Submissions on the National Medical Commission, Registered Medical Practitioner (Professional Conduct) Regulations, 2022

22 June 2022

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A. Introduction:

This document contains comments on the Draft National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2022 (Hereafter, “Draft Regulations”) in response to the public notice dated 23rd May 2022 from the Ethics and Medical Registration Board (Hereafter, “EMRB”). These comments have been drafted by the Centre for Health Equity, Law & Policy (Hereafter, “C-HELP”), Indian Law Society, Pune and the Centre for Mental Health Law & Policy (Hereafter, “CMHLP”), Indian Law Society, Pune.

C-HELP aims to use the law as a tool for health transformation, embedding its work in the right to health as envisaged within India's constitutional framework and her international commitments. It advocates for equity and justice in health through generation, sharing and use of knowledge that informs related law and policy. C-HELP's intervention is directed towards ensuring that these regulations are revised in a manner that is consistent with the rights and obligations as shaped by the Constitution, court judgements, legislation and India's international obligations.

CMHLP’s mission is to strengthen and transform the mental health of communities to be holistic and responsive in addressing individual and collective well-being. Policy change is a primary focus area of the Centre, where we support governments in drafting evidence-based policies and the implementation of mental health and suicide prevention laws, specifically the Mental Healthcare Act 2017 (Hereafter the “MHCA, 2017”).

As the definition of licensed medical professionals includes Psychiatrists and Medical Practitioners who encounter and treat persons with mental illnesses, CMHLP examines the Draft Regulations alongside the provisions of the MHCA, 2017. The MHCA, 2017 lays down the duties and obligations of mental health professionals to ensure the rights-based treatment and care of persons living with mental health conditions. The MHCA prioritises the right to confidentiality, informed consent, and protection from cruel, inhumane, and degrading treatment. Further, the Act also details the procedures for admission, treatment and discharge including a list of identified prohibited procedures and it places restrictions on the duties that can be carried out by a mental health professional. In the comments, CMHLP has identified sections within the Draft Regulations that are pertinent to the MHCA, 2017 and have provided recommendations and comments on the interfacing complementary and contradictory provisions between both documents.

B. Substantive Comments on Regulations:

Chapter 2: Professional Conduct of RMPs

I. Regulation 13: Responsibility of RMP regarding medical records

a. Regulation 13B allows a Registered Medical Practitioner (RMP) to supply medical records to a patient, "authorised attendant or legal authorities". It is not clear who the quoted persons are. If by these terms it is meant representative of the patient, then the circumstances under which such a person can seek the patient's medical records and in which they can be given to this third party need to be specifically stipulated. Otherwise, there would be a breach of confidentiality of health status, which is violative of the right to privacy, and contrary to stipulations in the HIV/AIDS Act, 2017 and the Mental Healthcare Act, 2017. If the term "authorised attendant" means a healthcare worker/ provider attending to the patient, such supply of records would again be a breach of confidentiality unless and only if the supply was necessary in the interests of the patient's health/ to look after the patient. If "legal authorities" means a court, police or other law-enforcing entities, then this supply too can be done only in very limited and specified circumstances.

b. Regulations under 13 B, C, and D of the Draft Regulations detail the responsibility of the RMP to address requests to access medical records by the patient. However, to be in accordance with section 25 of the MHCA, 2017 on access to medical records for persons with mental illness, please revise Regulation 13 as applicable. Section 25 (1) of the MHCA, 2017 states that every person with mental illness has a right to access their medical records and Section 25 (2) details the circumstances under which information can be withheld. Regulation 13 under the NMC guidelines must be **revised** as suggested below to include the rights of persons with mental illness as provided for under the MHCA 2017.

- **Revise** 13B to include the sections in bold, *"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 / authorised attendant or legal authorities involved, **including patients with mental illness as per Section 25 (1) of the MHCA, 2017**, the same may be duly acknowledged and documents shall be supplied within 5 working days. **Additionally, the release of medical records should be in accordance with the MHCA, 2017 which also details the exceptions to the release of information**"*
- **Revise** 13B to include the section in bold, *"In case of medical emergencies, the medical records should be made available on the same day**, and for patients with mental illness this is in accordance with the MHCA, 2017 which details the exceptions to the release of information**."*
- **Revise** 13D to include the section in bold, "*Efforts shall be made to computerise patient's medical records for quick retrieval and security. Within 3 years from the date of publication of these regulations, the RMP shall fully digitise records, abiding by the provisions of the IT Act, Data protection and privacy laws, **the MHCA, 2017,** or any other applicable laws, rules, and regulations notified from time to time for protecting the privacy of patient data.*"

II. Regulation 15: Torture and violation of human rights

While Regulation 15 of the Draft Regulations recognises that RMP should not aid or abet torture or inflict trauma on another person, the regulations have neither specified what comprises torture and trauma nor provided Guidelines that provide details. Thus, Regulation 15 must be **revised** to include "*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* ***as detailed in Section 20 of the MHCA, 2017."***

