Amendments needed in The Clinical Establishment Act

Chapter-1] Section 2 (c) (i)	“Clinic to be deleted”
Chapter-1] Section 2 (e)	“To be deleted”
Chapter-1, Section 2 (o) “To stabilize (with it’s grammatical variations and cognate expressions)” means, with respect to emergency medical condition specified in clause (d), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a clinical establishment”.	**This clause be deleted and replaced with “ To provide primary emergency first aid ” means, with respect to an emergency medical condition specified in clause (d), to provide primary emergency first aid, within the facilities available of the concerned specialty, in the given clinical establishment before the transfer of the patient to a referral clinical establishment for which financial resources will be provided by the patient or the attendants or the state govt. Each clinical establishment will have the right to decide the kind of emergencies it is capable of handling and according to it’s available human resources such as paramedical staff, Doctors, the time schedule of the availability of emergency services as per MCI guidelines (code of medical ethics CHAPTER 2** **2. DUTIES OF PHYSICIANS TO THEIR PATIENTS** **2.1 Obligations to the Sick** **2.1.1 Though a physician is not bound to treat each and every person asking his services,** he should not only be ever ready to respond to the calls of the sick and the injured, but should be mindful of the high character of his mission and the responsibility he discharges in the course of his professional duties. In his treatment, he

	should never forget that the health and the lives of those entrusted to his care depend on his skill and attention. A physician should endeavour to add to the comfort of the sick by making his visits at the hour indicated to the patients. **A physician advising a patient to seek service of another physician is acceptable, however, in case of emergency a physician must treat the patient. No physician shall arbitrarily refuse treatment to a patient. However for good reason, when a patient is suffering from an ailment which is not within the range of experience of the treating physician, the physician may refuse treatment and refer the patient to another physician.**
Chapter 2, Section – 3 (2) (c)	Deleted and replaced by "one representative from Ayush councils on rotational basis from different streams".
Chapter 2, Section – 3 (2) (d)	Deleted and substituted by "one representative from Govt. Doctors Association each from two states of the union on rotational basis"
Chapter 2, Section – 3 (2) (e)	Add "and two representative elected from different state council of IMA on rotational basis."
Chapter 3, Section - 5 b, c, d, To classify clinical establishments, develop minimum standards	Delegate these powers to The State Council
Chapter 3, Section- 7. National Council to Classify Clinical Establishments	Delete it and delegate to The State Council
Chapter 3, Section – 8 (2) (b)	Ex officio chairman instead of Ex officio member secretary.
Chapter 3, Section – 8 (2) (c)	Deleted and substituted by Director Ayush
Chapter 3, Section – 8 (2) (e)	Deleted and substituted by one representative from Ayush State Council on rotational basis from different streams.
Chapter 3, Section – 8	(e) to be added "one representative from recognized govt. doctors association.
Chapter 3, Section- 8, subsection (5) regarding Functions of The State Council	Add in the functions of The State Council (i). Classify clinical establishments into such categories as may be prescribed by it from time to time. **All clinical establishments be graded according to the treatment facilities offered and the quality of care provided and not merely on the size of the clinical establishment and let the**

	people chose according to their paying capacity. The Standards cannot be same from Delhi to remote areas (for example Kusheshwarsthan in Darbhanga District of Bihar). **(ii). The council will follow a consultative process for preparing minimum standards and classification of clinical establishments. It is mandatory that the minimum standards will be in concordance with the prevailing socioeconomic conditions in each district of the state and the local IMA Branch and respective associations of all other systems of medicines and Civil Surgeon. It will be in consultation with all stakeholders including the District Registering Authorities in the State and especially after taking in confidence the medical fraternity represented by the Indian Medical Association and the respective associations of all other systems of medicine, for the registration of clinical establishments. The minimum standards should indeed be minimum standards. The requirement of legal licenses shall be kept to a minimum and The Authority will take the responsibility of developing a single window clearance system for all the legal formalities required.** **Appraisal of the standards regarding practical feasibility and financial viability and their impact in improvement of the quality of patient care, in concordance with the diverse socioeconomic conditions prevailing in different districts of the State, in the form of pilot projects especially in Govt. institutions and corporate hospitals.**
Chapter 3, Section - 10 Subsection (1) ; Members of The District Registering Authority	Change entire Section As (As per Maharashtra Clinical establishments Act):- i. Civil Surgeon cum Chief Medical Officer – Chairman ii. Additional Chief Medical Officer – member secretary iii. One member elected by the local Indian Medical Association Branch iv. A panel of Five Doctors from different systems of medicine elected or nominated by the respective associations

