

CENTRAL COUNCIL OF INDIAN MEDICINE

TELEMEDICINE PRACTICE GUIDELINES for Ayurveda, Siddha and Unani Practitioners

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BACKGROUND

India's digital health policy advocates use of digital tools for improving the efficiency and outcome of Healthcare system and lays significant focus on the use of telemedicine services especially in the health and Wellness centers at the grass root level wherein a mid level health care provider / health worker can connect the patient to the doctor through Technology platforms for providing timely and best possible care.

In spite of this policy till now there is no legislation or guidelines for ASU practitioners on the practice of telemedicine through video, phone and internet based platforms (webchat, apps etc.). Lack of clear guidelines has created significant ambiguity for registered medical professionals of the ASU systems raising doubts on the practice of telemedicine. The 2018 judgement of the honorable High Court of Bombay has created uncertainty about the place and legitimacy of telemedicine as appropriate Framework does not exist.

In India the practice of ASU medicine is mainly governed by concerned state acts along with IMCC Act 1970; drugs & cosmetics act 1940 & rules 1945; and Clinical Establishment Act 2012. Information technology is governed by IT Act 2000, and the information technology (reasonable security practices and procedure and sensitive personal data or information) rules 2011. Gaps in legislation and the uncertainty of rules force a risk for both the doctors and their patients.

It is need of the hour to Bridge the gaps in legislation and the uncertainty of rules. These guidelines will serve as a step forward to regulate the telemedicine practices in the field of ASU systems in this direction.

PURPOSE

- The purpose of these guidelines is to make ASU practitioners able to use the
 telemedicine tools. This will be done by providing information as well as training which
 will be updated from time to time as in coming years telemedicine will continue to grow
 and be adopted by more health care practitioners and patients in a wide variety of
 forms.
- These guidelines will provide norms and protocols relating to doctor patient relationship
 issues of liability and negligence, evaluation, management and treatment, informed
 consent, continuity of care, referral for emergency services, medical records, privacy
 and security of patient records and exchange of information, describing and
 reimbursement, health education and counseling.

- These guidelines will give practical advice to ASU registered medical practitioner regarding telemedicine to encourage them to consider the use of telemedicine as a part of their normal practice as well as in disasters and pandemics pose unique challenges to provide Healthcare which will help to treat patients without exposing doctors and their staff to infections at the time of such outbreaks.
- The telemedicine practice can prevent transmission of infectious diseases reducing the
 risk to both doctors and patients by avoiding social contact. Thus, health systems that
 are invested in telemedicine will be in a position to ensure that the patient with covid19
 kind of issues received the care they need.

ADVANTAGE OF TELEMEDICINE

- Telemedicine Provides rapid access to medical practitioners who may not be available in person.
- With telemedicine there is higher likelyhood of maintenance of records and documentation. Written documentation increases legal protection of doctors as well as patients.
- Telemedicine, when effectively used, reduces the burden on secondary health care system.
- Telemedicine is useful for regular routine checkup on continuous monitoring.
 Telemedicine provides patient's safety as well as doctor's & health worker's safety,
 especially in situations where there is a risk of contagious infections. A telemedicine visit
 can be conducted without exposing staff to viruses/infections at the time of such
 outbreaks.

PLEASE NOTE:

It is to be noted that unlike other technologies, the technology used for telemedicine has some risks, drawbacks & limitations, which can be mitigated through appropriate training, enforcement of standards, protocols & Guidelines from time to time.

These guidelines should be used in conjunction with the other national clinical standards, protocols, policies and procedures.

1. TELEMEDICINE: DEFINITIONS AND APPLICATIONS

1.1 DEFINITIONS.

1.1.1 Definition of Telemedicine

World Health Organization defines telemedicine as

"The delivery of health-care services, where distance is a critical factor, by all health-care professionals using information and communications technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and the continuing education of health-care workers, with the aim of advancing the health of individuals and communities."

1.1.2 Definition of Telehealth

NEJM Catalyst defines telehealth as "The delivery and facilitation of health and health-related services including medical care, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies."

In general, telemedicine is used to denote clinical service delivered by a Registered medical practitioner while telehealth is a broader term of use of technology for health and health related services including telemedicine.

1.1.3 Definition of Registered (Ayurveda, Siddha, Unani) Medical Practitioner (RMP or ASU RMP)

For the purpose of this document a 'Registered (Ayurveda, Siddha, Unani) Medical Practitioner' i.e. RMP or ASU RMP is defined as a person who is enrolled in the State Medical Register of Indian Medicine or the Central Register Indian Medicine under the IMCC act 1970.

1.2 SCOPE

Within the broad paradigm of telemedicine, these guidelines will be published under the IMCC act and are for privileged access only. These guidelines are designed to serve as an aid and tool to enable ASU RMPs to effectively leverage Telemedicine to enhance healthcare service and access to all

- The guidelines are meant for ASU RMPs under the IMCC act 1970
- The guidelines cover norms and standards of the ASU RMP to consult patients via telemedicine
- Telemedicine includes all channels of communication with the patient that leverage Information Technology platforms, including Voice, Audio, Text & Digital Data exchange

EXCLUSIONS:

The guidelines specifically explicitly **exclude** the following:

- Specifications for hardware or software, infrastructure building & maintenance
- Data management systems involved; standards and interoperability
- Use of digital technology to conduct surgical or invasive procedures remotely
- Other aspects of telehealth such as research and evaluation and continuing education of health- care workers
- Does not provide for consultations outside the jurisdiction of India
- Use of digital technology to conduct major Panchkarma procedures like Vaman,
 Virechan, Basti, Raktamoshan or similar procedures in Siddha and Unani including cupping therapy.