The MHCA, 2017 adopts a rights-based approach to understanding mental illness and treatment. However, at present, certain practices such as torture or trauma through medical treatment and discredited practices such as electroconvulsive therapy (ECT) and conversion therapy are followed by members of the medical fraternity. The use of conversion therapy as a practice to alter or 'treat' a person's gender or sexual identity in India led to the Court order directing NMC to take action against professional misconduct[1] **[For more details, refer to Section IV sub-section (f) on conversion therapy below].** To avoid the use of treatments that deliberately or inadvertently cause trauma, violate rights and are inhumane or degrading in nature, we recommend the EMRB **draft reference guidelines** that provide an exhaustive list defining what procedures and treatments qualify as torture, inhumane and degrading, as causing mental or physical trauma and violation of human rights. The guidelines should be drafted in accordance with

- Section 20 of the MHCA, 2017 which highlights the right to protection from cruel, inhuman and degrading treatment for mental illness.
- Section 21 (1a) of the MHCA, 2017 which highlights the right to equality and non-discrimination in healthcare, and no discrimination on any basis including gender, sex, sexual orientation, religion, culture, caste, social or political beliefs, class or disability. This is particularly important when it comes to conversion therapy.
- Section 95 of the MHCA, 2017 which lists prohibited treatment methods, namely electro-convulsive therapy without the use of muscle relaxants and anaesthesia or electro-convulsive therapy for minors, forced sterilisations, disproportionate use of physical restraints and use of chains.
- Section 97 of the MHCA, 2017 which details the circumstances under which restraints and seclusion are permitted, and the corresponding protocol and limits to be followed.
- Section 106 of the MHCA, 2017 which specifies the restriction on mental health professionals or medical practitioners to perform functions or recommend medicine or treatment not authorised by the field of profession.

[1] James S. Take Disciplinary Action Against "Conversion Therapy", Implement Revised CBME Curriculum For 2022-23: Madras High Court. Live Law. Published online February 20, 2022. Accessed June 17, 2022.
https://www.livelaw.in/news-updates/madras-high-court-action-against-conversion-therapy-by-doctors-revised-cbme-curriculum-for-2022-23-192365

III. Regulation 16: Euthanasia

Regulation 16 - the current legal status of euthanasia is governed by the SC decision in *Common Cause v Union of India (2018)*, wherein it was held that the right to refuse life-sustaining medical treatment is part of the right to life (autonomy and privacy) under Article 21 of the Constitution, and withholding or withdrawing life-sustaining treatment was valid as per instructions in the advance directives by a terminally ill person or persons in vegetative state (PVS). Consequently, advance directives are entitled to deference by treating physicians to respect the patient's right to refuse life-sustaining treatment. A treating physician, who in good faith exercises professional medical judgement and follows instructions as per the advance directive to withhold or withdraw medical treatment, is protected against liability. **To this extent, 'passive euthanasia' should be permitted as per detailed guidelines laid down by the court in *Common Cause*, instead of the prohibition prescribed by this Draft Regulations. The EMRB must draft guidelines on the use of Advance Directives for passive euthanasia, based on Section 5 of the MHCA 2017, in accordance with the Court's directive. Section 5 of the MHCA 2017, defines an Advance Directive as a written document made by a person stating how they would like to be treated and cared for, or not treated and cared for, if they have a mental illness and cannot make decisions regarding their mental healthcare and treatment without support.**

IV. Regulation 19: Informed consent

a. Regulation 19(A) - The rule states that in case a patient is unable to give informed consent the same should be taken from a "legal guardian or family member". The former is usually prescribed in cases of the patient being a minor. The latter term is too general - it can mean any family member. **Instead, the term "representative" should be used,** signifying a specific person that could include persons who are not recognised by law to be 'family', including people in same-sex/ queer relationships.

b. **Regulation 19(A) - Informed consent for sterilisation procedures**- the Regulations state that "*In an operation that may result in sterility, the consent of both husband and wife is required*". The requirement of spousal consent for operations that may or will result in sterility is in contravention of the MoHFW's *Standards for Female and Male Sterilisation Services.* Spousal consent is strictly not necessary for female and male sterilisation.[2] It is also violative of the fundamental right of individuals to privacy and bodily autonomy. **The requirement for consent of the spouse for such operations should be removed.**

c. It is further submitted that the **informed consent requirements for male and female sterilisation should follow the norms laid down by the Supreme Court in *Devika Biswas v Union of India*** ((2016) 10 SCC 733). The Supreme Court held that persons undergoing sterilisation must be explained the details of the procedure, its impact and consequences in the local language to obtain informed consent; a certificate of informed

[2] Ministry of Health and Family Welfare, *Standards for Female and Male Sterilisation Services,* 2006, Pg 6 and 20

consent must be certified by a doctor as well as a trained counsellor, and adequate time of about an hour (approx.) should be given to a patient to appropriately consider undergoing or refusing the procedure for sterilisation. These requirements should be included in the Regulations.

