

Bill No. LVIII of 2016

**THE CLINICAL ESTABLISHMENTS (REGISTRATION AND
REGULATION) AMENDMENT BILL, 2016**

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BILL

further to amend the Clinical Establishments (Registration and Regulation) Act, 2010.

BE it enacted by Parliament in the Sixty-seventh Year of the Republic of India as follows:—

1. (1) This Act may be called the Clinical Establishments (Registration and Regulation) Amendment Act, 2016.

Short title and commencement.

5 (2) It shall come into force at once.

23 of 2010.

2. In the Clinical Establishments (Registration and Regulation) Act, 2010, (hereinafter called the principal Act), after sub-section (2) of Section 12, the following sub-sections shall be inserted, namely:—

Amendment of section 12.

10 (3) The clinical establishment shall undertake that any individual, who comes or is brought to them in emergency medical condition or otherwise shall not be subjected to

unnecessary diagnostic tests and shall only confine to the diagnostic tests as may be required for assessing the clinical condition of the individual.

(4) The clinical establishment shall undertake that the medical doctors or practitioners or professionals or specialists working under its control shall prescribe generic medicines to the extent of availability and shall not compel the patients or their attendants to use branded medicines, leaving option for the patient and their attendants to choose the medicines of their choice and shall not advocate efficacy of the branded medicines over the generic medicines. 5

(5) The clinical establishment shall not charge more than the rates prescribed by Central Government under sub-section (3) of section 13 this Act for various diagnostic tests or procedures or surgeries or treatments based on classification and standards of clinical establishments as prescribed by Central Government. 10

(6) The clinical establishment shall display a notice board at prominent place in its premises about the concessions, subsidies, incentives, land at concessional rate, medical equipment obtained by exemption of various taxes or any other benefit it obtained from the Central Government, or the State Government or the Union Territory or any local body, as the case may be, for information to the public. 15

(7) The clinical establishments, which have availed concessions or benefits from the Central Government, or State Government or the Union Territory or any local body, as the case may be subject to certain conditions shall display the conditions on a notice board at prominent place in their premises along with the status of compliance of those conditions, which shall be updated on a monthly basis. 20

(8) The clinical establishments which offer medical examination or treatment in intensive care units or emergency wards, shall design the intensive care units or emergency wards, in such a way that the outer wall of one of its side shall be fitted with transparent glass, closed with cloth curtains to enable the attendants of the patient to see the patients, as and when deemed necessary. 25

(9) The clinical establishments shall brief, atleast two times in a day, the attendants of the patients being treated in intensive care units or emergency wards about the condition of the patient and treatment being extended and shall also video record each briefing and shall preserve it for a period of ninety days from the date of discharge of the patient from intensive care units or emergency wards or date of death of the patient during treatment in such clinical establishment, whichever is later. 30

Amendment of section 13. **3.** In the principal Act, after sub-section (2) of section 13, the following sub-sections shall be inserted, namely:— 35

(3) The Central Government shall prescribe maximum rates for various diagnostic tests or procedures or surgeries or treatments extended by clinical establishments based on their classification and standards prescribed by it under sub-sections (1) and (2):

Provided that in prescribing the maximum rates for the diagnostic tests or procedures or surgeries or treatments offered by clinical establishments, the Central Government shall have regard to the local conditions. 40

Amendment of section 52. **4.** In the principal Act, after clause (k) of sub-section (2) of section 52, the following clause shall be inserted, namely:—

"(kk) the maximum rates for the diagnostic tests or procedures or surgeries or treatments offered by clinical establishments under sub-section (3) of section 13;" 45

Amendment of section 56. **5.** In the principal Act, after sub-section (1) of section 56, the following sub-section shall be inserted, namely:—

(1A) The States, having enactments specified in the Schedule, may are revisit their enactments in the public interest and revise their enactments to make them more comprehensive by including the provisions of the Clinical Establishments (Registration and Regulation) Act, 2010, as amended from time to time, to improve the public health within a period of six months from the date of enactment of this Act.

23 of 2010.

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STATEMENT OF OBJECTS AND REASONS

The Clinical Establishments (Registration and Regulation) Act, 2010 was enacted to provide for the registration and regulation of the 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 Constitution of India for improvement in public health may be achieved.

2. This act was enacted in the year 2010. Certain Rules to operationalise the Act were also issued. However, there is wide-spread commotion and unrest in the public that certain clinical establishments are (i) subjecting the patients to unnecessary and unwanted diagnostic tests and threatening the patients of dire medical consequences if they do not undergo the tests prescribed to them, (ii) charging the patients with exorbitant prices for the diagnostic tests and treatments (iii) prescribing expensive branded medicines ignoring availability of generic medicines, (iv) totally keeping the attendants in dark about the condition of the patient being treated and the treatment extended in the intensive care units and emergency wards and (v) not complying with the conditions imposed by governments after getting concessions and relaxations from the Government.

3. In this context there is a definite need of evolving a proper procedure/ mechanism to streamline these clinical establishments and forcing them to adopt a uniform procedure in charging for diagnostic tests, doctor fees, charges for medical facilities offered by them. There shall be proper check on these clinical establishments and bills charged by them so that they cannot exploit the common people approaching them for treatment of various diseases apart from compelling them to use expensive branded medicines. There are instances wherein these clinical establishments are charging the CGHS/Health Card/ Insurance Patients to the extent of their maximum eligibility by compelling them to undergo various tests, treatments, which may not be necessary for their recovery. The proposed Bill addresses the above concerns to a certain extent.

Hence this Bill.

MOHD. ALI KHAN

ANNEXURE

EXTRACTS FROM THE CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2010

(23 OF 2010)

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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 subsection (1):

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

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52. Power of Central Government to make rules.—(1) The Central Government may, by notification, make rules for carrying out all or any of the provisions of this Act.

(2) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

- (a) allowances for the members of the National Council under sub-section (5) of section 3;
- (b) appointment of such person to be the Secretary of the State Council by the Central Government under sub-section (10) of section 3;
- (c) the determination of standards and for classification of clinical establishments under section 7;
- (d) the qualification and the terms and conditions for the members of the authority under clause (c) of sub-section (1) of section 10;
- (e) the procedure under which the powers of the authority may be exercised by the District Health Officer or Chief Medical Officer for the purpose of provisional registration of clinical establishment under sub-section (2) of section 10;
- (f) the minimum standards of facilities and services under clause (i) of sub-section (1) of section 12;
- (g) the minimum number of personnel under clause (ii) of sub-section (1) of section 12;

(h) the maintenance of records and reporting by the clinical establishment under clause (iii) of subsection (1) of section 12;

(i) other conditions for registration and continuation of clinical establishment under clause (iv) of subsection (1) of section 12;

(j) classification of clinical establishment under sub-section (1) of section 13;

(k) the different standards for classification of clinical establishments under sub-section (2) of section 13.

(l) the minimum standards for permanent registration under section 28;

(m) the form and particulars to be contained in the register to be maintained under section 38.

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56. Savings.—(1) The provisions of this Act shall not apply to the States in which the enactments specified in the Schedule are applicable:

Provided that the States in which the enactments referred to in sub-section (1) are applicable, and such States subsequent to the commencement of this Act, adopts this Act under clause (1) of article 252 of the Constitution, the provisions of this Act shall, subsequent to such adoption, apply in that State. (2) The Central Government may, as and when consider necessary, by notification amend the Schedule.

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RAJYA SABHA

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further to amend the Clinical Establishments (Registration and Regulation) Act, 2010

(Shri Mohd. Ali Khan, M.P.)