



**MEDICAL COUNCIL OF MALAWI**

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# **Regulations and Standards for Telehealth in Malawi**

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**FEBRUARY, 2026**

## Regulation Highlights Dashboard

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## Foreword

The rapid transformation of healthcare delivery in Malawi, driven by digital innovation and necessity, calls for deliberate regulation to safeguard quality, professionalism, and patient rights. The Medical Council of Malawi (MCM), in line with its legal mandate, has developed the **Regulations and Standards for Telehealth in Malawi** to guide the safe and ethical integration of technology into healthcare practice.

The practice of medicine is evolving beyond traditional physical settings. From live consultations to remote monitoring and diagnostics, telehealth offers tremendous potential to extend care to rural, remote, and underserved populations. Yet, with opportunity comes responsibility. It is the role of the MCM to ensure that all health services uphold the same standards of competence, accountability, and patient protection whether delivered in person or remotely.

This document provides the regulatory framework to govern telehealth services offered by medical, dental, and allied health practitioners, as well as health facilities across the country. It represents the Council's commitment to responsible regulation that embraces innovation without compromising patient safety or practitioner professionalism.

The Council commends all stakeholders including policymakers, practitioners, institutions, and the wider health community who contributed to the development of these regulations. Let this framework serve as both a safeguard and an enabler as Malawi strengthens its digital health future.



Dr Thandie Mabedi

**Chairperson, Medical Council of Malawi**

## Preface

In recent years, particularly in the wake of the COVID-19 pandemic, the landscape of healthcare delivery globally including in Malawi has changed dramatically. Increased connectivity, technological advancement, and demand for flexible service models have driven the rise of **telehealth**, an essential development that enhances access to care across geographic and socioeconomic barriers.

This evolution, however, has outpaced traditional models of regulation. The MCM, recognising its responsibility to protect the public and guide the professions, has developed the **Regulations and Standards for Telehealth in Malawi** to ensure that this mode of service delivery meets established ethical, legal, and clinical expectations.

These regulations are informed by the Medical Practitioners and Dentists Act, the Code of Ethics and Professional Conduct, relevant policies, regulations and laws. They are designed not to hinder innovation but to support its ethical and effective use. The regulations set out clear standards and procedures to promote patient safety, professional accountability, and equitable access to telehealth services both locally and in cross-border contexts.

This document should be read and applied by all licensed practitioners, health facilities, and training institutions involved in the provision or support of telehealth services. It is our collective responsibility to ensure that digital transformation in healthcare is inclusive, safe, and aligned with Malawi's health goals.



Dr Davie B.S Zolowere  
**Registrar and Chief Executive Officer**

## List of Abbreviations and Acronyms

AI	Artificial Intelligence
CEPC	Code of Ethics and Professional Conduct
CPD	Continuous Professional Development
DC	District Commissioner
ECFMG	Education Commission for Foreign Medical Graduates
EMR	Electronic Medical Record
ICT	Information Communication and Technology
IRC	Inspections and Registrations Committee
MCM	Medical Council of Malawi
MPDA	Medical Practitioners and Dentists Act
NDA	Non-Disclosure Agreement
NGORA	Non-Governmental Organisations Regulatory Authority
PMRA	Pharmacy and Medicines Regulatory Authority
SOP	Standard Operating Procedures
SSL	Secure Sockets Layer
UPS	Uninterruptible Power Supply
WSI	Whole slide imaging

## Definition of Terms

- **Asynchronous Telehealth (Store-and-Forward):** Transmission of recorded health information (e.g., images, test results) for later review by a provider.
- **Digital Pathology:** The use of digital imaging and telecommunications technology to facilitate the capture, sharing, transfer and/or storage of image-rich pathology data, and related data for the purposes of diagnosis, education, quality assurance and research.
- **Licensed Health Practitioner:** An individual registered and licensed by the Medical Council of Malawi to provide health services under a regulated profession.
- **mHealth (mobile health):** The use of mobile technologies (e.g., phones, tablets, apps) to support healthcare delivery and patient self-care.
- **Remote Monitoring:** The use of digital devices to collect and transmit patient health data to healthcare professionals for ongoing assessment.
- **Synchronous Telehealth:** Real-time interactions between a patient and provider (e.g., live video or audio consultations).
- **Telehealth:** The use of information and communication technologies to deliver healthcare services, health education, and health-related information remotely.
- **Telemedicine:** A subset of telehealth focused on the remote diagnosis and treatment of patients by healthcare professionals.
- **Teleassessment:** This refers to remote evaluation of patients' health status using digital technologies such as video conferencing, telephone calls or web-based tools enabling clinicians to gather important information, make clinical decisions and plan interventions.
- **Tele-diagnosis:** an essential component of telehealth that involves diagnosing patients' health condition remotely through sending and analysing digital images, reviewing remote monitoring data and using Artificial Intelligence (AI) enabled tools to interpret tests or images.
- **Tele-interaction or synchronous telehealth:** real time communication between healthcare providers and patients or between providers using technology.
- **Tele-monitoring:** involves tracking of patient's health status outside the clinic or hospital often in real time or near real time. data collected include chronic disease markers, vital signs and other metrics.
- **Telepathology:** The practice of digital pathology, in which the pathologist views digitized or analog video or still images, and renders an interpretation that is included in a formal diagnostic report or documented in the patient record.
- **Whole slide imaging (WSI)** is a relatively new technology that allows the digitisation of an entire glass slide, producing a digital image for review.

# 1.0 Introduction

## 1.1 The Mandate of Medical Council of Malawi

The Medical Council of Malawi (MCM) is a statutory body established under the Medical Practitioners and Dentists (MPD) Act of 1987 (Cap 36:01), mandated to regulate the training, practice, professional conduct, and registration of medical practitioners, dental surgeons, and allied health professionals. The MCM is also responsible for the registration and regulation of health facilities in Malawi.

As healthcare delivery evolves with the integration of digital technologies, MCM's mandate extends to ensuring that telehealth practices including remote consultations, diagnostics, monitoring, and digital health services adhere to professional, ethical, and clinical standards that protect the safety and rights of patients.

## 1.2 Regulations Rationale

In recent years, and particularly accelerated by the COVID-19 pandemic and advances in technology and internet connectivity, there has been a notable increase in the use of telehealth in Malawi. Healthcare providers are using digital platforms to deliver services across geographic boundaries, enabling greater access to care, particularly in rural and underserved areas. Apart from within country telehealth, there has also been global telehealth where healthcare providers located outside of Malawi provide services to patients residing in Malawi.

However, the rapid expansion of telehealth has outpaced the development of formal regulatory mechanisms to ensure:

- i. Patient safety and confidentiality.
- ii. Quality and continuity of care.
- iii. Accountability for professional conduct in virtual environments.
- iv. Compliance with ethical and legal obligations.
- v. Standardisation across health facilities and providers.

Without clear regulations and standards, there is a risk of variability in care, misuse of technology, professional misconduct, and erosion of patient trust. These regulations and guidelines are therefore essential to guide the safe, ethical, and effective provision of telehealth services in Malawi.

## 1.3 Citation and Application

This document shall be known and referred to as the Regulations and Standards for Telehealth in Malawi.

The standards and regulatory provisions apply to:

- i. All registered and licensed practitioners, health facilities and training institutions under the MPD Act;
- ii. Third-party telehealth service providers or platforms that partner with or support licensed practitioners or health facilities;
- iii. Cross-border teleconsultations, where the patient is in Malawi and the practitioner is based outside the country.

Practitioners and institutions offering telehealth services must comply with these regulations in addition to existing professional, ethical, and legal standards applicable to in-person care.

## 1.4 Goal of the Regulations and Standards

To provide a comprehensive regulatory framework that governs the delivery of telehealth services in Malawi, ensuring that such services meet established standards of professional conduct, service quality, data protection, and patient-centered care, as required under MCM's mandate.