d. Regulation 19(A) pertains to written informed consent requirements for *in vitro* fertilisation and artificial insemination procedures, where the consent of the "female patient and her spouse as well as the donor" is needed. The recently passed *The Assisted Reproductive Technology (Regulation) Act 2021* (ART Act) as well as *The Surrogacy (Regulation) Act 2021* regulate all aspects of assisted reproductive technology services and procedures. The ART Act allows both infertile married couples and single women to avail of ART procedures for the purpose of having a child. **The NMC Regulations should clearly state that RMPs must comply with the informed consent requirements in *The Assisted Reproductive Technology (Regulation) Act 2021* and *The Surrogacy (Regulation) Act 2021.*** This would include providing ART services to a single woman. The wording of the informed consent requirement should not have the unlawful effect of excluding single unmarried women from accessing ART services. It should therefore be clarified in the Regulations that **spousal consent for female patients would be required only in the case of married couples.**

e. While Regulation 19A and the corresponding guidelines (guideline 5) of the NMC regulations specify the importance of informed consent for specific procedures such as surgery and sterilisation, there is no mention of mental illness as a separate category. In accordance with Chapter III and IV of the MHCA, 2017, the following sentence in Regulation 19 A should be **revised** to include ***"...In case the person with mental illness lacks capacity to give informed consent as defined in Section 2 (i) of the MHCA, 2017, even after being provided with adequate supports and in the absence of an advance directive, the informed consent of the nominated representative must be taken till such time that the person with mental illness regains capacity to give informed consent..."***

f. **Conversion Therapies and Informed Consent:** In an ongoing matter with respect to the prohibition of the unscientific and harmful practice of 'conversion therapy' by RMPs against LGBTQ+ persons, the NMC has undertaken before the Hon'ble Madras High Court to classify such acts as professional misconduct under the appropriate regulations. According to the NMC's proposal, EMRB and SMC will be authorised to take disciplinary action against RMPs for violating this guideline. (See: order dated 17.02.2022 in *Sushma and Seema v. Commissioner of Police*, Writ Petition No. 7284/2021).

Conversion therapies are a range of medical, social and related interventions which claim to suppress the expression of lesbian, gay, bisexual, transgender and queer (LGBTQ) person's sexuality and gender identity. They are irrefutably proved to be unscientific and harmful to survivors. The evolution of the International Classification of Diseases (published by the World Health Organization) supports the conclusion that

pathologization of same-sex attraction (ICD-10 adopted by World Health Assembly (WHA) in 1990) and self-determination of gender identity (ICD-11 adopted by WHA in 2019) are not based in evidence, and de-classifying such identities and/or behaviours is essential for the protection of health and human rights of LGBTQ persons.

Apex medical bodies like the Indian Psychiatric Society (IPS) and the Indian Association of Clinical Psychologists (IAACP) issued position statements in 2020, condemning healthcare professionals and institutions who offer conversion therapies and declaring that medical practice must reflect the evolving consensus in health, law and policy.

The Hon'ble Supreme Court declared in *Navtej Singh Johar v. Union of India* (2018) that by virtue of guarantees of non-discrimination on basis of sexual orientation and gender identity under the Mental Healthcare Act, 2017 the Parliament recognises that same-sex attraction and gender diverse identities are not to be treated as pathologies, and mental healthcare professionals must direct their efforts at affirmation of LGBTQ persons' lived experiences. Moreover, Section 3 of the MHCA, 2017 states that the determination of mental illness must be done in accordance with national and international medical standards, including the latest editions of the International Classification of Diseases (ICD -10) by the World Health Organisation. The Hon'ble Madras High Court's orders in the aforesaid matter explicitly declared that conversion therapy is a violation of the constitutional rights of LGBTQ+ persons. Therefore, the scientific and legal consensus is abundantly clear that conversion therapies must be prohibited and outlawed completely.

In order for the current guidelines to make such violations actionable under Clause 38 as professional misconduct in compliance with the NMC's submission before the Hon'ble Madras High Court, **Clause 19 on Informed Consent must explicitly state that RMPs are prohibited from practising conversion therapy in all forms, as such practices are not based in any evidence, there is no medical indication for the same and in fact, they cause bodily and psychological harm to survivors. The draft regulation's current Guideline-5 on Informed Consent in Clinical Practice already recognizes that "*consent for illegal procedures would not be deemed valid either legally or ethically*".** This must be explicitly recognized in the context of conversion therapy as LGBTQ+ adolescents and adults seeking such medical interventions do so under coercion or apprehension of violence by natal families. Therefore, by virtue of the principle of informed consent, conversion therapies must be condemned and prohibited unequivocally under the regulations.