1.3 REGISTERED MEDICAL PRACTITIONERS ARE ENTITLED TO PRACTICE TELEMEDICINE: ALL OF THEM WILL TAKE AN ONLINE COURSE ON PRACTICE OF TELEMEDICINE.

- **1.3.1** *A Registered Medical Practitioner* is entitled to provide telemedicine consultation to patients from any part of India
- **1.3.2** ASU RMPs using telemedicine shall uphold the *same professional and ethical norms and standards* as applicable to traditional in-person care, within the intrinsic limitations of telemedicine
- **1.3.3** To enable all those ASU RMPs who would want to practice telemedicine get familiar with these Guidelines as well as with the process and limitations of telemedicine practice:
 - An online program will be developed and made available by the Central Council of Indian Medicine.
 - All registered medical practitioners intending to provide online consultation need to complete a mandatory online course within 3 years of its notification. This course will remain open for the coming generations of ASU RMP.
 - In the interim period, the principles mentioned in these guidelines need to be followed.
 - Thereafter, undergoing and qualifying such a course, as prescribed, will be essential prior to practice of telemedicine.
 - In case of extraordinary situation where patient to Doctor contact is either inadvisable or legally banned by the competent authorities; with prior consultation with Central or State Government as situation may arise CCIM or concerned State Council may authorize all RMP's to utilize the facility of telemedicine for specified limited period; provided that such period may be extended beyond one month only after due permission of Central Government.

1.4 TELEMEDICINE APPLICATIONS

1.4.1 Tools for Telemedicine

ASU RMP may use any telemedicine tool suitable for carrying out technology-based patient consultation e.g. telephone, video, devices connected over LAN, WAN, Internet, mobile or landline phones, Chat Platforms like WhatsApp, Facebook Messenger etc., or Mobile App or internet based digital platforms for telemedicine or data transmission systems like Skype/email/fax etc.

Irrespective of the tool of communication used, the core principles of telemedicine practice remain the same.

1.4.2 Telemedicine applications can be classified into *four basic types*, according to the *mode of communication, timing of the information transmitted, the purpose of the consultation and the interaction between the individuals involved*—be it ASU RMP-to-patient / caregiver, or ASU RMP to ASU RMP.

1.4.2.1 According to the Mode of Communication

- Video (Telemedicine facility, Apps, Video on chat platforms, Skype/Face time etc.)
- Audio (Phone, VOIP, Apps etc.)
- Text Based:
 - Telemedicine chat based applications (specialized telemedicine smartphone Apps, Websites, other internet-based systems etc.)
 - General messaging/ text/ chat platforms (WhatsApp, Google Hangouts, Facebook Messenger etc.)
 - Asynchronous (email/ Fax etc.)

1.4.2.2 According to timing of information transmitted

Real time Video/audio/text interaction	Asynchronous exchange of relevant information
Video/audio/text for exchange of relevant information for diagnosis, medication and health education and counseling	

1.4.2.3 According to the purpose of the consultation

For Non-Emergency consult:

First consult with any ASU RMP for	Follow-up consult with the same ASU RMP
diagnosis/treatment/health education/	
counseling	
Patients may consult with an ASU RMP for	Patients may use this service for follow up
diagnosis and treatment of her condition or	consultation on his ongoing treatment with
for health education and counseling	the same ASU RMP who prescribed the
	treatment in an earlier in-person consult.

Emergency consult for immediate assistance or first aid etc.

In case alternative care is not present, tele-consultation might be the only way to provide timely care.

In such situations, ASU RMPs may provide consultation to their best judgement. Telemedicine services should however be avoided for emergency care when alternative in-person care is available, and telemedicine consultation should be limited to first aid, life-saving measure, counseling and advice on referral.

In all cases of emergency, the patient must be advised for an in-person interaction with an ASU RMP at the earliest.

1.4.2.4 According to the individuals involved

Patient to ASU RMP	Caregiver to ASU RMP
Telemedicine services may connect patients to an ASU RMP	Telemedicine services may connect Care givers to an ASU RMP, under certain conditions as detailed in Framework (Section 4)

ASU RMP to ASU RMP	Health worker to ASU RMP
	A Health Worker ¹ can facilitate a
	Consultation session for a patient with an
ASU RMP may use telemedicine services to	ASU RMP. In doing so, the former can help
discuss with other ASU RMPs issues of care of	take history, examine the patient and convey
one or more patients, or to disseminate	the findings. They can also explain/reinforce
knowledge	the advice given by the ASU RMP to the
	patient.

¹ Nurse, Allied Health Professional, Mid-level health provider, ANM or any other health worker designated by an appropriate authority

2. TECHNOLOGY USED & MODE OF COMMUNICATIONS

Multiple technologies can be used to deliver telemedicine consultation. There are 3 primary modes: **Video, Audio, or Text** (chat, messaging, email, fax etc.) Each one of these technology systems has their respective strengths, weaknesses and contexts, in which, they may be appropriate or inadequate to deliver a proper diagnosis.

It is therefore important to understand the strengths, benefits as well as limitations of different technologies. Broadly, though telemedicine consultation provides safety to the ASU RMP from contagious conditions, it cannot replace physical examination that may require palpation, percussion or auscultation; that requires physical touch and feel. Newer technologies may improve this drawback.

