

दूरभाष/Phone : 25367033, 25367035, 25367036

ई-मेल /E-mail : ethics@nmc.org.in

वेबसाईट /Website : www.nmc.org

पॉकेट -14, सेक्टर-8, द्वारका, फेस-1,

नई दिल्ली-110077

Pocket- 14, Sector- 8, Dwarka,

Phase - 1, New Delhi-110077

राष्ट्रीय आयुर्विज्ञान आयोग
National Medical Commission
ETHICS & MEDICAL REGISTRATION BOARD

F.No.12013/01/2022/Ethics

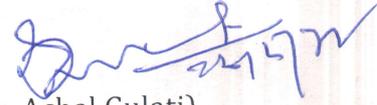
Date: 23.05.2022

PUBLIC NOTICE

Draft Regulations are placed in public domain through our website on 23.05.2022 in accordance with Section 27, 30, 31 & 57 of the National Medical Commission Act, 2019 inviting comments from public in general & Experts/Stakeholders/Organisations for the following proposed regulations:

"National Medical Commission, Registered Medical Practitioner (Professional Conduct) Regulations, 2022"

The comments should be sent to the email at emrb.ethics@nmc.org.in within one month i.e. by 22.06.2022.



(Dr. Achal Gulati)
President, EMRB

Encls: as above

NATIONAL MEDICAL COMMISSION
NEW DELHI, DATED

**National Medical Commission Registered Medical Practitioner
(Professional Conduct) Regulations, 2022**

No. xxxx/xxx/NMC._____ In exercise of the powers conferred by section 27(1)b, read with sections 10(b)(f), 16(2), and 57(2)zh of the National Medical Commission Act, 2019 (No.30 of 2019), the National Medical Commission hereby makes the following Regulations relating to Professional Conduct of Registered Medical Practitioners namely:-

Chapter-1

Preliminary

1. Short Title and Commencement:

(A) These regulations may be called the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2022

(B) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions:

(A) In these regulations, unless the context otherwise requires, -

- a) "Act" means the National Medical Commission Act, 2019 (No.30 of 2019);
- b) "Commission" or NMC means the National Medical Commission constituted under section 3
- c) " Ethics and Medical Registration Board" or EMRB means the Board constituted under section 16;
- d) "Form" means a Form appended to these regulations;
- e) "Modern medicine" or "Allopathy" is a healthcare discipline that involves a scientific understanding of disease processes and uses rational and evidence-based treatment methods. This system of medicine views disease as a biological abnormality in the function or structure of organs or organ systems, with effects on organs and the body as a whole. Animal experiments may be used to understand disease processes and the efficacy

of therapeutic measures. Medical research using blinded studies and statistical analyses informs all aspects of diagnosis, testing, treatment, and disease prevention. Modern medicine has international uniformity in theory and practice. It has found universal acceptance in India and is currently practiced and taught in Government and Private hospitals and medical colleges governed/regulated and accredited by the National Medical Commission, Government of India.

- f) "National Register" means a National Medical Register maintained by the Ethics and Medical Registration Board under section 31;
- g) "Registered Medical Practitioner" or "RMP" means a person whose name is either in the State Medical Register or the Indian Medical Register or the National Medical Register unless otherwise specified.
- h) "Schedule" means the Schedule appended to these regulations.
- i) "State Medical Council" means a medical council constituted under any law for the time being in force in any State or Union territory for regulating the practice and registration of practitioners of medicine in that State or Union territory.
- j) "State Register" means a register maintained under any law for the time being in force in any State or Union territory for registration of practitioners of medicine.

(B) The words and expressions used herein and not defined but defined in the Act shall have the same meanings as assigned to them in the Act.

Chapter 2

Professional Conduct of RMPs

3. **Duties and responsibilities of the Registered Medical Practitioners:** At the time of making an application for registration under the provisions of the NMC Act, it shall be deemed that the RMP has read and agreed to abide by these regulations.

4. **Prefix, Suffix and Modern Medicine:**

(A) Only those RMPs who are registered under NMC Act, 2019, can use

Medical Doctor (Med Dr.) as a prefix before their names. Every self-employed RMP shall display the unique registration ID assigned to her/him by EMRB in his/her prescription, certificate, and money receipts given to patients. Employed RMP shall get a seal made by the employer for displaying the unique registration number below the RMP's signatures. (L1).

(Guideline for prescription)

(B) The RMP shall display as suffix to his/her name only NMC recognized and accredited medical degrees/diplomas as provided in the nomenclature of the regulations and listed on the NMC website. (List of such Degrees and Diplomas will be on the website and updated regularly)RMPs qualified abroad and seeking registration to practice after clearing FMGE/NEXT must use NMC-approved equivalent Medical prefixes and suffixes to provide clarity to patients and the public at large. (L1).

(C) A RMP shall not claim to be a clinical specialist unless he/she has NMC recognized training and qualification in that specific branch of modern medicine (The list of recognized post-graduation and super-specialization degrees/diplomas will be available on the NMC website) (L1, L2)

(D) Every RMP shall practice the system of medicine in which he/she has trained and certified (for this purpose referred to as modern medicine* or allopathic medicine) and shall not associate professionally with any unqualified person to perform any treatment, procedure, or operation.(L2)

(E) A RMP shall not employ in connection with his/her professional practice any healthcare professional who is neither registered nor trained under the relevant Medical Acts in force related to the practice of modern medicine. Provided that having employed any other assistants in the practice, the ultimate responsibility rests on the self-employed RMP or the RMP responsible for administration and recruitment in case of hospital practice.(L2)

(F) A person qualified in more than one system of medicine should decide which system he wants to practice. Once licensed to practice Modern medicine under NMC Act, he shall not practice another system of medicine

simultaneously. Short courses in other systems of medicine do not qualify a practitioner to practice and prescribe in that system of medicine.(L2)

5.Continuing Professional Development Program: A RMP should attend continuing professional development programs regularly each year, totaling at least 30 credit hours every five years. Only recognized medical colleges and health institutions or medical societies accredited or authorized by EMRB/State medical Councils can offer training and credit hours for this purpose. Credit hours awarded shall be updated online against the Unique Registration Number of RMP on the EMRB-NMC website. Renewal of License to practice should be done every 5 years (from the publication of the Gazette notification), after submitting documentation of CPD credit hours. The license renewal form will allow updates of details like specialization, place of work, address, contact details, or any other detail specified by EMRB/NMC. RMPs who wish to practice in another State (due to transfer of work of residence) should inform that State Medical Council and apply for License to practice in that State. State will have to mandatorily provide license to practice charging appropriate fee within 7 days. (CPD guidelines) (L2)

6.Right to remuneration of A RMP: Consultation fees should be made known to the patient before examination or treatment of the patient. A reasonable estimation of the cost of surgery or treatment should be provided to the patient to enable an informed decision. A RMP can refuse to continue to treat a patient if the fees, as indicated, are not paid. This does not apply to doctors in Government service or emergencies and the doctor must ensure that the patient is not abandoned. (L1)

7.Prohibiting Soliciting of Patients: A RMP shall not solicit patients directly or indirectly or as a part of the group of RMPs, or institutions or organizations or hospitals or nursing homes, or corporate hospitals established, owned, controlled, or maintained by the appropriate Government, local authority, trust, whether private or public, corporation, co-operative society, organization or any other entity or person. (L2)

8.Prescribing Generic Medicine: Every RMP is expected to prescribe drugs using generic names written legibly and prescribe drugs rationally, avoiding unnecessary medications and

irrational fixed-dose combination tablets. (L1, L2) (Generic Drugs and Prescription guidelines)

9.Prohibition of Fee Splitting/Commissions: A RMP shall not directly or indirectly participate in any act of division, transfer, assignment, subordination, rebating, splitting, or refunding of any fee for diagnostic, scanning, medical, surgical, or other treatment. These provisions shall apply with equal force to the referring, recommending, or procuring by a RMP of any patient, specimen, or material for diagnostic purposes or other studies/work. However, nothing in this section shall prohibit payment of salaries by a qualified RMP to another duly qualified person rendering medical care under his/her supervision. RMP shall not use online forums or agents for procuring patients. (L3)

10.Prohibition of endorsement of the product or a person:

- A. A RMP individually or as part of an organization/association/society shall not give to any person or to any companies or to any products or to software/platforms, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report, or statement concerning any drug, medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode nor shall he boast of cases, operations, cures or remedies or permit the publication of report thereof through any mode. (L3)
- B. A RMP shall not issue certificates of proficiency in modern medicine to unqualified or non-medical persons. This does not restrict the proper training and instruction of bonafide students, midwives, dispensers, surgical attendants, or skilled mechanical and technical assistants & therapy assistants under the personal supervision of RMPs. (L2). Every certificate must contain the details regarding experience, skills and competency obtained, duration of the training, and kind of work done during training. The onus of the veracity of the certificates lies with the RMP. (L2)

11.Restriction on Advertisement:

- A. A RMP is permitted to make a formal announcement in any media (print, electronic or social) within 3 months regarding the following: (1) On starting practice (2) On change of type of practice (3) On changing

address (4) On temporary absence from duty (5) On resumption of practice (6) On succeeding to another practice (7) Public declaration of charges. (L2).

- B. A RMP or any other person including corporate hospitals, running a maternity home, nursing home, private hospital, rehabilitation center, or any type of medical training institution, etc. may place announcements in the lay press, but these should not contain anything more than the name of the institution, type of patients admitted, kind of training and other facilities offered and the fees. **(Guidelines on social media conduct)** (L1, L2)
- C. A RMP is allowed to do public education through media without soliciting patients for himself or the institution (L2)

12. Responsibility of RMP regarding the sale of drugs:

- A. A RMP shall not run an open shop to sell medicine prescribed by RMPs other than himself or for the sale of medical or surgical appliances. They are allowed to sell medication to his/her own patients. (L2)
- B. RMP can prescribe or supply drugs, remedies, or appliances as long as there is no exploitation of the patients. Drugs prescribed by a RMP or bought from the pharmacy for a patient should explicitly state the generic name of the drug. (L2)
- C. A RMP shall not dispense or prescribe secret remedial agents of which he does not know the composition or action in the body. The manufacture or promotion or use of these remedies is prohibited. (L3)

13. Responsibility of RMP regarding the Medical Records:

- A. Every self-employed RMP shall maintain medical records of patients (outpatients or inpatients) for 3 years from the date of the last contact with the patient for treatment, in a standard proforma-laid down by the NMC. **(Guideline)** (L2)
- B. If any request is made for medical records to a RMP responsible for patient records in a hospital or healthcare institution either by the patients / authorized attendant or legal authorities involved, the same may be duly acknowledged and documents shall be supplied within 5 working days. (L2)
- C. In case of medical emergencies, the medical records should be made available on the same day. (L2)
- D. Efforts shall be made to computerize patient's medical records for quick retrieval and

security. Within 3 years from the date of publication of these regulations, the RMP shall fully digitize records, abiding by the provisions of the IT Act, Data protection and privacy laws, or any other applicable laws, rules, and regulations notified from time to time for protecting the privacy of patient data. (L1, L2)

E. RMPs are in certain cases bound by law to give or may from time to time be called upon to give certificates, notifications, reports, and other documents of similar character, signed by them in their professional capacity for subsequent use in the courts or administrative or other purposes. Such reports, certificates, or documents should not be untrue, misleading, or improper. A self-employed RMP shall maintain a Register giving full details of such certificates issued by him/her. (L3)

14.A RMP shall cooperate in the investigation against incompetent, corrupt or dishonest conduct of other members of the profession without fear or favor. (L1)

15.The RMP shall not aid or abet torture, nor shall he be a party to either infliction of mental or physical trauma or concealment of torture inflicted by another person or agency in clear violation of human rights. (L3)

16.Practicing euthanasia shall constitute unethical conduct. However, in some instances, the question of withdrawing life-supporting devices or measures even after brain death shall be decided following the provisions of the Transplantation of Human Organ Act, 1994. (End of Life Guidelines)

17.The RMP should respect the boundaries of the doctor-patient relationship and not exploit the patient for personal, social, and business reasons (L2) and in particular, avoid sexual boundary violations. (L4)

18.RMP shall not refuse on religious grounds alone to assist in or conduct of sterility, birth control, circumcision, and medical termination of Pregnancy when there is a medical indication. (L3)

19.Informed Consent:

(A). Before performing any clinical procedure, diagnostic or therapeutic, or operation, the RMP should obtain the documented informed consent of the patient. In case the patient is unable to give consent, the consent of the legal guardian or

family member must be taken. The name of the operating surgeon must be mentioned in the medical records. In an operation that may result in sterility, the consent of both husband and wife is required. In case of an emergency, the doctor should try to obtain consent, but if this is not possible, he must act in the best interest of the patient. The medical records should describe the basis of decisions taken in an emergency. No act of in-vitro fertilization or artificial insemination shall be undertaken without the informed written consent of the female patient and her spouse as well as the donor. (Consent Guidelines) (L4)

(B). A RMP shall not publish photographs or case reports of patients without their permission in any medical or another journal in a manner by which their identity could be revealed. (L1)

(C). Clinical drug trials or other research involving patients or volunteers must comply with ICMR guidelines and the New Drugs and Clinical Trials Rules, 2018. Consent taken from the patient or participants for the trial of drug or therapy which is not as per the guidelines shall also be construed as misconduct. (Research Guidelines) (L2 - L4)

20. Conduct of RMP on Social/Electronic and Print Media shall follow the prescribed guidelines (Social Media Guidelines) (L1)

21. RMP should take due care in practice and exercise reasonable skills as expected, to preserve the life and health of the patient and follow the guidelines (Guidelines on Reasonable Care and Skill) (L4)

CHAPTER 3

DUTIES OF RMPs TOWARDS THEIR PATIENT

22. Keeping appointments:

(A). An RMP shall endeavor to be prompt in attending to patients and should keep in time with appointments or visiting/consultation hours. If the RMP is delayed for a valid reason, the patient should be informed. (L1)

(B) A RMP may also advise referral when necessary to another RMP who is specialized in the treatment of the patient's ailment. (L1)

(C) In case of emergency (life and limb saving procedure) an RMP shall provide first aid and other services to the patient according to his expertise and the available resources before referral. (L3)

23. Incapacity: A Registered Medical Practitioner having any incapacity (induced or otherwise) detrimental to the patient or professional practice, which can affect his decision-making or skill in treating the patient is not permitted to practice his profession for the period of incapacity. Use of Alcohol or other intoxicants during duty or off duty which can affect professional practice will constitute misconduct. (L3, L4)

24. Confidentiality: Every communication between RMP and patients shall be kept confidential. Such communication, whether personal, or related to health and treatment, shall not be revealed unless required by the laws of the state, or if non-disclosure may itself be detrimental to the health of the patient or another human being. (L2, L3)

25. Truth-telling: The RMP should neither exaggerate nor minimize the gravity of a patient's condition. He/ She shall ensure that the patient or legally appointed representative has such knowledge of the patient's condition that can assist in making decisions that will best serve the interests of the patient. (L1)

26. Patient care: A RMP is free to choose whom he will serve, except in case of a life-threatening emergency. Having accepted a case, the RMP should neither neglect the patient nor withdraw from the case without giving adequate notice to the patient and his family. If a change of RMP is needed (for example, the patient needs a procedure done by another RMP), consent should be obtained from the patient himself or the guardian. The RMP who attends to the patient will be fully accountable for his actions and entitled to the appropriate fees. In case of abusive, unruly, and violent patients or relatives, the RMP can document and report the behavior and refuse to treat the patient. Such patients should be referred for further treatment elsewhere. (L2-L4)

- 27. Referral:** Only such Follow up consultation should be planned as required by the patient. Likewise, laboratory investigations ordered for the patient should be justified. An update/summary of the clinical condition and reasons for referral must be documented and provided at the referral. Specialist referral must be sought to benefit only the patient and duly justified in medical documents (L2)
- 28. Signatures:** All signatures in the notes, prescriptions, certificates, orders, referral summaries etc, should carry the RMP's Name and NMC Registration number. Electronic generation of orders/prescriptions may help automation of this information. (L1, L2)
- 29. Consultation by Telemedicine:** Consultation through Telemedicine by the Registered Medical Practitioner shall be permissible following the Telemedicine Practice Guidelines **(Telemedicine Guideline)** (L1, L2)

CHAPTER-4

RESPONSIBILITIES OF RMPS TO EACH OTHER

- 30. Professional Integrity:** In consultations, professional rivalry should not be indulged in. All due respect is owed to the RMP in charge of the case, and no derogatory statement or remark be made which would impair the confidence reposed in him by the patient. For this purpose, professional discussions should not take place in the presence of the patient or family or legally appointed representative. The specialist must provide the clinical opinion only to the RMP who referred the patient. Every discussion/opinion regarding the patient should be kept confidential. If a referral is sought by an RMP, it should be clarified if the specialist will take over the care of the patient or if the patient will remain with the primary RMP. (L1, L2)
- 31. RMP as Locum:** Whenever a RMP requests another RMP to attend to his patients during his temporary absence from his practice, professional courtesy requires the acceptance of such appointment only when the RMP can discharge the additional

responsibility along with his /her other duties. The RMP acting under such an appointment should give the utmost consideration to the interests and reputation of the absent RMP and all such patients should be restored to the care of the latter upon his/her return. (L1, L2)

32. Reporting and Inspection: When it becomes the duty of a RMP occupying an official position to inspect and report on an illness or injury, he should communicate this to the RMP in attendance to give him the option of being present. The RMP occupying an official position should avoid making any derogatory remarks regarding the diagnosis or the treatment plan adopted. (L1, L2)

CHAPTER 5

DUTIES OF RMPs TOWARDS THE PUBLIC AND ALLIED HEALTHCARE PROFESSIONALS

33. Public Education and Awareness:

(A). RMPs, as good citizens, have a responsibility to disseminate scientific advice on public health issues in the public interest without self-promotion. They should particularly co-operate with the authorities in the administration of sanitary/public health laws and regulations. (L1)

(B). RMP should enlighten the public concerning quarantine regulations and measures for the prevention of epidemics and communicable diseases. At all times the RMP should notify the constituted public health authorities of every case of notifiable disease under his care, following the laws, rules, and regulations of the health authorities. RMP needs to involve in public education and awareness activities without involving in the advertisement. When an epidemic occurs, a RMP provided with all the necessary medical protection and his own health permitting should not abandon his duty for fear of contracting the disease himself. (L1, L2)

34. RMP as a team leader, should recognize the importance of teamwork and respect the practice of different paramedical services. (L1)

- 35.** RMPs and their families must not receive any gifts, travel facilities, hospitality, cash or monetary grants, consultancy fee or honorariums, or access to entertainment or recreation from pharmaceutical companies, commercial healthcare establishments, medical device companies, or corporate hospitals. However, this does not include salaries and benefits that RMPs may receive as employees of these organizations. Also, RMPs should not be involved in any third-party educational activity like CPD, seminar, workshop, symposia, conference, etc., which involves direct or indirect sponsorships from pharmaceutical companies or the allied health sector. RMP should be aware of the conflict of interest situations that may arise. The nature of these relationships should be in the public domain and should not be in contravention of any law, rule, or regulation in force. An RMP himself or as part of any society, organization, association, trust, etc. should be transparent regarding the relationship with the pharmaceutical and allied health sector industry. (L3)
- 36.** RMPs may be required to file an affidavit regarding their financial earnings and or benefits received in the past 5 past years from any pharmaceutical companies or allied health sector. (L3)
- 37.** Power to Draft guidelines: EMRB will draft the guidelines/codes etc on Generic Drugs and Prescription, CPD guidelines and accreditation of organizations, Telemedicine Guidelines, Code of Ethics, Guidelines on Penalties for Misconduct including the monetary penalty, Advertisement Guidelines, End of Life guidelines, Consent in Medical Practice, Guidelines on Research by RMPs, Guidelines on Social Media Conduct of RMPs, Guidelines on Reasonable care, skill and Guidelines on Interaction with Pharmaceuticals, as and when required and amended from time to time by EMRB.

