CUTS COMMENTS

On National Medical Commission's

Registered Medical Practitioner (Professional Conduct) Regulations, 2022

Background

Consumer Unity & Trust Society (CUTS) expresses its gratitude to the National Medical Commission for inviting stakeholder and public comments on 'Registered Medical Practitioner (Professional Conduct) Regulations 2022.'[1]

About CUTS

In its 38 years of existence, CUTS has come a long way from being a grassroots consumer protection organisation headquartered in Jaipur to opening overseas Resource Centres in Vietnam,[2] Africa,[3] Switzerland,[4] and most recently in the United States of America[5]. It continues to remain an independent, nonpartisan, and non-profit economic policy think tank while opening various programme centres, namely: Centre for International Trade, Economics & Environment (CITEE)[6]; Centre for Consumer Action, Research & Training (CART)[7] ; Centre for Human Development (CHD)[8]; and Centre for Competition, Investment & Economic Regulation (CCIER)[9] . It has been working towards enhancing the regulatory environment through evidence-based policy and governance-related interventions across various sectors and national boundaries. Further details about CUTS are available here.

CUTS has previously submitted comments on Health Data Retention Policy,[10] Unified Health Interface[11] and Health Data Management Policy.[12] CUTS has observed a few critical issues in the draft regulations which have been discussed in the subsequent sections of our comments.

CUTS Submissions

CUTS welcomes the newly released draft for National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2022 (RMP Regulations 2022) along with 11 guidelines on various issues concerning the Registered Medical Practitioners (RMP).

[1] Registered Medical Practitioner (Professional Conduct) Regulations 2022., *available at* NMC RMP REGULATIONS 2022 Draft
[2] http://cuts-hrc.org/en/
[3] http://www.cuts-international.org/ARC/
[4] http://www.cuts-geneva.org/
[5] http://www.cuts-wdc.org/
[6] https://cuts-citee.org/
[7] https://cuts-cart.org/
[8] https://cuts-chd.org/
[9] https://cuts-ccier.org/
[10] https://cuts-ccier.org/pdf/comments-on-proposed-health-data-retention-policy-consultation-paper.pdf
[11] https://cuts-ccier.org/pdf/comments-on-the-consultation-paper-on-unified-health-interface.pdf
[12] https://cuts-ccier.org/pdf/cuts-submission-of-comments-on-health-data-management-policy.pdf

CUTS Submissions will focus on thematic areas provided in the regulations which are further cross referenced in the guidelines. Though the draft remains quite extensive, we are focussing on few important issues in the regulations and guidelines and submitting our comments on the same.

On Professional Conduct of the RMPs

a. Prefix, Suffix, Modern Medicine and the Continuous Professional Development requirement

Chapter 2 Regulation 4 Clause A provides that RMPs registered under the National Medical Commission (NMC) Act 2019 should use the prefix of 'Med. Dr.' before their name while displaying a unique registration ID in their prescription slips and money slips by use of specially made seal under their signature. This unique registration ID will be assigned to the RMP by the Ethics & Medical Registration Board (EMRB).

There is a special requirement of registering under the NMC Act 2019 keeping in view these RMP Regulations 2022. The community is not excited with the prospect of duplication of efforts to register under the NMC Act 2019. Further, **Regulation 4 Clause B** allows for suffixes which are recognised and accredited degrees by the NMC.

Regulation 5 of the regulations under Continuous Professional Development, RMPs who wish to practice in another State (due to transfer of work of residence) should inform that State Medical Council (SMC) and apply for Licence to practice in that State. The state will have to mandatorily provide a licence to practise charging an appropriate fee within seven days. This means that each RMP will be confined to practice within a state and would not be able to practise across India freely. This might lead to concentration of RMPs in particular states with states with difficult terrains being left without adequate number of RMPs. The regulations do not address the issue of emergency cases where one expert with a state practice licence in Rajasthan might not be able to treat a patient in Haryana due to the geographical restriction on practice location.

