**TITLE: KPME Act - commentary**

**Review Comments**:

**Reviewer 1:**

1. The authors start off with the presumption that end users ‘prefer less to be treated in a public health system since the private health system provides flexibility and ease of access which patients value. This tries to locate private sector as superior without factoring in several issues that have been made public – ranging from clinical trials, unwanted procedures, exorbitant costs, cuts and commissions etc. (page 3)
2. The article highlights the problems faced by the private sector but doesn’t describe in detail the ethical concerns that are being raised about the private sector. Also, private sector being the largest provider surely means that there is all the more reason to regulate it.

Page 8 ‘The act mandates the right to receive treatment in case of emergency, without being asked for Advance Payments by patients”. What is the solution they offer? The Act says that patients should not be denied treatment and that emergency treatment should be offered. Subsequently patients can be transferred and the cost of care can be claimed from the Government. Would the authors suggest that patients who cannot pay be turned away in an emergency? Also, this clause is specifically for a life-threatening emergency. It is not for a routine health related issue.

“The KPME Act has excluded both public hospitals and defence establishments and has made these establishments non- accountable in its functioning” – this is misconceived because the public/defence establishments are more accountable with inbuilt grievance redressal mechanisms.

“KPME Act also regulates vexatious complaints by charging a penalty for the same, whereas the Clinical Establishment Act is silent in regards to vexatious complaints. The penalty although minimal is an effective way to curb vexatious complaints.” Again, the focus is more on vexatious complaints rather than trying to address the ethical dilemmas that the medical profession now faces especially the private sector. The authors only seem to be trying to prove that the private sector need not be regulated.

“Communicable and NonCommunicable Diseases to better the Government data base. It is advisable for the Government to make a digital solution and interfaces for data sharing with private health system through public – private partnership.” – page 8. Here again they give no basis to show that PPP is a good model but just seem to be promoting it. The PPP model has been severely criticized especially in India, so what is the basis (with evidence) for advocating this model especially in Karnataka?

“The private medical establishment act of 2017 which governs the private health sector will bring about a uniform platform for the registration and monitoring of the establishment. This would pave the way to curtail quackery, which is deep rooted in our country”. Page 9.Is there no other benefit to regulation? No benefit for patients?

The authors feel that KPME will affect medical tourism adversely. On the other hand, if patients are coming in from other countries, isn’t there an even bigger need for regulation? Or should both Indian and international patients be left completely at the mercy of the private sector? Also, why do unethical practices have to be highlighted by media? Why were they not picked up by the regulatory bodies such as IMA? Does this not show a gap? Subsequently, after the media highlighted issues, what actions have been taken to prevent these in future?

“Once the law comes into the interface of medicine, ethical empathetic clinical practice will suffer due to over-reliance on documentation” Page 9 –Without documentation, there is no proof to hold hospitals accountable for unwanted procedures, negligence etc. are they saying documentation is not required? How will patients seek a second opinion? How will patients access grievance redressal? What are the ways to ensure a hospital will be held accountable if there are no records at all?

“OOP can be reduced only by increasing public expenditure on health and by setting up widespread public health service providers” OOP is mainly in the private sector and the authors have no suggestions as to what the private sector could do to reduce OOP. Page 9

“This should also not create roadblocks for people who are inclined to take up a private practice and provide a quality of care to patient who can afford the service.” Page 9 – This point about patients who can afford it, doesn’t put any onus on the hospital. For eg if the patient can ‘afford’ to pay 2 lakhs for a 10 thousand rupees procedure, then no one should complain about it. Affordability in the context of a life-threatening situation is a very unethical way of looking at things. It’s a serious ethical issue to make this statement.  
  
           Are there any important omissions?  
When they quote from the Act it would be better to directly insert clauses from the Act rather than interpret or reword it.

Page 7: they ask why the public health system committee should not come under the purview of the act. The aspects covered under the KPME are specific to private sector and related to display of prices, not withholding expired patient’s body pending payments, etc. The legislative intent of the principal Act is the **Private** Medical establishments act. Public hospitals function as part of social mandate on a range of public interest activities. They also have department oversight, vigilance cell, lokayukta, civil service rules, hospital committees etc. these have to be strengthened. The private sector however was only held liable to a consumer court where healthcare is viewed as a commodity and heavily tilted in favour of the expert. The IMA has failed as a regulatory body.

Page 7 “Instead of putting a cap on the private sector, the Government could have taken adequate measures to improve the public health sector so that it could deliver services to the population”. Does regulation work as ‘either/or’? Are they saying that the private sector should not be regulated pending improvement of the public sector? Since the private sector is the largest provider of healthcare, by their own admission, shouldn’t it also have strict regulation?

Mission hospitals have issued a statement that they are completely okay with regulation. Why has this been conveniently left out?

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**Reviewer 2:**

1. The subject is relevant but the interpretation is unwarranted and poorly developed.
2. The paper dwells at length on the various provisions of the KPME act, (which are mostly the same as in the CEA-2010 and hence well known) instead of focusing on: (i) to what extent the KPME act is different from the Central CEA, on what has been the criticism of IMA and of the Civil Society groups about the KPME act (for example, the Jan Aarogya Chalavalee) and on

(ii) what are the authors’ reasoned views about it. It merely gives author’s unsubstantiated arguments about the act without engaging with the views of other stakeholders, experts.

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