Chapter 3, Section - 12 (1) Subsection (ii) Minimum requirement of personnel	**Paramedical staff currently trained under qualified doctors be treated as trained healthcare personnel and be included in the mainstream of healthcare and deemed to be qualified staff.**
Chapter 3, Section 12 (1) Subsection (iii) Maintanence of records and reporting	be as per MCI guidelines and reporting only of notifiable diseases
Chapter 3, Section 12 (1) Subsection (iv) Such other conditions as may be prescribed	Be Deleted
Chapter 3, Section 12 (2) The clinical establishment shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to **stabilize** the emergency medical condition of any individual who comes or is brought to such clinical establishment	Delete Stabilize and insert "primary first aid, for which financial support will be provided by the patient or the State" **Each clinical establishment will have the right to decide the kind of emergencies it is capable of handling and according to it's available human resources such as paramedical staff, Doctors, the time schedule of the availability of emergency services as per MCI guidelines (Code of Medical Ethics** **CHAPTER 2** **2. DUTIES OF PHYSICIANS TO THEIR PATIENTS** **2.1 Obligations to the Sick** **2.1.1 Though a physician is not bound to treat each and every person asking his services,** he should not only be ever ready to respond to the calls of the sick and the injured, but should be mindful of the high character of his mission and the responsibility he discharges in the course of his professional duties. In his treatment, he should never forget that the health and the lives of those entrusted to his care depend on his skill and attention. A physician should endeavour to add to the comfort of the sick by making his visits at the hour indicated to the patients**. A physician advising a patient to seek service of another physician is acceptable, however, in case of emergency a physician must treat the patient. No physician shall arbitrarily refuse treatment to a patient. However for good reason, when a patient is suffering from an ailment which is not within the**

	range of experience of the treating physician, the physician may refuse treatment and refer the patient to another physician.).
Chapter 3, Section 13 Classification of clinical establishments by The Central Govt.	Delete it and delegate it to The State Council
Chapter 4, Section 16, Subsection (2) The authority after the grant of provisional registration , cause to be published in such a manner as prescribed, all particulars of the clinical establishment so registered provisionally	Delete it
Chapter 4, Section 23 Regarding grant of provisional and permanent registration, Subsections (i), (ii), and (iii)	Modify:- . **Provisional registration be granted to every clinical establishment being run by a qualified Doctor registered with MCI or respective councils of different streams of medicine. The Certificate of Registration be placed in the clinical establishment at a prominent location. No compulsory display of information by the authority in public domain.** **Relevance of the minimum standards regarding their practical feasibility and financial viability and their impact in improvement of the quality of patient care, in concordance with the diverse socioeconomic conditions prevailing in different districts of the State, in the form of pilot projects especially in health facilities run by the Govt.** **The procedure for permanent registration will be started after the notification of minimum standards. The clinical establishments running in already constructed buildings before the notification of minimum standards should be permitted to carry on and be kept in a separate category. <u>Explanatory Note;</u> (What will be the fate of current clinical establishments which have been made after a huge investment and loans from financial institutions? Should these investments and loans be converted to bad loans? Who will pay the damages?)** **The Certificate of Registration shall placed in the clinical establishment at a prominent location. There be no compulsory display of information by the authority in public domain.**

Chapter 4, Section 26: As soon as the clinical establishment submits the evidence of having complied with the prescribed minimum standards, the authority shall cause to be displayed the above information for public at large for a period of 30 days for filing objections before processing for grant of permanent registration.	Be deleted
Chapter 4, Section 27: if objections are received they shall be communicated to the clinical establishment for response within 45 days.	Be deleted
Chapter 4, Section 28: Permanent registration will be granted only when a clinical establishment fulfills the **prescribed standards for registration by the central govt.**	Change as; **prescribed standards for registration by The State Council**
Chapter 4, Section 30 (2) validity of permanent registration	be valid for 10 years
Chapter 4, Section 35 The State Government may charge fees from different categories of clinical establishments, as may be prescribed	Be kept reasonable as the financial burden will fall on patients
Chapter 4, Section 36; Regarding appeal in The State Council	Provision should be made to approach a court of law for justice apart from an appeal to the state council and the clinical establishment should be allowed to function till the final verdict is given by the court
Chapter 5, Sections 40,41,42,43,44,45 and 46 regarding penalties	**Delete these sections and replace with" whosoever contravenes any section of the act shall be given warning and a time of 30 days for explanation. The monetary penalty should be in accordance with the nature of offence, financial health of the clinical establishment and prevailing socioeconomic conditions. For first offence or contravention of rules the penalty should be Rs 5000, for second contravention Rs. 10000, for third and subsequent contraventions Rs. 25000.**
	There must be provision for approaching a court of law if a clinical establishment or the concerned doctor or health care worker is harassed by the officials of the National Council, State Council or District Registering Authority or if aggrieved by a decision of the above said authorities
	In the rules it should be mentioned that before inspection of any clinical establishment a notice must be served at least 15 days in advance and under extraordinary circumstances the inspection should be postponed in order that patient care does not suffer

Central Rules Section 9 regarding other conditions for continuance of registration	**Delete it** **In the rules there must be no provision to fix the professional fees charged by clinical establishments by any person other than the management concerned. Explanatory Note: There is no such provision to regulate the professional fees of other professionals such as lawyers, engineers, accountants and so on and so forth. Medical profession deals with quality of life and treatment of ailments demanding best of talents and medical profession must be lucrative enough in order to attract best of talents in the country in comparision with finance, industry, law or any other faculty**
	Taxation and Electricity charges: The Govt. must ensure that the clinical establishments are not charged for electricity on commercial rates and there must be 24 hours availability of electricity for hospitals. The local self governing bodies such as municipal corporations charge the highest rate for the land revenue which must not be charged at commercial rates at all and must be minimum. Explanatory Note: Any clinical establishment serves the sick and healthcare comes under service sector and is not an industry! Also the burden of these charges is ultimately borne by the patients
Chapter 7, Section 52 (1)	Deleted and substituted by "the central government may by notification make rules for carrying out the function of national council"
Chapter 7, Section 52 (2)	(b) to (m) Delete.
Chapter 7, Section 54 (1)	Delete and substitute by "the state government may be notification make rules for carrying out all or any provision of this act except the matter provided in section 52

Regarding government of India, Ministry of Health and Family Welfare, G.S.R. 387 (E) dated 23rd May 2012 (Rules under Clinical Establishment (Registration and Regulation) Act 2010). The whole G.S.R. should be annulled and new rules to be made according to the amended act.

