REPORT OF TECHNICAL WORKING GROUP TO DEVELOP GUIDELINES AND CHECKLISTS FOR REPORT ON THE REGULATION OF ELECTRONIC HEALTH PRACTICE IN THE COUNTRY

INTRODUCTION

The Cabinet Secretary, vide letter Ref. No. MOH/ADM./1/1 VOL. VI, directed the Director General and the CEO of the Medical Practitioners and Dentists Council to prepare a draft regulatory framework for electronic health (eHealth).

The directive took into consideration the increased presence of eHealth solutions and platforms in the market and the challenges that come with it, including substandard applications, high costs, low ICT literacy levels, lack of interoperability of eHealth systems, market fragmentation, weak regulatory framework and possible violation of patient confidentiality.

To this end, the Director General and the CEO, MPDC, constituted a technical working group to carry out the task of coming up with a proposal towards regulatory framework that safe-guards the Kenyan patient.

1. Dr. Gladwell Kiarie, Chair of the technical working group (MPDC)
2. Dr. Ian Njeru, Member (MOH, Head, department of health informatics)
3. Dr. Andrew Were Onyino, Member (MPDC, Chair, Inspection and Licensing Committee)
4. Dr. Nelly Bosire, Member

The TWG held a consultative time meeting and agreed on the following:

1. **e Health** is a broad term that refers to the use of information and communications technologies in healthcare. It is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through internet and related technologies. It includes health applications and links on mobile phones referred to as m Health.

2. "**Virtual medicine**" where patients and doctors use digital tools to communicate; shall be defined as the application of information and communication technologies across the whole range of functions that affect the health care sector and is made up of E Health, M Health and telemedicine. A virtual health delivery platform that needs to be registered as a "virtual institution" under Cap 253. This would enable the regulation of the

institution and all affiliated staff in liaison with the various boards spread over different ministries.

3. Further, the TWG shall, in part, adopt the European Commission's inclusions in the definition, which includes the following categories of applications:
    a. clinical information systems
    b. telemedicine and home care, personalized health systems and services for remote patient monitoring, tele-consultation, tele-care and telemedicine.
    c. Integrated regional/ national health information networks, distributed electronic health record systems and associated services such as e-prescriptions or e-referrals
    d. Secondary usage of non-clinical systems (such as specialized systems for researchers, or support systems such as billing systems)
    e. Health tourism

    Further, the TWG shall consider inclusion of:

    a) E Learning
    b) Telepathology, teleradiology, tele-pharmacy, tele-laboratory etc.
    c) Robotic medicine
    d) Artificial Intelligence (AI)
    e) Any other emerging eHealth solutions

REGULATORY ASPECTS OF E MEDICINE:

Currently in Kenya, there exists several constitutional and legal provisions that speak to eHealth. These include:

    f. Kenya standards and guidelines for m Health systems (2017),
    g. Standards and Guidelines for Health Information Systems interoperability (2015),
    h. Kenya Health Enterprise Architecture (2016)
    i. Kenya e-Health Policy (2016-2030)
    j. Health Act No. 21 of 2017
    k. The Medical Practitioners and Dentists Act (Amendments 2019)
    l. The Pharmacy and Poisons Board Act
    m. The Nursing Council Act
    n. The Clinical Officers Act
    o. Radiation Protection Act
    p. Kenya Medical Laboratory Technicians and Technologists Act
    q. Health Sector ICT Standards and Guidelines- Ministry of Health June 2013
    r. Kenya National eHealth Strategy 2011-2017
    s. Draft Kenya National eHealth Strategy 2019-2023

t. Draft Kenya HIS certification framework
u. Kenya Standards and Guidelines for Electronic Medical Record Systems

4. The existing Ministry of Health Policy and Strategy address the technical aspect of eHealth comprehensively. However, the challenges existing are as a result of the following gaps:
    a. Lack of implementation of the existing eHealth policy
    b. Lack of incorporation of the service aspect of eHealth, thereby not addressing the patient
    c. Absent regulation guiding some parts of the service aspect of eHealth, thereby leaving the patient exposed to unregulated practice

PROPOSED IMPLEMENTATION GUIDE

Having identified the above gaps, the technical working group shall review all existing regulation and legal provisions with the purpose of developing appropriate eHealth implementation guide that is enshrined in law.