Recommendation: CUTS recommends that the process of registering with the NMC for accredited and recognised degrees is not as straightforward a process as it seems. As the main registration lies in the hands of state medical councils and there is no direct monitoring of the registration process, there are discrepancies in various state procedures. For instance, recently, Madhya Pradesh High Court of Jabalpur while considering a plea, issued notices to Centre and State governments, NMC and State Medical Council. A number of doctors claimed that despite completion of Diploma in Medical Radiology and Electrology their registration was denied.[13]

The regulation needs to do away with the state specific licence to practice for doctors and make the registration process a national process as the country moves towards such reforms in several areas thus improving the ease of doing business and ease of living. In this age of digitalisation keeping a track of each doctor will be easy, unless tampered with. Thus, this means that the registration process under the state medical council needs to be dropped and

[13] Misra, Barsha, 'Doctors Denied Registration after completion of DMRE course', 21 May 2022, Medical Dialogues, *available at* Doctors denied registration after completion of DMRE course, HC notice to NMC, MP Medical Council

a national registry for doctors can be explored as a viable solution from re-registration, transfer from one state to another etc.

Also, the use of the prefix 'Med Dr' is not in accordance with international practices and also is in contradiction to the spirit of modern medicine as defined in the draft as medicine that has international uniformity in theory and practice. The use of such prefix might exclude Indian Doctors from a community of international doctors who do not carry such prefix. In case there is any compelling need for use of such prefix then it needs to be outlined in the regulation.

b. RMPs cannot practice more than one system of medicine

It is a welcome step that RMP unless trained in accordance with NMC requirements would not be able to claim to be a clinical specialist.[14] It is also praiseworthy that the regulation takes a step in forward direction while stopping RMPs from employing[15] and associating[16] with an unqualified person for performance of any procedure or technique. **Regulation 4 Clause D** which calls for choosing one system of practice for a person trained in multiple systems has ended up causing issues in the medical communities. This regulation is not in harmony with the sharp contrast with the endorsed 'integrated system of medicine' by the government and Niti Aayog.[17]

Presently, the National Rural Health Mission, 2005, which had first suggested giving rural people across states that have a weak health infrastructure the option of choosing ayurvedic, homoeopathic and other traditional medicines apart from allopathic drugs. A shortage of MBBS doctors who are willing to serve in rural areas, prompted some states to permit AYUSH doctors in rural primary health clinics to prescribe allopathic drugs; some like Uttar Pradesh (2015)[18], Bihar and Maharashtra among a few others have even issued official notifications to that effect. The cost of such decisions will be faced by areas where Public Health Centres (PHC) and rural Community Health Centres (CHCs) are run entirely by AYUSH doctors and have no MBBS doctors.

There exists a contradictory view of the same as well. Experts in public health have stated that in many states AYUSH doctors had been permitted to oversee childbirths, conduct minor surgeries and prescribe allopathic medicine without much training. This is unethical and also dangerous to patients in some cases. However, the underlying issue responsible for such a practice is the collaboration between Lack of adequate investment in health and lack of insights in healthcare.

Recommendation: A blanket ban on practising more than one system of medicine will have a human cost in the form of communities with less than adequate access to medical health professionals. The Karnataka State's committee headed by State's Drug Controller had recommended that AYUSH practitioners at PHCs undergo a six-month crash course under senior doctors in district hospitals after which they may be allowed to practice or prescribe

[14] Regulation 4 Clause C.
[15] Regulation 4 Clause E.
[16] Regulation 4 Clause D.
[17] 'NITI Aayog looking at reform ideas in health sector, says VK Paul', 25 October 2020, The Hindu, *available at* NITI Aayog looking at reform ideas in health sector, says VK Paul - The Hindu
[18] 'Ayush docs may prescribe allopathy drugs', 29 April 2015, The Times of India, *available at* Ayush docs may prescribe allopathy drugs | Lucknow News - Times of India

allopathic medicine. This recommendation was later revoked after three years of practice due to there being no scope for cross- practice in the old laws.[19] *The regulator needs to consider the impact of such regulation on all stakeholders along with the most important one that is the consumer of the healthcare system.*

c. Prohibition on soliciting of patients

As per **Regulation 7**, a RMP shall not solicit patients directly or indirectly or as part of the group of RMPs or institutions or organisations or hospitals or nursing homes, or private hospitals established, owned, controlled, or maintained by the appropriate Government, local authority, trust, whether private or public, corporation, co-operative society, organisation or any other entity or person. The regulations remain silent on whether institutions like corporate hospitals can solicit patients directly or indirectly.