STRENGTHS AND LIMITATIONS OF VARIOUS MODES OF COMMUNICATION

MODE	STRENGTHS	LIMITATIONS
VIDEO: Telemedicine facility, Apps, Video on chat platforms, Facetime etc.	 Closest to an in person-consult, real time interaction Patient identification is easier ASU RMP can see the patient and discuss with the caregiver Visual cues can be perceived Inspection of patient can be carried out 	 Is dependent on high quality internet connection at both ends, else will lead to a sub optimal exchange of information Since there is a possibility of abuse/misuse, ensuring privacy of patients in video consults is extremely important
AUDIO: Phone, VOIP, Apps etc.	 Convenient and fast Unlimited reach Suitable for urgent cases No separate infrastructure required Privacy ensured Real-time interaction. 	 Non-verbal cues may be missed Not suitable for conditions that require a visual inspection (e.g. skin, eye or tongue examination), or physical touch Patient identification needs to be clearer, greater chance of imposters representing the real patient

MODE	STRENGTHS	LIMITATIONS
TEXT BASED: Specialized Chat based Telemedicine Smartphone Apps, SMS, Websites, messaging systems e.g. WhatsApp, Google Hangouts, FB Messenger	 Convenient and quick Documentation & Identification may be an integral feature of the platform Suitable for urgent cases, or follow-ups, second opinions provided ASU RMP has enough context from other sources, No separate infrastructure required, Can be real time 	 Besides the visual and physical touch, text-based interactions also miss the verbal cues Difficult to establish rapport with the patient. Cannot be sure of identity of the doctor or the patient
ASYNCHRONOUS: Email Fax, recordings etc.	 Convenient and easy to document No specific app or download requirement Images, data, reports readily shared No separate infrastructure required More useful when accompanied with test reports and follow up and second opinions 	 Not a real time interaction, so just one-way context is available, relying solely on the articulation by the patient Patient identification is document based only and difficult to confirm Non-verbal cues are missed There may be delays because the Doctor may not see the mail immediately

3. GUIDELINES FOR TELEMEDICINE IN INDIA

The professional judgment of a Registered Medical Practitioner should be the guiding principle for all telemedicine consultations: An ASU RMP is well positioned to decide whether a technology-based consultation is sufficient or an in-person review is needed. Practitioner shall exercise proper discretion and not compromise on the quality of care. Seven elements need to be considered before beginning any telemedicine consultation (see panel)

Seve	Seven Elements to be considered before any telemedicine consultation	
1	Context	
2	Identification of ASU RMP and Patient	
3	Mode of Communication	
4	Consent	
5	Type of Consultation	
6	Patient Evaluation	
7	Patient Management	

3.1 TELEMEDICINE SHOULD BE APPROPRIATE AND SUFFICIENT AS PER CONTEXT

3.1.1 The Registered Medical Practitioners should exercise their professional judgment to decide whether a telemedicine consultation is appropriate in a given situation or an in-person consultation is needed in the interest of the patient. They should consider the mode/technologies available and their adequacy for a diagnosis before choosing to proceed with any health education or counseling or medication. They should be reasonably comfortable that telemedicine is in the patient's interest after taking a holistic view of the given situation.

3.1.2 Complexity of Patient's health condition

Every patient/case/medical condition may be different, for example, a new patient may present with a simple complaint such as headache while a known patient of Diabetes may consult for a follow- up with emergencies such as Diabetic Ketoacidosis. The ASU RMP shall uphold the same standard of care as in an in-person consultation but within the intrinsic limits of telemedicine.

3.2 IDENTIFICATION OF THE REGISTERED MEDICAL PRACTITIONER AND THE PATIENT IS REQUIRED

- 3.2.1 Telemedicine consultation should not be anonymous: both patient and the ASU RMP need to know each other's identity.
- 3.2.2 An ASU RMP should verify and confirm patient's identity by name, age, address, email ID, phone number, registered ID or any other identification as may be deemed to be appropriate. The ASU RMP should ensure that there is a mechanism for a patient to verify the credentials and contact details of the ASU RMP.
- 3.2.3 For issuing a prescription, the ASU RMP needs to explicitly ask the age of the patient, and if there is any doubt, seek age proof. Where the patient is a minor, after confirming the age, tele consultation would be allowed only if the minor is consulting along-with an adult whose identity needs to be ascertained.
- 3.2.4 An ASU RMP should begin the consultation by informing the patient about his/her name and qualifications.
- 3.2.5 Every ASU RMP shall display the registration number accorded to him/her by the State Medical Council/ CCIM, on prescriptions, website, electronic communication (WhatsApp/ email etc.) and receipts etc. given to his/her patients.

3.3 MODE OF TELEMEDICINE

- 3.3.1 Multiple technologies can be used to deliver telemedicine consultations. All these technology systems have their respective strengths, weaknesses and contexts in which they may be appropriate or inadequate in order to deliver proper care.
- 3.3.2 Primarily there are 3 modes: Video, Audio or Text (chat, images, messaging, email, fax etc.). Their strengths, limitations and appropriateness as detailed in Section 2 need to be considered by the ASU RMP.
- 3.3.3 There may be situations where in order to reach a diagnosis and to understand the context better; a real-time consultation may be preferable over an asynchronous exchange of information. Similarly, there would be conditions where an ASU RMP could require hearing the patient speak, therefore, a voice interaction may be preferred than an email or text for a diagnosis. There are also situations where the ASU RMP needs to visually examine the patient

and make a diagnosis. In such a case, the ASU RMP could recommend a video consultation. Considering the situation, using his/her best judgment, an ASU RMP may decide the best technology to use to diagnose and treat.

3.4 PATIENT CONSENT

Patient consent is necessary for any telemedicine consultation. The consent can be Implied or explicit depending on the following situations:

3.4.1 If, the patient initiates the telemedicine consultation, then the consent is implied².

3.4.2 An Explicit patient consent is needed if:

A Health worker, ASU RMP or a Caregiver initiates a Telemedicine consultation.

3.4.3 An Explicit consent can be recorded in any form. Patient can send an email, text or audio/video message. Patient can state his/her intent on phone/video to the ASU RMP (e.g. "Yes, I consent to avail consultation via telemedicine" or any such communication in simple words). The ASU RMP must record this in his patient records.