## 1.5 Objectives

The specific objectives of these Regulations and Standards are to:

- i. Define the scope and acceptable practices of telehealth for medical, dental, and allied health practitioners.
- ii. Ensure ethical and professional accountability in telehealth service delivery.
- iii. Establish licensing and accreditation criteria for health practitioners and facilities providing telehealth services.
- iv. Protect patient rights, including informed consent, confidentiality, and access to in-person care when necessary.
- v. Promote equitable access to telehealth, especially for underserved populations.
- vi. Align telehealth practices with national health policies, including digital health and universal health coverage goals.

## 1.6 Outcomes of the Regulations and Standards

The implementation of these regulations and standards is expected to achieve the following outcomes:

- i. Improved access to healthcare services across Malawi, including rural and remote areas.
- ii. Increased confidence in telehealth by both patients and healthcare providers.
- iii. Reduced risk of harm or malpractice in virtual care settings.
- iv. Standardised practices across public and private health sectors.
- v. Strengthened oversight and enforcement by the MCM.
- vi. Integration of telehealth into the health systems in a safe, sustainable, and ethical manner

## 2.0 Legal Framework for the Telehealth Regulations and Standards

The MPD Act empowers the MCM to regulate the training, registration, and professional conduct of medical, dental, and allied health practitioners in Malawi. This mandate includes the responsibility to set and enforce professional standards, ensure ethical compliance, and safeguard public health.

As the use of telehealth expands across the country, the MCM's regulatory authority extends to healthcare services delivered through digital and remote platforms. MCM is therefore legally empowered to oversee telehealth in the same manner as conventional healthcare delivery, ensuring that practitioners maintain the highest standards of ethical and professional conduct, regardless of the mode of service delivery.

MCM's regulatory framework is informed by the MPD Act, the Code of Ethics and Professional Conduct (CEPC), and other relevant national laws (Public Health Act, Data Protection Act, Access to Information Act, Communications Act, Electronic Transactions, Cybersecurity Act, Malawi Bureau of Standards Act etc.), regulations and health sector policies. These instruments collectively require that all healthcare services—whether provided in person or virtually be safe, ethical, and patient-centered.

Through these Regulations and Standards for Telehealth, the MCM seeks to provide clear guidance to practitioners and institutions while protecting the public. This framework affirms MCM's commitment to responsible innovation in healthcare, ensuring that telehealth is used to expand access without compromising quality or accountability.

## 3.0 Regulations and Guidelines for Telehealth

The MCM is mandated to regulate healthcare provision by ensuring that healthcare services are provided by qualified, skilled, and competent healthcare practitioners. The requirements for telehealth focus on three categories namely: general requirements applicable to telehealth services as a whole; procedural requirements relevant for the interaction between patient and the practitioner itself; and specific requirements which relate to particular applications of telehealth. In general, these requirements seek to ensure that telehealth replicates as far as possible traditional face-to-face care by ensuring that standard of care is provided.

### 3.1 Types of Telehealth

Below is a minimum list of Telehealth that may be provided by MCM licensed practitioner, MCM certified facilities after meeting the minimum standards:

- i. Teleradiology
- ii. Telepathology
- iii. Telemedicine
- iv. Telepsychology
- v. Telesurgery
- vi. Telepsychiatry
- vii. Teledermatology
- viii. Telerehabilitation
- ix. Telenutrition

The model of delivery for telehealth services can be supported by a combination of physical tasks and virtual tasks, like assessment, diagnosis, interactions, monitoring treatment.

### 3.2 Requirements for Conducting Telehealth Services

#### 3.2.1. Premises Requirements/Physical Infrastructure

- i. The facility seeking to provide telehealth services must comply with MCM laws and regulations and be licensed by MCM
- ii. The provision of telehealth services shall only be offered through an MCM licensed telehealth facility or MCM licensed standalone telehealth platform. Telehealth services shall be practitioner led.
- iii. The location where the patient/client access telehealth services must have adequate lighting, a power source and acoustics.
- iv. Practitioners shall implement Standard Operating Procedures (SOPs) governing telehealth services.
- v. Health facilities providing telehealth services that establish collaborative partnerships shall be

aware of applicable legal and regulatory requirements for appropriate written agreements, memorandum of understanding, or contracts. Those contracts, agreements shall be based on the scope and application of the telehealth services offered, and shall address all applicable administrative, clinical, and technical requirements.

- vi. Health facilities shall have infection control policies and procedures in place for the use of telehealth equipment and patient peripherals that comply with MCM requirements.
- vii. Health facilities must have in place an electronic medical record (EMR) system that guarantees patient identification, authentication, collection of safe, secure, and comprehensive patient information during the provision of telehealth services, including voice recording for quality control and quality improvement.
- viii. Health facilities providing telehealth services should ensure their services are effective, safe and of high quality to meet the needs of patients.
- ix. Practitioners must ensure complete documentation of information and communication in accordance with the laws and regulations of Malawi.
- x. Facility must comply with patient privacy, consent, confidentiality, protection, and security of data.

### 3.2.2 ICT Infrastructure

Telemedicine can be conducted in real time or retrospective. Real-time telemedicine involves live, two-way communication between a patient and provider, typically through video or audio calls. Retrospective or store-and-forward telemedicine, on the other hand, involves transmitting medical data, such as images or records, for later review by a practitioner. The basic Information Communication and Technology (ICT) technologies to enable Real time or retrospective telemedicine must comprise the following at a minimum:

The following must be present at the location of the patient/client:

- i. **Communication technologies:** Reliable connectivity and messaging tools to enable flow of information between the location of the patient and the location of the practitioner.
- ii. **Imaging and audio tools:** High resolution imaging devices and audio devices to enable video conferencing between the client and practitioner locations. In store-and-forward or retrospective telehealth the imaging devices and audio devices will enable recording and compilation of images and audio for forwarding to the practitioner.
- iii. **Software platform:** Software solutions that facilitate and document the service activities such as scheduling appointments and conducting video consultations to managing prescriptions and tracking health data.
- iv. **Power backup solution:** Either Generators, Solar power or Uninterruptible Power Supply (UPS) power backup systems should be available for a reliable and uninterrupted telehealth service.

- v. **Security:** All technologies should incorporate data protection measures such as firewall and antivirus software, secure login protocols (2FA), and encryption. e.g. Secure Sockets Layer (SSL). The telehealth service should comply with the Malawi's Data Protection Act.

The following must be present at the location of the practitioner:

- i. **Communication technologies:** Reliable connectivity and messaging tools to enable flow of information between the location of the patient and the location of the practitioner.
- ii. **Imaging and audio tools:** High resolution imaging devices and audio devices to enable video conferencing between the client and practitioner locations. In store-and-forward or retrospective telehealth the imaging devices and audio devices will enable viewing of images and listening to audio information forwarded from patient/client.
- iii. **Software platform:** Software solutions that facilitate and document the service activities such as scheduling appointments and conducting consultations to managing prescriptions and tracking health data.
- iv. **Power backup solution:** Generators, Solar power or UPS power backup systems should be available at the facility for a reliable and uninterrupted telemedicine service.
- v. **Security:** All technologies should incorporate data protection measures such as firewall and antivirus software, secure login protocols (2FA), and encryption. e.g. SSL. The telehealth facility should follow Malawi's Data Protection Act.

### 3.2.3 Equipment, Materials and Supplies

The delivery of telehealth services requires the use of other equipment, materials and supplies. Emerging technologies are supporting telehealth due to advances in technologies. The following equipment's, materials and supplies can be used:

- i. **Wearable Devices:**
  - a. Examples include Fitbit, smartwatches, and other wearable devices that track activity and vital signs.
  - b. Informed consent must be solicited for Provider issued wearable devices.
  - c. Providers must engage continuous monitoring for early detection and addressing of adverse effects such as skin irritation and indentation.
  - d. Wearable devices must be approved by national regulators like the Pharmacy and Medicines Regulatory Authority (PMRA), or international regulatory bodies.
- ii. **Remote Patient Monitoring devices:**
  - a. Includes scales, blood pressure monitors, glucometers, and other devices that transmit vital signs remotely.
  - b. Devices should meet minimum standards provided by Malawi Bureau of Standards and other international or regional independent quality assurance standards.