AMMENDMENTS in the draft minimum standards proposed by the committee formed by the central council

Objections suggestions, deletions and modifications suggested in the draft minimum standards for level 1 hospital

It appears on going through the whole text that the minimum standards drafted that instead of being minimum standards with practical feasibility they are the ideal or maximum imaginable standards for many parts of the country.

It should be noted that the time given in the notice is inadequate and it should be extended; it was also not published prominently in the leading national newspapers for information of public at large in time. The common man must be able to understand that these guidelines will lead to corporatization of entire healthcare sector and healthcare will go away from the hands of Doctors to the hands of wealthy businessmen! This will not be in the interest of the common man. The prescribed minimum standards will wipe out superspeciality care such as neurosurgery, neurology, retina surgery, cardiology etc. from 2nd tier cities, towns and rural areas in its entirety and poor public in these areas will be forced to seek costly medicare in capital cities and metros. Will this be in the best interests of the nation? Will it serve the purpose of this Act? It appears the results will be exactly opposite to the intentions of this legislation in its current form and format. It will either lead to unprecedented corruption in the field of health care or to corporatization of entire healthcare sector; neither of which will be in the interest of the country and especially of a poor state like Bihar. There should be a countrywide debate on this important issue before enforcing this Act.

In Page 1 in introduction the Indian Medical Association suggests that The Act should be tested for its practical feasibility and financial viability and its role in improvement of the quality of patient care, in concordance with the diverse socioeconomic conditions prevailing in different districts of the States, in the form of pilot projects especially in Govt. institutions, which are heavily funded by the public money by the Govt. The standards will be uniform for all the clinical establishments in their respective category. The results of these pilot projects will be analyzed by an expert committee of eminent doctors of all the specialities working in different districts of the state and eminent economists of the country and it should be proved on ground that the quality of care is improved at an affordable cost and the medical education continues to attract the best of talent in the country as medical profession deals with diseases and ailments involving risk of death. Only after this exercise it will apply to the entire state of Bihar and process for registration of all the clinical establishments will begin.

In view of the above, The Act should be suitably amended and the State Council should be entrusted with the responsibility of finalizing the minimum standards taking into account the socioeconomic conditions of the state and it should safe guard the interests of the patients and healthcare providers alike. The council will follow a consultative process for preparing minimum standards and classification of clinical establishments. It will be in consultation with all stakeholders including the District Registering Authorities in the State and especially after taking in confidence the medical fraternity represented by the Indian Medical Association, for the registration of clinical establishments. It is mandatory that the minimum standards will be in concordance with the prevailing socioeconomic and law and order conditions in each district of the state and after taking into confidence the local IMA Branch and Civil Surgeon and a forum of specialist doctors drawn from different specialties in the district.

In the first stage the Act should be enforced in the Medical Colleges & Hospitals and corporate hospitals and there should be same minimum standards for government as well as private clinical establishments in their respective category. The Act in addition to exempting The Defence health establishments, should also exempt Charitable health institutions with proven credentials and having a track record of providing healthcare for the last 20 years.

The Act should aim at standardization of the health facilities by providing patient and doctor friendly minimum standards, abolition of quackery and making treatment socially and economically viable for poor patients as well. The older clinical establishments existing at the time of notification of minimum standards should be given 30% flexibility in space requirements and if needed a minimum period of 10 years of time to modify, alter, expand or shift in order to conform to the minimum standards.

It should be clear in the minds of our policy makers, what is desirable and what is minimum that is practically feasible keeping in view the vast diversity of our country and varying social, educational and economic conditions in different parts of our country.

On page 5 under the heading of Categorization of hospitals; in categorization of hospitals Location of the clinical establishment (metro, cities, town, sub division and villages), older facilities and new ones coming after the enactment of The Act, Scale of operation and level of care , all must be taken into account.

In Hospital level 1 ophthalmic medicine clinic doing refraction, optometry and orthoptics should also be included. Day care surgery should also be included at level 1.

Regarding Hospital level 2; superspeciality hospitals in towns, 2nd tier cities or running on a small scale like a 30 bedded facility having a small 6 bedded ICU should be included, likewise smaller surgical and medical clinical establishments having small ICUs in a town should be considered in level 2.

On page 7 the list of specialties should include General practice, ophthalmic medicine clinic doing refraction, optometry and orthoptics and day care surgery units should also be included

Under section 2.7 category (b) diagnostic services should be either optional or outsourced.

2.7 Waste Management (general and Biomedical) (c) outsourced

As per clause 3.1.6 clarify that the fee structure will be displayed inside the clinical establishment.

As per clause 3.1.7 Add tentative before timings.

Clause 3.1.10 delete it; Explanation (first the patient's rights and responsibilities should be fixed from the point of view of practicality and they must not affect the sensitive Doctor Patient relationship in any way, which is based only on trust and forms the very basis of treatment of the patient.)