3.5 EXCHANGE OF INFORMATION FOR PATIENT EVALUATION

ASU RMPs must make all efforts to gather sufficient medical information about the patient's condition before making any professional judgment.

3.5.1 Patient's Information

- An ASU RMP would use his/her professional discretion to gather the type and extent of
 patient information (history/examination findings/Investigation reports/past records
 etc.) required to be able to exercise proper clinical judgement.
- This information can be supplemented through conversation with a healthcare worker/provider and by any information supported by technology-based tools.
- If the ASU RMP feels that the information received is inadequate, then he/she can request for additional information from the patient. This information may be shared in

² Implied Consent: In an in-person consultation, it is assumed the patient has consented to the consult by his/her actions. When the patient walks in an OPD, the consent for the consultation is taken as implied. Like an in-person consultation, for most of the tele-consultations the consent can be assumed to be implied because the patient has initiated the consultation.

real time or shared later via email/text, as per the nature of such information. For example, an ASU RMP may advise some laboratory or/and radiological tests to the patient. In such instances, the consult may be considered paused and can be resumed at the rescheduled time. An **ASU RMP may provide health education as appropriate at any time**.

- Telemedicine has its own set of limitations for adequate examination. If a physical examination is critical information for consultation, ASU RMP should not proceed until a physical examination can be arranged through an in-person consult. Wherever necessary, depending on professional judgement of the ASU RMP, he/she shall recommend:
 - Video consultation
 - Examination by another ASU RMP/ Health Worker;
 - In-person consultation

The information required may vary from one ASU RMP to another based on his/her professional experience and discretion and for different medical conditions based on the defined clinical standards and standard treatment guidelines.

ASU RMP shall maintain all patient records including case history, investigation reports, images, etc. as appropriate.

3.6 TYPES OF CONSULTATION: FIRST CONSULT/ FOLLOW-UP CONSULT

There are two types of patient consultations, namely, first consult and the follow-up consult.

An RMP may have only a limited understanding of the patient seeking teleconsultation for the first time, when there have been no prior in-person consultation. However, if the first consult happens to be via video, RMP can make a much better judgment and hence can provide much better advice including additional medicines, if indicated.

On the other hand, if a patient has been seen in-person earlier by the RMP, then it is possible to be more comprehensive in managing the patient.

3.6.1 First Consult means

- The patient is consulting with the RMP for the first time; or
- The patient has consulted with the RMP earlier, but more than 6 months have lapsed since the previous consultation; or
- The patient has consulted with the RMP earlier, but for a different health condition

3.6.2 Follow-Up Consult(s) means

- The patient is consulting with the same RMP within 6 months of his/her previous inperson consultation and this is for continuation of care of the same health condition. However, it will not be considered a follow up if:
- There are new symptoms that are not in the spectrum of the same health condition;
 and/or
- RMP does not recall the context of previous treatment and advice

3.7 PATIENT MANAGEMENT: HEALTH EDUCATION, COUNSELING & MEDICATION

- 3.7.1 If the condition can be appropriately managed via telemedicine, based on the type of consultation, then the RMP may proceed with a professional judgement to:
 - Provide Health Education as appropriate in the case; and/or
 - Provide Counseling related to specific clinical condition; and/or
 - Prescribe Medicines
- **3.7.2 Health Education:** An RMP may impart health promotion and disease prevention messages. These could be related to diet, physical activity, cessation of smoking, contagious infections and so on. Likewise, he/ she may give advice on immunizations, exercises, hygiene practices, mosquito control etc.
- **3.7.3 Counseling:** This is specific advice given to patients and it may, for instance, include food restrictions, do's and don'ts for a patient on anticancer drugs, proper use of a hearing aid, home physiotherapy, etc. to mitigate the underlying condition. This may also include advice for new investigations that need to be carried out before the next consult.

3.7.4 Prescribing Medicines

Prescribing medications, via telemedicine consultation is at the professional discretion of the RMP. It entails the same professional accountability as in the traditional in-person consult. If a medical condition requires a particular protocol to diagnose and prescribe as in a case of inperson consult then same prevailing principle will be applicable to a telemedicine consult.

Tailor made formulations is a very old tradition in an ASU system. Personal formulations of mixing some ingredients will be allowed. It is mandatory for ASU RMP to disclose all the ingredients of such formulations along with the preparation of the drugs.

Manufacturing and right to prescribe medicine are governed by State acts hence varies from state to state. The ASU RMP should always keep in mind this variation in state act while prescribing the medicines, even though these guidelines allow him to practice telemedicine all over India.

RMP may prescribe medicines via telemedicine ONLY when RMP is satisfied that he/ she has gathered adequate and relevant information about the patient's medical condition and prescribed medicines are in the best interest of the patient.

Prescribing Medicines without an appropriate diagnosis/provisional diagnosis will amount to a professional misconduct.

3.7.4.1 Specific Restrictions

There are certain limitations on prescribing medicines on consult via telemedicine depending upon the type of consultation and mode of consultation. The categories of medicines that can be prescribed via tele-consultation will be as notified in consultation with the Central Government from time to time.

- **Prohibited Medicines:** An RMP providing consultation via telemedicine cannot prescribe medicines in this category. These medicines have a high potential of abuse and could harm the patient or the society at large if used improperly
- "All ASU medicines containing Vishadravyas (Poisonous Substances) including any *Narcotic* and *Psychotropic* substances listed in the Narcotic Drugs and Psychotropic Substances, Act,
 1985 are not allowed to prescribe through telemedicine.