### 3.2.4 Human Resources for telehealth

Refers to the personnel and workforce involved in delivering telehealth care services remotely through digital platforms.

- i. Telehealth practitioners: These are practitioners that are licensed by the MCM and other relevant health regulators. Minimum requirements for practicing telehealth mirror those required to operate a private practice.
- ii. All practitioners providing private telehealth services must obtain a private license from the medical council of Malawi.
- iii. Qualifications and titles: A practitioner must declare their Qualifications when providing telemedicine.
- iv. All practitioners must undertake continuous professional development (CPD) that includes activities related to telehealth.
- v. The facility shall accommodate periodic internal and external quality assurance assessments.
- vi. A practitioner must not make claims about their qualifications, experience or expertise that could mislead patients by implying the practitioner is more skilled or more experienced than is the case. This will be a breach of ethical conduct.

### Supporting services

Support services are essential services that ensure both patients and providers use telemedicine services effectively and get the most out of their virtual experiences. details of some key support services are as follows:

- i. Help Desk: provides assistance with login issues, connectivity problems, or software glitches.
- ii. Clinical support: Assist patients in preparing for telehealth visits, reviewing symptoms and explaining what to expect during the appointment and remote monitoring of patients.
- iii. Technical support and maintenance (on-site or remote): IT personnel that will support every technical aspect at the facility e.g. system maintenance schedule, Backup data (on-premise server or cloud server), updates.

## 3.3 Specific guidelines for performing Telehealth

### 3.3.1 Assessment of patient suitability

Telehealth should only be offered where it is ethically appropriate without endangering patients' lives. Both the practitioner and the patient must meet specific requirements to ensure that any telehealth service offered is deemed appropriate and safe.

### 3.3.1.1 Practitioner's considerations

- i. Practitioners must operate strictly within their licensed scope of practice and professional competence, regardless of the telehealth modality.
- ii. The responsibility for determining the appropriateness of any telehealth service lies with a licensed health practitioner.
- iii. Every health practitioner should evaluate each patient individually and justify the necessity of the service, prioritising the patient's safety before proceeding.
- iv. The quality and safety of care provided via telehealth must be equivalent to, or not fall below, the standard of care expected in an in-person consultation for the same condition.
- v. Ability to determine when and how to discontinue telemedicine services and refer a client/patient for in-person-care.
- vi. Second Opinion via teleconsultation:
  - a. Where a need arises, a primary healthcare provider may consult another practitioner via telecommunication methods, typically through video conferencing, secure messaging, or online medical platforms if this is for the purpose of confirming a diagnosis, clarifying treatment options, or seeking expert advice on complex conditions.
  - b. Patient cases requiring high-risk and highly invasive procedures should be reserved for in-patient/face-to-face care, to reduce harm done to patients and the responsibility to determine so lies within the correct determination of the telehealth provider.
  - c. Refer to the section on Privacy and confidentiality for more information.

### 3.3.1.2 Patient's/Client's Consideration

The following are key considerations that a practitioner should critically assess for each patient:

- i. Patient's capacity to participate in telehealth:
  - a. Consider the patient's cognitive and sensory deficits.
  - b. Criticalness of patient's condition (urgent vs non-urgent conditions).
  - c. Patient's technical expertise to operate the required technology and troubleshoot any issues during a telehealth session.
- ii. Client's/patient's clinical needs and whether they can be assessed remotely
  - a. Telehealth shall be deemed appropriate if offered to stable patients whose condition is not worsening and not requiring acute/emergency care.
- iii. Patient's safety and efficacy of telehealth
  - a. Telehealth should be provided in situations where a patient's safety is not compromised and where the patient receives adequate support, similar to what would be offered during an in-person consultation.

- iv. Rapport and therapeutic consideration
  - a. Determine whether a therapeutic relationship can be established and maintained remotely.
- v. Cost and financial consideration
  - a. Where necessary, a practitioner should assess whether there are any financial barriers to accessing telehealth services such as lack of insurance coverage or exorbitant costs

**NB:** Patients who do not meet all of these criteria should be considered unsuitable for telehealth services. A healthcare provider should therefore immediately refer all such patients for inpatient care at their nearest or preferred health facility.

### 3.3.2 Patient consultation type and timing

- i. The practitioner must establish a provider-patient relationship and inform the patient on the mode of communication and the real-time nature of the interaction. i.e.
  - a. **Video Consultation:** The practitioner must specify conditions or situations where video consultations are deemed clinically appropriate and list scenarios where an in-person visit is mandatory.
  - b. **Audio-only Consultations (Phone Calls):** A practitioner shall engage in live, two-way voice communication exclusively with a patient.
  - c. **Real-time Text-based Communication:** A practitioner shall conduct live, two-way communication primarily through written text.
  - d. **Store-and-forward (asynchronous):** A practitioner utilising this modality shall facilitate the transmission of medical data from a patient to the practitioner, or from another healthcare provider to the practitioner.
- ii. Practitioners engaged in telehealth shall provide timely and effective care to their patients, ensuring that the modality of delivery does not compromise the quality or safety of the medical intervention. Practitioners must consider the nature of the consultation and available scheduling options:
  - a. **Pre-booked Appointments:** This allows the practitioner to efficiently allocate the practice resources, adequate preparation time for both the practitioner and the patient, and ensures a structured approach to non-urgent care.
  - b. **On-demand/Urgent Consultations:** Practitioners may offer telehealth services for urgent conditions suitable for immediate advice.
- iii. Practitioners should ensure that there is sufficient time for assessment, patient education, and addressing concerns, while also managing provider workload.

### 3.3.3 Telehealth service provision

- i. Practitioners involved in telehealth are expected to be proficient in the use of telehealth technologies and understand their technical capabilities and limitations.
- ii. Practitioners must hold a valid, current license from the MCM.
- iii. Cross-border Practice: External practitioners must be licensed by both their country's regulatory body and the MCM.
- iv. Clinical decisions must adhere to established national clinical guidelines and professional best practices.
- v. Practitioners must fully comply with provisions of regulations regarding informed consent, data security, data breaches, and patient's rights.
- vi. Prescribing medications via telehealth must follow the same legal and professional standards as in-person prescribing, ensuring a thorough assessment and clinical appropriateness.
- vii. Practitioners shall only prescribe medications when sufficient clinical information has been gathered to make a safe and informed decision.
- viii. Practitioners must establish clear pathways for referring patients to other healthcare providers, specialists, or for in-person follow-up when necessary.

### 3.3.4 Documentation of services

All telehealth consultations must be thoroughly documented in the patient's medical record, adhering to the same standards as in-person visits. This includes:

- i. Date, time, and duration of the consultation
- ii. Type of consultation (e.g., video telehealth, audio-only call, secure text chat)
- iii. Identity of the practitioner and patient
- iv. Presenting complaint, relevant history, clinical assessment (including limitations due to modality), diagnosis, treatment plan, and follow-up instructions
- v. Any technical issues encountered during the consultation
- vi. Rationale for any referrals

Practitioners should aim for seamless integration of telehealth documentation into existing or developing EMR systems to ensure continuity of care.

## 3.4 Ethical conduct and professionalism in Telehealth

### 3.4.1 Privacy and Confidentiality

Telehealth Practitioners must ensure that their service provision aligns with the MCM Code of Ethics and Professional Conduct, including protecting patient confidentiality and adhering to privacy laws and regulations in Malawi.

