(2012) 07 DEL CK 0378

In the Delhi High Court

Case No : Writ Petition (C) No. 3490 of 2012

Dr. Ashwani Goyal — APPELLANT

Vs

Union of India and Another — RESPONDENT

Date of Decision : 31-07-2012

Acts Referred:

Bureau of Indian Standards Act, 1986 — Section 3
Constitution of India, 1950 — Article 14, 19(1), 19(1)(g), 249, 250
Dentists Act, 1948 — Section 3
Homoeopathy Central Council Act, 1973 — Section 3
Indian Medical Council Act, 1956 — Section 3
Indian Medicine Central Council Act, 1970 — Section 3
Indian Nursing Council Act, 1947 — Section 3
Pharmacy Act, 1948 — Section 3
States Reorganisation Act, 1956 — Section 15

Citation : (2012) 07 DEL CK 0378

Hon'ble Judges : Rajiv Sahai Endlaw, J;A.K. Sikri, J

Bench : Division Bench

Advocate : Rajshekhar Rao and Ms. Zehra Khan, for the Appellant; Saqib, Advocate for the Respondent No. 1, Mr. Shawana Bari, Advocate and Mr. Rajiv Nanda, Advocate, for the Respondent

Final Decision : Dismissed

Judgement

A.K. Sikri, Acting Chief Justice

1. The petitioner, who is a medical practitioner by profession, has filed this writ petition, purportedly as a Public Interest Litigation, challenging validity of various provisions of the Clinical Establishments (Registration & Regulation) Act, 2010 [hereinafter referred to as ''the Act'']. These provisions are Sections 1(3), 2(c), 2(d), 2(h), 2(o), 3, 10(1), 11, 12, 13, 25 & 41 of the said Act. This Act was notified on 28.2.2012 and came into force with effect from 01.3.2012. Notification pertains to four States, viz., Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim and the Union Territories and thus, is applicable in the NCT of Delhi. The various provisions of the Act taken note of above read as under:

1. Short title, application and commencement. -

(1) .....

(2) .....

(3) It shall come into force at once in the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim and the Union territories, on such date as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, mean the date on which this Act comes into force in such State or Union territory:

Provided that different dates may be appointed for different categories of clinical establishments and for different recognised system of medicine.

2. Definitions. - .....

(a).....

(b).....

(c) "clinical establishment" means-

(i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities 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 shall include a clinical establishment owned, controlled or managed by-

(a) the Government or a department of the Government;

(b) a trust, whether public or private;

(c) a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government;

(d) a local authority; and

(e) a single doctor,

but does not include the clinical establishments owned, controlled or managed by

the Armed Forces.

Explanation.- For the purpose of this clause "Armed Forces" means the forces constituted under the Army Act, 1950 (46 of 1950), the Air Force Act, 1950 (45 of 1950) and the Navy Act, 1957 (62 of 1957);

(d) "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in-

(i) placing the health of the individual or, with respect to a pregnant women, the health of the woman or her unborn child, in serious jeopardy; or

(ii) serious impairment to bodily functions; or

(iii) serious dysfunction of any organ or part of a body;

(e).....

(f).....

(g).....

(h) "recognised system of medicine" means Allopathy, Yoga, Naturopathy, Ayurveda, Homoeopathy, Siddha and Unani System of medicines or any other system of medicine as may be recognised by the Central Government;

(i).....

(j).....

(k).....

(l).....

(m).....

(n).....

(o)"to stabilise (with its grammatical variations and cognate expressions)" means, with respect to an emergency medical condition specified in clause (d), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a clinical establishment.

3. Establishment of National Council. - (1) With effect from such date as the Central Government may, by notification appoint in this behalf, there shall be established for the purposes of this Act, a Council to be called the National Council for clinical establishments.

