The health services planning in India is characterised by its failure to take into account the holistic picture of the health care services. In the mixed economy model the social sector is planned with a view to provide for the externality and to redistribute the services in favour of the underprivileged masses. In the post independence period the growth of the private health sector has been tremendous. This is inspite of the fact that the First Five Year Plan has clearly set out the purposed of planned development vis-à-vis the private sector. The distinction between the public and the private sector is, it will be observed, one of relative emphasis, private enterprise should have a public purpose and there is no such thing under present conditions as completely unregulated and free enterprise. Private enterprise functions within the conditions created largely by the State. Apart from the general protection that the state gives by way of maintenance of law and order and the preservation of sanctity of contracts, there are various devices by which private enterprise derives support from the government through general or special assistance by way of tariffs, fiscal concessions and other direct assistance, the incidence of which is on the community at large. In fact, as the experience of recent years has shown, major extension of private enterprise can be rarely undertaken except through the assistance of the state in one form or another (First Five Year Plan 1951-56, Planning Commission, GOI pg. 33). Over the period this has not happened in the planning process simply because the planning commission never had a holistic picture of the size, distribution and growth trends in the health care services. India has probably the largest private health sector in the world. Even in the USA about half the resources of the health sector are provided by the public exchequer. Right through the Seven Five-Year Plan the planners and policy makers have never discussed the private health sector, which provides two-thirds of the health care in the country. Hence plans and policies are bound to be limited in their impact.

The private health sector consists of, on the one hand, private general practitioners and consultants of different systems (allopathy, Indian system and homeopathy) and a variety of non-qualified practitioners and on the other hand hospitals, nursing homes, maternity homes, special hospital etc. In the hospitals, nursing homes, maternity homes etc, the private sectors share is a **** over half of all such facilities in the country. Besides this there is the pharmaceutical and medical equipment manufacturing industry, which is overwhelmingly private and pre-dominantly multi-national. There are also laboratories, which carry tests right from blood testing to CAT scans. The share of the private health sector is between 4% to 5% of the gross domestic product (GDP). This share at today's prices works out to between Rs.16,000 Crores and Rs.20,000 Crores per year.

This paper deals with regulation that exists in the private health sector. The implementation of the Bombay Nursing Homes Regulating Act in Bombay as a case in point is discussed and subsequently issues relating to a comprehensive
regulation system for the private sector are thrown up for debate. Let us make it clear in the beginning that privatization and liberalization are not synonymous with lack of monitoring or of regulation. Even in the USA with a 'free market' operating there are stringent regulations for medical practice and running hospitals and nursing homes.

1. **Existing Regulations**

The private health sector consisting of general practitioners, nursing homes and hospitals involve two thirds of the medical human power in the country. Despite this there is hardly any regulation of the practice of this sector of health. This is indeed surprising because such activity cannot be carried out without registration. The medical professional has to be registered with the Medical Council which is a statutory body that sets the standard of medical practice, 'disciplines' the professionals, monitors their activities and checks any malpractice's. The doctors who decide to set up their own clinics as well as hospitals, nursing homes, polyclinics etc., have to register with the respective local body. The problem with the above is that the controlling bodies are virtually non-functioning. The reason for this is not only lack of interest but also weak provisions in the various acts. They are also heavily influenced by the private health sector.

Another agent in the private health sector which needs to be regulated further is the pharmaceutical industry. As a chemical industry this agent is regulated to some extent but as a participant in the health sector it operates virtually unregulated.

Whereas the public health sector due to bureaucratic procedures is forced to maintain at least some minimum requirements (e.g. they will not employ non-qualified technical staff, follow certain set procedures of use of equipment or purchase of stores etc) and is subject to public audit, the private health sector operates without any significant controls and restrictions.

As per existing law the health sector has provision for regulation under three different authorities.

**The Medical Council:** The Medical Council of India and the respective state Councils have to regulate medical education and professional practice. Presently beyond providing recognition to medical colleges the Medical council does not concern itself with the practitioner, unless some complaint is made and a prima facie case established. Even the list of registered practitioners is not updated properly by the Medical Councils. The national body at present concerns itself with only recognizing and de-recognizing medical colleges whereas the State bodies function only as registers for issuing a license for practicing medicine. (The state Councils also facilitate recognition of private medical colleges which the National Council has de-recognized).

**The Local Bodies** (Municipalities, Zilla Parishads, Panchayat Samitis etc.) have the authority to provide a license to set up a nursing home or hospital and regulate its functions. However, besides providing the certificate to set up a
hospital or nursing home the local bodies do not perform any other function, inspite of provision in the Act.

The Food and Drug administration (FDA) has the jurisdiction to control and regulate the manufacture, trading sale of all pharmaceutical products. This is one authority which has been provided some teeth by the law. But its performance is most embarrassing. It is ridden with corruption. Inspite of the ridicule it faced as a result of the Lentin commission inquiry its behaviour remains more or less unchanged.

Given this state of affairs the people of the country are left entirely to the whims of the goodness of doctors. With highly commercialized medical practice the latter is very rare today. In view of the existing health situation and health practices, regulation of those who provide health care is an urgent necessity. Regulation exists in other sectors so why not in health? Hence there is an urgent need for strong measures to control and regulate the private health sector.