1. In line with the Health Act (2017), Section XV, article 104, the Cabinet Secretary shall enact legislation to provide for the following parts:
    a) The administration of health information banks, including interoperability framework, data interchange and security.
    (In the implementation of this article, the MOH has in place well defined standards and guidelines for health systems interoperability systems. Therefore, the TWG shall be responsible for proposing a mechanism for enforcement of the guidelines.)
    b) Collection and use of personal health information
    c) Management of disclosure of personal health information
    d) Protection of privacy
    (The MOH has Health Sector ICT Standards and Guidelines that address the above subsections. The TWG shall propose a mechanism of enforcement of these guidelines)
    f) Health service delivery through m Health, e learning and telemedicine
    (The MPDC vide mandate provided for in the amended Cap 253, is in the process of developing rules governing m Health and telemedicine as the providers are considered to be health institutions. The rules shall effectively regulate the practice and the MPDC shall have the mandate to enforce.
    Further, the NCK, PPB, KLTTB, RPB shall all be requested to consider their existing regulations to make provision for eHealth)

2. The technical working group shall compile a comprehensive regulatory framework to the Cabinet Secretary for consideration by the 20th of September 2019.

Workplan

29th July 2019	TWG review of existing legislation, policy and guidelines and communication to other regulatory Boards and Councils regarding need for comprehensive rules governing eHealth within their jurisdiction
12th August 2019	TWG meeting with other regulatory authorities and MOH officials to discuss proposed rules to ensure concurrence
19th September 2019	Draft presentation to stakeholders for input prior to final draft preparation.

INCORPORATION OF THE SERVICE ASPECT

Healthcare is very interdependent: you have the doctor, the pharmacy, the patient, the insurance provider, and a dozen other stakeholders that any one service has to coordinate with.

1.REMOTE PATIENT MONITORING:

Remote patient monitoring is the technology to enable monitoring of patients outside the conventional clinical settings.

This involves continuous round the clock patient surveillance where there is continuous inflow of patient data from their bedside monitoring devices. It keeps track of the changes in the condition of the patient (improvement or deterioration by bedside monitors which can be viewed effectively.

The technology has other notable features of an alarm notification and an escalation process that notifies clinicians about their patients irrespective of where they are.

It is meant to increase access to care and decrease healthcare delivery costs, incorporated into chronic disease management which can significantly improve an individual's quality of life.

2.ARTIFICIAL INTELLIGENCE:

This is the ability of the computer program or a machine to mimic cognitive functions that humans associate with the human mind such as learning and program solving. In healthcare there is use of complex algorithms and software to estimate human cognition in the analysis

of complicated medical data. The computer will approximate conclusions without direct human input. Informing clinical decisions making through insights from the past data is the essence of evidence-based medicine. The tasks are clearly defined inputs and AI commonly handles tasks that are essential but limited enough in scope as to leave the primary responsibility of patient management with a human doctor.

AI can support large populations and is ideal in situations where human expertise is a scarce resource.

In a consultation the clinician spends time reading past medical records, test results and finding clinical guidelines form a number of disconnected systems. AI could automatically convert recorded dialogue of the consultation into a summary which the clinician can approve or amend. This could save considerable time and be implemented quickly because they assist rather than replace clinicians.

3. E RESEARCH:

This is defined as the use of advanced information and communication technologies to support research.

It extends e science and cyberinfrastructure to other disciplines, including humanities and social sciences.

The themes revolve around Data driven research, computationally intensive research, collaborative research across geographical and discipline boundaries.

E research outcomes include improved collaboration, using local, state and national IT structures, accessing data repositories and collections, utilizing advanced computing facilities and managing and reusing research data.

4. HOMECARE:

Home care allows a person with special needs to stay in their home where they get medical and personal care by medical personnel. This is led by a physician who provides continuous and coordinated care throughout a patient life time to maximize health outcomes.

Communication about the patient's condition can be done using m medicine platform. This allows terminally ill patients or patients suffering from chronic illness can be at home in a supportive environment yet have supportive nursing with input from a doctor remotely.

5. E LEARNING:

A learning system based on formalized teaching but with the help of electronic resources is known as E learning. It can be termed as network enabled transfer of skills and knowledge and the delivery of education is made to a large number of recipient at the same or different times. This is learning conducted via electronic medica typically on the internet.

Learning is delivered online via internet ranging from distance education to computerized electronic learning, online learning, internet learning etc. Real life interaction can be done. Grading participation, assignments and tests can be done.

6. ROBOTIC MEDICINE:

A medical robot is used in medical sciences including surgery. They are tele manipulators which use a surgeon's actions on one side to control the effector on the other side. Surgical robots allow surgical operations to be carried out with greater precision than an unaided human surgeon or allow remote surgery where a human surgeon is not physically present with the patient.

