To

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Dear Sir

We have gone through the draft minimum standards of clinical establishment act as published and displayed on MOHFW website. We have strong reservations and objections to these draft minimum standards. Our suggestions are;

1) Extend last date for comments on this as 9 th October does not give us sufficient time to collect data under RTI and respond in a legal fashion.

2) Of utmost concern is Annexure 6 list of legal requirements for minimum standards being prescribed for level I & II hospitals. AERB licences, Completion certificates, NOC from fire department, Deisel storage license, DG set approval for commissioning, Retail and bulk drug licence, Narcotic drug license, medical gases / explosive act license, boiler licences, Spirit license, NOC under Pollution control act, sales tax registration. It is also not clear what is being asked for under electricity rules. These licenses and registrations are being imposed to perpetuate and re-establish inspector Raj and all small and medium scale healthcare facilities will close down.

a) *Need for a completion certificate in legal requirements is an example. Completion certificates are commonly refused for minor building byelaw violations and in any city this may include upwards of 60 % buildings. Also need of dependence on landlord for this requirement under CEA will close many healthcare facilities as the level 1 or 2 hospital may not be in self owned premesis. How the clinical standards of a facility is to be determined on the fact whether or not the building has completion certificate is a mystery. What this effectively means is that the facility has to apply to Estate office for completion, inspection of premesis by inspector, objections, removal of these objections by any means (usually unfair) and overal wait of average 1 year for the certificate. Meanwhile the healthcare facility should close down awaiting its certificate*

b. *This however is also not in isolation, the NOC from fire department , now under the new rules for hospitals whether level 1 or tertiary care, has extremely stringent requirements of roof top water tanks, sprinkler systems and smoke detectors. To get this NOC is going to be another formidable challenge for the establishments already in existence in older buildings.*

c. Under the draft rules one has to provide 24 power backup but you need a diesel storage license, DG set approval for commissioning, Air and water pollution control certification etc. Each of these licences can be a 2-3 year plan for the doctors and impossible to achieve without sufficient administrative staff .

d. There is also a need for Spirit license, medical gases / explosive Act license, boiler license and a wireless operation certificate from Department of Posts and Telegraph to operate wireless equipments like nurse call systems or monitors. It does not require high intellect to know how these licences are to be obtained and what the procedure entails. An individual or couple managing a small nursing home or level 2 hospital will find it impossible to comply with the requirements of all these certifications. This will leave no option but for these units to close down. Only the Corporate hospitals with their deep pockets and required administrative staff will be in a position to satisfy all these requirements. Unfortunately corporate penetration in India is limited to less than 2 %. Should the remaining 98 % Government as well as Private hospitals shut shop.

3) Clarification needed on whether AYUSH resident doctors may be employed in Level I allopathic hospitals as mentioned in Definition. This would be against the Hans Charitable Hospital judgment of NCDRC. There however is a universal need for Resident doctors and this should be fulfilled by including Foreign Medical Graduates who have not passed the MCI / NBE conducted exam who should be allowed to work under supervision as resident doctors in Level I & II less than 25 bed hospitals.
4) For dialysis centers in India where a population of 2.5 lac a year are added yearly to the already existing 1 cr plus population of Chronic Kidney Disease and only 10 % of these patients are able to get specialized care, and 90 % do not get any care. With only 1200 -1500 DM Nephrologists in the country to expect a DM Nephorology to visit each and every dialysis center. A trained MBBS / MD with sufficient dialysis experience should be adequate.
5) This is also true for minor urological procedures which can be done by surgeons or even MBBS, UGI Endoscopy / Colonoscopy which can be done by MD Medicine, MS surgery and other similar procedures.
6) For level I hospital in point 10 basic processes the list should be simplified and reduced to include only 10.3 and 10.8
7) Incinerators and burial pits in Annexure 3 of requirements should be removed for level 1 & II hospitals. It is surprising that a level II hospital does not require an electrocautery but requires CO2 monitors. The Co2 monitors should be removed from list of essential items.
8) The category of Hospital level II needs to be divided into those less than 25 bed and those more than 25 bed. The hospitals less than 25 bed strength should be categorized under small scale units and should ideally be given single window clearances. The legal requirements for level one and two hospitals which are less than 25 bed strength should be very limited eg.

