

REPUBLIC OF KENYA



MINISTRY OF HEALTH

Quality of Care Certification Framework for the Kenyan Health Sector

MARCH 2020



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Framework for the
Kenyan Health Sector**

FOREWORD

The Government of Kenya is fully committed in ensuring that right of every person to the highest standard of health is upheld in line with the Constitution of Kenya 2010. In this regard, this Quality of Care Certification Framework for the Kenya Health Sector has been developed to guide the Sector in shaping the modalities for monitoring the quality of inputs, processes and outcomes of health services delivery in order to ensure that they are of high standard, safe, acceptable and provide positive experiences for both providers and users.

The Framework will guide the establishment of a collective quality assurance platform for all service providers in the light of Universal Health Coverage thus creating a level playing ground to facilitate strategic purchasing of health services from different providers and to act as comparative frame for users in decision making while accessing services.

The Framework has leveraged on the synergies created by mandates and strengths of different players to define a division of labour that focuses on three key components namely; Licensure by the Regulatory Authorities, Certification by Conformity Assessment Bodies, and Accreditation by the Kenya Accreditation Services; with strategic purchasing function expected to create incentives for quality standards compliance for counties and service providers.

It is my hope that all the relevant stakeholders and key players in the certification and accreditation process will join hands in the entrenchment of this Certification Framework in a bid to advance patient safety and high quality service delivery in order to derive the desired health outcomes.



Hon. Mutahi Kagwe, EGH

Cabinet Secretary of Health

EXECUTIVE SUMMARY

This certification framework outlines clearly the background in which the document was developed and includes consideration for the anchorage in the health act 2017 and health related laws, the constitution of Kenya 2010 and the health policy.

The framework provides the rationale for its development and relating it to the greater need for delivering High Quality Universal Health Coverage (UHC),

The framework explains the current situation where there are challenges in carrying out smooth licensure, registration and gazettelement. It further outlines the use of both the Kenya Quality Model for Health (KQMH) and the joint health inspection checklist for the purpose of supporting the certification and accreditation process.

The stakeholder analysis was done and it includes the national and county governments, private sector and faith based organizations. The framework considered all players in the regulation field, assessment area and the professional bodies.

The framework has a proposed structure detailing the processes of licensure, registration and gazettment, certification and accreditation and includes the roles of different players in the certification process.

The framework has an implementation plan to guide its implementation. The implementation plan for the certification framework highlights the identification of pilot counties, training of quality improvement mentors and peer assessors, training on KQMH standards compliance and assessments.



Susan N. Mochache, CBS

Principal Secretary for Health

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We wish to extend our heartfelt thanks to the smaller team that painstakingly refined the document through triangulation of views from various stakeholders. These included Dr Maurice Wakwabubi (MoH), Dr Charles Kandie (MoH), Dr Aisha Mohamed (MoH) and Dr Jared Nyakiba (MoH), Frank Wafula (IFC/World Bank), Susan Munyiri (KENAS), Doris Mueni (KENAS), Dr Joyce Lavussa (WHO), Mary Nyachae (NHIF), Faith Muigai (PharmAccess), Dr Elizabeth Wala (Amref Health Africa), Walter Kibet (Amref Health Africa), Irene Omogi (GIZ), and Dr Daniel Kiura (Mater Hospital). Our appreciation also goes to World Bank that provided technical assistance through a consultant Dr Salome Ngata and financial support to various activities.



Dr. Patrick O. Amoth

Ag. Director General for Health

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LIST OF ACRONYMS

AFRAC	African Accreditation Corporation
AMREF	Africa Medical and Research Foundation
CABs	Conformity Assessment Bodies
COHSASA	Council for Health Service Accreditation of Southern Africa
CPD	Continuous Professional Development
DHSQAR	Directorate of Standards and Quality Assurance and Regulations
EAAB	East African Accreditation Board
EFQM	European Foundation for Quality Management
FSMS	Food Safety Management Systems
IAF	Inter-Accreditation Forum
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
ISO/IEC	International Organization for Standardization/ International Electro-technical Commission
ISQua	International Society for Quality in Health Care
JCI	Joint Commission International
JHIC	Joint Health Inspection Checklists
KAMMP	Kenya Association of Muslim Medical Professionals
KEBS	Kenya Bureau of Standards
KENAS	Kenya Accreditation Service
KEPH	Kenya Essential Package of Health
KePSIE	Kenya Patient Safety Impact Evaluation
KHP	Kenya Health Policy
KHPOA	Kenya Health Professions Oversight Authority
KHSSP	Kenya Health Sector Strategic Plan
KMLTTB	Kenya Medical Laboratory Technician and Technologists Board
KMPDB	Kenya Medical Practitioners & Dentists Board
KQMH	Kenya Quality Model of Health

KQMH	Kenya Quality Model for Health
MoH	Ministry of Health
NHIF	National Hospital Insurance Fund
NHIF	National Hospital Insurance Fund
QMS	Quality Management Systems
UHC	Universal Health Care
WHO	World Health Organization

DEFINITION OF TERMS

Licensure¹	Process by which a governmental authority grants time-limited permission to an individual practitioner or health care organization to operate or to engage in an occupation or profession related to health care delivery. The organization or individual meets minimum standards to protect public health and safety. Licensure to individuals is usually granted after some form of examination or proof of education and may be renewed periodically through the payment of a fee and/or proof of continuing education or professional competence. Organizational licensure is granted following an on-site inspection to determine if minimum health and safety standards have been met.
Registration	<p>For individuals: The recognition of successful completion of mandated requirements for the practice of a particular profession. Once a health professional has been registered, they can then be licensed to practice as either full time or part-time private practice.</p> <p>For institutions: The health facility has met all the infrastructural, technical and medical approvals with duly licensed and or retained practitioners deemed necessary by the Regulatory Authority to provide the relevant health service(s).</p>
Gazettement	Formal notification by the national government of the existence of a health facility and published by the Kenya Government Press
Certification²	Formal notification by the national government of the existence of a health facility and published by the Kenya Government Press
Accreditation³	Third-party attestation that fulfilment of specified requirements have been demonstrated related to products, processes, systems or persons. Therefore Certification is defined as the compliance with a standard or specification for a system or product.
Inspection	Third-party attestation that a conformity assessment body has demonstrated competence to carry out specific conformity assessment tasks. Accreditation is the recognition of specific competence of an organization normally based on a highly specific scope that evaluates people, skills, and knowledge.
Regulatory Body	A regulatory body is a public authority or government agency responsible for exercising autonomous authority over some area of human activity in a regulatory or supervisory capacity. An independent regulatory agency is a regulatory agency that is independent from other branches or arms of the government. Regulatory bodies usually enforce safety and standards and are responsible for protecting consumers

¹Licensure, Accreditation, and Certification: Approaches to Health Services Quality: Rooney A, Ostenberg P, (1999)

²ISO/IEC 17000:2004. Conformity assessment - Vocabulary and general principles

³ISO/IEC 17000:2004. Conformity assessment - Vocabulary and general principles

Conformity Assessment Activity	Activity conducted by a conformity assessment body to assess compliance. These may include but are not limited to testing, calibration, inspection, certification, proficiency testing, validation and verification
Conformity Assessment Body	An accredited body that performs conformity assessment activities and seeks to demonstrate that specified requirements relating to a product, process, system, person or body are fulfilled
Certification Body	An accredited body that offers a third-party attestation of compliance with standards related to products, processes, systems, or persons
Accreditation Body	<p>An organization that issues credentials to third parties to attest competence to conduct specific conformity assessment tasks. Some accreditation bodies have specific capabilities, such as accreditation of the competence of laboratories, or for accreditation of certification bodies. Accreditation bodies are often appointed by national governments and hold an important position in the conformity assessment hierarchy. They provide confidence in the impartiality and competence of conformity assessment bodies. The criteria for accreditation bodies are specified in ISO/IEC 17011:2004.</p> <p>As accreditation bodies are at the top of the confidence pyramid, there is no higher-level body to assess their conformity with the requirements. Instead, accreditation bodies from different countries have formed multi-lateral agreements through which they carry out peer assessments on each other</p>