Biorobots: These imitate cognition of animals and humans
Telepresence robots: Allow off site medical professionals to move look around and communicate and participate in patient care from remote locations.
Pharmacy automation: robotic systems dispense oral solids in a retail pharmacy setting or preparing sterile IV admixtures in a hospital pharmacy setting.
Companion Robot: has capability to engage emotionally with users to keep them company and alerting them if there is a problem with their health.

Disinfection Robot: These disinfect whole rooms using ultraviolet light and can be used in highly infectious epidemics.

7. M HEALTH

This is the use of Mobile phones and other wireless technology in medical care. The most common application is use of mobile devices to educate consumers in preventive healthcare services. It is used for disease surveillance, treatment support, epidemic outbreak tracking and chronic disease management.
It provides easy access to management advice to remote patients and a single medical resource can serve a large population. For consumers a major benefit of m medicine is convenience. Mobile technology allows users to continuously track and manage certain health data without having to see their healthcare provider. There is a plethora of apps available for various conditions. Issues of privacy and accuracy may be a disadvantage.

8. TELEMEDICINE:

This is remote diagnosis and management of patients by use of telecommunication technology. There is remote delivery of healthcare services such as health assessments or consultations over the telecommunication infrastructure.
There are three main types of telemedicine

1. Store and forward
2. Remote monitoring
3. Real time interactive services.

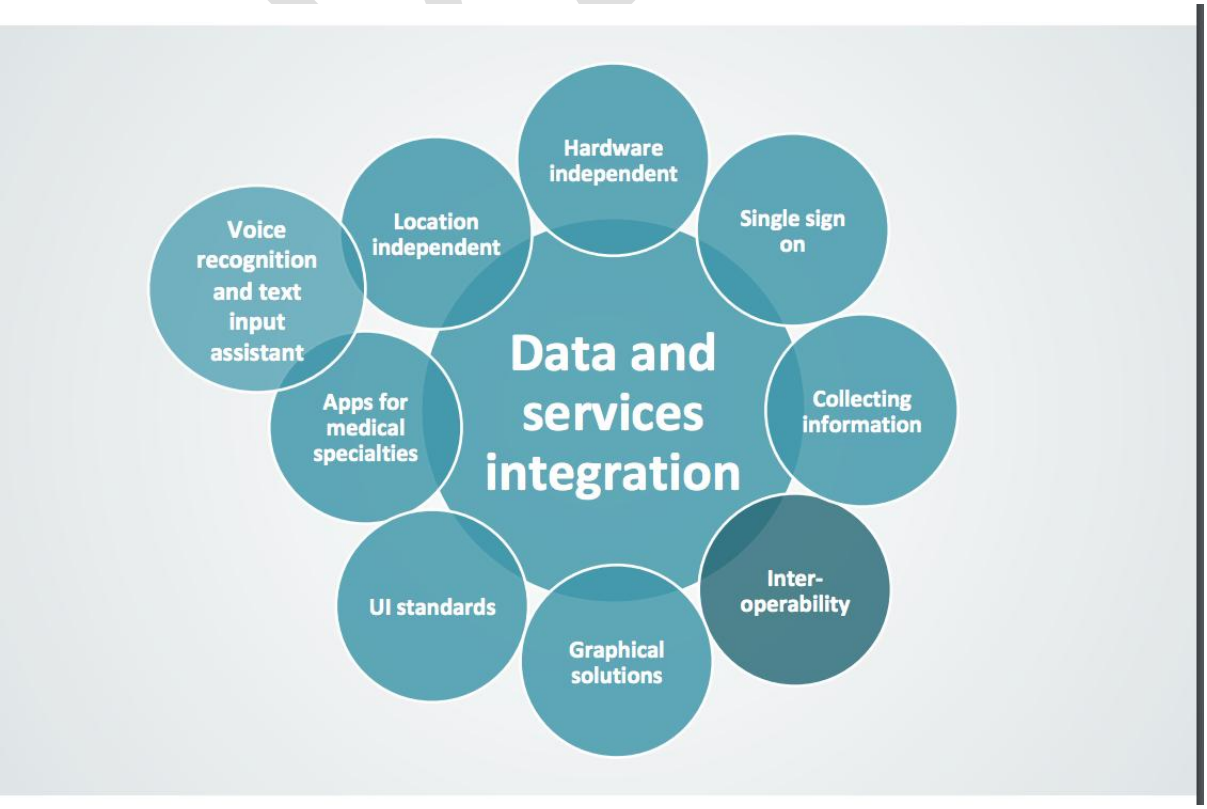
When utilized properly it can offer tangible benefits for both healthcare workers and patients.