CHAPTER 6

PROFESSIONAL MISCONDUCT

- 38.** Professional Misconduct: Any violation of these regulations, or other applicable Acts related to medical practice which are in force, shall constitute professional misconduct. By issuing these regulations, the EMRB, NMC, and the State Medical Councils are in no way precluded from considering and dealing with any other form

of professional misconduct by registered medical practitioners which do not fall under any of the categories mentioned in the regulations or guidelines or codes appended. RMPs bound by these regulations will not engage in any activities which violate these regulations and should not enter into any employment or other contract that engages in activities in violation of any of these regulations. Conviction of RMP in cases of a cognizable offence involving moral turpitude may result in the suspension of license to practice.

39. Procedure for a complaint of professional misconduct

- A. The aggrieved person will file the complaint to the State Medical Council through the website portal/offline, ordinarily within 2 years of the cause of action. (The complaint will be lodged in the SMC where RMP is located at the time of cause of action, both in teleconsultation or in person consultation)
- B. Where the aggrieved person is unable to make a complaint on account of physical or mental incapacity, a complaint may be filed by —
 - a. a family member or relative or friend; or
 - b. the guardian or authority under whose care treatment was received
 - c. the legal heir or guardian in case of death of the patient
- C. The EMRB or state medical council can initiate a suo-moto case against any RMP taking cognizance of gross misconduct. The suo-moto complaint will be taken up if a simple majority of the EMRB or State medical council members agrees to proceed against the RMP

40. Manner of Inquiry into the complaint

(A) At the time of filing the complaint, the complainant shall submit to the EMRB or state medical council five copies or for offline applications (till the whole process is made online) of the complaint along with supporting documents and the names and addresses of the witnesses.

(B) On receipt of the complaint, the council shall send one of the copies received to the respondent within 15 working days. For online complaints, the State Medical Council/EMRB/NMC will send an e-copy/physical copy of the complaint to the respondent.

(C) The respondent shall file his reply to the complaint along with his list of documents, and names and addresses of witnesses, within a period not exceeding 15 working days from the date of receipt of the documented complaint

(D). The state medical council or EMRB/NMC shall conduct an inquiry into the complaint following the principles of natural justice.

(E) On receipt of the complaint, the State Medical Council shall refer the case for review to the designated committee, with assistance from a panel of experts, if required, specifically formed for this purpose in the stipulated time.

(F) If more than one hearing is required, The /State Medical Council or EMRB/NMC shall have the right to terminate the inquiry proceedings or to give an ex-parte decision on the complaint if the complainant or respondent fails, without sufficient cause, to present herself or himself for two consecutive hearings or three hearings in total convened by the /SMC or EMRB/NMC. In such situations, the termination or ex-parte order may not be passed without giving a notice fifteen days in advance to the party concerned.

(G) The parties shall not be allowed to bring in any lawyer to represent them in their case at any stage of the proceedings before the state medical council or EMRB/NMC.

(H) In conducting the inquiry, a quorum shall be ensured.

(I). No new documents or certificates or evidence or witness will be entertained from either of the parties once the proceedings are initiated (meaning -after the parties have been called for a hearing) unless its admission is cleared by the majority of the members. The complaint cannot be withdrawn after it is admitted by the SMC or EMRB/NMC.

(J). The State Medical Council or EMRB/NMC may either of its motion or on an application made by either of the parties have the power to change the subject matter experts, if appointed, by providing a valid reason.

41. Disposal of the complaints: The State Medical Council or EMRB/NMC after giving the parties concerned an opportunity of being heard, may make any of the following recommendations:

- 1) dismiss the complaint
- 2) reprimand or warn the RMP
- 3) recommend counseling to the RMP
- 4) an alternative penalty can be considered

(Guidelines for alternative penalties can be given by EMRB as and when required)

- 5) may restrain the RMP from performing the clinical procedure(s) or examination as deemed fit. Holding Suspension i.e. restraining RMP from practice until the case is decided- only with full consensus
- 6) Suspend the RMP from practice for a temporary period as it may deem fit by removing the name of the RMP temporarily from the National Medical Register
- 7) Award monetary penalty to aggrieved party as it deems fit as per Section 30 of the NMC Act, 2017 can be given by EMRB only as and when required.
- 8) SMC can charge monetary penalty up to 10 times of the license fee in case it is found during misconduct complaint case that the RMP has not taken license to practice in that state.
- 9) May direct the RMP to undertake specific training courses related to the misconduct/some certificate course/ethics sensitization etc.
- 10) Punishment of Permanent removal from NMR under exceptional circumstances by SMC must be ratified by EMRB.

42.Prohibition of review of the order: SMC or EMRB/NMC will not have the power to review its order, and the order will be executed only after the expiry of the period of appeal.

43.Power of the SMC/EMRB. The SMC and EMRB/NMC shall have the same powers as are vested in a civil court under the Code of Civil Procedure, 1908 while trying a complaint against an RMP in respect of the following matters, namely: —

- 1) the summoning and enforcing the attendance of any defendant or witness and examining the witness on oath.
- 2) requiring the discovery and production of any document or other material object as evidence.
- 3) receiving evidence on affidavits.
- 4) the requisitioning of the report of the concerned analysis or test from the appropriate laboratory or any other relevant source.
- 5) issuing of commissions for the examination of any witness, or document; and any other matter which may be prescribed by the Central Government.
- 6) penalty so awarded and confirmed to the RMP by State Medical Council or EMRB/NMC shall be publicized widely on its website and other platforms as they deem fit and communicated to the employer, the hospital /healthcare institution of the RMP and respective Medical Associations/Societies/Bodies.

44.Delay in decision: Where the EMRB is informed that any complaint against a RMP has not been decided by a State Medical Council within six months from the date of the complaint, and the EMRB has reason to believe that there is no justified reason for not deciding the complaint within the said prescribed period, then EMRB can direct the SMC to hear the case daily until the case is closed. The reasons for not deciding the case within the stipulated time shall be mentioned in the order of the SMC or withdraw the complaint pending with the concerned State Medical Council immediately.

45.Appeal

- 1) A RMP who is aggrieved by the decision of the State Medical Council shall have the right to file an appeal to the Ethics and Medical Registration Board (EMRB)

within 60 days from the date of receipt of the order passed by the said State Medical Council: Provided that the Ethics and Medical Registration Board may if it is satisfied that the appellant was prevented by sufficient cause from presenting the appeal within the aforesaid period of 60 days, allow it to be presented within a further period of 60 days.

- 2) A RMP who is aggrieved by the decision of the Ethics and Medical Registration Board may prefer an appeal before the National Medical Commission within 60 days from the date of passing of an order by the EMRB.
- 3) Order of SMC will become operational after the expiry of the period of appeal (60days+60days). Once in appeal, the order of SMC will be deemed stayed unless decided otherwise by EMRB/NMC.

Draft

Guidelines - 1

GENERIC MEDICINE AND PRESCRIPTION GUIDELINES

Preamble:

India's out-of-pocket spending on medications accounts for a major proportion of public spending on health care. Further, generic medicines are 30 to 80 % cheaper than branded drugs. Hence, prescribing generic medicines may overtly bring down health care cost and improve access to quality care.

Generic medicines vs Generic names:

Generic Name:

Non-Proprietary or approved name of a drug is also known as the generic name of the drug.

Non-proprietary name is the name accepted by a competent scientific body/ regulatory authority.

Generic drug/medicine:

A generic drug is defined as a "drug product that is comparable to brand/reference listed product in dosage in dosage form, strength, route of administration, quality and performance characteristics, and intended use"

Branded Generic drug:

A branded generic drug is one which has come off patent and is manufactured by drug companies and sold under different companies' brand names. These drugs may be less costly than the branded patent version but costlier than the bulk manufactured generic version of the drug. There is less regulatory control over the prices of these "branded" generic drugs.

Guidance to RMPs:

1. Prescribe drugs with "generic"/"non-proprietary"/"pharmacological" names only
 - 1.1. In the case of drugs with a narrow therapeutic index, biosimilars, and similar other exceptional cases, this practice can be relaxed.
2. Prescribe drugs rationally and optimally
 - 2.1. Both overprescribing and under prescribing are to be avoided keeping in mind possible drug interactions
3. Fixed-dose combinations are to be used judiciously
 - 3.1. Only approved and rational fixed-dose combinations are to be prescribed
4. Advocate for hospitals and local pharmacies to stock generic drugs. Prescribe only those generic medicines that are available in the market and accessible to the patient
5. Avoid prescribing "branded" generic drugs.
6. Encourage patients to purchase drugs from Jan Aushadhi kendras and other generic pharmacy outlets

7. Educate medical students, patients, and the public regarding the equivalence of generic medicine with their branded counterparts
8. Should actively participate in programs related to promotion and access to generic medicines
9. MBBS & PG students will be trained in the value of prescribing generic medicine
10. Written Prescriptions should be legible and preferably in full CAPITALS to avoid misinterpretation. As far as possible prescriptions should be typed and printed to avoid errors.

Draft

Guidelines-2

The following template may be used for writing prescriptions rationally

Dr.XXXX Registration no: XXX Address Emergency Contact number:	
Patient name:	Date:
Age :	
Sex:	Weight :
Diagnosis/Provisional Diagnosis	Height
Rx	
1. Inj XXX ...mg IV/IMhourly fordays	
2.Tab/ Cap XXXXmg per oral after food three times a day for 3 days	
3.Syrup/suspension XXXX --- ml per oral after food three times a day for 3 days	
4. Oint /gel/cream.... Necessary quantity/finger tip to be applied over the affected area times a day till improvement.	
5. Eye Drops XXXX --- drops to be instilled in the right/left eye every 6 th hourly for 3 days	
Not to be repeated	
To review after 3 days	
Signature (With Seal)	
Name	
Unique ID/Reg No (NMC)	
Qualification)	

Guideline-3

NMC Code of Medical Ethics

Preamble:

The National Medical Commission proposes this Code of Medical Ethics, which will serve as the set of commitments of the registered medical practitioner towards patients, society, professional colleagues, and self. NMC Code of Ethics is framed as a self-regulatory set of guidelines reflecting professional as well as social expectations.

The ethical principles that underpin this code of ethics include beneficence, empathy, non-maleficence, respect for patient autonomy and confidentiality, integrity, honesty, and justice. Medical practitioners are expected to uphold these principles for their inherent value in medical practice, and also to foster trust in patients and maintain the dignity of the medical profession.

NMC code of ethics is not intended to establish legal or clinical standards in practice but to provide a set of ethical guidelines according to which the doctor is expected to practice as a medical professional. Ethical guidelines must be differentiated from laws, as ethical standards expected of the medical professional may sometimes exceed legal requirements.

[Note: The words 'must', 'shall / should 'and 'may 'are used purposefully in these guidelines and indicate the degree of obligation that the doctor has to follow the guidelines. The word 'must 'indicates a higher level of commitment and obligation required of the doctor, while in the case of 'shall/should 'the level of obligation is less and there could be room for individual judgment.]

Code of Ethics:

The registered medical practitioner

1. Must provide care for the patient with compassion and respect, keeping the best interest of the patient in mind at all times.
2. Should be respectful of the patient's rights and opinion, communicate clearly with the patient, and be honest and transparent in all professional interactions.
3. Must protect patient confidentiality and privacy, and treat every patient equally, without discrimination.
4. Shall ensure one's competency and fitness to practice, and keep up to date with advancements in medical practice. They shall consult with other health professionals, as and when required for the benefit of the patient.
5. Should function in accordance with the laws of the land. When there is a conflict between ethics and law, the doctor is expected to advocate for changes in the law, in the interest of patient care.
6. Shall be responsive to individual and community health needs, and advocate for patients and the wider community they serve in matters of health and welfare.
7. Must not refuse to treat a patient in case of medical emergency, nor discriminate between patients based on gender, race, religion, caste, social, economic or cultural grounds. No patient should be abandoned.

8. Should practice according to his conscience and ethical guidelines, free from external pressures. They should not provide treatments that are not medically indicated, and must not participate in any act of torture.
9. Should promote and model the ethical standards of the profession in the work place, mindful of the moral and professional obligation owed to the patient and society who have reposed trust in the profession.
10. Should not hesitate to report unethical acts, fraud, incompetence, dishonesty, exploitation or misconduct on part of other health care professionals that could result in harm to the patient.
11. Should recognize conflict of interest situations that may arise in practice as they are detrimental to the patient and should avoid or minimize them. In such situations, the patient's interest should take precedent over any other consideration.
12. Should not engage in endorsement or promotion of any drug or medical product for commercial purposes or for personal gains. In sharing findings of research with peers and scientific societies, the practitioner is expected to be neutral and unbiased in the interest of science and patient care.
13. Should protect and minimize risk of patients who participate in medical research, conscious that the dual role as researcher-practitioner would require disclosure to patients and additional regulatory and ethical compliance.
14. Should ensure that professional boundaries of the doctor patient relationship are respected and not violated

Inclusions:

Declaration of Geneva 2017 called 'The Physician's Pledge'

1. AS A MEMBER OF THE MEDICAL PROFESSION:
2. I SOLEMNLY PLEDGE to dedicate my life to the service of humanity;
3. THE HEALTH AND WELL-BEING OF MY PATIENT will be my first consideration;
4. I WILL RESPECT the autonomy and dignity of my patient;
5. I WILL MAINTAIN the utmost respect for human life;
6. I WILL NOT PERMIT considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing, or any other factor to intervene between my duty and my patient;
7. I WILL RESPECT the secrets that are confided in me, even after the patient has died;
8. I WILL PRACTISE my profession with conscience and dignity and in accordance with good medical practice;
9. I WILL FOSTER the honour and noble traditions of the medical profession;
10. I WILL GIVE to my teachers, colleagues, and students the respect and gratitude that is their due;

11. I WILL SHARE my medical knowledge for the benefit of the patient and the advancement of healthcare;
12. I WILL ATTEND TO my own health, well-being, and abilities in order to provide care of the highest standard;
13. I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat;
14. I MAKE THESE PROMISES solemnly, freely, and upon my honour.

Draft

Guideline-4

Guidelines on Penalties

Preamble:

The document is prepared with the purpose of bringing uniformity across the country in the assessment of liability and award of disciplinary action in case of Professional Misconduct as per these regulations bearing the principle of proportionality in mind.

In both civil and criminal cases, the law enforcement authorities and courts may expect the statutory bodies to examine the case and fix responsibility on RMP as per these regulations. If misconduct of criminal nature not listed in the regulation is identified by the SMC or EMRB the same may be reported to the relevant lawful authority for further action.

Assessment of attributability and the severity thereof

- a) During the assessment, the SMC/EMRB/NMC should consider and evaluate other issues that may have contributed to the situation being assessed, including the final outcome of the patient, beyond the role played by the doctor.
- b) The severity of the situation must be decided for each allegation made against the doctor. Harm should be assessed in the context of the following:
 1. The fault (s), if any, of the doctor; may or may not have had a direct bearing on the outcome.
 2. Other, extraneous factors may have contributed to the outcome. Some examples are listed below:
 - (1) The disease diagnosed and the associated risk to health/life, according to the prevailing knowledge in the medical literature and as opined by peer professionals, within the inherent limitations/side-effects/complications of medical science
 - (2) The health/immunity/present condition of the patient and the past medical and other histories relevant to the case.
 - (3) The reversibility and the probable impact of the line of treatment on the patient's health condition/life.
 - (4) The availability, condition, and maintenance of infrastructure; skill, qualifications, and expertise of the doctor/paramedical personnel/health-care team.
 - (5) The progress and severity of the disease along with compliance with medical advice.
 - (6) The cooperation by the patient and family/caregivers.