- i. Principles of medical ethics, including professional norms for informed consent, standard of care, protecting patient privacy and confidentiality shall be binding and must be upheld and practiced.
- ii. Telehealth Practitioners would be required to fully abide by the relevant provisions of the Malawi Data Protection Act, e-Transactions and Cybersecurity Act, Access to Information Act, Malawi constitution or any applicable rules notified from time to time for protecting patient privacy and confidentiality and regarding the handling and transfer of such personal information regarding the patient.
- iii. Telehealth Practitioners must ensure both privacy and confidentiality of all patient information. Access to this information should only be limited to those directly involved in patient's management.
  - a. Where a practitioner intends to share any patient's information or images for the purpose of obtaining a second opinion from other health professionals, the practitioner must de-identify the information or images to protect the patient's privacy.
  - b. The practitioner shall be responsible for using platforms that are safe when sharing patient information with other practitioners.
- iv. Telehealth Practitioners will not be held responsible for breach of confidentiality if there is reasonable evidence to believe that a patient's privacy and confidentiality has been compromised beyond their control, by a technology breach or by a person other than the practitioner.

### 3.4.2 Informed consent for Telehealth Services

Obtaining informed consent is an ethical and legal obligation of practitioners registered by the MCM. The Telehealth Practitioner must take reasonable steps to ensure that the patient understands the information provided such as the scope of the services to be provided and the types of transmissions consented to using Telehealth technologies (e.g., prescriptions, refills, appointment scheduling, patient education etc.). Patients should be made aware of how their personal data will be used, stored, and or shared with other platforms. Consent must be documented within health records to demonstrate compliance with privacy and ethical standards. (CEPC,2022.)

#### Informed Consent process

The consent must be appropriately documented and the following should therefore be taken into consideration:

- i. Informed consent for the use of Telehealth can be obtained in writing or recorded orally. If an oral consent has been given, the provider should document the same in the patients' records.
- ii. Informed consent documentation for Telehealth practice should include the following;
  - a. The identities of the patient and the servicing healthcare practitioner (including the healthcare practitioner's practice number).
  - b. Agreement by the patient or their substitute decision maker that the practitioner is to decide appropriateness for a Telehealth consultation. If there is no consensus, the servicing practitioner in charge must ensure that face to face consultation is conducted.
  - c. Details of the security measures taken with the use of Telehealth technologies, such as encrypting data, password protected screen savers and data files, or the use of other reliable authentication techniques. The secure storage of any recordings of the consultations should be included in the statement.
  - d. Any material risks to confidentiality arising from the use of Telehealth technologies that may influence the patient's decision to consent.
- iii. When Telehealth is used, the patient should be informed regarding who will access their information, the purpose of the Telehealth service, the cost of the service and what the implications of the use of such information will be.
- iv. A copy of the informed consent form should be kept with the patient's records and a duplicate given to the patient, when required.
- v. The processes of informed consent above should also be applied when photographs and videos are to be taken during telehealth service provision.
- vi. Patients can withdraw their consent at any point during the Telehealth service provision.

### **3.5 Patient Management in Telehealth**

Telehealth facilitates effective patient management by enabling timely, accessible, and continuous care through digital platforms. It supports clinical decision-making, enhances patient engagement, and improves healthcare delivery across diverse settings. The practitioner who performs or renders the service should adhere to the following:

- i. The practitioner utilising telehealth must be registered with MCM and is responsible for patient safety and well-being while utilising the digital platforms.
- ii. The Practitioner should adhere to the CEPC during telehealth patient management
- iii. The practitioner must remain available for the whole session to provide care or attend to the patient according to clinical practice guidelines. If unavailable, they must establish formal, prearranged alternative care plans, including appointing a suitably MCM registered practitioner. These arrangements must be documented and clearly communicated to the patient and any other involved healthcare providers.

- iv. The practitioner and patient should be familiar and comfortable with the technology used during telehealth service provision sessions.

### **3.6 Telehealth Medical Records Management**

All medical records generated during telehealth and in the course of patient management must be accurately documented, securely stored, and managed in accordance with the CEPC of 2022, and compliance with the Access to Information Act of 2016 and Data Protection Act of 2024. The practitioner should adhere to the following:

- i. Record all patient interactions, assessments, diagnoses, and treatment plans clearly and thoroughly.
- ii. Ensure that medical records are stored and transmitted securely to comply with CEPC.
- iii. Follow all applicable laws, regulations, and professional guidelines related to medical record keeping.
- iv. Update records promptly after each telehealth service provision.
- v. Ensure records are accessible to consented guardians, practitioners, and patients as appropriate.
- vi. Retain telehealth medical records for the legally required period according to the relevant laws like the Data Protection Act of 2024 or Access to Information Act. Medical records are expected to be kept for 4 years, after which they can be archived for up to 7 years.
- vii. Clearly verify patient identity and shared patient information, including medical images and verification methods used.
- viii. Keep recorded informed consent specific to telehealth services.
- ix. Use secure, encrypted systems for storing and sharing medical records.
- x. Maintain an audit trail for record access, modifications, and disclosures.

### **3.7 Advertising and marketing for Telehealth**

- i. Advertising material, including practice and practitioner websites and social media, must comply with the CEPC, which serves as a valuable guide when promoting these services.
- ii. Advertising should not glamorise telehealth services to imply that they can achieve outcomes that are not realistic.

### **3.8 Handling of Telehealth Complaints**

- i. Patients who are dissatisfied have the right to make a complaint. The practitioner must provide all patients with information before utilising telehealth facilities.
- ii. Raising and resolving the complaint directly with the practitioner who provided the

service.

- iii. Patients shall be encouraged to make complaints at the facility or to the MCM.
- iv. Practitioners must ensure any non-disclosure agreement (NDA) they use makes clear that a patient, or a person on behalf of the patient, can still make a complaint to MCM or the Office of the Hospital Ombudsman.

### **3.9 Telehealth Complications management**

- i. The practitioner must document all complications arising from remote patient management.
- ii. The practitioner must communicate all complications to all relevant healthcare team members involved in the patient's management.
- iii. The practitioner is responsible for coordinating care and referrals to in-person healthcare services when necessary and ensuring seamless transitions of care.
- iv. Practitioners must prioritize patient safety and well-being in the event of complications.
- v. Clear protocols for managing complications must be available and implemented to ensure accountability and continuity of care.

## 4.0 Implementation Arrangement

The Regulations identified various stakeholders who have crucial roles in Telehealth services. Their respective roles shall be as follows:

### 4.1 Registrar and Chief Executive Officer

The Registrar is responsible for providing overall leadership in the implementation of the regulations and standards. Specifically, the Registrar or his/her designate shall:

- i. Lead all secretariat responsibilities in the implementation of these regulations.
- ii. Receive and process applications from practitioners and institutions.
- iii. Institute inspection team for telehealth assessment.
- iv. Review reports from the inspection team.
- v. Serve as the Secretary to the Inspections and Registrations Committee (IRC) and Council.
- vi. Publish outcomes for the registered practitioners and premises, consistent with the MPD Act.
- vii. Safely store applications, assessment reports, certificates and all critical documents.
- viii. Manage a database of applications from time to time.
- ix. Monitor implementation of the practice, consistent with the MPD Act.
- x. Analyze the MCM completed applications and assessments to inform regulations review.
- xi. Perform any other duties as delegated by the IRC and Council consistent with the MPD Act.

### 4.2 The Inspection and Registration Committee

The specific roles and responsibilities of the IRC shall be as follows:

- i. Attend the IRC meetings.
- ii. Receive and review committee meeting packs.
- iii. Actively participate and vote in proceedings of the IRC meetings including those for Telehealth.
- iv. Adhere to the procedures and Code of Conduct of IRC meetings.
- v. Be knowledgeable of the MPD Act

### 4.3 The Council

The Council shall be responsible for policy direction on issues related to the administration of

Regulations and Standards for Telehealth. The specific roles and responsibilities shall be as follows:

- i. Attend Council meetings.
- ii. Appoint the Registrar and CEO, management of the MCM, and permanent members of the IRC. The permanent members of the Registration and Inspections Committee shall be appointed for three consecutive years. The term of office shall correspond to the duration of the Council appointment.
- iii. Review and approve recommendations of the IRC for further processing by the Secretariat.
- iv. Approve Policies and Procedures of the IRC consistent with the MPD Act.

