Critical Issues in Regulatory Provisions for Private Medical Sector

Anant Phadke

This article is based on discussions in various meetings of representatives of various organizations in Mumbai & Pune -- CEHAT, Association of Medical Consultants, Mumbai,, Forum for Medical Ethics, ACASH, Health Committee Lokvidnyan Saanghatana Pune, WACHA , Women's Centre. In a way it reflects the consensus amongst these organizations as it emerged during these meetings.

It is well known that in India though the private medical sector is the main provider of medical services, there is hardly any system to regulate the quality, ethicality and pricing in this sector, It is also well known that different studies have shown that the quality of care in majority of establishments in the Private Sector is quite questionable. There has been therefore, the long-standing demands of the People's Health Movement that regulation be brought in to ensure minimum standards. Therefore in Maharashtra, when the govt. initiated the process of strengthening the Bombay Nursing Home Registration Act, (BNHRA) 1949, health groups welcomed this step, though this step was taken as part of a World Bank supported project. The Draft of the amended BNHRA has been circulated for almost a year now. Detailed discussions have been held on this Draft. Many issues as regards framing of regulatory provisions for the private medical sector have surfaced during these discussions. These issues are not specific to Maharashtra and hence have been shared below.

1) State regulation or self-regulation?

Self –regulation by the medical professionals is of course much more desirable. It would avoid the undesirable strengthening of the State Power as an alien power ruling over the civil society, would avoid the possibilities of unnecessary harassment of medicos and avoid of corruption. But the private medical sector in India is so disorganized, so much used to the totally unregulated, system of medical care, so far away from enlightened self-interest, that today, there are no hopes that in the foreseeable future, it would come together to form the necessary regulatory mechanism for itself. Hence today, there is no alternative to state regulation. However, the latter itself can be so organized that different stake-holders in the provision of medical services, would have considerable role in deciding and monitoring, the key aspects of the state regulation. Thus these different stake- holders can participate actively in framing the various provisions under this act. The act itself can provide for a much larger role for the different stake holders in controlling the execution of the act and its monitoring. This is what is being attempted in Maharashtra.

2) Stake holder's involvement in the regulatory process-

If different stake holders are involved in the regulatory process, right from the constitution of the regulatory authority, its functioning later would be much more smooth. The Draft amendments to the BNHRA, prepared by Sunil Nandaraj providers for inclusion in the regulatory bodies one representative each from each of the recognised therapy and from hospital owners, owners of Diagnostic Centres and one representative each from consumer, women's and Non-government health organizations. In both the local and state level bodies, such non-governmental representatives as suggested in the Draft amendment, out number govt. appointed officials.

The Clinical Establishment Board, which would be the highest regulatory body at the state level, as suggested in the Draft amendment, would decide the bye rules, and the minimum standards for various types of clinical establishments. Since this body would also not be predominantly of govt. officials, its easier for various stake holders to actively lobby to

see that the minimum standards set by this body are reasonable. Similarly the Draft providers that the Competent Authority, at the district/municipality level would also have similar representation from stake holders. The C.A. would surprise, guide critical decisions of the Local Supervisory Authority, which will be involved in the day to day management of the regulatory mechanism. In the Revised Draft, there is no place for a representative from the Indian Medical Association in the C.A. IMA representative should be included as the IMA is the largest, oldest body of medical professionals.

3) Limited Scope of the proposed regulatory system-

There would be two limitations of the regulatory system that can be initiated in the immediate future –

a) Mainly structural standards –

The regulatory provisions would be limited primarily to lay down minimum infrastructural and human power

Standards. Thus out of the three aspects of the work of the medical establishments- structure, process and outcomes, only the first one would be covered in the immediate future. To prepare and to monitor consensus standards for diagnostic and therapeutic protocols in order to monitor process-standards is a very tall order today, given the totally amorphous nature of medical establishments in India. However, a beginning can be made with simple measures like giving a copy of the case-paper to patients, giving adequate information to the patients etc. Standards for outcomes are much more difficult to agree upon and monitor. Hence, today, this needs to be deleted today. Consensus about minimum structural norms for various types of medical establishments would itself be a major task today.