(2) The National Council shall consist of-

(a) Director-General of Health Service, Ministry of Health and Family Welfare, ex officio, who shall be the Chairperson;

(b) four representatives out of which one each to be elected by the-

(i) Dental Council of India constituted u/s 3 of the Dentists Act, 1948 (16 of 1948);

(ii) Medical Council of India constituted u/s 3 of the Indian Medical Council Act, 1956 (102 of 1956);

(iii) Nursing Council of India constituted u/s 3 of the Indian Nursing Council Act, 1947 (48 of 1947);

(iv) Pharmacy Council of India constituted u/s 3 of the Pharmacy Act, 1948 (8 of 1948);

(c) three representatives to be elected by the Central Council of Indian Medicine representing the Ayurveda, Siddha and Unani systems of medicine constituted u/s 3 of the Indian Medicine Central Council Act, 1970 (48 of 1970);

(d) one representative to be elected by the Central Council of Homoeopathy constituted u/s 3 of the Homoeopathy Central Council Act, 1973 (59 of 1973);

(e) one representative to be elected by the Central Council of the Indian Medical Association;

(f) one representative of Bureau of the Indian Standards constituted u/s 3 of the Bureau of Indian Standards Act, 1986 (63 of 1986);

(g) two representatives from the Zonal Council set-up u/s 15 of the States Reorganisation Act, 1956 (37 of 1956);

(h) two representatives from the North-Eastern Council set-up u/s 3 of the North-Eastern Council Act, 1971 (84 of 1971);

(i) one representative from the line of paramedical systems excluding systems that have been given representation under clause (b);

(j) two representatives from National Level Consumer Group to be nominated by the Central Government;

(k) one representative from the Associations of Indian Systems of Medicines relating to Ayurveda, Siddha and Unani to be nominated by the Central Government;

(l) the Secretary-General of the Quality Council of India, ex officio.

(3) The nominated members of the National Council shall hold office for three years but shall be eligible for re-nomination for maximum of one more term of three years.

(4) The elected members of the National Council shall hold office for three years,

but shall be eligible for re-election:

Provided that the person nominated or elected, as the case may be, shall hold office for such period till he holds appointment of the office by virtue of which he was nominated or elected to the council.

(5) The members of the National Council shall be entitled for such allowances as may be prescribed by the Central Government.

(6) The National Council may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(7) The National Council shall meet at least once in three months.

(8) The National Council may constitute sub-committees and may appoint to such sub-committee, as it deems fit, persons, who are not members of the Council, for such period, not exceeding two years, for the consideration of particular matters.

(9) The functions of the National Council may be exercised notwithstanding any vacancy therein.

(10) The Central Government shall appoint such person to be the Secretary of the National Council as the Central Government may prescribe, and may provide the National Council with such other secretarial and other staff as the Central Government considers necessary.

xxx xxx xxx

10. Authority for registration.- (1) The State Government shall, by notification, set-up an authority to be called the district registering authority for each district for registration of clinical establishments, with the following members, namely:-

(a) District Collector - Chairperson;

(b) District Health Officer - Convenor;

(c) three members with such qualifications and on such terms and conditions as may be prescribed by the Central Government.

11. Registration for clinical establishments. - No person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of this Act.

12. Condition for registration. - (1) For registration and continuation, every clinical establishment shall fulfil the following conditions, namely:-

(i) the minimum standards of facilities and services as may be prescribed;

(ii) the minimum requirement of personnel as may be prescribed;

(iii) provisions for maintenance of records and reporting as may be prescribed;

(iv) such other conditions as may be prescribed.

(2) The clinical establishment shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilise the emergency medical condition of any individual who comes or is brought to such clinical establishment.

13. Classification of clinical establishments. - (1) Clinical establishment of different systems shall be classified into such categories, as may be prescribed by the Central Government, from time to time.

(2) Different standards may be prescribed for classification of different categories referred to in sub-section (1):

Provided that in prescribing the standards for clinical establishments, the Central Government shall have regard to the local conditions.

xxx xxx xxx

25. Verification of application. - The clinical establishment shall submit evidence of having complied with the prescribed minimum standards in such manner, as may be prescribed.

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41. Monetary penalty for non-registration. -

(1) Whoever carries on a clinical establishment without registration shall, on conviction for first offence, be punishable with a monetary penalty up to fifty thousand rupees, for second offence with monetary penalty which may extend to two lakh rupees and for any subsequent offence with monetary penalty which may extend to five lakh rupees.

(2) Whoever knowingly serves in a clinical establishment which is not duly registered under this Act, shall be punishable with monetary penalty which may extend to twenty-five thousand rupees.

(3) For the purpose of adjudging under sub-sections (1) and (2), the authority shall hold an inquiry in the prescribed manner after giving any person concerned a reasonable opportunity of being heard for the purpose of imposing any monetary penalty.

