

# The Kerala Clinical Establishment Act: Will Regulatory approach alone be sufficient enough to achieve 'Health System Quality'?

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## ABSTRACT

Published on 30th March 2026

After a long time of debate and discussions, the clinical establishment act is now on the roll out. This article is a brief narrative review on the current situation and suggestions to effectively implement the act along with few suggestions for increasing quality dimensions of clinical practice ecosystem in Kerala. The history of clinical establishment act is described first. The situation in the country and Kerala about the implementation of the act is then reviewed. Importance of private sector provision of health care is described. Popular criticisms regarding private health industry are mentioned. Salient attributes of functioning of public health system are briefly discussed. Efforts taken by Govt. to ensure quality of clinical service provision is briefly discussed and the role of Clinical Establishment Act in this regard is mentioned. Suggestions for achievement of quality of clinical service provision are listed. The purpose of clinical establishment act is to ensure minimum standards or quality in health care. The basic initiative proposed is clinical governance which is already popular in most of the developed countries. The message is that reforms for improvement of quality and effectiveness of clinical practice ecosystem should happen through physician led initiatives like clinical governance. Accreditation focus mainly on structural elements of clinical service provision while clinical governance address process elements.

**Keywords:** Clinical establishment act, Quality in health care provision, private sector in health system functioning, Clinical governance.

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## SHORT HISTORY OF THE ACT

In India, the initiative for regulation of clinical establishments had its origin in 2010 with initial attempts for a central act. Even before that, attempts to regulate the private medical institutions started in the form of Bombay nursing home act (1949). At present there are various agencies to ensure quality of medical care provision in the country. The National medical commission and its allies namely the Kerala medical council, the Kerala Panchayat and Municipalities act, Quality council of India and accreditation agencies are having directly or indirectly the mandate of ensuring quality of medical care provision.<sup>1</sup>

## THE SITUATION IN THE COUNTRY

The central bill was introduced in the Loka Sabha

on April 15<sup>th</sup> 2010 and was passed by the Parliament without any debate by a voice vote.

Considering the diverse needs and complexity of state specific issues in health care, one central act was found to be not enough and that was why each state was asked to make its own act. Many states started initiatives in this regard which led to noisy public pressure and court directives. For example, the Patna high court directed the state of Bihar to frame rules to implement the act.<sup>2</sup> However, in spite of such pressures, Practitioners expressed the previous experience of implementation in suspect.<sup>3</sup>

Perhaps due to the long inception time, the act had maximum discussions in the public forums and professional association platforms. Sizable academic literature is also available now about the implementation of the act.<sup>4,5</sup>

*Cite this article as:* Rajamohanam K. The Kerala Clinical Establishment Act: Will Regulatory Approach Alone Be Sufficient Enough to Achieve "Health System Quality"? Kerala Medical Journal. 2026 Mar 30;19(1):43-47.

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In different instances professional associations have submitted so many memorandums, held discussions with national and state level authorities.<sup>6</sup> They did much advocacy and lobbying for clarifying many of their concerns and highlighting potential threats to the medical profession in the form of vanishing clinics of general practitioners and close out of small hospitals in the state after the implementation of the act. Many grievances were patiently heard though all were not solved as suggested by professional associations. During this period there were multiple court interventions and finally the honourable supreme court cleared all complaints and gave the final verdict to implement the act.

## SITUATION IN KERALA

Initially the Clinical Establishment Bill was tabled in Kerala Legislature on February 2014. The then Govt. understood the bill as a monitoring mechanism of the functioning of private hospitals and Laboratories. Professional associations like Indian Medical Association and Qualified Private Medical Practitioners Association put forth many suggestions about the implementation of the bill at the national as well as the state levels. Major concerns were as follows.

- Lack of clarity on the definition of emergency medical condition
- Issues related to council structure and functioning
- Many clauses applicable to commercial establishments were just copied.

The Kerala act was finally passed on February 1<sup>st</sup> 2018.