CHAPTER 3 - Duties of RMPs towards their patients

V. Regulation 24: Confidentiality

Owing to the emergence of teleconsultations and digital health services, medical records are increasingly being shared across virtual and electronic formats. This applies to digital mental health as well which is evidenced in the growth of telepsychiatry and the recently announced government National Tele Mental Health Centres. Since data will be exchanged across digital

platforms, the risk of violating this right to confidentiality is higher. The MHCA, 2017 in Section 24 recognises that “the right to confidentiality also applies to information stored in an electronic and digital format in real or virtual space”.

Thus, in line Section 24 of the MHCA, 2017, the following sentence in Regulation 24 should be **revised** to include a clause specifying confidentiality in digital or electronic communication, to read *“Every communication between RMP and patients **including that in the digital or electronic domain**, shall be kept confidential...”*

The Right to Confidentiality with regards to the treatment of the mental health and physical health of a person with mental illness is stipulated under Section 23 of the MHCA, 2017 and is subject to the following exceptions:

- release of information to the nominated representative (individual appointed by a person with mental illness who has the duty to represent and provide support to such person in taking decisions regarding their mental healthcare treatment) to enable him to fulfil his duties under this Act;
- release of information to other mental health professionals and other health professionals to enable them to provide care and treatment to the person with mental illness;
- release of information if it is necessary to protect any other person from harm or violence; only such information that is necessary to protect against the harm identified shall be released;
- release only such information as is necessary to prevent a threat to life;
- release of information upon an order by the concerned Board or the Central Authority or High Court or Supreme Court or any other statutory authority competent to do so; and release of information in the interests of public safety and security

Therefore, Regulation 24 should be **revised** to specify the exceptions for the release of medical records without the informed consent of the person with mental illness, as laid down by Section 23 of the MHCA, 2017.

VI. Regulation 29: Consultation by Telemedicine

In addition to the Telemedicine Guidelines, Regulation 29 must be **revised** to include the **Telepsychiatry Operational Guidelines –2020** prepared by the Indian Psychiatric Society & Telemedicine Society of India, in collaboration with the National Institute of Mental Health and Neurosciences, Bangalore (NIMHANS). The guidelines include the details on telepsychiatry consultations initiated by patients and family members, prescription of medication online and tele-psychotherapy and tele-counselling. **A copy of the guidelines is attached (Annexure 1).**

Further comments on the practice of telemedicine are made below on the specific guidelines for telemedicine i.e. Guideline 11.

Chapter 6: Professional Misconduct

Preliminary comment: The fact that the SMC, EMRB and NMC are dominated by doctors raises questions on the impartiality of any proceedings that will take place under Section 30 and the Ethics Code.

VII. Regulation 38: Professional Misconduct

Regulation 38 states: "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." It is not clear what other forms of professional conduct (not mentioned in the Draft Regulations) can invite inquiry over professional misconduct, and hence be open to misuse. Hence, this provision should be deleted.

VIII. Regulation 39: Procedure for a complaint of professional misconduct

Under Section 14 of the MHCA, 2017 a nominated representative may be appointed by a person with mental illness to provide support with respect to the individual's mental healthcare and treatment. The Nominated Representative may take decisions on behalf of the person with mental illness, in accordance with their will and preferences, in matters relating to their mental care and treatment, provide support in decision-making and informed consent in situations when the individual may not have the capacity to make decisions. Section 14 (4) provides a list of who may be deemed a Nominated Representative in order of precedence if an individual has not appointed anyone. The process of assessing the capacity of a person with a mental illness is detailed under Section 4 of the MHCA, 2017. The details and process of appointment of Nominated Representatives are under Sections 14, 15 and 16 of the MHCA, 2017 and the duties of the nominated representative under Section 17.

Regulation 39.B, specifically, under the Draft Regulations, should be **revised** to include the following text in bold *"Where the aggrieved person is unable to make a complaint on account of physical or mental incapacity, a complaint may be filed by —*

- *a family member or relative or friend; or*
- *the guardian or authority under whose care treatment was received* ***or the nominated representative appointed under section 14 of the MHCA, 2017***
- *the legal heir or guardian in case of death of the patient* ***or the nominated representative appointed under section 14 of the MHCA, 2017"***

IX. Regulation 40: Manner of Inquiry into the Complaint

Regulation 40 places an onerous expectation on the complainant - five copies of the complaint, with supporting documents and the names and addresses of the witnesses. For persons without the means to pay for multiple copies or obtain the addresses of witnesses the burden to file a complaint would be cumbersome. The process should be simplified and made accessible.

X. Regulation 41: Disposal of the Complaints

Under Regulation 41, penalties are in the nature of 'recommendations'; it is not clear whether these recommendations are binding. Hence, Regulation 41 should be modified to make orders by the SMCs, EMRB and NMC in relation to the Draft Regulations, enforceable.

XI. Regulation 45: Appeal

Under Section 30 and Regulation 45, the right of appeal is only given to the registered medical practitioner. Keeping in mind the principles of natural justice and the rule of law, the right of appeal should be available to both parties, the complainant and the RMP.