- (7) The work pressures in the treatment setting, related to patient flow (e.g., the doctor to patient ratio); or availability of infrastructure/facilities in a particular district/town/or remote area.
- (8) The scope for corrections, in case of error; the reversibility of the outcome.
- (9) The role expected to have been played by the doctor and the scope of duties/obligations imposed as per law. This may be influenced by the Hospital/Clinic/Institution (Public, Private, Charitable, Specialized, General)
 - c) The quantum of fees/charges at the treatment facility should not influence the judgement of severity.
 - d) Therefore, the responsibility of the doctor and the extent of liability may be decided after evaluating the alleged harm caused to the patient in the context of the limitations inherent in the patient's clinical features and treatment setting. A balanced decision in this regard must be taken based on consensus by the SMC/EMRB/NMC. This will help in arriving at the level of the disciplinary action, as described in a later section of this document.

Levels of Disciplinary Action as per Breach of Conduct

When the State Medical Council or EMRB or NMC investigates a case, the disciplinary action awarded needs to be in keeping with the severity of the act of commission or omission. The disciplinary action may be graded at five levels:

Exoneration This level is appropriate when the Council finds that the doctor is not at fault and has followed all regulations of the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2022. No disciplinary action is warranted and the RMP is Exonerated. This decision should be widely published.

Level 1: Reformation-This may be awarded singly or in conjunction with other levels, in the form of advisory, instruction or warning. Some examples are provided below:

- (1) General/detailed instructions to the doctor to be more careful (Advisory)
- (2) Instruction to display qualifications/degree appropriately, especially with regard to specialization/super specialization.
- (3) Instruction to attend a workshop or academic programs on Ethics, personal/social relations, and/or professional training for medical professionals
- (4) Instruction to attend Continuing Professional Development (CPD) programs in a specified field; the number of CME credit points to be specified.
- (5) Instruction to attend specialized workshop/conference/training (with NMC accreditation)
- (6) Warning to be careful in future

Level 2: This penalty may be awarded even when the role of the doctor in causing direct harm was not conclusively proved but the doctor was found to have breached any of the codes listed above.

The maximum action is a suspension of the license to practice for up to one month (30days).

Level 3: This penalty may be awarded when the role of the doctor in causing direct harm was conclusively proved and the doctor was found to have breached relevant regulation.

This maximum action is a suspension of the license to practice for a maximum period of three months. Holding suspension can be given in this level as per regulations.

Level 4: This penalty may be awarded when the role of the doctor in causing direct harm was conclusively proved and the doctor was found to have breached relevant regulations.

(1) The maximum action is a suspension of the license to practice for a period ranging from 3 months to 3 years.

At each of Levels 2, 3, and 4, the extent of action recommended may range from reformation alone to a maximum of suspension for the period indicated at the level, depending on the quantum of responsibility of the RMP for the harm/injury caused.

Level 5: The last resort is to debar a member permanently from practice (Permanent suspension of license). This penalty may be awarded only after a detailed inquiry, carried out by an Expert Group constituted under the Guidelines, finds that the treating doctor has committed a wilful, or intentionally harm/unlawful, prohibited action. This will be taken as a ‘unique case’ and no precedent will need to be cited.

RMPs who have been exonerated and those who have completed penalties under Level 1 should not be barred from receiving “good standing” certificates if required later.

Guideline-5

GUIDELINES ON INFORMED CONSENT IN CLINICAL PRACTICE

Preamble :

The aim of this guidance document on informed consent in a clinical situation is to promote awareness amongst RMPs of the critical importance and ethical requirement of providing information to patients and taking consent before investigations, treatment, clinical procedures and surgery. It does not apply to consent in medical research situations which should follow the ICMR Guidelines, 2017. This document does not exhaustively list every clinical situation where informed consent is required but applies to all clinical interventions that require documentation of consent. In the context of patient autonomy and patient rights, informed consent highlights the importance of respecting the patient's right to know about the clinical condition, treatment, and prognosis as well as right to refuse treatment. Proper documentation of the information shared and the consent procedure is needed to prevent denials, misunderstandings and legal action.

Type of consent:

Consent can either be implied or explicit.

Implied consent is applicable for clinical examination, including pelvic and PR examinations (The presence of a chaperone is essential when male physicians examine female patients). Explicit informed consent is required for all procedures, treatments, surgery and interventions that have commonly known risks to the patients.

Informed consent can only be taken from adult patients and must be free and voluntary and in a language understood by the patients.

The RMP should be transparent and truthful in disclosing all risks and benefits of the clinical procedure to the patient as well as alternatives to treatments. There should be neither deception nor coercion on the part of the RMP. The information should include all that the patient would need to know to make the decision (Montgomery vs L Health Board)

Consent for illegal procedures would not be deemed valid either legally or ethically.

Type of information :

The information that must be shared with the patient before consent will depend on the clinical procedure, treatment, and the risks involved.

The information shared must be that which any reasonable man would want to know, particularly the most common side effects or complications that can arise.

Surgery

Consent must be taken for all operative procedures minor or major.

The concept of blanket consent when the patient is admitted or before surgery cannot be defended legally or morally.

The consent must be procedure-specific. Pre-printed procedure-specific informed consent can be made available after prior approval from the SMC or EMRB. However, the responsibility of administering the informed consent is on the primary physician

The primary surgeon/surgeon's name should be on the consent form in all surgical procedures.

The standard consent form for surgery under anesthesia used by RMPs and hospitals should include specific risks and information related to each case where necessary and the patient's consent documented for the same.

A patient undergoing two separate elective procedures (example: cholecystectomy and appendectomy) needs to give consent for each operations.

Similarly, fresh consent must be taken for every new procedure planned for the patient. Consent must be taken separately for surgery and anesthesia because the nature of these procedures as well as the complications, is different.

In major surgeries, it is in the interest of the patient to execute an advanced directive nominating a legal representative who can give consent on their behalf if required for further procedures during surgery when the patient is incapacitated

Since 2013, it has been a legal requirement to document video recording of consent for transplant surgeries.

Emergencies:

In emergencies, consent for treatment should be taken from patients whenever possible or from legal representatives (wherever available) when the patient is unable to give consent. However, the consent process should not interfere with emergency care and response in the best interest of the patients.

When a patient is brought unconscious and without identification, all efforts should be made to identify the next of kin even while emergency treatment is being provided. The doctor can document the absence of surrogate decision-makers and proceed in the best interest of the patient.

Special situations

In the case of minors, the parents or guardians must provide consent, although assent may also be needed from children above 8 years of age.

In case of vulnerable groups, it is safer to have a witness during the informed consent procedure, and take the signature of the witness as well.

Informed consent process should never be curtailed or neglected for the reason that the patient is unable to "fully understand".

The elderly, marginalized, illiterate and other vulnerable patients may require additional time and efforts at communication prior to consent.

In the case of extended treatments or complicated cases, consent may need to be an ongoing process.

Patients who are indisposed should be encouraged to assign surrogates who will take decision and give consent on their behalf, should the need arise. This should be documented in the patient's records.

Medical Students and consent:

In examining patients by medical students for teaching/learning purposes, students must be educated about the process and importance of consent.

Medical students should take verbal permission from their patients before examining them and the patient's decision must be respected, including refusal to be examined by the medical student.

Patients do not need to give any reason for this refusal and clinical care of the patient must not be adversely affected in such cases.

Sterilization :

In the case of operative procedures which may result in permanent sterilization, it is prudent to take informed consent from both the patient and the spouse unless denial of consent could put the life of patients in danger. RMP should encourage honest disclosure by the patient in their best interests.

Particular care must be taken with consent in infertility treatments like in-vitro fertilisation, embryo transfer or artificial insemination to protect the rights of patients and donors.

Refusal of consent :

Patients have the right to refuse treatment, and this right should be respected. RMP should communicate all possible outcomes of the refusal to be treated especially in emergency and acute conditions. It is important to document the patient's refusal to be treated and the reasons given for the refusal.

Use of clinical data

Personal data that can reveal the identity of the patient should not be disclosed under any circumstances. However, for the use of patient's data in academic teaching or clinical case discussions, patient's consent is required. Under no circumstances will the patient's data be posted on social media.

Guideline -6

CONDUCT OF RMPs ON SOCIAL MEDIA

Key principles

- (1) The broader principle of medical ethics should guide the use of social media by RMPs
- (2) RMPs need to distinguish between telemedicine consultation and social media.
- (3) All written and visual communication should be truthful, respectful, and professional.

Conduct

- 1) RMPs can provide information and announcement on social media. However, the information should be factual and can be verified. The information should not be misleading or deceptive, nor should it exploit the patient's vulnerability or lack of knowledge
- 2) RMPs should avoid discussing the treatment of patients on public social media or prescribing medicine to patients on the public social media platform. If a patient approaches doctors through public social media, the doctor should guide the patient toward a telemedicine consultation or in-person consultation as the situation warrants.
3. RMPs should not post patients' photographs or scan images (ct/pet scans) on social media. Once an image is posted in social media, it becomes data that is owned by the social media company or the general public.
4. RMPs behavior on social media towards his colleagues should be guided by general principles of medical ethics on professional behaviour.
5. RMPs should not directly or indirectly indulge in the practice of purchasing "likes" , "followers" , or paying money so that search algorithms lead to their name being listed at the top or registering on software programs (apps) that charge fees for higher ratings or soliciting patients.
6. RMPs should not request or share patients 'testimonials or recommendations or endorsements or reviews in social media.
7. RMPs should refrain from sharing images of healed/cured patients, or surgery/procedure videos or images displaying impressive results under any circumstances.
8. RMP is allowed to share educative material for the information of the general public. However, communication should be limited to the expertise of the RMP.

9. RMP's webpage should also follow the same guidelines as above.

10 On social media, RMPs should refrain from boundary crossings or violations and conduct themselves with dignity and decorum.

11 Soliciting of patients directly or indirectly through social media is unethical

Draft

Guideline-7

FORM OF CERTIFICATE RECOMMENDED FOR LEAVE OR EXTENSION OR COMMUNICATION OF LEAVE AND FOR FITNESS

Signature of patient

Or thumb impression.....

To be filled in by the applicant in the presence of the government Medical Attendant, or Medical Practitioner.

Identification marks:-

1.....

2.....

I, Dr., after careful examination of the case certify hereby that.....whose signature is given above is suffering from.....and I consider that a period of absence from duty of.....with effect fromis absolutely necessary for the restoration of his health.

I, Dr., after careful examination of the case certify hereby thaton restoration of health is now fit to join service.

Place.....

Signature of Medical attendant

Date.....

Registration No.

(Medical Council of India/State
Medical Council of.....State)

Note:- The nature and probable duration of the illness should also be specified. This certificate must be accompanied by a brief resume of the case giving the nature of the illness, its symptoms, causes and duration.

Guideline-8

FORMAT FOR MEDICAL RECORD

(See regulation 13)

Name of the patient :
Age :
Sex :
Address :
Occupation :
Date of 1st visit :
Clinical note (summary) of the case :
Prov: Diagnosis :
Investigations advised with reports :
Advice :
Follow up :
Date Observations :

Signature in full.....
Name of Treating Physician

Guideline-9

LIST OF CERTIFICATES, REPORTS, NOTIFICATIONS ETC. ISSUED BY DOCTORS FOR THE PURPOSES OF VARIOUS ACTS/ADMINISTRATIVE REQUIREMENTS

- 1) Under the Acts relating to birth, death or disposal of the dead.
- 2) Under the Acts relating to Lunacy and Mental Deficiency and under the Mental Illness Act and the rules made there under.
- 3) Under the Vaccination Acts and the regulations made there under.
- 4) Under the Factory Acts and the regulations made there under.
- 5) Under the Education Acts.
- 6) Under the public health Acts and the orders made there under.
- 7) Under the Workmen's Compensation Act and Persons with Disability Act.
- 8) Under the Acts and orders relating to the notification of infectious diseases.
- 9) Under the Employees' State Insurance Acts.
- 10) In connection with sick benefit insurance and friendly societies.
- 11) Under the merchant shipping Act.
- 12) For procuring/issuing of passports.
- 13) For excusing attendance in courts of Justice, in public services, in public offices or in ordinary employment.
- 14) In connection with Civil and Military matters.
- 15) In connection with matters under the control of Department of Pensions.
- 16) In connection with quarantine rules.
- 17) For procuring driving licence.

Guideline-10

Continuous Professional Development Guidelines

INDEX

- a) Aim and Purpose of CPD**
- b) Organizations that can deliver CPD Programmes**
- c) CPD: Delivery and Review**
- d) Guidance For Registered Medical Practitioners**
- e) CPD: Special Considerations**
- f) CPD Credits**
- g) Roles And Responsibilities of State Councils:**
- h) Building An Evidence Base for The Future of CPD in India**
- i) Logistics**
- j) Proposal for Accreditation Committee**
- k) Tables**
- l) Forms**

Preamble:

This document explains the broad purpose of Continuing Professional Development (CPD) for all registered medical practitioners. It also outlines the process of delivery of CPD programmes, the assignment of CPD points, the linkage of CPD points with renewal of licences by the EMRB or the State Medical Council, and the penalties involved in the event of non-compliance to mandated CPD requirements. Emphasis will be on creating culture where RMPs do not view CPD and recertification as a threat but as a responsibility to provide patient care and services of highest order.

1. AIM AND PURPOSE OF CPDNeed for CPD:

- (a) The practice of medicine is continually changing. Large advances are being made with regard to new evidence for disease causation, pathogenesis, diagnostics, therapeutics and procedures. If health professionals are to keep abreast of these advances and practice optimal care for the patients, they require to upgrade their knowledge and skills on a regular basis. Professionals also need to evaluate evidence in order to make informed choices about the validity of available options related to healthcare.
- (b) New diseases are emerging. The Covid-19 pandemic is an example of this. New diseases require health professionals to understand diseases from a public health point of view and work across disciplines to achieve optimal benefits for populations. This may take on special needs in the event of national or regional health crises.
- (c) New technologies bring with them new bioethical issues. Apart from ensuring compliance to existing guidelines, medical practitioners need to grapple with bioethical issues in emerging fields of medicine. Depending on their nature of work, medical professionals may need to upgrade their abilities in specific areas of bioethics – clinical/medical, research, public health, medical education.
- (d) As the public grows increasingly aware of health-related issues, and increases their expectations of the health profession, it becomes contingent for health professionals to be able to better communicate with their peers, patients and public at large. This will ensure the maintenance of public trust.

CPD versus Continuing Medical Education (CME)/ Continuing Education

- a. Continuing Medical Education largely addresses the needs of health professionals with regard to updating knowledge and skills. This may take the form of workshops, seminars, lectures etc.
- b. CPD is a more holistic approach – it recognises the need for the health professional to develop all facets – this goes beyond knowledge and skills to include, among others effective communication, evaluation of emerging evidence, the practice of ethics, the application of law in healthcare, and an understanding of public health, health policy and health economics, among others.

CME	CPD
Episodic events targeted to a group of learners	Lifelong based on self-assessments addressing educational needs for better healthcare
Speaker/Teacher centred	Learner centred
Mainly targeting technical skills and clinical management	Comprehensive for wide arrays of skills
Format are fixed or structured	Based on active learning principles. Need more intense planning
Usually, podium based	Wide variety of methods customizable according to subject and target audience

In summary, **CPD** can be defined as:

“The wide-ranging competencies beyond clinical update, research and scientific writing, multidisciplinary context of patient care, ethical practice, communication, management and behavioural skills, team building, information technology, audit, and appropriate attitudinal change to ensure improved patient outcomes and satisfaction.”

2. ORGANISATIONS WHO CAN DELIVER CPD PROGRAMMES

a. Organisations who can deliver CPD

A range of organisations / associations and institutions may deliver CPD. These include:

- (1) Registered Medical Professional Bodies / Associations (state, national, International)
- (2) Medical Colleges recognized/permitted by National Medical Commission (NMC)
- (3) Hospitals approved for the DNBE programme

- (4) Research institutes involved in healthcare research
- (5) National Institutes like AIIMS and Institute of National Importance
- (6) Government organizations like National Disaster Management Authority (NDMA)/
National Institute of Disaster Management (NIDM)
- (7) Other institutions involved in healthcare training / education

b. Application process:

- i. Institutions who aim to deliver CPD programmes should be registered with the EMRB of National Medical Commission and the State Medical Council.
- ii. The form for registration shall be available online at EMRB website
- iii. All SMC will have special section for CPD on their web portal

c. Roles and Responsibilities:

Organisations conducting CPDs are responsible for:

1. Developing the CPD programme
2. Identifying speakers
3. Obtaining approval to conduct the CPD from the EMRB/State Medical Council
4. Disseminating information regarding the CPD to ensure enrolment, including of those practitioners in peripheral areas
5. Conducting the CPD
6. Obtaining feedback
7. Submitting a report to the State Medical Council / EMRB at National Medical Commission

3. CPD: DELIVERY AND REVIEW

Content approval: Development of the CPD programme

- a. Organisations conducting a CPD programme are urged to develop the content based on needs assessment
- b. The programme should have clearly documented objectives and learning outcomes
- c. Speakers need to be identified with the appropriate expertise. Organisations are urged to also look beyond their own membership / institutions where appropriate. If topics are of relevance to general practitioners, attempts should be made to include a speaker who can provide a perspective from the periphery. Alternately, panel discussions should include members from the across the target group for the CPD.