a) Permission from local authority / Estate Office / Municipal Corporation to run nursing home/hospital in the building. (It is the Estate office / municipal corporation which consults with various Departments for clearances including Fire / Electricity / Water).

b. Registration with Pollution Control Board for Generating Biomedical Waste.
c. Agreement with Common service provider for disposal of biomedical waste.
d. Doctor's registration in State Medical Council.
e. Registration under MTP Act if applicable.
f. Registration with Registrar Birth & Death.
g. Registration under PCPNDT Act if applicable.
h. ESI / EPF Registration if Employee strength is more than 20
i. PAN Nos / TAN Nos

9) The Level II less than 25 bed hospital should be further subdivided into NABH approved / NABH not approved categories. Those hospitals which wish to go for NABH approval would be charging higher rate for services rendered than non NABH approved hospitals. However the quality control requirements, systems and certifications for NABH approved hospitals would correspondingly be more stringent and may include the legal requirents as currently envisaged in draft minimum standards..

10) Equipment required for level II hospitals less than 25 bed should include;

a) Boyles Machine
b) Cautery machine
c) Portable suction machines at least 3 in number or central suction
d) Cardiac Monitors
e) Multiple oxygen cylinders with or without central oxygen supply
f) ECG
g) BS monitor
h) Nebulizer
i) Defibrillator
j) Pulse oxymeter
k) Laryngoscope, Endotracheal tubes, tracheostomy tubes, Ambu Bag.
l) Inverters and generators
m) Solar water heaters
n) Ventillators and ICU facility should be optional and not part of minimum requirements. Similarily Oxygen concentrator is unnecessary requirement mentioned.

11) Annexure 5 Staff requirement for level 1 hospitals is making it mandatory for pharmacist to be employed. It is not clarified whether emergency drugs stocked for only inpatient use is classified as pharmacy requiring services of pharmacist.

12)What is the need for a 4 wheel drive vehicle in a Level 2 hospital in the city. All hospitals are not located in remote areas and in a city a 4 wheel drive is unnecessary.

13)Annexure 5 Human Resource for Level I & II hospitals Nurses "per unit per shift" is vague and non specific. For less than 25 bed hospital minimum requirement should be altered to 1 registered nurse / GNM / ANM / midwife for every 10 patients per shift. Also need of Pharmacist should be done away with for emergency stocking of medicines for inpatients without opening a shop to sell medicine by level and II hospitals.

14)In Standards for Medical Imaging Services the list of licences and statutuary obligations needs to be curtailed as per scale of operations. A simple ultrasound machine in a clinic , or a C Arm in OT of a level II hospital with less than 25 beds is in no position to fulfill suchlike obligations and this effectively restricts appropriate and widespread use of technology. Standards keeping in view scale of operations need to be designed. Also need of radiologist simply to operate a C Arm will put added burden on small hospitals with occasional need of C Arm.

15)It is surprising how the minimum standards for hospitals under ayurveda stream do not require such stringent legal clearances.The list of statuary compliances seem to be only things like vehicle registration certificate of ambulance, Right to Information Act , Consumer Protection Act, Medical Negligence. What is expected of these hospitals under the RTI Act or CPA is unclear. It is also surprising that hospitals under ayurveda which are having surgical facility like operation theater , labour room do not seem to require basic life saving equipments like defibrillator, pulse oxymeter etc whereas smaller allopathic establishments are being burdened with unnecessary requirements. A hospital whether allopathic or ayurvedic has to have similar legal, building, labour, electricity, pollution, drug licensing. The requirement for Ayurvedic Hospitals even 100 bedded seem to be more in line of a general advisory rather than the minimum standards as prescribed for small allopathic hospitals 1/ 10 th the size.

