

ಕರ್ನಾಟಕ ಜನಾರೋಗ್ಯ ಚಳುವಳಿ

Karnataka Janaarogya Chaluvalli

To
Additional Chief Secretary
Health and Family welfare Services
Government of Karnataka

23rd February 2018

Dear Sir,

Subject: Citizens' deep disappointment and condemnation of the draft KPME Rules 2018 and demand to redraft the same

The state government initiated the amendments to the KPME Act 2007 purportedly to "protect citizens' wellbeing and patients' interests". The Act introduced certain measures to ensure transparency and accountability of Private Medical establishments, protection of patients' rights and mechanisms to ensure enforcements of the same. But the draft Rules of the Karnataka Private Medical establishments Act 2018 have taken the Act further away from these objectives. It has invisibilized citizens/ patients' interests while leaning towards large private/ corporate hospitals and other such entities.

The Rules blatantly allow for inclusion of pro-corporate entities into various expert committees which will skew both standards and costing in favor of large corporate hospitals. This will escalate costs that will only push citizens into pauperization and destitution. By including such entities within various expert committees under the Act the government is willfully allowing exploitation of citizens and is setting a dangerous precedent.

On the other hand the Rules are ominously silent on enforcing the Patient Rights Charter or the Private medical Establishments Charter. The Rules do not clarify how each of the Rights in the Patient Rights Charter is to be interpreted, the procedure to be followed for filing complaints leaving it open to confusion. There are no Rules that prevent misuse of the various provisions by vested interests against patients and vulnerable citizens. These Rules betray the state government's lack of commitment to serve citizens' interests.

We demand that the Rules be redrafted and incorporate the following crucial changes to prevent conflict of interest, prevent misuse of the Act, ensure protection of all patient rights and improve access to redressal for patients as well as members of the public.

Amendment 7B related to composition of the Registration and Grievance Redressal Authority

1. The number of non-medical members in the Registration and Grievance redressal Authority who will oversee complaints should be at least three. Presently there is only one member who is in the minority against all other medical and ex-officio members

2. The requirement for this woman member should not be “medical profession”. Instead it should be a “non- medical person”, a representative of progressive citizens’ groups
3. This person should declare that she has no conflict of interest with any private hospital in any capacity.

Inspection Committee

4. Amendment to 7C: Inclusion of representatives of medical professional bodies/ private medical establishment in the inspection committee violates the principles of natural justice and takes away power from the state /regulator and hands it to the private authorities who are supposed to be regulated under the Act. The local inspection committee therefore should NOT include members of the Medical professional bodies or representatives of private medical establishments. Instead it should consist of only representatives from public health institutions.

Composition of All Committees constituted by the government under the Act

1. The Rules should not name any particular non-state entity as it is a serious conflict of interest and violates principles of neutrality and natural justice.
2. The Act gives power to the state to constitute the committees under the Act. It is unacceptable that the state government has used this power and chosen only to include private hospital representatives and other private entities. “Experts” include citizens’ groups that work closely with various constituencies and civil society groups. Therefore there **should be compulsory representation of citizens groups, civil society organizations and charitable hospitals on all committees constituted under the Act.**
3. **We demand that representative of NABH be excluded from any of the expert committees under the Act.** One of the nonofficial members to the expert committee on classification, standards of infrastructure, staffing pattern and staff qualification (Chapter V, Sr. 12) is a representative of the National Accreditation Board for Hospitals (NABH). NABH standards and accreditation play into market norms and are known to seriously escalate costs of health care and skew standards in favor of large, multi -national corporate hospital chains. This will seriously jeopardize the survival of small and medium hospitals particularly charitable hospitals. Patients will bear the burden of such cost escalation. The NPPA has recently exposed the exploitative and profiteering pricing in private hospitals particularly corporate hospitals. NABH standards will only add to such profiteering motives. Presence of an NABH representative on the expert committee is an indicator that the government is trying to make NABH standards mandatory under the Act. By this the government would be willfully allowing for cost escalation.
4. **We demand that the name of Public Health Foundation of India (PHFI) be dropped from the rules.** PHFI is not a government body. Even though it receives public money its Board is dominated by representatives of corporate hospitals, multi -national drug companies and bilateral donor agencies. Response to RTI queries related to its compositions and status have been found to be contradictory and confusing. These various kinds of mixed “PPP entities” use government money to push for pro-corporate, market driven health care policies. Including such non-state entities within the ambit of the Act is a serious conflict of interest, violates principles of neutrality and natural justice. We demand that the name of PHFI be dropped from the Rules.

