

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

**LOK SABHA  
UNSTARRED QUESTION NO. 2360  
TO BE ANSWERED ON 13<sup>TH</sup> FEBRUARY, 2026**

**REGULATION OF DIAGNOSTIC CENTRES IN RESIDENTIAL AREAS**

†2360. SHRI IMRAN MASOOD:

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

- (a) whether the Government has taken any steps to regulate diagnostic centres operating in residential areas which generate hazardous biomedical waste;
- (b) if so, the details thereof including the action taken against laboratories operating without valid registration certificates;
- (c) whether there is any plan to make primary treatment facilities mandatory for the treatment of medical waste; and
- (d) if so, the details thereof and if not, the reasons therefor?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY  
WELFARE  
(SMT. ANUPRIYA PATEL)**

(a) to (d) : ‘*Health*’ being a State subject, the primary responsibility to regulate and register diagnostic centres and to address the issue of biomedical waste lies with the respective States/UTs.

Nonetheless, the Government of India enacted the Clinical Establishments (Registration and Regulation) Act, 2010 (CE Act) and notified the Clinical Establishments (Central Government) Rules, 2012 amended in 2018 and 2020 (CE Rules) to provide for registration and regulation of Government (except those of Armed Forces) as well as private clinical establishments belonging to recognized systems of medicine. As per CE Act, the clinical establishments are required to fulfill the conditions of minimum standards of services provided for each type of service provided. The CE Act is applicable in 19 States/UTs (12 States of Arunachal Pradesh, Assam, Bihar, Jharkhand, Haryana, Himachal Pradesh, Mizoram, Rajasthan, Sikkim, Telangana, Uttarakhand & Uttar Pradesh and 7 UTs of Andaman & Nicobar Islands, Chandigarh, Dadra & Nagar Haveli and Daman & Diu, Jammu & Kashmir, Ladakh, Lakshadweep & Puducherry).

Further, management of biomedical waste generated by diagnostic laboratories is governed by the Bio-Medical Waste Management Rules, 2016, notified under the Environment (Protection) Act, 1986 by the Ministry of Environment, Forest and Climate Change. These rules apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form including hospitals, nursing homes, clinics,

pathological laboratories and so on. Compliance with these provisions forms part of the conditions for registration and continued operation of clinical establishments under the CE Rules.

The States / UTs which have adopted the CE Act are primarily responsible for enforcing/implementing the provisions of the CE Act for regulating their diagnostic laboratories. The Act has empowered a registering authority at the district level under the chairmanship of the District Collector / District Magistrate to take actions including imposing penalties in respect of violation of its provisions. The Act also provides for cancellation of registration, if the provisions of the Act are not complied with. The clinical establishments in the States/UTs, which have not adopted and implemented the CE Act, are registered and regulated by the respective State Acts.

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