The following are telemedicine platforms

1. Telepathology
2. Telecare
3. Tele-laboratory
4. Teleradiology
5. Telerehabiliation
6. Telesurgery
7. Teledentistry

The service aspect of all the above e health should be:

- **Usability**: fast and simple solutions
- **Implementation**: central training programs
- **Service update**: continuous feedback
- **Balance between security and usability**
    i. PIN for every document
    ii. PIN or ID-card



GUIDELINES ON THE REQUIREMENT OF E MEDICINE PLATFORMS

1.INTEROPERABILITY:

eHealth promotes interoperability standards for aligning strategic direction with business activities and technology enablement. Agencies should assure that enterprise architecture covering solutions conform to standards whenever possible.

Interoperable Applications: Application and Infrastructure to provide data interchange, consolidation and security for all medical data

There are various types of interoperability, categorized as follows:

1. Presentation Integration/Interoperability: - Used to describe a common look-and-feel approach for applications guiding the user to the underlying functionality of the set of application services. This is primarily the user experience sub-domain focusing on rich Internet applications, fat / thin-client applications etc. This layer of interoperability covers the non-physical channels that deliver services.

2. Operational or Business Interoperability: - Used to describe how business processes are to be shared. This is primarily the sub-domain for Business Process Management (BPM) and workflows.

3. Information Interoperability: - Used to define how information is to be shared. This is primarily be the sub-domain of semantics and common data dictionary.

4. Technical Interoperability: - Used to define how technical services are to be shared or connect to one another. This is primarily the sub-domain of message exchange protocols and mechanisms such as XML, web services and RMI (Remote Method Invocation) through the Enterprise Service Bus (ESB).

B) HEALTH INFORMATION EXCHANGE (HIE):

Health Information Exchange (HIE) allows health care professionals and patients to appropriately access and securely share a patient's medical information electronically. Proper HIE allows, Better patient care, Improved Efficiency, reduction of redundancies and Promotes universal healthcare through continuity and referrals.

eHealth and Health Information Systems should follow international data exchange standards, which include:

1.Clinical Terminology Standards: Systematized Nomenclature of Medicine (SNOMED) for point of care clinical work, International Classification of Diseases-10 (ICD-10) for administrative aggregate data, Logical Observation Identifiers Names and Codes (LOINC) for laboratories, RxNorm for pharmacies; and the current specified implementation guidelines for each of these. (RXNorm is a normalized naming system

for generic and branded drugs, and a tool for supporting semantic interoperation between drug terminologies and pharmacy knowledge base systems.

2. **Clinical Messaging Standards:** Health Level 7 (HL7) V 2.0 and above standards– e.g. Fast Healthcare Interoperability Resources (FHIR), and Digital Imaging and Communications in Medicine (DICOM)/Picture Archiving and Communication System (PACS) for imaging; and their respective current implementation guidelines

3. **Administrative and Document Standards:** The standards will indicate the type of information included in the document and the location of the information. Examples of document standards include the paper-based Subject Objective Assessment Protocol (SOAP) standard, and the HL7 derived standards –e.g., Clinical Document Architecture (Health Level 7 Clinical Document Architecture, abbreviated HL7 CDA) for electronic sharing of documents, the Continuation of Care Document (Health Level 7 Continuation of Care Document, abbreviated HL7 CCD), and the Discharge Summary (Health Level 7 Discharge Summary, abbreviated HL7 DS) – along with the current implementation guides for these standards.

To augment the above, it is recommended that the ministry/CCK specifically adopts the following **medical classification standards**:

1. **Classification of diagnoses**: ICD10. In addition, early adoption of ICD11 is encouraged and should be accepted by Health Insurance Providers for claims processing as soon as possible.
2. **Classification of procedures**: ICHI. To align ICHI with KMPDB procedure list.
3. **Classification for Laboratory tests, laboratory procedure and clinical evaluations**: LOINC
4. **Communication and management of medical Imaging:** DICOM
5. **Classification of Medications:** ATC Coding
6. **Classification of Commodities:** Develop master list based on KEMSA and MEDS
7. **Clinical Messaging Standards:** HL7 FHIR
8. **Unique identifiers for health providers:** MFL code with possible development of an industry-wide shared master-list with additional details such as geo-coding and branch relationships
9. **Unique identifiers for patients:** Identity Card(National ID card, Alien ID card or Passport), biometrics and if/when possible, Huduma Number

10. **Standard format for patient identification technology:** Standard Biometric solution adopted by the Ministry of Health (MOH) team driving the National Healthcare Information Technology (HCIT) program.