- d. A detailed programme indicating the duration of the entire programme and its breakup needs to be developed. This impacts the number of CPD points that can be awarded.
- e. 70 % of the programme can be devoted to knowledge updates and skill development within the specified subject area essential for patient care. This will constitute **Category 1 CPD**. These are based on most contemporary issues, guidelines and patient management must for everyone.
- f. 30% of the programme should be devoted to cross-disciplinary areas which include, (this list is not exhaustive) bioethics, professionalism, communication, public health, policy, evaluating evidence, biostatistics etc. This will constitute **Category 2 CPD**. They are helpful for improving quality of care backed by scientific evidence.
- g. Self- directed online CPD/ scholarly work will constitute **Category 3 CPD**.
- h. Once the above issues are developed, the organiser needs to submit a request for approval form to the EMRB/State Medical Council (**Form 2**). Time for approval of a CPD may vary from state to state. The approval should then be submitted to CPD Committee of EMRB for registration and grading of the CPD.

CPD delivery

- i. CPD programmes may take the form of face-to-face (**Category 1 and 2**), online/self-paced or hybrid forms, depending on the nature of the CPD. Not more than 50% of CPD shall be online/virtual/hybrid (**Category 3**). Following National Mission on Education through Information and Communication Technology (NMEICT) can be utilized, and credit points mentioned against them.
 - i. National Digital Library of India (NDLI)
 - ii. SWAYAM (Study Webs of Active Learning for Young Aspiring Minds)
 - iii. e-PG Pathshala
 - iv. Swayam Prabha: 32 DTH channels
 - v. E-Shodh-Sindhu
 - vi. National Programme on Technology Enhanced Learning (NPTEL)
 - vii. Virtual Labs

This will be **Category 3** and will also include Scholarly work and publications by Academician/RMP. Scholarly activities/CPD carried out by RMP internationally through conferences/ research work will also be counted in Category 3.

- j. Attempts must be made to ensure that CPD involves active participation and not merely attendance of an event. If the CPD is being conducted online, organisers must indicate how they intend to ensure active participation during the entire programme.
- k. Active participation may be documented through exercise during the CPD or on-line questionnaires e.g. google forms.
- l. Participants are required to present for the whole of the programme and should not be given certificates of CPD points if they have not attended the whole programme.
- m. Every CPD programme should have an internal evaluation process which can broadly assess key participant learnings. These can take the form of Pre/Post test, but other methods of evaluation can be explored. Attempts may be made to evaluate at least first two levels of Kirpatrick's Four Level of Training Evaluation. These first 2 levels are Reaction and Learning. While reaction (**Level 1**) can be captured by feedback, pre-post test or Retrospective Post-then-Pre types of questionnaire can evaluate Learning (**Level 2**).
- n. Procedure may be established at EMRB to capture evaluation at workplace for **Level 3 and 4** (Behaviour and Result)
- o. Provision of Academic leaves for attending CPD by each Institute/college/hospital

CPD review process

- (1) CPD Review is an integral part of the conduct of a CPD programme
- (2) Organisers of the CPD should obtain feedback from the participants. This can include, among others, participant perception of fulfilment of the CPD objectives, gaps if any (this can inform the development of future CPDs), evaluation of course content and delivery, and overall satisfaction.
- (3) Organisers of the CPD should also reflect on the success of the CPD from their perspective, the extent to which they felt participants had active participation, challenges faced and overcome, lacuna etc.
- (4) Based on the above, CPD organisers are required to provide a completion and feedback report to the EMRB/State Medical Council electronically. A template for this is available online at EMRB/SMC website as **FORM 6**.

- (5) Grading of the CPD based on Quality Control indicators. A Committee for accrediting CPDs shall be constituted by EMRB (evaluating speakers, quality of content, sessions, audience participation, etc)
- (6) EMRB can develop a web portal where all current and upcoming CPDs can be visible to all thus helping the RMPs to plan their calendar well in advance. **Updating of the proposed activity to be done by State Medical Council or organizing body at least 1 month in advance.**

4. GUIDANCE FOR REGISTERED MEDICAL PRACTITIONERS

- a. This document is applicable to all registered medical practitioners (RMP).
- b. Every RMP is required to reflect on his/her own professional needs. This will allow them to register for CPD programmes based on their individual needs.
- c. Every RMP is responsible to meet their mandated CPD points on a yearly basis.
- d. Every RMP is required to maintain a record of their CPD points and RMP/SMC/EMRB to update onto the EMRB/State Medical Council portal on a regular basis.
- e. RMPs must be aware of the penalties that accompany non-compliance with mandated CPD points.
- f. RMPs must be aware that mandated CPD points constitute a '**minimum**' requirement. They are encouraged to enhance their CPD exposure based on their needs assessment. This process is thus, self-directed. RMPs have to attend both Category 1 and Category 2 CPDs in 70:30 proportion. Not more than 50 % shall be Category 3 barring special situations.

5. CPD: SPECIAL CONSIDERATIONS

- a. Organisers of CPD activities must be aware of the diverse needs and placements of RMPs in India. Thus, RMPs are employed in government and private establishments, they may work alone or in institutions, in rural or urban areas and may be specialists or in general practice. They may also be engaged in multiple responsibilities given to them as per the health needs of the State. The CPD information need to be updated on the portal at least **one-month** in advance ensuring requisite permissions at their end.
- b. The diversity of RMPs creates a problem of access to CPD. Natural justice requires that CPD activities of a sufficient quality be made available to all RMPs. In this context, organisers of CPD activities should:
 - i. Ensure widespread dissemination of announcements of CPD programmes

- ii. Conduct CPD activities in rural areas for those RMPs who would find it difficult to access CPD activities in urban areas. The organisation are also encouraged to conduct a proportion of their CPD activities for RMP in remote / rural area as part of a broader social responsibility. This can also be in online mode as per the logistics permit.
- c. Knowledge sharing should not be one-way. Organisers of CPD programmes must be open to learnings from participants that can inform the entire group participating in the activity. This includes general practitioners working in rural/remote areas and low resource settings. They can be involved and engaged as speaker/panellist to hear their views.
- d. Various programs conducted by State government for National Program can also be accredited for CPD.
- e. As a profession, we need to encourage a culture where doctors do not view CPD and recertification as a threat. RMP will need to understand that they are accountable to their patients and should prioritize and build CPD into their practice to boost their own confidence.

6. CPD CREDITS

- a. CPD credits must be obtained every year. It is expected to obtain 6 CPD points every year but at least 3 credit points must be obtained per year. Emphasis shall be on regularity of participation in CPD.
- b. A minimum of 30 CPD credit points must be obtained at the end of 5 years for renewal of license.
- c. While faculty in recognised medical colleges /recognised DNBE hospitals are engaged in the training of medical students (undergraduate / postgraduate), routine medical education will not be allocated CPD credit points (earlier awarded as 2 points every 6 months). Thus, these faculty will be required to achieve the mandated CPD credit hours as for other RMPs.
- d. A full list of how the CPD credit points is to be awarded is provided in **Table 1**.

7. ROLES AND RESPONSIBILITIES OF STATE MEDICAL COUNCILS:

State Medical Councils have a special role in the conduct of Continuing Professional Development of RMPs. These include:

- a. Updating and maintain the database/records of RMPs

- b. Dissemination of CPD activities for RMPs to register
- c. Auto-reminders of CPD activities to ensure maximum completion of required credit hours, registration of such activities
- d. suggestions for CPD based on their area of practice/ subject expertise/local epidemiology/ disease patterns etc
- e. Creation of a portal linked to EMRB for uploading of CPD credit points for each RMP.
- f. To get the review of proposed CPD programs submitted by organizers, State Medical Councils are encouraged to use the expertise of the Medical Education Units present in the Medical Colleges of the State.

State Health Department may also develop CPD for District Hospitals in consultation with SMCs.

8. BUILDING AN EVIDENCE BASE FOR THE FUTURE OF CPD IN INDIA

The ongoing development of CPD activities in India requires a continuous assessment of ongoing CPD activities in terms of their coverage, teaching-learning methods, and effectiveness. Organisers are encouraged to:

- a. Conduct scholarly research into the CPD programmes that they conduct
- b. Disseminate widely, and to the State Medical Council and EMRB/NMC, the results of this scholarly work.
- c. Develop robust approaches to improve quality of CPD
- d. Make efforts to determine substantive equivalency with Global systems.
- e. Explore innovative methods for engaging RMPs in CPD activities, impact on learning and improvement in health services and sharing their best practices with wider community

The intent of this on-going exercise is to build a large body of evidence that will inform the CPD programme for quality and global equivalency in the future.

9. LOGISTICS

(1) Development of Online platform by EMRB for accreditation, to be shared with all stakeholders

- a. There will be arrangement for online submission of application for CPDs with facility for uploading the data. The certification will be paperless.

- b. The Observer will fill the data for the delegates online against their registration number for specific credit points, for which every observer will be allotted specific code and the password. The credit points will be thus directly deposited with the concerned registration of RMP which can be seen on website with periodical updates.
- c. All the CPD activities will be displayed on the website in a calendar form. Details of type, organizer, registration charges etc will be available giving flexibility to the participants to make a choice as per their requirement and needs. There will be specific code number for program and will be displayed on website under "**CPD Program**" with details of organizers.
- d. It will be responsibility of the organization arranging the CPD to satisfy the requirements for enrolment of their event viz payment of dues etc.
- e. Online / Manual application will have to be made preferably two months in advance in required format with completion of a checklist. Accreditation committee will have power to waive this time limit in some specific circumstances.

(2) Common Registry as well as State Medical Council Register maintenance

10. Creation of CPD Committee under EMRB: See the details below

EMRB CPD Committee

EMRB Committee for Assessment of Eligibility and Promotion of CPDs

1) Introduction

EMRB CPD Committee is a Committee under EMRB with the objective of providing Government and Private Health establishments and registered medical societies, trusts etc., a scheme of assessment and accreditation of CPD activities. This may also involve assessment of the various medical education systems and programmes with a view to achieving a level of desired competence in the era of fast changing medical science.

Committee will offer accreditation services in a non-discriminatory manner. These services are accessible to all national bodies and state medical councils, medical societies, medical professionals and all those involved in furthering the cause of medical education in India. The

organisation shall be accessible internationally with a goal to liaising with accreditation bodies and strive for a system where integration of cross-recognition is possible.

Grading of the CPD based on Quality Control indicators (domain and expertise of speakers, quality of content/ sessions, audience participation, etc)

EMRB will develop a web portal where all current and upcoming CPDs can be visible to all thus helping the RMPs to plan their calendar well in advance.

2) Organisational Structure

- a. CPD Committee of EMRB for recognizing Eligible organisations
- b. Panel of Experts to provide requirements for eligibility to conduct CPD

3) International Recognition

A key area of focus would be to bring in parity with international standards of medical education by bringing in cross-standardization and recognition by various international accrediting organizations (like ACGME etc). This would reduce barriers and help facilitate global recognition of the standards of medical education in India and bring it at par with the latest and the best. In order to achieve this goal, details of similar cross-platform accreditation groups will be compared, and their processes will be drawn to arrive at our framework for equivalency.

4) Accreditation Framework

The accreditation will be offered in the respective fields at three broad levels of Professional Bodies, Conferences and Individuals and are listed below:

a. Professional Bodies

- i. National, recognized
- ii. State, recognized
- iii. Unrecognized, others

b. Delivery methods: Conferences/Symposium/Workshops etc (CPDs)

c. Individual: Registered Medical Practitioners

- i. Published work (Journals/Chapters)
- ii. Participation in Conferences
- iii. Presentations in Conferences (Speaker/Paper/Poster/Chairperson)
- iv. Memberships of Recognised Professional Bodies
- v. Positions held in Recognised Professional Bodies

vi. International travel for conferences, research work, higher degree or fellowships

Detailed scoring is mentioned in the **Table 1**.

Draft

Table 1: Framework for accreditation –EMRB

S No	Description	CPD activities	Credit Rating
Category 1 (Accredited Group Learning) (70 % of credit hours)			
	Activities that have been deemed to meet a set of administrative, educational and ethical standards established by the EMRB/State Medical Council. Only recognized bodies will be considered. (Activity organized by Pharma/drug companies/vendors for equipment/commercial lab are ineligible)	<ul style="list-style-type: none"> Conferences, symposia, seminars, and workshops Online synchronous OR blended learning activities 	0.25 credits/hour of active learning
		Invited Speaker (National/International)	+1 credit hours
		Invited Speaker (State)	+0.75 credit hours
		Oral Presentation	+1 credit hours
		Poster Presentation	+0.5 Credit hours
Category 2 (Accredited Group Learning- General Professional) (30% of Credit Hours)			
	Activities provide individual, or groups of healthcare practitioners, or inter-professional health teams, with knowledge, competence, or performance in General Professional Development. All accredited assessment programs, activities, or instruments must meet the standards established by the EMRB	Group activity through simulation, exercises, demonstrations on: Research and Biostatistics Epidemiology NMC Code of Ethics Hospital Management Tele-Health and Tele-Medicine Communication Skills General Practice/Family doctor Quality Improvement (QI/QC) Clinical Audits	0.25 credits/hour of active learning
Category 3 - Self-Directed Learning Activities (Not more than 50% of Credits) *			
	Self-learning activities are planned and implemented by a health care practitioner to: Address needs related to clinical practice/Educational needs/Research/Quality Improvement	Completing self-learning modules Webcasts/Podcasts Attending online webinar	As per predefined by the organizers (Usually 0.1 to 0.25 credit hours) Self-paced
	Publications (RMP has shown their scholarly work published in that year)	Editor of Journal of recognized Association/Society/Organization	1 credit hour
	Book through Standard Publishers	Author (for one book only one chapter will be considered)	0.5 credit hour
	Journals	Original article in journals recommended by NMC	1 credit hour

		Systematic review/Meta-analysis	0.5 credit hour
		Original article in Pubmed indexed with IF>2	2 credit hours
		Reviews/Letter to Editor/Commentary	0.25 credit hours

* This can be relaxed for certain special circumstances like doctors residing out of country, females on maternity/childcare leave, remote setting, approved by accreditation committee, a 100 % online credit points shall be allowed.

^a Scoring will be for articles excluding abstracts

Table 2: Criteria for Evaluating CPDs by observer for Quality Improvement

S No	Level	Criteria	Score
1	Duration (50)	4 days	50
		3 days	40
		2 days	30
		1 day	20
	Speaker Assessment (50)	Qualifications	(1-10)
		Content Quality	
		Content Validity	
		Communication skills	
		Audience rating	
	Programme (50)	Content	(1-10)
		Quality	
		Workshop	
		Post-Assessment	
		Feedback	
	Organizational (50)	Time management	(1-10)
		Academic environment	
		Speaker reputation	
		Speaker representation	

		Feedback response	
--	--	-------------------	--

*** Duration of 1 day is equivalent to 8 academic hours**

***Scoring will be on a visual analogue scale (VAS) of 1 to 10 where 1 is lowest and 10 is highest score**

Scores will be converted to 25 for each of the above 4 categories for a total maximum score of 100. (Grade A 80-100, Grade B 60-79, Grade C 40-59, Ungraded <40).

Table 3: Framework for grading Professional Bodies

S No	Level	Criteria	Score
	Registered		
	Recognized by CPD Committee		
	State/National/International		
	Events per year		
	Grading of events		
	Type of events (Online/Physical)		
	Organizational Transparency		
	Financial Audit		

	Website		
	Number of Members		

***Scoring will be on a scale of 1 to 10 where 1 is lowest and 10 is highest score**

Draft

Form 1

Application for obtaining Eligibility for conducting CPD from EMRB/

APPLICATION FOR CONDUCTING CPD PROGRAMMES

To,
THE President,
EMRB
CITY.....
Website – <http://nmc.org.in>

Sub.: Issue of Certificate of eligibility

Sir,

Our organization regularly conducts CPD programs/workshops/seminars for updating knowledge of RMPs and we have demonstrated ability to plan & implement above programs to cover the targeted doctors. Brief details of our organization are as below:

Name & Address of organization/Association/Institute:

Branch:		Parent Organization (State or National)	
---------	--	---	--

Registration & Date with Charity Commissioner	
---	--

Report of last Audit (Attested Xerox copies audited report)	
---	--

Statement of CPDs/Conferences held in last one year	
---	--

Name of President /Dean Mobile: Fax: Email

Name of Secretary Mobile: Fax: Email

MCI/DNB recognition letter (Xerox copy to be attested)

(For teaching institutes)

Bank Account Details(To be Used for CPD):

Name of Bank

Branch Account No.

P
a
n
C
a
r
d
N
o
.

Any Other Details

I request you to issue certificate of eligibility to our institute/Organization. We hereby agree to follow the rules and regulations as prescribed by STATE Medical Council/EMRB/NMC from time to time to conduct CPDs

Thanking you.

Yours truly,
Signature of Office Bearer

Name

Official Stamp

Note:

- 1) Application should be made from official email of organization/Association/Institute.
- 2) If online facility is not available. Please send a Demand Draft of Rs. 25000/- (Rupees Five Thousand only),
- 3) Hardcopy of application along with necessary required documents should be send to EMRB within 15 days of online application.
- 4) The Certificate will be valid for 5 years after which the organization has to reapply.

Form 2

**FORMAT OF CERTIFICATE FOR
DELEGATES**

**Name of organization
(Organizing CPD / Workshops/ Seminars
Conferences etc.)**

Eligibility Code no.- _____

SMC Permission Number -----

Type of CPD- Category 1/ Category 2/Category 3

This is to certify that

Med. Dr. XXX (NMC Unique ID)

**_____ has
participated as delegate in _____
(CPD Programme / Workshops / Seminars/Conferences) held on the
Date/Month/Year.**

State Medical Council has granted _____ Credit hours for delegates.

**Signature & Name of
Org. Secretary**

**Signatures & Name of
Org. Chairman**

Form 3

FORMAT OF CERTIFICATE FOR FACULTY

**Name of organization
(Organizing CPD / Workshops/ Seminars
Conferences)**

Eligibility Code no.-_____

SMC Permission Number -----

Type of CPD- Category 1/ Category 2/Category 3

This is to certify that

**Med Dr. _____
*has participated as faculty member in***

**_____ (CPD Programmed /
*Workshops / Seminars / Conferences) held on the Date/Month/Year.***

State Medical Council has granted _____ Credit hour for this speaker.