The clinical establishment board cannot by itself make standards. Making standards is a specialised job. The board would establish committees to harness expertise in specialised branches of medicine.

b) Regulation of non-statutory practitioners

Statutory bodies for regulating the quality and ethics of medical care also exist for homeopathy, Ayurveda and Unani systems, in the form of their respective councils. Though today, they are quite inactive, they are at least there. But therapies like acupressure/acupuncture, naturopathy, are devoid of such regulatory councils. [It is highly doubtful whether electropathy, reiki, chromotherapy etc. have any scientific basis.] Unless such councils are set up and some standards of diagnosis and treatment for these therapies are set, medical professionals belonging to these streams can not be regulated through acts like the amended BNHRA. But this function is outside the purview of the act like BNHRA. To bring such non allopaths under some statutory control would require a parallel process.

4) Avoiding unnecessary harassment of doctors-

In the minds of the doctors, the most common and strong fear about State regulation is that the regulatory officials would harass doctors by misusing the discretionary powers that they acquire. The scope for such harassment needs to be reduced without scarifying the affectivity of regulation. Following specific provisions have been included or have been suggested towards this end-

a) Time –frame for disposal of applications-

The concerned medical establishment would be deemed to have been registered if there is no response from the C.A. within 3 months of the receipt of application for

registration. [The C.A. would be the town level regulatory authority] The owns of taking decision about the application for registration within a defined time-frame would be with Competent Authority (C.A.)

b) Reminder notice for renewal –

The C.A. should send by registered post, one month in advance, notice to the medical establishment, reminding the medical establishment about the renewal date of registration. The charge for this service would be included in the overall service fee to be charged to the M.E. Such reminder notice is necessary if the regulatory process is to be doctor friendly also, in addition to being consumer-friendly.

c) Rectification period-

If the C.A. feels on inspection of the medical establishment that it is inadequate in respect of certain minimum standards laid down by the Clinical Establishment Board, (the state level, highest regulatory authority), the M.E. should be given a reasonable rectification period to rectify these inadequacies. The rectifications needed should be given in writing and no fresh points be raised where application is submitted again after effecting these rectifications.

d) Non-routine, surprise inspections-

There is a fear amongst medical professionals that the state officials may make surprise visits to hospitals, dig up some lacunae and harass the hospital owner, to get a bribe. The act provides for inspection only on application for registration or for renewal. However, it can be specified in the bye-rules that surprise visits can take place only on receipt of a written complaint from a patient/citizen/or its representative body about sub standards facilities. On receipt of such a complaint, the decision to carry out surprise visit should taken at the highest level in the C.A. The reason for this inspection, the findings of this inspection, the recommendation to the C.A. by the LSA should be recorded in writing and a copy be given to the M.E. The competent authority must give written order with reasons for cancellation of registration..

If the complaint turns out to be vexatious [as different from a wrong complaint] the complainant should be heavily fined. Secondly, there should be a clear distinction between administrative lapses and evading registration, imprisonment should be reserved only for evaders for a second and subsequent offence as has been provided in the existing BNHRA.

e) Ombudsman :

The appeal against the order of any body under this act should be heard by a Ombudsman-who could be a retired High court judge who will constitute an appellate authority and also serve as grievance redressal authority. Since the various authorities /boards created under the act are part of decision making process for rejection of application for registration, can they can not hear appeal against their own orders. There should be a provision to appeal to the health secretary or such high level health bureaucrat in case the ombudsman is on leave or non-functional for any reason. Otherwise appeals may not be heard for months together.

5) Reducing unnecessary administrative work-

Most hospitals, medical establishments in India are very small and do not have separate administrative human power. To reduce their administrative work to the minimum (without reducing the quality of regulation) the renewal of registration should be triennial and not

annual. Standards are unlikely to change every year or it is less likely that M.E's infrastructural standards would deteriorate in one year.

The M.E. should not be subjected to different registration procedures for different facilities it provides to the patients. Thus separate registration process to register as MTP centre, as sonology centre, as hospital etc. should be avoided. There should be a single form, with different annexures, to be submitted to a single authority. At least, there should be a single window system for registration under different acts.

