The Indian Medical Association and the Clinical Establishment Act, 2010: irrational opposition to regulation

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The Clinical Establishment Act was passed by the Lok Sabha in May this year and then by the Rajya Sabha on August 3, 2010. The Bill was to be passed in 2007; it lapsed and was reintroduced this year. Some important aspects of the implications of this Bill have been covered by an editorial in this journal in 2008 (1). The 'statement of objects and reasons' from the Central Act, summarising its background, rationale and main provisions, is given in the box accompanying this comment. Here I will comment mainly on doctors' opposition to the legislation.

Health service regulation: a must

Predictably, the Indian Medical Association (IMA), the association of allopathic doctors in India, has opposed the Bill. The grounds for opposition have not been articulated in any statement by the IMA and must be pieced together from the comments of leaders of the national association and its various branches. These statements indicate that the leadership has a poor understanding of the issue. G Samaram, the national president, has said: "The sincerity of the govt. may be appreciated, if it initiate[s] and strives to eradicate the quacks and quackery from our country which has been crippling our society's health in the guise of providing first-aid care." Further, putting "corporate hospitals and rural area hospital in same line to accreditate is unjustifiable as it favors corporatization of health care and jeopardizing the health services within reach of common man". Dr Samaram issued a challenge to the government: "First implement these 'good to hear regulations' in govt. & corporate hospitals to make them as model health care delivery service points." (2)

It is mere polemics to declare that there should be no regulation unless the government first demonstrates the capacity to eliminate practice by unqualified practitioners. It is also simplistic to say that only unqualified people are guilty of quackery and irrational practice. Irrational practice by qualified people at various levels, even in corporate hospitals and many of the so called trust hospitals, is a major problem today.

Such opposition to regulation also fails to take into account that, in developed countries, some form of regulation of the quality and price of services by private doctors has been an essential component of the healthcare system. In the post-second world war era, governments or employers in developed countries either provide healthcare themselves or buy private healthcare from private providers for certain sections of the population. In India, too, we need to move towards such a system. This purchasing of private healthcare should be supplementary to strengthening, expanding and improving the public health system.

Need for standardised, publicly-funded healthcare

Given the overall low income of the majority of people, the poor as well as a large section of the middle class cannot get good quality private care when they need it. The only way to make private healthcare accessible to all people is to reduce unnecessary medical expenses in the private sector through standardisation of healthcare and by the government paying, through tax revenues, the bills of this standardised private sector.

We should not have a dual system - a public system for the poor and a private system for the rich; any system meant only for the poor remains poor. We must bring the private system under a national health service. For this to occur, private doctors' bills must be paid through public funds. And this payment must be based on certain norms and standardisation. This does not mean applying the same norms to all levels of care. In this context a provision in the Act is welcome: through clause 13, it empowers the Central Government to make rules to classify clinical establishments of different systems into categories, and for different standards for different categories keeping in view the local conditions (3).

Such a system of standardisation and payment of private bills through public funds would benefit those private practitioners who want to carry on scientific medical practice. Today, doctors have to be adept not only at medical science, but also at business and marketing. Many doctors do not like such business competition and will benefit from a regulated system. The regulated system would mean a win-win situation for both doctors and patients. Patients would not be deprived of healthcare due to their poverty, and doctors would get more patients. It is difficult to achieve standardisation and regulation without creating an "inspector raj". But that challenge must be faced head on.

In such a system of regulated medical practice, as in other countries, the IMA will have to employ professional, paid staff to do advocacy and negotiations at various levels to foster legitimate interests of doctors. The IMA leadership cannot continue to perform these tasks purely through voluntary, amateur work.

Irrational opposition to the Bill

The IMA leadership has articulated other reasons for its opposition. At a public meeting to protest against the Bill, N Diwan, president of the IMA, Ludhiana, said that doctors were already regulated by laws like the Pre-Natal Diagnostic Techniques Act, biomedical waste laws and the Consumer Protection Act. The Bill would give regulators excessive

authority and prevent doctor from protecting themselves against accusations (4). He has also been quoted as saying: "The National Council, which is proposed to be the governing body, will be composed of quasi-literate persons drawn from Unani, Siddha, Nursing and Paramedical sections of the profession. Of the total 18 members of the National Council, only two will be medical graduates. If passed, this Bill will open the doors for every unqualified person to get registered in the guise of Yoga, Unani, Siddha, Nursing and Pharmacy branches." (5)

It is arrogant to describe only allopathic graduates as medical graduates, or to imply that paramedics are "quasi-literate". Similar views have been expressed by the president of the IMA's Mumbai chapter, Shivkumar Utture, in a programme in Mumbai. He stated that the bill would lead to a license raj and to the demise of the family physician who provides affordable healthcare. IMA secretary Rajendra Trivedi has said that "regulations and license raj" would exacerbate the trend of young medical graduates to avoid family practice and work in specialty hospitals. (6) This too is a polemical argument. There is no mention of how much money is needed to implement minimum standards. If we look at the infrastructural standards in the Bengal Act or in the proposed rules in Maharashtra under the Bombay Nursing Home Registration Act, they are quite modest.