The SMC and EMRB must upload all orders under Section 30 and the Ethics Code on their website and make these publicly available (after satisfying the confidentiality requirements of both parties to the complaint).

Substantive Comments on the Guidelines:

XII. Guideline 3: Code of Ethics

The provision on discrimination under the guidelines does not cover all the grounds that are considered prohibited grounds for discrimination by the law of the land (Supreme Court judgements and legislations). Clause 7 must cover and include **RMP's duty of non-discrimination on grounds of 'sexual orientation', 'gender identity', 'sex characteristics', 'HIV status' and other status of patients.**

In *National Legal Services Authority (NALSA) v. Union of India* (2014), the Hon'ble Supreme Court declared that anti-discrimination on grounds of gender identity is covered by the prohibition of 'sex-based discrimination in Article 15 of the Constitution of India.

In *Navtej Singh Johar v. Union of India* (2018), the Hon'ble Supreme Court likewise declared that anti-discrimination on grounds of sexual orientation is covered by 'sex' in Article 15.

In *Arunkumar and Sreeja v. Inspector General of Registrations* (2019), the Hon'ble Madras High Court declared that anti-discrimination on basis of sex characteristics is similarly covered by 'sex' in Article 15.

In *Inspector (Mahila) Ravina v. Union of India*, the Hon'ble Delhi High Court declared that anti-discrimination on basis of pregnancy is protected by the prohibition of sex-based discrimination in Article 15.

Moreover, statutory law provides additional protections on grounds discussed herein and other status. Sections 18(2) and 21 of the Mental Healthcare Act, 2017 mandate non-discrimination on basis of sexual orientation and gender identity in access to mental healthcare goods, services and facilities. Section 18(2) also mandates non-discrimination on the ground of political beliefs.

Section 3 of the Transgender Persons (Protection of Rights) Act, 2019 mandates non-discrimination on basis of gender identity in access to healthcare.

Section 3 of the Rights of Persons with Disabilities Act, 2016 mandates non-discrimination on the ground of disability in all spheres of public life.
Lastly, Section 3 of the HIV/AIDS (Prevention and Control) Act, 2017 mandates non-discrimination on basis of HIV status in access to healthcare.

XIII. Guideline 4: Guidelines on penalties

a. Ideally, any finding of professional misconduct under the Ethics Code should be reflected in the online national and state registers under Section 31, like how exoneration is meant to be widely publicised (Guideline 4). This practise is followed in other jurisdictions, like Australia and the United Kingdom, with the objective of minimising the information asymmetry inherent in a doctor-patient relationship.
b. Guideline 4, Regulation 2(a) states: "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." The clause should be amended to include consideration of whether the doctor followed protocols on standard treatment guidelines.
c. The EMRB should highlight that the MHCA, 2017 in Section 108 details the penalties and punishment for any person (including mental health professionals) who contravenes any provisions of the Act. The punishment may include a fine ranging from INR 10,000 – 5,00,000 with or without imprisonment up to a period of 6 months. This may be in addition to the revocation of licences under the NMC Draft Guidelines.

XIV. Guideline 5: Informed Consent in Clinical Practice

a. The right to withdraw consent should be recognised.
b. Emergencies - The guidelines must provide the complete protocol guiding consent in emergencies as the current draft misses on key points such as:
    - In an emergency where consent cannot be obtained, medical treatment may be given, **provided the treatment is limited to what is immediately necessary** to save life or avoid significant deterioration in the patient's heath
    - However, any **valid advance refusal,** which is known to the RMP or is brought to their attention, should be respected
    - As soon as the patient is sufficiently recovered to comprehend, **the patient should be told what interventions have been done and why**

c. The EMRB should revise the guidelines to include a section on persons with mental illness that either details or explicitly cites Chapters III and IV of the MCHA. Chapter III of the MHCA clarifies how advance directives act as a tool for pre-emptive consent of a person with mental illness if they do not have the capacity to make decisions related to treatment. Chapter III also specifies circumstances under which advance directives are not applicable or are subject to change, including that an advance directive will not be applicable once the person regains capacity or is able to make decisions on their own. Chapter IV of the MHCA discusses the roles and responsibilities of a nominated representative to provide support for an individual's mental healthcare and treatment.

XV. Guideline 6: Conduct of RMPs on Social Media

Guideline 6, Regulation 10 states: “On social media, RMPs should refrain from boundary crossings or violations and conduct themselves with dignity and decorum.” This provision is vague, open to abuse and may violate the fundamental right to free speech under Article 19(1)(a). Specifically, it is not clear what qualifies as ‘boundary crossing’ and ‘dignity and decorum’. Hence, it should be deleted.

XVI. Guideline 9: List Of Certificates, Reports, Notifications Etc. Issued By Doctors For The Purposes Of Various Acts/ Administrative Requirements

Guideline 9.2 should be **revised** to omit the terms ‘Lunacy’ and ‘Mental Deficiency’ as they denote the older laws on mental health (The Lunacy Act, 1912 and the Mental Health Act, 1987) which have been repealed and replaced by the MHCA, 2017. Please include provisions and regulations as mandated under the MHCA, 2017, as per which the state authorities may notify regulations for the manner in which the register of mental health professionals is to be published.