These restrictions are also applicable to the practice of soliciting patients directly or indirectly through social media unethical and discourage sharing of patient testimonials or their recommendations and endorsements on social media. It also discourages doctors from sharing patients' photographs or scan images (CT, MRI, PET) on social media saying once these images are posted, it loses its discretion.[20] However, a one size fits all and blanket ban approach is rarely successful in cases that require case by case consideration.

Recommendation: The regulation should not adopt a myopic approach but adopt a case-to-case discretionary approach for such soliciting and sharing of reports for purposes of treatment, second opinion and telemedicine where reports can be shared online through social messaging apps for consumer's convenience.[21]

Thus, EMRB's role can be further expanded to outline the criteria where the soliciting of patients and sharing of their reports might be allowed. Such criteria may include situations of emergency, during the course of medical treatment and after informed consent of the patient among others.

d. Requirement to Prescribe Generic Medicine

As per **Regulation 8**, each RMP is 'expected' to prescribe drugs using generic names written legibly and prescribe drugs rationally, avoiding unnecessary medications and irrational fixed dose combination tablets as outlined under the Generic Drugs and Prescription Guidelines.

The use of the word 'expected' dilutes the degree of seriousness, and hence will be taken very lightly by RMPs. Instead it should at least be replaced with 'shall', if not 'must' in order to bestow some degree of seriousness. The similar earlier MCI regulation of 2002 the phrase was '…should, as far as possible, prescribe drugs in generic names'.[22]

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[19] Yasmeen Afshan, 'Order allowing AYUSH practitioners to prescribe allopathic medicines withdrawn', 8 September 2020, The Hindu, *available at* Order allowing AYUSH practitioners to prescribe allopathic medicines withdrawn - The Hindu

[20] Guideline 6, Conduct of RMPs on social Media.

[21] 'Doctors welcome inclusion of guidelines for social media usage', 25 May 2022, Hindustan Times, *available at* Doctors welcome inclusion of guidelines for social media usage | Mumbai news - Hindustan Times

[22] Clause 1.5 of the Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002

But mere writing of prescription by RMPs in generic names will not suffice, and the problem is likely to shift to pharmacy level, as they will be the decision maker. Therefore, the NMC should advocate for disciplining pharma companies to refrain from unduly inducing decision makers (whether doctors or pharmacy). In this regard, a suitable Market Promotion Code of Conduct should be issued. An effort was made some time back by the Department of Pharmaceuticals in this regard, but it did not take off.

In a patient centric healthcare system, there needs to be a choice in the form of an informed consent after adequate counselling, to choose between generic and branded alternatives of the same drug. Without getting the consent of the patient, and without informing about the choice of drugs available to the patient, without giving any freedom of choice to the patient, forcing him/her to consume a drug whose efficacy and reliability are at question, tantamount to violation of basic human rights, and is against the spirit of modern medicine. [23]

Moreover, the 2022 regulations go a step further, adding that doctors should encourage patients to purchase drugs from Jan Aushadhi Kendra and other generic pharmacy outlets' and to encourage hospitals to 'keep stock of generic drugs.

This is especially important in our country, where there is no proper regulation of the generic market, like in the United States of America, for example where the production and distribution of generic drugs is tightly monitored with the process like Abbreviated New Drug Application (ANDA).[24] There are various issues with this requirement, such as the uncertainty about India's market contribution to global drug research due to use of generic drugs. There is no possibility of continuously doing 'compulsory licensing' as per the World Trade Organisation (WTO) free trade agreement. Voluntary licensing of 'in patent' drugs will not be introduced as generics but as branded drugs, as the licensed company will have to pay royalty to the originator company.[25] These complex financial-legal issues have been dealt with in the regulations in an astonishingly lacklustre manner.

