

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
STARRED QUESTION NO.329
TO BE ANSWERED ON THE 25TH MARCH, 2022**

ILLEGAL PATHOLOGICAL LABORATORIES

†*329. SHRI SANTOSH KUMAR:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Government is aware that a large number of illegal and unauthorised pathological laboratories are operating unchecked throughout the country;

(b) if so, the details thereof;

(c) whether the Government proposes to set up a regulatory body in this regard and if so, the details thereof; and

(d) the other steps taken by the Government in this regard as per the guidelines of the apex court?

**ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR MANSUKH MANDAVIYA)**

(a) to (d) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO. 329* FOR 25TH MARCH, 2022**

(a) to (d) 'Health' is a State subject, and it is within the ambit of respective State/ Union Territory (UT) Government's responsibility to regulate pathological laboratories in their territorial jurisdiction.

Government of India on its part has enacted the Clinical Establishments (Registration and Regulation) Act, 2010 (CEA) and notified Clinical Establishments (Central Government) Rules, 2012 to register and regulate clinical establishments, including the pathological laboratories.

The Clinical Establishments Act, 2010 provides that in each District there shall be a District Registering Authority under the District Collector to be notified by the State Government, empowered to enforce all provisions of the Act including grant and cancellation of registration. Further every State shall constitute a State Council for Clinical Establishments at State Level, under the chairmanship of State Health Secretary, by notification for hearing appeals against orders of the aforesaid authority.

As per the provisions of the aforesaid Act, no one can run a pathological laboratory, in the States/UTs, where the said Act is applicable, unless it is duly registered under the Act. For registration and continuation, every pathological laboratory is required to fulfil, among others, the conditions of minimum standards of facilities and services and minimum requirement of personnel.

Following the Apex Court's Judgment dated 12.12.2017, and after consultations with various stakeholders, the Government notified Clinical Establishments (Central Government) Amendment Rules, 2018, specifying minimum standards of medical diagnostic laboratories / pathological laboratories. These Rules were further amended in 2020 specifying the qualifications of Technical Head of laboratory/Specialist/Authorized Signatory of all three categories of laboratories, i.e., Basic, Medium and Advanced, which clearly demarcate the scope of work of the medical and non-medical laboratory professionals.

Further, the Ministry of Health and Family Welfare has issued advisory to all States and UTs to regulate online health service aggregators and related service providers including laboratory services as per the applicable laws. The States / UTs have been further advised that the Department of Home of the concerned State may also be requested to investigate such matters, with an objective to prevent any kind of violation (civil or criminal / cyber or otherwise) of applicable laws.

As on date, the Clinical Establishments Act, 2010 is applicable in 11 States namely Arunachal Pradesh, Himachal Pradesh, Sikkim, Mizoram, Bihar, Jharkhand, Rajasthan, Uttar Pradesh, Uttarakhand, Assam, Haryana and 7 Union territories namely Andaman & Nicobar Islands, Daman & Diu, Dadra & Nagar Haveli, Puducherry, Chandigarh, Lakshadweep, Jammu and Kashmir and Ladakh.

Other 17 states and 1 Union Territory have their own state specific Acts.