## 4.4 Practitioners and Health Facilities

The specific roles and responsibilities of practitioners and health facilities shall be as follows:

- i. Familiarise themselves with these Regulations and Guidelines, MPD Act, CEPC and other relevant regulations and rules.
- ii. Submit adequate and all relevant and complete documents in support of their applications; See Appendix 1, 2,3 and 4.
- iii. Provide honest and complete details to the inspections team.
- iv. Address any critical recommendations from the inspections reports before commencing services.
- v. Provide contact details through which they can be contacted.

## 5.0 Monitoring, Evaluation and Review

### 5.1 Monitoring

Monitoring shall ensure that these Regulations and Standards are effectively implemented and remain aligned with the MCM's objectives. The Registrar and CEO shall have overall responsibility for monitoring the implementation of this Regulation by;

- i. Collecting data for monitoring and evaluation of necessary processes.
- ii. Periodically convening meetings to monitor and evaluate the effects of the Regulations.
- iii. Gathering feedback from various stakeholders to assess their satisfaction with administration of cosmetic and aesthetic procedures.

## 5.2 Regulations Evaluation and Review

It is the MCM's intention to periodically review the Regulations to accommodate changing realities. Therefore, the Regulations shall be reviewed if significant changes have been observed in the practice of telehealth.

## 6.0 List of Appendices

### Appendix 1: MCM Practitioner application requirements and eligibility

It is the responsibility of the applicant to ensure that requirements for registration are complied with. The application requirements include:

- i. Complete MCM application and statutory declaration form (electronic or hard copy).
- ii. A duly commissioned statutory declaration form by a lawyer, district commissioner (DC) or magistrate.
- i. Legible certified copies of original Degrees, Diplomas, and Certificates must be attached to the application form. MCM may require legible certified copies of academic transcript issued by a university.
- ii. MCM may request for verification of the documents of credentials by the Education Commission for Foreign Medical Graduates (ECFMG) and other independent local and international credential verifiers. These credential verifying services have to be obtained at the applicant's own cost. Where MCM determines the need to have this verification, and the candidates fail to meet this requirement they will not be permitted to proceed with the application.
- iii. Certified copy of highest secondary school education certificate or its  
  - i. equivalent.
- iv. Sworn translated copies in English must be attached if the documents are in other languages, not in English.
- v. Two passport size photos.
- vi. Personal curriculum vitae.
- vii. Proof of adequate knowledge of the English Language where the candidate obtained their qualifications in any other language except English. The proof may include ability to communicate fluently in English or may submit certificate of English proficiency testing.
- viii. A copy of valid passport or identity document.
- ix. Relevant application fees must be paid.

Note that in addition to the above minimum requirements, MCM may request the applicant to submit additional documents as it sees fit.

## Appendix 2: Telehealth facility application requirements for Individuals

- i. Complete MCM private practice application form (electronic or physical).
- ii. Those who are to indulge in a private practice should be in good standing with the MCM (not under MCM disciplinary or conduct sanctions and up to date in paying renewal and other fees)
- iii. Letter of consent from their employer if they are still employed. Alternatively, resignation letter from their employer if they have resigned, or Retirement letter from their former employer, if they retired, or End of contract document for those who were previously on contract.
- iv. Request for initial inspection when the clinic /Hospital is ready for inspection (has fulfilled the minimum requirements).
- v. Pay relevant fees (application and registration and inspection related costs) as prescribed by MCM.

## Appendix 3: Facility application requirements for Corporate Organisations

- i. Write and submit a letter of intent addressed to the MCM Registrar clearly indicating the types of Telehealth services to be offered.
- ii. Attach certificate of incorporation or registration certificate from Non-Governmental Organisations Regulatory Authority (NGORA).
- iii. Request for initial inspection when the Clinic /Hospital is ready for inspection (has fulfilled the minimum requirements).
- iv. Pay relevant fees (application and registration and inspection related costs) as prescribed by MCM.

Note that in addition to the above minimum requirements, MCM may request the applicant to submit additional documents as it sees fit.

## Appendix 4: Telemedicine Facility Inspection Checklist



### TELEMEDICINE INSPECTION CHECKLIST: MINIMUM REQUIREMENTS

Name of facility: ..... Ownership: .....

Postal address: .....

Physical address: .....

Name of Contact Person: .....

Phone Number: .....Email: .....

Name and Registration Number of facility telemedicine Personnel:

1: .....

2: .....

3: .....

4: .....

Remote Supporting practitioner

Name and Registration number: .....

Phone Number: ..... Email: .....

Name and Registration Number of other remote practitioners (if multiple):

1: .....

2: .....

3: .....

4: .....

Requirement	Availability		Remarks
	Yes	No	
<b>Section 1: General Requirements</b>			
Facility registered by MCM			
Availability of SOPs for telemedicine services			
Availability of the Code of Ethics and Professional Conduct			
Availability of the Medical Practitioners and Dentists Act No. 17 of 1987			
Availability of Data Protection Act, Access to Information Act and Cybersecurity Act			
<b>Section 2: Clearly Defined scope of Telemedicine</b>			
Real-time Interactive			
Store-and-Forward			
<b>Section 3: Requirements for Conducting Telemedicine Service</b>			
<b>3.1: Premises Requirements/Physical Infrastructure</b>			
Availability of dedicated room or space within the hospital for telemedicine consultations **			**
Availability of adequate lighting in an examination area			
Availability of adequate power sockets			
Availability of soundproof to ensure patient privacy and confidentiality			
<b>3.2: ICT Infrastructure</b>			
Availability of adequate connectivity to allow the messaging and flow of information (Minimum 5mbps) **			**
Availability of a high-resolution imaging device such as web camera			
Availability of a microphone to enable capturing of voice			

Requirement	Availability		Remarks
	Yes	No	
Availability of a software platform to enable documentation of patient/client information			
Availability of data back up/back up plan			
Availability of the security of the software including encryption and user access control			
Availability of a power backup			
Availability of contingency procedures in case of technical failure during telemedicine sessions			
Availability of communication devices (phone, computers, etc)			
<b>3.3: Equipment, Materials and Supplies</b>			
Availability and use of approved wearable devices			
Availability of documented Informed consent for each device			
Staff trained in the use of telemedicine equipment and protocols			
<b>3.4: Human Resources for telemedicine</b>			
Adequate number of staff based locally and remotely (At least practitioner based at the facility and one external)			
Availability of telemedicine practitioner(s) in good standing with MCM			
Practitioners undertaken continuous professional development (CPD) related to telemedicine			
Roles of the technical personnel clearly outlined and consistent with MCM scope of practice			
Availability of IT personnel for regular system maintenance, data backup, and updates **			
Availability of clinical support staff /system to assist patients in preparation for scheduling of telemedicine appointments			
<b>Section 4: Specific guidelines for performing Telemedicine</b>			
<b>4.1: Assessment of patient suitability</b>			
Regulatory requirements processes for suitability of patients' selection for telemedicine			
Availability of the criteria for when to discontinue telemedicine and refer for in-person care			
Assessment of patient's technical expertise to operate the telemedicine technology			
Availability of safeguards to escalate the services to in-person or emergency care if necessary			
Provider confirmation of the sufficiency of quality of information available via telemedicine to make clinical decisions			
Availability of documented telemedicine patient's rights and responsibilities			
Systems are in place to ensure adherence to consent processes for minors or those not to consent on their own			
Availability of the access to follow up/ continuity of care after the telemedicine visit (tools to be used for follow up/ continuity of care)			
<b>4.2: Telemedicine service provision</b>			

