclature to rate the quality of services delivered by health providers, monitor health facility operations routinely, and offer a more reliable method to deal with noncompliant facilities. Local political interference in the inspection and closure of noncompliant health facilities. Weak enforcement of regulations because the boards rely on the KMPDB to close noncompliant facilities.. 7. Not enough resources to conduct regular intensive inspection to ensure compliance. 8. Overlapping mandates between regulatory boards. 9. Delays in concluding cases in the courts. 10. Frequent blanket circulars from the MOH that affect planned activities, such as: • Freeze on employment. • Freeze on procurement of vehicles, laptops or even construction. • Key staff transfers. 11. Lack of differentiated service delivery standards for various levels of care (stand-alone clinics, PHC, or hospitals)	Establish the Kenya Health Profession Authority, as called for in the Health Act 2017, to coordinate regulatory boards. Implement the Health Facility Accreditation Framework of 2017. Establish a Health Facility Accreditation Authority as an independent body to ensure fairness in health facility accreditation. Revise all health regulatory acts to ensure harmony and eliminate overlaps that lead to conflicts. Provide more resources to the regulatory boards to ensure routine supervision and enforcement of the regulations in all parts of the country. 6. Provision for a budget line in the MOH annual budget to support establishment of county-based enforcement offices and additional staff for county offices.
Regulatory targets:	Disagree	Current regulations are a good starting point for	Multiplicity of regulators and fragmented requirements	Harmonize and more effectively coordinate the various regulators.

Stakeholder	Are Regulators Fulfilling Their Mandate in Regard to PHC?	Implementation and Performance Strengths	Implementation and Performance Weaknesses	Suggested Changes
Faith-based provider association and doctor's union		bringing order and setting standards for health care. The Kenyan constitution strongly supports the right of citizens to receive quality health care The Health Act 2017 improves health regulation in Kenya. The country has strong health regulators at the national level.	Inadequate capacity/resources to enforce regulations. Ineffective coordination of health sector regulatory boards. Lack of differentiated standards for various levels of care (standalone clinics, PHC, or hospitals) Current regulations require registration of a health facility under the name of a health worker, ignoring the owners / management team, who may not be clinicians. Regulators are regulating health workers but not the health practices or the industry. Lack of a clear strategy that recognizes the role of the private sector, and provides for responsibilities and obligations. Partisan enforcement of the standards and regulation favoring the public sector.	Consider developing different health standards for various levels of health facilities (for example, major labs in hospitals and smaller labs in dispensaries). Update health regulations to allow lower-level facilities to use available technologies to offer care that is currently only permitted in hospitals. Update regulations to enable health institutions to be registered as institutions in their own right and not under the name of an individual health worker, and then employ duly registered professionals to deliver care. Separate the ownership of health facilities from the regulator in the public sector; both regulators and managers of health facilities currently report to the MOH. MOH needs to define a clear health financing strategy to ensure all Kenyans have access to their constitutional right to a basic package of care. MOH needs to establish an organization/authority to accredit health facilities and ensure consistent improvement of quality health services.

Stakeholder	Are Regulators Fulfilling Their Mandate in Regard to PHC?	Implementation and Performance Strengths	Implementation and Performance Weaknesses	Suggested Changes
Academics: Local university professor	Strongly disagree	The presence of several generally strong health sector regulators is a major strength in implementing the various health-related acts and protecting patients. Government support for regulators is a strength because it helps manage the commercial interests of the private sector.	Outdated laws and regulations. Ad hoc and reactive amendments that are not informed by evidence Inadequate capacity of the regulators to implement their mandate fully (inadequate skills and numbers of staff). The private sector generally does not build human resources capacity as required. Current regulatory requirements are not sensitive enough to detect poorly updated health staff and force them to obtain the necessary training.	Commission a nationwide study to identify existing health regulation gaps and then update the various regulations to align them and eliminate overlaps and gaps. Enact regulations that require qualified health staff to take examinable capacity building activity or training. Consider expanding the capacity (skill mix, staffing numbers, and funding) to enable them to effectively discharge their mandate funded by the Government and partners.
Media: Health television journalist	Neutral	Most health professions are regulated by their own regulatory board or council. The regulatory boards are empowered by law to regulate the entire scope of the health profession, from training and licensing to health care delivery practice. Regulation of health professional training and licensing is well done.	Regulation of the quality of care delivered is a major gap. Inspection of health care providers is ad hoc and limited to reports of malpractice. Regulators and health providers withhold information from the media, forcing the media to publish incorrect information based on rumors. Regulators do not engage the media to help disseminate information that would be useful to the public and empower then to demand better care and report malpractice in a timely manner.	To be pro-consumer, regulators should include a consumer representative in health facility inspections. Conduct regular facility inspections and ensure strict compliance with regulations. Improve free flow of information to the media. Government and partners should provide additional resources to regulators to ensure enforcement of health regulations.