Clause 3.2.1 delete it

Clause 3.2.3 – delete the word clean (explanation – cleanliness is an elastic term perception of which varies from person to person and is very likely to be misused by the controlling authority and it is also the responsibility of the patient)

Clause 3.2.4 – For provision of 24 hours supply of water and electricity, exception must be made for unforeseen difficulties such as equipment failure.

Clause 3.2.5 – delete the word clean public toilets and use the term " toilets for patients, their attendants and staff " (explanation – cleanliness is an elastic term perception of varies from person to person and is very likely to be misused by the controlling authority and it is also the responsibility of the patients and their attendants)

Clause 3.2.6 should be modified that the required furniture and fixture should be based on the judgment of the management of the concerned clinical establishment.

Clause 4.1 the hospital shall have adequate medical equipment and instruments commensurate with the scope and level of service, and available financial resources.

Clause 5.2 remove the clause "at all times" and replace it with term "under usual circumstances"

Clause 6.1 under this clause regarding trained medical and nursing staff; the staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained staff. The same should also apply to the nursing staff also. Also the number of staff shall be decided as per the level and scope of services provided and financial viability of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)

In Clause 6.2 under this clause regarding trained paramedical and support staff; the staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained staff. The same should also apply to the nursing staff also. Also the number of staff shall be decided as per the level and scope of services provided and financial viability of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)

Clause 6.3 Modify and change the personal record as a register for paramedical staff shall be maintained regarding their qualification and training

Clause 6.4 delete "as prescribed by the professional bodies and as per local laws" and add "to be provided by doctors of the health facilities as per needs".

Regarding clause 7.5 the arrangement of transportation by the hospital must be optional and duly paid for by the patent's attendants.

Regarding clause 8.1 there should be a mechanism in place so that the Doctors and owners of clinical establishments are not made scapegoats of red tapism. It should be the duty of the district regulatory authority to liaison with different departments and procure the different legal licenses or certificates after charging a reasonable fee. In the indicative list of legal requirements as per Annexure 6 many of them are unnecessary and therefore they should be deleted from the list of requirements, such as Building completion license, DG set Approval for commissioning, Diesel storage license, Narcotic Drug License (if Govt. is already registering a facility as a clinical establishment, what is the need of such a license?) Medical gases Licenses/ explosive act., Boiler's licenses, MoU/ agreement with outsourced human resource agencies as per labor laws, Spirit Licenses, Provident Fund/ESI Act, Sales Tax Registration, NOC under Pollution Control Act (Air/Water). There are many other licenses which should be required if applicable such as; MTP Act, PNDT Act, Blood Bank Licenses, Food Safety License, Retail and bulk drug license (Pharmacy) Ambulance services should be optional and there should not be any requirement of commercial vehicle permit or Commercial Driver license for an ambulance, and AERB Licenses.

Clause 9.1 Delete this clause and provide for "maintenance of records of Indoor Patients and Medico legal Cases".

Clause 9.3 In the end Add "in usual circumstances and except in case of unforeseen circumstances like natural calamities, Fire, Theft, etc."

Clause 9.5 delete the word "Emergencies".

Annexure 7 modify content of medical record as "Indoor Patient Medical Record"

Delete point no 4 (explanation Investigation reports are given to patients)

Clause 10.1 Delete "all patients who visit the hospital" and substitute "those who avail the facility of the hospital"

Clause 10.10 Delete "There shall be appropriate arrangement for safe transport of patient" and substitute "The patient shall be guided to the appropriate facility"

Clause 10.12 After the phrase employed female attendant/female nursing staff add "female attendant of the patient"

Clause 10.14 Modify this entire clause as "The hospital shall provide care of the patient as per the best clinical judgment of the clinician concerned"

Clause 10.15 After the phrase "The hospital shall provide first Aid to emergency patients" delete the entire paragraph and add "the bills of which will be paid either by the patient's attendants or reimbursed by the Government, and after that the patients will be guided to the appropriate healthcare facility"

10.16 Delete the word legible in this clause; explanation – legible is an elastic term perception of varies from person to person and is very likely to be misused by the controlling authority.

Clause 10.17 Modify this clause as "Drug Allergies shall be ascertained for drugs commonly causing hypersensitivity reactions and for those drugs communicated by patient's attendants and in case of any such allergies, it shall be communicated to patient's attendants as well"

Clause 10.21 Modify this clause in its entirety as " The hospital shall ensure safety and security of staff and patients, as per the ways and means available and on the grounds of prevailing local socioeconomic and law and order situation and the patients' attendants will have to cooperate in every possible manner in achieving this goal"

Clause 10.22 Delete the word "explained" and substitute with "counseled keeping in mind the ever changing nature of the concepts in medical science"

Suggested Modifications in annexure 1 :- Keeping in mind that the minimum requirement should indeed be minimum requirement keeping in view the harsh socioeconomic realities in different parts of the country, the following are suggested :-

1. **Total Area of hospital level 1 including 20% of circulation area for other utilities 15 sqm/bed as carpet area**
2. **Ward bed and surrounding space 5 sqm/bed , in addition 20% circulation area**
3. **OT for minor procedures 9 sqm**
4. **Labour room - Labour table and surrounding space 9 sqm / labour table, other areas as per judgment of the doctor in charge and prevailing socioeconomic conditions**
5. **Bio medical waste – As per the judgement of the doctor in charge and prevailing socioeconomic conditions**

Other requirements : -

1. **Other areas for Doctor's duty room, Nursing station etc. will be as per the judgment of the doctor in charge and prevailing socioeconomic conditions**
2. **For a general ward of 12 beds a minimum of one working counter and one hand wash basin shall be provided**
3. **Distance between two beds 0.9 meters**

4. **Distance at head end of bed 0.2 meters**

5. **Door width 1.2 meters and corridor width 1.5 meters**

Emergency Room (if available)

1. **Emergency bed and surrounding space area 6 sqm/bed**

Annexure 2. required furniture and fixture should be based on the judgement of the clinical establishment.