Signature & Name of

Org. Secretary

**Signatures & Name
of**

Org. Chairman

Form 4

Template for evaluating the impact of your CPD

Often it won't be possible to directly measure the effect of a particular CPD activity on patient outcomes or patient safety. It is recommended that you should try to identify the ways in which your CPD activities could help improve the quality of care. It is recognised that impact might occur a significant time after an activity.

Details of the CPD experience or event

This can be referenced to a written reflective record.

Impact on patient care

Did the CPD and your reflection on it help you meet your learning objectives?

How did it impact on patient care?

Evaluation strategies

In what ways might you evaluate your new practice (for example audit, workplace-based assessment, gathering feedback from patients / colleagues)?

Further learning needs

Have you identified any new learning needs?

How might you address these?

Proforma for evaluation of educational program

Please rate the CPD activity where 1= poor and 5= Excellent

Part A

S.N	Parameter	1	2	3	4	5
1	I received precise information in advance about CPD activity and it's schedule ?					
2	The goals of the CPD appeared to me to be of Immediate interest for my academic activities					
3	The content of the CPD dealt with issues I generally encounter in my practice					
4	Considering my other professional commitments, the CPD Scheduling was appropriate					
5	I found the documents provided of acceptable quality.					
6	Time was provided to seek clarification on issues included in the background documentation					
7	The working methods used during the activity encouraged me to take an active interest in the session themes					

8	The pace of presentation of the subject content was appropriate.					
9	The general atmosphere of the activity was conducive to serious work.					
10	The organisers gave me opportunity for critical comment					
11	The organizers made use of any critical comments I made during the symposium					

Part B

Gain in knowledge and skills

Were you already familiar with the problem, which has been dealt with in this CPD and in what way have you gained in the following areas?

- a. Knowledge in respect of clinical course, mechanism, prevention and management of disease or ill health.
- b. have you attained new skills and will you be able to utilize them in your practice?.
- c. In what way do you think it has improved your competence in managing such problems in future?

Additional information

- a.If you are a post-graduate student, has this workshop helped you in the improvement of your skills and competencies?
- b. What additional topic areas should be included in a workshop of this nature?
- c. What topics/subjects should be deleted or under-emphasized if this CPD is to be repeated in future?
- d. Is one activity on this subject sufficient?
- e. Would you like more CPD in future on this theme?
- f. Would you like to suggest any improvements?

	Date reflective note completed
--	---------------------------------------

Guideline-11

NATIONAL MEDICAL COMMISSION

Guidelines for Practice of Telemedicine in India

**Enabling Registered Medical Practitioners to Provide Healthcare Using
Telemedicine**

2022

TABLE OF CONTENTS

S. No.	Description	Page No.
	Background	7
1	<p>Definitions</p> <ul style="list-style-type: none"> • Definitions of Telemedicine • Definition of Telehealth • Definition of a Registered Medical Practitioner <p>Scope of Telemedicine</p> <p>RMP's are entitled to Practice Telemedicine</p> <p>Applications of Telemedicine</p> <ul style="list-style-type: none"> • Mode of Communication • Timing of Information Transmitted • Purpose of the consultation • Individuals involved 	11
2	<p>Technology Used/ Modes of Communications</p> <ul style="list-style-type: none"> • Video, Audio, Text 	15
3	<p>Guidelines for Telemedicine in India</p> <p>Elements specific to Telemedicine</p> <ul style="list-style-type: none"> • Appropriateness of Telemedicine as per context • Identification of RMP and the patient • Mode of Telemedicine communication/Appropriateness of technology • Informed Consent • Type of consultation • Patient Evaluation • Patient Management: Health education, counseling and medication <p><i>Duties and responsibilities of RMP in general</i></p> <ul style="list-style-type: none"> • Ethical issues in Telemedicine • Medical Ethics, Data Privacy & Confidentiality • Documentation and Digital Records of Consultation • Fee for Telemedicine 	16

<p>4 ·</p>	<p>Framework for Telemedicine</p> <ul style="list-style-type: none"> • Patient and RMP • Care Giver and RMP • Patient and RMP through Health Worker at a Sub Center or peripheral center • RMP and another RMP / Specialist • Telemedicine Triage and COVID Care for Patients 	<p>27</p>
<p>5 ·</p>	<p>Guidelines for Technology Platforms enabling Telemedicine</p>	<p>36</p>
<p>6 ·</p>	<p>Special Responsibilities of NMC</p>	<p>37</p>
<p>7 ·</p>	<p>Figures (Teleconsultation flow charts 1-3)</p>	<p>38</p>
<p>8 ·</p>	<p>Annexures</p> <ol style="list-style-type: none"> 1. Drug Lists 2. Sample Prescription Format 3. Sample Patient Information Sheet 4. Sample Informed Consent format 	<p>43</p>

(1) Telemedicine: Definitions and Applications

1.1 DEFINITIONS

i. 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 the 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.”

ii. 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.

1.2 SCOPE

- These guidelines are designed to serve as an aid and tool to enable RMPs to offer access to medical and health services to patients in remote locations and vulnerable populations. The guidelines cover norms and standards of the RMP to consult patients via telemedicine
- Telemedicine includes all communication channels with the patient that leverage Information Technology platforms, including Voice, Audio, Text & Digital Data exchange.

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

EXCLUSIONS:

The guidelines **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.
- RMPS outside the jurisdiction of India. **REGISTERED MEDICAL PRACTITIONERS ARE**

ENTITLED TO PRACTICE TELEMEDICINE

- i. **A Registered Medical Practitioner (RMP)** is eligible to provide telemedicine consultation to patients from any part of India. In case of any complaints of misconduct, the complaint will be lodged in the State Medical Council of the State, where the RMP is located at the time of providing teleconsultation.
- ii. RMPs using telemedicine shall uphold the **same professional and ethical norms and standards** as are applicable in routine in-person consultations within the intrinsic limitations of telemedicine.
- iii. All RMPs who wish to practice telemedicine should be made familiar with these Guidelines as well as with the processes and limitations of telemedicine practice. They need to undergo CPD training in telemedicine practice as per the ethics guidelines of NMC 2022:

1.4 TELEMEDICINE APPLICATIONS

i. Tools for Telemedicine

RMPs may use any telemedicine tool suitable for carrying out technology-based consultations with patients / caregivers or colleagues.

For example: Telephone, Video, devices connected over LAN, WAN, Internet, Mobile or Landline phones, Chat Platforms like WhatsApp, Facebook Messenger etc., or Mobile Apps 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.

2. Telemedicine applications can be classified into **four basic types**, according to 1) **mode of communication**, 2) **timing of the information transmitted**, 3) **the purpose of the consultation** and 4) **the interaction between the individuals involved** – be it RMP to patient/caregiver, or RMP to RMP.

2.1. According to the Mode of Communication

- 1) Video (Telemedicine facility, Apps, Video on chat platforms, Skype/Face time etc.)
- 2) Audio (Phone, VOIP, Apps etc.)
- 3) 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.)

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	Transmission of summary of patient complaints and supplementary data including images, lab reports and/or radiological investigations between stakeholders. Such data can be forwarded to different parties at any point of time and thereafter accessed per convenience/need

2.3. According to the purpose of the consultation

For Non-Emergency consult:

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

Emergency consult for immediate assistance or first aid etc.

- 1) In case alternative in-person care is not available, tele-consultation might be the only option for timely care. In such situations, RMPs should provide consultation to the best of their 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 measures, counselling and advice on referral.
- 2) In all cases of emergency, the patient should be advised to seek an appointment for in-person care with an RMP at the earliest possible.

2.4. According to the individuals involved

Patient to RMP

Telemedicine services may connect patients to an RMP

Caregiver to RMP

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

RMP to RMP

An RMP may use telemedicine services to discuss issues of care of one or more patients with other RMPs (specialist), or even for the purpose of dissemination of information or to share knowledge.

Health worker to RMP

A Health Worker¹ can facilitate a consultation for a patient with an RMP. In doing so, the former can help in taking history, examining the patient and convey the findings. They can also explain/reinforce the advice given by the 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 may be employed for telemedicine consultation. There are 3 primary modes of doing so: 1) **Video**, 2) **Audio**, and 3) **Text** (chat, messaging, email, fax etc.) Each one of these have their respective strengths, weaknesses and contexts, in which they may either 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 consultations offer safety to the RMP from contagious conditions, however, they cannot replace physical examination that may require palpation, percussion or auscultation. Newer technologies may provide solutions to overcome this drawback.

STRENGTHS AND LIMITATIONS OF VARIOUS MODES OF COMMUNICATION

Mode	Strengths	Limitations
VIDEO: Telemedicine facility, Apps, Video on chat platforms, Facetime etc.	<ol style="list-style-type: none"> 1. Closest to an in person-consult, real time interaction 2. Patient identification is easier 3. RMP can see the patient and discuss with the caregiver 4. Visual cues can be perceived 5. Inspection of patient can 	<ol style="list-style-type: none"> 1. Is dependent on high quality internet connection at both ends, else will lead to a sub optimal exchange of information 2. Since there is a possibility of abuse/misuse, ensuring privacy of patients in video consults is extremely important
AUDIO: Phone, VOIP, Apps etc.	<ol style="list-style-type: none"> 1. Convenient and fast 2. Unlimited reach 3. Suitable for urgent cases 4. No separate infrastructure required 5. Privacy ensured 6. Real-time interaction. 	<ol style="list-style-type: none"> 1. Non-verbal cues may be missed 2. Not suitable for conditions that require visual inspection (skin, eye or tongue examination), or for physical touch 3. Patient identification needs to be clearer, higher chances of impersonation
TEXT BASED: Specialized Chat based telemedicine Smartphone Apps, SMS, Websites, Messaging systems e.g. WhatsApp, Google hangout, FB Messenger	<ol style="list-style-type: none"> 1. Convenient and quick 2. Documentation and Identification may be an integral feature of the platform 3. Suitable for urgent cases, or follow-ups, second opinions provided RMP has enough context from other sources, 4. No separate infrastructure required 5. Can be real time 	<ol style="list-style-type: none"> 1. Besides visual examination and physical touch, text-based interactions also tend to miss the verbal cues 2. Difficult to establish rapport with the patient. 3. Both, the RMP and the patient cannot establish each other's identities with surety.

<p>ASYNCHRONOUS: Email, Fax, recordings etc.</p>	<ol style="list-style-type: none">1. Convenient and easy to document2. No specific app or download requirement3. Images, data, reports readily shared4. No separate infrastructure required5. More useful when accompanied with test reports and follow up and second opinions	<ol style="list-style-type: none">1. Not a real time interaction, so just one-way context is available, relying solely on the articulation by the patient2. Patient identification is document based only and difficult to confirm3. Non-verbal cues are missed4. There may be delays because the Doctor may not see the mail immediately
---	--	--

(3) Guidelines for Telemedicine in India

A. ELEMENTS SPECIFIC TO TELEMEDICINE

The professional judgment of a Registered Medical Practitioner (RMP) should be the guiding principle for all telemedicine consultations:

An RMP is well-positioned to decide whether a technology-based consultation is sufficient or an in-person review is needed. The practitioner shall exercise proper discretion and not compromise on the quality of care.

Seven essential elements listed in the panel below need to be considered by the RMPs before beginning any telemedicine consultation.

7 Key Elements of Telemedicine Consultations	
1	Context
2	Identification of RMP and Patient
3	Mode of Communication
4	Consent
5	Type of Consultation
6	Patient Evaluation
7	Patient Management

3.1 CONTEXT - TELEMEDICINE SHOULD BE APPROPRIATE AND SUFFICIENT

1. The RMPs should exercise professional judgment to ascertain whether a telemedicine consultation would be appropriate in a given situation or would an in-person consultation be a better option keeping the patient's best interest in mind.
2. RMPs should consider the mode of communication and technologies available based on their strength and limitations to ascertain adequacy for a proper working diagnosis before proceeding with any sort of intervention - health education, and/or counseling and/or medication.

3. The Complexity of Patient's health condition

No two patients/cases/medical conditions are the same. Two patients with similar symptoms may have very different presentations and findings on the one hand, while on the other a new patient might present with a complaint of a headache and a known diabetic during a follow-up may present

with an emergency such as Diabetic Ketoacidosis. The RMP should uphold the standard of care as s/he does for in-person consultations within the inherent limitations of telemedicine.

4.The Complexity of Patient's location and connectivity

The RMP should also be aware that the choice of mode of communication may at times be dependent on the quality of the patient's connection (phone, internet etc.) in case the patient resides in a remote location with below-par connectivity.

IDENTIFICATION OF THE RMP AND THE PATIENT IS MANDATORY

- 1.1. Telemedicine consultation should not be anonymous: the patient and the RMP should know and establish each other's identities.
- 1.2. The teleconsultation should be carried out by the RMP in a language that the patient is comfortable in comprehending for an effective consultation.
- 1.3. RMPs should begin the consultation by introducing themselves to the patient with details of their name, qualifications (modern medicine or other systems of medicine duly enrolled in the State Medical Register/Indian Medical Register under the IMC Act 1956), area of specialty if any, and their location along with affiliation to a hospital or institution if applicable.
- 1.4. For specialty consultations, the RMPs/specialists may choose to disclose their specialty qualifications (MD/MS and/or DM/MCh/other equivalent recognized qualifications).
- 1.5. The RMP should verify and confirm the patient's identity by name, age, address, email ID, phone number, registered ID (Aadhar/Voter ID) or any other identification as may be deemed to be appropriate and document the same for the purpose of records. The RMP should then ensure that there is a mechanism for the patient to verify the credentials and contact details of the RMP.
- 1.6. For issuing a prescription, the RMP should explicitly ask the age of the patient, and if there is any doubt, seek proof of age. In cases where the patient is a minor, after confirming the patient's age, tele consultation should proceed only if the minor is accompanied by an adult (preferably a parent or adult sibling or legally appointed guardian) during the entire duration of the consultation. The identity of the adult should be ascertained and documented for records.
- 1.7. Every RMP shall display the registration number accorded to her/him by the State Medical Council or NMC, on all prescriptions, their website, electronic communications (WhatsApp/ email etc.) and receipts etc. given to her/his patients.

3.3 MODE OF COMMUNICATION

1. Multiple technologies can be used for telemedicine consultations. They all have strengths, weaknesses and contexts in which they may be appropriate or inadequate to deliver proper care.
2. Primarily there are three modes: 1) Video, 2) Audio, and 3) Text. The RMP should consider their strengths, limitations, and appropriateness as detailed in Section 2 before utilizing them for a consultation. Invariably, the combination of the above mode occurs to complete a telemedicine consultation.

3. There might be situations in which, in order to arrive at a diagnosis and to better understand the context, a real-time consultation is preferable over an asynchronous exchange of information. Similarly, there might be instances when the RMP wishes to hear the patient speak, and hence a voice interaction may be preferred over an email or text for a diagnosis. Also, in some circumstances, the RMP might want to visually examine the patient to clinch a diagnosis. In such a case, the RMP could recommend a video consultation. Considering the situation, by using their best judgment, RMPs should decide on the best technology to be employed to arrive at a diagnosis and treat the patient.

3.4 PATIENT CONSENT – MANDATORY REQUIREMENT

1. Obtaining and duly recording the Patient's consent is mandatory for any telemedicine consultation. The RMP must ascertain whether the patient is competent to give consent for it to be considered valid. Also, the RMPs should ensure that consent is obtained in a language that the patients can comprehend with ease.
2. Consent may be **implied** or **explicit**, depending on who has initiated the telemedicine consultation:
 - If, the patient has initiated or solicited the telemedicine consultation, then the consent is **implied** as is the case with in-person consultations, wherein it is assumed that the patients has consented for a consultation by the very act of reaching the hospital or RMPs clinic, willingly soliciting a consultation.
 - If the RMP, healthcare worker or a caregiver initiates the consultation, then the consent is **explicit** and hence, mandatory. These instances are likely to be very few, but in these circumstances, the RMP should obtain consent from the patient (verbal or written) and document it for records.
3. **Explicit consent must be recorded** in any form. Electronic media can be used to provide information as in the written in-person informed consent process. Consent can be administered and documented using electronic formats such as text, graphics, audio, video, podcasts or interactive websites to explain information related to a study and to document informed assent/consent from a participant or Legally Appointed Representative. The RMP must retain this in his patient records.
 - The RMP should obtain the Patient's Signature or Thumb impression and Date of Signing on the Informed Consent document either as a scanned document through email or as an image over the smartphone in cases where written consent is required, or record the same by having the patient read it aloud in a language they understand and give consent for the consultation. In case the patient is illiterate or is not competent to give consent, the RMP may request the patient to have an independent adult explain the same and affix a Thumb impression and emailed as mentioned above or read it out aloud to the patient and the same may be recorded as an audio-visual file wherein the patient says that the same has been fully understood.
 - **In case of minors (less than 18years), consent has to be obtained from a parent or from an adult sibling or legally appointed guardian.**

3.5 TYPES OF CONSULTATION: FIRST CONSULTATION/ FOLLOW-UP CONSULTATION

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

An RMP may not have a very comprehensive idea about the patient seeking audio or text consultation for the first time, if there have been no prior in-person consultations. If the first consultation happens to be via videoconferencing, the RMP can make a much better judgment and hence may be in a position to provide much better advice including additional medication, health education or counseling if indicated.

On the other hand, if a patient has been seen in-person earlier by the same RMP, then it is possible to have a more comprehensive picture of the patient's condition, which helps managing the patient more effectively.