Thus, Guideline 9.2 should be **revised** as follows, *“Under the ~~Acts relating to~~ ~~Lunacy and Mental Deficiency and under the Mental Illness Act~~* ***Mental Healthcare Act, 2017*** *and the rules* ***and regulations*** *made thereunder and the Rights of Persons with Disabilities Act, 2016 and the rules and regulations made thereunder.”*

XVII. Guideline 11: Telemedicine

1. **RMPs who wish to practice telemedicine must undergo CPD training on telemedicine.**

   Section 1.2 “Scope” of the Telemedicine Guidelines state that the RMPs need to undergo CPD training on telemedicine to be entitled to practice telemedicine. The Guidelines must specify whether the RMPs are required to undergo training in telemedicine as a condition precedent to practising telemedicine. If yes, then this must be clearly mentioned in the guidelines. Further, the telemedicine apps and the telehealth providers must be instructed to only engage with RMPs who have undergone this training [add this stipulation under para 5, clause 5.4.- Guidelines for RMPS and Technology Platforms Enabling Telemedicine]

2. **The professional judgement of a Registered Medical Practitioner (RMP) should be the guiding principle for all telemedicine consultations**

   The guidelines in section 3.1 setting out the context, must specify that the ‘professional judgement’ to decide to proceed with telemedicine in lieu of an in-person consultation, must be recorded in writing by the RMP and form part of each patient record. This will bring in accountable and transparent practice as well as help in discharging RMP’s obligation to arrive at a considered view.

In fact, throughout the guidelines, wherever reference is made to professional judgement or discretion of the RMP, it must be specified that they must record their considered decisions in writing and keep it as part of the patient record.

3. Minimum threshold to establish a doctor-patient relationship in telemedicine - first consultation must be via videoconferencing, if not in-person

3.1 Section 3.3. on "modes of communication" permit the RMP to hold the 'first' teleconsultation with a patient via any mode – video, audio and text, based on their professional judgement. It is submitted that the first consultation in telemedicine that meets the requirements of establishing a doctor-patient relationship, must be via videoconference, as a rule. In the case of certain listed exceptions, the first consultation could be in audio mode. Where it is up to the discretion of the RMP, reasons must be recorded in writing and form part of the patient record.

3.2 Apart from being necessary from the point of view of establishing a doctor-patient relationship, videoconferencing will also ensure better identification of doctor and patient identity (to the satisfaction of both parties), facilitate better engagement and communications to minimise the deficiencies due to the absence of in-person consultation and facilitate processes of informed consent – all of which are points that are equally emphasised by the guidelines.

3.3 There are countries that restrict the use of telemedicine and enforce the threshold requirement of the doctor-patient relationship more cautiously, in the interest of patient safety:

- In Japan, telemedicine is subject to the Medical Practitioners' Act, which does not consider telemedicine a "medical examination" unless the first examination of each patient is conducted face to face to collect accurate information from such patienst.[3]

- In Germany, as a general rule, physicians, dentists, psychotherapists as well as other healthcare professionals may advise and treat patients in in-person visits exclusively. However, ICT, e.g. authorised e-mail or audio-video chat platforms, may be used to assist in the in-person treatment of and communication with patients. By contrast, exclusively remote visits, diagnostics and/or treatments, i.e. without any prior real-life interaction between healthcare professionals and patients, are only permitted within very strict limitations requiring a case-by-case evaluation of the medical appropriateness.[4]

    - In Australia, telehealth general practice providers are required to have an existing and continuous relationship with a patient in order to provide telehealth services. Therefore, unless an exception applies (e.g., the

[3] Telehealth around the world: A Global Guide. Available at: https://www.dlapiperintelligence.com/telehealth/countries/handbook.pdf?c=BR
[4] Ibid

patient resides in an area where their movement is restricted by a public health requirement or the patient is less than 12 months old), a medical practitioner can only provide telehealth services to patients who have seen the practitioner for a face-to-face service in the last 12 months or have seen another medical practitioner at the same practice for a face-to-face service during the same period. Recently though the government permits videoconferencing in lieu of in-person consultation and audio-only services can be offered in limited circumstances.[5]

3.4 In light of the above, the guidelines must distinguish between different modes of teleconsultation (video, audio, text) and specify that the first teleconsultation must be via videoconferencing as a rule. In case of certain very limited exceptions, (which must also be listed) the first consultation could be via audio mode. However, it must be followed up by a videoconference. Where an RMP provides the first teleconsultation via audio route, they must record the reasons for the same in writing and document it as a part of the patient record.