Annexure 3. – Equipments

a. **Emergency Equipment – delete no 4 defibrilator and accessories, no. 7 ECG Machine, no. 8 Pulse Oximeter, no. 9. Nebuliser with accessories**

b. **Other Euipments – Delete storage tank for water supply, waste disposal may be out sourced, delete – incinerator or burial pit, Child register and pregnant woman register (there will be OPD register for all patients), oxygen tank and concentrator. The following should be optional or as per the scope of services and judgement of the doctor incharge :- Medical Storage, Laundry services, Out patient rooms, inpatient wards (delete washable mattresses), central supply**

Annexure 4. – a. list of Emergency drugs delete item 17. Naloxone (explanation – it is not available in small towns and remote areas) modify item 21. inj Tetanus to inj Tetanus Toxoid

Annexure 5. - Keeping in mind that the minimum requirement should indeed be minimum requirement keeping in view the harsh socioeconomic realities in different parts of the country, the following are suggested :-

1. **Doctor – Qualified doctor should be available as per specified clinic hours and on call if in patient services are provided**

2. **Nurses - regarding nursing staff; the nursing staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained nursing staff. Also the number of the staff shall be decided as per the level and scope of services provided and financial viabilty of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)**

3. **Multipurpose worker – minimum 10th pass**

Objections suggestions, deletions and modifications suggested in the draft minimum standards for level 2 hospital

On page 5 under the heading of Categorization of hospitals; in categorization of hospitals Location of the clinical establishment (metro, cities, town, sub division and villages), older facilities and new ones coming after the enactment of The Act, Scale of operation and level of care , all must be taken into account.

In Hospital level 1 opthalamic medicine clinic doing refraction, optometry and orthoptics should also be included. Day care surgery should also be included at level 1.

Regarding Hospital level 2; superspeciality hospitals in towns, 2nd tier cities or running on a small scale like a 30 bedded facility having a small 6 bedded ICU should be included, likewise smaller surgical and medical clinical establishments having small ICUs in a town should be considered in level 2.

Under section 2.22 Diagnostic Services category should be either optional or outsourced.

Clause 2.23 Pharmacy and stores - optional

Clause 2.24 delete “CSSD”

Clause 2.25 optional or outsourced

Clause 2.26 - optional

Clause 2.27 Waste Management services (general and biomedical) - outsourced

Clause 2.29 Ambulance Services - optional

As per clause 3.1.6 clarify that the fee structure will be displayed inside the clinical establishment.

As per clause 3.1.7 Add tentative before timings.

Clause 3.1.10 delete it; Explanation (first the patient’s rights and responsibilities should be fixed from the point of view of practicality and they must not affect the sensitive Doctor Patient relationship in any way, which is based only on trust and forms the very basis of treatment of the patient.)

Clause 3.2.1 delete it

Clause 3.2.3 – delete the word clean (explanation – cleanliness is an elastic term perception of which varies from person to person and is very likely to be misused by the controlling authority and it is also the responsibility of the patient)

Clause 3.2.4 – For provision of 24 hours supply of water and electricity, exception must be made for unforeseen difficulties such as equipment failure.

Clause 3.2.6 – delete the word clean public toilets and use the term " toilets for patients, their attendants and staff " (explanation – cleanliness is an elastic term perception of varies from person to person and is very likely to be misused by the controlling authority and it is also the responsibility of the patients and their attendants)

Clause 3.2.8 After internal and external communication facilities, add " using mobile phones"

Clause 3.2.9 should be modified that the required furniture and fixture should be based on the judgment of the management of the concerned clinical establishment.

Clause 4.1 the hospital shall have adequate medical equipment and instruments commensurate with the scope and level of service, and available financial resources.

Clause 5.2 remove the clause "at all times" and replace it with term "under usual circumstances"

Clause 6.1 under this clause regarding trained medical staff; the staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained staff. Also the number of staff shall be decided as per the level and scope of services provided and financial viabilty of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)

In Clause 6.2 under this clause regarding trained nursing staff; the staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained nursing staff. Also the number of nursing staff shall be decided as per the level and scope of services provided and financial viability of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)

In Clause 6.3 under this clause regarding trained paramedical staff; the staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained paramedical staff. Also the number of nursing staff shall be decided as per the level and scope of services provided and financial viability of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)

Clause 6.4 Modify and change the personal record as a register for paramedical staff shall be maintained regarding their qualification and training

Clause 6.5 delete "as prescribed by the professional bodies and as per local laws" and add "to be provided by doctors of the health facilities as per needs".