The NMC with this decision might end up making the citizen wait for five years till a new drug goes off patent. Nowadays, a new drug is brought to India in the same month it is launched in the U.S, only because the pharma companies are spending a large part of the extra money generated by branded drugs, to pay royalty to the originator company as royalty, to get 'voluntary licencing' even when the original drug is 'in patent' protected period.[26] Thus, the hallmark of modern medicine is constant research and progress without stagnation. The NMC is attempting to nullify the spirit and essence of modern medicine in a single stroke.

Recommendation: The words 'is expected to' in the Clause 8 should be replaced with 'shall'. Further, the NMC must put in place a fool proof system at par with the prevailing international standards, that ensures that the generic drugs are of equal efficacy and carry a 'certificate of analysis' (CoA) for each batch. Further, NMC should give statutory assurance and be responsible for the highest possible quality standards, and the responsibility to

[23] Galani V. Choice of better medicine in India: branded vs generic medicine. Pharm Pharmacol Int J. 2017;5(3):124-125 *available at* https://medcraveonline.com/PPIJ/choice-of-better-medicine-in-india-branded-vs-generic-medicine.html

[24] Abbreviated New Drug Application (ANDA) Forms and Submission Requirements | FDA

[25] Chawla, Sarthak, 'Voluntary Licensing of Patents in India – An analysis', 30 June 2018, IPleaders *available at* Voluntary Licensing of Patents in India - An analysis

[26] *Ibid.*

continuously assure the same quality in all the batches of the generic drugs. RMPs must not be made to take blame for mishaps that may be caused by inferior quality of generic drugs. There is no mention of 'fixing the responsibility' in the draft. This is a serious issue, and needs to be addressed clearly.

e. Responsibility of RMP regarding the sale of drugs

As per **Regulation 12 Clause A**, an 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. This clause infringes upon the RMP's right as an individual human being/ a citizen of Indian union, to open/ run any business deemed legal as per the law of the land. Being an RMP should not be a hindrance or handicap to a citizen just because he/ she happen to be an RMP.

Recommendation: The regulator is urged to not use a one-size-fits all approach. In various geographical locations with limited connectivity, doctors or RMPs end up acting as the pharmacy or prescription fulfilment centre for patients. Thus, a blanket ban on such activities might lead to exclusion of marginalised communities from access to healthcare.

f. Data records storage for three years by RMPs

Regulation 13 Clause A states that 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 preform laid down by the NMC. Further, **Clause B of Regulation 13** states that 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, the same may be duly acknowledged and documents shall be supplied within five working days. Also, **Clause D of Regulation 13**, efforts shall be made to computerise patient's medical records for quick retrieval and security. Within three years from the date of publication of these regulations, the RMP shall fully digitise records, abiding by the provisions of the Information Technology Act, 2008, 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.

CUTS respectfully submits that in case of outpatients, the RMP might be expected to be responsible for handing over the prescription and other medical reports to the patient at the end of each visit, and properly instruct the patient to store the data safely. The onus of maintaining the outpatients' records should not be placed on the RMP so as not to burden him/her from unnecessary expenses and wastage of time. Moreover, any medical record starts with the identification of the patient. This essentially means that the patient has to prove their identity by submitting one government authorised photo identity document at the time of seeking consultation as outpatient/ inpatient for the first time, and every time thereafter.[27]

Further, the clause about retrieving the data within five days by RMP directly contradicts the clause on confidentiality, stating that "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 of another human being".

[27] https://cuts-ccier.org/pdf/comments-on-proposed-health-data-retention-policy-consultation-paper.pdf

Recommendations: Firstly, the RMPs should be empowered to collect the identity of each patient, and the NMC must get legal clearance for this from the union government. As without this identification system in place, it would be impossible to retrieve the data of any patient after three years when in most cases, the RMP would not be sure about the identity of the patient. We further recommend that the NMC remove the word – the patient/authorised attendant and mention only 'the legal representatives', in the clause. The patient should be expected to preserve his/her record, while the word "authorised attendant" is not adequately defined or explained clearly.