Now after the long-term push and pull from all stakeholders like the authorities, professional associations, media, and other civil service organizations and multiple times of court interventions (See reference on Court interventions sited as reference no.3) the clinical establishment act after a long period of being on the anvil is now getting in to practice.<sup>7</sup> The act and rules related resources are available now on open-source domain. The very purpose of the act was registration and regulation to ensure minimum standards for facilities. Minimum standards are with reference to personnel, maintenance of records and reporting and other conditions as specified. The justifications for all this like stabilizing patients in emergency conditions and reporting of significant events to authorities and even sharing the relevant health information in pandemic like setting were agreed by all concerned. The act also explains category wise classification of clinical establishments. As this is central act, context specific modifications are

possible and that is what the Kerala legislature did to develop the Kerala clinical establishment act.<sup>8</sup>

We can assume that the purpose of this regulation is to ensure quality of services or minimum standards through regulation. Perhaps the sociopolitical environment in Kerala might have been be pressurising for the act. Remarkably high Out of Pocket Spending in Kerala and the existence of unexplainable variations in price along with few incidents of media reports on delayed access to emergency medical care were few instances of this pressure. Up on this background It is since a long time that social reformers and public health experts argued for implementation of such an act to regulate the private sector.<sup>9,10</sup>

### Importance of private sector in health system functioning

Qualified private medical practitioners Association (QPMPA) represents more than 3000 doctors in private sector and 400 clinics & hospitals in Kerala. This pioneer organization representing the private health care institutions welcomed and supported the clinical establishment act. See the statement of QPMPA officials Comment by the chairman "QPMPA is the first organisation in India to have demanded a Clinical Establishments Regulation Act in 1980s. We are proud of our founder president Dr. T. M. Paul, who proposed this, for his farsightedness. That has become a reality now in India within forty years and we are happy" It is the most promising as well as inspiring fact that the QPMPA welcomed and supported this initiative of Govt. See for more details.<sup>11</sup> Major contribution to the Gross Domestic Product of this country is from the private sector. Many private institutions have facilities not available in public system, especially cutting-edge technology applications, investment capacity including human resource capacity. Most of them are willing to collaborate and areas of collaboration and model Memorandum of Understanding (MOU) is needed. A patronising attitude and supportive administrative mechanisms from authority is the need of the hour in this direction.

One of the major issues here is the attitude towards the private sector. Kerala's position of being equal to none in rankings as well as successful control of pandemic with acceptable levels of mortality was achieved by significant contributions by private sector also. Studies shows that 70% of health seeking and deliveries happen in private sector.<sup>12</sup> A partnership model called Private public mix was planned in Kerala at the time of health policy development. Many successful models are

before us for this as in the case of Tuberculosis control and the case of family planning services in the country. In the planning of integrated trauma care services for the state this was planned with involvement of Indian Medical Association KSB but could not be achieved completely. At least few stakeholders continue to keep the prejudiced attitude towards private sector that they are working for profit maximization and tries to hide many relevant things from people and may exploit the ignorance of people through even unscrupulous practices. Critics on private health sector make a blame due to issues like

- Lack of uniformity of price and charges between institutions
- Lack of transparency regarding wage structure, incentives and cuts,
- Overmedicalization, medical errors, and exorbitant cost recovery
- Corporate ownership and cut throat competition spirit etc.

Occasional blames are also due to diagnostic services having no explicit standards, expensive tests taken as panels, kickbacks and commissions, unholy nexus with Pharma industry, Continuing private practice of faculty of medical colleges and violation of practice guidelines of Government doctors etc.

We particularly need to see the positive aspects about private sector. But for this sector, Kerala would not have achieved the Kerala model of health development. There is tremendous potential of human resources as well as diagnostic infrastructure in the private sector which most of the managements are willing to share for the poor on a pro-poor approach. Many institutions render services totally free for poor eligible patients. We can see that most of the unethical practices mentioned as criticisms, are now getting slowly vanished due to the ombudsman activities of the profession as well as the regulatory efforts of the Government.

Let us discuss little about the mandate of public health system in our country. The general feeling is that primary mandate of health system is clinical service provision and research is thus considered as secondary or not as a function at all. Documentation is generally for defending medical litigations and not primarily for research purpose. This is in fact a missed opportunity in the research context. Continuity of care and preventive orientation are two important mandates now happening not to the extent that ought to be in the health system functioning.

The health system suffers from many problems as indicated by public health experts. Govt takes unparalleled efforts to rectify this but due to the skyrocketing of cost, unlimited demand and information asymmetry many things hampering satisfaction of patients are seen as still continuing. Inadequate budgetary allocation, not Placing Primary health care as an effective gate-keeping mechanism, not realizing epidemiological approach in health service planning and lack of practice of evidence based medicine in its true spirit, ineffective referral system, incomplete implementation of 'generic medicine initiative' and related ones like Drug formulary, Essential drug list etc are few of the quality reforms still continuing as unfinished agendas. Many of these can be completed by authorities with the support from professional associations and successful public participation. The most frustrating issue revealed from media reports, from few districts is regarding human resources without adequate competency at the point of care service delivery with either task shifting or substitution.