1. First Consultation

- This is when the patient is consulting with the RMP for the very first time; (or)
- The patient has consulted with the same 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.

2. Follow-Up Consultation

- This happens when the patient is consulting the same RMP within 6 months of their previous in-person consultation for continuation of care for the same health condition for which the previous consultation was sought (or) for a pre-specified longer duration up to no longer than 1 year in cases where the RMP has advised the patient to fix up an appointment for review after a period between 6 to 12 months. For e.g. the RMP advises a patient with hypothyroidism for a review after 1 year, to revise the dose of medication based on TSH levels.
- If a patient is not able to obtain an appointment with the same RMP for a follow-up consultation owing to operational reasons of the digital platform being used, consultation with another RMP will be considered as a follow-up consultation **ONLY** if the second RMP is comfortable in comprehending the patient's medical condition after having been provided with adequate information (details of the condition and reports of all relevant investigations) by the patient.

*This will, however, **not be considered** as a follow-up consultation if:*

- There are new symptoms that are not in the spectrum of the same health condition; and /or
- The RMP does not remember the details and context of the previous in-person consultation as well as the advice and treatment provided.

3.6 PATIENT EVALUATION - EXCHANGE OF INFORMATION

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

1. Patient's Information

- RMPs should use their 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 may be **supplemented** through conversation with a healthcare worker/provider or by any information supported by **technology-based tools**.
- If the RMPs feel that the **information received is inadequate**, they can request for additional information from the patient. This may be shared in real-time or later via email/text, depending on the nature of the information. For e.g., the RMP may require laboratory and/or radiological investigations. In such cases, the session may be considered as suspended to be resumed at a later predetermined time. RMPs should provide health education as deemed appropriate at any time.
- Telemedicine has its own set of limitations as far as adequacy of examination is

considered. **If the information desired from a physical examination is critical for the management of the patient, the RMP should not proceed with the consultation till such time that a physical examination can be arranged through an in-person consultation.** Whenever deemed necessary, depending on professional judgement of the RMP, they shall recommend:

- Video consultation
 - Examination by another RMP/ Health Worker;
 - In-person consultation
- The nature and/or amount of information required from the patient may vary from one RMP to another based on their professional competence, experience and discretion, and may also vary for different medical conditions based on defined clinical standards and standard treatment guidelines.
 - RMPs shall maintain all patient records including case history, investigation reports, images, etc. meticulously and ensure their safety at least for a period of three years from the day of last consultation.

3.7 PATIENT MANAGEMENT: HEALTH EDUCATION, COUNSELING & MEDICATION

1. If the patient's condition can effectively and appropriately be managed via telemedicine, following a successful consultation, the RMP may proceed with a professional judgement in order to:
 - Provide **Health Education** as appropriate in the case; and/or
 - Provide **Counseling** related to the specific clinical condition; and/or
 - Prescribe **Medicines** as per standard of care or standard practice
2. **Health Education:** RMPs may impart education related to health promotion and prevention if diseases. These could be in relation to lifestyle - diet, physical activity, cessation of smoking, cutting down on or stopping consumption of alcohol or about precautions to follow and other measures to avoid contagious infections and so on. Likewise, they may also provide advice on immunization, exercise, personal and household hygiene practices, mosquito control and so on. It would also be very relevant if the RMP can educate and counsel the patients regarding measures to protect the environment in the context of health and disease.
3. **Counseling:** This is specific advice given to patients and it may, for instance, include food restrictions, dos and don'ts for patients on anticancer drugs, advise on proper use of a hearing-aid, instruction for home-based physiotherapy and so on to mitigate the underlying condition. This may also include advice for investigations that may be required before the next consultation.
4. **Prescribing Drugs:** Prescribing medication via telemedicine consultation is solely at the professional discretion of the RMP. It entails the same professional accountability as for in-person consultations. If a particular medical condition requires a specific protocol to be followed for the diagnose and prescription as for in-person consultations, then the same prevailing principles will be applicable to a telemedicine consultation.
5. RMPs may prescribe Drugs via telemedicine ONLY when they are satisfied that they possess adequate and relevant information about the patient's medical condition and that the prescribed Drugs are appropriate for and in patient's best interest.
6. **Prescribing Drugs without following due process of arriving at an appropriate provisional**

diagnosis/diagnosis might amount to professional misconduct.

7. **Specific Restrictions:** There are certain limitations on prescribing drugs during consultation via telemedicine depending upon the type and mode of consultation. After a telemedicine appointment, doctors often have enough information to advise patients on which over the counter medications to take or to write a prescription. Majority of decisions and recommendations can be made based on the patient interview and reviewing lab and diagnostic studies. The RMPs are expected to prescribe drugs for all conditions that they are able to diagnose with certainty, with the **EXCEPTION** of **Schedule X drugs** mentioned in the **Drugs and Cosmetics Rules 1945**, substance regulated under the under Narcotics Drugs and Psychotropic Substance Act, 1985 and all pharmaceutical drugs that can cause addiction or dependency.
8. The categories of drugs that can be prescribed during a teleconsultation will be notified in consultation with the Central Government from time to time. The categories of drugs that can be prescribed are listed below. This list is only **INDICATIVE** and does not restrict the RMPs from prescribing other drugs. RMPs may prescribe any drug (except Schedule X drugs) provided they are satisfied that the drugs being prescribed are optimal for the patient's medical condition in any type of consultation be it for the First-consultation or a Follow-up consultation which might require an add-on drug or a re-fill/repeat prescription:
 1. **List O:** It will comprise those drugs that are safe to be prescribed through any mode of tele-consultation.
 - Drugs for common ailments that are available 'over the counter' called OTC drugs, defined as drugs that are safe and effective for use by the general public without seeking treatment by a health professional. **OTC Drugs** are legally allowed to be sold '**Over the Counter**', **without the prescription of RMPs**. All the drugs that are not included in the list of 'prescription drugs' are considered as non-prescription drugs (or OTC drugs). **For example:**
 1. [Anti-Hemorrhoid Drugs](#)
 2. [Topical Antibiotics](#): Some topical antibiotics are available without a prescription
 3. [Cough-Suppressants](#)
 4. [Anti-acne Drugs](#)
 5. [Non-steroidal Anti-inflammatory Drugs](#): Some can be bought OTC; others are available only with a prescription from a physician or dentist.
 6. [Antiseptics](#)
 7. [Analgesics](#)
 8. [Decongestants](#): Some require a physician's prescription but many are OTC products.
 9. [Aspirin](#)
 10. [Vasodilators](#): Some Vasodilators such as Minoxidil are sold without prescription.
 11. [Antacids](#)
 12. [Expectorants](#): Many expectorants are available OTC.
 13. [Anti-fungal Drugs](#)
 14. [Anti-Histamines](#): Some can be bought without a prescription.
 15. [Anti-flatulence Agents](#)
 16. [Smoking Cessation Drugs](#): Many drugs can be bought OTC without prescription.
 - Drugs that may be deemed necessary during public health emergencies and pandemics.

2. **List A:** These are drugs which can be prescribed during the first consultation **ONLY** in cases of video consultations, and if they are being repeated, prescribed for a re-fill, in case of follow-up consultations.
 - This list would include relatively safe drugs with low potential of misuse/ abuse. RMPs may prescribe these drugs to patients during a follow-up consultation if they are repeated for a re-fill. For e.g., drugs that were earlier prescribe in an in-person consultation being prescribed again (repeated) in a follow-up teleconsultation. In these situations, the patient has been seen, investigated and the diagnosis has been established by the RMP.
3. **List B:** Is a list of drugs that RMPs may prescribe for patients during follow-up consultations as add-on drugs, in addition to those drugs that were prescribed during an earlier in-person consultation for the same medical condition **NOT** a new drug for a different medical condition or disease. For e. g. to better control the Hypertension, the RMP may prescribe an add-on diuretic to a patient on an anti-hypertensive drug prescribed earlier. Prescriptions for injectable medicines can only be given if the consultation is between an RMP with another RMP or a Health Worker for administration to a given patient. In such a scenario, the RMP must be confident of the facility's setting and the technical expertise of the RMP or the Health Worker. The exceptions to these would be prescribing some follow-up medications which are marketed as self-administered drug injections, such as insulin.
4. **List of Prohibited drugs:** These are drugs that RMPs providing consultation via telemedicine **CANNOT prescribe**.
 - These drugs have a high potential for abuse and harm to the patient and/or the society at large if used improperly. Drugs regulated in **Schedule X** of the Drug and Cosmetic Act and Rules or any **Narcotic** and/or **Psychotropic** substance listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985. Except Clobazam, Clonazepam and Phenobarbitone as per MCI-211(2/2019)(ethics)/201874, dated 11.04.2020. **See Annexure 1.**

9. Issue a Prescription and Transmit

- The RMP who has prescribed drugs shall issue a prescription as per the NMC Act and shall not contravene the provisions of the Drugs and Cosmetics Act and Rules. A sample format suggested in Annexure 2 may be followed. The following **essential elements**, however, **MUST** be included in all prescriptions:
 1. Name, qualifications, registration number, address and contact details of the RMP.
 2. Name, age, sex, identification and contact details of the patient.
 3. Name of the drug/s being prescribed in CAPITAL letters along with a clear mention of the formulation, dose, frequency and duration for which the drug/s is/are to be taken.
 4. Date, time and place of writing the prescription with signature and stamp.
- RMPs shall provide a clear photograph, scanned or digital copy of a duly signed prescription (e-Prescription) to the patient via email or over any other messaging platform with their full name, qualifications and registration number with the State medical council or the Indian Medical register clearly visible on the prescription.
- Prescriptions can be conveyed to patients who do not have a smartphone by using an online web application that can be accessed from a mobile browser. Link for the prescription can be sent as SMS to the recipient.
- There is no need to take print out of the e-prescription. E-prescription should comply with the guidelines. The e-prescription is valid for two weeks from the date of issue or once a pharmacist dispenses the prescribed medications, whichever is earlier. In cases where RMPs have to

transmit the e-prescription directly to a pharmacy, they must **ensure** that the patient explicit consent is taken or the patient's right of choice of the pharmacy where the prescription has to be transmitted is respected so that they procure the drugs dispensed from a pharmacy of their choice and convenience.

Table: Matrix of permissible drug lists based on the type and mode of Teleconsultation

List	Mode of Consultation [Video/Audio/Text]	Nature of Consultation [First / Follow-up]	List of Drugs (Refer section 3.7.7)
O	Any	Any	List O ¹
A	Video	First consultation Follow-up or for continuation of medication; refill	List A ²
B	Any	Follow-up	List B ³
Prohibited	Not to be prescribed	Not to be prescribed	Prohibited List ⁴

1. Drugs that are safe to be prescribed through any mode of tele-consultation, that are used for common conditions and are often available 'over the counter' without a prescription from RMPs. These drugs are NOT included in the list of 'Prescription drugs'. For e.g. Antacids, anti-histaminics, antipyretics, analgesics, expectorants, oral rehydration packets and so on, Drugs that may be deemed necessary during public health emergencies and shall be notified from time to time.
2. These are drugs which can be prescribed during the first consultation ONLY in cases where the diagnosis is established over video consultations or if they are being repeated, prescribed for a re-fill, in case of follow-up consultations. For e.g. antifungal agents for skin ailments, antibiotic eye drops for conjunctivitis, antibiotics for abscesses, laryngitis and other conditions that can be diagnosed over video consultations and in follow-up consultations, drugs for chronic ailments like Asthma, diabetes, hypertension, tuberculosis etc.
3. This list is of 'add-on' drugs which can be used to optimize or better manage an existing condition not a new drug for a different medical condition or disease. For e.g. an ACE inhibitor like Enalapril prescribed as an add-on drug to a patient with hypertension whose blood pressure is not controlled on Atenolol that was prescribed earlier.
4. For instance, Anti-Cancer drugs; Psychotropic drugs and Narcotics such as Morphine, Codeine etc. (Drugs listed in the 'Schedule X' of the Drug and Cosmetic Act and Rules, and substances regulated in the Narcotic Drugs and Psychotropic Substances, Act, 1985.)

[List of [Approved New Drugs \(cdsco.gov.in\)](http://cdsco.gov.in).]

DUTIES AND RESPONSIBILITIES OF RMPs IN TELEMEDICINE

1. Ethical issues in telemedicine

These imply a consideration of patient's best interest and professional conduct in providing telemedicine services and the patient's right to consent to the therapy and complaint about unsatisfactory services. Telemedicine is used for patients who cannot visit an appropriate RMP in time because of inaccessibility due to distance, physical disability, employment, family commitments (including caring for others), patients' cost and physician schedules. It has capacity to reach patients with limited access to medical assistance and potential to improve health care.

Face-to-face or in-person consultation between physician and patient remains the gold standard of clinical care. The delivery of telemedicine services must be consistent with in-person services and discretionary. The principles of medical ethics that are mandatory for the profession must also be respected in the practice of telemedicine.

1.1. Physicians must respect the following ethical guidelines when practicing telemedicine:

1. The RMP-patient relationship should be established. Telemedicine should be employed primarily in situations in which an RMP cannot be physically present within a safe and acceptable time period. It could also be used in management of chronic conditions or follow-up after initial treatment where it has been proven to be safe and effective.
2. The RMP-patient relationship must be based on mutual trust and respect. It is therefore essential that the RMP and patient be able to identify each other reliably when telemedicine is employed. In case of consultation between two or more professionals within or between different jurisdictions, the primary RMP remains responsible for the care and coordination of the patient with the distant medical team/other professionals.
3. The RMP must aim to ensure that patient confidentiality, privacy and data integrity are not compromised. Data obtained during a telemedicine consultation must be secured to prevent unauthorized access and breaches of identifiable patient information using appropriate and up to date security measures in accordance with prevailing legislation. Electronic transmission of information must also be safeguarded against unauthorized access.
4. Proper informed consent requires that all necessary information regarding the distinctive features of telemedicine visit be explained fully to patients including, but not limited to: explaining how telemedicine works, how to schedule appointments, privacy concerns, the possibility of technological failure including confidentiality breaches, protocols for contact during virtual visits, prescribing policies and coordinating care with other health professionals in a clear and understandable manner, without influencing the patient's choices.

1.2. Autonomy and privacy of the RMP

5. The RMP should not participate in telemedicine, if it violates the legal or ethical framework of professional behaviour or any rules/regulations under the NMC Act 2019.
6. Telemedicine can potentially infringe on the free time of RMPs if there is round the clock virtual availability. The RMP needs to inform patients about their availability and recommend alternative or emergency services if they are inaccessible.
7. The RMP should exercise their professional discretion in deciding whether a telemedicine or an in-person consultation would be appropriate.

8. RMPs should exercise professional judgement & discretion in selecting the appropriate telemedicine platform to be used. The RMP has the right to pause his/her teleconsultation and recommend an in-patient consultation.

1.3. Responsibilities of the RMP

9. RMPs should keep a detailed record of the advice they deliver as well as the information they receive on the basis of which advice was given to ensure accountability, responsibility and traceability.
10. If a decision to use telemedicine is made, it is necessary to ensure that the users (patients and healthcare professionals) have optimal access to the necessary telecommunication system optimally.
11. The RMP must seek to ensure that the patient has understood the advice and treatment suggestions given and take steps in so far as possible to promote continuity of care.
12. The RMP asking for another RMP's advice or a second opinion remains responsible for treatment and other decisions and recommendations given to the patient.
13. RMPs should be aware and respect special difficulties and uncertainties that may arise when they are in contact with the patient through telecommunication. They must be prepared to recommend direct RMP-patient contact when they believe it is in the patient's best interests.
14. Only Qualified and licensed RMPs only should practice telemedicine-
15. RMPs should ensure that their medical indemnity cover includes cover for telemedicine.

1.4. Quality of Care

16. The possibilities and weaknesses of telemedicine in emergencies must be duly identified. If it is necessary to use telemedicine in an emergency situation, the advice and treatment suggestions will be influenced by the severity of the patient's medical condition and the competency of the persons who are with the patient. Entities that deliver telemedicine services must establish protocols for referrals to emergency services.

2. MEDICAL ETHICS, DATA PRIVACY & CONFIDENTIALITY

- 2.1. Principles of medical ethics, including professional norms for consent, standard of care, protecting patient privacy and confidentiality as per NMC Act, 2019 shall be binding and must be upheld and practiced.
 - 2.2. RMPs would be required to fully abide by NMC Act, 2019 rules & regulations 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.
 - 2.3. RMPs will not be held responsible for breach of confidentiality if there is reasonable evidence to believe that patient's privacy and confidentiality has been compromised by a technology breach or by a person other than the RMP. The RMPs should ensure that reasonable degree of care is undertaken while hiring such services.
 - 2.4. It is the responsibility of the RMP and / or the telemedicine service provider to be cognizant of the current Data Protection and Privacy laws. RMPs shall protect the patient's confidentiality as in normal circumstances
- 3. Misconduct:** It is specifically noted that in addition to all general requirements under the MCI 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:

- 3.1. RMPs insisting on Telemedicine, when the patient is willing to travel to a facility and/or requests an in-person consultation.
- 3.2. RMPs using patient images and data without the consent of the patient
- 3.3. RMPs who use telemedicine to prescribe drugs from the prohibited list and all those drugs are known to cause dependence or addiction.
- 3.4. **RMP prescribes medicine without diagnosis or provisional diagnosis**
- 3.5. RMPs are not permitted to solicit patients for telemedicine through advertisements or inducement.

1. **Penalties:** As per, NMC Act 2019, and other prevailing laws.

2. **MAINTAIN DIGITAL TRAIL/ DOCUMENTATION OF CONSULTATION**

It is incumbent on RMPs to meticulously maintain the following records/documents for three years from the date of the last consult with the patient.