CHAPTER 1: INTRODUCTION: QUALITY OF CARE CERTIFICATION FRAMEWORK

1.1. Background

The Quality of Care Certification Framework is premised on the Constitution of Kenya 2010 which enshrines the right of every person to the highest standard of health which includes access to the provision of promotive, preventive, curative, palliative and rehabilitative services. It obligates the State to observe, respect, protect, promote and fulfil this right to the highest attainable standard by ensuring that policies, laws and other measures necessary to protect, promote, improve and maintain the health and well-being of every person are developed and operationalized. The country's long-term development agenda Vision 2030 and the Kenya Health Policy (2014–2030) have also underscored the health sector's commitment to ensuring that the country attains the highest possible standards of health, in a manner responsive to the needs of the population in compliance with the constitution and global commitments.

1.2. Constitutional Commitments to Quality of Health Care in the Light of Devolution

According to Article 46 of the Constitution, consumers have the right to protection of their health, safety, and economic interests. In this regard Article 189-191 of the Constitution obligates cooperation between National and County Governments for the purpose of enhancing the performance of respective functions in coordinating policies, exchanging information and improving capacity. As such the National level shall define Health Policy, facilitate capacity building and provide technical assistance to Counties, while the Counties are responsible service provision at health facilities, promotion of primary healthcare; licensing and staffing within the framework of the Norms and Standards set by the National government in accordance with the relevant legislation and policies.

1.3. Kenya Health Policy

In the Ministry of Health's endeavour to ensure the highest standard of health for the population, the Kenya Health Policy (2014–2030) commits to:

- Develop a Quality Management Policy to act as a guide for quality management implementation and coordination
- Establish a framework for the health sector through a recognized legal body to provide certification to health provider institutions in compliance with standards of health care
- Establish mechanisms for a regular review of standards of care
- Ensure that clients/patients have a positive experiences during the utilization of health and related services
- Ensure the provision of health services in the most effective way and in a manner that ensures patient/client safety.

1.4. Universal Health Coverage

Universal Health Coverage (UHC) is one of the Country's Big Four Agenda towards socio-economic development in the country. UHC is based on the principle that all individuals and communities should have equitable access to quality essential health services without suffering financial hardship. UHC calls for a holistic systems approach to improving health system performance in all public, faith-based and private institutions.

Universal Health Coverage has among its key objectives to progressively expand the scope of the health benefit package that is accessible to all Kenyans, increase the availability of quality essential interventions, enhance equity and efficiency in allocating and using resources, provision and maintenance of adequate health resources that will be appropriate for the delivery of health services, and to strengthen leadership and governance within the health sector.

As such, the Ministry of Health in collaboration with other key stakeholders are obligated to optimize oversight, coordination, certification, quality control and patient safety, and quality improvement in service delivery through the establishment of a sound and functional Certification System to guide the UHC purchasing entities on selection of credible service delivery providers.

1.5. Kenya Health Sector Strategic Plan

The Kenya Health Sector Strategic Plan (KHSSP) 2018-2023 is grounded on the need to accelerate attainment of UHC while incorporating Sustainable Development Goals (SDGs) priorities and targets, and the African Union Agenda 2063 of expanding access to quality health care services, particularly for women and girls.

Among the flagship projects for the five years implementation period are; Social Health Protection aimed at enhancing social health protection to the population by expanding financing schemes to cover a harmonized benefit package to targeted populations; Health Infrastructure aimed at developing a robust health infrastructure system; Human Resources for Health focused on building the capacity of health workers to increase the skills pool in the health sector to improve health outcomes and Improving Quality of Care for patients and enhance the safety of patients and health workers.

The flagship projects which are deemed to be transformational, high impact and instrumental in addressing the challenges experienced in the health sector and have a direct bearing on the quality of health care improvement.

1.6. Rationale for the Quality of Care Certification Framework

The Quality of Care Certification framework is envisaged to shape health care services delivery in a manner that promotes and monitors safety and quality, accessibility of services⁴, acceptability and minimizes risk. The framework will put in place modalities to monitor inputs, processes and outcomes of health services delivery and enable comparison of performance among health facilities of the same level across public, faith-based and private sectors. The framework will also provide the government with appropriate tools for strengthening oversight of the health sector.

The framework will guide the strategic purchasing function of the UHC to identify health care institutions for empanelment as well as guide the proportionate rebate compensation in line with the quality and level of service provision. Monitoring outcomes through the Quality of Care Certification framework will also stimulate efficient use and allocation of limited health care resources and ensure that a predetermined package of preventive and curative services is being realized.

The framework benefits the institutions and organization it adjudicates by improving the quality of internal operations, safeguarding the credibility of results of conformity assessment activities, improving the market image of the institutions and organizations, and placing them in a more competitive position. The certification process also provides the tools to identify and create Centers of Excellence based on an identified package of services that are provided with a high level of quality, competence with ensuring desired outcomes.

1.7. Development Process of the Quality of Care Certification Framework

The Quality of Care Certification framework was developed based on foundational guiding documents of the Kenyan Health Sector, international best practices and through a multi-stakeholder consultative process with an aim of ensuring that it abides by the various laws, policies and strategic documents incorporates the needs and mandates of the various stakeholders, and is in tandem with the current practices while taking cognizance of the priorities of the country especially the envisaged UHC.

Among the foundational documents appraised were the various Acts of Parliament outlining the mandates of various relevant institutions, Kenya Health Policy and Strategic plans, UHC guiding documents and various international documents among others. Several consultative meetings were held with KENAS, NHIF, UHC advisory team, regulatory bodies, various partners, Faith-based organizations and International Society for Quality in Health Care (ISQua) team among others. Internal and external validation meetings were also held at various stages to validate the drafts and the final documents.

⁴Through demonstration of provision of a minimum package of services for the Level as defined through UHC

CHAPTER 2: SITUATIONAL ANALYSIS

The Quality of Care Certification Framework is anchored on three key components namely; Licensure/Registration/Gazettement, Certification of health facilities, and Accreditation of Conformity Assessment Bodies (CABs). Below is the situational analysis of the different components in the envisaged framework.

2.1. Licensure/ Registration/Gazettement

According to the Public Health Act Cap 242, all Health facilities should undergo gazettement and registration/licensing for non-public health facilities based on fulfilment of entry-level requirements which include attainment of minimum patient safety standards. Public health facilities are recommended for gazettement by the respective Counties or oversight government Institutions (Prisons, Defense Forces etc.), while the registration/licensing for private, Faith-Based Organization (FBO) and Non - Governmental Organization (NGO) is conducted by the nine independent regulatory agencies namely:

- Kenya Medical Practitioners and Dentists Board (KMPBD)
- Nursing Council of Kenya (NCK)
- Pharmacy and Poisons Board (PPB)
- Clinical Officers Council (COC)
- Kenya Medical Lab Technicians and Technologists Board (KMLTTB)
- Kenya Nutritionists and Dieticians Institute (KNDI)
- Radiation Protection Board (RPB)
- Public Health Officers and Technicians Council (PHOTC)
- Physiotherapy Council (PC)

However, in recent years' defragmentation of the licensing processes has been noted to lead to inadequate regulatory enforcement, duplication of efforts and poor information sharing among the regulators and MoH. This has necessitated the cultivation of Joint Health Inspections which uses combined tool comprising of key inspection elements from all the Regulatory Bodies as stipulated in the respective Acts of Parliament. The tool, the Joint Health Inspections Checklist (JHIC) has been gazetted⁵ for inspection purposes in both public and private facilities. The inspections are conducted for three broad purposes namely:

- Pre-registration, pre-licensing and pre- gazettement inspection done for new Health facilities before issuing licenses/gazettement.
- Regularly scheduled inspections to ensure providers comply with licensing requirements and meet minimum patient safety standards
- Reactive inspection of facilities which are done on existing facilities in response to complaints from the public/media etc.

