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Kindly recall our conversations on the legislative framework to enhance transparency and accountability of clinical establishments in Andhra Pradesh, and the desirability of the adopting the Clinical Establishments (Registration and Regulation) Act, 2010 (Act No. 23 of 2010) (CEA) enacted by the Parliament under Article 252 of the Constitution.

We have examined the issue carefully and studied the CEA and its status of application in various states. We have also carefully studied the issues raised by the Indian Medical Association on the subject. We held two detailed consultations and interactions – one in Hyderabad on 17th August, 2017, and another in Guntur on 19th August, 2017 with reputed professionals, experts and representatives of professional bodies.

1. Applicability and Desirability of CEA to Andhra Pradesh

CEA was enacted by Parliament in August 2010. Public health and regulation of hospitals and dispensaries falls under the legislative jurisdiction of states (item 6 of List II of Seventh Schedule). However, Parliament can make laws in respect of state subjects under Article 252 if two or more State legislatures

pass resolutions to that effect, and any Act so passed shall apply to such states and other states which adopt it by resolution of the Legislature. Accordingly the Legislatures of Arunachal Pradesh, Himachal Pradesh, Sikkim and Mizoram passed such resolutions seeking enactment of a law by Parliament, and CEA came into effect in those four states and 6 Union Territories in 2012. Subsequently six more states (Bihar, Jharkhand, Rajasthan, Uttar Pradesh, Uttarakhand and Assam) adopted CEA by resolutions. We also understand that Telangana State Legislature resolved adopting CEA (Legislative Assembly on 25th March 2017 and Legislative Council on 27th March, 2017).

Without going into merits or demerits of the CEA, we strongly recommend **against** the State adopting the law by resolution. Under Article 252 (2), once the State legislature requests the Parliament to enact such a law or adopts it by resolution, the law of Parliament can be amended or repealed only by another Act of Parliament. **The State permanently loses legislative jurisdiction over that aspect of a state subject, and the State Legislature cannot withdraw from the legislation in respect of the subject matter once it cedes jurisdiction to the Parliament.** Therefore it is wholly inadvisable for the State to adopt CEA by resolution, because no amendment can be carried out, nor can the law be repealed by the State legislature. **It is preferable to enact a State law for the purpose so that the State retains the legislative jurisdiction, and has the power to take corrective action as and when needed.**

2. Key Provisions of Clinical Establishment Act

The stated objective of CEA is to "provide for the registration and regulation of clinical establishments with a view to prescribe minimum standards of facilities

and services which may be provided by them so that the mandate of Article 47 of the Constitution for improvement in public health may be achieved". The cardinal features of the law are as follows:

a. CEA covers all institutions and facilities offering diagnostic, treatment, or care services, small or big, owned by government or private sector, single doctor or big hospitals, encompassing all systems including AYUSH.

b. The law prescribes minimum mandatory standards of facilities, services, personnel and maintenance of records and reporting to be fulfilled.

c. CEA provides for mandatory registration without which a clinical establishment cannot be run.

d. The law provides for inspection of registered clinical establishments and their cancellation if conditions are violated. The law also provides for monetary penalties for violation.

e. CEA provides for prescribing a range of tariffs for all services provided by the clinical establishments.

f. The law provides for patient management guidelines for all health conditions.

3. A Case for a Law to Enhance Public trust in Clinical Establishments

Healthcare is a vital service for all citizens. In India about 75% of healthcare costs are borne by the citizens; most of it is out-of-pocket expenditure. As public health facilities are overcrowded and underfunded, more and more people are forced to seek private care at personal cost. As primary healthcare

is inadequate, underfunded and often unavailable, people are compelled to seek hospital care even for relatively simple problems which are neither prevented, nor addressed early to prevent complications. As a result, many primary and family care problems are converted into secondary and tertiary care cases. The private sector is stepping in to meet the growing, unmet demand for healthcare. But modern hospital care is costly involving large infrastructure and space in urban settings, high cost diagnostic and therapeutic equipment in a sector that is witnessing rapid infusion of sophisticated, albeit costly technology, and highly trained, skilled medical and paramedical personnel. As a result, private hospital care has become expensive. As many hospitals are over capitalized, the temptation to resort to inflated billing in order to service the debt is very high. In addition, in the prevailing climate of low public morality and lack of accountability, malpractices, spurious or unnecessary diagnostics and procedures, and heroic costly interventions in the last days and weeks of a terminally ill patient's life have become increasingly common. In healthcare, there is a natural asymmetry of power and knowledge between the care giver and patient facing physical discomfort, economic privation and potentially life threating illness. In the absence of mechanisms to enhance transparency and accountability and promote informed choice, patients and their families are helpless in dealing with sickness, high costs of medical care and potential consequences of serious illness.

In the current climate in India, there is a growing mistrust between the medical profession and care givers on one side, and the patients, their families and society at large on the other side. Mistrust between the profession and general public is detrimental to the interests of both. The physicians, hospitals and care givers who are traditionally regarded as symbols of compassion and divinity are losing public esteem and even ethical, responsible practitioners

are besmirched by a general decline in public trust. The patients and society are losing even more.

As every wise physician understands and acknowledges, a large part of patient's recovery from illness is based on his/her confidence and trust in care giver. While doctors, care givers, medications and interventions are vital, recovery and cure are critically dependent on the patient's mind, the trust in the care giver and the optimism and confidence that he/she is getting a fair deal and the best possible care. Once this trust is eroded, patients and society suffer as grievously as medical profession loses. Therefore a legal framework to promote accountability and restore public trust is necessary.