3.7.4.2 Issue a Prescription and Transmit

- If the RMP has prescribed medicines, RMP shall issue a prescription as per the Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982 and shall not contravene the provisions of the Drugs and Cosmetics Act and Rules.
- RMP shall provide photo, scan, digital copy of a signed prescription or e-Prescription to the patient via email or any messaging platform
- In case the RMP is transmitting the prescription directly to a pharmacy, he/ she must ensure explicit consent of the patient that entitles him/her to get the medicines dispensed from any pharmacy of his/ her choice

3.8 DUTIES AND RESPONSIBILITIES OF A RMP IN GENERAL

3.8.1 Medical Ethics, Data Privacy & Confidentiality³

3.8.1.1 Principles of medical ethics, including professional norms for protecting patient privacy and confidentiality as per IMCC Act shall be binding and must be upheld and practiced.

3.8.1.2 Registered Medical Practitioner would be required to fully abide by Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982 and with the relevant provisions of the IT Act, Data protection and privacy laws 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. This shall be binding and must be upheld and practiced.

3.8.1.3 Registered Medical Practitioners will not be held responsible for breach of confidentiality if there is a reasonable evidence to believe that patient's privacy and confidentiality has been compromised by a technology breach or by a person other than RMP. The RMPs should ensure that reasonable degree of care undertaken during hiring such services.

3.8.1.4 Misconduct

It is specifically noted that in addition to all general requirements under the IMCC Act for professional conduct, ethics etc., while using telemedicine all actions that willfully compromise patient care or privacy and confidentiality, or violate any prevailing law are explicitly not permissible. Some examples of actions that are not permissible:

- RMPs insisting on Telemedicine, when the patient is willing to travel to a facility and/or requests an in-person consultation
- RMPs misusing patient images and data, especially private and sensitive in nature (e.g. RMP uploads an explicit picture of patient on social media etc.)
- RMPs who use telemedicine to prescribe medicines from the specific restricted list

³ It is the responsibility of the RMP to be cognizant of the current Data Protection and Privacy laws. RMP shall not breach the patient's confidentiality akin to an in-person consultation. For example: If the RMP is planning to create virtual support group for disseminating health education for patients suffering from a particular disease condition then he/she shall be wary of the patient's willingness and not violate patient's privacy and confidentiality by adding them to the group without their consent.

 RMPs are not permitted to solicit patients for telemedicine through any advertisements or inducements

3.8.1.5 Penalties: As per IMCC Act, ethics and other prevailing laws.

3.8.2 MAINTAIN DIGITAL TRAIL/ DOCUMENTATION OF CONSULTATION

It is incumbent on RMP to maintain the following records/ documents for the period as prescribed from time to time:

3.8.2.1 Log or record of Telemedicine interaction (e.g. Phone logs, email records, chat/ text record, video interaction logs etc.).

3.8.2.2 Patient records, reports, documents, images, diagnostics, data etc. (Digital or non-Digital) utilized in the telemedicine consultation should be retained by the RMP.

3.8.2.3 Specifically, in case a prescription is shared with the patient, the RMP is required to maintain the prescription records as required for in-person consultations.

3.8.3 FEE FOR TELEMEDICINE CONSULTATION

3.8.3.1 Telemedicine consultations should be treated the same way as in-person consultations from a fee perspective: RMP may charge an appropriate fee for the Telemedicine consultation provided.

3.8.3.2 An RMP should also give a receipt/invoice for the fee charged for providing telemedicine based consultation.

4. FRAMEWORK FOR TELEMEDICINE

This section lays out the framework for practicing telemedicine in 5 scenarios:

- 1. Patient to Registered Medical Practitioner
- 2. Caregiver to Registered Medical Practitioner
- 3. Health Worker to Registered Medical Practitioner
- 4. Registered Medical Practitioner to Registered Medical Practitioner
- 5. Emergency Situations

Essential Principles:

- The professional judgement of a Registered Medical Practitioner should be the guiding principle: an ASU RMP is well positioned to decide whether a technology-based consultation is sufficient, or an in-person review is needed. Practitioner shall exercise proper discretion and not compromise on the quality of care
- Same principles apply irrespective of the mode (video, audio, text) used for a telemedicine consultation. However, the patient management and treatment can be different depending on the mode of communication used.
- ASU RMP should exercise his/her professional discretion for the mode of communication depending on the type of medical condition. If a case requires a video consultation for examination, ASU RMP should explicitly ask for it
- The ASU RMP can choose not to proceed with the consultation at any time. At any step,
 the
- o ASU RMP may refer or request for an in-person consultation
- o At any stage, the *patient has the right to choose to discontinue* the teleconsultation
- Providing Telemedicine facility to the patient will be absolute right of the doctor in case the RMP would like to deny the patient he or she shall not attract any legal provision.

4.1 CONSULTATION BETWEEN PATIENT AND REGISTERED MEDICAL PRACTITIONER

Specifically, this section details with the key elements of the process of teleconsultation to be used in the First consults and Follow up consults when a patient consults with an ASU RMP.

In these 2 situations, the patient initiates telemedicine consultation and thereby consent is implied.

4.1.1 First Consult: Patient to Registered Medical Practitioner

4.1.1.1 First Consult means

- 1. The patient is consulting with the ASU RMP for the first time; or
- 2. The patient has consulted with the ASU RMP earlier, but more than 6 months have lapsed since the previous consultation; or
- 3. The patient has consulted with the ASU RMP earlier, but for a different health condition

4.1.1.2 Tele-Consultation Process

The flow of the process is summarized in the Figure 1 and the steps are detailed below.