⁵Kenya Gazette Supplement No. 31, 21st March, 2016, (Legislative Supplement No. 25). Legal Notice No. 46
The Public Health Act (Cap. 242)

However, as of 2019, only 4% of the Health facilities in the country had ,had regular inspections.

2.2. The Joint Health Inspections Checklist

The JHIC has 13 key elements aimed at ensuring minimum standards for patient safety, appropriate infrastructure and equipment for service provision and infection control measures are in place. The JHIC key elements overlap to some extent with Kenya Quality Model for Health (KQMH) standards that aim to ensure continuous quality improvement of services. Table 1 below illustrates the 13 key elements of focus in the JHIC.

Table 1: Key Inspection Elements of the Joint Health Inspection Checklist.

Joint Health Inspection Checklist Areas of Focus	
Administrative Information (<i>including licenses</i>)	Theatre
Health Facility Infrastructure	Pharmacy
General Management and Recording of Information	Laboratory
Infection Prevention and Control	Radiology
Medical and Dental Consultation Services	Nutrition and Dietetics Service Unit
Labour Ward	Mortuary
Medical and Pediatric Wards	

2.3. Kenya Patient Safety Impact Evaluation Pilot

In 2015, the World Bank Group supported Kenya Patient Safety Impact Evaluation (KePSIE) that was piloted in three (3) counties namely Kakamega, Kilifi and Meru and with participation of 1,114 Health Facilities where some key features of the regulatory framework were tested. These included Patient Safety as measured by the JHIC, practices related to Infection Prevention and Control and quality of diagnosis and treatment as measured by Standardized Patients guidelines. This was boosted by the participation of full-time cadre of inspectors representing all regulatory boards and councils, the inclusion of both public and private facilities with assignment of JHIC scores augmented with warnings & sanctions where necessary.

At baseline, 75% of health facilities were minimally compliant with Joint Health Inspection Standards. However, after repeated joint health inspections, 92% of the Health Facilities were noted to increase their scores with 60% of the health facilities increasing their scores sufficiently to move to a higher compliance category. The worst performing facilities were noted to demonstrate the highest improvement.

Among the key factors attributed to the improvement of JHIC scores were facilitation of the health facilities to identify low-cost interventions that could enhance compliance; these included introducing Standard Operating Procedures and protocols, the introduction of quality controls at various units, creating feedback mechanisms and improved health facilities cleanliness. The lessons learnt have been used to scale up Joint Health Inspections nationally with the training of 141 County nominated inspectors.

2.4. Certification

Certification of Health Facilities in Kenya has not followed a defined structure. A number of Health Facilities have been seeking certification from various bodies among them Kenya Bureau of Standards (KEBS) based ISO 9001 Quality Management System and NGO Pharmaccess based on Safecare Standards. Non-certification initiatives using KQMH standards have been carried out by Amref Health Africa and Nairobi County among others. However, there is no formal MoH mechanism for recognition of the certification efforts and other initiatives by the participating health facilities.

2.5. Accreditation of Health-Related Activities by KENAS

Kenya Accreditation Service (KENAS) established under the States Corporations Act, Cap 446, Legal Notice 55/2009 is the sole national accreditation body for Kenya mandated to offer accreditation services in the country. KENAS is a Mutual Recognition Arrangement (MRA) signatory at International Laboratory Accreditation Cooperation (ILAC) and African Accreditation Corporation (AFRAC) and a Multi-Lateral Arrangement (MLA) Signatory at International Accreditation Forum (IAF). Additionally, KENAS is a key player in the East African Accreditation Board (EAAB) established under the EAC Standards Quality Assurance and Measurements Act 2006.

The health sector-related accreditation services that have been offered or are in place at KENAS include:

- Accreditation of different health services delivery units e.g. Medical Laboratories (ISO 15189); Diagnostic Imaging Accreditation (ISO 15189) and Pharmaceutical laboratories (ISO 17025).
- Accreditation of Certification Bodies such as Management Systems Certification Bodies ISO/IEC 17021-1 (hospital certification, Quality Management Systems (QMS), Food Safety Management Systems (FSMS)); Personnel Certification Bodies ISO/IEC 17024 (Kenya Medical Practitioners & Dentists Board- KMPDB, Nursing council etc.); and Product Certification Bodies ISO/IEC 17065.
- Accreditation of Inspection Bodies (ISO/IEC 17020). This is where most regulatory bodies that carry out inspection fall, and in due course, the Joint inspection activity done for licensure may also be included if regional or international recognition is desired.
- KENAS has so far accredited 39 medical laboratories (government, private, faith-based organizations), 46 testing and calibration laboratories, seven (9) inspection bodies, three (3) certification bodies and three (3) Proficiency Test Service Providers.
- KENAS has a system in readiness for accreditation of Health Facilities in the framework of ISO/IEC 17021-1+ KQMH.

2.6. Accreditation Efforts from International Bodies

Some health facilities have made own efforts to seek accreditation from International bodies. Among them are Aga Khan University Hospital and Gertrude's Garden Children Hospital from Joint Commission International (JCI), and Nairobi Women Hospital by Council for Health Service Accreditation of Southern Africa (COHSASA). However, as with certification, there is no formal mechanism set by MoH to recognize these accreditation efforts.