Requirement	Availability		Remarks
	Yes	No	
Availability of formal approval of the telemedicine service by hospital administration and integration into clinical services (Hospital Director or Administrators authority)			
Availability of hospital policy for documentation of patient records in Telemedicine consultation			
Availability of trained health care providers in telemedicine technology communication skills			
Availability of clinical protocols and pathways for different types of telemedicine services			
Availability of National Treatment Guidelines, Treatment Protocols, Infection Prevention protocols and other guidelines			
Protocols on good prescribing practice			
<b>4.3: Documentation of services</b>			
Availability of electronic medical records			
Availability of the referral forms			
<b>Section 5: Ethical conduct and professionalism in Telemedicine</b>			
<b>5.1: Privacy and Confidentiality</b>			
Availability of systems to ensure full privacy and confidentiality of all patient information			
Availability of procedures to de-identify patient information or images when seeking second opinions			
Compliance to relevant Data Protection Laws and Acts- Access to information Act, Data protection Act, and Electronic Transactions Cybersecurity Act			
Statement on ownership of the patient data gained through telemedicine			
<b>5.2: Informed consent for Telemedicine Services</b>			
Informed consent gathered in line with standard practice expectations for each type of service			
User Agreements utilized where applicable			
<b>Section 6: Patient Management in Telemedicine</b>			
Evidence of verifying patients identities prior to initiating telemedicine services (tools to confirm patients' identity)			
Systems are available for patient to confirm the practitioner identity and that the practitioner is registered			
Availability of protocols for triaging patients who require in-person care			
<b>Section 7: Telemedicine Medical Records Management</b>			
Tools or platform for documentation of Telemedicine consultations			
Medical records are updated promptly following each telemedicine consultation			
Availability of secure platform for sharing medical images and patient data in compliance with Malawi data protection laws			
Medical records are stored using secure, encrypted systems			

Requirement	Availability		Remarks
	Yes	No	
Availability and maintenance of backups of telemedicine records performed and securely maintained			
Availability of access logs to monitor who views or modifies medical records			
<b>Section 8: Advertising and marketing for Telemedicine</b>			
Marketing materials compliant with MCM Code of Ethics and Professional Conduct			
Credible evidence of claims about outcomes or services			
Provider licensure and qualification clearly disclosed in promotional materials			
<b>Section 9: Handling of Telemedicine Complaints</b>			
Availability of patient complaint handling process			
Availability of the formal and clear procedures for lodging a complaint with the individual practitioner or telemedicine facility			
Availability of formal process to ensure that all complaints related to telemedicine services are received, documented, and resolved in a timely, fair, and transparent manner			
<b>Section 10: Telemedicine Complications management</b>			
Availability of protocols for managing complications			
Availability of quality assurance team to review investigate and respond to telemedicine complications			
Availability of clear referral systems of complicated cases to in-person healthcare services			
Availability of documented complaint resolution procedures			

**Findings and Recommendations:**

1. Finding and its corresponding recommendation

**Conclusion:** *(Does the facility meet the requirements for Telemedicine?)*

**Criteria**                      **Tick**

Met all requirements                     

Partially met requirements                     

Did not meet requirements                     

**Recommendation for Licensing:** *(Should the facility be licensed for telemedicine?)*

Criteria	
Recommendation for Licensing	<input type="checkbox"/>
Recommendation with Conditions	<input type="checkbox"/>
Not Recommended	<input type="checkbox"/>

**Inspection Team**

1. **Inspector Name:** .....**Designation:** .....

**Signature:** ..... **Date:** .....

2. **Inspector Name:** ..... **Designation:** .....

**Signature:** ..... **Date:** .....

3. **Co-opted Expert:** ..... **Designation:** .....

**Signature:** ..... **Date:** .....

4. **Co-opted Expert:** ..... **Designation:** .....

**Signature:** ..... **Date:** .....

Appendix 5: Teleradiology Facility Inspection Checklist



**TELERRADIOLOGY INSPECTION CHECKLIST**

Name of facility: ..... Ownership: .....

Postal address: ..... Physical address:.....

Name of Contact Person: .....

Phone Number: .....Email: .....

**Site based practitioners**

Name, Registration Number of Radiologist.....

Name and Registration Number of other primary facility radiology practitioners:

1: .....

2: .....

3: .....

4: .....

**Remote based radiologists**

Name, Registration Number of Remote Radiologist .....

Postal address..... Physical address.....

Name and Registration Number of other remote Radiologists (if multiple):

1: .....

2: .....

3: .....

4: .....

Requirement	Availability		Remarks
	Yes	No	
<b>1: Human Resource Requirements</b>			Review files
MCM registered Medical Imaging Practitioners available on site			
MCM registered Radiologists personnel available on site (or in country), for quality control or vetting of remote radiologists who may never have practiced in Malawi			
MCM registered remote Radiologists (other Radiology practitioners (e.g. Radiographer, Sonographer, CT & MRI Technologists etc. relevant for the type of service)			
Availability of clinical support staff /system to assist patients in preparation for scheduling of teleradiology appointments			
Adequate number of staff based locally and remotely (At least practitioner based at the facility and one external)			
Availability of IT personnel for regular system maintenance, data backup, and updates			
Roles of the technical personnel clearly outlined and consistent with MCM scope of practice			
The practitioners are trained on teleradiology and competent at utilizing the equipment available			
Practitioners undertake continuous professional development (CPD) related to teleradiology			
<b>2. Premises Requirements/Physical Infrastructure</b>			
Facility holds valid license from MCM (existing facility) or is in the process of registration			
The Radiology infrastructure and equipment licensed with AERA (For radiation emitting devices) or is in the process of registration			
Air conditioning or climate control system available			
Workstation compliance with Data Protection Act and other relevant laws of Malawi			
Picture Archiving and Communication System (PACS) installed and functional			
Sufficient electrical outlets for equipment			
RIS availability			
Clean and well-maintained environment meeting IPC guidelines			
Compliance with local health and safety standards			
<b>3. ICT Infrastructure for Teleradiology</b>			
Reliable internet connectivity; Minimum Speed: $\geq 5$ Mbps upload/download (higher for video consultations).			
Redundancy: Backup connectivity (e.g., mobile data router, satellite link).			
Adequate high resolution imaging monitors and audio tools			
Role-based access controls (Levels of access within a system)			

Requirement	Availability		Remarks
	Yes	No	
Security protocols (firewall, antivirus, 2 Factors of Authentication, encryption)			
Capability to receive and transform transmitted radiological images (DICOM)			
Power backup and energy stability (e.g., UPS, generator, solar).			
Radiology workstations (laptop/desktop) with: Webcam and microphone			
Diagnostic high resolution reporting station			
Viewer station (does not need to be high resolution)			
Mobile tablets or phones (for remote field workers)			
Headset or speaker setup			
<b>4. Equipment, Materials and Supplies</b>			
Imaging devices meet diagnostic standards.			
Medical devices approved by relevant regulatory authority(ies) (PMRA, AERA)			
Wearable or monitoring devices (if used) are approved and monitored			
Documented system for equipment maintenance and servicing, and calibration conducted			
Licensed and updated radiology viewing/reporting software			
Radiation safety measures: Shielding, signage, radiation badges in use			
<b>5. Supporting Services</b>			
Help desk available for technical issues			
ICT personnel available for system maintenance.			
Data backup: on-premises or cloud server			
User manuals and training materials for clinical and non-technical staff			
<b>6. Service Delivery and Documentation</b>			
Availability of Radiology standard operating procedures			
Practitioners are trained in Teleradiology			
Protocols for Teleradiology are in place and followed			
Verification of patient's identity in accordance with regulatory requirements			
Availability of duty roster for all practitioners involved			
Availability of radiation safety signs and red bulb			
Documentation of image acquisition and interpretation is complete and within department turnaround time			
Patient data privacy, data confidentiality maintained during transmission			