- Log or record of Telemedicine interaction (e.g. Phone logs, email records, chat/ text record, video interaction logs etc.).
- Patient records, reports, documents, images, diagnostics, data etc. (Digital or non-Digital) utilized in the telemedicine consultation should be retained by the RMP for the duration prescribed by various acts and also to avoid problems in case of litigation.
- the RMP is required to maintain the prescription records as required for in-person consultations.
- If audio and/or video recording of the consultation is required, the RMP must take explicit informed consent from the patient. Similarly, if the patient and/or the family members want to record the audio and/or video of the consultation, they should take consent from the RMP. Those recording without consent will not be accepted as evidence

6. **FEE FOR TELEMEDICINE CONSULTATION**

- Telemedicine consultations should be treated the same way as in-person consultations with regard to consultation charges or fees. RMP may charge an appropriate fee for the Telemedicine consultation provided.
- RMPs should issue a duly signed receipt/invoice to the patient for the fees charged for the telemedicine based consultation provided.

(4) Framework for Telemedicine

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

- a. Patient with RMPs
- b. Caregiver with RMPs
- c. Health Worker with RMPs
- d. RMP with RMP
- e. Emergency Situations

Essential Principles:

- The **professional judgement** of the RMP should be the guiding principle: the 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.
- The RMP should exercise **their professional discretion** for choice of mode of communication depending on the type of medical condition being addressed. For e.g., if a case requires a video consultation for examination, RMP should explicitly ask for it.
- The RMP **can choose not to proceed** with the consultation at any time, after informing the patient of the decision.
- At any stage, the **patient has the right to choose to discontinue** the teleconsultation and may inform the RMP accordingly

4.1 CONSULTATION BETWEEN PATIENT AND RMPs

Specifically, this section details with the key elements of the process of teleconsultation to be used in the First consultation and Follow-up consultations between a patient and an RMP.

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

1. First Consultation: Patient with RMP

1.1. First Consultation means

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

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 the First Consultation

- The telemedicine consultation is initiated by the patient (For e.g., a patient may initiate an audio or video call with the RMP or send an e-mail or text with a health query)

- RMP accepts to undertake the consultation

2. Patient identification and consent

- RMPs should establish the patient's identity to their satisfaction by asking their name, age, address, email ID, phone number or other identification that is reasonable
- If Telemedicine consultation is initiated by the patient, **consent is implied**.

3. Quick assessment:

- Based on the input received, the patient's condition is quickly assessed by the RMP who decides whether emergency care is required or not, using professional discretion.
- 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 RMP may ask the patient to provide relevant information (complaints, information about other consults for the same problem, available investigations and medication details, if any). The patient shall be responsible for the accuracy of information shared with the RMP.
- If the RMPs feel that the **information received is inadequate**, they can request for additional information from the patient. This may be shared in real-time or later via email/text, depending on the nature of the information. For e.g., the RMP may require laboratory and/or radiological investigations. In such cases, the session may be considered as suspended to be resumed at a later predetermined time. RMPs should provide health education as deemed appropriate at any time.
- If the RMP is satisfied that adequate patient information for offering a professional opinion, has been received, then they shall exercise their professional judgment for appropriateness and suitability for management via telemedicine.
- If the situation is NOT appropriate for further telemedicine consultation, then the 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 RMP may take a professional judgement to either:

- Provide **Health Education** as appropriate in the case; and/or
- Provide **Counseling** related to a specific clinical condition, including advice related to new investigations that may be required before next consult; and/or
- Provide **specific treatment by prescribing drugs** as in List O (which are over the counter drugs or others as notified). Additional drugs (as per List A) can also be prescribed if the ongoing tele-consultation is on video.

2. Follow-up Consult: Patient with RMP

In a follow-up consultation, as the RMP-patient interaction has already taken place for the specific medical condition being followed-up and the RMP comprehends the context well with previous records available, it allows for a more definitive and secure interaction between the RMP and the patient.

2.1. Follow-Up Consultation means

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

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

- Patients may initiate a follow-up consultation with the RMP for the continuation of their ongoing treatment or for a new complaint or complication arising in the course of their ongoing treatment using any mode of communication. For e.g., the patient may initiate an audio or video call with the RMP or send them an email or text message with a specific health query.
- RMP accepts to undertake the consultation.

2. Patient identification and consent

- RMPs should be reasonably sure that they are communicating with the same patient. For e.g., if the patient is communicating with RMP through a previously saved or registered phone number or previously used or registered email id.
- In case of any doubt the RMP should request the patient to reinitiate the conversation from a registered phone number or email id or should establish the patient's identity to their satisfaction by asking their name, age, address, email ID, phone number or other identification that is reasonable [Details in the section 3.2].
- , The patient, initiates the Telemedicine consultation and thereby, **consent is implied**

3. Quick Assessment for Emergency Condition

- Suppose the patient presents with a complaint that the RMP identifies as an emergency condition necessitating urgent care. In that case, the RMP should provide advice 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, then they may proceed with the continuation of care.
- RMPs shall use their professional discretion regarding type of consultation based on adequacy of patient information (history, examination findings, Investigation reports, past records) available.
- If additional information is warranted, the RMP should seek the required information before proceeding and resume the teleconsultation at a later point in time.

5. Patient Management

- If RMPs are satisfied that they have access to adequate patient information and if the

condition can appropriately and satisfactorily be managed by teleconsultation, they should go ahead with the management of the patient.

- If the follow-up is for continuation of care, then the RMP should make a professional judgement to either:
 - Provide **Health Education** as appropriate in the case; and/or
 - Provide **Counseling** related to specific clinical condition, including advice related to new investigations that may be required before next consult; and/or;
 - Prescribe **Medication**. The medications could be either of the below:
 - If the follow up is for **continuation of care for the same medical condition**, the RMP should repeat the original prescription for a refill (List A of drugs that have already been prescribed for the patient earlier).
 - If the RMP considers addition of a new drug as **'add-on' medication** to optimize the treatment of the underlying medical condition, then the RMP can prescribe additional drugs listed under List B.
 - If the follow-up consultation is for a new minor ailment necessitating only **'over the counter'** medications or those notified for this purpose, medications under List O may be prescribed.
 - If the follow-up consultation **reveals a new symptom pertaining to a different disease**, then the consultation is not considered as a Follow-up consultation and the RMP should inform the patient about the same and proceed with the condition as described for a first-time consultation (4.1.1).

4.2 CONSULTATION BETWEEN PATIENT AND RMP THROUGH A CAREGIVER

1. For the purpose of these guidelines a **Caregiver** could be a family member, or any person authorized by the patient or law to represent them.
2. There are 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. The Patient is a minor (under the age of 18 years) or the patient is incapacitated, for example, in medical conditions like dementia or physical disability etc. In these circumstances the caregiver is authorized to represent the patient.
 - 2b. The **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 in-person consultation (explicit consult).

In all of the above situations, the consultations shall proceed as stipulated in the case of a Patient with the RMP (First consultation or Follow-up consultation, vide 4.1)

3. CONSULTATION BETWEEN HEALTH WORKER AND RMP

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

3.2. 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, State or National level. Health and Wellness centers are an integral part of comprehensive primary health care.
- This setting will also include health camps, home visits, mobile medical units or any community-based interaction.

3.3.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 with an RMP

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

2. Patient Identification (by RMP)

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

3. Patient Consent (by RMP):

- RMP should reaffirm that patient's consent has been obtained to continue the consultation

4. In case of Emergency,

- The Health Worker urgently communicates the patient's underlying condition to the RMP.
- If, based on information provided, the RMP identifies it as an emergency necessitating urgent care, they should advise 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 the patient's problem to the RMP which can be supplemented by additional information by the patient, if required.
- The RMP shall apply 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.

- If the RMPs feel that the **information received is inadequate**, they can request for additional information from the patient. This may be shared in real time or later via email/text, depending on the nature of the information. For e.g., the RMP may require laboratory and/or radiological investigations. In such cases, the session may be considered as suspended to be resumed at a later predetermined time. RMPs should provide health education as deemed 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 they should proceed with the management. Health worker should document the same in their records.
- The RMP may take a professional judgement to either:
 - Provide **Health Education** as appropriate in the case; and/or
 - Provide **Counseling** related to specific clinical condition, including advice related to new investigations that may be required before next consult; and/or;
 - Prescribe **Medication**:
 - as prescribed for use in guidelines from time to time for a particular cadre of Health Workers.

Role of Health Workers:

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

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

- Reinforcing health education and counseling advise provided by the RMP
- Providing drugs prescribed by the RMP and counseling on their treatment.

4.4 CONSULTATIONS – RMPs WITH OTHER RMPs

1. RMPs might use telemedicine services to consult with another RMP or a specialist for a patient under their care. Such consultations can be initiated by the RMP on their professional judgement.
2. The RMP asking for another RMP's advice remains the treating RMP, and shall be totally responsible for the treatment, and other recommendations, provided to the patient.
3. It is acknowledged that many medical specialties like Radio-diagnosis, Pathology, Ophthalmology, Cardiology, Dermatology to name just a few may be at advanced stages of adoption of technology for exchange of information and some others may be in early stages. Guidelines support and encourage interaction between RMPs and specialists using information communication technology for diagnosis, management and prevention of disease.
 - **Tele-radiology** is concerned with the **transmission of** radiographic images (X-rays, CT, MRI, Ultrasound etc.) from one location to another for diagnostic purposes.

- **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** delivers care by providing access to eye specialists for patients in remote areas for ophthalmic diseases screening, diagnosis and monitoring.
4. The management of critical/severe cases in 'e-ICUs' may be considered in consultation with specialists in situations of limited availability of ICU beds during emergencies like Covid-19 pandemic.

4.5 EMERGENCY SITUATIONS

1. In all telemedicine consultations, as per the judgment of the RMP, if it is an emergency situation, the overarching goal and objective should be to provide in-person care at the earliest . However, in the interim, critical steps could be life-saving; timely guidance and counseling could be critical. For example, in cases involving trauma, the correct advice and guidance around maintaining the neck position might prove life-saving by protecting the spine in some cases. The guidelines are designed to provide a balanced approach in such conditions. The RMP, based on their professional discretion, may:
- Advise first aid
 - Counseling
 - Facilitate referral

Patients may call any RMP during a medical emergency and insist on teleconsultation. However, the RMP may not reply or give any specific advice. In all emergency cases, the patient **MUST** be advised for in-person interaction with a Registered Medical Practitioner or specialist at the earliest possible.

5. Guidelines for RMPs and Technology Platforms enabling Telemedicine

This specifically covers those technology platforms which work across a network of RMPs and enables patients to consult with RMPs through the platform.

- 5.1. RMPs must ensure that any platform they associate with must comply the following guidelines
- 5.2. RMPs shall not participate in telemedicine platforms that provide ratings by patient or others including reviews, advertisements, and promotions of RMPs any means. (manipulation of algorithms/search engines etc). Advertising of RMPs is not allowed by anybody under any pretext.
- 5.3. Technology platforms (Mobile Apps, Websites etc.) providing telemedicine services to consumers shall be **obligated to ensure** that the consumers are provided services and are consulting with **RMPs** who are duly registered with the National Medical Register or their respective State Medical Councils and comply with their relevant provisions and laws amended from time to time.
- 5.4. The Platform must provide the **Name, Qualifications** (Graduate and Post-graduate with Super-specialty qualifications if any), **Registration Number, Contact details** (current Mobile numbers and e-mail addresses) **of every RMP** listed on their platform. The contact details of the RMPs, however, should not be displayed to the public or shared, except with the patient being consulted.
- 5.5. The onus of ensuring that all the information regarding the RMP and all their qualifications that have been mentioned on their portal have been authenticated and are registered with the National Medical Register or their respective State Medical Councils rests wholly on the Owners and Administrators of the Technology Platform.
- 5.6. In the event of non-compliance with these guidelines or infringement of the existing laws applicable to the provision of services provided by the Technology Platform, or if complaints against the Technology Platform are received by the NMC, appropriate action including legal action may be initiated against the Technology Platform by the NMC.
- 5.7. Technology platforms based on **Artificial Intelligence/Machine Learning are not allowed to counsel the patients or prescribe any drugs** to a patient. Only RMPs are entitled to counsel or prescribe and have to communicate directly with the patients 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 the RMP** on patient

evaluation, diagnosis or management, the final prescription or counseling has to be directly delivered by the RMP.

- 5.8. Technology Platform must ensure a proper grievance redressal mechanism for end users of their services.
- 5.9. In case any specific Technology Platform is found to violate these guidelines or any applicable existing laws applicable to them, the EMRB/NMC may designate the Technology Platform as blacklisted, and no RMP may then use that platform to provide telemedicine.

6. Special responsibilities of EMRB/NMC

- 6.1. The **drug-lists** contained in Guidelines for Practice of Telemedicine in India may be modified by the EMRB/NMC from time to time, as required. A formal mechanism for the same may be created.
- 6.2. The EMRB/NMC may issue necessary directions and/or advisories and/or clarifications with regards to these Guidelines, as and when required or deemed necessary.
- 6.3. The Guidelines for Practice of Telemedicine in India may be amended from time to time in the larger public interest

**First Consult:
Patient and Registered Medical Practitioner (RMP)**

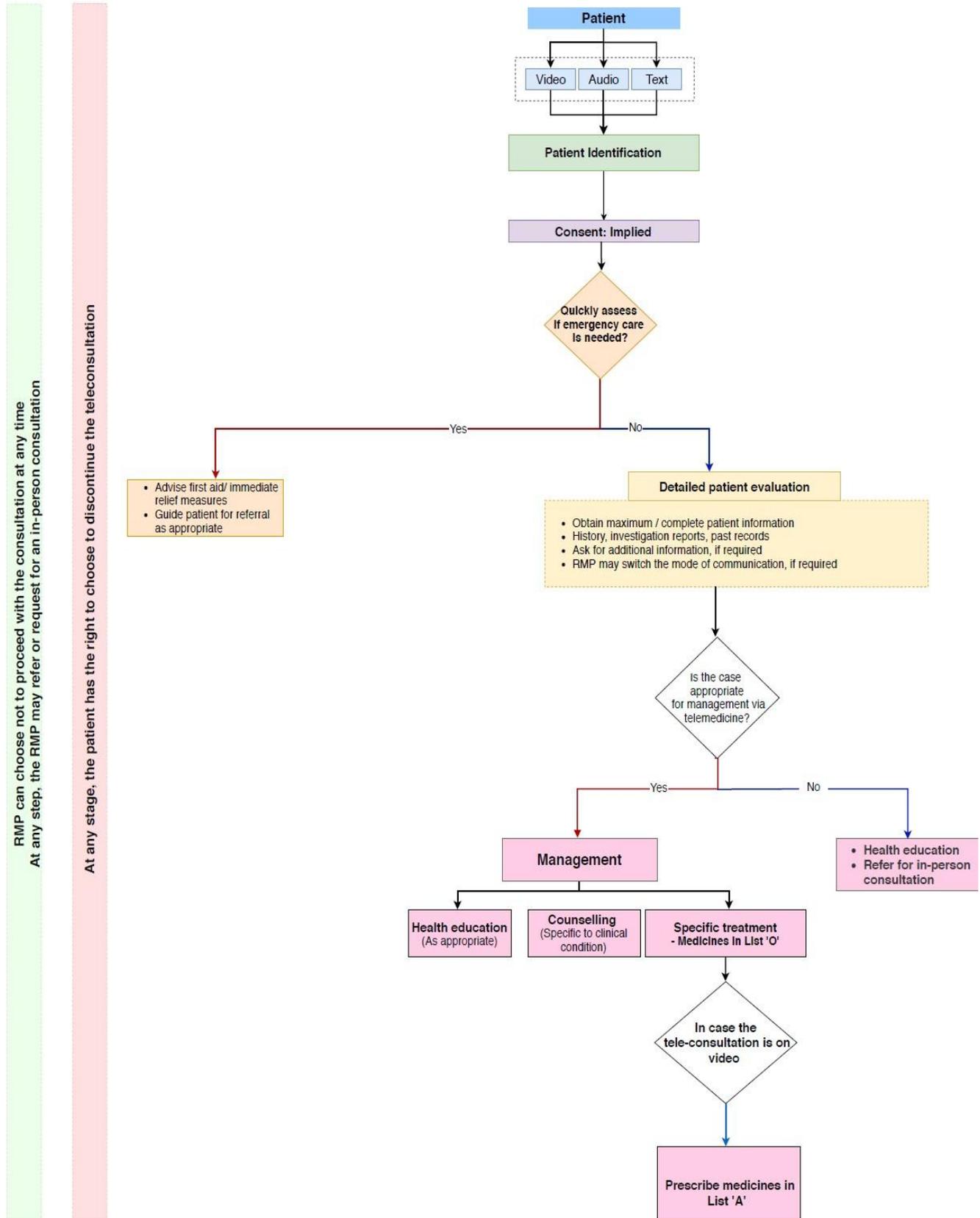
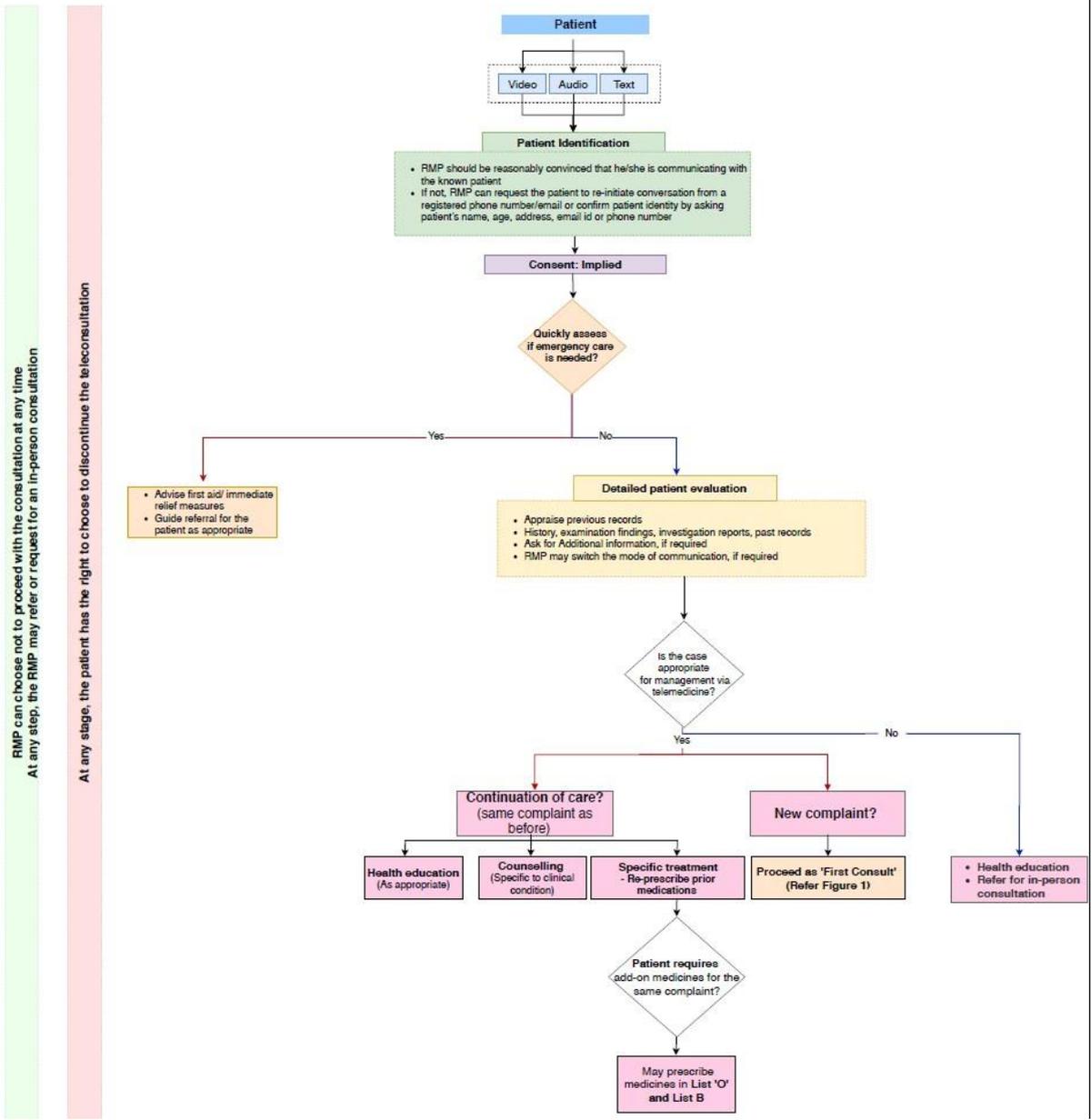