16) Annexure 3 Endoscopic cleaning machines are still not routinely used in even premier institutes and manual cleaning is the norm. Minimum standards should prescribe minimum standards and not what is latest technologically available. CO2 monitor and many other similar equipment are mentioned which may not be needed in places not running ICU.

17)There is no discrimination regarding size of Allopathic hospital as has been done for ayurvedic hospitals. Small super speciality hospitals have now sprung up in cities which provide limited GI endoscopy ? GI Surgery, Obs and Gyn, Laproscopic surgery, even cardiology set ups. A super speciality hospital may be less than 10 bed or more than 500 bed and there is no difference in requirement of minimum standards under the present list.

18) For Government sub district and sub divisional hospitals 31-100 bed size as well as for District Hospital 100-500 bed size it is interesting to note the

statutuary requirements include things which require no registration or licensing like Consumer Protection Act, Right to Information, Indian Nursing Council Act, Indian Medical Council Act, Fatal Accidents Act, Indian Lunacy Act, Maternity Benefit Act, Persons with disability Act. This when compared with list of legal requirements from a 10 bed level II hospital in private sector appears anamolous.

19) For Clinic with short stay;
a. At point 9.1 it is mentioned that records for Notifiable diseases under IDSP Project as per Annexure VII is to be maintained but there is no Annexure VII given
b. Need for infantometer for polyclinics with short stay on pg 16 is unnecessary

20)In minimum standards for Yoga, our objections are
a) It seems more a political statement to include Yoga among recognized modalities of treatment rather than an attempt to standardize health care.
b) It would be interesting to see how many Yoga Hospitals of various sizes upto 100 beds and more exist in the country. These many categories have not been made for allopathic hospitals where only level 1,2,3 are considered.
c) What kind of laboratory services is envisaged for 100 bed Yoga hospital and who will among the staff at the Yoga Hospital run the laboratory and sign reports.
d) Directional signages are necessary for large hospitals but should be advisable but not mandatory for smaller setups. Also sample of signages should be included in the draft minimum standards. Local inspectors have harassed medical professionals under the signage requirements for PCPNDT Act regarding size color.
e) What is need for Certificate under Narcotic and psychotropic substances Act or License to sale and distribute drugs Form 20,21,21C, or SMPV license for storage of liquid oxygen Form III , or commissioning approval of linear accelerator for a Yoga Institute.

21)For Unani Hospitals the list of emergency drugs includes Adrenaline, Dobutamine, Nitroglycerine, amiodarone, magnesium sulphate mannitol etc. What is not clear is are the Unani doctors supposed to use these allopathic drugs in emergency. There is no post for allopathic doctors in these hospitals and if they are to be called from outside the purpose of emergency treatment is anyway lost. If Unani doctors use these they are contravening the Supreme Court verdicts of Poonam Verma vs Ashwin Patel as well as Mukhtiar Chand vs State of Punjab judgments.

22) When the provisions of Clinical Establishment Act are clubbed with the draft Minimum Standards some other issues crop up. The provision of responsibility of stabilization and transfer of patients during emergencies under the CEA Act imposes on level 1 & II hospitals and solo clinics requires them to keep own ambulances / vehicles because they are responsible for the safe transfer of patients to higher levels.

The draft minimum standards does not require so but the Act itself with its provisions leaves only two options

a) In this situation to avoid liabilities they have to either have own vehicle and 24 hrs driver facility with stand-by vehicles with required doctors and para medical staffs with the vehicle during the transfer of patients, which may not be feasible for small establishments OR
b) They have to be some kind of franchisee of any corporate hospitals who can or will provide such facility 24hrs to transfer patients (to their hospitals and not to hospitals of the choice of the patients).This gives an impression that the Act is made with the hidden aim to help the big hospital in procuring patients from the small scale hospitals by own vehicle facilities.