4. Dangers of over-regulation of clinical establishments

In all civilized, modern societies, healthcare is regarded as public good, and governments have assumed the responsibility of providing quality care without out-of-pocket expenditure. In India, for a variety of reasons, government has largely failed to provide quality care to people. As a result, people are compelled to seek care from private providers, and the share of private sector in out-patient care, in-patient care and diagnostic services has been growing over the years. In such a climate, over regulation and creation of license-permit-control-inspection raj will be extremely counterproductive and dangerous. Excess control leads to corruption, high costs and rigid uniformity without improving quality of care.

a) The bulk of the family and secondary care is provided by small nursing homes with 20-30 beds or fewer, with the doctors, often wife and husband, living in the same premises, available 24x7, and providing low cost, reasonable quality care in small towns. Rigid standards of infrastructure,

equipment and personnel for such establishments will only escalate costs needlessly without improving quality. India is still a largely poor country, and cost control and quality care should go together.

b) Each establishment must have the right to decide the amenities, infrastructure and equipment it wishes to invest in. People have a right to know what they can expect from any establishment; but forcing the care givers to conform to a rigid, uniform standard will not benefit patients.

c) There are about 500,000 untrained, unqualified rural practitioners, acting as the first point of contact. Our paramount need is to encourage and facilitate spread of qualified and well-trained medical graduates and paramedical personnel to all corners of the nation, and create conditions for them to be the first point of contact. Excessive regulation of such single-doctor, out–patient practice will only act as a disincentive to the larger purpose of improving access to quality care at primary level.

d) Patients have a right to know the anticipated cost of service in an establishment. But prescribing standard tariffs for all or most services is simply not feasible. The quality of physical amenities, the equipment, and the skill, sophistication, experience, credibility and market demand of the expert care givers vary significantly from place to place. Therefore it is undesirable and counterproductive to prescribe tariffs. Instead, patients have a right to know the amenities, equipment and quality of personnel available in each hospital, and the approximate cost of services the establishment charges. Such knowledge will facilitate informed decision making by each patient, allowing market forces and competition to operate to the advantage of the society. Mindless regulation of tariffs will only

create avenues of corruption, and will ultimately undermine competition, choice and quality of care.

e) Broad institutional guidelines for care of patients are necessary. But detailed guidelines for handling each ailment are best left to competent professionals and experts in each specialty. The broad objective of the law should be to reconcile harmoniously the cost and quality of care. Excessive laboratory investigations, defensive medicine, needless procedures to exclude obscure and rare causes, overenthusiastic interventions in cases of even terminal illness will escalate costs dramatically, cause needless pain and suffering and cause great hardship to families. If law seeks to give clinical guidelines, they will tend to cover all contingencies, without regard to costs and benefits. Therefore it is preferable to have by law broader institutional guidelines for investigation and clinical practice, harmoniously reconciling cost and quality. Regarding individual care giver's responsibilities and liability, the other laws – notably the Medical Council of India Act, and the Consumer Protection Act already provide for them, and it is best to avoid duplication and overlap of legislation.

5. Focus on draft legislation for Andhra Pradesh

Keeping these factors in mind, and in the light of the feedback in consultations with experts and professionals in Hyderabad and Guntur (details enclosed), I am of the considered view that public interest is best served if the law has the following approaches:

a) Complete transparency in respect of clinical establishments should be the defining feature of the law. All information regarding the infrastructure, equipment, personnel, background and experience of medical

professionals, and the tariffs charged for various facilities, investigations, services and interventions should be available to the public mandatorily, and there should be a mechanism to verify the disclosures and prevent false claims. Informed choice and genuine competition are true guarantors of cost-effective delivery of healthcare and quality, not imposition of uniform standards of infrastructure and tariff regulation.

b) Regulation must not degenerate into a licence-control-inspection raj which becomes a breeding ground for corruption. The mechanism must be facilitatory with market and competition driving the system towards better care at low cost, and not degenerate into an intrusive, corrupt process.

c) Healthcare is a complex issue involving difficult decisions and choices informed by professional skills, experience, insights and wisdom. Therefore the institutional mechanism to monitor and regulate clinical establishments should be largely driven by medical experts and healthcare professionals to ensure informed decision making.

Keeping these factors and issues in mind, and in the light of feedback from experienced professionals and reputed care givers, a draft legislation, “The Andhra Pradesh Informed Choice of Clinical Establishments Act” has been drafted with the help of Sri Kalanidhi Satyanarayana, former Law Secretary of the erstwhile State of Andhra Pradesh. This law, if enacted, will replace the existing Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002. The philosophy of the law is focus on complete transparency, accountability and informed choice rather than control, rigid uniformity and arbitrariness. Also out-patient based single doctor establishments are proposed to be exempt from the registration requirements, so that the focus on hospitals and diagnostic centres is not diluted. The process of registration and

disclosure are made simple, easy and free from harassment or corruption. At the same time, to the extent regulation is needed, the enforcement should be effective and swift. This legislation gives the State total flexibility and control so that the law can be amended suitably to meet emerging challenges based on experience.

I am enclosing the draft legislation for the consideration of your government and enactment by the Andhra Pradesh Legislature, along with the other relevant documents. Should you need any further clarification, we will be glad to provide it. Foundation for Democratic Reforms will be happy to provide any assistance required in your endeavor to ensure better quality of care, enhance public trust in clinical establishments and control costs of care.

Jayaprakash Narayan

Enclosures:

1. Draft Bill – “The Andhra Pradesh Informed Choice of Clinical Establishments Act”
2. A background note on the subject
3. A brief presentation for consultations
4. Minutes of consultation in Hyderabad on Aug 17, 2017
5. Minutes of consultation in Guntur on Aug 19, 2017
6. List of participants in consultations in Hyderabad and Guntur
7. Indian Medical Association views on Clinical Establishments Act