The IMA Punjab observed a half-day bandh on July 15 in protest against this Bill, the dissolution of the Medical Council of India and the introduction of the Bachelor in Rural Medicine and Surgery programme. RS Parmar, president, argued in a memorandum: "The Govt. is trying to regulate a body which is already regulated by the state medical council, the medical council of India and 41 other acts, and the patients who are visiting the doctors and are satisfied with the services provided." He conveniently glossed over the fact that the registration of individual doctors does not and cannot specify the minimum standards for a hospital. The memorandum continues: "The Govts and the administration have miserably failed to check the misuse of allopathic and ayurvedic medicine by the unqualified persons. The stringent requirements to be incorporated in this act, of having number of trained paramedical staff will also not be possible to meet, due to the shortage of trained manpower, which is prevalent even in Govt. institutions. In addition, it will add to the cost of treatment which may raise many folds. Inspection will lead to deleterious effects on the minds of the patients sitting in the waiting areas as if the doctor has committed a crime, thus shaking their faith in the doctor. Imposing fines for minor infringements is unwanted." (7)

In the Central Act, no humanpower requirements have been laid out. This will be done as part of the rules. However, if we go by the number of qualified nurses as stipulated in the draft rules of the legislation in Maharashtra, the Bombay Nursing Home Registration Act (BNHRA), amended 2005, we can see that though this requirement is rational it is impractical to implement at present. With the emaciation of nursing education, the required number of trained nurses is simply not available. Hence, doctors' apprehensions on this point are quite justified. However, the IMS Punjab memorandum's criticism of the requirement that hospitals submit to regular inspections is off the mark. How can the registering authority grant a certificate without verifying, through a visit, the facilities and infrastructure claimed in the registration application? Inspection is done at the time of registration and may be done again, once in five years. On what rational grounds can it be opposed? The argument that minimum standards will increase costs should be supported by evidence. Second, the definition of "minor offences", mentioned in this memorandum, for which exemption from fines has been sought, must be clarified.

In general, the IMA has not made a thoughtful response to the Act. Instead, some IMA leaders have been putting forth very general and invalid arguments.

IMA Bengal has come up with suggestions about specific provisions in the West Bengal Clinical Establishments (Registration and Regulation) Bill (8). A similar detailed response is needed in the case of this Central Act.

In Maharashtra, civil society organisations, including the Jan Aarogya Abhiyan, came up with concrete suggestions about the rules to be formulated in the BNHRA. The Centre for Enquiry into Health and Allied Themes, CEHAT, a non-governmental organisation, was entrusted with the task of formulating minimum standards under this Act. CEHAT organised a number of consultations with representatives of doctors and civil society organisations and, based on these deliberations, prepared draft rules. The director of health services finalised these draft rules, with some modifications, and submitted them to the government in June 2006 for final approval. Unfortunately, three consecutive health ministers of Maharashtra have not found time to give the bill final approval. The BNHRA was enacted in 1950 but the rules were not prepared for 55 years after its enactment. Even after the rules were drafted, their final approval has been pending for the last four years.

Clearly there is a long way to go after the enactment of the Central Act, 2010. The IMA still has time to lobby for the legitimate interests of doctors. But it must come up with concrete, substantive suggestions.

Unresolved problems in the Act

There are several problem areas in the Act. Some of these arise out of certain sweeping provisions. For example, according to 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 stabilise the emergency medical condition of any individual who comes or is brought to such clinical establishment." *[emphasis added]* This means that all clinical establishments will be expected to intervene to "stabilise" the patient with an emergency medical condition – whether myocardial infarction or appendicitis – before transferring them. This imposes too much responsibility on clinical establishments. Though there is a caveat - that such interventions should be made "within the staff and facilities available" - its interpretation will become a matter of dispute. The original Supreme Court directive was in the context of life-saving first aid for accident victims. It is irrational, unrealistic and

unfair to expect doctors to extend it to all kinds of emergency situations. Inclusion of such provisions gives a good handle for doctors to oppose the very idea of regulation. Indeed, doctors' organisations may challenge the constitutional validity of this provision and this will delay the implementation of the Act.