2.7. National Hospital Insurance Fund Health Facilities Empanelment

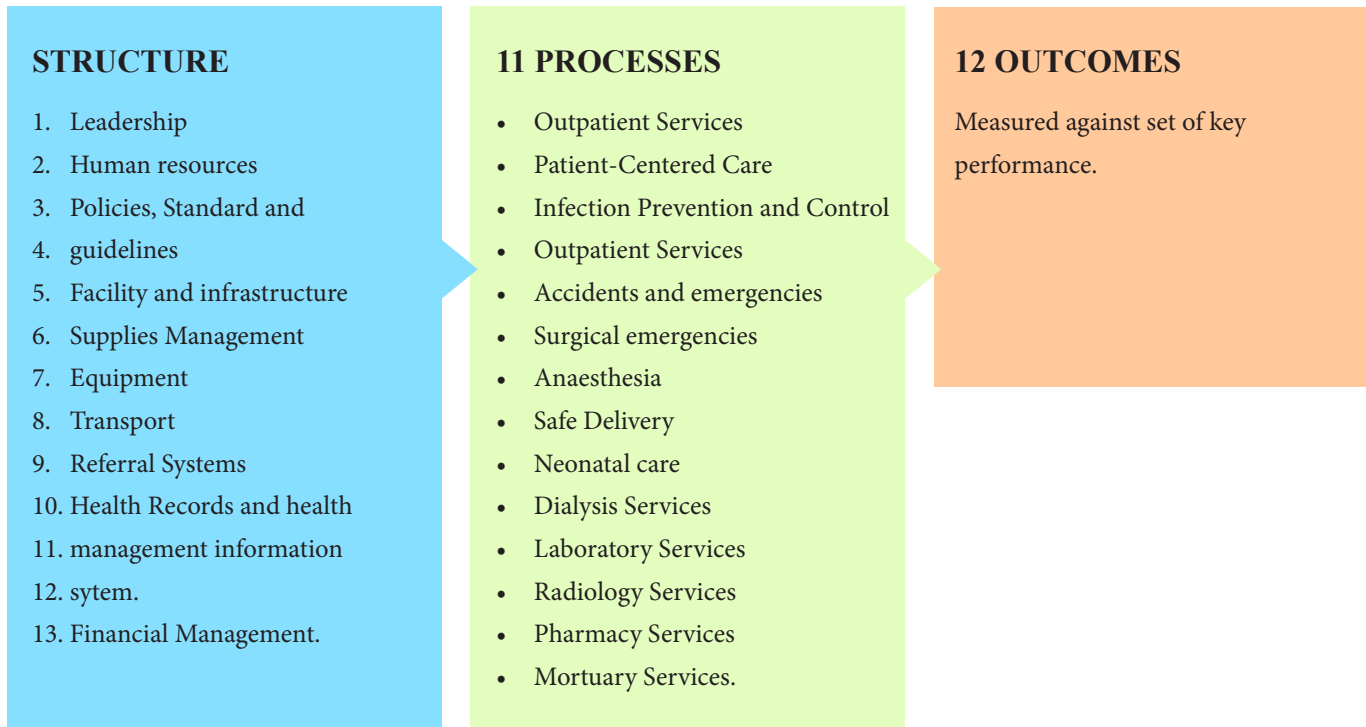
NHIF empanels health facilities through a mutual contractual obligation that recognizes the health institutions' capability to provide acceptable quality healthcare to its members. The empanelment process involves numerous steps including availing the prerequisite documents from regulatory authorities. By 2018, NHIF had empanelled 5,000 health facilities for service provision; out of these, 45% were private, 44% are public while 11% are faith-based health facilities. The empanelled health facilities are expected to maintain and improve the quality of services based on KQMH standards. However, due to the heavy workload and low number of quality assurance officers, there has been inadequate quality assurance follow up to ensure continued compliance of the empanelled health facilities.

2.8. Kenya Quality Model for Health

The Kenya Quality Model for Health (KQMH) provides the nationally recognized conceptual and implementation framework for quality improvement of health services and systems in the country. It was initially developed in 2001 by the Department of Standards and Regulatory Services of the Ministry of Health and borrowed heavily from the European Foundation for Quality Management (EFQM). It has undergone several revisions to reflect various emerging priorities and policy environment changes. These include customizations of the standards and checklists for the various Kenya Essential Package of Health (KEPH) levels, alignment with the new Constitution (2010); the development of a new health policy (Kenya Health Policy 2014-2030); adaption of the World Health Organization (WHO) Health Systems Building blocks in the Kenya Health Sector Strategic and Investment Plan (KHSSP) 2014-2018; and the development of various clinical standards and guidelines, and alignment with international developments and best practices in the delivery of health services.

The KQMH focuses on 12 dimensions that are categorized into Structure, Processes and Results/ Outcomes. The model identifies structures and processes that health providers would need to establish, implement and maintain in order to produce the desired results/outcomes. An electronic tool has been developed to facilitate the efficiency of assessments and results transmission. Figure 1 below illustrates the 12 KQMH dimensions.

Figure 1: *KQMH Dimensions*



CHAPTER 3: STAKEHOLDER ANALYSIS

Several key stakeholders will play prominent roles in the operationalization of the Quality of Care Certification framework. Below is a description of their core mandate and organization.

3.1. Directorate of Standards and Quality Assurance and Regulations

The Directorate of Health Standards, Quality Assurance and Regulation (DHSQAR) is one of the six departments at the Ministry of Health at the National Level. It has three key Divisions - Division of Standards and Quality Assurance, Division of Legislation and Regulations, and Division of Traditional and Alternative Medicine. The Department has working linkages with the Regulatory Bodies.

The Department of Health Standards and Quality Assurance is responsible for developing standards for the various Health Policy orientations to guide the health sector. The Department has developed and revised various versions of KQMH, Human Resources for Health Norms and Standards, and Health Infrastructure Norms and Standards, Infection Prevention and Control and Antimicrobial Resistance Policies. The Department of Legislation & Regulations is responsible for facilitating legislation of various standards and policies for the Ministry of Health and has facilitated the gazettelement of the JHIC

3.2. Kenya Health Professions Oversight Authority

The Health Act 2017 section 45 established the Kenya Health Professions Oversight Authority (KHPOA) whose functions are to:

- Maintain a duplicate register of all health professionals working within the national and county health system
- Promote and regulate inter-professional liaison between statutory regulatory bodies
- Coordinate joint inspections with all regulatory bodies
- Receive and facilitate the resolution of complaints from patients, aggrieved parties and regulatory bodies
- Monitor the execution of respective mandates and functions of regulatory bodies recognized under respective Acts of Parliament
- Arbitrate disputes between statutory regulatory bodies, including conflict or dispute resolution amongst Boards and Councils
- Ensure the necessary standards for health professionals are not compromised by the regulatory bodies

Noteworthy is that currently there is no legal and independent body that has the mandate expressly spelt out to provide oversight over certification activities. There is therefore need to identify the most suitable oversight body to coordinate and delegate assessment activities in order to ensure compliance with certification standards while acting as a repository for quality assessment data for dissemination to the relevant stakeholders including the public.

3.3. Kenya Accreditation Service

KENAS has the legal mandate to accredit Conformity Assessment Bodies (CABs) in the country. The CABs would, in turn, assess and provide certification to Health Facilities using the government-approved KQMH Standards. KENAS signed a Memorandum of Understanding (MoU) with MoH in May 2016 agreeing to a division of labour on the certification framework with KENAS providing accreditation of the CABs. KENAS has been involved in the development of KQMH standards and has a system in readiness for accreditation of CABs in line with ISO/IEC 17021-1 +KQMH.

3.4. National Hospital Insurance Fund

The National Hospital Insurance Fund (NHIF) was established in 1966 as a department under the Ministry of Health and has evolved over the years into a State Parastatal that is currently governed by the Parliamentary Act of Act No. 9 of 1998. It has the legal mandate of providing medical insurance cover to all its members and their declared dependents. Its core duties are registration of eligible members from the formal and informal sector, contracting Healthcare Providers based on recommendation from the relevant government regulatory bodies, and processing rebates for Health Care providers based on the various benefits Packages in line with NHIF Strategic Plan.

The absence of Quality of Care Certification Framework has previously necessitated NHIF to conduct own quality of care assessment and monitoring activities of Health Facilities in order to determine their suitability in empanelment in providing services to NHIF members.

3.5. Regulatory Boards and Councils

The various Boards and Councils are governed by various Acts of parliament. They have the legal mandate is to oversee and regulate standards of training, registration and licensing of cadres under their jurisdiction and enforcement of codes of regulation. The various Boards and Councils are also responsible for licensing and monitoring various functions in Health Care Facilities. To avoid duplication, the Boards and Councils have developed modalities for conducting Joint Inspections encompassing all aspects of Service provision. Noted duplications still persist with different regulatory bodies seeking to license/register health facilities based on ownership of their members. The activities of the various Boards and Councils are set to be overseen by the newly created KHPOA.

3.6. Conformity Assessment Bodies

There are a number of health-related Conformity Assessment Bodies (CABs) in the country among them General Society of Surveillance (SGS), Bureau Veritas Certification (BVC) and Kenya Bureau of Standards that have demonstrated interest in conducting conformity Assessment activities based on KQMH standards and have been involved in the accreditation framework for hospital certification. However, KEBS is the only Government-owned CAB that has been accredited by KENAS.