1. Start of a Telemedicine Consultation for First Consult

- The telemedicine consultation is initiated by the patient (For example, a patient may do an audio or video call with a ASU RMP or send an email or text with a health query)
- ASU RMP accepts to undertake the consultation

2. Patient identification and consent

- ASU RMP should confirm patient identity to his/her satisfaction by asking patient's name, age, address, email ID, phone number or any other identification that may be reasonable
- Telemedicine consultation should be initiated by the patient and thereby consent is implied

3. Quick assessment:

- The patient's condition needs to be quickly assessed by the ASU RMP based on available inputs and ASU RMP uses his professional discretion if emergency care is needed, to decide if emergency care is needed.
- o If the condition of the patient merits emergency intervention, then advice for first aid/immediate relief is provided and guidance is provided for referral, as appropriate.

If the condition does not merit an emergency intervention, the following steps are undertaken:

4. Exchange of Information for Patient Evaluation

- The ASU RMP may ask the patient to provide relevant information (complaints, information about any other consults for the same problem, available investigation and medication details, if any). The patient shall be responsible for accuracy of information shared by him/her with the ASU RMP.
- o If the ASU RMP feels that the information provided at this stage is inadequate, then he/she shall request for additional information from the patient. This information may be shared in real time or shared later via email/text, as per the nature of such information. The consultation may be resumed at a rescheduled time after receipt of the additional information (this may include some laboratory or radiological tests). In

- the meantime, the ASU RMP may provide health advice as appropriate.
- If the ASU RMP is satisfied that he/she has adequate patient information for offering a professional opinion, then he/she shall exercise one's professional judgment for its suitability for management via telemedicine.
- If the situation is NOT appropriate for further telemedicine consultation, then the ASU RMP should provide Health advice/ Education as appropriate; and/or refer for in-person consultation.

5. Patient Management

If the condition can be appropriately managed via telemedicine, then the ASU RMP may take a professional judgement to either:

- o Provide Health Education as appropriate in the case; and/or
- Provide Counseling related to specific clinical condition, including advice related to new investigations that need to be carried out before next consult; and/or
- Provide specific treatment by prescribing medicines

4.1.2 Follow-up Consult: Patient to Registered Medical Practitioner

In a follow-up consultation, since the ASU RMP-patient interaction has already taken place for the specific medical condition under follow-up, there is already an understanding of the context, with availability of previous records. This allows a more definitive and secure interaction between the ASU RMP and the patient.

4.1.2.1 Follow-Up Consult means

The patient is consulting with the ASU RMP within 6 months of his/her previous in-person, and this consultation is for continuation of care of the same health condition. Follow-up can be in situations of a chronic disease or a treatment (e.g. renewal or change in medications) when a face-to-face consultation is not necessary. Examples of such chronic diseases are: asthma, diabetes, hypertension and epilepsy etc.

4.1.2.2 Tele-Consultation Process

The flow of the process is summarized in Figure 2 and the steps are detailed below:

1. Start of a Telemedicine Consultation for Follow Up

 Patient may initiate a follow up consult with a ASU RMP for continuation of his/her ongoing treatment or for a new complaint or complication arising during the course of the ongoing treatment using any mode of communication. For e.g., the patient may do an audio or video call with a ASU RMP or send him/her an email or text message with a specific health query

ASU RMP accepts to undertake the consultation

2. Patient identification and consent

- RMP should be reasonably convinced that he/she is communicating with the known patient, for e.g. if the patient is communicating with RMP through the registered phone number or registered email id o If there is any doubt RMP can request the patient to reinitiate the conversation from a registered phone number or email id or should confirm patient identity to his/her satisfaction by asking patient's name, age, address, email ID or phone number. [Details in the section 3.2]
- o Patient initiates the Telemedicine consultation and thereby consent is implied

3. Quick Assessment for Emergency Condition

 If the patient presents with a complaint which the RMP identifies as an emergency condition necessitating urgent care, the RMP would then advice for first aid to provide immediate relief and guide for referral of the patient, as deemed necessary.

4. In case of routine follow-up consultation, the following would be undertaken:

- If the RMP has access to previous records of the patient, he/ she may proceed with Continuation of care.
- RMP shall apply his/her professional discretion for type of consultation based on the adequacy of patient information (history/examination findings/Investigation reports/past records).
- If the RMP needs additional information, he/ she should seek the information before proceeding and resume tele-consultation for later point in time.

5. Patient Management

- If RMP is satisfied that he/she has access to adequate patient information and if the condition can be appropriately managed by tele-consultation, he/she would go ahead with the tele-management of the patient.
- If the follow-up is for continuation of care, then the RMP may take a professional judgement to either:
- Provide health education as appropriate in the case; or o Provide counseling related to specific clinical condition including advice related to new investigations that need to be carried out before next consult; o And/or Prescribe Medications. The medications could be either of the below:

- If the follow up is for continuation of care for the same medical condition, the RMP would re-prescribe original set of medications for a refill (List A of medications, which has been previously prescribed for the patient).
- If the RMP considers addition of a new drug, as an 'add-on' medication to optimize the underlying medical condition, then the RMP can prescribe medications listed under List B.
- If the follow-up consult is for a new minor ailment necessitating only 'over the counter' medications or those notified for this purpose, medications under List O can be prescribed.
- o If the follow-up consult reveals new symptom pertaining to a different spectrum of disease, then the RMP would proceed with the condition as enunciated in the scenario for a first-time consultation (4.1.1).

4.2 CONSULTATION BETWEEN PATIENT AND RMP THROUGH A CAREGIVER

- 4.2.1 For the purpose of these guidelines "Caregiver" could be a family member, or any person authorized by the patient to represent the patient.
- 4.2.2 There could be two possible settings:
 - 1. Patient is present with the Caregiver during the consultation.
 - 2. Patient is not present with the Caregiver. This may be the case in the following:
 - 2a. Patient is a minor (aged 16 or less) or the patient is incapacitated, for example, in medical conditions like dementia or physical disability etc. The care giver is deemed to be authorized to consult on behalf of the patient.
 - 2b. Caregiver has a formal authorization or a verified document establishing his relationship with the patient and/or has been verified by the patient in a previous inperson consult (explicit consult).