Second, there is no provision for additional machinery to handle the additional workload of regulating private clinical establishments. So either the Act will be not implemented or it will be implemented in a bureaucratic manner - in either case, both honest doctors and patients will suffer. For example, though the National Council to be established under this Act will have a special secretary, it will also have the director-general (DG) of health services, Ministry of Health and Family Welfare, as an ex-officio member and chairperson. One implication is that crucial meetings and decisions can get delayed because the DG will not have time for this additional duty. At the state level, there will not be any new appointment to manage the work - the secretary, health and the director of health services will be the ex-officio chairman and secretary respectively. The situation at the district level will be even worse because the chairperson and the secretary of the district eregistering authority, which will be the basic functional unit of implementation of this Act, will be the district collector and the district health officer, respectively. For all these functionaries, the Act will increase their work substantially, and the work will not be completed in time, and with due justice.

Third, hospital owners wishing to appeal against the order of the district health authority will have to approach the state council. There are thousands of medical establishments in each state and at least in the initial period, there are bound to be many disputes with the district registering authority. These doctors will have to go to the state capital for all work associated with these disputes. When the draft rules were being formulated for the Bombay Nursing Home Registration Act in 2005, the Jan Aarogya Abhiyan had suggested a "multi stakeholder district advisory committee" to advise the district authority so that there would be some forum for dialogue with the district registering authority and thereby some accountability at the district level. This suggestion has not been accepted. If all stakeholders put pressure on the government, such suggestions can still be pushed. But this will require using logic and facts to engage with the authorities.

A much more vigorous and concrete debate will have to take place while formulating minimum standards under this Central Act. In Maharashtra, the Jan Aarogya Abhiyan has argued that minimum standards must not be limited to structural standards like physical space, equipment and staff; they should include some process standards, including observance of human rights of patients. This was accepted and some patients' rights were included in the draft rules under the BNHRA, though currently this is in limbo. The point is that the government must be forced to enter into a dialogue with stakeholders; all stakeholders must have a role in the formulation and implementation of rules and procedures under the new Act.

But for this to happen, doctors' organisations must change their attitude and come up with more credible arguments and concrete suggestions.

There are many other issues, all of which require proactive, vigorous engagement with the concerned authorities.

Very recently the central government announced that it would chart out a "National Standard Treatment Policy". (9). This policy is meant to ensure that doctors use optimum medical procedures and prescribe limited drugs so that patients are neither overcharged nor over-drugged during treatment. Ranjit Roy Chowdhary, a leading clinical pharmacologist, who is part of the policy making team, has stated: "The policy will also safeguard doctors." He has added: "If a patient dies due to a drug which is not as per the schedule that we give, [the doctor] can be in trouble. But for those who follow the policy, there will be a ring of protection since the medicines and treatments were as per standard policy prepared by experts from across the country,"

With such initiatives coming up, doctors' organisations will have to be more active and positive about regulation. Will this happen?

References

1. Kannabiran K. The Clinical Establishments (Registration and Regulation) Bill, 2007: a brief review. *Indian J Med Ethics*. 2008 Jul-Sep;5(3):108-9.
2. Samaran G. Presidential address. Indian Medical Association [Internet]. 2010 Jun 22 [cited 2010 Sep 23]. Available from: http://www.ima-india.org/Dr%20Samaram%20Presidential%20Address.pdf
3. The Clinical Establishments (Registration and Regulation) Bill, 2010. Bill No 43 of 2010 [Internet]. 2010 Mar [cited 2010 Sep 27]. Available from: http://www.prsindia.org/uploads/media/Clinical%20Establishments/Clinical%20Establishment%20bill%202010.pdf
4. Kasimi K. Indian Medical Association disapproves Clinical Establishmente Bill. *Top News* [Internet]. Arab Emirates. 2010 Jun 30 [cited 2010 Sep 27]. Available from: http://topnews.ae/content/22653-indian-medical-association-disapproves-clinical-establishment-bill
5. Express News Service. IMA doctors against Clinical Establishments Bill. *Indian Express* [Internet]. 2010 Feb 9 [cited 2010 Sep 27]. Available from: http://www.indianexpress.com/news/ima-doctors-against-clinical-establishment-b/576939/
6. IMA opposes Clinical Establishment Bill. Zeenews.com [Internet]. 2010 Jul 16 [cited 2010 Sep 23]. Available from: http://www.zeenews.com/news641303.html
7. Parmar RS. Memorandum: IMA to observe Punjab Bandh on 15th July 2010. Indian Medical Association Punjab [Internet]. [cited 2010 Sep 27]. Available from: http://imapunjab.org/memorandum-for-15th-july.pdf
8. Indian Medical Association, Bengal State Branch. Observation on the West Bengal Medical Clinical Establishments (Registration and Regulation) Bill, 2009, Bill No. 15 of 2009. Published in the Kolkata Gazette, Wednesday, October 28, 2009 [Internet]. 2009 Oct 28 [cited 2010 Sep 23]. Available from: http://www.imabengal.org/bills_acts_rules-byelaws__judgements
9. Pandey V. New medical policy to ensure docs don't over-drug patients. *DNA* [Internet]. 2010 Sep 9 [cited 2010 Sep23]. Available from: http://www.dnaindia.com/india/report_new-medical-policy-to-ensure-docs-don-t-over-drug-patients_1435532