Other CABs e.g. Pharmaccess are affiliated to international organizations, International Society for Quality in Health Care (ISQua) accredited Safecare standards. PharmAccess had by end of 2019 facilitated 1,100 private and public healthcare providers to use SafeCare standards to assess clinical quality and safety as well as to improve organizational management and processes.

3.7. Health Professional Bodies

There are various professional bodies whose one of the core mandates to provide Continuous Professional Development (CPD) to their members in order to ensure that health workers have requisite competencies at all times in the core areas of their professional practice to facilitate the provision of quality health care to their clients. However, this function has not been fully entrenched. Lack or non-enforcement of CPD guidelines in Kenya has contributed to low uptake of CPD training and non-compliance by health professionals.

3.8. County Governments

The County governments are responsible for county health services including county health facilities and pharmacies, ambulance services, promotion of primary health care and county planning and development. The County Health Management Teams have been carrying out the initial inspection of new health facilities and recommendation to the regulatory authorities for licensing/registration/gazettement. As such the inspection of new health facilities has not been standardized leading to proliferation of non-standard health facilities. Through the Joint Inspection initiative, the counties have nominated staff for training to facilitate uniformity of the Joint Inspections.

It is envisaged that Counties being the custodians of the health facilities will play a crucial role in facilitating the health facilities to improve on the quality of services through resources allocation. The counties are also expected to champion County-based Health Inspectors, QI mentors and peer assessors who will, in turn, support the health facilities in the Quality Improvement journey.

CHAPTER 4: PROPOSED STRUCTURE OF THE QUALITY OF CARE CERTIFICATION FRAMEWORK

The Quality of Care Certification framework is envisaged to facilitate the Ministry of Health establish a collective quality assurance framework for all service providers thus creating a level playing field for purchasers and providers of healthcare services. This will be achieved by ensuring that all healthcare facilities are evaluated for quality services in a consistent manner according to international best practice.

The Quality of Care Certification framework will also integrate the mandate and strengths of several key players in the sector to ensure coordination and leverage of synergies to create incentives for the certification process. The certification standards will, however, need to be consistently and uniformly applied in order to maintain its credibility and health consumers' confidence.

4.1. Goal

To advance high-quality service delivery, patient care and safety and to derive desired outcomes by objective application of recognized health standards through entrenching continuous monitoring and quality improvement and recognition.

4.2. Objectives

- All Health Facilities comply with state laws and regulations.
- Health Facilities attain formal recognition for compliance with set quality improvement standards.
- Conformity Assessment Bodies have the requisite capacity and competence and are recognized and facilitated to continuously monitor and evaluate the implementation, use and adherence of the set health standards in the health sector.
- Identification and strengthening of a Certification Oversight Body to provide guidance on Certification activities and act as a repository for quality of care data and information for the purposes of dissemination to key stakeholders to support strategic purchasing and to the public to support informed decision making.

4.3. Components of the Quality of Care Certification Framework

The proposed structure of the Quality of Care Certification Framework is envisaged to be anchored on three main components namely; Licensure/ Registration/ Gazettement, Certification and Accreditation. The components will be operationalized as described in Table 2 below.

Table 2: Components of the Quality of Care Certification Framework

Process	Legal Obligation	Issuing Organization	Object of Evaluation	Requirements	Standards	Incentive
Licensure/Registration	Mandatory	Joint Health Inspection	All Health Facilities	Compliance with minimum standards	JHI Checklist for different levels	Authorization to open
Gazettement	Mandatory	GoK	All Health Facilities	Compliance with minimum standards	JHI Checklist	Authorization to open
Certification	Voluntary	Certification Oversight Body on assessment by Authorized/ Accredited CAB	All Health Facilities	Compliance with published standards, on-site evaluation and demonstration of continuous improvement	KQMH, (Other standards benchmarked against KQMH)	Linked to the NHIF rebates level scalable on the star rating and KEPH level / other insurers funding/ risk management
Accreditation	Voluntary	KENAS	Conformity Assessment bodies	Compliance with minimum requirements	ISO/IEC 17021-1 + KQMH	Authorization through accreditation

4.4. Licensure/ Registration/Gazettement

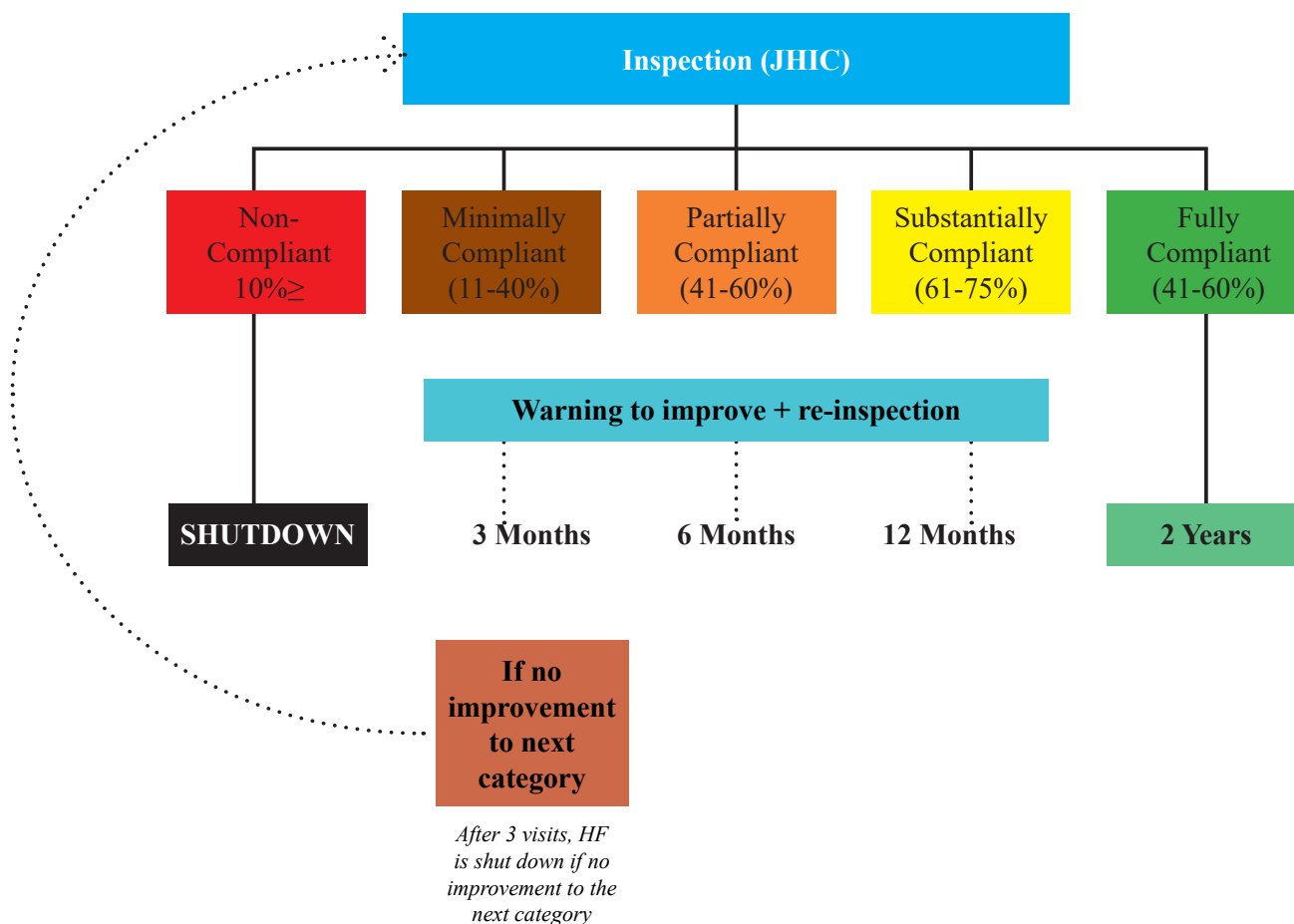
This component addresses the first objective of the accreditation framework: All Health Facilities comply with state laws and regulations. Among the envisaged Quality of Care Certification Framework components, the Licensure/Registration/Gazettement structures are the most established. However, the assessment for Licensure/Registration/Gazettement has biasedly focused on private and faith-based health facilities with little attention being paid to the public health facilities. Though currently only 4% of the country’s health facilities have been subjected to the regular inspections, the activity is set to be scaled up countrywide with the training of more County supported Inspectors.

