



BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT

DATED: 18.12.2019

CORAM:

THE HONOURABLE MR.JUSTICE A.P.SAHI, CHIEF JUSTICE

AND

THE HONOURABLE MR.JUSTICE SUBRAMONIUM PRASAD

W.P. [MD]No.7496 of 2019

and

W.M.P. (MD) Nos.5993 and 5994 of 2019

Dr.D.Dharmabalan

: Petitioner

Vs.

1.The Secretary

Department of Health and Family Welfare
Government of Tamil Nadu
Fort St. George,
Chennai.

2.The Director

Medical and Rural Health Services,
Directorate of Medical and Rural Health Services,
Chennai.

3.The Joint Director,

Medical and Rural Health Services,
Pudukottai District,
Pudukottai.

: Respondents

PRAYER: Writ Petition is filed under Article 226 of the Constitution of India for issuance of a Writ of Declaration to declare Sections 2(a), 3, 4 and 5 of Tamil Nadu Private Clinical Establishments (Regulation) Act, 1997 as amended by Tamil Nadu Act 19 of 2018 and Rule 6, 7, 8, 11 and 12 of Tamil Nadu Private Clinical Establishments (Regulation) Rules, 2018 as ultra vires, unconstitutional, arbitrary insofar as they are made applicable to the consulting rooms of medical practitioners.

For Petitioner

: Mr.G.Sridharan

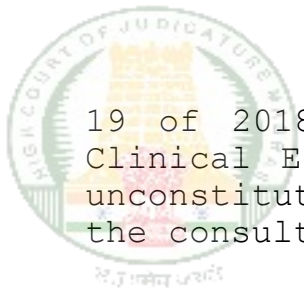
For respondents

: Mr.V.R.Shanmuganathan
Special Government Pleader

ORDER

[Judgment of the Court was delivered by **SUBRAMONIUM PRASAD, J.**]

The instant writ petition is for a Writ of Declaration declaring Sections 2(a), 3, 4 and 5 of Tamil Nadu Private Clinical Establishments (Regulation) Act, 1997 as amended by Tamil Nadu Act



19 of 2018 and Rules 6, 7, 8, 11 and 12 of Tamil Nadu Private Clinical Establishments (Regulation) Rules, 2018 as ultra vires, unconstitutional, arbitrary insofar as they are made applicable to the consulting rooms of medical practitioners.

2. The writ petitioner is a registered Medical Practitioner practising for the past 38 years. The Tamil Nadu Clinical Establishments Regulation Act, 1997, as amended by Tamil Nadu Act 19 of 2018 (hereinafter referred to as 'the Act') was brought in for regulation of clinical establishments in the State of Tamil Nadu and matters connected therewith or incidental thereto.

2.1. Section 2(a), deals with the definition of clinical establishments, which reads as under:

"2. Definitions- In this Act, unless the context otherwise requires, -

(a) "Clinical establishment" means a clinical establishment under any recognized systems of medicine and includes -

(i) a general hospital including dental hospitals, maternity hospital, dispensary, consulting room, clinic, polyclinic or nursing home;

(ii) an institution or a centre, by whatever name called, where physically or mentally sick, injured or infirm person is admitted either as in-patient or out-patient for treatment with or without the aid of operative procedures;

(iii) a clinic catering to radiological, biological or other diagnostic or investigative services with the aid of laboratory or other medical equipments; established and administered or maintained by any person or body of persons, whether incorporated or not or the State Government or Central Government or any Department of the State Government or Central Government or a Trust, whether public or private or a company, whether or not owned by the Government or a Local Authority, but does not include the clinical establishments controlled or manages by the Armed Forces....."

2.2. Section 3 deals with registration of clinical establishments, which reads thus:

"3. Registration of Clinical Establishments:

No person shall carry on any clinical establishment unless such clinical establishment is duly registered under this Act:

Provided that every clinical establishment in existence on the date of the commencement of the Tamil Nadu Private Clinical Establishments (Regulation) Amendment Act, 2016 (Tamil Nadu Act 19



of 2018) (hereinafter referred to as the notified date), shall apply for registration within nine months from the notified date and a clinical establishment established after the notified date, shall apply for registration within a period of six months from the date of its establishment:

Provided further that every clinical establishment in existence on the notified date shall cease to carry on its business on the expiry of twelve months from the notified date unless such clinical establishment has applied for registration and is so registered or till such application is disposed of, whichever is earlier.

(2) Every application for registration under sub-section (1) shall be made to the competent authority in such form and in such manner and shall be accompanied by such fee not exceeding five thousand rupees as may be prescribed.

(3) No (Clinical establishment) shall be registered under this Act unless the competent Authority is satisfied that such (Clinical establishment) is in a position to provide such specified services and facilities, possesses such a skilled manpower and equipments and conditions, as may be prescribed."

2.3. Section 4 deals with certification or registration, which reads as under:

"4.Certification of registration - (1) The competent authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder, grant to the clinical establishment a certificate of registration in such form and subject to such conditions as may be prescribed.