5. Representatives of IMA, NABH and PHFI are referred to “representatives of state government” This is a gross misrepresentation. These three organizations have to be dealt with as private entities and therefore should not be referred to as representative of “state government”
6. Suvarna Arogya Suraksha Trust (SAST) is a similar entity the Board of which includes representatives of empanelled private hospitals. This is a serious conflict of interest which has caused damage in the past. The government has been twice held to ransom by empanelled private hospitals demanding that their package rates be increased. This amply illustrates the compromised nature of SAST. **Reconstitution of SAST Board to exclude private hospitals should be a precondition to include the SAST representative in any committee under the Act. Else SAST should not be included in any of the committees under the Act.**
7. Costing exercise should be done exclusively by experts from public health institutions using IPHS standards and a rational scientific formula incorporating elements such as the location, size, type and classification of hospitals.

Rules related to expansion and enforcement of Patient Rights included in the Patient Charter and Establishment Charter in the Schedule of the Act

8. Rules related to Right to voluntary informed consent as in Schedule I(A)(3)(iii)

"Informed consent" is defined in Taber's Cyclopedic Medical Dictionary thus:

"Consent that is given by a person after receipt of the following information: the nature and purpose of the proposed procedure or treatment; the expected outcome and the likelihood of success; the risks; the alternatives to the procedure and supporting information regarding those alternatives; and the effect of no treatment or procedure, including the effect on the prognosis and the material risks associated with no treatment. Also included are instructions concerning what should be done if the procedure turns out to be harmful or unsuccessful."

- a. Any treatment, intervention, or operation, including procedures like surgery, anesthesia, blood and blood product transfusions and any invasive or non-invasive/ low -risk or high-risk procedures / treatment, providing medications, physiological states like pregnancy, testing and diagnostics for any condition shall be provided or performed only after informed consent is received from the person seeking health care.
- b. Such informed consent shall be taken in writing on a prescribed consent form in a language understood by the person seeking medical/ health care which should clearly state the nature of the treatment, intervention, operation or procedure to be undertaken and the possible risks. The person seeking medical/ health care should sign the prescribed form after having understood all the details.
- c. Consent is to be treated as informed consent only if it is given by the person seeking medical/ health care after receiving the information on the benefits, risks, discomforts, side-effects, costs and alternatives of the treatment or procedure in a language and manner in which the person seeking medical/ health care is able to understand.
- d. This information shall be given with enough advance time (at least 48 hours notice except in case of emergency situations), to enable the person seeking medical/ health care to actively participate in the therapeutic choices regarding his/her state of health.
- e. The provision for opting out should always be open to the person seeking medical/ health care throughout the procedure/treatment. The person seeking medical/ health care has the right to refuse any of the treatment alternatives, choices presented.

- f. In the case of a minor or person incapable of giving consent, the consent of a parent or guardian shall be taken.
- g. In case of a minor unaccompanied by a guardian, the consent of the Head of the Health Care Establishment or a member of the staff so authorized by the Head of the Health Care Establishment shall be taken, after adequate measures to contact the guardian of such person have been made.
- h. If the informed consent is given by a person other than the patient, such person shall, where possible, consult the patient before giving the required consent.
- i. A person seeking medical/ health care who is capable of understanding shall be informed, even if he or she lacks the legal capacity to give the informed consent required under this Act.
- j. Only in cases where the patient is unconscious and unaccompanied and lacks the capacity to give or withhold consent, and where a qualified medical doctor determines that the treatment or other procedure is urgently necessary in order to prevent immediate or imminent harm, he/ she may give treatment in good faith without an explicit consent.
- k. Without prejudice to the general nature of this section, special attention shall be paid regarding obtaining informed consent before the performance of any treatment or operation, on women, transpersons and girls in relation to their reproductive and sexual health.
- l. The informed consent form should be specific to the health condition of the patient and the proposed treatment / intervention being planning.
- m. Such a consent form should be accompanied by an undertaking by the health care provide that the private medical establishment has all the necessary licences under related laws and acts to undertake such a procedure/ treatment/ intervention.
- n. Use of blanket consent forms will not be considered as informed consent under the Act
- o. It shall be the duty of the health care provider to write with respect to every person seeking medical/ health care, the provisional diagnosis and a confirmed diagnosis
- p. No interventions. Procedures, tests will be performed without the consent of the patient unless it is an emergency where a procedure is undertaken in order to save the life or preserve the health of the patient.

9. Rules related to right to information of Schedule I(A)(3)(5)

- a. The estimate of costs given to the patient should include the costs of consumables and medicines.
- b. The estimate should NOT exceed the actual cost by more than 20%.
- c. The name and contact details of all members of the District Registration and Redressal Authority should be prominently displayed in the hospital.
- d. The patient should be provided with information regarding cheaper generic formulations of medicines and places where patients can buy them.