Currently the private sector is concerned mainly with curative care only, all immunizations under the national immunization schedule is available at Govt. or the public institutions only. Hence the public sector can be considered as the custodian of preventive care.

Another issue of concern is regarding administration of these institutions. General mode of consideration for health institutions is as commercial establishments and the regulation also is applied in this background. The QPMPA stopped requesting exemption from shops act from 2005 onwards from the labour ministry (Communication from Sushama Anil to IMA officials on February 4, 2014 regarding Clinical Establishment act in Kerla.) For many of the solo practitioners, competition is for survival and it is extremely difficult to survive in this environment of competition and corporate intrusion.

At this juncture of discussion on quality concerns of 'health system functioning' in the state, let us think aloud on few pertinent questions regarding the implementation of clinical establishment act in the state. We already mentioned a few pressurising social concerns about the Kerala context. Skyrocketing of cost of treatment especially the catastrophic spending mounting to the extent of negative wealth shock in the event of a major life event is sometimes reported. Many a times unexplainable variations in the outcome of treatment are seen to be due to complex reasons, intrinsic to the health system functioning. Regulatory mandate apparently seems to be perhaps one of the

easiest means of controlling these unhealthy trends to make the health system towards people centric direction. But this is only a means and cannot be considered as an end. What else need to be done other than regulatory control is the subject matter of this article.

## HOW QUALITY IS DEFINED IN HEALTHCARE

Quality is a buzzword used by academia, administration as well as the lay people. The definition of Quality depends on the prevailing socio-political climate and culture —Quality is the concept of achieving what is desired to be achieved according to the societal expectations and compatible with the social incremental opportunity cost.<sup>13</sup> The institute of medicine now the national academy of medicine define quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”.<sup>14</sup> This is the degree to which health care services increase the likelihood of desired health outcomes that are consistent with current professional knowledge. How care is provided should reflect appropriate use of the most current knowledge about scientific, clinical, technical, interpersonal, manual, cognitive and organizational and management elements of health care.

Basically quality means that a product/service must have features, which meet customer needs and thereby provide customer satisfaction. Quality also means, satisfying customers on continuous basis. Here onus is on the supplier to keep assessing the customer's needs (which are dynamic) and make sure that products/services take care of such needs.

Quality can be attributed to final product, to a process or to an organization. When we refer quality in healthcare, be it in context of healthcare organization, clinical SOP (standard operating procedures) or clinical outcome, it relates to patient safety. Quality in healthcare therefore plays direct and key role, which amounts to saving human lives.

If we consider regulation as a quality imperative, in the neoliberal market model it can serve as a market solution. One major area for consideration of quality in clinical service delivery is laboratory diagnosis. On the one side there is daily mushrooming of laboratories and on the other side is the uncertainties due to intrinsic complexities of diagnostic process. In the contemporary era no physician can make a diagnosis without laboratory-support. Hence mushrooming of laboratories is an observation like multiplicity of pharmaceutical products in the market.

There are many quality standards but how far these are integrated with routine clinical practice is the question. Govt. started many quality reforms like generic medicine initiative, re-registration of medical practitioners, referral system to streamline patient flow, clinical audit and related ombudsman activities, standard practice guidelines and protocols, smart hospital initiative etc. Many of these initiatives though started with much enthusiasm, are seen now on halfway and few only are evaluated for ‘reach, reason and accountability for spending’.

No body can disagree on the purpose of Clinical Establishment act as to ensure quality and minimum standards of clinical service delivery. Though this is a concern of every citizen, a genuine question is: Will this act alone ensure quality in health system functioning and what else is needed is posed as suggestions in next few lines.

1. Looking through the perspective of clinical practitioners, apart from the rat race for registration, have all concerns being addressed and doubts cleared through dialogues and discussions?
2. Through a societal perspective, what will be the expected net gain for the public. Are there sufficient enough institutional arrangements for public education and getting feedback, especially on smooth and harmonious implementation.
3. How far we can rectify the public health system deficiencies already pointed out by experts through this platform is a pertinent question.
4. Considering the complexities of health sector especially medical care, it is a herculean task to define standard of care. The state of art and technically sound definition is in the context of evidence-based practice. The resource centre of the council has started this for few clinical conditions. This covers mostly to conditions applicable to tertiary care facilities. This need to be periodically updated and extended to the so called ‘little ticket items’ also. Considering the complexity of this process, a permanent establishment akin to the health technology evaluation group at the centre is needed in the state for this purpose. This platform can address most of the clinical governance issues mentioned in this article including Standard care
5. There are many reforms which happened as part of modernization in govt. program, SDG (sustainable development goals) related activities, introduction of comprehensive primary health care etc. Are we exploiting the potential for such internal reforms in the private public participation mode especially through feedback from social audit or citizen's charter?.