6) Cost of the regulatory process-

The Draft amendment to BNHRA provides for registration fee (for three years) ranging from Rs. 7500/- for small rural hospitals to Rs, 20,000/- for Scan Centres in metropolis. Doctors are hotly contesting these charges. Firstly as confirmed by a Supreme Court verdict, registration charges have to be nominal. But the state can levy service fee for providing the regulatory service. Instead of debating about figures, proposed arbitrarily by different stakeholders, let there by an agreement that the service fee should be just adequate to pay for the cost of regulation. This cost be proportionately distributed over various medical establishments, depending upon their size turnover. This cost would not be much, as the only active service that the regulatory authority would provide for most MEs is an inspection once in three years. Including administrative overheads, the cost per M.E. per year would not be burdensome. This cost would be ultimately borne by the people, through increased cost of health care. But this cost would not be a burden to the patient. The charge of Rs. 1500/- per three years for small hospitals in rural areas as suggested in the Draft amendment to BNHRA, would be less than half a percent of the income of these hospitals from their patients.

This cost of the regulatory system would increase if doctors insist that the team that would inspect the Medial Establishment should consist of doctors. In reality a substantial part of the work of the inspection would involve cross-checking the availability of various infrastructural and human power norms, as laid down by the Clinical Establishment Board. These norms would pertain. to

i. Floor space, water supply etc
ii. Certain medical equipments depending upon the nature of the Medical Establishment
iii. Availability of trained human power.

A well-trained paramedic can very well do this job and the help of an expert would be required only occasionally.

The government institution should also pay the registration fees and other charges as applicable especially when the fees collected will be used for implementation and enforcement of the act.

7) Punishment for non-registration

If a M.E. is found to have been carrying out the profession without registering itself, BNHRA 1949, providers for imprisonment for up to 3 months for second and subsequent offence and a fine of Rs. 500/-. There is strong sentiment amongst doctors against this clause of imprisonment; especially when the Draft amendment proposes to increase it. This second offence is tantamount to a criminal offence, hence the provision for imprisonment is justified. However, it need not be increased. As provided in the existing BNHRA, imprisonment should be there only for second and subsequent offence. This makes a clear distinction

between failure of registration and evading of registration and hence this clause would be directed only against bogus doctors and criminals.

8) Obligations towards patients and public health :

a) Life saving first aid: As per Supreme Court judgement, ME must administer necessary first aid and take other life saving or stabilising emergency measures appropriate for that grade of establishment in medico-legal or potentially medico-legal cases such as victims of road accidents, accidental or induced burns or poisoning or criminal assaults and the like which present themselves at the establishment.

There are nursing homes which conduct only minor day-surgeries like ophthalmic or ENT. There is no doctor available after the surgeon has left, since generally this is not needed. Such set-ups can not cater to any general medical or accident emergency even to provide life saving support. So only hospitals should have this obligation.

However, even the nursing staff in all clinical establishments should be trained to give life saving first aid consisting of clearing of the airway, mouth to mouth breathing, external cardiac message, starting an IV line, arresting external bleeding by pressure bandage, proper positioning of the unconscious patient.

b) Participation in national health programmes : The reasonable obligation would be as follows -All the private clinical establishments will follow the mandatory therapeutic guidelines for diseases covered under various national health programmes and as declared by the state and central government from time to time, and to co-operate with the state health authorities for implementing National Health Programmes.

c) Obligation towards HIV positive patients : The consensus about this issue is as follows: The government with the help of concerned experts in the field including those in NGOs, should prepare Standard Orientation courses about care of HIV positive patients, for different types of medical care workers ranging from doctors to attendants. It would include basics of HIV, AIDS including its social aspects, about Universal Precautions, and the duty of doctors, and other medical professionals towards HIV positive patients.

This course should be aimed at dispelling the excessive scare of medical workers getting HIV infection from HIV positive patients. This course be publicly funded. Half the funds can come from the service charges collected from MEs under the MME Act. The Maharashtra government must set up adequate facilities so that all medical workers in the MEs can undergo this course within a year's time of the enforcement of this amended act.

All medical workers must register themselves to undergo this course within a year of the enactment of MEA. As soon as all the staff any M.E. have completed this course, it shall certainly execute the policy that there shall not be any discrimination against any HIV positive patients. After two years no ME shall employ any person as medical staff who has not undergone this certificate course.

Conclusion

There are some critical issues in framing the regulatory provisions for the private medical sector. If the stakeholders, especially the medical establishment are involved in framing of the regulatory provisions, many of these issues can be satisfactorily resolved. It is up to the leadership amongst medical professionals, NGOs, health and consumer activists, politicians and bureaucrats to work towards a realistic, viable, regulatory system which would do justice to all the stakeholders in the private medial sector in India.

****