4. Informed consent should be taken from every patient, irrespective of whether the teleconsultation was initiated by the patient or the doctor

4.1 In Section 3.4, the guidelines state that informed consent will be taken from patients only when the RMP initiates the teleconsultation. Consent will be implied when patients initiate teleconsultation. It is submitted that telemedicine constitutes a very different mode of consultation than in-person consultation and with significantly higher risks to patient autonomy, confidentiality and privacy. In this context, the differentiation on the basis of who initiates the consultation is unjustified and incomprehensible. Even if a patient initiates the teleconsultation, they may be unaware of the risks of and alternatives to telemedicine, how the modality works, their rights pertaining to this mode, and the obligations of the RMP or the service provider etc.

4.2 Afterall, the Guidelines themselves state that *"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." (Ethical obligations of the RMP, sub-clause 4, Clause 1.1).*

It would follow from the above, that the patients who initiate teleconsultation must also be given an information sheet, privacy policy and their informed consent should be recorded. They cannot be presumed to know all the details about telemedicine and its implications and rights and liabilities and limitations arising from it, only because they registered for it.

[5] Ibid

4.3 It is for this reason that several countries unequivocally mandate that it is the duty of the RMP to take explicit informed consent for telemedicine from every patient.

- In Japan, each medical practitioner shall enter into an agreement regarding telehealth with each patient after providing sufficient information to the patient.[6]
- In New Zealand[7] and Finland,[8] RMPs are required to ensure that they have the informed consent of the patient before proceeding with the teleconsultation.
- France requires the RMP to ensure that the patients have been taken through an information sheet and have given their informed consent.[9]
- In the UK, the principles for remote consultations and prescribing (the "High-Level Principles"), 2019 state that the UK registered healthcare professionals must prioritise patient safety, protect vulnerable patients, ensure patients understand how remote consultations work and that there may be limitations on prescribing and obtain informed consent.[10]
- In Australia, the Federal Department of Health has issued a “Privacy Checklist for Telehealth Services”, which among other things, categorically places obligations with respect to obtaining informed consent from every patient.[11]

4.4 Considering the above, the Guidelines must make it mandatory that patients be provided with the information sheet and privacy policy at the time of registering for teleconsultation; and that the RMP must ensure that a) the patient has read and understood the information sheet and privacy policy, and b) take the patient through the informed consent form and record the informed consent and keep it as part of the patient record.

4.5 Similarly, in the context of public health settings particularly in primary health care settings, or any setting where the patient is being assisted by a health worker, it should be the health worker's responsibility to ensure that the patient has read and understood the information sheet and the privacy policy and take the patient through the informed consent form and record the patient’s consent and maintain a patient record. The RMP providing teleconsultation must ensure that the patient has given informed consent before the consultation begins and record it in the patient record at their end.

5. Information sheet

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[6] Ibid.
[7] Medical Council of New Zealand (2020). Telemedicine . Available at: https://www.mcnz.org.nz/assets/standards/c1a69ec6b5/Statement-on-telehealth.pdf
[8] Id. fn 2
[9] Id. fn 2
[10] Health & Care Professionals Council, UK: High Level Principles for good practices in remote consultations and prescribing. Available at: https://www.hcpc-uk.org/standards/meeting-our-standards/scope-of-practice/high-level-principles/
[11] Department of Health, Government of Australia: Factsheet - Privacy Checklist for Telehealth Services. Available at: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/F47F4FC1848FAEC2CA25855D008395C9/$File/Factsheet-privacy-checklist-for-telehealth-services-20200804.pdf

The Information sheet must contain all relevant information pertaining to the rights of patients in the context of telemedicine, obligations of RMPs and service providers, grievance redress mechanisms etc. This should be made available in all the relevant languages.

6. Responsibility of RMPs with respect to protecting confidentiality and privacy

6.1 Some of the most serious vulnerability causes in the context of telemedicine within a hospital relate to poor encryption, flaws in the process of separating internal networks from external networks, lack of inventories regarding computer devices and other equipment authorized to access the hospital network, deficiencies in user's authentication, and inability to identify intruder devices on the wireless network.[12] The duty of care of RMPs to maintain patient confidentiality and privacy becomes significant in telemedicine and their obligations towards it must be clearly outlined.

6.2 **The Guidelines must specify the privacy and security protection measures, protocols, processes and mechanisms that an RMP or a hospital must employ.** In order to avoid liability issues, it may prove useful to implement solutions such as data encryption, closed networks and electronic signatures, all of them valuable tools aimed to maintain the confidentiality, integrity and authenticity of the transmitted health data.[13]

For example, the Federal Department of Health in Australia has issued a "Privacy Checklist for Telehealth Services". This checklist provides high-level guidance on key obligations, including obtaining patient consent, disclosure of cross-border transfers, privacy notices, and ensuring that other "relevant measures" (such as end-to-end encryption, multi-factor authentication, etc.) have been adopted in accordance with guidance made available by bodies such as the Australian Cyber Security Centre.[14]

6.3 Section 5 of Telemedicine Guidelines provides a checklist for RMPs to consider while engaging services of telemedicine providers/vendors. However, it does not provide any guidance on privacy and data protection measures to look for. **It would be important and useful to include certain tools or guidelines in Section 5, to enable RMPs to select appropriate vendors** and to otherwise ensure secure systems and processes and protocols at their end.