Additionally, it is imperative that we strengthen our National Registry: Creating a National Registry of approved Partners, Health Systems and Programs in line with the KHIE Integration Policy.

C) THE NATIONAL INTEGRATED REFERRAL SYSTEM:

A real-time integrated model that connects all points of care (Primary, Secondary and Tertiary points of care) to actualize efficiencies and controls of such a system.

National EMR and CPI: National level data structure of what an electronic medical record (EMR) should constitute; build around a National Central Patient Index (CPI).

D) THE KENYA UNIVERSAL HEALTHCARE (UHC) REFERENCE MODEL:

Adopting a framework that ensure interoperability between eHealth players and native hospital systems will accelerate achievement of a quality, accessible and affordable healthcare services. The country shall be promoting;

I) **Interoperable Applications:** Application and Infrastructure to provide data interchange, consolidation and security for all medical data.

II) **National EMR and CPI**: National level data structure of what a electronic medical record (EMR) should constitute; build around a National Central Patient Index (CPI).

III) **Common Secure Infrastructure:** A shared infrastructure that interconnects the various facilities, partners and initiatives

4. STANDARDS FOR INTEGRATED DATA REPOSITORIES

5. SHARED INFRASTRUCTURE: ECONOMIES OF SCALE IN EXECUTION

6. DATA CONFIDENTIALITY AND PROTECTION

7. SYSTEM SECURITY:

a. A secure authentication of all users with ID-card or Mobile ID or other identification
b. Digital signing or stamping of all medical documents

c. A maximum accountability (transparency):
d. All actions will leave an unchangeable (and unremovable) secure trail
e. Encrypted database that allows to remove the confidentiality risk from the technical administrators
f. Monitoring of all actions together with the corresponding countermeasures (both organizational and technical)

8. **E HEALTH INNOVATION AND COLLABORATION**: coordination of new and evolving solutions in e medicine

9. **COMPREHENSIVE PLANNING: PROCESSES, STANDARDS AND LEGISLATION.**

PROPOSAL ON REGULATION IMPLEMENTATION AND LISCENSING:

1. A facility or institution seeking registration to provide medical services through e-health, mhealth or telehealth as defined in this guideline will first have to be registered as a company or person at the registrar of companies/ business.
2. The virtual facility will be based in a recognised and registered health facility which will be ensure adherance to accepted evidence based clinical practises and standards of care.

3. Upon providing the registration certificate as an institution, the institution will apply for a compliance certificate, through the Ministry of Health, e-health department. The E-Health department will check on compliance of technology with MoH policies on E-Health. These will address issues of data privacy and security, interoperability of the system, data storage and system standards.

4. The virtual institution will then provide the following documents to the MPDC for licencing of the health institution:-
    a. Registration of institution certificate,
    b. Compliance certificate from MoH, E-health department,
    c. Registration certificates and licences of the medical director of the system by the MPDC,
    d. Registration certificates and licences of the medical personnel using the system from MPDC; if they are doctors and other regulatory bodies of the other Health Professional Bodies.
    e. Standard Operating Procedures copies to the MPDC.
    f. Internal Quality Controls with focus on patient safety.
    g. Prescribed registration and licensing fees as determined by the Council.