In all of the above, the consult shall proceed as in the case of RMP and the patient (first or follow up consult, vide 4.1)

4.3 CONSULTATION BETWEEN HEALTH WORKER AND RMP

For the purpose of these guidelines, "Health worker" could be a Nurse, Allied Health Professional, Mid-Level Health Practitioner, ANM or any other health worker designated by an appropriate authority.

Proposed Set up

- This sub section will cover interaction between a Health Worker seeking consultation for a patient in a public or private health facility.
- In a public health facility, the mid-level health practitioner at a Sub-center or Health and wellness center can initiate and coordinate the telemedicine consultation for the patient with a RMP at a higher center at district or State or National level. Health and Wellness centers are an integral part of comprehensive primary health care.
- o This setting will also include health camps, home visits, mobile medical units or any
- community-based interaction.

Tele-Consultation Process

The flow of the process is summarized in Figure 3 and the steps are detailed below:

1. Start of a Telemedicine Consultation through a Health Worker/RMP

- The premise of this consultation is that a patient has been seen by the Health Worker
- o In the judgment of the health worker, a tele-consultation with a RMP is required
- Health Worker should obtain the patient's informed consent
- Health worker should explain potential use and limitations of a telemedicine consultation
- He/she should also confirm patient identity by asking patient's name, age, address, email ID, phone number or any other identification that may be reasonable
- Health Worker initiates and facilitates the telemedicine consultation.

2. Patient Identification (by RMP)

- RMP should confirm patient identity to his/her satisfaction by asking patient's name, age, address, email ID, phone number or any other identification that may be reasonable
- o RMP should also make their identity known to the patient

3. Patient Consent (by RMP):

RMP should confirm the patient's consent to continue the consultation

4. In case of Emergency,

- The Health Worker would urgently communicate about the underlying medical condition of the patient to the RMP.
- If based on information provided, if the RMP identifies it as an emergency condition necessitating urgent care, he/she should advice for first aid to be provided by the Health Worker for immediate relief and guide for referral of the patient, as deemed necessary.

In case, the condition is not an emergency, the following steps would be taken:

5. Exchange of Information for Patient Evaluation (by RMP)

- The Health Worker must give a detailed explanation of their health problems to the RMP which can be supplemented by additional information by the patient, if required.
- The RMP shall apply his professional discretion for type and extent of patient information (history/examination findings/Investigation reports/past records) required to be able to exercise proper clinical judgement.
- o If the RMP feels that the information provided is inadequate, then he/she shall request for additional information. This information may be shared in real time or shared later via email/text, as per the nature of such information. For e.g., RMP may advice some laboratory or/and radiological tests for the patient. For such instances, the consult may be considered paused and can be resumed at the rescheduled time. RMP may provide health education as appropriate at any time.

6. Patient Management

- Once the RMP is satisfied that the available patient information is adequate and that the case is appropriate for management via telemedicine, then he/she would proceed with the management. Health worker should document the same in his/her records.
- The RMP may take a professional judgement to either:
 - o Provide health education as appropriate in the case,
 - Provide counseling related to specific clinical condition including advice related to new investigations that need to be carried out before next consult;
 - And/or prescribe medications.
 - As prescribed for use in guidelines from time to time for a particular cadre of Health Workers

5.2 Role of Health Worker:

In all cases of emergency, the Health Worker must seek measures for immediate relief and first-aid from the RMP who is being tele-consulted. Health worker must provide the immediate relief/first aid as advised by the RMP and facilitate the referral of the patient for appropriate care. The Health Worker must ensure that patient is advised for an in-person interaction with an RMP, at the earliest.

For patients who can be suitably managed via telemedicine, the Health Worker plays a vital role of

- Reinforcing the health education and counseling provided by the RMP
- Providing the medicine prescribed by the RMP and providing patient counseling on his/her treatment

4.4 REGISTERED MEDICAL PRACTITIONER TO ANOTHER RMP/ SPECIALIST

- Registered Medical Practitioner might use telemedicine services to consult with another RMP or a specialist for a patient under his/her care. Such consultations can be initiated by a RMP on his/her professional judgement.
- The RMP asking for another RMP's advice remains the treating RMP and shall be responsible for treatment and other recommendations given to the patient.
- o It is acknowledged that many medical specialties like radiology, pathology, ophthalmology, cardiology, dermatology etc. may be at advanced stages of adoption of technology for exchange of information or some may be at early stage. Guidelines support and encourage interaction between RMPs/ specialists using information technology for diagnosis, management and prevention of disease.
- Tele-radiology is the ability to send radiographic images (x-rays, CT, MRI, PET/CT, SPECT/CT, MG, Ultrasound) from one location to another.
- Tele-pathology is use of technology to transfer image-rich pathology data between distant locations for the purposes of diagnosis, education, and research.
- Tele-ophthalmology access to eye specialists for patients in remote areas, ophthalmic disease screening, diagnosis and monitoring.

4.5 EMERGENCY SITUATIONS

In all telemedicine consultations, as per the judgment of the RMP, if it is an emergency situation, the goal and objective should be to provide in-person care at the soonest. However critical steps could be life-saving and guidance and counseling could be critical. For example, in

cases involving trauma, right advice and guidance around maintaining the neck position might protect the spine in some cases. The guidelines are designed to provide a balanced approach in such conditions. The RMP, based on his/ her professional discretion may

- o Advise first aid o Counseling
- o Facilitate referral

In all cases of emergency, the patient MUST be advised for an in-person interaction with a Registered Medical Practitioner at the earliest.

5. GUIDELINES FOR TECHNOLOGY PLATFORMS ENABLING TELEMEDICINE

This specifically covers those technology platforms which work across a network of Registered medical practitioners and enable patients to consult with ASU RMPs through the platform.

