EDITORIAL

The Clinical Establishments (Registration and Regulation) Bill 2007: A brief review

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Relevance of the Bill

Article 47 of the Constitution of India says:

The state shall regard the raising of the level of nutrition and the standard of living of its people, and the improvement of public health, as among its primary duties and, in particular, the state shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and drugs which are injurious to health.

At a time when the meaning of the fundamental right to life has been expanded and would even in minimalist terms include the right to health and nutrition, the National Health Policy 2002 expresses concern that the "existing public health infrastructure is far from satisfactory", and locates the problem in insufficient funding and trained personnel, gross inadequacy of consumables, obsolescent equipment, dilapidated buildings, non-availability of essential drugs, low quality of services, and overcrowding of poor facilities. The policy goes on to trace the implications of this negligence on poor and marginalised communities that are pushed to private facilities "despite the fact that most of these patients do not have the means to make out-of-pocket payments for private health services except at the cost of other essential expenditure for items such as basic nutrition" (1). The Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure, constituted by the Planning Commission for the 11th Five-Year Plan, points out in its report that although the "for-profit private sector accounts for...50% of inpatient care and 60-70% of outpatient care...[it] has...remained largely fragmented and uncontrolled", with problems ranging from "inadequate and inappropriate treatments, excessive use of higher technologies, and wasting of scarce resources, to serious problems of medical malpractice and negligence" (2).

The Clinical Establishments (Registration and Regulation) Bill 2007 (3) reiterates the concerns of the Working Group in its statement of objects and reasons. This is an Act that is proposed to be brought into force to streamline the functioning and provision of services by clinical establishments. Importantly, it is a matter that regulates not just allopathic facilities, but also clinical establishments that provide services in a range of Indian systems of medicine. The relevance of this enactment lies in the fact that there has been an increasing concern about the gross inadequacy of public health facilities on the one side and the lack of any standards to regulate the existing facilities – both public and private – on the other. The virtual collapse of the public health system, particularly in rural and remote tribal areas, has rendered already marginalised communities totally vulnerable to unregulated, unmonitored health care providers. In the cities there has been a takeover of health services by corporate health care, without any transparent processes of accountability being put in place. With the recent discovery of the theft of kidneys from unsuspecting poor people and the offer of huge sums of money in return for kidneys to people on the brink of survival by a "homoeopathic" doctor who ran a hospital that specialised in kidney transplants near Delhi, the question of regulation of clinical establishments is an urgent one.

Main features

The Bill defines a "clinical establishment" as:

(i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities with beds requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or

(ii) a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not, and includes clinical establishments owned, controlled or managed by the Government, a Trust, a Corporation, a local authority and a single doctor establishment, but does not include the clinical establishments owned, controlled or managed by the Armed Forces. [(Section 2[c])

Recognised systems of medicine include allopathy, yoga, naturopathy, ayurveda, homoeopathy, siddha and unani, or any other system of medicine as may be recognised by the central government.

The Bill envisages the constitution of a national council that will draw representatives from professional bodies in the fields of dentistry, nursing, associations of the different systems of medicine, etc. The function of this council will be to determine standards for clinical establishments, prescribe minimum standards, develop classifications of these establishments, and take responsibility for periodic review and maintenance of a national register of clinical establishments. The state director

of health services or any officer subordinate to him will be designated state registrar of clinical establishments, and will be responsible under the proposed legislation for the performance of functions of classification, review and compilation of records at the state level, to be sent to the national council periodically. Registration, under the proposed legislation is mandatory; the Bill provides for provisional registration for a period not exceeding three years for establishments already in existence without prior inquiry. Permanent registration will be granted only to those establishments that are found to fulfil the standards set by the central government.

The proposed legislation envisages a pyramidal structure for the registering authorities from the district to the national level, with the authorities both at the state and district level being personnel of the department of health services.

The legislation will not apply in the states of Andhra Pradesh, Maharashtra, Madhya Pradesh, Manipur, Nagaland, Orissa, Punjab and West Bengal. Of these states West Bengal and Maharashtra have in place Acts that came into force in 1950 and 1949 respectively, Madhya Pradesh in 1973, the other states relatively recently between 1991 and 2002.