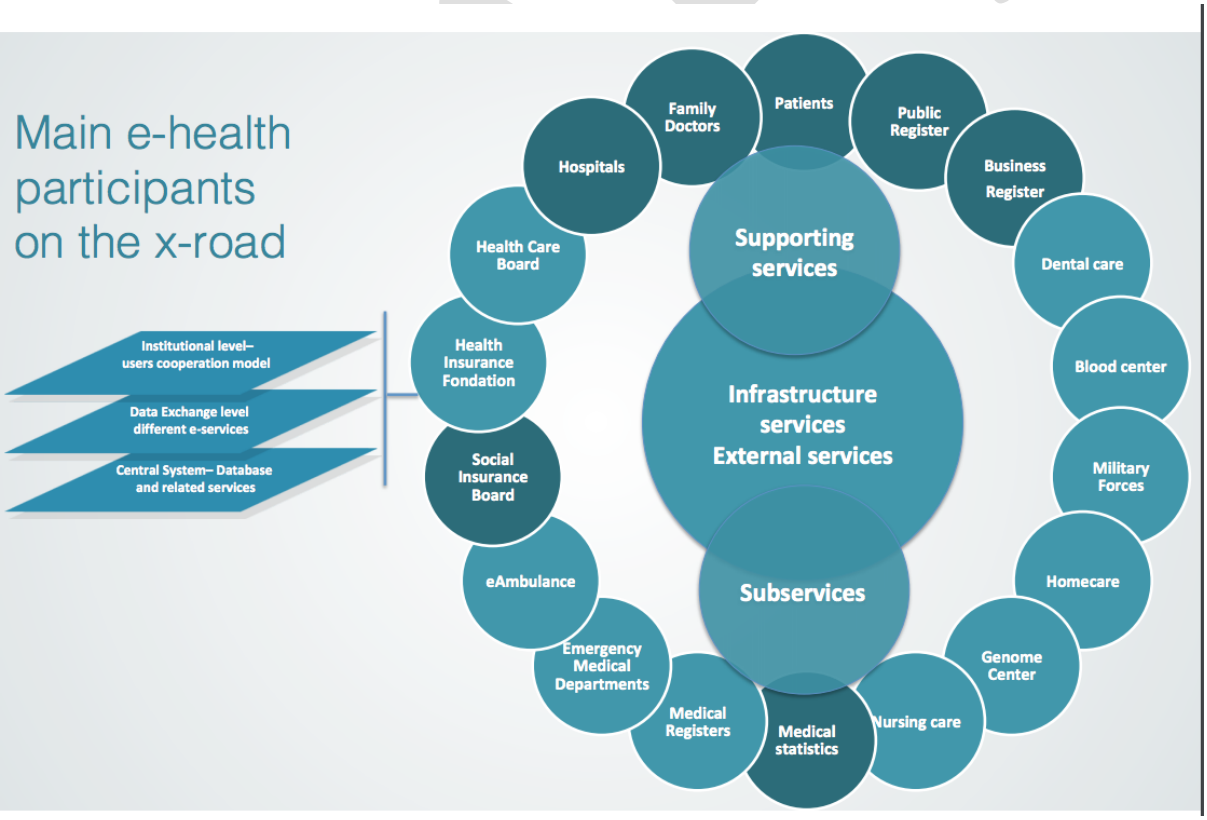
5. Fill in the application form as attached in the schedule showing:-
    a. Directors of the institution.
    b. Medical Director of the virtual institution.
    c. Names, qualification and licences of the Health Care Providers operating the system.
    d. Address and location of the registered office
    e. Data storage site of the institution.
    f. Any other information as determined by the MPDC.

6. Registration certificates and licences issued by the MPDC. Once the above requirements are met.
7. A virtual facility or institution seeking registration to provide medical services through e-health, mhealth or telehealth as defined in this guideline will first have to be registered as a company or person at the registrar of companies/ business.
8. Upon providing the registration certificate as an institution, the institution will apply for a compliance certificate, through the Ministry of Health, e-health department. The E-Health department will check on compliance of technology with MoH policies on E-Health. These will address issues of data privacy and security, interoperability of the system, data storage and system standards.
9. The virtual institution will then provide the following documents to the MPDC for licencing of the health institution:-
    a. Registration of institution certificate with CCK
    b. Compliance certificate from MoH, E-health department based on components above.
    c. Registration certificates and licences of the medical director of the system by the MPDC,
    d. Registration certificates and licences of the medical personnel using the system from MPDC; if they are doctors and other regulatory bodies of the other Health Professional Bodies; NCK, PPB, KLTTB, RPB etc.
    e. Standard Operating Procedures copies to the MPDC.
    f. Internal Quality Controls with focus on patient safety, confidentiality based on evidence based standards of clinical care.
    g. Prescribed registration and licensing fees as determined by the Council.

10. Fill in the application form as attached in the schedule showing:-
    a. Directors of the institution.
    b. Medical Director of the virtual institution.

c. Names, qualification and licences of the Health Care Providers operating the system.
d. Address and location of the registered office
e. Data storage site of the institution.
f. Any other information as determined by the MPDC.

11. Registration certificates and licences issued by the MPDC. Once the above requirements are met.
12. The institution will be subject to liscense renewal based on compliance with the MPDB and interval inspections to determine compliance.



Dr. Gladwell Gichuru
Chair

Date:

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Daniel M. Yumbya, MBS
Chief Executive Officer

August 2019