Statement of objects and reasons for the Central Bill

1. At present, the supervision and regulation of the quality of services provided by the health care delivery system to the people by both public and private sectors has largely remained a contentious and therefore, unresolved issue. The current structure of the health care delivery system does not provide enough incentives for improvement in efficiency. The private sector health care delivery system in India has remained largely unregulated and uncontrolled. Problems range from inadequate and inappropriate treatment, excessive use of higher technologies, and wasting of scarce resources to serious problems of medical malpractice and negligence.
2. Despite many State Legislatures having enacted laws for regulating health care providers, the general perception is that current regulatory process for health care providers in India is inadequate or not responsive to ensure health care services of acceptable quality and prevent negligence. Concerns about how to improve health care quality have continued to be frequently raised by the general public and a wide variety of stakeholders, including Government, professional associations, private providers, agencies financing health care, National Human Rights Commission and also by judiciary.
3. Accordingly, a need has long been felt for a central legislation for ensuring uniform standards of facilities and services by the clinical establishments throughout the State where the Legislative Assemblies have passed resolutions under article 252 of the Constitution and the Union territories and the States which may adopt the legislation by such resolutions.
4. In view of the above, the Clinical Establishments (Registration and Regulation) Bill, 2007 was introduced in Lok Sabha on the 30th August, 2007 and the same was referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare which made certain recommendations on the provisions of the said Bill. However, the said Bill was lapsed due to dissolution of the Fourteenth Lok Sabha.
5. It is now proposed to introduce the Clinical Establishments (Registration and Regulation) Bill, 2010 on the lines of above Bill incorporating therein certain recommendations made by the Department-related Parliamentary Standing Committee on Health and Family Welfare.
6. The salient features of the proposed legislation, inter alia, are as follows:-
   i) the proposed legislation provides for the constitution of a National Council consisting of representatives of Medical Council of India, Dental Council of India, Nursing Council of India, the Pharmacy Council of India, the Indian Systems of Medicines representing Ayurveda, Siddha, Unani and Homoeopathy systems, the Indian Medical Association, the Bureau of Indian Standards, the Zonal Councils setup under the States Reorganisation Act, 1956, the North-Eastern Council, etc.;
   ii) the function of the National Council shall be to determine the standards for the clinical establishment, classify the clinical establishment into different categories, develop the minimum standards and their periodic review, compile, maintain and update a National Register of clinical establishments, perform any other function determined by the Central Government, from time to time;
   iii) the function of the State Council shall be to compile, maintain and update the State Registers of clinical establishments and to send monthly returns for updating the National Registers. The State Councils shall also publish reports on the implementation of standards within their respective States, annually;
   iv) the concerned State Governments shall, by notification, set-up an authority to be called the district registering authority under the chairmanship of District Collector for registration of clinical establishments;
   v) no person shall carry on a clinical establishment unless it has been registered in accordance with the provisions of the proposed Bill. The legislation would not apply to the clinical establishments of the Armed Forces;
   vi) it is proposed that clinical establishments already in existence may be allowed for provisional registration to carry out their business. There shall be no prior enquiry for provisional registration. But the authority shall have power to make enquiry in accordance with such rules as may be prescribed.
   vii) the clinical establishment having provisional registration shall fulfil the standards which may be notified for the purpose. The provisional certificate shall not be granted or renewed beyond a period of two years from the date of notification of standards;
   viii) any clinical establishment may apply for permanent registration in such form and shall pay such fee as may be prescribed by the State Government. A detailed procedure for permanent registration is being provided in the proposed legislation;
   ix) the authority shall have power to cancel the registration of the clinical establishment which fails to comply with the conditions prescribed by the Central Government. The authority shall have power to inspect a registered clinical establishment. Any person aggrieved by an order of the registering authority shall prefer an appeal to the State Council;
   x) the clinical establishments shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilise the emergency medical condition of any individual who comes or is brought to such clinical establishment;
   xi) the certificate of permanent registration issued by the authority is valid for a period of five years from the date of issue;
   xii) there shall be register of clinical establishment at the district level, State level and the National level;
   xiii) if any person contravenes any provisions of the proposed legislation or any rules made there under, he shall be punished with fine. The maximum penalty being provided is rupees five lakh;
   xiv) conferring power upon an authority, to levy monetary penalty for violation of the provisions of sections 41 and 42 of the proposed Bill;
   xv) any person aggrieved by the decision of authority may prefer an appeal to the State Council.