(4) While holding an inquiry the authority shall have power to summon and enforce the attendance of any person acquainted with the facts and circumstances of the case to give evidence or to produce any document which in the opinion of the authority, may be useful for or relevant to the subject matter of the inquiry and if, on such inquiry, it is satisfied that the person has failed to comply with the provisions specified in sub-sections (1) and (2), it may by order impose the penalty specified in those sub-sections to be deposited within thirty days of the order in the account referred to in sub-section (8) of section 42.

(5) While determining the quantum of monetary penalty, the authority shall take into account the category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated.

(6) Any person aggrieved by the decision of the authority may prefer an appeal to the State Council within a period of three months from the date of the said decision.

(7) The manner of filing the appeal referred to in sub-section (5) shall be such as may be prescribed."

(Emphasis supplied)

The main ground on which challenge is predicated is that there is no rationale nexus between the Act, in its present form, and the objects it seeks to achieve. It is submitted by the Learned Counsel for the petitioner that in the guise of a regulatory regime, the impugned Act permits unguided control to the State over clinical establishments and also directly infringes the right of clinical establishments to carry on an occupation inasmuch as it has the effect of virtually eliminating small and medium scale clinical establishments, creating a monopoly in favour of large hospitals, in the guise of regulatory framework. As per the petitioner, the best example of the statute creating a monopoly in favour of large hospitals in Section 12(2) of the Act, which prescribes that the clinical establishment shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilize the emergency medical condition of any individual who comes or is brought to such clinical establishment. As a consequence, any clinical establishment would have to have all varieties of apparatus and medication pertaining to several different specializations. For example, an ophthalmologist will have to provide for emergency medical treatment facilities even for a cardiac patient or a pregnant woman. Essentially, each clinical establishment irrespective of its especiality or expertise will have to provide for multi-especiality emergency care, in order to comply with the provisions of the legislation. The only type of clinical establishments that will be able to fulfil this condition would be large hospitals, which currently constitute a very slim minority of health care providers in India, because they are often unaffordable and beyond the reach of the common man.

2. It is also argued that the unreasonable burden cast on clinical establishments by this requirement also amounts to an abridgment of the fundamental right of medical practitioners to carry on their profession. The provision is disguised as a prescription of standards, when in effect, it impermissibly takes away the fundamental right of medical practitioners. The Act creates a monopoly in favour of large medical hospitals, which alone would be in a position to comply with the expansive mandate cast by the Act. Therefore, though no monopoly has been expressly granted to any particular hospital, and while it is facially neutral, in applying unreasonable conditions to all "clinical establishments" without distinction, it treats unequal equally, contrary to the mandate of Article 14 of the

Constitution of India.

3. In support of this petition, the Learned Counsel for the petitioner also submitted that the medical profession is already subject to sufficient regulatory regime through other States and central enactments and there was hardly any need to provide this additional regulatory measure by this Act. It is also argued that the impugned Act gives uncanalized powers to the Central Government and the National Council inasmuch as, though, the Act purports "to prescribe minimum standards of facilities and services" and to "determine the standards for clinical establishments", no such prescription of any standards for facilities and services, are discernible from the text of the Act. Instead, the impugned Act delegates legislative power to the Central Government and the National Council, empowering them to prescribe the necessary standards which, the petitioner submits, is tantamount to an abdication by parliament of its constitutional duty to lay down the law and constitutes an arbitrary, uncanalized excessive and unconstitutional delegation of non-delegable legislative power to the Executive Government and the National Council.

4. In the counter affidavit filed by the respondents, the aforesaid submissions are refuted.

5. We have considered the submissions of the Learned Counsel for the parties. It is difficult to accept the contentions advanced by the Learned Counsel for the petitioner. Legislation in respect of "public health and sanitation, hospitals and dispensaries" are relatable to Entry 6 f 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. It is not in dispute that the Legislature has requisite power to enact such a legislation and in that sense, it is intra-vires from the introduction as well as statement of objects and reasons of the Act, it would be apparent that the Legislature was concerned with the supervision and regulation of the quality of services provided by health care delivery system to the people by both public and private sectors has largely remained a contentious and unresolved issue. It is noted that the current structure of the health care delivery system does not provide enough incentives for improvement in efficiency. The private sector health care delivery system in India has remained largely unregulated and uncontrolled. Problems range from inadequate and inappropriate treatment, excessive use of higher technologies, and wasting of scarce resources to serious problems of medical malpractice and negligence. Despite many State Legislatures having enacted laws for regulating health care providers in India is inadequate or not responsive to ensure heath care services of acceptable quality

and prevent negligence. General public and a wide variety of stake holders, including Government, professionals associations, private providers, agencies financing health care, national Human Rights Commission and also judiciary have expressed their concerns to improve the health care quality.