4.4.1. Licensure/Registration/Gazettement Process

The Licensure/Registration/Gazettement will be based on the Joint Health Inspection Checklist with the 13 key elements that are earmarked for inspection (*Table 1*). An electronic tool has been developed to facilitate the efficiency of inspections. The scores of the various components are aggregated to give a cumulative score that is converted to a percentage. Depending on the score the facility is categorized as Non-compliant (0-10%), Minimally Compliant (11-40%), Partially Compliant (41-60%), Substantially Compliant (61-75%) or Fully Compliant (>75%). The follow-up actions are based on a risk-based approach with least scoring health facilities being re-inspected more regularly coupled with warning notices to ensure improvement before the next inspection.

For new Health Facilities, Licensure/ Registration /Gazettement will be undertaken after the Health Facility has achieved partial compliance that is, a score of at least 50% of the JHIC. However, the Health Facility will be expected to improve to the ‘substantially compliant’ category in the subsequent three months or lose the License/ Registration /Gazettement. Figure 2 below illustrates the risk-based actions based on the JHIC scores of the health Facilities.

Figure 2: Joint Health Inspection Findings and Risk Based Actions



To strengthen the Licensure/Registration/Gazettement function it will necessitate the following:

- The nine regulatory bodies to enforce and streamline the regulation of the respective professionals and functions within the health facilities. This will entail ensuring the conditions for licensing/registration/gazettement and renewal of licenses/registration are met including the CPD requirements.
- Strengthening of the joint inspection function through training of more county-based and sponsored inspectors.
- Continued implementation of the Joint Health Inspections to all facilities including the public health facilities
- Linkage of JHC scores/outcomes to the certification process.
- The KHPOA to strengthen its capacity in order to provide oversight, division of labour and conflict resolution to the boards and councils.

4.5. Certification

4.5.1. Certification Process

The assessment for certification of Health facilities will be based on KQMH standards. Before a Health facility can seek certification it will need to fulfil the Licensure/ Registration / Gazettement standards to the level of ‘substantially compliant’. Upon assessment using the KQMH standards and checklist for the KEPH level, the Health facility will be graded as follows:

- » **50% and above score on the KQMH - 1 star**
- » **60% and above score on the KQMH - 2 stars**
- » **70% and above score on the KQMH – 3 stars**
- » **80% and above score on the KQMH – 4 stars**
- » **90% and above score on the KQMH - 5 stars**

However, some health facilities have made the initiative to utilize other standards for quality improvement activities. These include Safecare, JSI standards and ISO standards among others. While the use of other standards is not discouraged, it is worthwhile to note that NHIF rebates and benchmarking for awards will be based on KQMH standards.

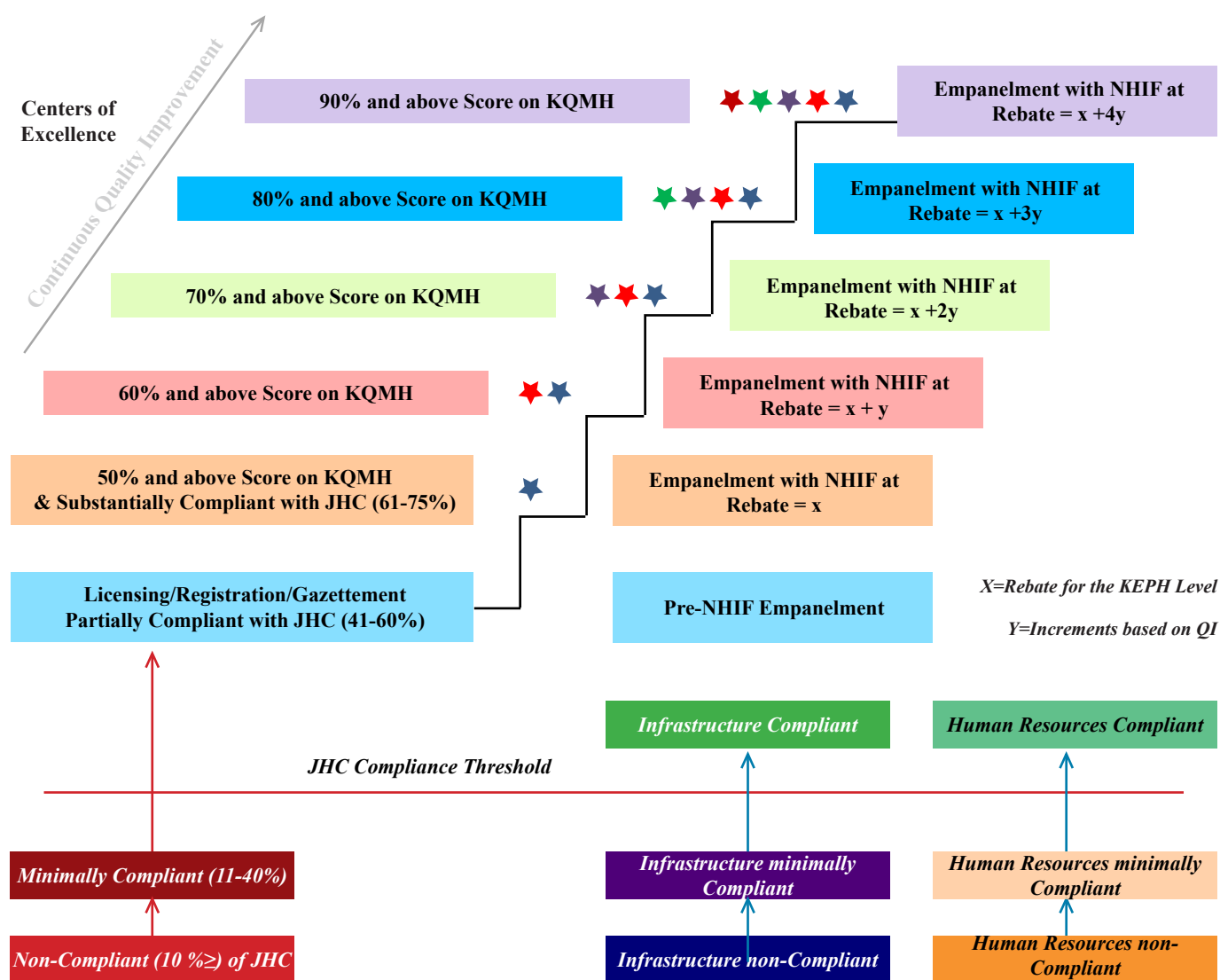
Therefore, the health facilities utilizing other standards will have to undergo periodic assessment using the KQMH standards in order to determine their Quality Improvement status based on government-approved KQMH. This will ensure a level playing field for rebates reimbursements and recognition.

4.5.2. Incentives for Quality Improvement

The certification process is a voluntary process and therefore it is crucial to create incentives to motivate health facilities toward quality improvement. To achieve this, the certification process will create leverage with insurance institutions especially NHIF. It is recommended that NHIF only empanels health facilities that have attained 50% and above score on KQMH. A grace period of 2 years will be given to Health Facilities to comply with this requirement. The rebates will be set at a minimum for the KEPH level for Health Facilities that have attained 50% score and increments will be dependent on demonstrated quality improvement score on the KQMH.