10. Rules related to Preferences of Schedule I(A)(4)

- a. All records including images should be made accessible to patients including inpatients admitted in the hospital.
- b. The patient should be able to use her/ his records including scan images either as an out- patient or as an inpatient to enable her / him to seek a second opinion BEFORE and AFTER giving her/ his consent to any medical procedure / intervention.

- c. Both in -patients and out patients should be able to exercise her/ his choice to buy medicines and consumables from any pharmacy of their choice.

11. Rules related to emergency care: In case of patients admitted during an emergency the private hospital should continue treatment till such a time that the patient is stable without pressuring for payment. In case of patients who cannot afford to pay for the emergency services provided, the private hospital should not collect the amount from patients. Instead the private hospital should apply to the government for reimbursement.

12. Rules related to confidentiality and privacy of Schedule I(A)(2): Private hospitals should not use or sell patient data for any purpose including research to any entity.

13. Rules related to Right to Redress of the Schedule IA(5)

17a. Nature of Complaints that can be made under the Act

- a. Defective or sub-standard quality of services
- b. Grievances regarding inadequate personnel, infrastructure or supplies experienced related to provision of care
- c. Grievances regarding any malpractice, including collection of cuts or commissions, levying charges that are in excess of estimated costs beyond the limit specified in the Act
- d. Grievances regarding any sexual harassment of the person seeking health /medical care by health care providers and staff of PHME
- e. Violation of any rights specified in this Act
- f. Negligence, with relation to provision of services
- g. Failure to adhere to the STG specified under the Act
- h. Failure to comply with any of the provisions of the Act

17b. Rules related to procedure for filing complaints

- a. Government should establish a district level cell to help patients and members of the public to file and process complaints
- b. Patients, patient's relatives, citizens' groups, civil society organizations and any member of the public should be able to file complaints regarding any violation of any provisions in the Act in public interest.
- c. Members of the public should be able to file complaints both offline and online

17c. As provided for in the Act under Section 11, every PME should constitute a facility level redressal committee:

- a. Protection of patient rights should be made the responsibility of the Director or CEO or the head of the PME
- b. A specific member of the staff shall be appointed as person in charge of internal redressal for the purpose of receiving applications for grievances from any aggrieved person.
- c. All private health care /medical establishment will have a five member committee- the CEO/ head of the institution and one other member from the PHME and three external members not linked to any private hospital (of whom one will be a woman member and one member from the SC/ST community)
- d. This committee shall meet periodically to respond and act on grievances

- e. This committee will hold meetings /hearings with the aggrieved persons and the specific health care provider in the medical establishment against whom the complaint is filed
- f. The Committee will take appropriate corrective measures within the PHME and institute disciplinary measures against the concerned staff within a specific period of time

14. Rules related to false complaints

Inclusion of “false” complaint and a fine of Rs.10000 for the same is a serious threat to the patient’s right to redress. **Instances where the defendant alleges that the complaint is “false” the following procedure must be followed:**

- a. Hearing of such cases should exclude representatives of the medical associations in the grievance redress committee
- b. Hearing should be conducted only by ex-officio members in the District Registration and Redressal Committee who can co-opt representatives from public health institutions
- c. The burden of proof of false complaints should lie with the person alleging that it is a willfully false complaint.
- d. It needs to be proved beyond doubt that the person at the time of filing the complaint was fully aware that the complaint being made was willfully false.
- e. Actions against a willfully false complaint should be taken only after a full hearing conducted by the grievance committee excluding members representing medical association bodies.

Other Rules to be included

15. The District Registration and Grievance Redressal Committee should hold public hearings one in three months at taluk and district levels to listen to grievances of citizens seeking care in private hospitals and proactively provide feedback to the government to identify issues not addressed by the Act.
16. Private hospitals that repeatedly fail to comply with the provisions of the Act should be blacklisted for a period of five years.
17. The name and contact details of all members of the District Registration and Redressal Authority should be prominently displayed in the hospital.
18. The Hospital should display rates in a prominent place in Kannada, English and any other locally spoken language on its premises.

We demand that the state government incorporate all these suggestions into the draft Rules and by that demonstrate that it is committed to protecting citizens interests.

Thanking you

Karnataka Janaarogya Chaluvalli
Manthan Law
Safai karmachari kavalu Samiti
Lancha Mukta Karnataka Nirmana Vedike
Swaraj Abhiyan
Samaana Shikshanakkagi Janandolana

Alternative Law Forum
Slum Janandolana Karnataka
Karnataka Janashakti
Grameena Koolie Karmikara Sanghatane
Mahila Munnade
Dalita Sangharsha Samiti

FEDINA
Jagrutha Mahila Sanghatane
Samaana Shikshanakkagi Janandolana
Karnataka Sex Workers' Union

Garment and Textile Workers' Union
Swaraj Sanghatane
Sangama
Jan Sangram Parishad