Requirement	Availability		Remarks
	Yes	No	
Informed consent is obtained for services and image sharing (formal or informal)			
Communication of results: Secure delivery to primary facility (or referring clinician) with a system of alerts for critical findings			
Image is securely stored, backup and disaster recovery plan in place			
Data storage duration: adheres to national policy, minimum 5 years at facility then archived up to 7 years			
Audit trail: Complete log of sent images and received reports			
<b>7. Ethical conduct and professionalism in Teleradiology</b>			
Availability of systems to ensure full privacy and confidentiality of all patient information			
Availability of procedures to de-identify patient information or images when seeking second opinions			
Compliance to relevant Data Protection Laws and Acts- Access to information Act, Data protection Act, and Electronic Transactions Cybersecurity Act			
Informed consent gathered in line with standard practice			
<b>8. Quality Assurance and Monitoring</b>			
Regular audits and quality checks are conducted			
System for peer review of reports: Evidence of double reads, audits or peer review especially for the first 6 weeks for practitioners who were not physically oriented in Malawi by a practitioner who was oriented and registered by MCM.			
Logs of service delivery and system performance are maintained			
Error reporting mechanism: system in place for discrepancies or missed findings			
Equipment: Verified calibration and quality assurance records			
Mechanisms for handling complaints and complications are in place			

### General Findings and Recommendations:

1. Finding and its corresponding recommendation

**Conclusion:** *(Does the facility meet the requirements for Teleradiology?)*

Criteria	Tick

Met all requirements

Partially met requirements

Did not meet requirements

**Recommendation for Licensing:** *(Should the facility be licensed for teleradiology?)*

Criteria	
Recommendation for Licensing	<input type="checkbox"/>
Recommendation with Conditions	<input type="checkbox"/>
Not Recommended	<input type="checkbox"/>

**Inspection Team:**

**1. Inspector Name:**

**Designation:**

**Signature:**

**Date:**

**2. Inspector Name:**

**Designation:**

**Signature:**

**Date:**

**3. Co-opted Expert:**

**Designation:**

**Signature:**

**Date:**

**4. Co-opted Expert:**

**Designation:**

**Signature:**

**Date:**

Appendix 6: Tele-laboratory Inspection Checklist



**TELELABORATORY INSPECTION CHECKLIST**

Name of facility: ..... Ownership: .....

Postal address: .....

Physical address: .....

Name of Contact Person: .....

Phone Number: .....Email: .....

Name and Registration Number of primary facility Laboratory Personnel:

1: .....

2: .....

3: .....

4: .....

Remote Specialist/Laboratory expert

Name and Registration Number: .....

Phone Number: ..... Email: .....

Name and Registration Number of other remote practitioners (if multiple):

1: .....

2: .....

3: .....

4: .....

Requirement	Availability		Remarks
	Yes	No	
<b>Section 1: Human Resources</b>			
Facility registered by MCM or in the process of being registered			
Adequate number of staff based locally and remotely (At least practitioner based at the facility and one external)			
Registered laboratory personnel available at primary laboratory in good standing with the MCM			
A registered specialist/laboratory expert available at remote site in good standing with the MCM			
Category A has at least a Laboratory Assistant			
Category B1 has at least either a Technician or a Technologist			
Category B2 has at least a Technologist and Technician			
Roles of the technical personnel clearly outlined and consistent with MCM scope of practice			
<b>Section 2: The Building</b>			
Roof: Permanent structure well maintained thatched with corrugated iron sheets and no leakages			
Adequate lighting			
Good ventilation, especially in rooms handling volatile chemicals (e.g., formalin); fume hoods and exhaust systems are essential			
Floor: Permanent structure well maintained Smooth floor not slippery			
Walls: Permanent structure Plastered and painted with washable paint.			
Layout of the laboratory is designed to allow unidirectional workflow (from sample receipt → processing → reporting), with separation between clean and dirty zones.			
<b>Section 3: ICT Infrastructure</b>			
<b>3.1 Hardware</b>			
<b>Server Infrastructure:</b> On-premise servers (LIMS LIS)			
<b>Server Infrastructure:</b> Backup servers or cloud failover			
<b>Server Infrastructure:</b> Server room with cooling, UPS, and physical security			
<b>Workstations and End-User Devices:</b> Desktop computers			
<b>Workstations and End-User Devices:</b> Laptops for mobile			
<b>Workstations and End-User Devices:</b> Tablets or mobile devices			

Requirement	Availability		Remarks
	Yes	No	
<b>Workstations and End-User Devices:</b> Barcode/RFID scanners (medication, inventory, patient ID)			
<b>Networking Devices:</b> Routers, switches, firewalls			
<b>Networking Devices:</b> Wireless Access Points (hospital-wide Wi-Fi)			
<b>Networking Devices:</b> Secure VPN gateways (remote access/telemedicine)			
<b>Telelaboratory Equipment:</b> High-resolution webcams and microphones			
<b>Telelaboratory Equipment:</b> Video conferencing systems where applicable			
<b>Power Management:</b> Uninterruptible Power Supplies (UPS)			
<b>Power Management:</b> Backup power- generators or solar system			
<b>Power Management:</b> Surge protectors			
<b>Backup and Recovery Systems:</b> Automated daily/weekly data backups			
<b>Backup and Recovery Systems:</b> Cloud storage integration			
<b>Backup and Recovery Systems:</b> Disaster recovery plan and testing protocol			
<b>3.2 Software Infrastructure</b>			
<b>Software Infrastructure, Security and Compliance</b>			
Role-based access control (RBAC) systems			
Antivirus and endpoint protection			
Data encryption software (at rest and in transit)			
Security Information and Event Management (SIEM) tools			
<b>Software Infrastructure, Communication Tools</b>			
Internal messaging platform (e.g., Slack, Microsoft Teams)			
Email services with secure encryption			
SMS/notification systems for patient alerts			
<b>Data Analytics and Reporting</b>			
Clinical decision support systems (CDSS)			
Health data visualisation and dashboard tools			
AI-assisted diagnostic tools (optional for advanced setups)			
<b>Backup and Recovery Systems</b>			
Automated daily/weekly data backups			
Cloud storage integration			
Disaster recovery plan and testing protocol			
<b>3.3 Connectivity &amp; Internet Service</b>			
High-speed internet connectivity ( $\geq 5$ Mbps minimum for clinics)			
Redundant ISP connections (failover readiness)			
Local Area Network (LAN) infrastructure			

Requirement	Availability		Remarks
	Yes	No	
Hospital Intranet for internal access to services			
<b>3.4 Physical &amp; Cybersecurity</b>			
Secure server room access (ID card or biometric)			
CCTV systems (especially around IT infrastructure)			
Fire detection and suppression system in server areas			
Routine vulnerability assessments and penetration testing			
<b>3.5 Document &amp; Policy Infrastructure</b>			
IT Asset Register (inventory of all ICT equipment)			
ICT Use Policy (acceptable use, restrictions)			
Data Protection and Confidentiality Policy			
Incident Response Plan (cybersecurity and IT failure)			
<b>3.6 Human Resource &amp; Training</b>			
Dedicated ICT officer or department			
Staff training on software systems and onsite software validation			
Cybersecurity awareness training			
Vendor support agreements (for key software/hardware)			
<b>3.7 Regulatory &amp; Standards Compliance</b>			
Compliance with relevant Data Protection Laws and Acts- Access to information Act, Data protection Act, and Electronic Transactions Cybersecurity Act			
Alignment with health ICT standards (e.g., HL7, FHIR)			
Compliance with relevant MCM regulations and MoH policies			
<b>Section 4. Laboratory Design and Layout</b>			
Waiting area, and sample collection area has adequate benches and chairs			
Sample Preparation has bench sink and handwashing basin			
Refrigerator / Freezer available at all designated areas			
Washing Up Area meets the requirements			
Waste Disposal adheres to IPC standards			
Drainage functioning			
<b>Section 5. Equipment and Supplies</b>			
Category A Laboratories meet the minimum requirements			
Category B1 Laboratories meet the minimum requirements			
Category B2 Laboratories meet the minimum requirements			
<b>Section 6. Safety</b>			
Availability of functional and unexpired firefighting equipment (extinguishers, fire blankets etc.)			
Presence of the evacuation routes			
Presence and accessibility of Fire exit door			
Appropriate labeling of doors, sections etc.			