6. Accordingly, the Parliament felt the need for Central legislation for ensuring uniform standards of facilities and services by the clinical establishments. In the statement of objects and reasons, following salient features of the Legislation are mentioned:

(i) The proposed legislation provides for a constitution of a National Council consisting of representatives of Medical Council of India, Dental Council of India, Nursing Council of India, the Pharmacy Council of India, the Indian Systems of Medicines representing Ayurveda, Siddha, Unani and Homoeopathy systems, the Indian Medical Association, the Bureau of Indian Standard, the Zonal Councils set-up under the States Reorganisation Act, 1956, the North-Eastern Council, etc.;

(ii) The function of the National Council shall be to determine the standards for the clinical establishment, classify the clinical establishment into different categories, develop the minimum standards and their periodic review, compile, maintain and update a National Register of clinical establishments, perform any other function determined by the Central Government, from time-to-time;

(iii) The function of the State Council shall be to compile, maintain and update the State Registers of clinical establishments and to send monthly returns for updating the National Registers. The State Councils shall also publish reports on the implementation of standards within their respective States, annually;

(iv) The concerned State Governments shall, by notification, set-up an authority to be called the district registering authority under the chairmanship of District Collector for registration of clinical establishments;

(v) No person shall carry on a clinical establishment unless it has been registered in accordance with the provisions of the proposed Bill. The legislation would not apply to the clinical establishments of the Armed Forces;

(vi) It is proposed that clinical establishments already in existence may be allowed for provisional registration to carry out their business. There shall be no prior enquiry for provisional registration. But the authority shall have power to make enquiry in accordance with such rules as may be prescribed;

(vii) The clinical establishment having provisional registration shall fulfil the standards which may be notified for the purpose. The provisional certificate shall not be granted or renewed beyond a period of two years from the date of notification of standards;

(viii) Any clinical establishment may apply for permanent registration in such form and shall pay such fee as may be prescribed by the State Government. A

detailed procedure for permanent registration is being provided in the proposed legislation;

(ix) The authority shall have power to cancel the registration of the clinical establishment which fails to comply with the conditions prescribed by the Central Government. The authority shall have power to inspect a registered clinical establishment. Any person aggrieved by an order of the registering authority shall prefer an appeal to the State Council;

(x) The clinical establishments shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilize the emergency medical condition of any individual who comes or is brought to such clinical establishment;

(xi) The certificate of permanent registration issued by the authority is valid for a period of five years from the date of issue;

(xii) There shall be register of clinical establishment at the district level, State level and the National level;

(xiii) If any person contravenes any provisions of the proposed legislation or any rules made thereunder, he shall be punished with fine. The maximum penalty being provided is rupees five lakh;

(xiv) Conferring power upon an authority, to levy monetary penalty for violation of the provisions of selections 41 and 42 of the proposed Bill;

(xv) Any person aggrieved by the decision of authority may prefer an appeal to the State Council.

7. These salient features provide necessary guidelines to the Central Government. Therefore, it cannot be said that any uncanalized and unguided powers are conferred upon the Central Government. Even the main provisions of the Act provide adequate guidelines. Section 13 of the Act, which gives powers to the Central Government to classify clinical establishment of different systems into such categories as may be prescribed by the Central Government from time to time clearly mentions that while doing so "the Central Government shall have regard to the local conditions".

8. We also do not agree with the contention of the petitioner that it infringes the right of the medical practitioners to carry on their occupation as provided under Article 19(1)(g) of the Constitution. It is the right of the Legislature to make regulatory framework in respect of health care delivery system and that is what is sought to be achieved. Therefore, the provisions are reasonable and protected under Article 19 (1) of the Constitution.

9. There is hardly any case of violation of Article 14 of the Constitution made out or was even argued. We, thus, do not find any merit in this petition, which is dismissed in limine.