The Main Features of the Bombay Nursing Home Act (1949)

This act applies only to private hospitals and nursing homes. It must be pointed out that the public health sector has its own internal regulation based on the Hospital administration Manual. As indicated earlier the very fact of the existence of a bureaucracy brings about certain minimum controls and regulation. But this does not mean that we ignore the public health sector. Our suggestions are equally applicable to the public health sector also.

The objective of the Act is to provide for registration and inspection of nursing homes. This Act extends to the whole of Maharashtra. Nursing home means any premises which is providing for treatment and nursing of persons suffering from any sickness, injury or infirmity (and includes maternity). Anybody intending to carry on a nursing home shall make every year an application for registration or renewal to the local supervising authority which could be the municipal corporation, municipal body, district board, district panchayat and other like bodies constituted by the government.

The Act lays down conditions under which the local authority can grant or refuse to grant a certificate of registration to any private nursing home or hospital. This certificate should be kept affixed in a conspicuous place in the nursing home. Detailed information should be provided in terms of qualified staff, adequate staff, sufficient or proper equipment and adequate accommodation, floor space for patient beds, whether the sanitary conditions are suitable on its staff a qualified midwife. The local authority has the authority to refuse to register to renew registration for any hospital, or nursing home if it is not satisfied in terms of the provisions of the Act. The Act provides that the local authority formulate bye-laws.

The implementaiton of the Act by the Bombay Municipal Corporations (BMC) in the city of Bombay is in a very sorry state of affairs. The private hospitals and
nursing homes have over the years become lax in observing the provisions of the Act because of the indifference of the concerned authorities. Redressal can be sought in government hospitals because of some amount of accountability and public audit, but in private hospitals this is not the case. As a consequence we find that private hospitals are functioning in a very arbitrary manner without any control over them.

In connection with the court case referred to above the BMC has given a list of hospital and the visits made by their staff in the last 5 years. This list is not complete since many of the wards have not filed their returns. Registrations and renewals have become mere formalities. Visits are rarely, if ever, made by the representatives of the supervisory authority to the nursing homes, hospitals etc.

There are not many instances of registration cancelled or refused to any nursing homes or hospitals. Many nursing homes, hospitals etc. Continue to operate without being registered. Hospitals, nursing homes etc. continue to exist in unhygienic conditions without the basic amenities like water, proper ventilation, basic equipment, deficient on various matters. It does not lay down minimum standards to be followed for setting up of nursing homes. The rules do not prescribe any standards for facilities. The rules have kept the criteria for staff equipment, accommodation etc. vague by just mentioning 'adequate'. It is not that this cannot be done, since there is a minimal standard to be followed by govt. hospitals and nursing homes. For govt. hospitals there is a manual which provides indepth instructions about hospital management. It is divided into chapters like hospitals, buildings and compound; casualty services, organization of out patient wards, operation theatres, x-Ray department, blood bands, medical records , etc. Though there is much scope for improvement atleast they prescribe a minimum standard. Private hospitals could be made to follow atleast this to begin with especially when they charge such exorbitant fees. The bye-laws which have been formed are very limited in scope.

What should a comprehensive legislation seeking regulation include?

The following suggestions on regulation encompass the entire health sector. However, they are not an exhaustive list but only some major important areas needing regulation.

(a) Nursing Homes and Hospitals

- Setting up minimum decent standards and requirements for each type of unit; general specifications for general hospitals and nursing homes and special requirements for specialists care, example: maternity homes, cardiac units, intensive care units etc. This should include physical standards of space requirements and hygiene, equipment requirements, human power requirements (adequate nurse: doctor: bed ratios) and their proper qualifications etc.

- Maintenance of proper medical and other records which should be made available statutorily to patients and on demand to inspecting authorities
• Fixing reasonable and standard hospital and professional charges.

• Filing of minimum data returns to the appropriate authorities e.g. data on notifiable diseases details death and birth record, patient and treatment data etc.

• Regular medical and prescription audits which must be reported to the appropriate authority.

• Regular inspection of the facility by the appropriate authority with stringent provisions for flouting norms and requirements.

• Periodic renewal of registration after a through audit of the facility

(b) **Private Practitioners:**

• Ensuring that only properly qualified persons practice.

• Compulsory maintenance of patient records, including prescription, with regular audit by concerned authorities.

• Fixation of standard reasonable charges.

• Regulating a proper geographical distribution and switching over to family practice.

• Filing appropriate data returns about patients and their treatment.

• Provision for continuing medical education medical education on a periodic basis with license renewal dependent on it.

(c) **Diagnostic Facilities:**

• Ensuring quality standards and qualified personnel.

• Standard reasonable charges for various diagnostic tests and procedures.

• Audit of tests and procedures to check their unnecessary use.

• Proper geographical distribution to prevent over concentration in certain areas.

(d) **Pharmaceutical industry and Pharmacies:**

• Allowing manufacture of only essential and rational drugs.
• Regulation of this industry should be switched to Health Ministry from Chemical Ministry.

• Formulation of a National Formulary of generic drugs which must be used for prescription by doctors and hospitals.

• Ensuring the pharmacies are run by pharmacists through regular inspection by the authorities.

• Pharmacies should accept only generic drug prescriptions and must retain a copy of the prescription for audit purposes.

In view of the existing health situation and health problems and the context of commercialized practice, regulation of those who provide the nations health care is an urgent necessity and this entire process of regulation must have the end user (consumer) represented on the regulating bodies.