Below clause 7.7 from CSSD/Sterilisation Area delete "CSSD"

Clause 7.9 delete this clause

Regarding clauses7.12, 7.13 and 7.14 the management of general, toxic and biomedical waste should be outsourced to local civic bodies.

Clause 7.18 Delete "at all times" and substitute "in usual circumstances and except in case of unforeseen circumstances like equipment failure etc."

Regarding clause 7.19 the arrangement of transportation by the hospital must be optional and duly paid for by the patent's attendants.

Clause 7.20 Ambulance services will be optional

Regarding clause 8.1 there should be a mechanism in place so that the Doctors and owners of clinical establishments are not made scapegoats of red tapism. It should be the duty of the district regulatory authority to liaison with different departments and procure the different legal licenses or certificates after charging a reasonable fee. In the indicative list of legal requirements as per Annexure 6 many of them are unnecessary and therefore they should be deleted from the list of requirements, such as Building completion license, DG set Approval for commissioning, Diesel storage license, Narcotic Drug License (if Govt. is already registering a facility as a clinical establishment, what is the need of such a license?) Medical gases Licenses/ explosive act., Boiler's licenses, MoU / agreement with outsourced human resource agencies as per labor laws, Spirit Licenses, Provident Fund/ESI Act, Sales Tax Registration, NOC under Pollution Control Act (Air/Water). There are many other licenses which should be required if applicable such as; MTP Act, PNDT Act, Blood Bank Licenses, Food Safety License, Retail and bulk drug license (Pharmacy) Ambulance services should be optional and there should not be any requirement of commercial vehicle permit or Commercial Driver license for an ambulance, and AERB Licenses.

Clause 9.1 Delete this clause and provide for "maintenance of records of Indoor Patients and Medico legal Cases".

Clause 9.3 Delete "at all times" and substitute "in usual circumstances and except in case of unforeseen circumstances like natural calamities, Fire, Theft, etc."

Clause 9.5 delete the word "Emergencies".

Annexure 7 modify content of medical record as "Indoor Patient Medical Record"

Delete point no 4 (explanation Investigation reports are given to patient)

Clause 10.1 Delete "all patients who visit the hospital" and substitute "those who avail the facility of the hospital"

Clause 10.3 Delete it; Explanation - first the patient's rights and responsibilities should be fixed from the point of view of practicality and they must not affect the sensitive Doctor Patient relationship in any way, which is based only on trust and forms the very basis of treatment of the patient.

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Clause 10.31 delete

Clause 10.32 After "All fire safety measures as per local law will be adopted" delete entire paragraph

Clause 10.33 in the end add "as per the capability of the hospital and the hospital bills for the same shall be reimbursed by the Government"

Clause 10.34 Delete the word "explained" and substitute with "counseled keeping in mind the ever changing nature of the concepts in medical science"

Suggested Modifications in annexure 1 :- Keeping in mind that the minimum requirement should indeed be minimum requirement keeping in view the harsh socioeconomic realities in different parts of the country, the following are suggested :-

6. **Total Area of hospital level 1 including 20% of circulation area for other utilities 15 sqm/bed as carpet area**
7. **Ward bed and surrounding space 5 sqm/bed , in addition 20% circulation area**
8. **ICU if available 6 sqm/bed, in addition 20% circulation area, doctor's duty room optional**
9. **OT for minor procedures 9 sqm**
10. **Labour room – if available - Labour table and surrounding space 9 sqm / labour table, other areas as per judgement of the doctor incharge and prevailing socioeconomic conditions**
11. **Operation Room Area 18 sqm**
12. **Emergency and Casualty (if available) 6 sqm/bed, other areas as per judgment of the doctor in charge and prevailing socioeconomic conditions**
13. **Pharmacy (if available) same as given**
14. **Bio medical waste – As per the judgment of the doctor in charge and prevailing socioeconomic conditions**

Other requirements: -

6. **Other areas for Doctor's duty room, Nursing station etc. will be as per the judgment of the doctor in charge and prevailing socioeconomic conditions**
7. **For a general ward of 12 beds a minimum of one working counters and one hand wash basin shall be provided**
8. **Distance between two beds 0.9 meters**
9. **Distance at head end of bed 0.2 meters**
10. **Door width 1.2 meters and corridor width 1.5 meters**

ICU if available

Clause 3 Delete terms "adequate" and "uninterrupted"

Clause 5 delete nurse call system for each bed

Clause 6 delete - areas for Doctor's duty room, Nursing station etc. will be as per the judgment of the doctor in charge and prevailing socioeconomic conditions

Operation Theatre

Clause 1 delete

Clause 2 areas for Doctor's duty room, etc. will be as per the judgment of the doctor in charge and prevailing socioeconomic conditions (again we would like to remind the difference between what is desirable or ideal which may be useful for accreditation and what is minimum and practically feasible in the remotest and poorest part of the country and not in the affluent metro city of our country)

Clause 3 Doors of the preoperative and recovery rooms 1.0 meter clear widths

Clause 6 delete

Clause 7 Modify as "medical gases will be available as per needs"

Clause 8 in the end add "when operational and except in case of insurmountable difficulties such as equipment failure"

Clause 9 delete "uninterrupted" exception has to be made about in case of equipment failure

Emergency Room (if available)

2. **Emergency bed and surrounding space area 6 sqm/bed**

Clinical Laboratory - if available NABH CEA LAB cannot be used as it is not minimum but used for accreditation hence delete it

Imaging - Delete all clauses and frame what is minimum. NABH CEA IMAGING cannot be used as it is not minimum but used for accreditation hence delete it

Delete CSSD

Annexure 2. required furniture and fixture should be based on the judgement of the clinical establishment.