For instance, the Ministry of Health in France has published a list of teleconsultation tools that meet the technical safety standards for the tools used. The tool is considered to be secure when it complies with frames of references and/or reference methodologies in the application of Articles 66, II and 73 of the French Data Protection Act of 1978.[15] The Australian Government

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[12] McLaughlin P. The Proliferation of Mobile Devices and Apps for Health Care: Promises and Risks. Privacy & Security Law Report. 2011 Jun 27; Available at: https://www.foley.com/files/Publication/384118ed-894a-48e0-9594-6b4b1cf13d1c/Presentation/PublicationAttachment/197c3d9f-5c8e-4762-8284-7102074d86e3/PVLR.pdf. [Google Scholar]

[13] Telemedicine: the legal framework (or the lack of it) in Europe. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987488/#R7

[14] Id. fn. 10

[15] Id, fn 2.

has also issued 'checklists' that tell RMPs what data security measures they should look for while selecting telemedicine providers/ vendors.[16]

The guidelines must add as a duty that the RMP must have a **data breach action plan** in place, including guidance on responding to a security or service provider breach. The Guideline itself could include an annexure on a data breach action plan that could then be adhered to by the RMP/Hospital. (see OAIC Data breach action plan for health service providers developed by the Australian Government).[17]

7. Criminal or other legal liability of Technology Platforms not clear: "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. "

Per the above direction, there is no clarity on the nature of 'appropriate action' or legal action that NMC/EMRB may take for breaches of the guidelines by platforms. The guidelines are also silent on the issue of penalties for breaches of the patient's data or fixation of liability in cases of a breach. The guidelines do not comprehensively regulate the data practices of online telemedicine platforms. The guidelines are silent apropos the use, storage and transfer of data generated from a telemedicine consultation, and rely on the existing regulatory framework to regulate the treatment of data.

8. Section 4.6 "Telemedicine Triage and COVID Care for Patients" is empty.

9. These guidelines, including the Annexures (in particular, Annexures 3 and 4) must be made available in local languages.

10. While the Guidelines recognize the 'patient's right to consent to the therapy and complain about unsatisfactory services' (Duties and Responsibilities of RMPs in Telemedicine, point 1), they do not contain mechanisms to ensure timely and appropriate grievance redress.

11. Annexure 3 to the guidelines states the following: "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

[16] Id. fn 10
[17] Government of Australia. Data Breach Action Plan for health service providers. Available at: https://www.oaic.gov.au/privacy/guidance-and-advice/data-breach-action-plan-for-health-service-providers

Confidentiality and Safety, Data Privacy Laws, and Ethical Standards of Medical Practice in India." The guidelines may also include the following:

- Due-diligence standards for RMPs before they commit to using a particular tool or platform for telemedicine;
- An annexure detailing the specific data-related regulations that RMPs must adhere to, in addition to other NMC regulations and medical ethics.
- Specific responsibilities of RMPs to ensure that patient data is protected.
- Penalties for breaches of patient data.
- Fixation of liability in cases of breaches.

In conclusion, we note that the regulations/guidelines on telemedicine are limited in scope as they primarily prescribe standards pertaining to the ethical obligations of the RMPs in the context of telemedicine. There are several other aspects of telemedicine which require regulation. For instance, the guidelines repeatedly refer to rights and liabilities arising from data protection and privacy laws as applicable to the practice of telemedicine, but there is no such law in the country yet, while the practice of telemedicine is increasing. Similarly, the use of wearables and IOT in telemedicine can also be regulated by a comprehensive law on medical devices, which is still on the drawing board.

To properly regulate the practice of telemedicine the Indian Government must enact comprehensive legislation regulating telemedicine that is binding not only on the healthcare practitioner providing consultation by way of telemedicine but also on the platform providing telemedicine services. This legislation should account for the following:

- Specify system requirements that telemedicine platforms should adhere to
- The rights and obligations of the patient, telemedicine platform and the healthcare practitioner in relation to others
- Framing rules for telemedicine that are specific to practitioners of Ayurveda, Siddha and Unani systems of medicine e.g. how consultations should take place and what medicines may be prescribed. Some telemedicine platforms, such as Lybrate, already feature homoeopathy practitioners on their platforms.
- Cross border telemedicine and telesurgery. There are already instances where telesurgery has been performed in India, making it important to regulate this practice.
- Rules on who owns the huge amounts of data generated as telemedicine activity increases. With the explosive growth of wearable health monitoring devices & IoT, how will the data be used, shared and managed?
- Rules on scope and limit of use of machine learning and AI assistance for RMPs
- Insurance providers are not to refuse insurance claims arising from the use of telemedicine when the insurance policy does not expressly cover telemedicine-related claims
- Regular audit of telemedicine practice