Issues of concern

In a situation of complete lack of accountability, any move towards regulation and monitoring is welcome. While generally concerns have been raised with respect to the impossibility of monitoring rural health care and unscrupulous practices at the lower end, what is equally necessary to address is the lack of accountability in corporate health care and unregulated practices at the upper end of the cost ladder. Between these two points lie a host of variations in health care delivery that are unregulated and for the most part uncharted. There is also the encouraging reality of community health care initiatives across the country that have done remarkable work under extremely difficult conditions, developing priorities, standards and measures, and demonstrating results with complete transparency and accountability. What these initiatives have foregrounded is the positive impact of community involvement in public health. Somewhat along these lines, the Working Group, in its report, recommended the involvement of *panchayati raj* institutions in the monitoring and audit of clinical establishments (para 39). Building capacities at the local level to undertake these tasks and delegating the tasks to representatives of local communities would go a long way in strengthening democratic systems of governance. It would also create the possibilities for community participation in effective health care delivery, and would temper state regulation with participatory decision making. Similarly, in urban areas it should be possible to constitute a regulatory body that draws on demonstrated commitment and work in the areas of health care and institutional ethics.

The Bill, however, proposes a bureaucratic structure controlled by the office of the director of health services, who is also in charge of state-run health facilities over which the Bill exercises jurisdiction. The question is not whether the state department of health will report its own lapses, but on the propriety of regulating and judging establishments including its own.

There are already in place a network of agencies that exercise specific jurisdictions over clinical establishments. Apart from constituting the national councils, the proposed legislation does not delineate overriding powers with respect to other agencies and/or laws, a gap that will inevitably pose problems in implementation.

Finally, the Clinical Establishments (Registration and Regulation) Bill 2007 will come into force only in the states of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim, and in the Union Territories. Schedule I of the Bill lists eight states where it will not apply as there are laws already in place. However, as the Working Group reports, in at least three states/Union Territories, the legislations remain completely ineffective and unimplemented. There has been no audit of state legislations that may point us to areas of concern and the regional specificities in efficiency or otherwise in each of the states that have these laws.

Conclusion

Health and human rights activists have for at least two decades now demanded a closer scrutiny of medical establishments and health care systems. This demand has focused on a range of specific concerns – mental health care, primary health care and sex-selective abortions, to randomly name a few – alongside a more general demand for more effective public health services. There has also been a growing acknowledgement among practitioners of allopathy of possible conversations between it and other systems of Indian medicine. At the same time there has been a resistance to controls by medical professionals across the board, the most telling example being the case of regulation under the Pre-conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act (PCPNDT Act) 1994 (4).

This Bill comes as a response to the demand for greater scrutiny in the wake of spiralling malpractices and gross negligence. In terms of its objects and reasons, therefore, it is a welcome move. In terms of its operational elements, however, there are too many gaps, which might well mean that we have one more legislative response to a public demand that is a mere "action taken report" that cannot be implemented. Finally, the question of self-regulation, transparency and its prospects where clinical establishments are concerned is one that must be revisited time and again by professional bodies and individual practitioners. The resistance to the commodification of health services, and unethical, illegal practices need to come as much from within as without.

References

1. Ministry of health and family welfare, government of India. National Health Policy, 2002, para 2.4 [cited 2008 Jun 5]. Available from: http://mohfw.nic.in/np2002.htm
2. Government of India. Report of The Working Group on Clinical Establishments: Professional Services Regulation and Accreditation of Health Care Infrastructure. New Delhi: Planning Commission; 2006, p.6.
3. The Clinical Establishments (Registration and Regulation) Bill 2007 [cited 2008 Jun 5]. Available from: http://rajyasabha.nic.in/legislative/amendbills/health/Clinical_bill.pdf
4. Ministry of health and family welfare. Government of India. The Pre-conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex-selection) Act, 1994. [cited 2008 Jun 5]. Available from: http://pndt.gov.in.