Annexure 3. – Equipments shall be according to the speciality concerned and as per the judgement of the Doctor in charge, if everything is spoonfed by the central committee then we should close down our medical colleges and take a training course instead under guidance of the committee

c. **Emergency Equipment – delete no 4 defibrilator and accessories, no. 7 ECG Machine, no. 8 Pulse Oximeter, no. 9. Nebuliser with accessories**

d. **Other Euipments – waste disposal may be out sourced, delete – incinerator or burial pit, Child register and pregnant woman register (there will be OPD register for all patients), oxygen tank and concentrator, 4= wheel drive vehicle, Waheble mattresses.**

e. **The following should be optional or as per the scope of services and judgement of the doctor incharge :- Medical Storage, Laundry services, Kitchen, Out patient rooms, inpatient wards (delete washable mattresses), central supply**

Annexure 4. – a. list of Emergency drugs delete item 17. Naloxone (explanation – it is not available in small towns and remote areas) modify item 21. inj Tetanus to inj Tetanus Toxoid, delete item 22 inj adenosine

Annexure 5. - Keeping in mind that the minimum requirement should indeed be minimum requirement keeping in view the harsh socioeconomic realities in different parts of the country, the following are suggested :-

4. **Doctor – Qualified doctor should be available as per specified clinic hours and on call if in patient services are provided**

5. **MBBS Doctor will be on call if available (Explanation - due to the redundancy of MBBS Degree, MBBS Graduates prefer to study for entrance exams rather than work in a hospital. Hence there is an acute shortage of this human resource in remote areas, so there will be no level 2 hospitals to cater to the needs of the residing population. Even in a developed country like**

Canada, it is a reality that many hospitals are manned only by trained nurses and these centers are guided by a single specialist with the help of telemedicine.)

6. **Nurses - regarding nursing staff; the nursing staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained nursing staff. Also the number of the staff shall be decided as per the level and scope of services provided and financial viabilty of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)**
7. **Multipurpose worker – minimum 10th pass – one**

Annexure 7 - Medical records of only in door patients and Medico legal cases to be maintained

Delete point 4 – investigation reports

Objections suggestions, deletions and modifications suggested in the draft minimum standards for level 3 hospital

On page 5 under the heading of Categorization of hospitals; in caregorization of hospitals Location of the clinical establishment (metro, cities, town, sub division and villages), older facilities and new ones coming after the enactment of The Act, Scale of operation and level of care , all must be taken into account.

In Hospital level 1 opthalamic medicine clinic doing refraction, optometry and orthoptics should also be included. Day care surgery should also be included at level 1.

Regarding Hospital level 2; superspeciality hospitals in towns, 2nd tier cities or running on a small scale like a 30 bedded facility having a small 6 bedded ICU should be included, likewise smaller surgical and medical clinical establishments having small ICUs in a town should be considered in level 2.

Under section 2.2 diagnostic services should be either optional or outsourced.

Clause 2.3 Pharmacy and stores - optional

Clause 2.4 delete "CSSD"

Clause 2.5 – optional or outsorced

Clause 2.6 – optional

Clause 2.7 Waste Management services (general and biomedical) - outsourced

Clause 2.9 Ambulance Services - optional

As per clause 3.1.6 clarify that the fee structure will be displayed inside the clinical establishment.

As per clause 3.1.7 Add tentative before timings.

Clause 3.1.10 delete it; Explanation (first the patient's rights and responsibilities shuld be fixed from the point of view of practicality and they must not affect the sensitive Doctor Patient relationship in any way, which is based only on trust and forms the very basis of treatment of the patient.)

Clause 3.2.1 delete it

Clause 3.2.3 – delete the word clean (explanation – cleanliness is an elastic term perception of which varies from person to person and is very likely to be misused by the controlling authority and it is also the responsibility of the patient)

Clause 3.2.4 – For provision of 24 hours supply of water and electricity, exception must be made for unforeseen difficulties such as equipment failure.

Clause 3.2.6 – delete the word clean public toilets and use the term " toilets for patients, their attendants and staff " (explanation – cleanliness is an elastic term perception of varies from person to person and is very likely to be misused by the controlling authority and it is also the responsibility of the patients and their attendants)

Clause 3.2.8 After internal and external communication facilities, add " using mobile phones"

Clause 3.2.9 should be modified that the required furniture and fixture should be based on the judgment of the management of the concerned clinical establishment.

Clause 4.1 the hospital shall have adequate medical equipment and instruments commensurate with the scope and level of service, and available financial resources.

Clause 5.2 remove the clause "at all times" and replace it with term "under usual circumstances"

Clause 6.1 under this clause regarding trained medical staff; the staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained staff. Also the number of staff shall be decided as per the level and scope of services provided and financial viability of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)

In Clause 6.2 under this clause regarding trained nursing staff; the staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained nursing staff. Also the number of nursing staff shall be decided as per the level and scope of services provided and financial viability of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)

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Clause 6.4 Modify and change the personal record as a register for paramedical staff shall be maintained regarding their qualification and training

Clause 6.5 delete "as prescribed by the professional bodies and as per local laws" and add "to be provided by doctors of the health facilities as per needs".