23) For Polyclinic with observation / short stay;

a) Definition needs to include minor procedures like Upper GI Endoscopy, Colonoscopy, bronchoscopy, laryngoscopy, sigmoidoscopy even diagnostic laproscopy, cystoscopy.
b) There are number of other minor procedures which require short stay clinics like urologists where catheterization, urethral dilatation may be performed. Similarily for esophageal stricture dilatation, achalasia balloon dilations, Colonoscopic polypectomy, Variceal band ligation a Polyclinic with short stay is the ideal to keep cost of procedures down as well as provide safe post procedure care.
c) Even chemotherapy is given on short stay basis and should be part of the list of procedures which can be done in such establishments. Bone marrow aspiration, ultrasound guided FNAC, all these require short stay / observation but not hospitalization.
d) Facility of minor OT and facility for anesthesia is integral part of such setup.
e) Dressing and injections will need to be given in Polyclinic only consultation and this is already included in the definition of such Clinical Establishments. So for Polyclinics with short stay procedures mentioned above are the appropriate procedures.
f) If we see the Annexure 5 list of Emergency drugs for polyclinics only consultation we find, IV fluids, , Inj Adrenaline, In Deriphylline, Inj Frusemide. If these injections are intended to be used basic observation is needed even in these clinics. So the category of Polyclinics with short stay obviously cannot be only to give injections and do dressings but for small procedures mentioned above.

24) The new standards posted on the CEA website regarding Speciality and Superspeciality specific standards are arbitrary and need rethink.
25) Template for minimum standards for orthopedic hospital even providing Advanced services does not require arthroscope, C arm etc which are available even in basic existent orthopedic clinics.

26) Plastic surgery clinics can only perform consultations and no procedures whereas even simple clinics of a general practitioner are permitted various procedures. A plastic surgery hospital even doing only aesthetic surgery or minor procedures requires 4 MBBS doctors mandatorily, one pharmacist, one OT Technician, one medicosocial worker. Most of plastic surgery is done in day care setting and need for round the clock MBBS doctor, pharmacist , driver besides the requirement for anesthesiologist is impractical.
27) All GI Surgery hospitals require a critical care specialist or intensivist besides the pharmacist, OT technician, ECG technician, Dietician and medicosocial worker, transport facility including driver (own or outsourced) and housekeeping staff. ABG machine is mandatory in GI surgery hospital. Blood storage unit or blood bank is required besides medical gas/ manifold.
28) All Neurosurgery hospitals should have 1 MCh neurosurgery and 3 MS General Surgeons besides 4 MBBS doctors for round the clock cover. Need for laproscopy equipment in Neurosurgery hospital is also debatable to say the least.
29) For Gynae & Obstetrics indoor services MBBS doctors round the clock, ECG technician,Dietician, Physiotherapistpsychologist and medicosocial worker are needed. Requirement of colposcope , pharmacy with outsourced pharmacist for all such hospitals is questionable.
30) Template for Minimum Standards for Gastroenterology hospital Hospital under CEA
    a. Qualification debars an MD medicine doctor and even a DM Hepatology doctor or MCh GI Surgery doctor with specialized training in endoscopic procedures and large experiences from doing basic gastroenterology procedures like ERCP, Therapeutic Endoscopy and Colonoscopy.
    b. Qualification debars an MS Surgery trained in GI Endoscopy from doing basic Gastroscopy, Colonoscopy, ERCP, and therapeutic Endoscopy and colonoscopy. Some of the best Endoscopists in the country today are MS surgeons.
    c. Clarity needed on whether X Ray technician is needed for operating C Arm used for ERCP even without regular radiology work like X Ray.
    d. Role of Physiotherapist in any Gastroenterology hospital is mystery