(2) If, after the inquiry and after giving an opportunity to the applicant of being heard, the competent authority is satisfied that the applicant has not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

(3) Every certificate of registration is valid for a period of five years and may be renewed for a period of five years at a time.

(4) Every application for renewal of registration shall be made within such time as may be prescribed and the provisions of this Act shall, as far as may be, apply in relation to the renewal of a



registration as they apply in relation to registration.

(5) If a certificate of registration is lost, destroyed, mutilated or damaged, the competent authority may, on application and on payment of such fee as may be prescribed, issue a duplicate certificate."

2.4. Section 5-A deals with maintenance of facilities and services by clinical establishments, which reads as under:

"5-A Maintenance of facilities and services by clinical establishments. - (1) Every clinical establishment shall maintain minimum standards of facilities and services, as may be prescribed.

(2) The Government shall prescribe minimum standards of facilities and services in respect of different categories of clinical establishments under all recognized systems of medicines.

5-B. Duties and responsibilities of clinical establishments. - Every clinical establishment shall perform the following duties and responsibilities, namely :-

(a) administer first aid and take other life saving or stabilizing emergency measures in all medico-legal or potentially medico-legal cases such as road accidents, accidental or induced burns or poisoning or criminal assaults and the like when the victims present themselves at the clinical establishment;

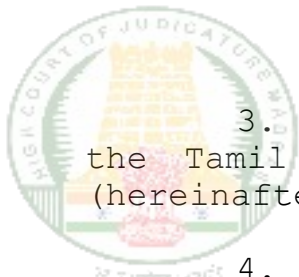
(b) participate in the implementation of all National and State health programmes in such manner as the Government may specify, from time to time, and furnish periodical reports thereon to the authorities specified therein;

(c) maintain medical records in such form and in such manner as may be prescribed for the respective system of medicine;

(d) carry out necessary action to prevent the spread of communicable diseases and to control non-communicable diseases, as the Government may direct, from time to time; and

(e) such other duties and responsibilities, as may be prescribed.

5-C. Annual publication of lists of clinical establishments. - The Competent authority shall maintain, in such form as may be prescribed, a register of clinical establishments and shall during the month of January in each year, publish in the Tamil Nadu Government Gazette, a list of clinical establishments registered together with such details pertaining to them as may be prescribed."



3. Under the Act, the State of Tamil Nadu has brought into the Tamil Nadu Clinical Establishments (Regulation) Rules, 2018 (hereinafter referred to as 'the Rules').

4. Rule 6, 7, 8, 11 and 12 of the said Rules, 2018 read as under:

“6. Minimum facilities of a clinical establishment. - The floor space and other facilities, the minimum number of staff and their minimum qualification, the minimum equipment and other conditions required for a clinical establishment of different systems, for providing different medical services including specialized services shall be in accordance with the norms and conditions specified in Annexure - I to these rules.

7. Application for registration.- (1) Every application for registration of a clinical establishment shall be made, either in person or by registered post with acknowledgement due to the competent authority in Form - I, accompanied by a fee for a sum of rupees five thousand in the form of demand draft or treasury challan drawn in favour of the competent authority.

(2) If a clinical establishment is offering services in more than one recognised system of medicine separate application shall be made for each such system of medicine.

8. Certificate of registration.- On receipt of an application for registration of a clinical establishment, the competent authority shall, after satisfying itself that the applicant fulfils all the requirements of the Act and these rules, grant a Certificate in Form-II within one eighty days from the date of receipt of the application. The Certificate of Registration is non-transferable.

.....

11. Duties of clinical establishment.- In addition to the duties and responsibilities specified in the Act, every clinical establishment shall,-

a) display a copy of the Certificate of Registration in a prominent place of the premises open to the public;

(b) maintain records in electronic form showing the names, addresses and the qualifications of its employees and the equipments maintained by it;

(c) record and preserve all changes in the employment of the staff and the equipments and intimate the same to the competent authority;



(d) maintain clinical records (i.e any paper, film, printout, slide, solution, medium which can be deciphered or used to indicate and diagnose the condition of the human body or a part of it or any material taken out of it and the course of treatment administered to or undergone by the person), of its activities relating to a patient.

(e) keep every record open for inspection by the competent authority;

(f) surrender the Certificate of Registration and apply for fresh registration on change of ownership of the clinical establishment, on change of system of medicine for treatment;

(g) surrender the Certificate of Registration, on ceasing to function as a clinical establishment.

12. Maintenance of medical records.- Every clinical establishment shall maintain records with particulars relating to the clinical observation, test, investigation, diagnostic opinion advice and treatment given to the person, who has visited the hospital either as an in-patient or out-patient in Form III."

5. Annexure (1), which is under Rule 6 specifies the minimum facilities in the clinical establishment, which are as under:

"I. Consulting Room:

(1) *Infrastructure.-* Consulting room shall have a space of not less than 100 square feet with sufficient light and ventilation. Separate space for the patients waiting for consultation have also to be provided.