Further, digitisation of extremely high volumes of medical records with limited resources at disposal entails recurring diversion of monetary resources and wastage of precious productive human hours. These hours could otherwise be spent on making health care more affordable. Expenses towards the storage of data and protecting it carefully will entail a huge overhead expense which will ultimately increase cost of healthcare and affect the common citizen of the country. Data storage and protection from data leaks and cyber-attacks which are not under the direct control of the RMP, will affect the primary responsibility of RMP which is patient care at affordable cost, especially in absence of a data protection framework.[28]

On duties of RMPs[29] and Procedure for a complaint of professional misconduct[30]

a. Keeping Appointments, incapacity, involvement in educational activities

Chapter 3 Regulation 22 Clause A provides that a RMP shall endeavour 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. Further under **Regulation 23** provides that a RMP 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 practise 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. **Chapter 5, Regulation 35** further states that 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 allied health sectors.

These clauses treat RMPs as just an RMP with no worldly connections and human errors. In the cases of delay in visiting hours, the regulation intended to provide access to healthcare to patients however, providing information to patients does not solve their purpose. In cases of hospitals, PHCs and CHCs adequate measures to ensure substitution in cases of RMP's unavailability must be taken.[31] While it is perfectly acceptable that the use of alcohol or other intoxicants during duty constitutes misconduct, the NMC has crept into individual rights of RMPs. Further the cause of keeping the pharmaceutical sector out of academics is detached from the ground reality as big pharma sponsorship allows for RMPs to cross ideate and attend conferences without it being an out-of-pocket expense. This will in turn, affect the

[28] https://cuts-ccier.org/pdf/comments-on-the-consultation-paper-on-unified-health-interface.pdf
[29] Chapter 3.
[30] Chapter 6.
[31] https://medicaldialogues.in/news/health/hospital-diagnostics/hp-nurpur-civil-hospital-reels-under-shortage-of-specialists-93548

quality of patient care, in the guise of reducing cost. The RMPs would be forced to literally "buy" credit hours by organising physical conferences while consequently, the cost of healthcare will also rise because the cost of "buying" credit hours will ultimately be passed on to the patient. A RMP cannot be expected to collect consultation fees, save it and spend it on "buying" credit hours alone.

Recommendations: Regulations should be focussed towards addressing the lack of substitute doctors in case of unavailability. The absence of a doctor should be notified to patients, the responsibility of the regulator does not end there as adequate measures to provide for substitute doctors also need to be prepared. Further, setting a professional code of conduct is under the purview of the NMC, however, regulating personal choices of the RMPs is not under the purview of the NMC. Thus, use of alcohol and intoxicants can't be punished; however, undertaking professional activities while intoxicated can constitute misconduct.

b. Procedure for a complaint of professional misconduct

Chapter 6 Regulation 39 Clause B provides for the procedure for complaint of professional misconduct in its last chapter. Where an 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 legal heir or guardian in case of death of the patient. In the list of eligible complainants, the term 'friend' has been used which is vague and subjective in nature. Anybody can pose as a friend of the aggrieved person with an ulterior motive against RMP, with the aim of extortion of money, as we see everyday.

The use of the term friend frivolously doesn't sit well as the Supreme Court in the case of *Aruna Ramchandra Shanbaug v. Union of India & Ors*[32] though refused to divulge into whether the petitioner was next friend of the patient did place weight on who can claim to be the next friend in cases of filing legal cases on behalf of the patient. The regulations however do not define the meaning friend who can file these complaints.

Recommendation: The use of the term 'friend' should be explained in the regulation such that it encompasses the meaning of a related party in the context of a complaint for the RMP's professional misconduct.

Conclusion

CUTS hopes that the new draft of National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2022 will incorporate CUTS' recommendations. CUTS looks forward to NMC considering the suggestions given above and assisting the NMC in its endeavours of creating optimal regulations for RMPs and in future for the health sector.

For any clarifications/further details, please feel free to contact Neelanjana Sharma (njs@cuts.org), Senior Research Associate, CUTS International. We will be happy to make in-person representation to the government.

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[32] Aruna Ramchandra Shanbaug vs Union of India & Ors on 7 March, 2011