## SUGGESTIONS

In order to popularize the concept of quality and keep minimum standards in health care, along with implementation of Clinical establishment act following steps can also be undertaken.

- Clinical governance initiatives: These are basically physician led initiatives. Study of clinical processes and outcomes are part of quality. Providing good quality health care which is safe and cost-effective is implementation of clinical governance through good practice or evidence based clinical guidelines. We need to conduct regular clinical audits. Clinical governance is not much popular in the Indian context. In India many components of this quality framework is already implemented and coordinated by the quality council of India. Accreditation and related activities look in to the structural elements of quality while clinical governance looks in to the functional or process elements. It was originally elaborated within the United Kingdom National Health Service (NHS), and its most widely cited formal definition describes it as Clinical governance is in short a framework through which the health services are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This definition is intended to embody three key attributes: recognizably high standards of care, transparent responsibility and accountability for those standards, and a constant dynamics of improvement. Clinical governance.<sup>15</sup>
- Teaching and training activities regarding quality: In India the concept of quality as well as safety are new concepts and during this nascent phase, more and more physicians as well as administrators need to be sensitized about both quality as well as safety. This need to be integrated in to the medical curriculum. In most of western countries quality initiatives are usually physician led activities.
- Research for development of evidence base for standard protocols, benchmarks and references for administrative decision making, definition of standard care, normal laboratory parameters etc. need to be initiated.
- Regarding the cost recovery for emergency stabilization and related expenses it is not justful to say that the institutions should bear the expenses. Either a common pool of fund to be raised on philanthropy basis(at the initiative of local self Govt.) or met

from the state exchequer or respective Hospital Development Society funds.

- In short just an act alone cannot realize quality in clinical care. Physician being the prime player of clinical practice, physician driven initiatives focusing on clinical governance need to be started.

## END NOTE

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**Conflict of Interest:** None declared

## REFERENCES

1. Singh MM, et al. Laws applicable to medical practice and hospitals in India. *Int J Res Found Hosp Healthc Adm.* 2013;1(2):19-24.
2. Patna High Court. HC: frame rules to enforce Clinical Establishment Act [Internet]. *Times of India.* 2014 [cited 2026 May 7].
3. Pingle SH. The Clinical Establishments Act, 2010: laws must be implemented in the right spirit. *Indian J Med Ethics.* 2010;6(4):223-4.
4. Kannabiran K. Editorial: the Clinical Establishments Bill 2007: a brief review. *Indian J Med Ethics.* 2008;5(3):108-9.
5. Phadke A. The Indian Medical Association and the Clinical Establishments Act-2010: irrational opposition to regulation. *Indian J Med Ethics.* 2010;7(4):242-4.
6. Kammappa KA. Clinical Establishment Bill and corporate intrusion. *Nammude Arogyam.* 2026 Jan;27:48.
7. Kerala State Council for Clinical Establishments. Kerala Clinical Establishments Act 2018 and Amendment 2021 [Internet]. Thiruvananthapuram: Kerala State Council for Clinical Establishments; 2021 [cited 2026 Jan 30].
8. Kerala Legislative Secretariat. The Kerala Clinical Establishment Registration and Regulation Bill, 2013. Bill No. 230. Thiruvananthapuram: Kerala Niyamasabha Printing Press; 2013.
9. Rajiv Sadanandan (2025) clinical establishment Bill Mathrubhumi daily dated 13-01-2025
10. Ekbal B. Articles on Clinical Establishment Bill and healthcare regulation. *Kerala Kaumudi.* 2012 Oct 12 onward.
11. QPMPA. Comments, suggestions, objections including deletions/additions to the draft minimum standards for various categories of clinical establishments submitted before the Chairman, National Council for Clinical Establishments [Internet]. 2014 [cited 2026 May 7].
12. Aravindan KP. Kerala Patanam. Thiruvananthapuram: Kerala Sas-thra Sahithya Parishat; 2025. p.113-21.
13. Agency for Healthcare Research and Quality (AHRQ). Quality indicator toolkit for hospitals [Internet]. Rockville (MD): AHRQ; 2019 [cited 2026 May 7].
14. Atkinson S, Ingham J, Cheshire M, Went S. Defining quality and quality improvement. *Clin Med (Lond).* 2010;10(6):537-9.
15. Macfarlane AJR. What is clinical governance? *Br J Anaesth.* 2019;122(2):174-5.