e. A Gastroenterology clinic & Hospital both seem to have permission only to perform Gastroscopy and colonoscopy. A Gastroenterology hospital having inpatient services with OT should also be permitted to perform therapeutic endoscopic and Colonoscopic procedures including basic ERCP and capsule Endoscopy Argon Plasma Coagulation. Advanced Non Teaching hospitals should be dealing with advanced procedures like Enteroscopy, Diagnostic and therapeutic Endoscopic ultrasound, Endoscopic cystogastrostomy, advanced therapeutic ERCP specially pancreatic therapy, Peroral Endoscopic Myotomy (POEM), Natural orifice transluminal Endoscopic surgery (NOTES), Submucosal Endoscopic dissection / Resection, .

31) Anesthesiology / Intensive care / Emergency Department;

a. It is unclear what is expected. Whether the standards are for a stand alone Anesthesia / Intensive care / Emergency hospital (which is an absurdity) or part of nursing home / hospital. Anesthesia Department of a small nursing home Level II with less than 10 beds usually have Anesthetist on call. Full time anesthetist availability in a small level II hospital will in itself cause majority of small nursing homes to close down.

b. Requirement of 4 MBBS doctors to provide 24 hr cover in a ICU which may be only 2 bed in a small 10 bed level II Allopathic hospital will become a disincentive for small hospitals to invest in ICU (Ventillator/ Monitors/ Pulse oxymeters/ syringe pump etc) whereas these should be available in all places where surgery is conducted.

c. 1 nurse per ventilator patient is a requirement which cannot be fulfilled in the best of Govt set ups. A study in Mumbai reported 1 nurse for 60 patients in its Government hospitals.

d. Why Receptionist Billing / Medical records Department/CCTV, transport facility / data entry operator / house keeping are needed for Anesthesia department

e. Neuromuscular monitor, Nerve stimulator and ultrasound for IV cannulation and for nerve blocks in OT of a small level II allopathic hospital with 10 beds is a case of wishful thinking when large Government hospitals and teaching Institutes do not possess the same.

f. Poisoning antidotes (anti snake venoms) and Rocroronium injections requiremnt in OT of small nursing homes is an absurd expectation which needs to be deleted.

g. Inhalation agents like halothane are now out of vogue. Also requirement to stock pethidine and morphine needs a drug license and is no longer easily available even to hospitals.

h. Adequate storage of all blood groups and blood products is through blood banks only and even in a city like Chandigarh

only 4 blood banks operate which supply blood to either their own hospital or to other hospitals on demand. In small towns and suburbs this is unthinkable.

32) General Medicine and Gediatric template for Minimum standards of Hospital require 4 MBBS doctors for round the clock service for 10 beds. Most nursing homes have live in doctor couple who may be MBBS, MD, MS who do the consultant as well as the duty doctors role. Insistence on this requirement alone will make small nursing homes non viable.

a. For hospitals which do not dispense medicine and stock only for emergency use or for their inpatients do not require services of a pharmacist. Similarly role of dietician, physiotherapist, medicosocial worker, ECG technician in small hospitals is debatable. An ECG machine costs less than 50000 Rs. Keeping an ECG technician for 6 months will cost more. This again would be a disincentive for medical service providers to invest in to simple equipment which may be life saving.
b. What exactly is required under Policy Manpower / posting / rotation / of medical and Allied Health Professional is mandatory but is unclear as to what is expected of a 10 bed medicine nursing home under this. Similarly Standard pertaining to personal record keeping and training are irrelevant.
c. Annual mantainance contracts are not done by majority of the smaller setups. Repair and mantainance is on as needed basis. There is no clarity on what major equipments is this constitutionally mandatory.

Sir the minimum standards proposed are similar to asking a Maruti 800 to provide airbags, four wheel drive and antiskid breaking. It is possible but then the Maruti 800 will no longer cost 2 lacs it does today

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