The revision of the rebate will be done on a yearly basis (financial year) to capture any commensurate improvements (or decline) that may have taken place in the course of the year. The quality improvement rating and incentive structure is illustrated in Figure 3 below.

Figure 3: Certification Rating and Incentive Structure



4.5.3. Centres of Excellence

Centres of excellence will be a selection of health care institutions that deliver specialized programs in a particular medical discipline and demonstrate a high level of competence and interdisciplinary collaboration, and with required resources to deliver the service in a comprehensive manner. Examples are; Maternal and Neonatal centres, Orthopaedic centres, Fistula Management centres, Eyecare centres among others.

For a Health care institution to qualify as a centre of excellence, it must attain 80% score on the KQMH and score highly on a set of identified outcome indicators for the medical discipline whose service it offers.

4.6 Accreditation of Conformity Assessment Bodies

4.6.1. Accreditation Process

KENAS has the legal mandate to accredit Conformity Assessment Bodies (CABs). Accreditation focuses on competence and promoting best practices rather than merely ensuring compliance with minimum standards. Therefore CABs are evaluated and recognized for competence to carry out specific conformity assessment activities. The CABs in turn regularly assess the Health Facilities using the government-approved KQMH Standards. The utilization of independent CABs rather than MoH to conduct quality of care assessments allows for impartiality and a level playing ground for all health facilities including the public ones.

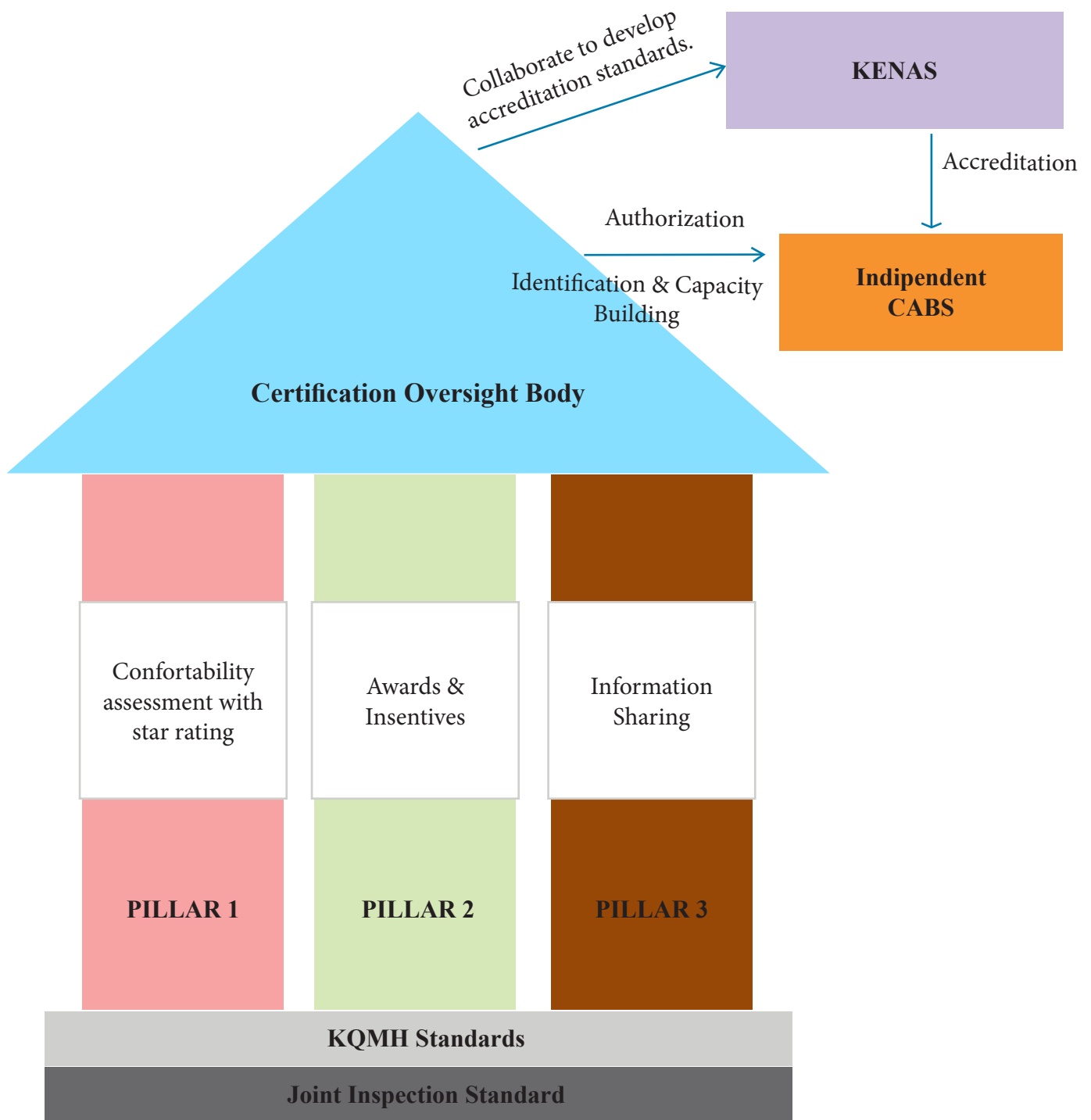
The Certification Oversight Body will oversee all certification activities, harmonize the roles of multiple players in the framework and confer interim authorization to CABs to conduct quality of care assessments. The Certification Oversight Body will also facilitate quality assessment activities through liaison with the counties and other non-devolved service providers; acts as a repository for data and information and disseminate information to the relevant stakeholders (e.g. UHC, NHIF, private insurers and financiers), and the public.

4.5.2. Functions of the Certification Oversight Body

The following are the envisaged functions of the Certification Oversight Body;

- Identify and contract possible CABs for the purposes of delegation of quality assessment activities. To ensure that the country is adequately covered it would require a minimum of 8-10 functional CABs to conduct assessments in the country.
- To build the capacity of the CABs in preparation for assessments and accreditation based on KQMH
- To facilitate conformity assessments by the CABs through Intergovernmental Health Forum with the Counties
- To maintain a database of the results of the conformity assessments from the health facilities
- To liaise with other stakeholders- UHC, NHIF, private insurers, financiers on quality performance of Health Facilities for the purposes of empanelment and rebates determination
- To identify and recognize the best performing Health Facilities for the purposes of recognition and awards
- To mobilize resources for Quality of Care Certification Framework activities and develop branding for Certified Health Facilities.

