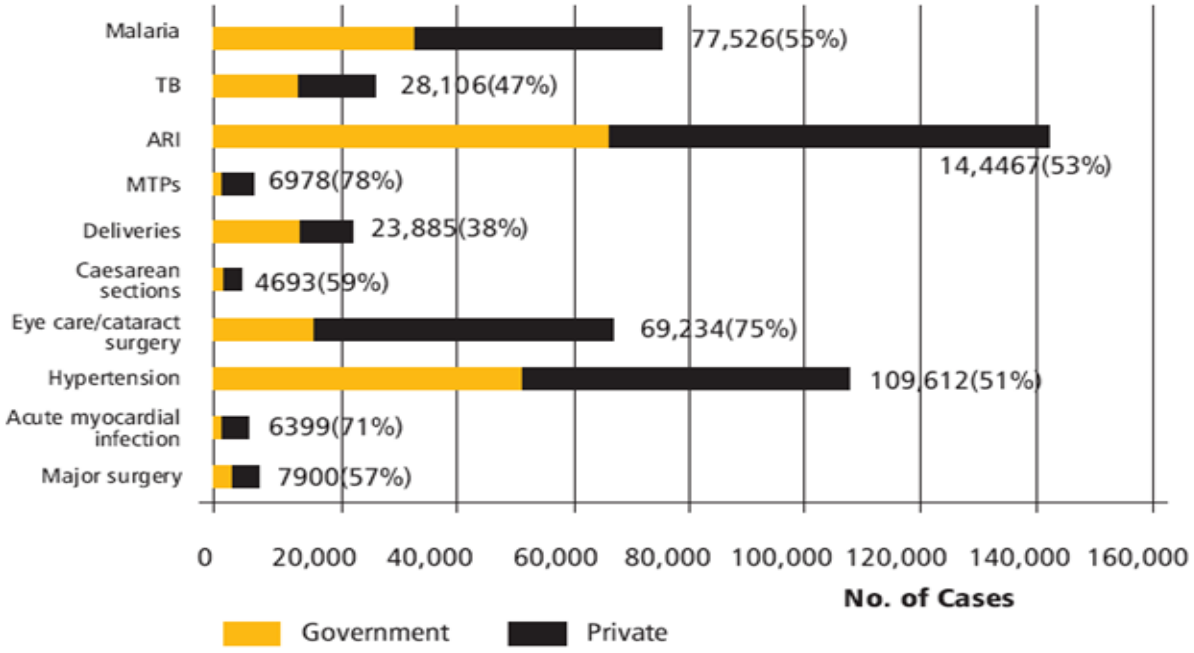
CLINICAL ESTABLISHMENTS(Registration and Regulation) BILL 2010- IMA VIEW POINT

1. The Lok Sabha has passed the Clinical Establishments(Registration and Regulation) Bill 2010 to regulate private hospitals and clinics on 03.05.10. According to Health and Family Welfare Minister Shri Ghulam Nabi Azad it would ensure that no clinic runs unless it has been duly registered in accordance with the prescribed procedure. The bill was passed without any discussion. It is a matter of serious concern for the citizens of the nation, who have always reposed faith in their family doctors and patronized their hospitals.
2. Legislation in respect of "Public health and sanitation, hospitals and dispensaries" are relatable to Entry 6 of List II — State List in the Seventh Schedule to the Constitution and Parliament has no power to make a law in the State (apart from the provisions of articles 249, 250 and 252 of the Constitution) under article 252 of the Constitution where the Legislatures of two or more States pass resolutions in pursuance of article 252 of the Constitution empowering Parliament to pass the necessary legislation on the subject, a Bill may be introduced in Parliament. The Legislatures of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim have passed such resolutions.
3. 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.
4. Initiatives to address quality of health care have become worldwide phenomena. Many countries are exploring various means and methods to improve the quality of health care services. In India the quality of services provided to the population by both public and private sectors remains largely an unaddressed issue. The current structure of the healthcare delivery system does not provide enough incentives for improvement in efficiency. Mechanisms used in other countries to produce greater efficiency, accountability, and more responsible governance in hospitals are not yet deployed in India. The private sector accounts for a substantial proportion of health care in India (50% of inpatient care and 60-70% of outpatient care), but has received relatively less attention from the policy makers as compared to the public sector.
5. **Current status of the private health sector in India** (Ref 1)
   The private health sector consists largely of sole practitioners or small nursing homes having 1-20 beds, serving an urban and semi urban clientele and focused on curative care. A survey of the qualified provider markets in eight middle-ranging districts: Khammam (AP), Nadia (WB), Jalna (MH), Kozhikode (Kerala), Ujjain (MP), Udaipur (RJ), Vaishali (BH) and Varanasi (UP) showed:
   (a) A highly skewed distribution of resources — 88% of towns have a facility compared to 24% in rural areas, with 90% of the facilities manned by sole practitioners.
   (b) The private sector has 75% of specialists and 85% of technology in their facilities.
   (c) The private sector account for 49% beds and an occupancy ratio of 44% whereas the occupancy rate is 62% in the public sector.
   (d) 75% of service delivery for dental health, mental health, orthopedics, vascular and cancer diseases and about 40% of communicable diseases and deliveries are provided by the private sector.
   (e) Public-Private share in national health programmes,:



Note: Total number of cases and the figures in parentheses are % of the total for private sector

6. Licensure, certification and accreditation of healthcare organizations have been used in many countries as tools for defining the required characteristics of acceptable healthcare services.

   Licensure : a government administered mandatory process that requires healthcare institutions to meet established minimum standards in order to operate.

   Certification : a voluntary governmental or non-governmental process that grants recognition to healthcare institutions that meet certain standards and qualifies them to advertise services or to receive payment or funding for services provided.

   Accreditation : a process by which a government or non-government agency grants recognition to healthcare institutions that meet certain standards that require continuous improvement in structures, procedures or outcomes. It is usually voluntary, time-limited and based on periodic assessments by the accrediting body, and may, like certification, be used to achieve other desirable ends such as payment or funding.

7. Various states have also enacted their own legislations for regulating clinical establishments.
   i. Bombay Nursing Homes Registration Act, 1949
   ii. The AP Private Medical Care Establishments Act,
   iii. Delhi Nursing Homes Registration Act, 1953
   iv. Orissa Clinical Establishment (Control and Regulation) Act, 1991
   v. Punjab State Nursing Home Registration Act, 1991
   vi. Manipur Nursing Home and Clinics Registration Act, 1992
   vii. Sikkim Clinical Establishments, Act 1995
   viii. Nagaland Health Care Establishments Act, 1997
   ix. MP Clinical Establishments Regulation Act.
   x. Tamilnadu private clinical establishment Act 1997

   It is also gathered that some more states such as Rajasthan, Karnataka Kerala and Haryana have drafted the regulatory legislations but have not been able to get them tabled and considered by their respective legislative assemblies.

8. The working group of planning commission has recommended (Ref 2)
   a. As far as possible, registration should be done on the basis of documents certified by licensed professionals such as Chartered Accountants, approved valuators, assessors etc.**The setting up of administrative paraphernalia for inspection is to be discouraged.**
   b. To the maximum extent possible, the responsibility of actual registration should be entrusted to Panchayati Raj Institutions (PRIs). **There is already a multiplicity of licensing/inspector authorities under various health related legislations. These are, therefore, required to be consolidated.**
   c. Due care would have to be taken to avoid over emphasis on standards for infrastructure. otherwise investments required to comply with standards might have a spiraling effect on service costs in the health sector. Greater focus would, therefore, be required on standards for service delivery.

9. Accreditation:-
   Accreditation is defined as public recognition of achievement of accreditation standards by a healthcare organization, demonstrated through an independent external assessment of that organization's level of performance in relation to the standard. It calls for excellence on continued basis. It is this feature which makes it market driven involving all stakeholders. Accreditation is also one of the established mechanism world over, as means to promote acceptance conformity assessment results, nationally as well as internationally. Accreditation is voluntary. It focuses on learning, self-development, improved performance and reducing risk. Accreditation is based on optimum standards, professional accountability and encourages healthcare organization to pursue continual excellence.

10. The basic expectations for an accreditation system are that it provides for:
    - an independent, objective evaluation process;
    - be highly credible and unbiased;
    - represent the broadest possible consensus among users and stake holders;
    - encourage improvement in the delivery of healthcare; and be relied upon by key users and stakeholders

    With rapid growth of state of art private sector in the healthcare, the accreditation program is moving closer to regulatory agenda. In most developed economies there are very strong financial incentives to seek accreditation. Governments acknowledge that independent assessment program by way of accreditation should be encouraged with incentives, more so for secondary/tertiary level of hospitals to bring in the best in terms of patient safety and quality of care.