- **5.1** Technology platforms (mobile apps, websites etc.) providing telemedicine services to consumers shall be *obligated to ensure* that the consumers are consulting with *Registered medical practitioners* duly registered with CCIM or respective state councils and comply with relevant provisions.
- **5.2** Technology Platforms shall conduct their *due diligence* before listing any ASU RMP on its online portal.

Platform must provide the *name, qualification and registration number, contact details of every ASU RMP* listed on the platform.

- **5.3** In the event some non-compliance is noted, the technology platform shall be required to *report* the same to CCIM who may take appropriate action.
- **5.4** Technology platforms based on *Artificial Intelligence/Machine Learning are not allowed to counsel the patients or prescribe any medicines* to a patient. Only an ASU RMP is entitled to counsel or prescribe and has to directly communicate with the patient in this regard. While new technologies such as Artificial Intelligence, Internet of Things, advanced data science-based decision support systems etc. could *assist and support an ASU RMP* on patient evaluation, diagnosis or management, the final prescription or counseling has to be directly delivered by the ASU RMP.
- **5.5** Technology Platform must ensure that there is a proper mechanism in place to address any queries or grievances that the end-customer may have.
- **5.6** In case any specific technology platform is found in violation, CCIM may designate the technology platform as blacklisted, and no ASU RMP may then use that platform to provide telemedicine

6. SPECIAL RESPONSIBILITIES OF CENTRAL COUNCIL OF INDIAN MEDICINE (CCIM)

- 6.1 Any of the <u>drug-lists</u> contained in Telemedicine Practice Guidelines can be modified by the CCIM/Ministry of AYUSH, Govt. of India from time to time, as required.
- 6.2 The CCIM may issue necessary directions or advisories or clarifications in regard to these Guidelines, as required.
- 6.3 The Telemedicine Practice Guidelines can be amended from time to time in larger public interest with the prior approval of Ministry of AYUSH, Government of India.

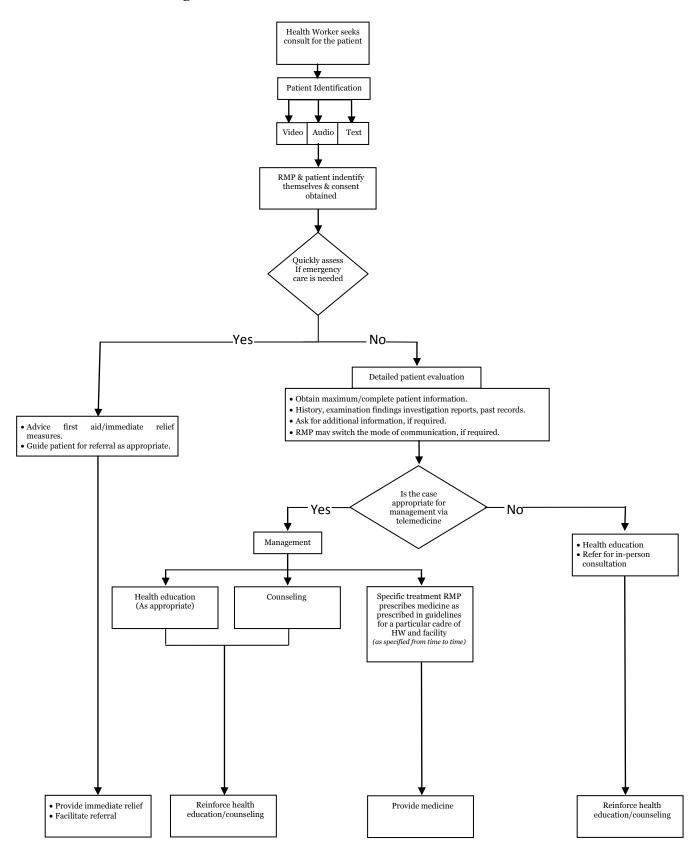
Flow Chart (Figure-1) **First consult:** Patient and Registered Medical Practitioners (ASU RMP) Patient Audio Text Patient Identification Consent: Implied Quickly assess If emergency . Yes No • Advice first Detailed patient evaluation aid/immediate measures. · Guide patient for referral as appropriate. \bullet Obtain maximum/complete patient information. · History, investigation reports, past records. • Ask for additional information, if required. • RMP may switch the mode of communication, if required. Is the case appropriate for management via telemedicine Yes. Management • Health Education • Refer for in-person consultation Counseling (Specific to clinical Health Specific education (As treatment appropriate) In case the telemedicine is on video Prescribe medicines

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Flow Chart (Figure-2) Follow up consult: Patient and Registered Medical Practitioners (ASU RMP) Patient Video Audio Text Patient Identification RMP should be reasonably convinced that he/she is communicating with the known patient. If not, RMP can request the to re-initiate conversation from a registered phone number/Email or confirm patient identity by asking patient's name, age, address, email ID or phone number. Consent: Implied Quickly assess If emergency care is needed Yes Advice first aid/immediate relief Detailed patient evaluation measures. • Guide patient for referral as appropriate. · Appraise previous records. • History, examination findings investigation reports, past records. • Ask for additional information, if required. \bullet RMP may switch the mode of communication, if required. Is the case appropriate for management via telemedicine No Continuation of care? New Complaint? Health education Counseling Specific treatment Proceed as 'First Consult' Health education (Specific to clinical condition) -Re-prescribe prior medications (As appropriate) (Refer Figure 1) Refer for inperson consultation Patient requires add-on-medicines for the same complaint? May prescribe medicines Page 32 of 33

Flow Chart (Figure-3)

Health Worker (HW) and Registered Medical Practitioner (ASU RMP)



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