Figure 1: Flow chart for teleconsultation for first consultation

**Follow up Consult:
Patient and Registered Medical Practitioner (RMP)**



RMP can choose not to proceed with the consultation at any time
At any step, the RMP may refer or request for an in-person consultation

At any stage, the patient has the right to choose to discontinue the teleconsultation

Figure 2: Flow Chart for teleconsultation on follow-up

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

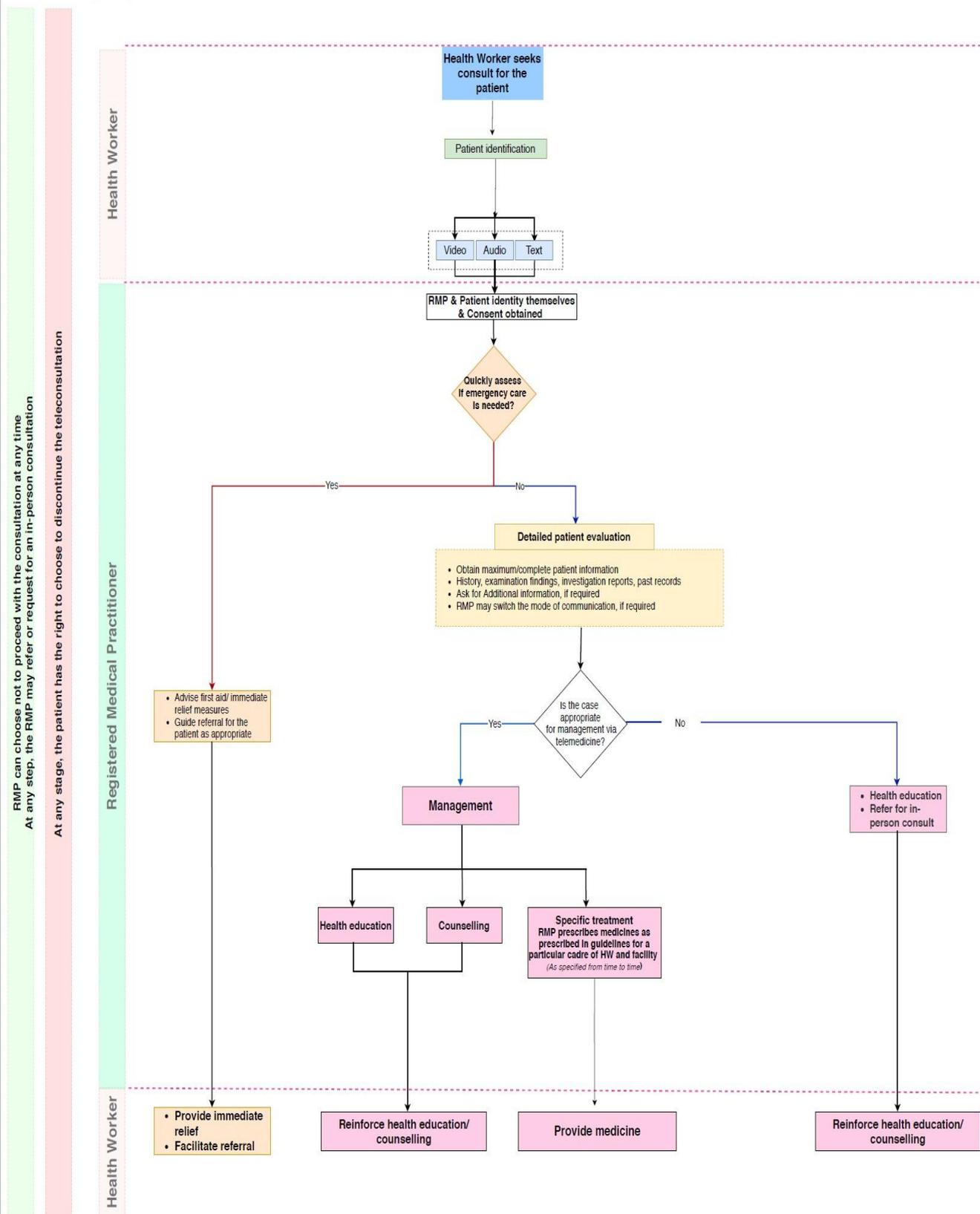


Figure 3: Flow chart for a teleconsultation between a Health Worker and RMPs

This page is intentionally left blank

Annexures

This page is intentionally left blank

DRUG LISTS

The list given below are INDICATIVE and do not restrict the RMPs from prescribing other drugs from the list of prescription drugs. RMPs may prescribe any drug (except Schedule X drugs) provided they are satisfied that the drugs being prescribed are optimal for the patient's medical condition be it a First-consultation or a Follow-up consultation.

LIST O:

- **Drugs for common ailments that are available 'over the counter' (OTC drugs) without the prescription of RMPs.** All the drugs that are not included in the list of 'prescription drugs' are considered as non-prescription drugs (or OTC drugs). **For example:**
 - [Anti-Hemorrhoid Drugs](#)
 - [Topical Antibiotics](#): Some topical antibiotics are available without a prescription
 - [Cough-Suppressants](#)
 - [Anti-acne Drugs](#)
 - [Non-steroidal Anti-inflammatory Drugs](#): Available OTC or few with prescription from RMP/dentist.
 - [Antiseptics](#)
 - [Analgesics](#)
 - [Decongestants](#): Some require a physician's prescription but many are OTC products.
 - [Vasodilators](#): Some Vasodilators such as Minoxidil are sold without prescription.
 - [Antacids and Anti-flatulence Agents](#)
 - [Expectorants](#): Many expectorants are available OTC.
 - [Anti-fungal Drugs](#)
 - [Anti-Histamines](#): Some can be bought without prescription.
 - [Smoking Cessation Drugs](#): Many drugs can be bought OTC without prescription.
- Medications notified by Government of India in case from time to time on an Emergency basis, such as Chloroquine for Malaria control for a specific endemic region, when notified by Government

LIST A:

- **First consultation drugs prescribed (Diagnosis made ONLY by video mode of consultation)**
 - Ointments/Lotion for skin ailments: Clotrimazole, Mupirocin, Calamine Lotion, Benzyl Benzoate Lotion etc; Local Eye drops such as: Ciprofloxacin for Conjunctivitis, etc; Local Ear Drops such as: Clotrimazole ear drops, drops for ear wax etc.
 - Follow-up consultations for above medications
- **Follow-up drugs being repeated, prescribed for a re-fill, in case of chronic illnesses.**
 - Hypertension: Enalapril, Atenolol etc
 - Diabetes: Metformin, Glibenclamide, etc
 - Asthma: Salmeterol inhaler etc

LIST B:

- **Drugs prescribed on follow-up consultations as add-on drugs to better manage existing disease**
 - Thiazide diuretic as add-on drug to Atenolol prescribed earlier for Hypertension
 - Sitagliptin as add-on drug to Metformin prescribed earlier for Diabetes mellitus

LIST OF PROHIBITED DRUGS:

- **Anti-Cancer, Psychotropic drugs and Narcotics (Morphine, Codeine etc.).** Drugs listed in 'Schedule X' of the **Drug and Cosmetic Act and Rules** [[2016DrugsandCosmeticsAct1940Rules1945.pdf \(cdsco.gov.in\)](#)]; and **substance listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985** [[Narcotic-Drugs-and-Psychotropic-Substances-Act-1985.pdf \(dor.gov.in\)](#)]. All those drugs, which are known to cause dependence or addiction

- Except Clobazam, Clonazepam and Phenobarbitone as per MCI-211(2/2019)(ethics)/201874, dated 11.04.2020.

This page is intentionally left blank

6.1 SAMPLE PRESCRIPTION FORMAT

REGISTERED MEDICAL PRACTITIONER'S NAME

QUALIFICATION

REGISTRATION NUMBER

ADDRESS

CONTACT DETAILS (EMAIL AND PHONE NUMBER)

Date Of Consultation

Name of Patient

Address

Age Gender

Height
(wherever applicable)

Weight
(wherever applicable)

LMP
(wherever applicable)

CHIEF COMPLAINTS

DIAGNOSIS OR PROVISIONAL DIAGNOSIS

RELEVANT POINTS FROM HISTORY

EXAMINATION / LAB FINDINGS

SUGGESTED INVESTIGATIONS

Rx

1. NAME OF MEDICINE (in capital letters only with generic name)
drug form, strength, frequency of administration & duration.
2. NAME OF MEDICINE (in capital letters only with generic name)
drug form, strength, frequency of administration & duration.
3. NAME OF MEDICINE (in capital letters only with generic name)
drug form, strength, frequency of administration & duration.

SPECIAL INSTRUCTIONS

RMP's Signature & Stamp

Note: This prescription is generated on a teleconsultation.

This page is intentionally left blank

Annexure 3

6.2 SAMPLE PATIENT INFORMATION SHEET

Introduction:

You are dealing with a communication platform owned and operated by _____ (Name of the RMP/Hospital/Service provider) for the purpose of providing a virtual space for a doctor-patient consultation otherwise known as Teleconsultation, Online Consultation or Telemedicine. Teleconsultation under this platform complies and follows the protocols and guidelines set forth by the NMC, Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 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, as well as the ethical standards of medical practice in India.

Teleconsultation involves using Information and Communication Technology (ICT) allows Medical Professionals to communicate and interact with their patients remotely and provide consultation, collection and sharing of information to improve patient care. The information exchanged may be used for diagnosis, therapy, follow-up and/or education and/or counselling, and may include any or all of the following:

1. Patient medical records
2. Medical images
3. Live two-way audio and video
4. Output data from medical devices and sound and video files

The ICT used will incorporate due diligence and best practice network and software security protocols to ensure confidentiality, protect your identity, imaging data and will include measures to safeguard the data and ensure its integrity against intentional or unintentional corruption, in compliance with Patient Confidentiality and Safety, Data Privacy laws, and Ethical Standards of Medical Practice in India.

Electronic systems used will incorporate certain protocols to protect the confidentiality of the doctor, and most importantly, of you, the patient. Please know that in line with the Privacy Policy, '**Any form of recording is prohibited**' except with the prior express written consent of you as the patient, your RMP as well as the associated Hospital/Service Provider. Reasonable and appropriate efforts would be made to eliminate any confidentiality risks associated with the telemedicine consultation and all existing laws regarding access to medical information and copies of medical records apply to this teleconsultation. Additionally, dissemination of any patient-identifiable images or information from this telemedicine interaction to researchers or other entities shall not occur without your consent, unless authorized under existing privacy and confidentiality laws of India.

Expected Benefits

Improved access to medical care by enabling you to remain at home or in a remote area for the consultation while allowing your RMP to collect information and make a diagnosis. You might also remotely access and obtain the expertise of a specialist through this platform which you would otherwise not have been able to routinely.

Possible Risks

As with any medical process, there are several potential risks involved in this procedure. However, we would like to draw your attention to the risks associated with use of telemedicine or online consultation. These include, but are not limited to:

1. Information exchanged may not be sufficient to allow appropriate medical decision making by the RMP in some instances, as there is no in-person contact to carry out a thorough physical examination of the patient.
2. Delays in medical evaluation and treatment may occur due to the limitations of teleconsultation related to access to healthcare facilities, diagnostic centers and other essential equipment.
3. In some instances, security protocols could fail, causing a breach of privacy of the patient's medical information.
4. Lack of access to all your medical records might result in adverse drug interactions or allergic reactions or other errors in judgement in some cases.
5. The counsel, advise, assessment, recommendation, and opinions rendered by the RMP should be considered for general guidance for your health condition only and should not be considered as replacement of actual diagnosis and physical examination by your personal physician.
6. Teleconsultation and is not a substitute for clinics, hospitals, and other medical centers.
7. Teleconsultation does not provide emergency services to its users nor is it meant to replace, or supplement emergency services.
8. Delays in communication, assessment and advice could occur due to failure of the electronic systems or connectivity.
9. In some instances, your failure to provide accurate and/or complete medical records to the RMP may result in adverse drug reactions or allergic reactions or other judgment errors.
10. You may expect the anticipated benefits from the use of the medical information or healthcare services provided by the RMPs, but no results can be guaranteed or assured.
11. The RMPs, in their sole discretion and professional judgment may determine that their medical information or healthcare services are not appropriate for some or all of your treatment needs and, accordingly, may elect not to provide medical information or healthcare services to you.
12. Temporary interruptions in service that are not within the control of the RMP may occur in connection with teleconsultation and telemedicine in general.

Annexure 4

6.3 SAMPLE INFORMED CONSENT FORMAT PATIENT EXPLICIT CONSENT FOR TELECONSULTATION

Patient Name:

Age:

Gender:

Location at the time of signing consent:

Home Address:

Date of Signing:

By signing this consent form, I state and understand that:

1. I am of legal age and within the territorial jurisdiction of India at the time of teleconsultation.
2. The RMP performing teleconsultation is licensed to practice medicine within the territorial jurisdiction of India.
3. The laws that protect privacy and confidentiality of medical information also apply to telemedicine, and that no information obtained in the use of telemedicine which identifies me will be disclosed to anyone, including people in the medical field, without my consent.
4. I have the right to withhold or withdraw my consent to the use of telemedicine during the course of my care at any point in time, without affecting my right to future care or treatment.
5. I have the right to examine all the information obtained and recorded in the course of the telemedicine interaction and may request and receive copies of this information for a reasonable fee.
6. My RMP has explained all the alternatives options of care to my satisfaction.
7. There are risks associated with the use of telemedicine services which I fully understand as risks that I have to take in order to receive teleconsultation service.
8. Telemedicine involves the use of electronic communication of my personal medical information, and is at times, prone to failure of security protocol.
9. Any form of recording including, but not limited to, taking screenshots and pictures, and recording audio or video is strictly prohibited, except with prior written consent of myself, the RMP, and the Hospital or Service Provider.
10. It is my duty to inform my RMP about any other electronic or in-person interactions regarding my care that I may have with other medical practitioners.
11. Any prescription given in the teleconsultation will be used only for this particular consultation and is only applicable in the territorial jurisdiction of India.
12. I may expect the aforementioned benefits from the use of telemedicine in my care, but as this is not the optimal means to having a consultation, no results can be guaranteed or assured.
13. A consultation fee of Rs. _____ (amount in figures and words) may be imposed by the RMP and a transaction fee of Rs. _____ (amount in figures and words) may be imposed by the Hospital/Service provider if any, for the use of the facility.
14. I agree to the Terms and Conditions and Privacy Policy and any other published policies shared with me by the RMP/mentioned in the website of the RMP, Hospital or Service Provider.

I have read and understood the information regarding the use of telemedicine provided above (or) the information regarding the use of telemedicine provided above has been read out and explained to me in a language that I fully understand, and I am willing to undergo this innovative means for my health condition to improve my care. I hereby give my informed consent for the use of telemedicine and teleconsultation with full agreement to its Terms and Conditions and Privacy Policy, for my medical care.

Patient's signature/Left Thumb impression