Requirement	Availability		Remarks
	Yes	No	
Restriction of access by non-laboratory staff.			
Protective wear: Gloves, lab coats, face masks, gumboots			
Consumables: Disinfectants			
Vaccination against vaccine preventable diseases i.e. Hepatitis B, PEP procedures			
<b>Section 7. Quality Assurance</b>			
<b>Lab organisation:</b> Job descriptions for each cadre, Organogram showing responsibility for quality and safety, signed confidentiality statements			
<b>Standard operating procedures:</b> Refer to MoH Quality manual and facility-based SOPs Book			
<b>Preventive maintenance:</b> Check in maintenance log and document properly			
<b>Internal quality control samples:</b> Check of use of QC samples when testing and records of corrective actions taken			
<b>External quality assessment:</b> Check if the laboratory is enrolled with National or international EQA scheme and see their evidence of participation and if there are any deficiencies the investigation reports must be documented			
<b>Temperature charts:</b> Completeness and records of corrective actions taken			
<b>Training:</b> Review copies of certificates, registration with MCM, CPD books, competency assessments			
<b>Laboratory Documents</b> Request forms, registers, records			

### General Findings and Recommendations:

2. Finding and its corresponding recommendation

**Conclusion:** *(Does the facility meet the requirements for telelaboratory?)*

Criteria	Tick
Met all requirements	<input type="checkbox"/>
Partially met requirements	<input type="checkbox"/>
Did not meet requirements	<input type="checkbox"/>

**Recommendation for Licensing:** *(Should the facility be recommended for telelaboratory?)*

Criteria	
Recommendation for Licensing	<input type="checkbox"/>
Recommendation with Conditions	<input type="checkbox"/>
Not Recommended	<input type="checkbox"/>

**Inspection Team:**

**1. Inspector Name:** ..... **Designation:** .....

Signature: ..... Date: .....

**2. Inspector Name:** ..... **Designation:** .....

Signature: ..... Date: .....

**3. Co-opted Name:** ..... **Designation:** .....

Signature: ..... Date: .....

**4. Co-opted Name:** ..... **Designation:** .....

Signature: ..... Date: .....

## Appendix 7: Telepathology Inspection Checklist



### Telepathology Facility Assessment Checklist

#### **(A) Pathology Laboratory manned by a pathologist (Primary diagnosis, Intra-operative diagnosis, Expert/Second opinion, & Ancillary tests)**

Name of primary facility: .....

Name & Reg Number of facility Pathologist.....

Name & Reg Number of other laboratory personnel:.....

Postal address: .....

Physical address: .....

Contact Person: ..... Phone Number: .....

Email:.....

#### **(B) Pathology Laboratory manned by Laboratory personnel (Primary diagnosis, Intra-operative diagnosis, Expert/Second opinion, research, external quality assurance & Ancillary tests).**

Name of primary facility: .....

Name & Reg Number of facility Pathologist.....

Name & Reg Number of other laboratory personnel:.....

Postal address: .....

Physical address: .....

Contact Person: ..... Phone Number: .....

Email:.....

#### **Supporting (consulting) pathologist within Malawi**

Name & Reg Number of supporting Pathologist:.....

Postal address..... Physical address: .....

Phone: ..... Email address: .....

#### **Remote Pathologist**

Name & Reg Number of Remote Pathologist:.....

Postal address..... Physical address: .....

Phone: ..... Email address: .....

Requirements	Availability		Remarks
	Yes	No	
<b>1. Human Resources Requirements</b>			
An MCM registered Pathologist in good standing available for services at the primary laboratory (very critical where the remote practitioner has never undergone MCM required orientation in Malawi)			
A registered Pathologist in good standing with MCM available to provide remote pathology services			
A registered Laboratory Personnel available at referring laboratory in good standing with the Medical Council of Malawi			
Other relevant MCM registered pathology supporting personnel available on site			
Roles of the technical personnel clearly outlined and consistent with MCM scope of practice			
There is evidence that the practitioners are trained on telepathology and competent at utilising the equipment available			
<b>2. Premises Requirements/Physical Infrastructure</b>			
Iron sheet roofed (not leaking)			
Smooth and non-slippery floor			
Wall plastered and painted with washable paint			
Sufficient electrical outlets for equipment			
Reception with sample receiving area			
Layout of the laboratory is designed to allow unidirectional workflow (from sample receipt → processing → reporting), with separation between clean and dirty zones.			
Cleanable work surfaces, sample accessioning desks and hand hygiene facilities			
Good ventilation, especially in rooms handling volatile chemicals (e.g., formalin); fume hoods and exhaust systems are essential.			
Continuous running water with backup tanks water if needed.			
Clean and well-maintained environment meeting IPC guidelines			
Compliance with local health and safety standards			
<b>3. ICT Infrastructure</b>			
Validation of ICT Equipment (is the ICT equipment validated before use)			
<b>3.1. Reliable Internet Connectivity</b>			
Minimum Speed: ≥5 Mbps upload/download (higher for video consultations).			

Requirements	Availability		Remarks
	Yes	No	
Redundancy: Backup connectivity (e.g., mobile data router, satellite link).			
Low Latency & Stability for video and voice connection.			
<b>3.2. Power Backup and Energy Stability</b>			
Uninterruptible Power Supply (UPS) for essential devices.			
Backup generator or solar power where national grid is unreliable.			
<b>3.3. Hardware &amp; End-User Devices</b>			
<b>Telepathology workstations</b> (laptop/desktop) with:			
Webcam and microphone			
Headset or speaker setup			
High-resolution display (Viewer)			
Mobile tablets or phones (for remote field workers)			
Validated medical device/s for imaging available			
<b>3.4. Software and Platforms</b>			
Telepathology Platform (secure video, chat, image sharing software)			
<b>3.5. Cybersecurity and Data Protection</b>			
Firewall and antivirus software			
Role-based access controls (Levels of access within a system)			
Secure login protocols (e.g., 2 Factor Authentication)			
Data encryption (in transit and at rest)			
Compliance with data protection regulations as stated in the Malawi Data Protection Act 2024			
<b>4. Technical Support and Maintenance</b>			
IT support personnel (on-site or remote)			
Data backup: on-premise or cloud server			
System maintenance schedules for updates, patching, and backups			
User manuals and training materials for clinical and non-technical staff			
<b>5. Pathology Laboratory Equipment, Supplies and Furniture</b>			
Clearly labeled bins, autoclave-safe, with color-coded segregation.			
PPEs like lab coats, gloves, eye protection			
Microtome			

Requirements	Availability		Remarks
	Yes	No	
Grossing table			
Staining setup and staining station			
Tissue processing station.			
Embedding station/Wax dispenser.			
Cold plate			
Slide warmer/Incubator			
Floatation bath			
Slides, Holders, Funnels, Slide trays			
Paraffin wax			
Brushes			
Forceps			
Tissue Cassettes			
Sink for sample processing			
Benches for sample processing			
Registers for specimen identification.			
Standard operating procedures for sample handling, staining, reporting			
Internal quality control logs maintained			
Running water and soap for hand washing			
Provision for waste disposal around the premises including incineration or MOU with another facility on incineration			

### Findings and Recommendations:

1. Finding and its corresponding recommendation

**Conclusion:** *(Does the facility meet the requirements for telepathology?)*

Criteria                      Tick

Met all requirements                     

Partially met requirements  

Did not meet requirements  

**Recommendation for Licensing:** *(Should the facility be approved for telepathology?)*

<b>Criteria</b>	
Recommendation for Licensing	<input type="checkbox"/>
Recommendation with Conditions	<input type="checkbox"/>
Not Recommended	<input type="checkbox"/>

**Inspection team:**

**1. Inspector Name:**

**Designation:**

**Signature:**

**Date:**

**2. Inspector Name:**

**Designation:**

**Signature:**

**Date:**

**3. Inspector Name:**

**Designation:**

**Signature:**

**Date:**

**4. Co-opted Expert:**

**Designation:**

**Signature:**

**Date:**