Figure 4: Proposed Quality of Care Certification and Accreditation Structure



CHAPTER 5: ROLES OF DIFFERENT KEY PLAYERS IN THE QUALITY OF CARE CERTIFICATION FRAMEWORK

The table below illustrates the roles of the different key players in the Quality of Care Certification Framework

	Key Player	Role	Comments
1	DHSQAR	Develops, reviews and disseminates Health Standards- KQMH, Infrastructure, Human Resources, Patient Safety Standards, CABs accreditation standards etc.	A number of standards are already in place
2	KHPOA/ Regulatory boards and councils	Through JHI conducts baseline and follow up inspections Licensure/Registration/Gazettement of Health facilities Maintain a database of qualified cadres of staff, enforces CPD	Using the JHIC
3	KENAS	Accredits the Conformity Assessment bodies based on the established framework for hospital certification and any additional guidance documents developed jointly with MoH and participation of stakeholders	Scheme Framework: ISO/ IEC 170021-1 + KQMH (Competence requirements) + Guidance documents established from time to time
4	Certification Oversight Body	Coordinates quality assessments in the country, delegates assessment to independent CABs, acts as a repository for data and information, shares information with NHIF, other insurances and the public	The mandate of the proposed body needs to be expanded to carry out the function
5	Conformity Assessment Bodies	Conducts independent quality assessments of Health facilities on delegation from the Lead Conformity assessment body	Need to be identified e.g. through a tendering process
6	County Governments	Facilitate Quality assessments in the respective counties, acts and follow up on the recommendation of the assessments	Collaboration on certification activities through the Intergovernmental forums
7	NHIF	Creates an incentive structure based on the Quality Assessment findings in order to stimulate improvements	Will need to create formulas for paying out rebates for different QI performances
8	Professional Bodies/ Training Institutions	Ensure that the respective health professionals have requisite competencies in the core areas of their professional practice to facilitate the provision of quality health care to clients.	Provision of training opportunities and CPD

CHAPTER 6: IMPLEMENTATION ROADMAP

The implementation of the Quality of Care Certification Framework requires several phases to be fully realized. This would realistically go up to the end of the current Kenya Health Sector Strategic Plan (2018-2023) implementation period. Among the key undertakings that require to be addressed are;

- Identification and strengthening of the Certification Activities Oversight Body and if necessary modify the mandate of the identified body through the amendment of the relevant Act of Parliament
- Continued strengthening of the regulatory function and identification and training of additional Health Inspectors per county
- Identification of the suitable CABs and building their capacity to conduct an assessment using KQMH
- Identification and training a critical mass of County based Quality of Care mentors and peer assessors
- Identification of pilot counties and health facilities
- Training of Health Facilities on KQMH standards compliance and assessments
- Phased KQMH assessments through different KEPH levels- Level 6, Level 5, Level 4, Level3 and Level 2.
- Creation of a Quality Improvement performance database in KHIS/KHMFL with separate self and external assessment access platforms
- Accreditation of CABs by KENAS
- Resource mobilization for Certification activities
- Create branding of Certified Health Facilities

6.1. Identification and Strengthening of the Certification Activities Oversight Body- Certification Oversight Body

This framework recommends identification and conferring of the Certification mandate to a suitable Oversight Body for the Quality of Care Certification Framework for the Health Sector. The Oversight Body can be an existing body whose mandate would necessitate expanding to ensure that the certification activities are well covered through amending the relevant articles in the Act of Parliament; or establishment of new independent Oversight Body- a Quality of Care Commission, Institute etc. The identified Certification Oversight Body would also require the requisite resource allocation and capacity strengthening to carry out this mandate.

6.2. Strengthening the Regulatory Function

The health regulatory function is overseen by nine independent regulatory agencies. Though the mandate of the regulatory bodies has clearly been spelt out in the respective Acts of Parliament, the regulatory function has sometimes experienced overlaps and conflict among the different regulatory bodies. Positive steps have recently been made with the establishment of KPHOA to oversee regulatory activities and development of the JHIC which has cultivated collaboration and participation aimed at a unified approach to health facilities inspections.

In addition, the regulatory bodies would need to strengthen the oversight of the different professions under their jurisdiction in ensuring that updated registers of professionals are in place and practising licenses renewal reflects demonstration of skills retention and update through Continuous Professional Development.

6.3. Identification of Pilot Health Facilities and Counties

Rolling out of the Quality of Care Certification Framework will follow a phased process; this will enable the lesson learnt to be applied on a wider scale and allow adequate timeframe for resources mobilization for full implementation. In this regard, this document recommends beginning with a level 5 health facilities and rolling down to other health facilities. The four KePSIE pilot Counties (Kakamega, Kilifi and Meru, plus one) where the regulatory function has been reasonably established would also serve as a good pilot platform. It is important to ensure linkages with UHC activities.

6.4. Identification and Training a Critical Mass of County Based Quality Improvement Mentors and Peer Assessors

Quality of Care will need to be cultivated as a continuous process and an entrenched culture change rather than reactive to assessments. In this regard, there is need to ensure that every county has a critical mass of Quality Improvement Mentors and Peer Assessors. The mentors and peer assessors will train health facilities on KQMH and provide mentorship on quality improvement strategies. The peer assessors from different counties will form Peer Assessment Teams which will periodically conduct quality assessments in counties other than their own and submit the results to the national Certification Oversight Body. The assessments will be validated by the independent CABs.

The Quality Improvement Mentors and Peer Assessors strategy is envisaged to ensure that health facilities are adequately supported at all times and to cut assessments costs. The activities of the Quality Improvement Mentors and Peer Assessors will be supported through a collaborative effort of both the Counties and the National level.

6.5. Training of Health Facilities on KQMH Standards Compliance and Assessments

A number of health facilities have already had training on KQMH. According to the Kenya Harmonized Health Facility Assessment conducted in 2018 in 2,927 Health facilities, 53% had formed Quality Improvement Teams though not necessarily based on KQMH. To operationalize the Quality of Care Certification framework, the health facilities would benefit from training /refresher on KQMH and the Certification process and how the QI outcomes are tied to Insurance rebates and UHC. The training is best cascaded through the County Quality Improvement Mentors and Peer Assessors who would in turn train the health facilities with the support of the Counties.

6.6. Identification of the suitable Conformity Assessment Bodies

The role of the CABs is to validate conformity assessments findings of health facilities once the County based Peer Assessors have conducted assessments for health facilities and submitted the findings to the Certification Oversight Body. Though there are a few CABs that have been accredited by KENAS, none has so far been accredited to conduct Quality of Care conformity assessment using KQMH. Therefore there is a need to identify suitable CABs, build their capacity to conduct assessments, issue them with authorization to conduct assessments and supervise the assessment. The CABs will thus gain the necessary know-how that will facilitate accreditation by KENAS upon demonstration of competence to conduct conformity assessments using KQMH.

6.7. Phased Health Facilities KQMH assessments

In order to obtain baseline data for health facilities, it would be important to conduct phased KQMH assessment of the health facilities through different KEPH levels- Level 6, Level5, Level 4, Level3 and Level 2. This will ensure the practicability of the framework implementation and to realistically conduct thorough assessments given the sheer volume of health facilities in the country. The health facilities will then be given a grace period of one year to work on quality improvements. Repeat assessments will then be conducted and performance tied to the insurance rebates

6.8. Creation of a Quality Improvement Performance Database

The Certification Oversight Body will act as a repository for all the QI data for all the health facilities. The data includes the regulatory data using the joint inspection checklist and continuous quality improvement monitoring using the KQMH. The data will be analyzed and shared with different stakeholders including the health facilities, Counties, strategic purchasers and the general public among others. It will be therefore crucial to ensure that there is an ample database that can receive, synthesize and generate the relevant information products for different target group. The database should either be a separate KHIS window or a separate database that is linked to KHIS/KHMFL.

6.9. Resource Mobilization for Quality of Care Certification Activities

The Quality of Care Certification framework requires concerted efforts to mobilize funds for different activities. This will be initiated by ensuring that the proposed Certification Oversight Body has been created and has a government vote. In addition, the key players will need to develop approaches to mobilize funds through different mechanisms e.g. creating activity plans with budgets, developing proposals, sourcing for partners funding, riding on UHC funding, collecting assessments fees among others. This will ensure that the funding bottlenecks are identified early and addressed.

6.10. Create branding of Certified Health Facilities

In order to create incentives for Certification, the Certification Oversight Body will create branding for Health Facilities that have been certified so that there are easily recognized for marketing and information purposes.

Though the certification process is voluntary, all health facilities are encouraged to undergo certification. Incentives and disincentives for participation in the certification process will be created and instituted.

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