Clause 7.8 delete Explanation – the liability of this kind of assurance rests with the manufacturer or supplying company

Below clause 7.8 from CSSD/Sterilisation Area delete "CSSD"

Clause 7.10 delete

Regarding clauses7.13, 7.14 and 7.15 the management of general, toxic and biomedical waste should be outsourced to local civic bodies.

Clause 7.19 Delete "at all times" and substitute "in usual circumstances and except in case of unforeseen circumstances like equipment failure etc."

Regarding clause 7.20 the arrangement of transportation by the hospital must be optional and duly paid for by the patent's attendants.

Clause 7.21 Ambulance services will be optional

Clause 7.22 Every effort should be made to comply with this clause and the accompanying staff must be protected by law from violence of any kind, however exception must be made in case of acute shortage of trained staff in towns, 2nd tier cities and rural areas; this should not mean that the patients are not transported to better health facilities at all. Or the hospital invites unnecessary litigation hampering its smooth functioning

Regarding clause 8.1 there should be a mechanism in place so that the Doctors and owners of clinical establishments are not made scapegoats of red tapism. It should be the duty of the district regulatory authority to liaison with different departments and procure the different legal licenses or certificates after charging a reasonable fee. In the indicative list of legal requirements as per Annexure 6 many of them are unnecessary and therefore they should be deleted from the list of requirements, such as Building completion license, DG set Approval for commissioning, Diesel storage license, Narcotic Drug License (if Govt. is already registering a facility as a clinical establishment, what is the need of such a license?) Medical gases Licenses/ explosive act., Boiler's licenses, MoU / agreement with outsourced human resource agencies as per labor laws, Spirit Licenses, Provident Fund/ESI Act, Sales Tax Registration, NOC under Pollution Control Act (Air/Water). There are many other licenses which should be required if applicable such as; MTP Act, PNDT Act, Blood Bank Licenses, Food Safety License, Retail and bulk drug license (Pharmacy)Ambulance services should be optional and there should not be any requirement of commercial vehicle permit or Commercial Driver license for an ambulance, Transplantation of human organs Act and AERB Licenses.

Clause 9.1 Delete this clause and provide for "maintenance of records of Indoor Patients and Medico legal Cases".

Clause 9.3 Delete "at all times" and substitute "in usual circumstances and except in case of unforeseen circumstances like natural calamities, Fire, Theft, etc."

Clause 9.5 delete the word "Emergencies".

Annexure 7 modify content of medical record as "Indoor Patient Medical Record"

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11. **Pharmacist if pharmacy is there**
12. **Lab technician if lab services are in house**
13. **X ray technician if in house imaging is there**
14. **Others – from point 8 to 12 optional**
15. **Multipurpose worker – minimum 10th pass – two**

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Delete point 4 – investigation reportsstation will be on descretion of the doctor incharge

Neurosurgery Minimum Standards

Neurosurgery is in its infancy in most parts of our state presently. A hospital is initially built on a small scale, it gains reputation by hard work in years and only then it develops into a big hospital. If this incubation period is not given in the garb of minimum standards then no superspeciality center will be able to come up from ground zero to a world class level. Only wealthy business houses with deep pockets will be able to build hospitals and healthcare will be a profit and loss account for them!

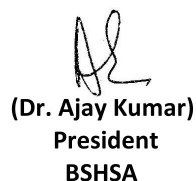
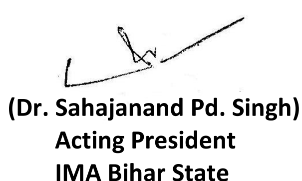
Suggested as acceptable minimum standards :-

One MCh/DNB Neurosurgeon on call

MBBS/Physician/Intensivist/General Surgeon on call and on site as per requirement and prevailing local socioeconomic conditions and financial viability of the clinical establishment.

Qualified/trained nursing and paramedical staff at all stations required- **trained paramedical/nursing staff; the staff trained under a qualified doctor in a health care facility for a period of two years or upto the concerned Doctor's satisfaction that the staff concerned has attained competence, he/ she shall be declared a trained paramedical/nursing staff. Also the number of nursing staff shall be decided as per the level and scope of services provided and financial viability of the clinical establishment keeping in mind the prevailing local socioeconomic conditions. Explanation - (It is essential to keep in mind the acute shortage of qualified paramedical staff/nurses and if these norms are strictly adhered to, it will lead to needless inflation in the cost of treatment without any qualitative improvement in the quality of healthcare, the brunt of which will fall on patients.)**

Other support services can **optional or as per the scope of services and judgment of the doctor** in charge **keeping in mind the prevailing local socioeconomic conditions and financial viability of the clinical establishment.**

(Dr. Ajay Kumar)	**(Dr. Sahajanand Pd. Singh)**	**(Dr. Raman Kr. Verma)**	**(Dr. Sanjiv Ranjan Kr. Singh)**
President	**Acting President**	**Convener**	**Hony. State Secretary**
BSHSA	**IMA Bihar State**	**IMA Bihar C.E. Committee**	**IMA Bihar State**