11. The accreditation of health services originated in the U.S. during the early nineties and today is the main instrument used by the U.S. Government for the distribution of financial resources to health institutions. The Government only contracts those health institutions that have been accredited. Other regions have also applied this method, such as Canada. Australia and the Province of Catalonia, in Spain. In the Australian system, a star rating is given to hospitals like the star ratings of hotels. The rating is given according to the facilities provided. The form of accreditation, however, would vary from country to country. The United Kingdom has self-accreditation program. In Latin America, after the II Accreditation Conference (1992), the process began to be implemented through national meetings in practically all countries. In Argentina, Chile and Uruguay initiatives have been observed at the central or state levels. In the Andean sub-region the success in Bolivia, Colombia and Peru has been significant. Guatemala stands out the most in Central America; and in the Caribbean, the Dominican Republic has fully embarked on the process of accrediting its private hospitals. Cuba, until the end of 1997, had 60 hospitals

accredited. In Southeast Asia significant progress in accreditation has been accomplished in Indonesia and Thailand.

12. National Accreditation Board for Hospitals and Healthcare Providers (NABH) has come up with a uniform standard for the hospitals throughout the country. NABH is a constituent Board of Quality Council of India (QCI). It has reportedly adopted its standards and accreditation process in line with worldwide accreditation practices. The formal launch of accreditation was announced in February 2006. Other organizations like Indian Confederation for Health Care Accreditation (ICHA) have also starting the process of accreditation of health institutions. Financial rating organizations like ICRA have also started rating hospitals.

13. Recommendations of planning commission working group:

    i) Accreditation would be purely voluntary

    ii.) There can be several accrediting agencies like NABH under the Quality Council of India, Indian Confederation for Health Care Accreditation and even the Bureau of Indian Standards can take up this task.

    iii.) There would be no funding from Central Government. All the organizations will have work on a self-sustaining process. However, Government of Indian would promote accreditation.

    iv.) Accrediting agencies will have to take into consideration the requirements of Medical Tourism for which international standards will recognized by developed countries need to be adopted for accreditation.

    v.) Accrediting agencies will also have to take into view the requirements of Insurance Companies.

    vi.) Accreditation standards should be based not only on physical infrastructure, but also on standard operating procedures (SOPs) for various kinds of identifiable medical Instruments.

    vii) The focus of accreditation should be on continuous improvement in the organizational and clinical performance of health services, not just the achievement of a certificate or award or merely assuring compliance with minimum acceptable standards.

14. List of enactments regulating various activities of the healthcare institutions:-

a) Laws regarding service delivery:-

1. The Drugs and Cosmetics Act,1940(Central Act of 23 of 1940) and Rules 1945 including blood bank rules.
2. Intoxicating Drugs(Control)Rules,1983
3. The Drugs (Prices Control)Order ,1995
4. Narcotic Drugs and Psychotropic Substances Rules,1985
5. The Mental Health Act,1987 and The Central Mental Health Authority Rules,1990
6. The Pre-Conception and pre-Natal Diagnostic Techniques(Prohibition of sex selection)Act 1994 and The Pre-Conception and pre-Natal Diagnostic Techniques(Prohibition of sex selection)Rules ,1996
7. The Drugs and Magic Remedies (Objectionable Advertisements)Act 1954 and The Drugs and Magic Remedies (Objectionable Advertisements)Rules,1955
8. Corneal Grafting Act ,1963 and Corneal Grafting Rules,1963
9. The Creation of Eye –Bank Rules ,1970
10. The Medical Termination of Pregnancy Act,1971 and The Medical Termination of Pregnancy Rules ,2003
11. The Transplantation of Human Organs Act,1994 and The Transplantation of Human Organ Rules,1995
12. The Bio –Medical Waste (Management and Handling)rules,1998
13. The Clinical Thermometers(Quality Control)Order,2001

14. The Poison Act,1919(central Act XII of 1919)
15. The Standards of Weights &Measures Act,1976(Central Act 60 of 1976)& The Standards of Weights& Measures(Enforcement)Act,1985(Central Act 54 of 1985)
16. Atomic Energy Act 1962
17. The Epidemic Disease Act of 1897

b) Laws regarding the professionals :-

1 The Indian Medical Council Act ,1956
2 The Medical Council of India Regulations,2000
3 The Indian Medical Degrees Act,1916
4 Medical Practitioners Act ,1953
5 The Indian Medical Council(Professional Conduct ,Etiquette and Ethics)Regulations 2002
6 The Indian Nursing Council Act,1947
7 The Nurses and Midwives Act,1953
8 The Pharmacy Act,1948 and The Pharmacy Council of India Regulations,1952