(2) *Staff.-* The examination of the patient and prescription of the treatment shall be done only by a registered medical practitioner as required under the Indian Medical Council Act.

(3) *Equipment.-* The following equipment and hospital accessories shall be available in the consulting room, namely:-

- (a) Examination couch
- (b) Blood Pressure Apparatus
- (c) Stethoscope
- (d) Torch light
- (e) Tongue depressor
- (f) Thermometer
- (g) Weighing Machine for Adult and Paediatrics
- (h) Knee hammer
- (i) Measuring tape
- (j) Special examination trays like proctoscopy, Pelvic Exam Tray(P.V.Tray), Eye testing screen and Ear Nose Throat examination trays as the case may be, and



(k) Besides screen or sufficient privacy for examination of the patient;

(4) *Records.*- Every Clinical Establishment shall maintain a register having the details regarding the name, age, sex and address of the patient, date of examination, date of admission. The patient shall be given a slip containing name, age, sex and date of consultation, diagnosis (either provisional or final) and treatment advised, the investigation result shall be entered, if it was undertaken.

(5) *Prescription slip.*- The Doctor shall sign the prescription slip with date and seal."

6. The primary contentions raised by the petitioner is that the said Act and the Rules do not make any distinction between hospitals and a consulting room used by Doctors to give consultation to patients. According to the petitioner, in a consulting room, there is no requirement to maintain any system for disposing biomedical waste. It is also submitted that there is also no necessity for maintaining a Register on admission of patients. The learned counsel for the petitioner would contend that the said Act and Rules treats unequals as equals and therefore, is violative of Article 14 of the Constitution of India. The petitioner would contend that the provisions of the Act and Rules must not be made applicable to the consultation rooms. The learned counsel also contends that consultation room does not form part of clinical establishment under the various Central Acts and it is also not there in any other State Acts dealing with the same subject. The learned counsel would further contend that the small medical practitioners, who gave consultation sitting in a small room, would find it extremely difficult to carry on their practice and that are all excessive restrictions, which affect their right under Article 19(1)(g) of the Constitution of India.

7. Heard the learned counsel for the parties.

8. The purpose of the Tamil Nadu Clinical Establishment Act is meant for regulation of clinical establishments. The purpose of the Act is to regulate the running of clinical establishments and ensure that clinical establishments work in a proper manner. The statement of objects and Reasons of the Act shows that the Act is meant for regulating and controlling the clinical establishments through registration. The said statement of objects and Reasons read as under:

"In recent years, there has been a mushroom growth of private hospitals, nursing homes and other clinical establishments in the State of Tamil Nadu and such hospitals, nursing homes and other clinical establishments are run in an unorganised and



haphazard manner. At present, there is no law to regulate such private hospitals, nursing homes and other clinical establishments. It has been considered necessary that such private hospitals, nursing homes and other clinical establishments shall be regulated and controlled by registration."

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9. The purpose of the Act is to ensure proper functioning of clinical establishments in State of Tamil Nadu. A perusal of the entire Act would show that there are different requirements for different types of clinical establishments. The requirements have been well defined. The requirements that have been stipulated in Annexure I to Rule 6 of the Rules cannot be said to be in any manner violative of the Article 19(1)(g) of the Constitution of India.

10. The learned counsel for the petitioner argued with vehemence that the Doctors operating from small consulting rooms would have to take approval from the Pollution Control Board for having a proper biomedical disposal system. A perusal of the Annexure I to Rule 6 of the Rules, insofar as it applies to consulting rooms, does not prescribe such a requirement. On the other hand, the norms required for maintaining a clinical establishment specifies that there has to be facilities to segregate waste, dress etc. as per Government of India and Tamil Nadu Pollution Control Board norms, a condition, which is absent in the requirements made for consultation.

11. There is no challenge to the competence of the State Government to bring out these legislations. This Court is not able to accept the arguments of the petitioner that the provisions of this Act are violative of Article 19(1)(g) of the Constitution of India. The Regulations, which are meant to ensure that the various clinical establishments in the State are regulated in a proper manner and are supervised to ensure the safety and interest of the patients, cannot be said to be violative of Article 19 (1)(g) of the Constitution of India. There is nothing on record to show that the restrictions are violative on any of the rights provided under Part III of the Constitution of India. It cannot be said that the said Act is so manifestly arbitrary so as to be struck down.

12. In view of the above, the challenge made to the said Act fails and the writ petition is dismissed. However, there is no order as to costs. Consequently connected Miscellaneous Petitions are closed.

Sd/-

Assistant Registrar (CS-III)

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Sub Assistant Registrar (CS)



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Department of Health and Family Welfare
Fort St. George,
Chennai.

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Directorate of Medical and Rural Health Services,
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3.The Joint Director,
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Pudukottai District,
Pudukottai.

+1cc to Mr.G.Sridharan, Advocate Sr.No.105774

JUDGMENT MADE IN
W.P. [MD]No.7496 of 2019
18.12.2019

VB(02.01.2020) 9P 5C