c) Laws regarding human resources

1 The Minimum Wages Act,1948(Central Act 11 of 1940)& Rules,1950
2 Payment of Wages Act 1936
3 The Maternity Benefit Act ,1961
4 The National and Festival Holidays Act
5 The Gratuity Act 1972
6 Weekly Holidays Act ,1942(Central Act 18 of 1942)
7 The Employees Provident Fund and Miscellaneous Provisions Act ,1952 (Central Act 19 of 1952)
8 The Employees State Insurance Act
9 The Payment of Bonus Act,1965 (Central Act 21 of 1965)&Rules,1975
10 The Welfare Fund Act
11 The Industrial Employment (Standing Orders)Act 1946
12 The Industrial Disputes Act 1947
13 Payment of subsistence Act ,1972(Act 27 of 1973)

15 Laws regarding the Institutions:-

1 The Building Tax Act 1975
2 Dangerous trades &Offensive Trades and practices Act
3 The Shops& Commercial Establishment s Act
4 The General Sales Tax Act,1963/VAT
5 The Municipality (Registration of Private Hospitals and Private Paramedical Institutions)Rules and The Panchayat Raj (Registration of private Hospitals and Private paramedical institutions)Rules

16. View point of IMA

a) The private health sector in India consists of mostly clinics and small hospitals .90% is constituted by sole practitioners.
b) 83% of healthcare expenditure is out of pocket. Healthcare expenditure share of a family's budget ranges from 15 to 33 percent. Every year 3.3 percent of the population is pushed below poverty line in their attempt to provide for a family member who had fallen sick.
c) There is an increasing trend towards corporatization of healthcare supported by private healthcare insurance. This apes the American model of healthcare which is expensive but not necessarily the best. The American model has come under severe criticism for its failure to be inclusive .Corrective steps have been taken by the U S Government with huge cost to the exchequer. This is the direction in which India is moving. Any move that would increase healthcare cost will hasten this process. Access and affordability of healthcare will be severely compromised.

d) More and more young medical graduates shun family practice and prefer to be employed in specialty hospitals. Regulations and license raj will further this tendency and impede free initiatives in this service sector. India is well served by its army of family physicians and small hospitals. They provide low cost service at the doorstep of the population 24x7.This draconian bill will further demotivate doctors with a result that very little of this low cost service will be available to the people in the future. In a country with 50% of inpatient care and 70 % of ambulatory care being provided by private sector with 83 percent out of pocket expenses in healthcare expenditure ,this bill strikes death knell on the healthcare.

e) This bill unleashes a license raj .The national council is chaired by Director General of Health services, Ministry of health and Family welfare. The State council is chaired by the Secretary Health with the Director of Health services as member secretary. The district authority is chaired by the District Collector with District health officer as the convenor. With one stroke the Government have effectively made this vibrantly independent sector into an extended Government department .Draconian powers have been vested with authorities at all levels with little provisions for appeal .Huge penalties have been contemplated .On top of all these injustices Parliament has passed this bill without discussion. People deserve better.

f) Clinical medicine and public health are two eyes of modern medicine. There are lot of issues affecting patient safety and quality of care when the two streams try to impose their objectives on each other .Government should restrict itself to public health leaving the clinical care to the medical profession.

g) This bill tantamount to war on the medical profession. It is anti people in character and is bound to curtail freedom of medical practice. It will increase the healthcare cost and put the common man in great difficulty.

h) If the multiple legislations already in force have failed to bring desired result this new bill is less likely to achieve anything tangential.

i) The Planning Commission has specifically warned not to create a beaurocratic paraphernalia. The Government have ended up in exactly doing this mistake.

j) There is no precedent to this law anywhere else in the world. The trend is towards accreditation.

k) The very fact only Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim have passed resolutions empowering the Parliament shows lack of political consensus amongst large number of states.

17. IMA demands:-

1) to freeze the bill and initiate a nation wide debate
2) to look at other options like accreditation which will retain the independence of this vital sector and ensure quality
3) to exempt the healthcare institutions run by doctors from this act, in case Government still feels it is in the interest of the country.
4) to bring all healthcare legislations under single window for better governance.

Dr G Samaram **Dr Dharam Prakash**
IMA National President **IMA Hony Secretary General**

Ref 1:-Report of the National Commission on Macroeconomics and Health 2005.
Ref 2:-Report of the working group of Planning Commission of India on clinical establishments professional services regulation and accreditation of health care infrastructure for the 11th Five year Plan.